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Working Together Through Challenging Times

The COVID-19 pandemic is presenting all of us with unprecedented challenges that are upending our usual routines. In the past several weeks alone, our community has faced sudden blood shortages, changes in blood utilization, updated guidances from the FDA on donor eligibility and the urgent need to protect our staff and donors. Now we are beginning to ramp up new systems for collecting and processing COVID-19 convalescent plasma.

At the moment, there are too many concerns to name. What are the best ways to ensure optimal safety for donors and staff? How can we best implement updated donor eligibility requirements? Will the pandemic cause further disruptions to the blood supply? Yet even with so many unanswered questions, every day brings more.

Maintaining a Collaborative Community

Throughout this crisis, we will need to continue to work together to address rapid changes in the health care system — and society as a whole. AABB is — and will continue — working with the blood and biotherapies communities, as well as government officials at regulatory agencies, to facilitate communication and share important information to enable us to continue providing life-saving products and services.

During this time, it has been inspiring to see members of the blood community continue to collaborate to ensure the safety and adequacy of the blood supply. Our challenges are great, but our community is stepping up in heroic ways. I am proud when I think about the work members of the blood community continue to do throughout the pandemic. I also want to specifically acknowledge those who have volunteered on AABB’s COVID-19 task forces; you are providing critical insight and planning and I thank you for this incredibly important work.

When the AABB Board meets later this month (in our first virtual meeting), we will discuss these urgent questions and consider the ways in which we can best support our members, and the communities we serve, during these uncertain times. Look for ongoing communications from AABB as we continue to work to weather this storm together.

Beth Shaz, MD
AABB President
The 2020 AABB Annual Meeting is the premier meeting connecting professionals in transfusion medicine and biotherapies, while providing the information you need about groundbreaking research and practice-changing advancements. Expand your knowledge while connecting with fellow attendees who share your passion for the field.

Member Registration Opens Wednesday, May 27
General Registration Opens Wednesday, June 3

Visit aabb.org/AnnualMeeting for more information, including meeting rates.
Stella Chou, MD, is an associate professor of pediatrics at the University of Pennsylvania’s Perelman School of Medicine and a pediatric hematologist and transfusion medicine specialist at the Children’s Hospital of Philadelphia with a specific interest in treating patients with sickle cell disease. Chou’s research interests include antibody identification and blood antigen matching using molecular tools, and her research laboratory uses induced pluripotent stem cells (iPSCs) and primary human cells to model blood diseases and study their underlying pathophysiology. Her work has demonstrated that the inheritance of variant or altered blood group antigens contributes to the high rate of red blood cell antibody formation in patients with SCD. She is also working on creating customized iPSCs with rare blood group antigen combinations to serve as renewable sources of RBC reagents, to improve antibody identification and donor RBC matching. Since transfusion therapy remains a critical treatment for hemoglobinopathies, Chou’s goal is to identify new approaches to minimize red blood cell alloimmunization, reduce complications and improve therapy.

Chou received a National Blood Foundation early-career Scientific Research Grant in 2013 for a study on generating red blood cells from iPSCs, and she was inducted into the NBF Hall of Fame in 2018.

Chou told AABB News that she became interested in hemoglobinopathies when she first trained in pediatric hematology oncology at the Children’s Hospital of Philadelphia, where she cared for many children and young adults with sickle cell disease and thalassemia. “The challenges we faced with safely transfusing patients who were heavily alloimmunized had a particular impact on me,” she said. “One of my clinical hematology mentors, Catherine Manno, MD, encouraged me to pursue a fellowship in transfusion medicine. I specifically remember her telling me that the transfusion medicine community would be incredibly welcoming to junior physicians and researchers, which was certainly what I experienced.”

She added that when she was a hematology-oncology fellow, she also trained with Mitchell Weiss, MD, PhD, whose laboratory studied the transcription factor GATA1, which is necessary for normal red cell and megakaryocyte development. Chou’s work focused on Down syndrome-associated blood disorders and related transient neonatal leukemia and acute megakaryocytic leukemia, which both harbor mutations in GATA1. “Since the primary samples we worked with from affected babies and children were extremely limited,” she said, “when iPSC technology became available, I started making these renewable iPSC lines that ultimately helped us better understand the pathophysiology of the disease. It then dawned on me to combine my expertise in transfusion medicine with iPSC and CRISPR-Cas9 technology!” Chou is optimistic that we will see these iPSC-derived red blood cells on hospital blood bank shelves within 2 years.

When asked about the effect of molecular technologies on diagnosing and treating hematological disorders, Chou said that DNA-based assays have had the greatest impact on finding compatible units for patients, both those with uncommon antigen phenotypes and those with complicated antigen evaluations. “Due to relatively
high throughput genotyping,” she explained, “donor centers are able to type many more donors, with expanded antigen data. Thus, rare and uncommon blood is no longer quite as rare or uncommon. For patients with sickle cell disease who have significant Rh genetic heterogeneity,” she added, “we can now easily identify those with partial Rh antigens, recognize their alloimmunization risk and, for some, improve red cell matching.”

She explained that having red blood cell genotype data to predict Rh variants — as well as predicted phenotypes on over two dozen other antigens — has reduced turn-around time for new antibody evaluations and, subsequently, decreased transfusion delays and harm.

The most rewarding aspect of her career, according to Chou, was when she recently started a pilot clinical trial, in collaboration with Connie Westhoff, SBB, PhD, at the New York Blood Center, to RH genotype-match red blood cells for patients with SCD requiring chronic red blood cell therapy. “It is incredibly rewarding to see our earlier findings be applied to the clinical care of our patients,” she said. “While our current study is a feasibility trial, we anticipate that parallel work by us and others will make RH genotyping affordable and, ultimately, become standard of care in the future.”

“While our current study is a feasibility trial, we anticipate that parallel work by us and others will make RH genotyping affordable and, ultimately, become standard of care in the future.”

Chou said she grew up with three sisters, a brother and 10 first cousins who were like siblings. So now, in her free time, she likes to spend time with her family, be it her husband and two children or her growing extended family. “It might be as simple as a board game — though I am super competitive!” she said, “to skiing on fake snow in the Poconos — global warming has taken away the real snow — to travelling to new destinations to eat and learn about other cultures,” which is her favorite thing to do. One thing that most people don’t know about her, she said, is that she has a terribly huge sweet tooth. “I love desserts, chocolates and ice cream.”
Screening for and Treating HEMATOLOGIC DISORDERS

New Applications for Established Technologies
Medical advances are expanding exponentially. Findings in robotics, genomic sequencing, big data and artificial intelligence have allowed physicians and scientists to make discoveries that continue to enhance and prolong human life. Sometimes, though, advances in medicine do not occur only as a result of new inventions and interventions. Sometimes they come from finding new applications for existing technologies.

*AABB News* recently spoke with two physicians about current technologies used to treat hematologic disorders that are being improved or adapted for new at-risk populations.

**POC Platelet Testing**

There are very few true point-of-care platelet function tests, when point of care is defined as “at the bedside,” according to Christopher A. Tormey, MD, associate professor of laboratory medicine at Yale University School of Medicine and director of transfusion medicine services at Yale-New Haven Hospital. However, this label is often applied to any platelet function test that is smaller and more efficient than the gold standard, the platelet aggregometry, which is traditionally performed in an outpatient setting, takes hours to perform and requires interpretation after being completed.

“Point of care” tests offer insight for platelet function in about an hour or two after the specimen is collected,” Tormey said. “They open an avenue for looking at platelet functionality and increasing the throughput with which we can assess platelet function.”

One of the most common situations for which this type of rapid platelet function assessment may be necessary is to assess the many thousands of patients prescribed anti-platelet medications to prevent complications of cardiac disease or for a history of stroke.

“If that individual is bleeding, needs a surgery or is post-surgery, you might want to get insight into what degree their platelets are inhibited or not functional,” Tormey said.

Complete blood counts for these individuals may show a normal platelet count, while, in contrast, the rapid tests can assess platelet function and let the clinicians know whether the patient might benefit from a transfusion.

There is also a population of patients with congenital platelet function defects who might benefit from point-of-care testing.

“These are individuals born with intrinsic defects in the clotting mechanisms of their platelets,” said Tormey. “If someone like this is scheduled for surgery or has a bleeding episode, it can be useful for quick insight into what their platelet function is.”

Although there is not a lot of data showing which point-of-care systems are most commonly used, Tormey believes one of the most popular assays is the PFA-100 platelet function analyzer (Dade-Behring). The system first received 510(k) approval in 1997.

“This test was designed to replace the bleeding time test,” Tormey explained. “With the bleeding time test, you would inflate a blood pressure cuff, cut the patient’s arm and measure the amount of time it took until bleeding stopped. It was not a very good test.”

PFA-100 uses a blood sample to test the time required for platelets to adhere and aggregate, resulting in occlusion of an aperture under higher shear conditions. Although the test has been widely available for many years, there are limited data on the use of PFA-100 in predicting surgical bleeding outcomes, Tormey said.

More true to its "point-of-care" name is the VerifyNow (Royal Phillips Electronics) test.

“This test was more specifically designed to be put in a cardiologist’s office,” Tormey said. “It is designed to reflect the degree to which platelets are inhibited when anti-platelet medications are prescribed.”

The goal, he said, is if a patient has a history of vascular disease or stroke and is prescribed anti-platelet medication, this test can tell the treating physician whether the patient is adhering to the medication and/or if they are a non-responder.

Tormey emphasized that both of these tests are really only used for screening. If the results are abnormal, more specific testing is necessary.

There are more assays in the pipeline that are expected to function more similarly to the gold standard aggregometry but with more rapid results. These include more rapid impedance-based tests, which push closer to a full assessment of platelet function than the screening tests described earlier.
In addition, there are platforms, such as the cone and plate test, which utilize the principle of shear force to rapidly assess platelet adhesion and aggregation. Finally, there are also emerging options for examining platelet functionality in viscoelastic testing, traditionally thought of as an assay that looks at whole blood clotting.

“These emerging viscoelastic assays are getting better at specifically isolating the platelet contributions to whole blood clotting and doing so with specific platelet activators, called agonists,” Tormey said. “As an example, the thromboelastography (TEG) assay has an application called platelet mapping that can be done as a modified version of the test, which can give insight into various aspects of platelet function and degree of inhibition with a rapid turnaround time similar to that of other point-of-care devices.”

One of the goals is to use these more rapid tests to guide transfusion therapy in these patients.

“As an example, if a patient has had a cardiac surgery and is having bleeding, we know that there are platelet defects that can occur as part of that surgery,” Tormey said. “Right now, we almost throw the kitchen sink at these patients without much functional information. I envision a time when we can do specific platelet function testing and tailor transfusion response therapy.”

Red Cell Exchange

The concept of red cell exchange is not new, explained Marisa B. Marques, MD, professor of pathology at the University of Alabama at Birmingham. Unlike transfusion, which replaces blood, red cell exchange removes and replaces a patient’s red blood cells only.

“In sickle cell disease, people have defective hemoglobin (S or HgS) that makes their cells sickle under certain conditions, causing all types of complications in their body,” Marques said. “The goal of the exchange is to decrease the percentage of HgS-containing cells with blood from people without sickle cell disease.”

With traditional transfusion, the number of cells with HgS cannot be decreased, and patients can only receive a few units of blood on any given day. With exchange, patients can receive as many as 12 to 15 units to replace the equivalent volume of the patient’s own red blood cells, Marques said.

Currently, there are no randomized clinical trials showing that red cell exchange is beneficial. However, there are studies showing that a reduction in HgS is beneficial to patients who have a high risk of having a stroke or have already experienced one.2,3

“With red cell exchange, we can lower HgS — which is the bad hemoglobin and the marker of sickle cell disease — to 15% of their total blood or even lower, instead of it being close to 100%,” Marques said. “Many experts have decided that if transfusion is good, exchange is better because it keeps HgS lower chronically, and it prevents some of the problems associated with transfusion, like an excess of iron.”

To date, the decision to do red cell exchange has been a physician’s judgment call. Last year, a clinical trial called SCD-CARRE was initiated to provide more evidence on the use of this procedure (ClinicalTrials.gov Identifier: NCT04084080).4 The trial will randomly assigned patients to either standard of care alone or in combination with monthly red cell exchange for 1 year. The goal is to see if exchange decreases deaths, reduces hospitalization and slows or reverses the development of organ damage.

Red cell exchanges are currently offered at many large academic and non-academic centers, as well as some large community hospitals, according to Marques.

Exploring New Areas

One of the new areas being explored for red cell exchange is in maternal fetal medicine.

“This is a very new area,” Marques said. “We are still at the beginning, but there are more studies in the last 5 years showing that when we perform red cell exchanges throughout pregnancy, there is an advantage to the mother.”

Women with sickle cell disease are more likely to have complications during their pregnancy that can affect their health as well as the health of the unborn baby. Among the risks are a higher likelihood for preterm labor, low birth weight or other complications.5,6 In addition, during pregnancy sickle cell disease can become more severe with more frequent pain episodes.
A 2015 review of prophylactic transfusion for pregnant women with sickle cell disease showed a reduction in maternal mortality, vasoocclusive pain episodes and pulmonary complications, and neonatal death and preterm birth.7

The same year, the results of a small retrospective study looking at prophylactic red blood cell exchange in pregnant women with sickle cell disease showed a significant decrease in maternal mortality among women who underwent red cell exchange, compared with those who did not. No difference in pain events was observed.8

In 2018, another retrospective study looking at prophylactic red cell exchange showed that among women with early treatment, there were no severe vasoocclusive crises, sepsis or severe infection. The researchers also noted an improvement in birthweights “compared to previous studies.”9 Newborn weight correlated with maternal hemoglobin levels. In fact, in its 2019 guideline, the American Society for Apheresis (ASFA) published an indication for red cell exchange during pregnancy.10 “Between the previous ASFA guidelines published in 2016 and the current guidelines, there were more studies suggesting that it is beneficial to do red cell exchange during pregnancy,” Marques said.

More recently, research has revealed another new indication for red cell exchange in sickle cell disease: fat embolism syndrome. “Fat embolism syndrome is very rare, but it is very lethal,” explained Marques. Fat embolism is a clinical condition in which circulating fat emboli, or macroglobules, from bone marrow necrosis lodge in the pulmonary microcirculation, a condition that can lead to multisystem dysfunction. In people with sickle cell disease, it is associated with increased morbidity and mortality, Marques said.

“Our group and hematologists in England have been publishing on this complication,” she said. “We believe from experience — there is no controlled study on this — that red cell exchange is the best treatment option for these patients and decreases their mortality risk.”

Data published by Marques and colleagues in 2019 assessed 85 reported cases of fat embolism syndrome and found a mortality rate of 24% in patients with the syndrome who received red cell exchange, compared with 92% in patients who did not receive any transfusion support.11

“Immediate red cell exchange is the cornerstone of treatment of fat embolism syndrome. It can be life-saving, and we strongly recommend it as soon as fat embolism syndrome is clinically suspected,” Marques and colleagues wrote in the paper.

A simple transfusion can help as well, she noted, but it is not as effective.

REFERENCES

AABB Releases 2 Association Bulletins in Response to COVID-19 Pandemic

AABB recently published two association bulletins related to the coronavirus disease 2019 epidemic. Association Bulletin (AB) #20-02 recommends strategies to help blood collection establishments provide a safe donation environment to protect both donors and staff and encourage blood donation during the pandemic to protect the availability of the blood supply nationally during the pandemic. Developed by AABB’s COVID-19 Working Group, these recommendations are based on Centers for Disease Control and Prevention recommendations to protect individuals from the spread of the virus and current practices shared by AABB members. AABB encourages blood collectors to adopt some or all of these strategies to demonstrate their commitment to the safety of their donors.

Association Bulletin #20-03 describes updated requirements to Reference Standard 5.4.1A, Donor Qualification, in the 31st and 32nd editions of Standards for Blood Banks and Transfusion Services (BB/TS Standards). These changes fall into two categories: changing donor deferral requirements affected by the Food and Drug Administration’s April 2 guidance addressing the urgent need for blood during the pandemic and discontinuing the use of the drug medication deferral list in the BB/TS Standards 31st edition. These are emergent standards that may be implemented immediately.

Both association bulletins are available on the AABB website at Programs & Services > Publications > Association Bulletins.

$2 Trillion COVID-19 Stimulus Legislation Includes Blood Donor Awareness Campaign, Funding for Blood Supply Chain

President Donald Trump recently signed the Coronavirus Aid, Relief and Economic Security Act (CARES Act), which includes AABB-supported provisions to promote blood donation and strengthen the blood supply chain during the coronavirus
disease 2019 (COVID-19) pandemic. The Senate unanimously passed the $2 trillion stimulus package on Wednesday, March 25, and the House of Representatives passed the bill by a voice vote on Friday, March 27.

The legislation requires that the Secretary of Health and Human Services carry out a national campaign to support awareness of the need for blood donations during the COVID-19 pandemic. Additionally, the legislation promotes outreach to the public and health care providers about the importance and safety of blood donation. The legislation requires the Secretary to report the activities carried out as part of the awareness campaign, current trends in blood donations and the impact of the public awareness campaign, including any geographic or population variations, to the House within 2 years.

The legislation also allocates $27 billion for the Public Health and Social Services Emergency Fund to prevent, prepare for and respond to the COVID-19 pandemic domestically and internationally. This funding may be used to address the blood supply chain, develop several necessary countermeasures and implement other preparedness and response activities.

FDA Announces Revised Donor Eligibility Criteria to Reduce Blood Shortages During COVID-19 Pandemic

The Food and Drug Administration released several new recommendations to support a safe and adequate blood supply during the COVID-19 pandemic. FDA based these changes on new data from recent studies.

FDA's updated HIV risk guidance reduces the donor deferral period to 3 months for risk associated with:
• Men who have sex with men (MSM) and their female contacts.
• Blood transfusion, recent tattoos and piercings.
• Injection of non-prescription drugs.
• Exchanging sex for money or drugs.

The agency also finalized the January 2020 draft guidance on Creutzfeldt–Jakob disease (CJD) and variant CJD that recommends the following:
• Deferral for the United Kingdom, France and Ireland.
• Eliminating deferral for time spent in numerous European countries or on military bases in Europe. FDA recommends allowing reentry of these donors.

Additionally, FDA issued updated malaria recommendations that reduce the deferral period following travel to malaria-endemic regions to 3 months and remove the travel deferral for certain donors of pathogen-reduced platelets and plasma.

FDA also provided alternative procedures during the pandemic that include the following:
• Blood centers are no longer required to discard collections based on errors in blood pressure, pulse, weight and donation interval.
• Blood centers now have 72 hours to clarify a donor’s response or obtain omitted information that is required to determine donor eligibility and component suitability.

FDA put forth these guidelines for immediate implementation and expects them to remain in place after the COVID-19 pandemic ends. The alternatives to certain donor eligibility requirements will apply only for the duration of the declared pandemic. Blood establishments are not required to implement the changes in the FDA recommendations or the alternative procedures.

CDC Issues Interim COVID-19 Infection Control Guidance for Blood, Plasma Collection Personnel

The Centers for Disease Control and Prevention issued interim guidance to protect the health of staff, volunteers and donors at blood and plasma collection centers and help them set up facilities to minimize spread of COVID-19. CDC's interim guidance reinforces routine measures that are currently followed by blood centers, including considerations described in FDA's March 11 communication on the COVID-19 outbreak. The guidance complements CDC's interim infection prevention and control recommendations and AABB's Association Bulletin #20-02, which outlines recommendations for providing a safe environment for blood donation.

Protocol for COVID-19 Convalescent Plasma Collection Updated

The AABB COVID-19 Convalescent Plasma Collection protocol has been updated. The protocol, prepared by the COVID-19 Convalescent Plasma (CCP) Working Group in consultation with FDA's Center for Biologics Evaluation and Research (CBER) serves as an FDA-reviewed protocol to help ensure CCP collections are rapidly available, well-coordinated locally and nationally, and meet FDA and AABB criteria for allogeneic blood donations with eventual administration to a patient under an FDA-approved individual new drug (IND) application. AABB hosted a COVID-19 conference call on April
1 with CBER director Peter Marks, MD, PhD, who shared FDA’s current thinking on CCP collections and administration under IND.

The changes to the protocol, highlighted for easy identification, reflect new information and clarification provided by Marks. AABB will continue to provide updates each time FDA releases new information.

**FDA to Coordinate National Effort to Develop Blood-Related COVID-19 Therapies**

FDA recently announced a new effort to facilitate the development of potential COVID-19 therapies made from blood donated by people who have recovered from the virus. According to the agency, limited data suggest that CCP and hyperimmune globulin (hyper-IG) collected from those who have recovered from COVID-19 may have the potential to lessen the severity or shorten the length of illness in patients currently fighting the infection.

The agency is facilitating access to CCP and hyper-IG, a blood product made from CCP, using multiple pathways. FDA's initial effort was focused on facilitating access to CCP through an emergency IND process. The agency provided information to help health care providers submit these applications to treat individual patients and to facilitate the implementation of well-controlled clinical trials at academic institutions to rigorously evaluate the safety and efficacy of convalescent plasma.

FDA and industry, academic and government partners developed and plan to implement a protocol to provide CCP to patients who may not have access to institutions with clinical trials in place. In this partnership, the Mayo Clinic will serve as the lead institution for the program and the American Red Cross will help collect plasma and distribute it for use across the country. FDA anticipates that this collaboration will facilitate the movement of thousands of units of plasma to the patients who need them in the coming weeks.

The agency is also working with industry and government partners to accelerate the development and availability of hyper-IG as a potential COVID-19 treatment. FDA is helping to coordinate a study of hyper-IG that will be conducted by the National Institutes of Health’s National Institute of Allergy and Infectious Diseases, as well as coordinating other efforts in this area.

In addition, FDA continues to provide advice, guidance and technical assistance to help expedite the development of these products. The agency intends to use regulatory flexibility in making these products and other critical medical countermeasures available to prevent and treat COVID-19.

**FDA Issues Updated Considerations for HCT/P Establishments**

FDA does not recommend the use of laboratory tests to screen asymptomatic donors of human cells, tissues, and cellular and tissue-based products (HCT/Ps) for evidence of COVID-19 infection, the agency stated in updated considerations issued recently. According to FDA, it appears that SARS-CoV2, the virus that causes COVID-19, has only been detected in blood samples of a small percentage of severely ill patients.

However, the HCT/P establishment’s representative must evaluate prospective donors and determine eligibility as per 21 CFR 1271.50. Based on the limited information available at this time, organizations may choose to consider whether, in the 28 days prior to HCT/P recovery, the donor cared for, lived with or had close contact with individuals diagnosed with or suspected of having COVID-19 infection; or were diagnosed with or suspected of having COVID-19 infection. The agency noted that while the potential for transmission of COVID-19 by HCT/Ps is currently unknown, there have not yet been any reported cases of transmission via these products.

FDA is continually assessing available scientific evidence to determine whether SARS-CoV-2 testing is warranted on certain types of HCT/Ps used in manufacturing biological products. The agency will continue to monitor the situation and issue updates as information becomes available.
FDA Announces Coronavirus Treatment Acceleration Program

FDA announced a new program to expedite the development of potentially safe and effective treatments for COVID-19. The program, known as the Coronavirus Treatment Acceleration Program (CTAP), aims to bring new therapies to sick patients as quickly as possible while supporting research to further evaluate whether these medical countermeasures are safe and effective for treating patients.

As part of the program, FDA staff is providing regulatory advice, guidance and technical assistance to developers and scientists seeking new drug and biologic therapies. The agency also redeployed medical and regulatory staff to serve on review teams dedicated to COVID-19 therapies, streamlined inquiry request processes and operations for developers and scientists, and provided resources to health care providers and researchers to assist them in submitting emergency requests to use investigational products.

FDA plans to enhance and expand the program to accelerate COVID-19 treatments and other medical countermeasures. The agency will outline additional information on the full breadth of this work in the future.

New FDA Guidance Addresses Discontinuance of or Interruptions to Drug, Biological Product Manufacturing

FDA issued a new guidance to assist applicants and manufacturers of certain drugs and biological products — including blood products — in notifying FDA of production changes to help the agency prevent or mitigate product shortages. In the guidance, FDA stated that under section 506C of the Federal Food, Drug, and Cosmetic Act, persons covered by the notification requirement must notify FDA of any permanent discontinuance or interruption in the manufacture of covered drugs and biological products that is “likely to lead to a meaningful disruption (or, in the case of blood or blood components intended for transfusion, a significant disruption) in the supply of such products in the United States,” and the reasons for such discontinuance or interruption.

The products covered by the notification requirement include prescription drugs and biological products, including blood products, for transfusion, that are life supporting, life sustaining or intended for use in the prevention or treatment of a debilitating disease or condition. This includes any such product used in emergency medical care or during surgery, but not radiopharmaceutical drug products or any other products designated as such by FDA.

Manufacturers covered by the notification requirement include applicants with an approved biologics license application (BLA) for a covered biological product, other than blood or blood components. Applicants with an approved BLA for blood or blood components for transfusion are included if the applicant manufactures a significant percentage of the U.S. blood supply.

Notifications must be submitted to FDA at least 6 months in advance of a permanent discontinuance or interruption in manufacturing. If the discontinuance or interruption in manufacturing was not reasonably anticipated, then the notification must be submitted as soon as practical and no later than 5 business days after the discontinuance or interruption in manufacturing occurs. Detailed instructions are outlined in the guidance.

Guidance on Conducting Clinical Trials During COVID-19 Pandemic Updated

FDA updated its March 18 guidance on conducting clinical trials of medical products during the COVID-19 pandemic to include an appendix of questions and answers that further explains the considerations outlined in the guidance. The considerations may assist sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practice and minimizing risks to trial integrity during the COVID-19 pandemic.

AABB Launches New COVID-19 CCP Website

AABB recently launched a new website to share information with the public, blood collectors and clinicians about convalescent plasma from individuals who have recovered from COVID-19. FDA recently announced new guidelines permitting the use of CCP as an investigational treatment for patients with moderate or severe COVID-19 infections. Many AABB-accredited blood centers are now collecting CCP. The website, www.COVIDPlasma.org, includes information to help identify eligible CCP donors and a tool to assist those donors in contacting their local blood center or hospital blood collector to schedule a CCP donation. In addition, the website provides CCP resources for blood collectors and the blood community.