

September 3, 2025

Re: Time in Range Coalition Comments to Docket No. FDA-2025-N-1157: Reauthorization of the Medical Device User Fee Amendments

To Whom It May Concern:

The Time in Range Coalition (TIRC) appreciates the opportunity to submit comments to the Food and Drug Administration (FDA) regarding the reauthorization of the Medical Device User Fee Amendments (MDUFA). For over two decades, the funding and performance management framework established by MDUFA has ensured that individuals living with diabetes and other serious and life-threatening conditions receive timely access to safe and effective medical devices. As part of the MDUFA VI reauthorization process, TIRC urges FDA to maintain the program's core strengths and stability while enhancing existing initiatives to improve the predictability and transparency of the medical device development and review process. This approach will ensure that people with diabetes and other conditions continue to have prompt access to innovative technologies that improve their health outcomes and quality of life 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.^{3–14}

More than 11% of the U.S. population has diabetes—a staggering 38.4 million people.¹⁵ 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 and ease the tremendous burden of disease management, 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.^{16–19} 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).^{16,20–22} 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 appropriations²³ and user fees—to maintain adequate staffing of review expertise and critical review support functions. Funding cuts and staffing reductions that reduce workforce capacity and institutional knowledge and result in slowed or halted device 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 technologies that help reduce disease complications and improve overall health. For example, CGMs have consistently been shown to lower A1C and increase TIR, and are associated with reduced hypoglycemia, hospitalizations, and mortality.^{3,24–32} Automated insulin delivery (AID) systems offer well-established improvements in A1c, TIR, and hypoglycemia for people with type 1 diabetes,^{33–35} with growing evidence demonstrating similar benefits in type 2 diabetes and other sub-groups.^{36–38} To ensure future, improved iterations of these technologies continue to reach people with diabetes, we request you ensure that MDUFA fees accommodate the staffing levels needed to facilitate timely product 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 may reduce regulatory burdens on sponsors and promote transparency and predictability in the medical device development process.

Ensuring Long-Term Stability and Trust

Regarding the program’s structure, we are aware of the Administration’s interest in potentially restructuring user fee programs 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 MDUFA 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 current efforts to promote financial transparency in the use of MDUFA fees, including providing increased tracking information to the public on where and how those fees are being spent.

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 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 medical products requires that those processes be adhered to and that decision-making be transparent to the fullest extent possible.

Facilitating Innovation in Medical Device Development

Diabetes technology is evolving rapidly, with distinct advancements in dosing algorithms, predictive alarm features, improved form factors, and more entering the market every year. These innovations serve to educate and empower people with diabetes and those who care for them.^{1,2,39,40} The reduction in disease management burden and actionable data that devices like AID systems and CGMs provide inform and greatly improve how people with diabetes feel, function and survive.^{31,41–45} The community continues to eagerly anticipate the development and approval of dual ketone and CGM monitors, non-invasive CGMs, and more customizable AID options, such as an overnight patch pump measuring time in range to manage glucose levels while the wearer sleeps. It is essential that MDUFA fees continue to support the infrastructure that enables the timely review and approval of these quickly-evolving and outcome-changing tools.

The diabetes field is seeing not only the rapid emergence of new devices, but also the use of existing devices in new patient sub-groups. For example, multiple AID systems were recently approved for use in people with type 2 diabetes. We encourage FDA to continue supporting inclusive trial design and post-market studies to support this broadened access to existing products, as well as for approval of novel products. Many of these expanded indications are long overdue—people with diabetes have only recently received regulatory clarity on CGMs determined to be safe for use during pregnancy, for example. Still, there are no commercially available AID systems approved for use in pregnancy in the US, lagging behind approvals in Europe, the United Kingdom, and Australia.

CDRH has been a leader in incorporating the patient perspective into regulatory decision making. We urge continued focus under MDUFA VI on efforts to develop and expand the use of patient-reported outcomes (PROs), in collaboration with patient organizations as well as with other Agency centers to ensure alignment on requirements to move innovation forward in the most streamlined and effective way possible.

Conclusion

Thank you for the opportunity to submit these written comments. 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 MDUFA.

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