July 16, 2024

Re: The diaTribe Foundation Comments to Docket No. FDA-2024-N-1809
Optimizing the Food and Drug Administration's Use of and Processes for Advisory Committees

To Whom it May Concern:

On behalf of The diaTribe Foundation, thank you for the opportunity to provide feedback on the Food and Drug Administration (FDA) advisory committee process. As an organization that represents individuals living with diabetes and their advocates, we strongly believe the voices of people with diabetes must be foremost as FDA and its advisory committees consider potential new medical products and debate broader policies that impact access to innovative treatments. As such, we are grateful for the chance to discuss our recommendations for more meaningfully incorporating the voice of patients in advisory committee meetings and for improving public understanding of the role of advisory committees.

The diaTribe Foundation

The mission of The diaTribe Foundation (diaTribe) is to help people with diabetes and to advocate for action. Our goal is to ensure that people have the resources and education needed to thrive with diabetes. The diaTribe Foundation is dedicated to bringing people with diabetes to the conversation on regulatory issues, connecting the field and the diabetes community, and changing the narrative around diabetes. Through our publication, *Learn*, which reaches more than six million people each year, we offer deep insights into the patient experience and closely cover the latest research, treatments, and initiatives in diabetes.

In addition, because everyone with diabetes deserves to have the tools, therapies, and technologies to live their best life, we established the Time in Range Coalition (TIRC) with a multi-stakeholder group of foundations, non-profit organizations, researchers, people with diabetes, clinicians, and industry with the goal of establishing time in range (TIR) as an essential part of diabetes care and making TIR accessible to all people with diabetes and their care teams. Research shows that using time in range in daily diabetes management can positively change lives—we are spearheading the work to make that a reality for everyone with diabetes.

The diaTribe Foundation also aims to reduce the impact of diabetes on society and improve the lives of people with diabetes by fostering an understanding of the disease and eliminating misplaced blame through the work of our program, *dStigmatize*.

Improving solicitation and integration of patient feedback

In June, I had the opportunity to bring my 26 years of lived experience and the resources of a patient advocacy organization to the forefront to provide oral and written comments at an advisory committee for the first time. From the perspective of a participant in the open public

hearing portion of that advisory committee, the process did not seem like one equally accessible to all patients. diaTribe appreciates FDA's efforts in recent years to solicit information from patients about the burden of our diseases, our views on benefits and risks, and to incorporate those perspectives into drug review and approval. However, within the advisory committee process, the consideration of patient perspective too often appears cursory and disjointed. Today, many patients are highly informed about their own disease state, and have valuable insights that are honed exclusively from lived experiences. But, to optimize patient participation and impact on advisory committees, additional support is needed. Most fundamentally, for those with no experience participating in advisory committees, basic resources such as tutorials on the role of advisory committees, standard meeting process, and how patient input is considered would be useful. In addition, FDA and applicant briefing documents were only made available a few days before the meeting, making it difficult to address key issues in the most thoughtful manner. Earlier availability of these materials would allow for more targeted input.

We also recommend that, prior to each advisory committee, the agency define in the committee meeting announcement the specific information patients could provide that would be helpful in review of a given product, just as is currently provided to the advisory committee members. This could include a list of focused discussion topics provided ahead of time in the advisory committee meeting announcement honoring patient expertise and empowering commenters to prepare more tailored feedback on the topics most relevant for the committee's consideration and the agency's ultimate approval decision. While patients should always be permitted to offer insights that may fall outside these topics, specific questions for patient input would also make offering comments more approachable for many, especially those less familiar with the advisory committee format. FDA and applicant briefing documents with these additional topics and proposed patient-centered questions should be shared a minimum of seven days in advance of the meeting to allow for thoughtful input.

When considering the voice of the people impacted most, it would be valuable for the Open Public Hearing portion of advisory committee meetings to take place before the presentations by the applicant and FDA, so those views are front of mind throughout the committees' discussions.

We further suggest that as part of the committee's discussion and voting, members should be asked specifically how patient information informed their decisions—whether from public comments or other patient preference information data provided in briefing materials and presentations.

Finally, while we appreciate that FDA has indicated its intention to return to in-person advisory committee meetings, we hope alternatives remain in place to ensure accessible patient participation. We believe there is tremendous value in FDA and committee members hearing

from patients firsthand. However, we would urge the Agency to keep a virtual option for patients whose illnesses, livelihoods and travel situations may make it difficult or impossible to appear in person.

Improving patient/public understanding of advisory committees

From media coverage and Congressional responses to high-profile and controversial FDA decisions following advisory committee meetings, it is evident that there is a lack of understanding of the role of advisory committees in drug review and approval. Most concerningly, that lack of understanding threatens to undermine the patients' and the public's trust in FDA decisions about the safety and effectiveness of medical products.

FDA should, at the beginning of each advisory committee and through its website, explain those roles in layman's language. This should include clarifying that advisory committees are composed of outside experts, invited to offer scientific and clinical advice to FDA, but that FDA has to work within the law and regulations as it incorporates that advice into its decisions. FDA should also clarify that it has risk mitigation tools at its disposal that can lead to different benefit-risk calculations than those made by advisory committees.

To that point, we would suggest that FDA consider not asking committees to vote on the question of whether the benefits outweigh the risks for specific products. We believe that voting in advisory committees has value—discussions can be complex and votes may force clarity on advisory committee members' views on specific topics. However, voting on what is typically framed as a final benefit-risk assessment—the question that FDA is statutorily mandated to decide—may contribute to public confusion about the meaning of that vote and thus, the role of advisory committees versus FDA.

Conclusion
The voices of people living with diabetes and other diseases and conditions must be heard when discussing advances in therapies and technologies that directly affect our lives. As one of those people, I thank you for this opportunity to share my views on how to ensure those voices are lifted up in the advisory committee process.

Sincerely,

Julie Heverly
Senior Director, Time in Range Coalition
The diaTribe Foundation