

FDA Liaison Committee Meeting – 05/16/19

Food and Drug Administration (FDA) staff from the Center for Biologics Evaluation and Research (CBER) met with AABB's FDA Liaison Committee to discuss topics of mutual concern regarding donor and patient safety. The FDA Liaison Committee includes representatives from AABB, American Red Cross (ARC), America's Blood Centers (ABC), Armed Services Blood Program (ASBP), AdvaMed, American Society for Apheresis and the College of American Pathologists (CAP).

FDA Initiatives and Priorities

Nicole Verdun, MD, director of CBER's Office of Blood Research and Review (OBRR), expressed appreciation for the opportunity provided by the AABB FDA Liaison Committee Meeting which supports the valuable exchange of open dialogue between FDA and the transfusion medicine community. Dr. Verdun acknowledged FDA's new acting commissioner, Ned Sharpless, MD, and his continued support for FDA initiatives. CBER's current priorities include:

- Active work on several guidance documents including the Final Bacterial Risk Control Strategies for Platelets for Transfusion due out this year;
- A commitment to the review of Male Sex with Male (MSM) policies with the goal of applying risk-based decision-making (RBDM) principles. FDA is reviewing data and experiences outside of the United States (U.S.) as well;
- Review of outdated policy to support operational efficiencies. The agency revisited universal individual donor Zika Virus (ZIKV) testing with possible consideration for regional testing;
- Pathogen Reduction Technology (PRT) continues to be a high priority. The agency is looking globally at the state of PRT and noted the infrastructure of a country is key to support of the technology. PRT has the potential to address diseases as they emerge, both known and unknown. While whole blood (WB) PRT is a top priority, FDA has robust technology which includes an increased budget to support research for all PRT products not just WB;
- Department of Defense Partnership to advance medical products in support of military personnel including such products as freeze-dried plasma and cold stored platelets.

AABB Initiatives and Priorities

AABB President, Mike Murphy, MD, FRCP, FRCPath, FFPPath, introduced AABB Chief Executive Officer, Debra BenAvram, FASAE, CAE, and ABC's new Chief Medical Officer, Rita Reik, MD FCAP. Dr. Murphy [presented](#) AABB's Initiatives and Priorities since the March 2018 FDA Liaison Committee Meeting, highlighting:

The work of AABB's Donor History Task Force (DHTF)-

- To develop donor risk assessment related to the use of pre-exposure prophylaxis (PrEP) to prevent Human Immunodeficiency Virus (HIV) infection, in collaboration with the Transfusion Transmitted Diseases Committee (TTD) for release as soon as possible and prior to the next version of Donor History Questionnaire (DHQ).
- The on-going preparation of the next version of the DHQ and accompanying materials. The update to version 3.0 will include FDA's final recommendations for Babesia and variant Creutzfeldt-Jakob disease (vCJD), once released;

The challenge of decreasing the occurrence of wrong blood in tube (WBIT)-

WBIT events are a significant threat to patient safety where ABO incompatibility can lead to a transfusion-related fatality. Preventable causes of WBIT include:

- Failure to label samples at the bedside;
- Failure by the Transfusion Service to reject unlabeled or mislabeled samples;
- Collection of “extra” sample tubes also known as “rainbow collection” for possible later use;
- ABO recheck samples drawn at the same time as first sample and held to send later;
- Remote label printing (i.e. the nurses station).

AABB’s continued collaboration with stakeholders on Regulatory issues-

- AABB remains committed to working with CBER and all stakeholders to advance patient and donor safety and to supporting the work of the OBRR under the leadership of Dr. Verdun.
- AABB understands the enhanced value to FDA of joint comments and statements. We follow a multi-step process to more fully engage our membership, allowing our comments and statements to represent the perspectives of our very diverse stakeholders while addressing the complexities of regulatory and operational challenges.
- As a result of this commitment, our organizations have submitted:

Six Joint Comments to the docket

- [Bacterial Risk Control Strategies for Platelets](#) – March 2019
- [HTLV-I/II Donor Regualification](#) – December 2018
- [Further Testing for HCV](#) – December 2018
- [Reducing Risk of Transfusion-Transmitted Babesiosis](#) – September 2018
- [Revised Recommendations for Zika](#) – June 2018
- [Revised Preventative Measures to Reduce the Risk of CJD/vCJD](#) – April 2018

Two Joint Statements

- [Joint Statement Before BPAC on Strategies to Control the Risk of Bacterial Contamination in Platelets for Transfusion](#) – July 2018
- [Joint Statement on Tolerable Risk in Blood Safety: Submitted to the Advisory Committee on Blood and Tissue Safety and Availability](#) – September 2018

And AABB’s work on issues beyond the regulatory environment -

- A 2019 AABB Association Bulletin with recommendations intended to assist hospitals and blood centers in working together to decrease the over-reliance on group O Rh(D)- RBCs;
- Navigation of a changing donor base, economic pressures, reduced utilization and implementation of voluntary and mandatory safety measures;
- Submission of a joint request to Centers for Medicare & Medicaid Services for a miscellaneous billing code to support reimbursement of new products;
- Support for the Pandemic and All-Hazards Preparedness and Advancing Innovation Act;
- Proposed draft of the *Standards for Blood Banks and transfusion Services*, 32nd Edition which includes flexible options for implementation of donor iron recommendations;
- Joint AABB/ABC National Academies event focused on challenges and opportunities related to the donor base;
- ABC/ARC/Association of Donor Relations Professionals/Sickle Cell Disease Coalition and diversity of the blood supply;
- Challenges to the donor base and competition from plasma industry.

Discussion of Specific Topics

1. Overly Burdensome Regulations - Revisiting Regulatory Reform

AABB and ABC have submitted letters to FDA requesting that the agency consider reevaluating certain regulations and recommendations that are considered outdated, duplicative, overly burdensome and unnecessary to protect the public health. We believe our requests were consistent with the CBER Interim Strategic Plan Fiscal Year 2017-19 and the agency's efforts to identify future needs and direction.

- **Blood Pressure (BP) Approval – Requirement for on-site evaluation by responsible physician**

AABB's [October 2017 letter](#) to the FDA Commissioner listed regulations in the [May 2015 Final Rule](#) for donor BP and on-site consultation by the responsible physician if the BP falls outside of the newly established range specified in [21 CFR 630.10\(f\)](#) which do not increase safety, are overly restrictive, and limit the authority of the medical director. The evidence for FDA BP requirements is not clear and is not consistent with published literature. We believe this regulation is unnecessary.

The regulatory burden is further increased by severe limitations placed on the responsible physician. The preamble states, "establishments may permit the donor to donate only when the responsible physician has examined the donor and determined that the health of the donor would not be adversely affected by donating." With the additional restrictions in [§§630.5\(b\)\(1\)\(i\)\(A\)](#) and [\(c\)\(1\)\(i\)\(A\)\(1\)](#), "the responsible physician is not authorized to delegate this examination and determination of the health of the donor and must personally perform this examination and determination." Therefore, it is necessary to have a responsible physician onsite for multiple blood drives, often held at the same time, for each day of the year. Clearly, that option is not feasible, nor would there be medical resources to support those operations, which leaves donor deferral as the only operationally feasible option.

We believe current data supports a less restrictive and less burdensome approach. However, given the current restrictions, we continue to believe that permitting the medical director to use his or her clinical judgment when evaluating an elevated BP would provide adequate protection for the donor whether evaluated onsite, by telephonic consultation, or through delegation of authority. This would also prevent unnecessary donor deferrals.

We also believe that the extended period of time between the 2007 comment period on the proposed rule and the publication of the [May 2015 Final Rule](#) was a missed opportunity to consider new information on risks related to BP that might have changed this overly restrictive approach for on-site consultation.

Questions:

1. *What data provided the evidence of risk that is the basis for adding the BP requirements in [§630.10\(f\)](#)?*
2. *What options are available to request FDA re-evaluate these requirements for a physician to "personally perform the examination."*

FDA Response:

The basis for the requirement can be found in the preamble to the [Final Rule](#) (pg. 29866). In 2009 FDA held a [Blood Products Advisory Committee Meeting](#) and discussed whether the available data support the utility of pre-donation BP measurement as a predictor of donation related adverse reactions. The majority responded that there was no correlation. However, many members of the committee felt that it should be retained as part of the donor assessment. Committee members noted that studies examining adverse events and BP have been restricted to donors with currently acceptable BP levels. Some were concerned that it was not safe for hypertensive individuals to donate. They noted a lack of data and the potential for adverse events in such donors. Other members noted that low BP could be predictive of adverse events in young female donors with a low blood volume. The responsible physician may not delegate this task. FDA would be interested in hearing new data.

The FDA provided that when developing an alternative approach, parsing of specific elements in the request for consideration would be helpful. For example, separate a request related to the requirement to perform the BP measurement from a request to review the acceptable BP range, or a request to reconsider the requirement for physician assessment.

AABB committee members reported difficulty in providing this type of data, when in most cases, because there is not an available physician to personally assess the donor, such collections do not occur. FDA indicated they would be open to consideration of data from outside the U.S.

- **Discard of otherwise acceptable blood products inadvertently collected from a donor (e.g. eligibility criteria were not met based on collection date, BP or pulse)**

In the [2017 FDA Liaison Committee Meeting](#), and again in the [October 2017 Letter](#), our organizations voiced concerns over the unnecessary discard of collections for reasons other than safety, purity, and potency. Specifically, the new requirements of [§§630.10](#) and [630.30](#) require the destruction blood products based on errors in eligibility criteria for BP, pulse, and date of collection. Errors related to collection date, BP, and pulse do not adversely impact product safety, purity, or potency. The regulations do not increase safety and unnecessarily restrict access to safe products.

We support compliance with FDA regulations for donor eligibility under [§§630.10](#) and [630.15](#) as necessary to protect patient safety, and we respect the value of life-saving products donated by altruistic volunteers. A collection error related to BP criteria is not equivalent to a donation deemed unsuitable due to the donor's increased risk for a relevant transfusion-transmitted infection (RTTI), such as HIV. Products that pose a risk of infection must be discarded. However, under these regulations a safe, pure, and potent blood product must also be destroyed as unsuitable.

At the [2017 FDA Liaison Committee Meeting](#), FDA stated that the regulations at [§630.30](#) are consistent with the agency's intent to prevent such collections, which should be prevented or minimized by a strong quality system. FDA indicated that a blood collection facility would be expected to comply unless the donation was a rare product or a selected/directed donation.

The destruction of a life-saving blood product that meets all criteria for safety, potency, and purity never protects the donor after an inadvertent collection that has already occurred in error. This punitive approach is also not an effective deterrent for an unintended error. We believe it is possible to address FDA's concerns that these errors would increase in the absence of this regulatory deterrent. With details to clarify FDA's expectations, we believe we can provide additional data on the frequency of errors, and the effectiveness of corrective actions to support an alternative procedure.

Questions:

1. *Would FDA consider a liaison to answer the questions of an ad hoc working group, similar to collaborations in the past, as they develop a model or template to assist blood establishments in preparing a submission?*
2. *We would task such a working group with developing a model to establish and monitor an acceptable error rate, minimum elements of acceptable standard operating procedures for investigations and corrective actions – what additional elements should be provided to support the variance request?*
3. *What are the minimum goals of an acceptable alternative approach?*

FDA Response:

FDA finalized [§§630.30, 630.10](#) and [§630.15](#) which included measures to protect the health of the donor. There was much debate particularly focused on the interdonation interval. The agency will allow certain exceptions for an urgent need or a very valuable, non-replaceable product. In 2017 we requested and received data on the number of nonconformances reported. We understand that this was not a formal scientific sampling, but it demonstrated extreme variability between centers in the range of zero to 190. We recognize that 2017 was the first year under the new rule and some of the variables contributing to the wide ranges reported may have improved. A larger scale, formal study would be very valuable for our consideration. FDA has representatives available who currently serve as liaisons.

AABB committee members described connectivity issues which are the cause of many early collections and the frustrations associated with the discard of these otherwise acceptable components. It is felt that the industry has made improvements using automated systems and there have been less discards. The establishment of an acceptable rate of nonconformance would be appreciated.

FDA believes data, stratified over time would be useful and would be open to hearing where the industry is today and looks forward to receiving new data.

2. Continued Challenges in Donor Risk Assessment

Our goals for this section are to inform FDA of the rapidly evolving experiences of our members and to request clarification in support of new strategies. AABB's DHTF and our members are facing compounding challenges with donor eligibility for a variety of reasons. These challenges are a result of many factors, including self-identified gender, evolving gender options, and other factors impacting risk assessment.

In addition, developing an optimal approach to establish donor eligibility is further complicated by emerging considerations on the use of PrEP and anti-retroviral (ARV) therapy, expectations to both

shorten the MSM deferral period and move to a gender-neutral process, while individual risk assessment has also been proposed as the next option.

Our members must find a path forward despite the challenges posed by these converging, complex issues.

- **Challenges posed by donor gender identification, including nonbinary**

We appreciate the non-prescriptive approach in the [December 2015 HIV Risk Guidance](#) which states:

“In the context of the donor history questionnaire, FDA recommends that male or female gender be taken to be self-identified and self-reported.”

In the years since, our member facilities have engaged community stakeholders to increase awareness and sensitivity and have conducted education and training to ensure a better understanding of the gender identification spectrum as related to blood donation. Our members were first to develop policies for transgender donor eligibility assessment.

AABB has discussed donor gender identification in various forums, and most recently on April 11 at the TTD Committee Meeting. For some time, we have seen increasing interest in donation by nonbinary individuals in many locations. Nonbinary individuals self-identify as neither entirely male nor female, or a combination of both, or present in a non-gendered way. Several states now allow a nonbinary designation on birth certificates and drivers licenses. For many centers, a driver’s license serves as the primary form of donor identification and is scanned directly into the blood establishment computer systems (BECS). Challenges exist when an individual chooses to not identify a gender, identifies as gender fluid (gender identity moves back and forth between male and female over time), or identifies as a “non-mainstream” gender (these terms vary regionally).

Our members are committed to consistent policies that protect blood safety and defer only when necessary based on evidence of risk. We are seeking an evidence-based approach to evaluate donor eligibility. Some of our members have successfully implemented new policies. Others are trying to determine the best approach. Operational issues are difficult to navigate, and there is mixed success reported with managing changes to the BECS. Some members report support from BECS manufacturers as slow or lacking which is an obstacle to a policy change of this magnitude. We believe FDA may also be seeing the increasing criticism from the public, news media, and state legislators with expectations that the issue be resolved quickly by revising current policies that provide for donation by male and female donors only.

Questions:

In support of efforts to consider policy changes to address emerging issues on gender identification, protect the blood supply, and meet FDA’s expectations, we have the following questions regarding the DHQ), donor safety, and challenges with BECS:

1. *What are FDA’s expectations and concerns related to moving away from gender identification as male or female, to include other options, such as nonbinary?*
2. *For centers interested in using a gender-neutral donor screening process, what is FDA’s current thinking on the minimum elements necessary to ensure donor and patient safety?*

3. *Once finalized, the version 3.0 DHQ will reflect new recommendations (based on final guidance for Babesia and/or vCJD) – Would FDA support a collaboration, such as an ad hoc working group, to support work on donor risk assessment using a gender-neutral DHQ and/or individual risk assessment?*

FDA Response:

FDA appreciates the complexity of this issue. As stated, the [December 2015 HIV Guidance](#) provided for the donor to self-identify and self-report. The agency has given further advice providing that the responsible medical director may choose to explain the reason for a deferral or need for additional questioning. As provided in the AABB presentation some centers use a more conservative approach for hemoglobin, apheresis settings, the pregnancy question and MSM questions to accommodate such donors.

The agency recognizes that there is a lot of data being generated overseas but comparison to the U.S. populations is difficult. We opened a [2016 docket](#) to receive additional information on the topic and will closely monitor any new, additional information provided. FDA follows [good guidance practices](#) and have representatives to the DHTF who serve in a liaison role.

- **Donor use of HIV PrEP**

In early May 2017, the DHTF raised concerns regarding donor eligibility criteria when the Task Force became aware, by way of our ASBP representative, of the rapidly increasing use of Truvada and the public health initiatives promoting PrEP in specific populations at risk for HIV. The early reports in literature described the potential for false negative testing as a result of a suppression of the viral load in PrEP users. As shared in other meetings with FDA, the DHTF and the TTD Committee have continued to monitor the data on this issue.

The April 2019 TTD Committee meeting included presentations from Dr. Mike Busch on PrEP and ARV, and discussion of potential risks, use in non-MSM populations, impact on donor deferral, and potential strategies. When polled, the majority of the TTD Committee supported recommending the DHTF propose an approach for further consideration, including new donor education material, a screening question, and deferral period (addition of Truvada to the Medication Deferral List was not viewed as the most effective option). In light of new data, and our plans to develop a proposed approach for use in the v3.0 DHQ (following release of final guidance on vCJD and Babesia), if not sooner, we remain interested in FDA's current thinking on PrEP use and blood donation by all individuals. Dr. Alan Williams presented an update at BPAC on March 21, 2019. He mentioned that Transfusion-Transmissible Infections Monitoring System (TTIMS) was responding to the need for data on use of PrEP and ARV by blood donors, and that additional data was expected later this year.

The DHTF understands the importance of developing questions that will be acceptable to donors while eliciting the necessary information. The DHTF developed the report, "[The Feasibility of MSM Individual Risk Assessment Using the AABB DHQ](#)," which offers considerations for use of acceptable questions in risk assessment which can be broadly applied to PrEP as well.

Additional AABB discussion:

In the absence of good data, we are taking a precautionary or theoretical approach. The industry feels some sense of urgency to act based on the increasing uptake of PrEP medications coupled

with the knowledge that individuals with HIV risk present to donate blood. There is a perception that use of PrEP removes HIV risk.

Questions:

Considering that:

- *A new approach could be proposed for use with the v3.0 DHQ, if not sooner.*
- *The Office of Biostatistics and Epidemiology expects additional TTIMS data will be available in the coming year related to PrEP and ARV use among those who attempt to donate blood.*
- 1. *Is FDA aware of additional information that should be considered now by the DHTF and the TTD Committee as they evaluate risk and consider donor deferral for PrEP and/or ARV, and define an appropriate deferral period?*
- 2. *What would be the process for an update on FDA's view as new information on the impact of PrEP use by blood donors becomes available?*

FDA Response:

FDA is not aware of additional information. This is a two-fold need. There is a need to determine the impact of PrEP on the level of detection of HIV and a need for the manufacturer to evaluate the performance of the test with respect to PrEP with an intent to improve the assay. Based on information provided to FDA, the agency would support the addition of a question to the DHQ. FDA, using [good guidance practices](#), provides representatives to serve as liaisons, including those currently with the DHTF.

3. Planning for FDA's Priority Initiatives, Policy Changes, and Evidence-Based Decisions on Risk

Our members strive for the ideal balance between risk and a safe, adequate blood supply. Our vision for the future requires that we carefully identify the areas of greatest need, prioritize time and resources, then commit to basic goals that have the greatest impact. To that end, these efforts will be most effective if we understand FDA's goals, priorities, and decisions, and the agency understands the complexity of sustaining both availability and a high degree of safety in our blood supply. The ideal balance would be built with a mutual understanding of goals and priorities, minimizing the push-pull effect of other influences, and focusing efforts to support the most important goals.

- **The following are a few of many examples, where an understanding of FDA's framework would inform the path forward.**

Evidence based decision-making and the path forward:

There are recurring comments that clarification of the FDA's framework for developing policies and evidence based decision-making would be far more beneficial than simply seeking specific details on a given issue. During the recent TTD Committee meeting, the importance of first considering a broad analysis of issues (prior to discussing PrEP) was again referenced. Such an analysis would first consider the impact on public health, the priority level and competing resources, before its application to specific areas. Clear goals, as emphasized above, and focused efforts more effectively support the hospitals, patients and donors we serve.

Understanding of the framework for FDA's priorities and preferred approach would help members find a path to align resources for competing priorities. Critical considerations on the data, acceptable risk versus zero risk tolerance, operations, and the impact on safety and availability would be more easily applied to regulatory responsibilities if there is a basic understanding of how best to develop innovative approaches to address growing challenges in all areas of manufacturing.

Clear path for testing options:

With regional testing options ahead for Babesia and ZIKV, we are looking for the optimal approach. For these cases, the first priority is establishing a framework for the risk assessment and how it would be applied to an RTTI. It would be possible for our members to consider and implement options for regional testing with a better understanding of the framework for risk assessment that reflects FDA's goals. We believe there are tremendous opportunities for collaboration in this area.

Such a framework could be applied to the West Nile Virus (WNV) testing requirements that pre-date the current evidence-based approach. Given that the industry has accumulated 15 years of data indicating that WNV donor screening has no yield in the winter months, would it be reasonable to revisit the testing model and the evidence of risk, with consideration toward relaxing test requirements throughout the U.S. for a several month period, if beneficial to blood donor centers?

Platelet safety and availability

One of the next challenges directly ahead is balancing platelet safety and platelet availability. Historically, the FDA has strived for zero risk in its decision-making. Many have concerns based on the most recent draft guidance, [Bacterial Risk Control Strategies for Blood Collections Establishments and Transfusion Service to Enhance the Safety and Availability of Platelets for Transfusion](#), which focused on reducing contamination risk at the expense of platelet availability. Did the agency consider a risk-based assessment of the impact of these changes on platelet availability which is also considered a safety issue?

The future of pathogen reduction

The agency's recent comments seem to focus mostly on a solution to treating WB that can be further manufactured into components as the "ideal" solution. When striving for the ideal balance and looking ahead, our members are asking:

- Could the FDA further expand on their future vision?
- Does the agency have a time frame for their vision? Are there specific checkpoints that the FDA sees as critical on this pathway?
- Has the FDA considered how changes in blood product utilization overall (e.g. Red Blood Cells [RBCs] declining, platelets increasing) might impact availability of certain pathogen reduced blood products if the only ideal solution is applicable to WB?
- Put another way, if the current trend of decreased utilization (and collection) of RBCs from WB continues while platelet utilization increases (collected mainly by apheresis), will there be sufficient WB collections to account for platelet demand?
- Will we have to collect more WB and discard RBCs to meet platelet demand? Wouldn't we still need to maintain a pathogen reduction option for apheresis platelets?

- Should equal resources be devoted to all pathogen reduction options and not limit the focus to WB?
- Pathogen reduction of platelets prepared using the buffy coat method is an option being used internationally. Given the existing international data available for review, will the FDA give consideration to preparation of buffy coat platelets in the U.S. and the application of pathogen reduction methods to those platelet products?

Question:

We need to understand all of the issues in these examples above but, more importantly, we need to understand FDA's decision-making, goals for risk assessment, and use of evidence-based decisions in pursuing priorities.

1. *What information can FDA share regarding a decision-making algorithm that can be applied to these and other examples, including risk assessment and evidence-based decision making?*

FDA Response:

RTTI's can be challenging. FDA holds public meetings and engages in [good guidance practices](#) to give everyone the opportunity to participate and provide feedback. Risk tolerability among blood centers, donors, physicians, and recipients is always considered.

The agency is committed to providing a clear path for testing options (ex: Babesia and ZIKV) and defining risk for various infections. We review with the intent to identify and consider opportunities for update. For WNV, it may be feasible to consider discussions on seasonal testing using an RBDM model. We are open to discussion and new data.

FDA has issued three draft guidance documents for bacterial risk control strategies for platelets and is currently finalizing the guidance following consideration of numerous public comments. Each comment is evaluated and discussed. Each comment is considered as the agency formulates recommendations. Risk benefit analysis varies as numerous options are considered. Many blood establishments reported the loss of product volume and have adjusted collection volume to compensate. The extension to 7 days has been appreciated. Safety and availability go together, and FDA recognizes that availability is part of safety.

FDA would consider providing an evaluation of comments to the docket similar to the preamble to the [Final Rule](#).

4. Guidance Documents and Rules Planned by FDA/HHS

The publication of the [CBER guidance agenda](#) is very important to our membership and the mid-year update is enormously helpful. We are pleased to see the publication of the Babesia final guidance and have noted that CJD/vCJD will come out as a second draft guidance. We hope to see final CJD/vCJD guidance follow shortly thereafter, as it is key to v3.0 of the DHQ. The ability to accommodate all changes necessitated by guidance within a single DHQ version update would be much appreciated.

Guidance Documents CBER is Planning to Issue in 2019 for Blood and Blood Components:

- *Implementation of Pathogen Reduction Technology in the Manufacture of Blood Components in Blood Establishments: Questions and Answers; Guidance for Industry;*

- *Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products; Draft Guidance for Industry;*
- *Testing for Biotin Interference in In Vitro Diagnostic Devices; Draft Guidance for Industry;*
- *Further Testing of Donations that are Reactive on a Licensed Donor Screening Test for Antibodies to Hepatitis C Virus; Guidance for Industry;*
- *Recommendations for Requalification of Blood Donors Deferred Because of Reactive Test Results for Antibodies to Human T-Lymphotropic Virus Types I and II (anti-HTLV-I/II); Guidance for Industry;*
- *Considerations for the Development of Dried Plasma Products Intended for Transfusion; Guidance for Industry;*
- *Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion; Guidance for Industry;*
- *Recommendations for Reducing the Risk of Transfusion-Transmitted Babesiosis; Guidance for Industry.*

We are concerned by recent reports of an [additional review](#) by the Office of Management and Budget’s Office of Information and Regulatory Affairs that could adversely impact CBER’s plans for future guidance.

Questions:

1. *Can you please clarify what this additional review would mean and provide an update?*
2. *What is the earliest date this could impact FDA’s existing guidance development process?*
3. *Are there any changes to the current Guidance Agenda?*

FDA Response:

FDA does not anticipate changes or delays to the guidance agenda based on the announced review by OMB *Office of Information and Regulatory Affairs*. Very little of the CBER agenda would be captured in the \$100 million threshold. Currently, all guidance development and review are on schedule.

FDA ATTENDEES

Office of the Center Director (OD)

Diane Maloney, JD, Associate Director for Policy, OD

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Ruth Sylvester, MT(ASCP)SBB – ABC
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