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ABC NEWSLETTER

CURRENT EVENTS AND TRENDS IN BLOOD SERVICES

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Issue #25
July 15, 2016

Older is Wiser and, Perhaps, a Better RBC Donor

In an observational study involving four academic hospitals and spanning over seven years, Canadian scientists examined whether a red blood cell (RBC) donor's age and sex were factors in the recipient's risk of death.

RBC transfusion is the most common medical procedure in contemporary medicine; the use of which grew 134 percent from 1997 to 2011. Donor age has been shown to affect certain RBC production processes, immune tolerance and responses, and could affect RBC structural characteristics. For these reasons, the authors hypothesized donor age and sex could be associated with recipient outcomes.

Some research into recipient outcomes has been reported for major organ (heart, kidney, lung and liver) and stem cell transplants. Multiple studies have shown a negative association with donor age and recipient survival. Certain types of donors are avoided for certain blood products as well. For instance, mothers are usually avoided as platelet donors, because of the association of alloimmunity with an increased incidence of transfusion-related acute lung injury (TRALI) in recipients. Women are typically avoided when recruiting transfusable plasma donors as well. However, to date, few studies of RBC donor characteristics and recipient outcomes have been reported.

The lone widely-reported study on RBC donor characteristics was published earlier this year using the Scandinavian Donations and Transfusions 2 (SCANDAT2) database, a database containing 25.5 million donor and 21.3 million recipient records in Sweden and Denmark. However, the SCANDAT2 study only followed recipients for seven days and the mean number of transfusion per patient was one (1) transfusion.

In the Canadian longitudinal cohort study, 80,755 RBC donors and 30,503 recipients with 187,960 transfused RBC units from October 2006 to December 2013 were analyzed. The Canadian Blood Services supplied the donor data, which was collected at the time of donation. Long and short-term outcome data was collected from the four participating hospitals in Ottawa, Canada.

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INSIDE:

Our Space:

OUR SPACE

ABC CEO Christine S. Zambricki, DNAP, CRNA, FAAN

Bench Strength On the Shelf

Recent events around the world underscore the need for continued preparedness and vigilance for blood centers. The attack in Nice, France, on July 14, follows a series of deadly attacks in the U.S. and abroad over the past few years, all of which seem to be escalating in recent months.

At one time, conventional wisdom had it that, in the face of major national disasters, blood may not be necessary due to the devastation of the attacks. For example, in the case of the nation's tragedy on 9-11, hospital operating rooms (ORs) were held open in anticipation of a torrent of victims; blood was sequestered and ready to be shipped. Sadly, the ORs and the blood were not needed.

The face of terrorism is shifting to soft targets: sports arenas, nightclubs, and open air gathering places with large groups of people. From California to Texas, from Florida to New York, terrorism has become a local phenomenon. And at the heart of these tragedies is that now more than ever there are hundreds of maimed and critically injured survivors in addition to those who lose their lives. Blood centers are at the heart of a coordinated rapid response system that mobilizes within minutes after these events.

When these incidents occur, the good citizens of America are moved to donate blood. Over 2,000 potential donors lined the street of our ABC member blood center in Orlando to do their part in saving a life. This gift of so many is met with respect and appreciation. Yet we all know that the blood that is saving the life of the trauma patient in the OR within an hour after the event is the blood that has been on the shelf, not the blood being donated that day. A critical question for our industry, and indeed for our nation, is how to tap into the reservoir of goodwill within everyday Americans to provide a steady stream of donors and a pipeline of life-saving blood products? Just as an athletic team with a strong bench ensures success, blood centers require the infrastructure and the steady state of a generous, donating public to respond to the needs of their communities, especially during times of distress.

Recently the ABC Board set direction for shifting the paradigm of blood donation from episodic good intentions during an emergency to habit grounded in a sense of duty. But how do we accomplish this seismic shift? Is it donor education at the community level? A public health initiative at the government level? Or is it a collective initiative within ABC to blanket the country with a new message, a public relations campaign about the need for "bench strength" on the shelf? We welcome your thoughts.

Christine S. Zambricki

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

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OLDER IS WISER (continued from page 1)

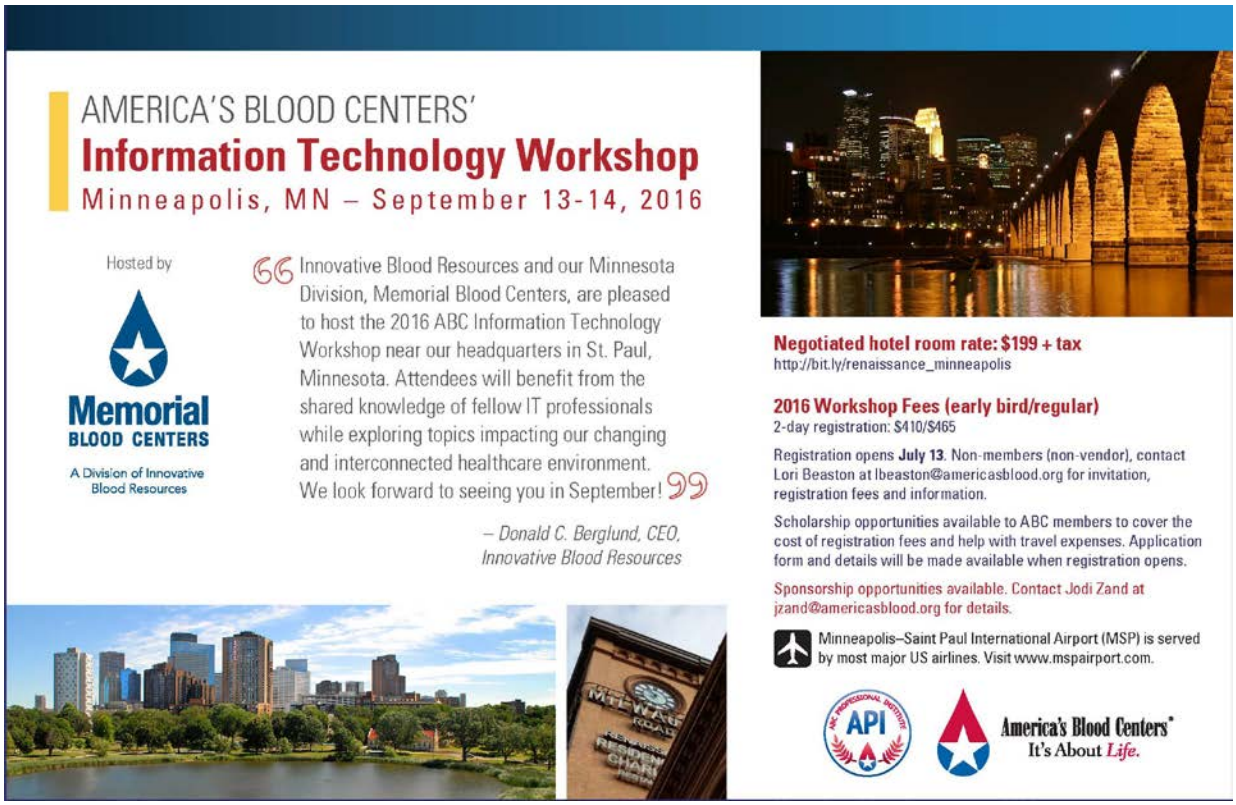
Perhaps counterintuitively, donor age was inversely associated with mortality. The younger the donor, the higher the risk of death: the adjusted hazard ratio (HR) compared to the reference age cohort (40-49.9 years) for the first transfusion was at 1.08 (95 percent confidence interval [CI], with 1.06-1.10 for each additional unit transfused) for the donor age-range 17 to 19.9; adjusted HR 1.06 (95 percent CI, 1.04-1.09) for donors between 20 to 29.9 years; 1.01 (95 percent CI, 0.99-1.03) for donors 30 to 39.9 years old. The highest risk of death was associated with the youngest donors (17 to 19.9 years old) giving to male recipients, with an adjusted HR of 1.14 (95 percent CI, 1.11 to 1.17). Receiving a female donor's RBC unit was associated with reduced survival as well for both male (adjusted HR, 1.08; 95 percent CI, 1.07-1.10) and female (adjusted HR, 1.03; 95 percent CI, 1.02-1.05) recipients. Overall, 13,118 (43 percent) of the study's recipients died within the seven years of the study.

The authors recognized—as did Harvey G. Klein, MD, at the Department of Transfusion Medicine with the National Institutes of Health, in an invited commentary—that bias and confounding are two major limitations of a retrospective, observational study. Clinical conclusions would be inappropriate, but the study can be viewed as hypothesis generating and more studies will shed light on whether there are preferable RBC donor characteristics like age and gender.

Citations: Chassé M., Tinmouth A., and English S., *et al*. Association of Blood Donor Age and Sex With Recipient Survival After Red Blood Cell Transfusion. *JAMA Internal Medicine*. July 11, 2016. Early Online. DOI: 10.1001/jamainternmed.2016.3324.

Klein H., Blood Donor Demographics and Transfusion Recipient Survival—No Country for Old Men? *JAMA Internal Medicine*. July 11, 2016. Early Online.

Vasan S.K., Chiesa S.F., Rostgaard K., *et al*. Lack of association between blood donor age and survival of transfused patients**.** *Blood*. February 4, 2016. DOI:10.1182/blood-2015-11-683862.



America's Blood Centers®
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INSIDE ABC

The programs and services described in the Inside ABC section are available to ABC member blood centers and their staff only, unless otherwise specified.

ABC is Pleased to Welcome Our New Chief Administrative Officer

Katherine Fry will join the ABC team as Chief Administrative Officer, effective July 27. In this role, Ms. Fry will oversee ABC's membership-facing operations and play a key role in our legislative and political advocacy efforts, including the mobilization of grassroots efforts to achieve strategic goals.

With over a decade of health care association experience at the manager and director levels, Ms. Fry brings significant bench strength to ABC. While in leadership positions at the National Association of Chain Drug Stores, the American Speech-Language-Hearing Association, and the American Association of Nurse Anesthetists, Ms. Fry was responsible for directing multi-faceted, national advocacy campaigns; communication efforts; building member value; and managing multiple, large-scale projects. In addition, Ms. Fry brings significant expertise in representing the views of associations before members of Congress and their staff.

Ms. Fry graduated from Dickinson College in Carlisle, Pa., with a Bachelor of Arts in Political Science and History and is currently enrolled at George Mason University to obtain a Master of Business Administration degree. In 2013, Kate was the recipient of the prestigious Public Affairs Council "Volunteer of the Year" award.

In her spare time, Ms. Fry enjoys competing in triathlons and relishes international travel. Born into a military family, Kate believes in giving back to U.S. veterans for their service to our country. As a dedicated volunteer guardian in the Honor Flight Network program, Ms. Fry accompanies veterans visiting war memorials in Washington, D.C.

Emergency Appeal for Donors Issued

ABC, AABB, and the American Red Cross issued a critical appeal for blood and platelet donors on July 11, 2016. The joint release highlighted the risk to the nation's blood supply as inventory became extremely low in parts of the country. We here at ABC touched on the summer supply issues a few times in the last month (see ABC *Newsletter*, Issue #22 and #23) and expressed our hesitation in putting out an emergency appeal. However, the triple threat of Zika deferrals, the Haemonetics bag recall, and the higher hemoglobin cut-off for male donors—on top of seasonal summer shortages already—resulted in a national call to action.

Missing Type Campaign Update

The international Missing Type Campaign will be taking place August 15 to 21. As you conduct your outreach efforts please keep ABC informed by contacting Mack Benton in order to keep the global participation list of partners accurate for all 21 international blood organizations involved. ABC is encouraging member blood centers to reach out to corporations, community organizations, athletic teams, local government, media, donor groups, iconic sites, and blood donors. The Missing Type Campaign started as a United Kingdom-based NHS Blood and Transplant (NHSBT) initiative to obtain new blood donors. Businesses,

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INSIDE ABC (continued from page 4)

brands, and influencers were asked to remove the letters, "A," "B," and "O" from their websites, Twitter handles and signage without an explanation. The campaign was a success and inspired 30,000 new donors to register and give blood. Visit the ABC Member Site for more on this campaign.

RESEARCH IN BRIEF

Scientists using two different vaccines completely protected mice from two strains of Zika virus (ZIKV) in controlled studies. Harvard Medical School researchers at the Center for Virology and Vaccine Research (CVVR) at Beth Israel Deaconess Medical Center and from Walter Reed Army Institute of Research designed DNA Zika vaccines and tested them in mouse models. At four weeks mice were injected intravenously with a strain of ZIKV from Brazil or a strain from Puerto Rico. Those injected with DNA vaccines containing prM-Env and IgG were found to be completely protected (<100 Zika RNA copies/ml) at any time point. Another group was injected at eight weeks, and again, all these vaccinated mice were completely protected. Mice injected with DNA vaccines lacking the prM-Env did express lower viral loads than the unvaccinated control groups, however, they were not fully protected. The mice receiving vaccines made with purified IgG from prM-Env serum with moderate to high antibody titers (2.35 and above) were also fully protected.

Citation: Larocca R., Abbink P., Peron J.P., *et al*. Vaccine protection against Zika virus from Brazil. *Nature*. June 28, 2016. DOI: 10.1038/nature18952.

BRIEFLY NOTED

Using Plasma-lyte A (PA)/HSA could be a safe and efficient solution for replacing dextran 40-based dilution solutions to thaw out umbilical cord blood units (CBU) for infusion. Since last winter, the industry has seen a shortage of injectable-grade dextran 40 dilution solutions. Scientists evaluated the performance of saline, Plasma-lyte, and hydroxyethyl starch (HES) with or without human serum albumin (HAS) for the thawing of CBU to find a potential replacement for the dextran 40–based solution. Frozen CBUs were rapidly thawed and immediately diluted 1:4 in each of 10 dilution solution variants. Researchers analyzed the viability of CD34, CD45, and colony-forming units recovery post-thaw. All solutions with 5 percent HSA gave recovery, viability, and potency figures similar to the dextran 40/HSA solution. Because Plasma-lyte A (PA)/HAS is already used to thaw out CD34 from mobilized blood, the authors concluded it was the mostly likely replacement for dextran 40 solutions.

Citation: Marc Cloutier M., Simard C., Jobin C., *et al*. An alternative to dextran for the thawing of cord blood units. *Transfusion*. July 2016. DOI: 10.1111/trf.13633.

The National Institutes of Health (NIH) is funding researchers to follow athletes, coaches, and other U.S. Olympic Committee members attending the 2016 Summer Olympics and Paralympics in Brazil. Researchers hope to enroll at least 1,000 participants and to determine the incidence of Zika virus infection and potential risk factors for infection, detect where the virus persists in the body (blood, semen, vaginal secretions or saliva), evaluate how long the virus remains in these fluids, and follow the reproductive outcomes of Zika-infected participants for up to one year. (Source: NIH press release, July 5. 2016.)

A probable case of Zika virus (ZIKV) transmission by transfusion has been published from Brazil. The blood donor called the donor facility three days after donation, and relayed his symptoms (fever, malaise and headaches). On testing, the donor's stored samples were positive for ZIKV using reverse transcrip-

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BRIEFLY NOTED (continued from page 5)

tion-polymerase chain reaction (RT-PCR) analysis. The blood bank lab linked the platelet concentrate to pooled units transfused to a liver transplant recipient, who developed no clinical manifestations attributable to ZIKV infection. The recipient was positive by RT-PCR and donor and recipient ZIKV nucleic acid sequences matched 99.8 percent. This case, and three more apparent transfusion transmissions, was discussed at the AABB Zika Virus Symposium on June 10.

Citation: Barjas-Castro M., Angerami R., Cunha M., *et al*. Probable transfusion-transmitted Zika virus in Brazil. *Transfusion*. July 2016. DOI:10.1111/trf.13681.

RECENT REVIEWS

In an analysis of data from Brazil and French Polynesia, researchers confirm a clear association between a mother being infected with Zika during the first trimester and the fetus developing microcephaly. Researchers from the Centers for Disease Control and Prevention (CDC) and Harvard T.H. Chan School of Public Health reviewed data from 2013 to 2015 in both the Brazilian state of Bahia and the Pacific island of French Polynesia and considered different infection-rate scenarios (from 10 to 80 percent), possible over-reporting (0 or 100 percent), and an uncertain baseline microcephaly rate (2 to 12 cases per 10,000 births). While the researchers found a strong association between the risk of microcephaly and Zika infection risk in the first trimester, the association is much less apparent with second and third trimester Zika infections.

Citation: Johansson M., Mier-y-Teran-Romero L., Reefhuis J., *et al*. Zika and the Risk of Microcephaly. *New England Journal of Medicine*. July 7, 2016. DOI: 10.1056/NEJMp1605367.

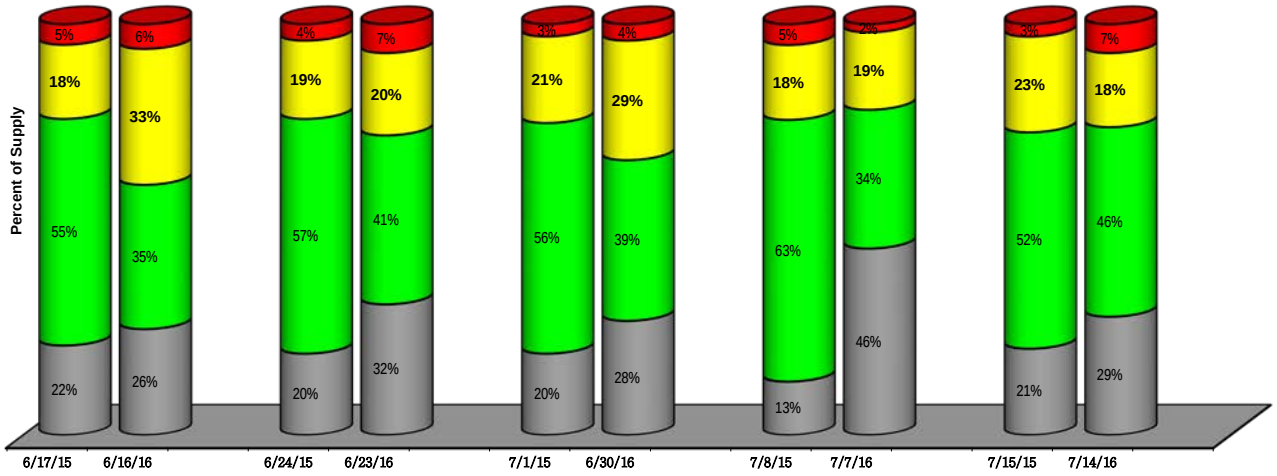
INFECTIOUS DISEASE UPDATES

Viral hepatitis is now the leading cause of death and disability around the world. In a joint study from the Imperial College London and the University of Washington and funded by the Bill and Melinda Gates Foundation, data from 183 countries during 1990 to 2013 was analyzed. Researchers found that viral hepatitis kills and disables more people across the globe than tuberculosis, malaria, or HIV/AIDs. The majority of deaths, 96 percent, are attributed to hepatitis B and C, both of which cause liver damage and cancer.

Citation: Stanaway J., Flaxman A., Naghavi M., *et al*. The global burden of viral hepatitis from 1990 to 2013: findings from the Global Burden of Disease Study 2013. *The Lancet*. July 6, 2016 (online first). DOI: http://dx.doi.org/10.1016/S0140-6736(16)30579-7.

The Centers for Disease Control and Prevention (CDC) released a Morbidity and Mortality Weekly Review Supplement on the CDC's response to the 2014 to 2016 Ebola Epidemic in West Africa and the U.S. To date, the CDC's response to this epidemic was the agency's largest in history. In the supplement, as a result of the outbreak, the CDC states that the U.S. government is committed toward establishing the Global Health Security Agency in 30 different countries to "accelerate progress toward detecting and mitigating infectious disease threats quickly and effectively." Other lessons include the need for stronger international support when countries are overwhelmed by an outbreak, and the importance of improving infection prevention and control in health care settings. A complete breakdown of the outbreak, response and lessons learned are on the website. (Source: CDC MMWR, July 8, 2016.)

STOPLIGHT®: Status of the ABC Blood Supply, 2015 vs. 2016



No Response	Green: 3 or More Days	Yellow: 2 Days	Red: 1 Day or Less

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

AMERICA'S BLOOD CENTERS
54TH SUMMER MEETING

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

"In the late 1700s, Polynesian navigators voyaged thousands of miles of open ocean and discovered Hawaii.

Using modern day wayfinding techniques, together we will explore ways to navigate the challenging times ahead facing the blood banking industry. Let the island host culture inspire us with its Aloha Spirit, high energy of world-famous Waikiki, natural beauty, entrancing hula and the thrill of fire knife dancing. Discover our paradise this summer."

– Kim Anh Nguyen, MD, PhD, president and CEO, Blood Bank of Hawaii

Blood Bank of Hawaii
Give Blood. It's Safe. It's Simple. It Saves Lives.

Honolulu International Airport (HNL) is served by most major airlines. Visit http://www.honoluluairport.org.

August 1-4, 2016 – Honolulu, HI
Hilton Waikiki Beach on Kuhio
special room rate: $240 + tax

Future Leader Scholarship Program
Supported by the FABC, these scholarships offer non-C-suite blood center executives the opportunity to advance professionally by attending the ABC Summer Meeting. Details available upon registration.

Registration Fees
ABC Summer Meeting: $760
Non-members (non-vendor), contact Lori Beaston at lbeaston@americasblood.org for invitation and registration fees and information.

Meeting Schedule
Monday August 1:
Links for Life Golf Tournament
Links for Life Golf Reception
Tuesday, August 2:
Medical Directors Workshop
Hospitality/Networking
Wednesday, August 3:
SMT Forum
Blood Center Leadership Forum
Host Event by Blood Bank of Hawaii
Hospitality/Networking
Thursday, August 4:
ABC Members Meeting

For sponsorship opportunities contact Jodi Zand at jzand@americasblood.org.

REGULATORY NEWS

The Centers for Disease Control and Prevention (CDC) awarded $25 million to state, city, and territorial health departments across the nation to protect the public from Zika. Funding recipients were selected based on the estimated range of the two *Aedes* mosquitos known to transmit the virus. The CDC also awarded 62 state and local public health departments $567.5 million as part of the Public Health Emergency Preparedness cooperative agreement (PHEP). The PHEP provides resources to local communities so they can respond to infectious disease outbreaks, natural disasters, and other unplanned emergencies. (Source: CDC news release, July 1, 2016.)

The Food and Drug Administration (FDA) has released two issue draft guidances **on next generation sequencing (NGS) technologies as part of the President's Precision Medicine Initiative.** The first draft guidance, titled "Use of Standards in FDA's Regulatory Oversight of Next Generation Sequencing (NGS)-Based In Vitro Diagnostics (IVDs) Used for Diagnosing Germline Diseases," deals with rare hereditary diseases, and the second, Use of Public Human Genetic Variant Databases to Support Clinical Validity for Next Generation Sequencing (NGS)-Based In Vitro Diagnostics," covers an approach wherein public databases of human genetic variants can serve as scientific sources and evidence for clinical claims of genotype and phenotype relationships. The draft guidances are open for public comments during a 90-day period. (Source: FDA news release, July 6, 2016.)

AABB has revised Tables 1A and 1B titled, "Minimal Requirements for Testing for Transmissible Agents in Cellular Therapy Products," of the Circular of Information for the Use of Cellular Therapy Products, **in June 2016's version.** The changes fixed the MNC(A) and NC(M) for U.S. requirements, and MNC(A), NC(M) and NC(WB) for EU requirements, which were listed in the incorrect column. AABB noted the error could "lead to performing donor sample testing for infectious disease testing within an incorrect testing period for donors of these products." The July 2016 version currently online fixes the problem and supersedes the June 2016 version. (Source: AABB SmartBrief, July 11, 2016.)

WORD IN WASHINGTON

Congress is at an impasse with opposing Zika proposals and unlikely to pass either of them before recessing for the rest of the summer.

On July 12, Senate Majority Leader Mitch McConnell blocked Sen. Bill Nelson (D-Fla.) from trying to resuscitate Sen. Patty Murray (D-Wash) and Sen. Roy Blunt (R-Mo.) co-authored bill proposing $1.1 billion in Zika-funding. Democrats refuse to sign the House's conference report, passed last month in the House, which provides the proposed $1.1 billion, but also blocks funding for Planned Parenthood and includes funding for military construction and other unrelated items. Democrats have already blocked the House proposal with a filibuster and President Obama has also threatened to veto the measure if it arrives at his desk. Congress adjourns until after Labor Day on July 16.

(Source: *Politico*, Senate War Escalates over Zika, July 12, 2016; *The Hill*, Reid: McConnell 'stringing us along' on Zika, July 12, 2016.)

PEOPLE

Jay Bhatt, DO, was named the new chief medical officer of the American Hospital Association (AHA) and president of the AHA's research arm, the Health Research and Educational Trust. A former CFO and head of data strategy with AHA, Dr. Bhatt will start his new role with AHA in September. Currently, Dr. Bhatt serves as the chief health officer for the Illinois Health and Hospital Association. As the new CMO for AHA, Dr. Bhatt will oversee the association's clinical leadership and health improvement activities. In addition, he will also direct the AHA's Institute for Diversity in Health Management and the Association for Community Health Improvement. Dr. Bhatt has worked at the Chicago Public Health Department as the managing deputy commissioner and chief strategy and innovation officer. (Source: AHA news release, July 8, 2016.)

After 20 years with Terumo BCT, Ray Goodrich is leaving the company to start his own consulting firm, Innovata BioConsulting, LLC. Terumo BCT has announced it will be one of Innovata BioConsulting's first clients to ensure a full transitioning and continuity of programs, projects, and overall momentum. Mr. Goodrich served as the vice president of Scientific and Clinical Affairs and chief science officer for Blood Bank Technologies at Terumo BCT where he oversaw the company's development and support efforts in the areas of scientific and clinical affairs as well as laboratory operations. Mr. Goodrich will continue to play an integral role in Terumo BCT, helping the company in adapting new technologies, developing the overall market for pathogen reduction technology (PRT), and driving market adoption of their Mirasol PRT system in both developed and developing countries. (Source: Terumo, July 12, 2016.)

GLOBAL NEWS

The European Commission (EC) has published new results from a survey into the development of more stringent Tissue and Cell donor testing requirements. The more stringent requirements go beyond the existing EC-defined mandatory tests that must be performed on tissue and cell donors each time they donate. The more strict measures can be adopted by European countries on a national level within their legislation and/or by national standards organizations to be used during regular inspections. The results of the survey, by country, can be viewed on the EC website. (Source: EBA newsletter, July 12, 2016.)

Israel will open its first ever bird blood bank in Tel-Aviv. After migrating for thousands of miles every year to Israel, some birds arrive exhausted, injured, and in need of medical treatment. One doctor at the Wildlife Hospital is quoted as saying there are 16 samples already in the bank and one common buzzard was the first patient to be helped. The project could be the first of its kind around the world. (Source: Ynetnews.com, July 6, 2016.)

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GLOBAL NEWS (continued from page 9)

Valneva in France joins the list of drugmakers developing a vaccine for Zika virus (ZIKV). Valneva told Reuters it has succeeded in generating a "highly purified inactivated vaccine candidate" based off the same vaccine it developed for Japanese encephalitis. The company has yet to obtain regulatory approval or begin clinical trials. Sanofi SA, Inovio Pharmaceuticals Inc., and NewLink Genetics Corp. are just some of the other drug companies looking to capitalize on a ZIKV vaccine. No vaccine is likely to be on the market until, earliest, 2017. (Source: *Reuters*, France's Valneva says has generated possible Zika vaccine. July 7, 2016; *Wall Street Journal*, Drugmakers Scramble to Find Zika Vaccine. March 6, 2016.)

MEMBER NEWS

BloodCenter of Wisconsin, a part of Versiti, and the Department of Transfusion Medicine at the National Institutes of Health (NIH) are teaming up to host the 6th Annual Red Cell Genotyping 2016: Clinical Steps Symposium on September 21. The symposium will review the laboratory aspects and clinical benefits of red cell genotyping in patients and blood donors. Attendees will discuss how advances in molecular immunohematology are changing patient care; patient care and genotyping strategies; and review the fundamentals of the molecular basis for blood group antigen expression. To attend the symposium, and to find out more information, visit the BloodCenter of Wisconsin's website.

COMPANY NEWS

Juno Therapeutics got the go-ahead to resume testing from the Food and Drug Administration (FDA) on July 12. The phase one clinical trial halted last week was a high-dose therapy and autologous stem cell transplantation, followed by infusion of Chimeric Antigen Receptor modified T-cells (CAR-T), for non-Hodgkin lymphoma patients. Three leukemia patients died after developing fatal brain swelling during the trial. All three had received the CAR-T infusions and all had been pre-treated with chemotherapy drugs. Juno blamed the deaths as an interaction between the chemotherapy drugs and the CAR-T treatments and the FDA speedily agreed. (Source: *STAT*, FDA lets cancer trial resume after three patient deaths. July 12, 2016.)

Federal regulators have barred Elizabeth Holmes, CEO and founder of Theranos, from owning or operating a medical laboratory for at least two years. Centers for Medicare & Medicaid Services (CMS) announced in a public letter on July 7, that the Agency is also revoking the company's laboratory certificate and cancelling the lab's approval to receive Medicare payments. The sanctions will not take full effect until September and the company can appeal. Meanwhile, Theranos, which has failed to comply with previous recommendations from CMS, will also be fined $10,000 for every day it is out of compliance with CMS recommendations, starting on July 12. Theranos' claim to fame was that it could supposedly test for blood-borne diseases using just a few drops of blood—claims which have been under scrutiny since the company's inception. (Source: *NPR*, Theranos Founder Elizabeth Holmes Barred From Operating Labs For Two Years. July 9, 2016.)

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COMPANY NEWS (continued from page 10)

The National Institute of Allergy and Infectious Diseases (NIAID) has provided additional $5.5 million in funding to BioCryst Pharmaceuticals for efficacy studies of BCX4430 in non-human primates. A phase one clinical development study for BCX4430—a broad-spectrum antiviral that has demonstrated survival benefits in non-clinical studies for Ebola, Zika, Marburg, and Yellow Fever infections—is close to completion. The new total NIAID contract could be valued at up to $39.5 million through the phase one clinical program if all options are exercised. (Source: BioCryst news release, July 5, 2016.)

MEETINGS

August 1 **6th Annual Links for Life Golf Tournament, Honolulu, Hawaii**

Held in conjunction with the Summer Meeting, the Links for Life golf tournament has developed into a successful and fun annual fundraiser for the Foundation for America's Blood Centers. This year's tournament will take place at the beautiful Kaneohe Klipper Marine Golf Course in Honolulu, Hawaii. Ranked as one of the world's best military courses, your golf score will be second to the breathtaking ocean and mountain views you will enjoy while playing. There is a $200 registration fee, which includes transportation to and from the course, lunch, green fees, cart, beverages and snacks on the course, and a reception with dinner and cocktails back at the meeting hotel. Sponsorship opportunities are also still available for vendors. Contact Jodi Zand for more information.

August 1 - 4 **ABC 54th Summer Meeting, Honolulu, Hawaii**

Registration is open for the ABC 54th Summer Meeting in Honolulu, Hawaii, hosted by Blood Bank of Hawaii, on August 1 to 4 at the Hilton Waikiki Beach on Kuhio Ave. It will feature the ABC Medical Directors Workshop and the Foundation for America's Blood Centers Links for Life Golf Tournament. Contact Lori Beaston for more information.

Sept. 8 **FDA Public Workshop on Development of HCT/Ps, Silver Spring, Md.**

This free, first-come-first serve, public workshop titled the Scientific Evidence in the Development of Human Cells, Tissues, and Cellular and Tissue-Based Products Subject to Premarket Approval was organized to identify and discuss scientific considerations and challenges to help inform the development of human cells, tissues, and cellular and tissue-based products subject to premarket approval, including stem cell-based products. The workshop will take place at White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, Great Room in Silver Spring, Md.

Sept. 12 **Red Cell Genotyping 2016: Clinical Steps, Bethesda. Md.**

The BloodCenter of Wisconsin and the Department of Transfusion Medicine at the National Institutes of Health (NIH) Clinical Center, and are co-hosting the 6th

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MEETINGS (continued from page 11)

Annual Red Cell Genotyping Symposium at Lister Hill Center Auditorium, National Library of Medicine, NIH Building 38A, 8600 Rockville Pike, Bethesda, Md., from 8:25 a.m. to 4:15 p.m. This symposium will review the laboratory aspects and clinical benefits of red cell genotyping in patients and blood donors. For information, program fee and advance registration visit our website or contact Phyllis Kirchner phyllis.kirchner@bcw.edu.

Sept. 12 - 13 **FDA Public Hearing on HCT/Ps, Bethesda, Md.**

This public hearing was created to collect comments on the draft guidances relating to the regulation of human cells, tissues or cellular or tissue-based products. The hearing will take place at the Masur Auditorium, Building 10, 9000 Rockville Pike, in Bethesda. More information can be found here.

Sept. 13 – 14 **ABC IT/Workshop, Minneapolis, Minn.**

Experts in the field will gather in Minneapolis to discuss the implications of blood center corporate mergers on IT, service metrics, and cost saving initiatives. Come for the discussions on pressing IT topics and stay to network with your peers at this ABC workshop. To register or learn more, contact the ABC Meetings Department at (202) 654-2901 or e-mail: meetings@americasblood.org.

Oct. 31 – Nov. 1 **FDA 510(k) Submissions Workshop, Washington, D.C.**

AvaMed hosts FDA and industry experts are coming together to teach the basics of 510(k) submissions. Learn about the FDA's updates to the 510(k) process, considerations for determining a product's regulatory route to market, factors to consider when planning and assembling a 510(k) submission. The workshop will take place at the Washington Marriott at Metro Center, 775 12th Street, N.W., in Washington, D.C. Find out more information and register here.

Nov. 2 **FDA IDE Submissions Workshop, Washington, D.C.**

Learn the regulatory and practical guidelines governing when an investigational device exemption is required during this interactive AvaMed workshop. The workshop will take place at Washington Marriott at Metro Center, 775 12th Street, N.W., in Washington, D.C. Find out more information and register here.

ABC Calendar of Events

ABC offers a variety of meetings, workshops and virtual opportunities for education and networking as well as participation in ABC business. The calendar of events includes annual and summer meetings, board meetings, workshops, and webinars, and details will be updated as confirmed. We look forward to your support and participation!

CLASSIFIED ADVERTISING

Classified advertisements, including notices of positions available and wanted, are published free of charge for a maximum of three weeks per position per calendar year for ABC institutional members. There are charges for non-members: $139 per placement for *ABC Newsletter* subscribers and $279 for non-subscribers. A six (6) percent processing fee will be applied to all credit card payments. Notices ordinarily are limited to 150 words. To place an ad, contact Leslie Maundy at the ABC office. Phone: (202) 654-2917; fax: (202) 393-5527; e-mail: lmaundy@americasblood.org.

POSITIONS

IRL Medical Technologist. The San Diego Blood Bank (SDBB) is a progressive and forward thinking company with a respected history of outstanding service and leadership in the blood banking industry. Synergies between SDBB, the community, the biotechnology industry and academic institutions allow us to save lives with quality blood services, innovative clinical research, new technologies, and health & wellness. With proactive and aggressive new approaches to core business, research, and sophisticated technology, SDBB is where you want to be! **Openings:** Night and Evening shifts available. **Qualifications:** Bachelor's degree in a biological science; MT(ASCP) / equivalent certification; SBB (ASCP) preferred; California State CLS or CIS License (or eligible); and a minimum of three years direct IRL experience preferred. **The San Diego Blood Bank is an Equal Opportunity Employer.** Apply at: https://sandiegobloodbank.applicantpro.com/jobs/. **EOE/Minority/Female/Disability/Vets**

Medical Laboratory Scientist. The Immunohematology Reference Laboratory at ARUP Laboratories is looking for a Medical Laboratory Scientist to join a team of experienced immunohematology reference laboratory technologists. The primary duty of IRL staff members is performing complex serologic testing. IRL technologists also participate in development and revision of procedures, consultation with medical directors, pathology residents and healthcare providers, mentoring and training new MLS and MLS students, and identification of rare donors. There is a career ladder available for promotion to Medical Technologist, Specialist position after one year experience at ARUP. ARUP Laboratories is a national clinical and anatomic pathology reference laboratory and a nonprofit enterprise of the University of Utah and its Department of Pathology. The ARUP IRL supports the complex transfusion service at the University of Utah Health Center, Huntsman Cancer Hospital and Primary Children's Hospital in addition to providing reference laboratory support for clients in Salt Lake City and surrounding area(s) as well as clients located throughout the United States. This position requires a current MLS(ASCP) or MT(ASCP) and approximately five years' experience in a transfusion service, SBB is preferred but not required. This position requires participation in rotating technical on-call duties. Please apply online to posting #16-0733 at www.aruplab.com/careers.

Medical and Scientific Director. The Irish Blood Transfusion Service (IBTS) is seeking to recruit a Medical and Scientific Director (M&SD). The M&SD is the chief medical advisor to the Board and Executive of the IBTS. The crucial aspect of the role is to ensure that the IBTS provides safe blood for the people of Ireland. He/She will be responsible for leading the development of medical, technical and research policy in IBTS and to provide strong leadership for all clinical staff to include line management responsibility for all consultant medical staff. As IBTS Medical & Scientific Director, accountable to the Chief Executive, the M&SD shares responsibility for the quality of the services provided by IBTS and for both strategic direction and the financial well-being of the organization. This will include a central role in driving forward a culture of change, innovation and service transformation. The successful applicant must hold a current appointment at consultant grade in Haematology or equivalent in an EU member state, or if not currently employed within the EU is eligible for such an appointment by qualification and experience and have at least ten years satisfactory experience (after becoming entitled to full registration) in the practice of the medical profession, including not less than four years satisfactory experience in haematology or in blood transfusion medicine. This is a very senior appointment so experience of working as a Head of Department would be essential. Initial enquiries in confidence to the Chief Executive of the IBTS.