TIME COALITION IN RANGE

August 8, 2025

Re: Time in Range Coalition Comments to Docket No. FDA-2025-N-0816: Reauthorization of the Prescription Drug User Fee Act

To Whom It May Concern:

The Time in Range Coalition (TIRC) appreciates the opportunity to submit comments to the Food and Drug Administration (FDA) on the reauthorization of the Prescription Drug User Fee Act (PDUFA). For more than 30 years, the funding and performance management structure provided by PDUFA has given individuals living with diabetes and other serious and life-threatening conditions timely access to safe and effective medicines. As part of the PDUFA VIII reauthorization, the TIRC urges FDA to preserve the program's strength and stability and build on existing efforts to improve the predictability and clarity of the drug development process. By doing so, people with diabetes and other serious and life-threatening conditions will continue to have timely access to innovative therapies to improve their health and extend their lives.

Background

Spearheaded by The diaTribe Foundation, the TIRC is a diverse group of global diabetes stakeholders, including nonprofit organizations, professional societies, industry, and patient advocates working to drive awareness and adoption of time in range (TIR). Reliable measurement of TIR, which is the percentage of time a person spends within a target glucose range and is reported alongside time above range (TAR) and time below range (TBR), is now possible through advancements in continuous glucose monitoring (CGM). As this technology empowers individuals living with diabetes to be aware of their glucose levels minute by minute, they can make real-time adjustments to their diet, activity, and medication dosing to improve health outcomes.[1,2] Studies have shown that as one's TIR increases, health complications from the disease—and associated healthcare costs—decrease.[3–13]

More than 11% of the U.S. population has diabetes—a staggering 38.4 million people.[14] Over the past decade, with the support of user fee programs, FDA approvals of safe and effective drugs and devices have transformed diabetes care and management. People with diabetes now have access to therapies and devices that not only improve glucose levels, but also support weight management, reduce hypoglycemia, and prevent some of the costly and often lethal complications associated with diabetes, including cardiovascular and renal disease. Furthermore, advances in the accuracy and ease of use of CGM technology has increased acceptability among clinicians and people with diabetes who are increasingly reliant on CGM metrics like TIR for daily diabetes management. A growing body of evidence shows that TIR has added value in clinical, research, and regulatory settings beyond the currently accepted gold standard of hemoglobin A1c (A1c).[15–18] However, despite treatment advances to date, people with diabetes still need improved tools to tackle the daily hurdles and burdens of managing this complex chronic condition.

Providing Sufficient Funding

Adequate funding for FDA is essential if the progress made thus far is to continue. To best serve patients, as noted above, FDA requires sufficient financial resources—both through annual discretionary appropriations[19] and user fees—to maintain adequate staffing of review staff and critical review support functions. Funding cuts and staffing reductions that reduce workforce capacity and result in slowed or halted drug reviews mean much-needed, innovative medical products no longer reach people with diabetes and other chronic conditions in a timely manner.

Sufficient FDA staffing facilitates access to state-of-the-art therapies that help reduce disease complications and improve overall health. Specifically, we request you ensure that PDUFA fees accommodate the staffing levels needed to facilitate timely drug reviews, including administrative support functions to properly process submissions. Additionally, preserving funding for adequate levels of policy staff and scientific reviewers is essential to develop and advance regulatory communications for innovative medical products and issue guidance for industry, which promotes transparency and predictability in the drug development process.

Ensuring Long-Term Stability and Trust

Regarding the program's structure, we are aware of the Administration's interest in potentially restructuring PDUFA to address the perception by some stakeholders that user fees create undue industry influence over review outcomes. While we are unaware of evidence substantiating that view, to the extent that any restructuring occurs, we would urge that it be undertaken in a manner that does not in any way impair the long-term stability of the program, reduce the predictability of the review process, hinder medical product research and development, or diminish FDA's ability to fully staff review and support functions essential to the administration of the program. Additionally, aligned with the Administration's priority of "radical transparency," we recommend that FDA expand on the efforts undertaken in PDUFA VII to promote financial transparency in the use of PDUFA fees. One way to address concerns about FDA transparency and use of PDUFA fees is to provide increased tracking information on the use of PFUFA fees, including where and how those fees are being spent, rather than only providing data on FDA review timing.

Regarding concerns about influence on review outcomes, we wish to note that preserving a predictable and consistent decision-making process that is evidence-based and free from political influence is essential to maintaining public trust in FDA's drug approval decisions. Many of the review decisions that FDA must make involve difficult scientific and regulatory questions. It has been a long-established practice for approval decision authority to reside with career scientific reviewers, with procedures in place for resolving scientific disputes among those staff. The public's faith in FDA's decisions and innovators' willingness to invest in the development of new therapies requires that those processes be adhered to and that decision-making be transparent to the fullest extent possible.

Facilitating Innovation in Drug Development

The need for appropriate levels of FDA staffing also extends to FDA's critical role in the development and issuance of guidance for industry. Guidance documents provide important clarity, consistency, and transparency to sponsors about the necessary testing and criteria to facilitate the development of new medical

products. Well-crafted guidance promotes greater predictability in drug development research, may reduce unnecessary testing, ensures that the value of patients' participation in clinical trials is optimized, and speeds new therapies to individuals living with chronic and rare diseases, thus improving health care outcomes. In particular, "Diabetes Mellitus: Efficacy Endpoints for Clinical Trials Investigating Antidiabetic Drugs and Biological Products: Draft Guidance," [FDA-2023-D-0625] is critical for delineating the FDA's perspectives on efficacy endpoints for diabetes drugs, including the use of CGM-based metrics. We encourage the incorporation of detailed recommendations for CGM-based metrics such as TIR, TAR, and TBR to establish clear expectations for trial designs. By ensuring consistency in the application of these measures, the guidance can significantly spur innovation in diabetes treatment and ensure that clinical trials deliver meaningful information on the efficacy of new therapies. We look forward to FDA finalizing that long-awaited, much-needed guidance without further delay.

Conclusion

Thank you for the opportunity to submit this written testimony. We look forward to partnering with FDA to ensure that the best possible science and commonsense approaches are brought to bear on efforts to improve the lives of people with diabetes, and appreciate your consideration of our recommendations for the reauthorization of PDUFA.

References

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