Blood Community & Federal Officials Launch Coordinated COVID-19 Response Amid Growing Pandemic

Federal Officials Urge Blood Donation. As countries across the globe work to contain COVID-19, federal officials in the U.S. and the blood community continue to communicate a unified message — donating blood is safe and blood is and will continue to be needed as social distancing measures disrupt blood center collections. “We know many of you are home practicing the President’s guidelines for social distancing,” said U.S. Surgeon General Vice Admiral (VADM) Jerome Adams, MD, MPH, during a press briefing at the White House on March 19th given by members of the President Trump’s Coronavirus Task Force. “But one thing we should all consider, especially our millennials and Gen Z, is donating blood… Social distancing does not have to mean social disengagement. So, give blood today.” He continued to emphasize the importance of blood donation by sharing a video message encouraging blood donation that linked to a news release disseminated by the Centers for Disease Control and Prevention (CDC) that further promoted blood donation.

America’s Blood Centers will continue to advocate directly to senior government officials and their staffs at various agencies throughout the Administration in alignment with blood community partners. The unified messaging has been shared by multiple agencies including the U.S. Food and Drug Administration (FDA) who issued a statement on March 19th from Center for Biologics Evaluation and Research (CBER) Director Peter Marks, MD, PhD who stressed that “[a]t this time the number of blood donations has been dramatically reduced due to the implementation of social distancing and the cancellation of blood drives… Blood donation centers can facilitate the safe donation of blood because they are skilled in infection control practices and already have procedures in place to prevent the spread of infections. Blood donation centers always take steps to prevent staff and donors who are not feeling well or who have a fever from reaching the donor area, and they are now taking additional social distancing precautions wherever possible, consistent with the President’s Coronavirus Guidelines for America. Donating blood is safe and takes only a little of your time.”

COVID-19 Impact on Blood Community. As of March 19th, blood centers nationwide had seen more than 12,000 blood drives canceled, resulting in some 355,000 fewer blood donations due to coronavirus concerns. The 12,000 figure represents canceled drives in March, April, May, June, and July and the 355,000 figure includes projections based on the number of canceled drives and appointments. Currently, inventories are down an estimated 30-40 percent depending on blood type from this same time last year.

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COVID-19 Response (continued from page 1)

Regulatory Updates. The FDA published a statement on March 18th that the agency would temporarily postpone all domestic routine surveillance facility inspections until further notice. It added that for-cause inspections will be handled on a case-by-case basis.

The FDA also issued a notice of “Updated Information for Blood Establishments Regarding the Novel Coronavirus Outbreak” on March 11th. It stated that the agency continues to monitor COVID-19 and reiterated that: “[t]he potential for transmission of SARS-CoV-2 by blood and blood components is unknown at this time. However, respiratory viruses, in general, are not known to be transmitted by blood transfusion, and there have been no reported cases of transfusion-transmitted coronavirus.” The notice expressed the agency’s support of the AABB Interorganizational Task Force on Disasters encouraging “healthy” individuals to donate and suggest that blood centers:

- evaluate emergency plans;
- do not use laboratory tests to screen asymptomatic blood donors at this time;
- may wish to consider donor educational materials to instruct individuals to self-defer and refrain from blood donation in cases where exposure to COVID-19 may have occurred;
- should have their responsible physician evaluate the prospective donor and determine eligibility (21 CFR 630.5); and
- may wish to consider updating post-donation instructions provided to all donors of blood and blood components to ask donors to report a subsequent diagnosis of COVID-19 as soon as possible to the blood establishment.

Routine blood donor screening measures that are already in place should prevent individuals with clinical respiratory infections from donating blood.

Also, AABB published Association Bulletin #20-02 entitled “Recommendations for Providing a Safe Environment for Blood Donation During the COVID19 Epidemic” on March 19th. It provides strategies and recommendations that blood centers should consider to:

- promote donor safety;
- address perceptions of infection risk; and
- encourage blood donation amid the COVID-19 pandemic.

The recommendations are voluntary and “based on a review of CDC recommendations to protect individuals from the spread of the virus.”

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COVID-19 Response (continued from page 2)

Coronavirus Resources for Blood Centers. ABC conducted a COVID-19 webinar this week on March 18th. It provided an update to the membership and other industry stakeholders of the association’s response to the pandemic and work to prioritize blood donation and maximize the reach and visibility of communications efforts to make messaging from the blood community resonate with external audiences. The webinar also included briefings on the collaboration between the blood community and federal officials. Slides from the webinar are available as attendees shared feedback regarding ABC’s outreach efforts, while discussing the current and future impact of the pandemic on blood center operations. Additionally, ABC will be holding forum calls for member centers and their staffs to join to discuss how COVID-19 is impacting their discipline/department within the blood center. The Quality Forum call took place on March 19th with the Human Resources Forum called scheduled for next week. Additional calls for other disciplines will be scheduled in the coming weeks and recordings/slides from all forum calls and webinars will be made available to members. ADRP, an international division of ABC, has created an “Idea Exchange” to promote the exchange of information and message sharing among blood centers and subscribers. Interested individuals can find more information on the ADRP website along with social media graphics and other resources on its resources page.

ABC, AABB, the American Red Cross, and the Armed Services Blood Program teamed up to issue a joint news release on behalf of the blood community. The organizations also had leaders from each organization record statements delivered via video as part of a media tool kit for blood centers to use. We have provided a link to the folder containing the videos from:

- Peter Marks, MD, PhD of FDA’s CBER
- A generic story/package with a voiceover for general use
- Clips/statements from leadership at ABC, AABB, ARC, the Armed Services Blood Program.

We encourage you to share and distribute these resources as you see fit on your social media channels and websites. Also, we have created a COVID-19 resources page on our public site in addition to one that currently exists on the Member site. ABC will continue to monitor the outbreak and provide timely updates to member blood centers.

COVID-19 Cases in the U.S.

[Map of COVID-19 cases in the U.S.]

Reported Cases
(last updated March 20, 2020)

- None
- 1 to 5
- 6 to 50
- 51 to 100
- 101 to 500
- 501 to 1000
- 1001 to 5000
- 5001 to 5000
- 5001 or more

(Courtesy of CDC as of March 20th)

(Sources: CDC News Release, 3/19/20; FDA Statement Encouraging Blood Donation, 3/19/20; FDA Inspections Statement, 3/18/20 White House Coronavirus Task Force Briefing, 3/19/20; CDC Update 3/20/20; ABC, AABB, American Red Cross, Armed Services Blood Program, Joint News Release, 3/12/20; ABC Webinar Slides, 3/18/20; Videos from Media Toolkit, 3/12/20)
ABC Comments on CJD & vCJD Draft Guidance

America’s Blood Centers (ABC) submitted comments this week on the U.S. Food and Drug Administration’s (FDA) draft guidance entitled “Recommendations to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Components; Draft Guidance for Industry.” In the comments, ABC thanks and supports the draft changes proposed by the FDA regarding donor deferrals for CJD and vCJD risk, incorporating feedback previously provided by the blood community. “By eliminating the deferrals for time spent in Europe and on military installations, this new guidance, once finalized, will enable thousands of previously dedicated donors to return to the donor base while maintaining the safety of the blood supply,” states the comments. Additionally, ABC encouraged the FDA to “rapidly finalize the draft as written for immediate implementation to allow the industry to recapture these historically loyal blood donors to help with the projected severe shortage of blood looming on the horizon,” due to the COVID-19 pandemic.

Earlier this year, ABC, the Board of Directors, and the Scientific, Medical, and Technical Committee published a position paper regarding the vCJD deferral that asked the FDA to rescind the current vCJD deferral and allow re-entry of U.S. military personnel, Department of Defense (DoD) civilians, and their families who spent time at U.S. military installations in Europe outside of the United Kingdom (U.K.) during the period of 1980-96. The draft guidance recommendations contain the following changes:

- removal of the deferral for injecting bovine insulin. Donors previously deferred may be requalified and reentered;
- removal of Human Growth Hormone from the medical deferral list. Donors previously deferred are not eligible for reentry;
- the ability to stop asking prospective donors about having blood relatives with CJD. If a donor volunteers information regarding a blood relative having a genetic form of CJD, then that individual should be deferred. Donors with family members diagnosed with the genetic form of CJD are not eligible for reentry; and
- indefinite deferral of donors who spent time in the United Kingdom (U.K.). (three months or more from 1980-96), or Ireland and France (five years or more 1980-2001) as well as transfusion in one of those countries at any time since 1980.

vCJD the human form of Bovine Spongiform Encephalopathy (BSE), is a fatal, progressive neurological condition that was first identified in the U.K. in 1996. It is generally transmitted by eating the beef of animals affected, though a few cases have been found to result from blood transfusion from donors that appeared healthy at the time of donation but later developed vCJD. As a result, the FDA has recognized vCJD as a relevant transfusion-transmitted infection. Since no licensed screening test for vCJD exists, the FDA implemented geographical deferrals for blood donors depending on time in areas considered at risk for vCJD transmission in 1999.

(Sources: FDA Draft Guidance, 1/30/20) ♦

Upcoming ABC Webinars – Don’t Miss Out!

- **ABC QA Education Webinar: FDA and the 356h Application Process** – May 19th from 3 – 4:30 p.m. (EDT) More information coming soon.

REGULATORY NEWS

The U.S. Food and Drug Administration (FDA) issued a guidance entitled “Biological Product Deviation Reporting for Blood and Plasma Establishments.” It provides revised recommendations for blood and plasma centers regarding “when a report is required, who submits the report, what information to submit in the report, the timeframe for reporting, and how to submit the report. The revised guidance explains that we do not consider post donation information (PDI) events to require biological product deviation reports.” It replaces the October 2006 final guidance that was entitled “Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other than Blood and Blood Components”. In the revised final guidance, FDA removes two obsolete memoranda for blood establishments:

- Responsibilities of Blood Establishments Related to Errors and Accidents in the Manufacture of Blood and Blood Components (issued March 1991); and

It also consolidates the agency’s current recommendations with respect to Biological Product Deviation Reports into a single document, which America’s Blood Centers has been universally advocating for rather than the prior practice of simply updating parts of multiple older guidance documents and memoranda. This revised guidance applies to whole blood, blood components, and source plasma. Additionally, another key change long advocated for by ABC is that PDI events no longer require BPDRs. The guidance also contains other technical updates and editorial revisions as well as expanded examples of who must report and examples of reportable and non-reportable events by manufacturing system. Comments can be submitted electronically.

(Source: FDA Guidance, 3/13/20)
COMPANY NEWS

The Medical Technology Enterprise Consortium (MTEC) recently honored BioBridge Global as one of its Prototype of the Year Award winners. BioBridge Global received the award based on their work in the development and manufacturing of adult stem cells for research. “This award recognizes flawless execution – on-time or ahead of schedule and on-budget for all milestones,” said Becky Cap, chief operating officer at GenCure, a BioBridge Global subsidiary in a BioBridge Global news release. “Getting to this point with four collaborators is a huge acknowledgement of excellence both for our execution teams and the supporting groups who worked through billing and reporting requirements.” MTEC, a nonprofit started by the U.S. Army’s Medical Research and Materiel Command, provided BioBridge Global with a $7.8 million grant to aid the company’s progress towards advancing new therapies. “The MTEC grant funded not just the development of new capabilities — it launched a whole line of services that will support the development of new therapies for wounded warriors and civilian patients,” added Ms. Cap in the release.

(Source: BioBridge Global News Release, 3/10/20)

CALENDAR

Note to subscribers: Submissions for a free listing in this calendar (published in the last issue of each month) are welcome. Send information to newsletter@americasblood.org or by fax to (202) 393-1282. (For a more detailed announcement in the weekly “Meetings” section of the newsletter, please include program information.)

POSTPONED


April 1. U.S. Food and Drug Administration (FDA) Public Meeting on FDA’s Communications About the Safety of Medical Devices. Silver Spring, Md. More details available here.


2020


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CALENDAR (continued from page 6)

July 21-23. 2020 ABC Medical Directors Workshop and Summer Summit, Cleveland, Ohio. More details coming soon.


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, e-mail: newsletter@americasblood.org

POSITIONS

Outside Sales Representative/Event Planner (Little Rock, AR, USA). Account Consultants must develop new partnerships with targeted decision makers in community organizations, educational and religious institutions and businesses to gain support in meeting the needs for volunteer blood donors. Responsibilities include organizing and promoting blood donation events; assessing, developing and implementing strategic/tactical plans to achieve recruitment objective/goals. She/he is expected to develop a customer-focused culture that will result in successful community partnerships and donation awareness. Identify opportunities for growth within current group base, and facilitate a plan to achieve growth percentage for total unit collection within territory. Book recurring blood drives for the following year. Develop and maintain relationships with key accounts. Give presentations in order to promote blood collection. Identify and provide feedback on issues regarding customer needs/requirements, customer issues/concerns and satisfaction, competitor activities/strategies, etc. Interact effectively and professionally with team members and all internal/external contacts. Qualifications: Associate/Bachelor’s degree preferred, one to three years sales related experience, public speaking/presentation experience preferred, excellent communication skills, and valid driver’s license with access to vehicle. Salary Range: Competitive salary, commission plan, and excellent benefits package including health, dental, vision, and life insurance. 401(k), paid time off, and holiday pay. How to apply: http://arkbi.org/careers/.

Outside Sales Representative/Event Planner (Fort Smith, AR, USA). Account Consultants must develop new partnerships with targeted decision makers in community organizations, educational and religious institutions and businesses to gain support in meeting the needs for volunteer blood donors. Responsibilities include organizing and promoting blood donation events; assessing, developing and implementing strategic/tactical plans to achieve recruitment objective/goals. She/he is expected to develop a customer-focused culture that will result in successful community partnerships and donation awareness. Identify opportunities for growth within current group base, and facilitate a plan to achieve growth percentage for total unit collection within territory. Book recurring blood drives for the following year. Develop and maintain relationships with key accounts. Give presentations in order to promote blood collection. Identify and provide feedback on issues regarding customer needs/requirements, customer issues/concerns and satisfaction, competitor activities/strategies, etc. Interact effectively and professionally with team members and all internal/external contacts. Qualifications: Associate/Bachelor’s degree preferred, one to three years sales related experience, public speaking/presentation experience preferred, excellent communication skills, and valid driver’s license with access to vehicle. Salary Range: Competitive salary, commission plan, and excellent benefits package including health, dental, vision, and life

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POSITIONS (continued from page 7)

insurance, 401(k), paid time off, and holiday pay. How to apply: http://arkbi.org/careers/.

Hematologist/Medical Director. OneBlood is expanding its clinical practice offerings in the areas of outpatient transfusion medicine, therapeutic apheresis & phlebotomy, pre-op anemia management, cell therapy, treatment of blood disorders. If you have a passion to join a team that is providing cutting-edge medical expertise in the areas of blood banking/transfusion medicine, hematology and outpatient clinical services, IRL, therapeutic apheresis, cellular therapy, research, consider joining our medical team as a regional Medical Director. This position includes a highly competitive salary, benefits package, including the option of free medical coverage, retirement plan with company contribution PLUS a company match, company vehicle lease/allowance, paid holidays, etc. The position is based out of the Ft. Lauderdale, Florida area. Qualified candidates should possess: minimum of 3 years’ experience, M.D. or D.O. degree with board certification in Internal Medicine/Hematology and sub-specialty board certification in Blood Banking/Transfusion Medicine by a Board Registry recognized by the American Board of Medical Specialties. Appropriate state licenses will be required as needed. Candidates must meet the eligibility requirements to obtain appointments at hospitals served by OneBlood. For more detailed information, visit OneBlood’s Careers page at www.oneblood.org. OneBlood, Inc., a proven leader in blood banking, is an Equal Opportunity Employer/Vet/Disability

Director, Regulatory Affairs. America’s Blood Centers (ABC), North America’s largest network of community-based, independent blood programs, is seeking a Director, Regulatory Affairs. The position will be actively involved and accountable for the development, implementation, execution and advancement of the ABC regulatory agenda before federal agencies and other stakeholders. In addition, the position will assist in the facilitation of member education, evaluation and coalescing of member input in the development of industry positions, data collection from internal and external sources, and primary and secondary research. The position will report directly to the Senior Director, Federal Government Affairs, providing strategic guidance on regulatory affairs and public policy issues pertaining to the nation’s blood supply. A bachelor’s degree is required for the position, which is based in Washington, D.C. This individual should: have a thorough understanding of the federal regulatory processes and landscape, particularly with the FDA; have knowledge of and experience in health policy; blood industry knowledge preferably (but not required); be able to collect, analyze, and synthesize information from varied sources; have strong critical thinking, analytical, and problem-solving skills; be self-motivated and goal oriented; have the ability to multitask and determine priorities; be able to network and collaborate effectively with colleagues and volunteers; have strong communication skills - verbal, written, and presentation; and be able to travel, sometimes at short notice. ABC offers a salary commensurate with experience as well as an excellent benefit package including medical, dental, LTD, and 401k contribution. We are a hybrid virtual office that promotes a flexible work environment. This is a full-time staff position including benefits and a stipend for internet and telephone services. ABC prohibits discrimination and provides equal employment opportunities to all employees and applicants for employment without regard to race, color, religion, age, sex, national origin, disability status, genetics, protected veteran status, sexual orientation, gender identity or expression, or any other characteristic protected by federal, state or local laws. The full job description is available here. Interested applicants should send a cover letter and resume to careers@americasblood.org.