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Written Testimony Prepared for the Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies
FY 2026 Funding for the Food and Drug Administration

The Time in Range Coalition (TIRC) appreciates the opportunity to submit outside witness testimony to the Subcommittee on Agriculture, Rural Development, Food and Drug Administration (FDA), and Related Agencies of the Senate Appropriations Committee regarding Fiscal Year (FY) 2026 funding for the FDA. The TIRC respectfully calls on the subcommittee to fund the FDA in FY 2026 at a level that allows it to meet its public health mission and avoids triggering automatic cuts due to user fee refunds under 21 U.S.C. 379h(f). Specifically, we request you allocate sufficient funding to ensure the agency can maintain: adequate staffing levels for timely drug and device reviews; administrative support functions to properly process submissions; library operations to support research and review of scientific questions; participation by reviewers in scientific meetings to ensure they are educated on the latest scientific developments; and, adequate levels of policy staff and scientific reviewers to develop and advance regulatory communications for innovative technologies and issue guidance for industry, which promotes transparency and predictability in the medical product development process.

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). This critical metric, made possible with continuous glucose monitoring (CGM), is the percentage of time a person spends within a target blood glucose range, as measured by CGM and includes times above range and times below range. As CGM empowers patients to be aware of their real-time glucose levels and patterns, individuals can make timely adjustments to their diet, activity, and medication dosing to improve health outcomes. Studies have shown that as one's TIR increases, health complications from the disease–and associated healthcare costs—decrease.[1–12]

More than 11% of the U.S. population has diabetes – a staggering 38.4 million people.[13] The FDA's work is vital in facilitating innovation in the care and treatment of people with diabetes and over the past decade FDA approvals of safe and effective drugs and devices have transformed diabetes care. People with diabetes now have access to therapies and devices that not only improve glucose control, but also support weight-control, reduce hypoglycemia, and prevent some of the complications associated with diabetes, including cardiovascular and renal disease. The FDA has substantially enabled the development of CGM-driven automated insulin delivery systems, which have revolutionized the management of type 1 and type 2 diabetes. Furthermore, advances in CGM technology now allow for easy and reliable measurement of TIR and 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. However, despite treatment and technology advances to date, people with diabetes still need improved tools to tackle the daily hurdles and burdens of managing this complex chronic condition.

Adequate funding for FDA is essential if the progress made to date is to continue; in particular, sufficient annual discretionary appropriations are key to ensure the agency has the financial and

staffing resources it needs to ensure innovations reach patients. As the subcommittee knows, Congress intentionally tied FDA's ability to spend user fee dollars collected under the Prescription Drug User Fee Act (PDUFA), Medical Device User Fee and Modernization Act (MDUFA), and similar acts (the "UFAs") to discretionary appropriations. Under these acts, discretionary appropriations for drug reviews and certain other activities must be at or above an annual inflation-adjusted level, or else FDA must start refunding user fees and cutting user fee-funded full-time equivalents (FTEs). If the subcommittee fails to meet the minimum appropriation under PDUFA, the adverse impact on individuals living with diabetes and other chronic conditions would be immense. The TIRC therefore asks the subcommittee to allocate FY 2026 discretionary appropriations for FDA at a level safely above any applicable user fee spending triggers.

That said, simply avoiding spending triggers is not enough. To best serve patients, as noted above, FDA requires sufficient financial resources – both through discretionary appropriations and user fees – to maintain adequate staffing of both review staff and critical review support functions. Funding cuts and staffing reductions that drop the workforce to a level where drug and device reviews are slowed or halted means much-needed medical products no longer reach people with diabetes and other chronic conditions in a timely manner. Ample FDA staffing helps facilitate timely access to state-of-the-art therapies and devices that help reduce disease complications and improve overall health.

The need for appropriate levels of FDA staffing also extends to FDA's critical role in the development and issuance of guidance for industry, which provides important clarity, consistency, and transparency to sponsors about the necessary testing and criteria to facilitate progress toward approval of new medical products. Guidance such as "Diabetes Mellitus: Efficacy Endpoints for Clinical Trials Investigating Antidiabetic Drugs and Biological Products: Draft Guidance," [FDA-2023-D-0625] is critical to clarifying the agency's views on efficacy endpoints for clinical trials of diabetes drugs, including the use of CGM-based metrics. This level of transparency is pivotal for accelerating the development of future diabetes treatments and we look forward to FDA finalizing that guidance without delay.

Thank you for the opportunity to submit this written testimony. The TIRC stands ready to serve as a resource to the subcommittee and appreciates your consideration of our recommendations for FDA's FY 2026 funding.

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