Planning Meeting Paves Way for Cellular Therapy Alliance

A group of international cellular therapy leaders met in Geneva, Switzerland, last week to discuss the next steps in forming the Cellular Therapy Alliance (CTA). The CTA, formed by America’s Blood Centers (ABC), the European Blood Alliance (EBA), and the National Marrow Donor Program (NMDP), will be the first international business alliance for not-for-profit organizations focused on cellular therapies.

ABC, EBA, and NMDP, announced the launch of CTA in January and have since held two open webinars discussing trends in cell therapy (see ABC Newsletter, 1/6/12; 2/10/12; 2/17/12). In Geneva, the group, which included representatives from ABC, EBA, the NMDP, and academic centers involved in cell therapies, again validated the need for the CTA and what their vision is for this organization. These leaders envision a trade organization whose membership would consist of non-profit organizations involved in cellular therapy.

“The NMDP appreciates the opportunity to work with ABC, EBA and others interested in the role of cellular therapies in sponsoring the CTA,” said NMDP CEO Jeffrey Chell, MD. “As these therapies are applied to a broader group of patients, the CTA will work with its members to improve the quality and efficiency of cellular therapy products and services consistent with our collective missions of saving lives.”

The idea for a CTA was born out of a 2009 meeting in Montreal, Canada, of representatives from various cell therapy organizations. ABC, EBA, and NMDP recognize that there are many well-functioning organizations involved in cellular therapy, but that an alliance of organizations can improve the quality, effectiveness, and efficiencies of their patient-oriented services. Such a group would provide one strong voice for non-profit cell therapy organizations in dealing with regulators, funders, and the public.

According to discussions at the meeting last week, the CTA would fill gaps that other preexisting cellular therapy organizations do not fill, but without duplicating services. The group identified the following key areas that CTA will focus on: networking; education, such as the operational issues in cellular therapy organizations; engagement of diverse groups of end-users with cellular therapy operators; regulatory advocacy; and benchmarking.

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As with other healthcare organizations, competition within the US blood community is now widespread. Much of this is stimulated by hospitals, especially hospital supply-chain managers, who wonder why their individual hospitals are paying such different prices. We also are beginning to see such competition emerging in other countries, such as Germany and Austria.

At first, we resisted competition for donors and hospitals. In reality, hospitals appreciate that we have to compete for their business. And most donors don’t mind being fought over, as long as they know their community blood needs are protected and their gift continues to save lives.

But an increasing casualty of this competition is cooperation at a national, and even international, level between blood organizations. Relations between ABC and the American Red Cross blood program at the national level are likely at their lowest ebb in over a decade. It is important to remember that patients and donors expect us to cooperate on issues of blood and patient safety, an adequate supply, and quality issues.

It isn’t just nationally. Increasingly some ABC members are reluctant to share data and best practices, even anonymously, because an ABC member competitor might benefit.

To be honest, much of this is a reflection of our newness in competing. If you look at other industries where companies fiercely compete, they cooperate to create markets and compete to carve them up. That’s an approach ABC strongly endorses.

Name any industry of competitors, such as hospitals, drug companies, banks, food manufacturers, even casinos and restaurants, and you will find they avidly share data and best practices. Indeed, a major role of their trade associations is to provide a “safe place” to learn by giving and getting.

Sure, new strategies and services can be considered proprietary, but does anyone seriously believe their basic financial and operational data and practices are a secret from their competition? Ironically, publicly traded companies legally must openly share enormous amounts of data.

It is time we competed like others in healthcare do; as both our customers and suppliers do. It is time to cooperate to better compete, and to better serve our patients.
CTA Planning Meeting (continued from page 1)

After discussing the main areas of service that CTA would provide to its members, the group decided that the next steps would be to identify committed organizations as well as a funding source for the initial work. The group hopes to complete those first steps by early June. Given the success of securing committed organizations and funding, the group would next move to develop a business plan for the CTA, which would include proposals for a legal framework, marketing plans, and key measurements for tracking success.

“In a very stimulating meeting with stakeholders from various horizons, we could elaborate a common great objective: to accelerate the advancement of cellular therapy to improve patient care through work on the cellular therapy supply chain and its efficiency, reducing regulatory burden, improving awareness, and data collection,” said Gilles Folléa, MD, PhD, executive director of the EBA. “This forms the basis of a very promising program. There is no doubt that all the involved experts will do their best to achieve this.”

During the meeting, Brian M. Freed, PhD, a professor in the Division of Allergy and Clinical Immunology and executive director of ClinImmune Labs at the University of Colorado’s School of Medicine, and Marc L. Turner, MD, medical director of the Scottish National Blood Transfusion Service, agreed to co-chair the CTA’s steering committee, comprised of leaders in cellular therapy.

“Cell therapies are on the verge of exploding. This CTA, which will focus on operational issues not addressed by other organizations involved in cell therapies, will prove beneficial to all involved – blood centers and academic centers – but mostly to patients by helping to assure access to therapy,” said ABC CEO Jim MacPherson.

Bike Ride for Blood Donation Will Reach Out to Young People

A foundation supporting Florida families in need and the Boys and Girls Club of St. Lucie County are teaming up to facilitate a 1,500-mile, 30-day bike ride from Miami, Fla. to Washington D.C., not only to advocate blood donation and coordinate blood drives along the way, but also to educate young people about the importance of blood donation.

The Van Duzer Foundation seeks to assist families in St. Lucie County, Florida who have been hit with financial and personal hardship due to an unexpected crisis or tragedy. The organization hopes to bring blood donation awareness to the national forefront with this long distance bike ride, beginning on June 11 and ending in Washington on July 11. US Deputy Surgeon General Boris D. Lushniak, MD, MPH, is planning to bike along in the last 50 miles of the ride, and the two organizations have planned a meeting with Surgeon General Regina M. Benjamin, MD, MBA, to discuss blood donation.

The foundation’s president and founder, Scott Van Duzer, along with the St. Lucie County Boys and Girls Club Executive Director Norman Penner, four teens from the Boys and Girls Club, and blood donation advocate, Larry Frederick, will ride to Boys and Girls Clubs from Miami to Washington to educate young people about blood donation. The group will also work with America’s Blood Centers’ members along the way to host blood drives, and will encourage the youths from various Boys and Girls Clubs to hold their own blood drives.

“Nothing is more powerful than education,” said Mr. Van Duzer. “The youth of today are our adult blood

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Bike Ride for Blood Donation (continued from page 3)

donors of tomorrow. If we can teach them now the importance of blood donation and really emphasize that it affects everyone, that is the best way to really change the statistics.” Mr. Van Duzer is referring to statistics such as, only 4 percent of the US population donates blood, although someone in the US needs blood every three seconds.

**A Dedication to Blood Donation.** The Van Duzer Foundation has recently held three major annual blood drives that have collectively raised more than 5,000 pints of blood. Florida’s Blood Centers has supported each of the “Be A Hero Day” drives and continues to support the foundation in its upcoming bike ride. After raising more than 1,300 pints of blood during last year’s event, the foundation holds the title for the largest blood drive in Florida.

Mr. Van Duzer, himself a regular blood donor, said that the foundation’s dedication to blood donation began a couple of years ago when he realized that many of the families aided by his foundation needed blood transfusions at some point and that very few people actually donate blood. This year, Mr. Van Duzer sought to gain national attention for blood donation by planning a meeting with the US surgeon general. He decided upon a blood donation bike ride at the suggestion of Mr. Frederick, blood donation advocate and creator of the “Life Across America” cross-country bike ride.

**Getting Young People Involved.** Four teens will be selected to train and cycle along in the blood donation bike ride. The teens will be chosen from Florida area Keystone Clubs, which are community service organizations associated with the Boys and Girls Club. These young people will create a Power Point presentation to teach their peers at other Boys and Girls Clubs why blood donation is so vital, with the goal of inspiring other kids to eventually become life-long donors.

“The connection between The Boys and Girls Club and blood donation comes out of a concern that if we don’t develop the next generation of blood donors, given the fact that you can’t manufacture blood, then we are in some serious trouble,” said Mr. Penner. “We think it is important for our teenagers today, who will be our future donors, have this information about blood donation to get them thinking about becoming lifelong donors.”

The organizations hope that their efforts result in the donation of one pint of blood for each mile traveled, totaling about 1,500 pints of blood as the goal, said Mr. Penner. The Boys and Girls Club teens on this bike ride will also be encouraging Boys and Girls Clubs across the US to hold their own blood drives on July 11 as the group finishes its long-distance ride.

The group is now accepting sponsorships to support their blood donation bike ride, and will donate any remaining funds to The Boys and Girls Clubs to create scholarships for kids in need. Those interested in donating to the cause or in finding out more about the bike ride may visit: http://thevanduzerfoundation.org/index.html.

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**We Welcome Your Letters**

The *ABC Newsletter* welcomes letters from its readers on any blood-related topic that might be of interest to ABC members. Letters should be kept relatively short and to the point, preferably about a topic that has recently been covered in the *ABC Newsletter*. Letters are subject to editing for brevity and good taste. Please send letters to ABC Publications Editor Betty Klinck at newsletter@americasblood.org or fax them to (202) 393-1282. Please include your correct title and organization as well as your phone number. The deadline for letters is Wednesday to make it into the next newsletter.
ABC Exec. VP Celso Bianco Among ISBT’s 2012 Board of Director Candidates

The International Society of Blood Transfusion (ISBT) has recently announced the candidates for its 2012 Board of Directors, including the nomination of America’s Blood Centers’ Executive Vice President Celso Bianco, MD, as a candidate for ISBT president-elect. Voting opened for ISBT members on April 10, and the elected new members of the Board of Directors will be officially appointed to their positions at the ISBT General Meeting during the 32nd International Congress of the ISBT in Cancun, Mexico, on July 10.

President-Elect Candidate Nominees. Dr. Bianco and Venetassen Ravi Reddy, MT, MBA, the chief operations officer of the South African National Blood Service (SANBS), are competing for the position of president-elect. Working in blood banking and transfusion medicine since the 1970s, Dr. Bianco has become a well-respected and influential leader in transfusion medicine research and blood safety. Prior to joining ABC, Dr. Bianco was the vice president for Medical Affairs at New York Blood Center, where he began working in issues related to transfusion transmitted diseases and blood safety in 1982, becoming particularly involved in the early days of the AIDS crisis.

Dr. Bianco has published many scientific papers and contributed to research in the areas of plasma membrane receptors of white blood cells, immunology, infectious disease, plasma proteins, and transfusion medicine. He is a member of AABB’s Transfusion Transmitted Disease Committee, the ISBT Working Party on Transfusion Transmissible Infections, and the American Society of Hematology. He was also a member of the Advisory Committee on Blood Safety and Availability of the US Department of Health and Human Services, and is currently the industry representative on the FDA’s Blood Products Advisory Committee.

Mr. Reddy has worked for Blood Transfusion Services in South Africa for 27 years, where his current responsibilities as COO of SANBS include overseeing collection, processing, and testing and issue of approximately 810,000 units of blood annually. Mr. Reddy has been instrumental in implanting several changes that have impacted the efficiency and safety of blood supplied by SANBS. He implemented molecular technology for specialized labs in the mid-1990s and played a key role in the merger of seven independent blood services to form the National Blood Service. He also assisted in managing the implementation of individual donation nucleic acid testing in SANBS in 2005.

Mr. Reddy is currently a member of the World Health Organization’s (WHO) Expert Committee on Testing for Infectious Diseases, a regional director representing Africa on the ISBT Board of Directors, a member and treasurer of the ISBT Working Party on Transfusion Transmissible Infections, an EXCO member of the African Society for Blood Transfusion, and an AABB member. Mr. Reddy has co-authored 17 scientific publications and presented numerous posters and abstracts at international meetings and symposia.

Vice President Candidate Nominees. The nominees for vice president are Miguel Lozano, PhD, MD, chief of the Hemotherapy Section of the Department of Hemotherapy and Hemostasis at the Hospital Clinic in Barcelona, Spain, and Diana Teo, MB,BS, the senior consultant and group director of the Blood Services Group, which is the national blood service in Singapore.

Dr. Lozano has been the chair of the Editorial Board of the AABB Press since 2008 and has been a scientific member of the Biomedical Excellence for Safer Transfusion (BEST) Collaborative since 2002. He also serves as the Spanish representative in the Council of Europe committee of Experts on Quality Assurance in Blood Transfusion Services. Dr. Lozano served as the vice president of the Spanish Society

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ISBT Board of Director Nominees (continued from page 5)

of Blood Transfusion from 2002-2006 and as the president of the Catalan Society of Blood Transfusion from 2000-2003. He is also a member of the Spanish Association of Hematology and Hemotherapy, the International Society of Blood Transfusion, AABB, and the American Society for Apheresis. Dr. Lozano has been invited to numerous conferences and meetings and has published several books and book chapters, as well as more than 100 scientific journal articles.

Dr. Teo has worked for the Blood Service Group in Singapore since 1983 and as the Western Pacific Regional director on the ISBT Board of Directors since 2004. She earned the Singapore National Day Honors in Public Administration Medal in 2008. Dr. Teo has also served as a member of the ISBT Foundation’s advisory committee from 2008-2009 and as a member of the Vox Sanguinis Standing Committee. She serves on the WHO Expert Advisory Panel for Transfusion Medicine and on the Board of Directors of the ICCBBA, as well as several other transfusion-related organizations and editorial boards.

Other ISBT positions. Steve Morgan, MBA, currently the associate director of the UK’s National Health Service Blood and Transplant, is the only nominee to serve as treasurer. Nominations were also made for regional directors of Africa, South East Asia, Western Europe, and the Western Pacific. More information about the nominees and the voting process is available at: http://bit.ly/IgP3Qe. The election will close on June 10. (Source: ISBT nomination information, 4/10/12)

NEW FOR 2012

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Published 46 to 48 times a year, the ABC Newsletter is a weekly chronicle of current events and issues affecting the blood banking and transfusion medicine communities. Editorial coverage includes regulation, legislation, litigation, science, technology, and new developments in blood services. Special sections highlight ABC member news and updates from ABC headquarters. A comprehensive calendar of events is published once a month and there is a classified advertising section for employment opportunities, equipment, and other notices.

Circulation: approximately 5,000; email only, <0.5% bounce back rate (subscription based)

Frequency: weekly, 46 to 48 issues per year on Fridays (unless Friday is a holiday, then Thursday)

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Study: Some Platelet Characteristics Have no Impact on Clinical Bleeding

Platelet transfusion is generally used to stop or prevent bleeding, and is commonly used in treating patients with bleeding disorders, leukemia, bone marrow or organ transplant, and other life-threatening diseases. The results of a recent study show that certain platelet characteristics, such as platelet dose, platelet source, platelet donor-recipient ABO compatibility, and duration of platelet storage, do not have a measurable impact on clinical bleeding.

The study was led by Darrell J. Triulzi, MD, of the Institute for Transfusion Medicine. The researchers conducted secondary analyses using data collected in the Platelet Dose Study (PLADO). The results were published online in Blood on April 10.

Background. Previous studies have shown that platelet characteristics such as the platelet dose (number of platelets per transfusion), platelet source [apheresis (AP) vs. whole blood platelet pools (WBP)], platelet donor-recipient ABO compatibility, and the duration of platelet storage, can affect post-transfusion platelet increments. However, past studies have been unable to make assertions as to whether these characteristics actually impact the platelet transfusions efficacy on clinical bleeding. The researchers analyzed the PLADO data, assessing the time from the first platelet transfusion to the first World Health Organization (WHO) ≥ grade 2 bleeding. WHO Bleeding Grades from 1 to 4 are used to assess the severity of clinical bleeding.

Method. The PLADO study is a recently completed large multi-center trial that compared platelet transfusions in hematology-oncology patients: lower dose (LD), medium dose (MD), or higher dose (HD), to determine whether platelet dose had an impact on clinical bleeding (it did not). The researchers of the current study were able to use the PLADO database to examine the impact of platelet characteristics on the clinical outcome of bleeding, because these characteristics, along with the patients’ bleeding status and platelet counts, were monitored and recorded throughout the PLADO study.

The researchers conducted a statistical analysis of the data in the PLADO database to determine the association between the platelet characteristics and bleeding by assessing the time from the first transfusion to the first WHO ≥ grade 2 bleeding event. The researchers also conducted platelet increment analyses, comparing the platelet increment and corrected count increment (CCI) before and after platelet transfusion.

Results. The PLADO study enrolled 1,351 patients at 26 sites between 2004 and 2007, of which 778 from 25 sites were eligible for analysis in this study. Overall, 383 (49.2 percent) experienced a ≥ grade 2 bleeding episode, including 121 in the LD group, 115 in the MD group, and 147 in the HD group. The platelet dose group did not affect the time to first ≥ grade 2 bleeding event.

Of the 772 patients available for an analysis of platelet source as a bleeding predictor, the source of the first platelet transfusion was AP in 552 patients (72 percent) of whom 251 (45 percent) experienced a ≥ grade 2 bleeding, and WBP in 220 patients (38 percent) of whom 103 (47 percent) experienced ≥ grade 2 bleeding. In the adjusted model, the platelet source did not predict the time to first ≥ grade 2 bleeding.

Of 740 patients that were available for analysis of ABO matching status as a predictor of bleeding, the first platelet transfusion was ABO identical in 467 patients (63 percent) of whom 167 (36 percent) experienced ≥ grade 2 bleeding, ABO minor mismatched in 75 patients (10 percent) of whom 18 (24 percent) experienced ≥ grade 2 bleeding, and ABO major mismatched in 198 patients (27 percent) of whom 48 (24

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Platelet Characteristics (continued from page 7)

percent) experienced ≥grade 2 bleeding. In the adjusted model, ABO matching status did not predict the time to ≥grade 2 bleeding.

In comparing patients transfused with platelets stored for zero to two days, three days, four days, or five days, the platelet storage duration also did not predict the time to ≥grade 2 bleeding. In conducting a multi-parameter model, adjusting for other platelet characteristics, the researchers found that overall none of these characteristics observed significantly predicted the time to ≥grade 2 bleeding.

In agreement with past studies, PLADO data confirmed that the platelet increments and CCI are generally higher with AP vs. WBP, ABO identical platelets, and platelets stored for three days vs. those stored for longer.

Discussion. The PLADO study provided the largest database of platelet transfusions in hematology oncology patients, who were carefully followed for bleeding and post-transfusion platelet responses. “The key finding from our analysis is that, although these platelet characteristics … had modest effects on platelet increments, these characteristics did not affect time to occurrence of ≥grade 2 bleeding,” wrote the authors. The researchers note that there has been significant controversy over the efficacy of AP vs. WBP platelets. The authors confirmed previous studies showing that that AP platelet transfusion leads to better platelet increments, but showed that the source of platelets does not affect the risk of bleeding.

Similarly, previous studies have shown ABO identical platelets to be associated with a slightly higher CCI than the transfusion of non-identical platelets. The PLADO data confirmed that major ABO mismatched platelet transfusions were associated with lower platelet increments than ABO identical transfusions, but did not show a statistically significant difference between ABO minor mismatched platelet transfusions and ABO identical transfusions. “This is the first large study however to demonstrate that platelet ABO compatibility does not affect the risk of bleeding,” wrote the authors. The data also showed that there is little functional advantage to “fresh” platelets when comparing outcomes of transfusing platelets stored for longer periods with those stored for lesser periods.

“These data suggest that a strategy for routine platelet support for hematology oncology patients, in general, does not require specific selection policies for these characteristics,” conclude the authors.

Citation: Triulzi, DJ, et al. The impact of platelet transfusion characteristics on post-transfusion platelet increments and clinical bleeding in patients with hypo-proliferative thrombocytopenia. Blood. 10 April 2012. [Epub ahead of print]

Registration Reminder for the IPFA/PEI Workshop

The International Plasma Fractionation Association (IPFA) and the Paul-Ehrlich-Institut (PEI) will be holding the IPFA/PEI 19th International Workshop on “Surveillance and Screening of Blood Borne Pathogens” from May 23-24 (see ABC Newsletter, 8/19/11). The workshop is set to be held in collaboration with the Hungarian National Blood Transfusion Service at the Budapest Marriott Hotel in Budapest, Hungary. The organizations would like to remind interested participants to register soon, as the cut-off date to book a room at the hotel is April 24. More information can be found at www.ipfa.nl.
Researchers at the National Institutes of Health Clinical Center have found a new technique for improving delivery of stem cells that may lead to better and faster tissue repair, NIH announced in a press release on April 2. This finding could be a breakthrough for sports medicine or military populations, said the release. Joseph A. Frank, MD, chief of the NIH Clinical Center of Radiology and Imaging Sciences Laboratory of Diagnostic Radiology Research, is the senior author of the findings. They were published online in *Stem Cells* on March 30. NIH researchers discovered a way to enhance delivery of transplant cells in rodents to a desired site by increasing the presence of chemicals that attract the introduced cells. Non-destructive pulsed focused ultrasound interacts with tissue to elevate levels of naturally produced chemicals (such as cytokines, chemokines, and growth factors) on target tissues. Transplanted stem cells have receptors for these chemicals, so an increased presence attracts more of them to the desired site. Regenerative medicine uses stem cells to replace damaged cells and tissues, and transplanting these cells intravenously is a noninvasive and easily replicated procedure. However, only 1 to 3 percent of intravenous transplanted cells make it to the desired target. By increasing the presence of chemically attractive factors, researchers in the laboratory saw 8 to 10 times more transplanted bone marrow stromal cells in a pulsed focused ultrasound-treated rodent kidney and untreated kidney, said NIH in the release.

The attractive chemical agents are enhanced during inflammation or injury, but their quantity elevations last for a short time. Researchers in the laboratory showed that they can extend that window or open a new one using pulsed focused ultrasound. The ultrasound increased the number of these agents expressed on the endothelial or vessel wall surfaces through approximately one day and returned to control levels by day three. The researchers did not observe any adverse effects to the treated tissue. Researchers saw an increased passage of stem cells into treated tissue and retention, and the focused ultrasound permeates deep so the human body composition is not a limitation. Since the technique increases the presence of more than 10 attractive chemical factors, the method is not cell specific and may be advantageous for a variety of cell products, such as neural cells or immune cells, said the release. The NIH press release is available at: [www.nih.gov/news/health/apr2012/cc-02.htm](http://www.nih.gov/news/health/apr2012/cc-02.htm). (Source: NIH press release, 4/2/12)

A new study shows that a treatment with kartogenin, which encourages stem cells to take on the characteristics of cells that make cartilage, may help in the treatment of osteoarthritis, reported *ScienceNews* on April 5. Peter G. Shultz of The Scripps Research Institute in La Jolla, Calif., and Kristen Johnson of the Genomics Institute of the Novartis Research Foundation in San Diego, Calif., led the study. The findings were published online in the journal *Science* on April 5. Researchers set out to find which compounds induce stem cells to produce chondrocytes, the only cells in the body that can manufacture cartilage. The new approach taps into mesenchymal stem cells, which naturally reside in the cartilage and give rise to the cells that make connective tissue, including the chondrocytes. The researchers found that kartogenin is what induces the stem cells to produce chondrocytes to begin forming cartilage. This is an essential step in the cartilage repair that falls behind when people with osteoarthritis, which develops from injury or long-term joint use, reported *Science News*. “In the blue-sky scenario, this would be a locally delivered therapy that would target stem cells already there,” study coauthor, Ms. Johnson, told *ScienceNews*. The researchers screened 22,000 components of cartilage and found one, kartogenin, induced stem cells to take on the characteristics of the cartilage-forming chondrocytes. The molecule activated genes that produce cartilage components called aggrecan and collagen II. Tests of mice with cartilage damage similar to osteoarthritis showed that kartogenin injections lowered the levels of a protein called oligomeric matrix protein. People with osteoarthritis have an excess of the protein, which is considered a marker of disease severity. Kartogenin also enabled mice with knee injuries to regain weight-bearing capacity on the joint within 42 days, reported *ScienceNews*. Lab tests revealed that

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BRIEFLY NOTED (continued from page 9)

kartogenin inhibits a protein called filamin A in the mesenchymal stem cells. This unleashes other compounds that can orchestrate the activity of genes useful in turning the stem cells into functional chondrocytes. In doing so, kartogenin seems to protect and repair the cartilage. The study abstract is available at: http://bit.ly/HhHcpc. (Source: ScienceNews, 4/5/12)

REGULATORY NEWS

The Food and Drug Administration has issued a request for industry organizations to participate in selecting a nonvoting industry representative to serve on the Blood Products Advisory Committee (BPAC), announced in the Federal Register on Thursday. The Federal Register announcement also requests nominations for individuals to serve as the nonvoting industry representative for BPAC. Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter to FDA by May 14. Also, nomination materials for prospective candidates should be sent to FDA by May 14. Interested candidates may nominate themselves, or organizations may make nominations. Nominees should be authorities knowledgeable in the fields of clinical and administrative medicine, hematology, immunology, blood banking, surgery, internal medicine, biochemistry, engineering, biological and physical sciences, biotechnology, computer technology,
REGULATORY NEWS (continued from page 10)

statistics, epidemiology, sociology/ethics, or other related professions. All letters of interest and nominations should be submitted in writing to Bryan Emery at: the Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike (HFM-71), Rockville, Md., 20852. Further questions can be directed to Mr. Emery at: bryan.emery@fda.hhs.gov. The Federal Register notice is available at: http://1.usa.gov/HDomtd. (Source: Federal Register announcement, 4/12/12)

GLOBAL NEWS

Men who donate blood in the UK may now do so more often as the UK’s National Health Service Blood and Transplant (NHSBT) has released a guidance changing the interdonation interval for men, reported NHSBT in a press release on April 2. After reviewing practices in other countries where men can donate more frequently, NHSBT mandated that men may now donate four times in 12 months, as long as they wait 12 weeks between each donation. This could mean a potential 100,000 extra units of blood donated by men each year, said NHSBT. Women can still only donate once every 16 weeks, equating to three times in a 12-month period. Blood services institute interdonation intervals to allow the donors’ bodies to replenish their iron stores. In the US, all donors (male and female) must wait eight weeks between each donation. The NHSBT’s change brings the UK in line with other European countries, such as Portugal and Italy, which allow men to donate four times a year, while women can donate three times a year, reported NHSBT in the release. (Source: NHSBT press release, 4/2/12)

INFECTIOUS DISEASE UPDATE

HIV

Recent National Institutes of Health-supported research provides some insight into how the first vaccine reported to modestly prevent HIV infection in people might have worked, NIH announced in a press release on April 4. Barton F. Haynes, MD, director of the National Institute of Allergy and Infectious Disease (NIAID)-funded Center for HIV/AIDS Vaccine Immunology based at Duke University, N.C., led the new analysis. Since the initial results of the RV144 vaccine clinical trial were published in 2009, more than 100 scientists from 25 institutions have been searching for molecular clues to explain why the vaccine showed a modest protective effect. Their most recent findings were published on April 4 in the New England Journal of Medicine. In the RV144 clinical trial, which involved more than 160,000 adult volunteers in Thailand, the group that received the vaccine had a 31 percent lower chance of becoming infected with HIV than the group that received the placebo. The new report describes the researchers’ analyses of blood samples taken from a representative subset of the study: 41 participants who were vaccinated and later became infected with HIV and 205 vaccinated participants who remained uninfected. The participants who made relatively high levels of one antibody to HIV were significantly less likely to become infected than those who did not. This particular binding antibody attaches to a part of the virus’s surface called the first and second variable regions, or V1V2, which may play an important role in HIV infection of human cells. The antibody belongs to a class called immunoglobulin G (IgG). Vaccinated study participants who had relatively high levels of a different type of HIV binding antibody, however, appeared to have less protection from the virus than vaccinated participants who had low levels of this protein. The antibody attaches to a part of the virus’s surface called the first constant region (C1) and belongs to a class called immunoglobulin A (IgA). The study hypothesizes that C1 IgA antibody either was associated with less benefit from HIV vaccination or directly reduced the benefit of the

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vaccination. The researchers plan to further evaluate these new findings in studies to be conducted in non-human primates using the RV144 vaccine regimen and other vaccines. The researchers note that they must conduct more tests to determine whether high levels of V1V2 antibodies directly caused the modest protective effect seen in the RV144 study or if it is simply linked to other, still unidentified factors. The NIH press release is available at: http://1.usa.gov/HR1wwS. (Source: NIH press release, 4/4/12)


MEMBER NEWS

Aaron’s, Inc., a retail chain, hosted a 10-hour blood drive with Carter BloodCare, Bedford, Texas, at the Gaylord Texan Resort on March 21. On that day in Dallas, 2,000 managers of Aaron’s, Inc. conducted a single day of what they call “extreme volunteering,” during their annual national managers meeting. The managers donated more than half-a-million dollars in product and monetary donations, coupled with 51,000 community service hours to eight Dallas-area non-profits. Carter BloodCare was one of the eight benefactors. Three-hundred eighty registered donors gave 363 units of blood and apheresis products including platelets and red cell/plasma combinations. These blood donations came at a time when high school spring breaks were underway and Carter BloodCare’s supply of several different blood types was at less-than-preferred levels, said the center. In 2010, Aaron’s managers gave 180 units of lifesaving blood. This year’s 102 percent increase in donations was believed to be, in part, due to an act of support for Assistant Regional Manager Mike Steward from Aaron’s Central North Carolina Region. Mr. Stewart’s 9-year-old granddaughter recently lost a battle with leukemia. The Be The Match Foundation was invited to host a bone marrow registry drive alongside Carter BloodCare’s blood drive. Carter BloodCare would like to thank Aaron’s Inc. for demonstrating

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MEMBER NEWS (continued from page 12)

how a visiting corporation can make a significant social contribution to another community while conducting company business. (Source: Carter BloodCare submission, 4/10/12)

Michigan Blood held a ribbon-cutting ceremony and open house at the new donor center inside the Dow Diamond baseball stadium on April 4, Michigan Blood reported in a recent press release. The Dow Diamond Donor Center is in the home of the Great Lakes Loons baseball team in Midland, Mich., and is the first donor center inside a sports stadium. Guests were able to tour the new donor center and enjoy hors d’oeuvres on the day of the ribbon-cutting and open house. The center also had four donors registered, screened, and ready to donate before 10 a.m. on its first day in operation. The first 50 people who attended and scheduled an appointment to give blood won Great Lakes Loons ticket vouchers. Individuals also had the opportunity to register to win Great Lakes Loons prizes valued at $500. The donation site is a result of a partnership between The Dow Chemical Company, the Michigan Baseball Foundation, and the Great Lakes Loons baseball franchise. Michigan Blood received an $80,000 donation from The Dow Chemical Company to support the renovations. The 1,000-square-foot facility features six new donor beds, two screening booths, new equipment, new furniture, and a flat screen television. A few days after the center’s grand opening, Michigan Blood CEO and President Bill Rietscha threw out the first pitch of this year’s season opener for the Great Lakes Loons. “The Dow Diamond Donor Center is a continuation of the rich history of blood donation in Midland. It’s an honor for Michigan Blood to be a part of this legacy,” said Mr. Rietscha. “We are very pleased to open a center right in the heart of the Great Lakes Bay Region that will offer donors another opportunity to help support the needs of our partner hospitals throughout Michigan.” (Source: Michigan Blood press release, 3/26/12)
**PEOPLE**

**Jeffrey D. Allen** has recently been appointed as BloodCenter of Wisconsin’s executive vice president, chief strategy officer, and chief financial officer, announced BloodCenter of Wisconsin in a press release on April 4. As chief strategy officer, Mr. Allen is responsible for developing and leading the organization’s long-range strategies, including the creation of strategic partnerships and alliances. As chief financial officer, Mr. Allen is responsible for all financial, accounting, treasury, and supply chain functions. He also provides executive oversight for BloodCenter’s IT and marketing functions and is responsible for business development. “Today’s complex healthcare environment brings both challenges and opportunities,” said Jacquelyn Fredrick, BloodCenter’s CEO and president. “Our commitment to our customers is to find better ways to lower costs and increase service and quality. Jeff is the right person to lead us in this effort.” Prior to joining BloodCenter in 2003, Mr. Allen worked with Baxter Healthcare International for 16 years, where he served most recently as vice president of Finance for the $2 billion renal group. Other positions held at Baxter included vice president of Finance for Europe, Middle East and Africa; vice president of Business for Nextran (a subsidiary of Baxter); and general manager of Research Medical, Inc. (a subsidiary of Baxter). Mr. Allen currently serves as assistant treasurer of BloodCenter Research Foundation, a supporting entity of BloodCenter. He also serves on the Investment and Finance Committee of Blood Centers of America, and previously served as chair of the Audit Committee for America’s Blood Centers. “I look forward to developing and implementing innovative programs to grow and better position BloodCenter of Wisconsin for the changing healthcare landscape of the future,” said Mr. Allen. (Source: BloodCenter of Wisconsin press release 4/4/12)

**David C. Fennell** has recently been appointed as Puget Sound Blood Center’s (PSBC) new chief operating officer, in addition to his current responsibilities as chief information officer, PSBC announced in a press release on April 4. Mr. Fennell will oversee all operational business lines including donor recruitment, blood components, donor testing, transfusion medicine, hemophilia and patient programs, and cord blood and tissue services. “Dave’s professional experience and perspective encompass both the private and non-profit sectors, and his expertise and insight in business leadership will help make our operations more efficient, quality-driven, and economically sustainable as we continue to focus on meeting the needs of donors, volunteers, patients, physicians, hospitals, and communities who rely on us,” said James P. AuBuchon, MD, president and CEO of PSBC. “Dave will be working with various business leaders in the implementation of their business plans, seizing opportunities for growth, and developing further strategies to position the blood center for success in a dynamically-changing health care sector.” Mr. Fennell’s career includes 28 years at Boeing Commercial Airplanes in various positions advancing to management and senior leadership, including five years as chief information officer and vice president of Boeing Information Technology. Prior to joining PSBC in 2010, Mr. Fennell served as CIO for three years at the Bill and Melinda Gates Foundation. He also served for six years as a board member of the Seattle Art Museum. Mr. Fennell graduated from the University of Maryland with a bachelor’s degree in economics and from the University of Washington with a Master of Business Administration. He will continue to report to Dr. AuBuchon in his new role. (Source: Puget Sound Blood Center press release, 4/4/12)

*PEOPLE (continued on page 15)*
PEOPLE (continued from page 14)

**Bruce Lenes, MD,** has been appointed as senior medical director with Blood Systems’ national office, reported Blood Systems in a press release on Tuesday. Dr. Lenes spent more than 30 years as Medical Director for Community Blood Centers of Florida. In addition to his responsibilities as medical director, Dr. Lenes will be working with Blood Systems physicians on numerous projects to improve transfusion practice and to reduce hospital costs while providing increasing value to customers. He trained in Internal Medicine at the University of Florida in Gainesville, Fla., and in Hematology at Georgetown University Hospital in Washington, D.C. He also trained in Transfusion Medicine at the National Institutes of Health in Bethesda, Md. (Source: Blood Systems press release, 4/10/12)

**IN MEMORIAM – Chet Somerville, 83**

Chester Raymond Somerville, known to most as Chet, of Atlanta, died on March 29 at age 83 while recovering from surgery at Northside Hospital, reported the *Atlanta Journal-Constitution* on April 12. Mr. Somerville worked for the American Red Cross for more than 30 years, and was remembered by many for his friendly personality and persistence. “I think everyone who met him had an experience with him,” Lloyd Wells, of Winder, Ga., a friend and former Red Cross co-worker, told the *Atlanta Journal-Constitution*. “I was talking to my sister the other day, and she’d only met him once or twice I think, and she had a memorable experience with him. He was just that kind of guy.” Mr. Somerville, born in Dodge City, Kansas, graduated from Washburn University with a bachelor’s degree in political science, and was preparing for law school when he was drafted into the Army. After his military service concluded in the late 1950s, Mr. Somerville decided to take a job with the Red Cross, and moved to Atlanta in 1960 while working for the organization. He served as an administrator for the Metro Atlanta Red Cross Blood Program, where he fielded many questions about blood donation in those early days of blood banking. During his tenure with the Red Cross, Mr. Somerville helped to expand the blood donation program and aided in the transition from collecting blood in glass bottles to plastic containers and tubes. In 1980, he was moved to the Red Cross’s national headquarters in Washington D.C., where he remained until retiring. In 1986, then-President Ronald Reagan commended Mr. Somerville for his work with the Red Cross and veterans exposed to certain toxins during the Vietnam War. Mr. Somerville is survived by several extended family members and friends. The full obituary is available at: [http://bit.ly/Hy4tya](http://bit.ly/Hy4tya). (Source: *Atlanta Journal-Constitution*, 4/12/12)

**Correction**

In the April 6 *ABC Newsletter* on page 6, we incorrectly identified the Avioq HTLV I/II Microelisa System as the only test available to screen for antibodies to both HTLV-I and HTLV-II. However, the Abbott PRISM HTLV-I/HTLV-II assay, available since 2008, also detects antibodies to both HTLV Type I and/or HTLV Type II in human serum and plasma specimens. The Avioq HTLV I/II Microelisa System is actually the only test available that can be used both to screen blood for antibodies HTLV-I and HTLV-II and to diagnose infection with these viruses. The *ABC Newsletter* apologizes for this error and thanks our readers who bring these issues to our attention.
MEETINGS

April 17-18  AdvaMed Medical Device Tax Workshop, Irvine, Calif.

AdvaMed is holding a medical device tax workshop to prepare the industry for the new medical device excise tax and regulations set to go into effect on Jan. 1, 2013. The workshop will be held at the Marriott Irvine in Irvine, Calif. The meeting will allow attendees to acquire new medical device tax legislative updates and to explore potential implementation challenges. The workshop will also cover comments issued in response to IRS Notice 2010-89 and how those comments may affect the upcoming final guidance from IRS. Industry leaders will provide information from meetings with IRS and Treasury staff. The medical device excise tax will affect both the domestic and international medical device companies and will affect the industry’s job market, patient care, clinical research, and device innovation, said AdvaMed. Interested participants can learn more or register at: www.advamedmtli.org/.


AdvaMed will hold a conference from April 23 to 24 at the Washington Marriott at Metro Center in Washington, D.C. regarding medical device recalls. The workshop will provide guidance from both regulatory and business perspectives on handling medical device recalls. It will teach participants how to properly prepare for managing product recalls. Key experts from the Food and Drug Administration’s Center for Devices and Office of Enforcement, together with leaders from the medical device industry will be present to discuss FDA regulations, guidances and expectations, internal company decision-making issues, and effective procedures/strategies. This conference will establish a clear understanding how the regulatory affairs function is pivotal to every recall and every team decision-making. Those interested can gain more information and register at: www.advamedmtli.org/.

CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC institutional members. There are charges for non-members: $139 per placement for ABC Newsletter subscribers and $390 for non-subscribers. Notices ordinarily are limited to 150 words. To place an ad, contact Leslie Norwood at the ABC office. Phone: (202) 654-2917; fax: (202) 393-5527; e-mail: mnorwood@americasblood.org.

POSITIONS AVAILABLE:

Leader - Biologics Training. OneBlood, Inc. a 501(c) 3 not-for-profit organization incorporated in the State of Florida providing blood and blood products to over 200 hospitals throughout Florida and the southern area of Alabama and Georgia. The organization is the result of the recent merger of three regional community blood centers: Community Blood Centers of Florida, Florida Blood Centers, and Florida Blood Services. OneBlood, Inc. is the third largest community blood center in the United States, with annual revenue over $300M, employing over 2,700 employees. Position reports to the Chief Medical Officer and manages all Biologics Training staff, including Instructors, Course Designers, Performance Assessors, Collections, Manufacturing, Distribution and Laboratory staff. Minimum of a bachelor’s degree in psychology, adult education, human factors science, psychometrics or a related field. Master’s degree preferred. Professional designations: Licensed RN, Medical Technologist, or SBB preferred but not required. This position is based out of St.

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POSITIONS (continued on page 16)

Petersburg, Orlando, or Lauderhill. To review job requirements and to apply for this position please visit the careers section at www.oneblood.org. OneBlood is an Equal Opportunity Employer (AA/M/F/D/V) & Drug Free Work Place.

Reference Laboratory Supervisors. Bonfils Blood Center partners with the Colorado community to save and enhance lives through transfusion medicine excellence. Currently, Bonfils has opportunities for Reference Laboratory supervisors and Quality Assurance professionals. Reference Laboratory Supervisors require a MT(ASCP) and five or more years full-time blood banking experience. Thorough knowledge of immunohematology, Donor Center and Transfusion Service operations, current GMPs and regulatory/accréditation requirements is also necessary. You can find out more about these open positions and apply on our website at http://www.bonfils.org/index.cfm/about-us/employment/.

Reference Laboratory Technologist. Kentucky Blood Center, located in Lexington. Ky., is seeking a medical technologist to perform and interpret serological procedures on specimens submitted for compatibility testing or problem resolution. Will resolve typing problems, antibody problems, and crossmatch problems, and communicate with hospitals as needed. MT(ASCP) with minimum two years’ recent blood bank experience, MT(ASCP)SBB preferred. Strong written and oral communication skills, a do-what-it-takes work ethic, and a team player attitude required. Competitive salary, comprehensive benefits including health/dental/life, LTD, paid sick/vacations/holidays, EAP, 403(b) retirement savings plan, and pension plan. For more information or to apply online, please visit www.kybloodcenter.org/. Drug-free and EOE/AAP

Quality Assurance Specialist (Lane Blood Center, Eugene, Oregon). Analyze and interpret blood banking regulations and inform management how to stay in compliance. Coordinate FDA variance reporting; process donor deferrals and other required notifications. Manage the research and submissions of Biological Product Deviation Reports, the Annual Report and Biologic License Amendments to the FDA. Manage all document control policies and procedures. College degree required; prefer biologic science. Minimum two years QA experience in regulated environment. Project management skills and close attention to detail required. Ability to think critically, solve problems and make decisions related to compliance. Conflict resolution skills essential. Must have basic understanding of FDA regulations; quality systems and cGMPs. Apply at www.laneblood.org. “Job Opportunities.” Lane Blood Center, 2211 Willamette Street, Eugene, OR. (541) 484-9112.

Regional Manager. LifeSouth Community Blood Centers is seeking an individual with a passion to make a real difference in the community as a Regional Manager in Dothan, Ala. Responsibilities include, but are not limited to: oversee established goals for percentage to inventory for all departments; ensure that region operates within its budget; represent and promote the company and its mission to the community; review weekly recruitment goals and projections.; implement corrective action when projections and goals are not being met; assist the Regional and/or District Director with the oversight of blood collection, donor recruitment, component production, blood labeling and blood distribution. Bachelor’s degree required. Three years of supervisory or management experience required. This is a full-time position. Salary range $50,000 - $55,000. Background check and drug test required. Equal Opportunity/Affirmative Action Employ-er/DFWP/Tobacco Free. Please click on the link to apply: https://home.eease.adp.com/recruit/?id=1346341.

Laboratory Services Director – IRL & Specialty (Job Code: LA001), QualTex Laboratories an affiliate of the South Texas Blood & Tissue Center (STBTC), seeks an individual to manage, supervise, and coordinate all activities for Immunohematology Reference and Specialty Laboratories (includes IRL, Confirmatory, Microbiology, and Research and Development) for QualTex Laboratories in Norcross, GA and San Antonio, TX. The position will be based at the Norcross, GA facility. QualTex Laboratories at present screens millions of whole blood and plasma donations for infectious agents each year for biotechnology companies locally and across the globe. Qualifications required include a bachelor’s degree in Science, Medical Technology, Microbiology or related discipline, six years laboratory experience and extensive management experience in laboratory operations. An MT (ASCP), SBB certification is also required along with a working knowledge of clinical laboratory techniques and current knowledge of regulatory/quality requirements (national and international, i.e. FDA, EU, GHA, ISO, OSHA & cGMP). For information, call Human Resources at (800) 292-5534, Ext. 1559. EOE/AAP. To apply, e-mail resume to hr_dept2@bloodntissue.org or fax to (210) 731-5581.

Hospital Services Manager. LifeStream, a $53M healthcare organization providing blood services for more than 70 hospitals in Southern California, is searching for a Hospital Services Manager to serve as LifeStream’s customer service representative and technical resource. Proactively ensures customer complaints, suggestions, and process problems are reported, documented, and pursued; works with other blood center departments to resolve problems. Manages, maintains, and analyzes statistical databases to support blood component inventory management and budgeting. Conducts (continued on page 18)
periodic customer surveys to determine level of service satisfaction; tracks and trends survey results. Researches new business opportunities and assists VP Business Development in managing hospital contracts. Four-year bachelor’s degree (BA or BS) in biological sciences or medical related discipline required. MT (ASCP) and or SBB (or equivalent) desirable. Minimum four years experience in blood banking or five years in hospital laboratory with transfusion service experience, (or equivalent). Must have exceptional interpersonal communicative skills developed and cultivated through extensive managerial and customer service experience. Excellent compensation and benefits plan. Apply online:
www.LStream.org. Or send cover letter, resume and salary history to: LifeStream, Attn: HR, 384 W. Orange Show Rd. San Bernardino, CA 92408. E-mail: employment@LStream.org. EOE

RN/LPN Therapeutic Apheresis Specialist. Florida’s Blood Centers (FBC) seeks a full-time RN/LPN Therapeutic Apheresis Specialist to perform Hospital Therapeutic Apheresis collection, as ordered by physicians. Requirements: graduate of an accredited school of nursing, current active Florida RN/LPN license, current CPR certification, strong computer skills, valid driver's license, good driving record, reliable car and proof of insurance. Must be available for travel, and customer focused. For more information & to apply on-line please visit our website at www.floridasbloodcenters.org. Position will remain open until filled. Florida’s Blood Centers is an Equal Opportunity Employer (AA/M/F/D/V) & Drug Free Work Place.

Manager, Transfusion Services. BloodCenter of Wisconsin has a leadership position that offers an opportunity to join a growing team! We seek an effective leader with excellent communication skills. We will depend on you to provide business and technical direction. You would be responsible for successful execution of business and strategic initiatives, managing the people and financial resources, and for ongoing and sustainable improvement in the areas of compliance, customer/employee satisfaction, and process control. The ideal candidate will have a bachelor’s degree in Clinical Laboratory Science, be ASCP certified (or equivalent), at least five years of experience in transfusion service, and three years lab supervisory experience. Strong teambuilding and customer service skills are essential. Candidate must be detail oriented and have demonstrated ability to exercise initiative and independent judgment. We offer a competitive salary and excellent benefits. Apply online at www.bcw.edu/careers. We embrace and encourage diversity in our workforce. EEO/AAP

Associate Medical Director. BloodCenter of Wisconsin seeks physician to join growing Transfusion Medicine (TM) service of the Medical Sciences Institute. Physicians in TM direct transfusion services within three healthcare systems in Milwaukee area; provide direct patient care for therapeutic apheresis; consult with physicians re: transfusion medicine issues and bleeding disorders; promote blood management; provide medical direction of specialized laboratories; and participate in on-call responsibilities. More than 110,000 blood products are transfused annually and nearly 2,000 therapeutic apheresis and stem cell collection procedures are performed at the institutions directly served. Successful candidate expected to participate in clinical and/or applied research. BloodCenter has Transfusion Medicine Fellowship and SBB Program. MD or DO degree and board-certification in Pathology, Internal Medicine or Pediatrics required, as well as board certified/eligible in Blood Banking/Transfusion Medicine. We offer a competitive salary and excellent benefits. Apply online at www.bcw.edu/careers. We embrace and encourage diversity in our workforce. EEO/AAP.