January 26, 2024

Dockets Management Staff
Food and Drug Administration
5630 Fishers Lane
Room 1061, (HFA-305)
Rockville, MD 20852

In Re: Docket No. FDA-2023-N-5653, Draft Report and Plan on Best Practices for Guidance

Dear Madams and Sirs:

The American Association of Tissue Banks (AATB or Association) and the American Association of Tissue Bank's Tissue Policy Group (AATB TPG or TPG) submit these comments related to the Food and Drug Administration (FDA) *Draft Report and Plan on Best Practices for Guidance*. Specifically, our comments respond to page 25 of the draft report, *"Use of Level 1 Guidance 'for Immediate Implementation,'"* and related issues.

The American Association of Tissue Banks (AATB) is a professional, non-profit, scientific, and educational organization. AATB is the only national tissue banking organization in the United States, and its membership totals more than 120 accredited tissue banks and over 7,000 individual members. These banks recover tissue from more than 70,000 donors and distribute in excess of 3.3 million allografts for more than 2.5 million tissue transplants performed annually in the US. The overwhelming majority of the human tissue distributed for these transplants comes from AATB-accredited tissue banks.

The AATB TPG includes Chief Executive Officers and senior regulatory personnel from U.S. tissue banks that process donated human tissue. The purpose of the TPG is to drive policy in furtherance of the adoption of laws, regulations, and standards that foster the safety, quality, and availability of donated tissue. The TPG's membership is responsible for the vast majority of tissue available for transplantation within the U.S.

Level 1 Guidance Documents "for Immediate Implementation." In the draft report, FDA notes that the Agency "intends to consider whether, consistent with the [Federal Food, Drug, and Cosmetic (FD&C)] Act, there are additional categories of Level 1 documents for which, or circumstances under which, FDA should consider issuing Level 1 guidance 'for immediate implementation.' FDA also intends to consider whether, consistent with the FD&C Act, there are additional categories of guidance that would meet the definition of Level 2 guidance and be appropriate for issuance using the procedures for Level 2 guidance documents." The AATB and TPG are astounded and troubled that the FDA is considering issuing new or updated guidance documents for immediate implementation, and at a minimum we encourage you to publish draft criteria (with an opportunity for feedback from the public and industry stakeholders) regarding the circumstances under which such guidance documents would be issued for immediate implementation without an opportunity for public comment.

As defined in the Agency's current Good Guidance Practices, outlined in 21 CFR 10.115, "Level 1 guidance documents" include those that "set forth initial interpretations of statutory or regulatory requirements; set forth changes in interpretation or policy that are of more than a minor nature; include complex scientific issues; or cover highly controversial issues." Compared to "Level 2 guidance documents," which are typically related to minor changes in policy, Level 1 guidance documents have the potential to significantly impact industry and the public. There is a risk that Level 1 guidance documents, because they set forth initial interpretations of statutory or regulatory requirements, could establish a precedent on a topic that would be more appropriately addressed through rulemaking. Additionally, issuing guidance on highly controversial issues without prior public participation stifles the conversation necessary to understand the impact on regulated industry and limits the opportunity to promote cooperation to the benefit of public health and access to new drugs, devices, biologics, and 361 HCT/Ps. A notice and comment period provides the public, including affected patients and industry, and other stakeholders an opportunity to prepare for changes and voice concerns to the Agency. Collaboration between FDA, industry, and other stakeholders is essential to achieve the most scientifically sound guidance based in the regulations, rather than only the Agency's perspective being heard. Therefore, except in cases of emergency or when a notice and comment period would otherwise be infeasible, we believe that FDA must proceed conservatively on the issuance of future Level 1 guidance documents and in a manner that provides industry and the public a meaningful opportunity to weigh in prior to implementation. Such an approach would result in a more deliberative and collaborative process with a reduced likelihood of unintended consequences.

The AATB and TPG recognize, as noted in the report, that FDA's ability to issue Level 1 guidance documents for immediate implementation "was a significant factor in FDA's success is (sic) implementing many COVID-19 guidances in a short timeframe." We agree that it may be appropriate for FDA to issue Level 1 guidance documents in rapidly evolving situations, as the COVID-19 pandemic was in 2020, and we appreciated the Agency's efforts during the pandemic to efficiently solicit comment, review comments received, and, as appropriate, revise guidance documents previously issued for immediate implementation. The benefit of immediately publishing clear Agency guidance in emergency situations like that posed by COVID-19 is likely greater than the consequences of issuing a guidance document without a public comment period. In less urgent situations, however, we believe the benefit of transparency and engagement with patients, industry, and other key stakeholders is likely to result in better public health outcomes and reduced burden on industry. We therefore request that the Draft Report and Plan on Best Practices for Guidance include clarification and examples of the types of situations and criteria FDA plans to use to issue a Level 1 guidance document without prior public participation.

Level 2 Guidance Documents for Immediate Implementation. The AATB and TPG note that while our comments in this letter generally focus on Level 1 guidance documents issued for immediate implementation, we appreciate any efforts made by FDA to solicit and review comments on Level 2 guidance documents issued without prior public participation. Additional efforts, such as town hall meetings and workshops, are also beneficial. For example, FDA recently issued the revised final Level 2 guidance, *"Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile,"* to include vaporized hydrogen peroxide (VHP) as an established method of sterilization for medical devices. Such a change, while relatively minor in nature, will have a significant impact across multiple industries, and we appreciate FDA's intent to hold a series of town halls to describe the Agency's plan for implementation of the revised guidance and to solicit feedback

and questions from affected industries and the public. We encourage the FDA to hold additional town halls and workshops, prior to the issuance of draft guidance as appropriate and practical, for future guidance documents issued without prior public participation.

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We hope that you will find this information useful in your deliberations. The AATB and the TPG stand ready and willing to assist the FDA with its deliberations in any way that you deem appropriate.

Respectfully,

Marc Pearce
President & CEO
American Association of Tissue Banks

Doug Wilson
Chair
Tissue Policy Group

The American Association of Tissue Banks
The American Association of Tissue Banks (AATB) is a professional, non-profit, scientific, and educational organization. AATB is the only national tissue banking organization in the United States, and its membership totals more than 120 accredited tissue banks and over 7,000 individual members. These banks recover tissue from more than 70,000 donors and distribute in excess of 3.3 million allografts for more than 2.5 million tissue transplants performed annually in the US. The overwhelming majority of the human tissue distributed for these transplants comes from AATB-accredited tissue banks.

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