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TIME COALITION IN RANGE

April 11, 2025

Martin Makary, MD, MPH
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Dr. Makary:

On behalf of the Time in Range Coalition (TIRC), we congratulate you on your recent confirmation as Commissioner of Food and Drugs at the U.S. Food and Drug Administration (FDA). We appreciate your willingness to serve the nation in this critical public health role. We stand ready to work with you and your colleagues within the FDA to address the epidemic of chronic diseases, including diabetes.

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 (TAR) and times below range (TBR). As this technology empowers patients to be aware of their glucose levels every few minutes, they can make real-time 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.[1–6]

More than 11% of the U.S. population has diabetes – now a staggering 37.3 million. We recognize and appreciate the vital work of the FDA in facilitating innovation in the care and treatment of people with diabetes. 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 costly complications associated with diabetes, including cardiovascular and renal disease. Furthermore, advances in CGM technology now allow for easy and reliable measurement of CGM metrics like TIR. 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).

However, as you have highlighted, there is still work to be done to ensure that advances in science and technology translate into Americans living longer and healthier lives. We appreciated your recent comments at your confirmation hearing before the Senate Health, Education, Labor, and Pensions Committee that broader access to CGM can help empower people to both improve their current health and prevent future disease. In addition to making CGMs more broadly available, we would like to raise several points that we believe are critical to improving outcomes for people with diabetes. We look forward to the opportunity to discuss these further with you at your convenience:

1) Closing the Gap between Clinical Practice and Regulatory Acceptance of TIR: CGM data is rich, actionable, and empowering. Clinical applications of CGM data are rapidly expanding, with successful use in a range of settings from treating T1D to the expansion of T2D treatment, as well as providing unique benefits in the care of pregnant and older individuals.[7–11] The 2025 American Diabetes Association Standards of Care reflect these benefits, recommending that technology such as CGM be

offered to all people with diabetes early, including at diagnosis.[12] A 2023 study found 90 percent of healthcare providers believe TIR is likely to become the standard of diabetes management, but that recognition by regulators was needed to broaden access to and adoption of TIR data for clinical decision making.[13] A central goal of the TIRC has been for CGM-derived metrics to be used in regulatory decision-making; specifically, for TIR metrics, including TAR and TBR, to serve as an endpoint to support diabetes drug approvals, as a complement to A1C, and for TIR data to be incorporated into the product prescribing information to support clinicians' treatment decisions. TIRC applauds[14] FDA's indication in its May 2023 draft guidance[15] of its willingness to include CGM metrics in Section 14 of the drug label. We ask for your assistance in securing prompt issuance of final guidance and support and clarity on generating additional evidence on the value of TIR for improving health outcomes.

2) Empowering Healthy Food Choices Through Technology: The Administration's goal to encourage the consumption of healthy, whole foods is well-aligned with what we know supports the prevention and treatment of diabetes. As you noted in your confirmation hearing, CGMs are an effective tool to help people understand how food choices influence their glucose levels, leading to more sustainable behavior changes.[16,17] In fact, CGM feedback has been shown to enhance individualized nutrition therapy, leading to significantly better TIR among those at risk of type 2 diabetes, even before pharmacological intervention.[18]

3) Bolstering FDA's Leadership Role in Accelerating Breakthroughs: Early and often engagement between FDA experts and sponsors with clear and consistent regulatory guidance is essential for accelerating access to innovative therapies and technologies. Efforts to transform the diabetes treatment landscape for patients will succeed only if individuals at the cutting-edge of science are recruited and retained at the Agency. We were pleased to hear your commitment to ensuring FDA is resourced to do the job the American people need and expect of it. We look forward to working with you to ensure FDA does not cede its place as first in the world in bringing new drugs and devices to patients.[19–22]

4) Ensuring Accessibility and Affordability: For medical advances to be effective in improving health, they must be accessible and affordable. Yet, the high cost of treatment and technology remains a critical barrier. Fundamentally, we know that adequate insurance coverage is inextricably linked to improving access and that better access expands uptake and improves health outcomes.[23] There is a significant body of evidence illustrating that even a small amount of cost-sharing or out-of-pocket costs can thwart patient access to medically necessary care, services, and devices.[24] As you focus on reducing the burden of chronic disease, we urge you to work closely with the Centers for Medicare and Medicaid Services (CMS) to ensure that FDA-approved treatments and technologies are accessible and affordable for all. Additionally, we recommend that FDA, CMS, and other relevant agencies within the Department of Health and Human Services (HHS) create a working group to ensure that policies across HHS facilitate timely access to innovative therapies and health technologies and integration into electronic health records. Without such a department-wide effort, the work of FDA to approve treatments and devices will not result in the intended outcome of improving health and well-being for individuals, community, and the nation.

We look forward to partnering with you to ensure that the best possible science and common-sense approaches are brought to bear on efforts to improve the lives of people with diabetes. Thank you for your willingness to serve and we look forward to an opportunity in the near future to discuss our public health objectives and explore opportunities to work with you throughout your tenure.

Respectfully,

Jim Carroll
CEO, The diaTribe Foundation

Julie K. Heverly
Vice President, Time in Range Coalition

cc: Jacquelyn Corrigan-Curay, M.D., J.D. – Acting Director, Center for Drug Evaluation and Research (CDER)
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References

1. Yapanis M, James S, Craig ME, O'Neal D, Ekinci EI. Complications of Diabetes and Metrics of Glycemic Management Derived From Continuous Glucose Monitoring. J Clin Endocrinol Metab. 2022;107(6):e2221-e2236. doi:10.1210/clinem/dgac034

2. Beck RW, Bergenstal RM, Riddlesworth TD, et al. Validation of Time in Range as an Outcome Measure for Diabetes Clinical Trials. Diabetes Care. 2019;42(3):400-405. doi:10.2337/dc18-1444

3. De Meulemeester J, Charleer S, Visser MM, De Block C, Mathieu C, Gillard P. The association of chronic complications with time in tight range and time in range in people with type 1 diabetes: a retrospective cross-sectional real-world study. Diabetologia. Published online May 24, 2024. doi:10.1007/s00125-024-06171-y

4. Shah VN, Kanapka LG, Akturk HK, et al. Time in Range Is Associated with Incident Diabetic Retinopathy in Adults with Type 1 Diabetes: A Longitudinal Study. Diabetes Technol Ther. 2024;26(4):246-251. doi:10.1089/dia.2023.0486

5. Kovatchev BP, Lobo B, Fabris C, et al. The Virtual DCCT: Adding Continuous Glucose Monitoring to a Landmark Clinical Trial for Prediction of Microvascular Complications. Diabetes Technol Ther. 2025;27(3):209-216. doi:10.1089/dia.2024.0404

6. IQVIA Institute for Human Data Science. Advancing Glycemic Management in People with Diabetes.; 201AD. Accessed March 20, 2025. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/advancing-glycemic-management-in-people-with-diabetes

7. Feig DS, Donovan LE, Corcoy R, et al. Continuous glucose monitoring in pregnant women with type 1 diabetes (CONCEPTT): a multicentre international randomised controlled trial. Lancet Lond Engl. 2017;390(10110):2347-2359. doi:10.1016/S0140-6736(17)32400-5

8. Rizos EC, Markozannes G, Charitakis N, et al. Continuous Glucose Monitoring in Type 1 Diabetes, Type 2 Diabetes, and Diabetes During Pregnancy: A Systematic Review with Meta-Analysis of Randomized Controlled Trials. Diabetes Technol Ther. Published online March 6, 2025. doi:10.1089/dia.2024.0599

9. Sanusi AA, Xue Y, McIlwraith C, et al. Association of Continuous Glucose Monitoring Metrics With Pregnancy Outcomes in Patients With Preexisting Diabetes. Diabetes Care. Published online October 2, 2023:dc230636. doi:10.2337/dc23-0636

10. Munshi MN, Slyne C, Adam A, et al. Continuous Glucose Monitoring With Geriatric Principles in Older Adults With Type 1 Diabetes and Hypoglycemia: A Randomized ControlledTrial. Diabetes Care. Published online September 26, 2024:dc241069. doi:10.2337/dc24-1069

11. Miller KM, Kanapka LG, Rickels MR, et al. Benefit of Continuous Glucose Monitoring in Reducing Hypoglycemia Is Sustained Through 12 Months of Use Among Older Adults with Type 1 Diabetes. Diabetes Technol Ther. 2022;24(6):424-434. doi:10.1089/dia.2021.0503

12. American Diabetes Association Professional Practice Committee. 7. Diabetes Technology: Standards of Care in Diabetes—2025. Diabetes Care. 2024;48(Supplement_1):S146-S166. doi:10.2337/dc25-S007

13. De Block C, Cheng AYY, Christensen TB, Patted URH, Ginovker A. Healthcare Professionals' Knowledge of and Attitudes Towards the Use of Time in Range in Diabetes Management: Online Survey Across Seven Countries. Diabetes Ther. 2023;14(8):1399-1413. doi:10.1007/s13300-023-01429-x

14. Time in Range Coalition. Time in Range Coalition Comments to Docket No. FDA-2023-D-0625. Published online August 24, 2023. Accessed May 13, 2024. https://www.regulations.gov/comment/FDA-2023-D-0625-0019

15. Center for Drug Evaluation and Research. Diabetes Mellitus: Efficacy Endpoints for Clinical Trials Investigating Antidiabetic Drugs and Biological Products. Published online May 2023. Accessed May 13, 2024. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/diabetes-mellitus-efficacy-endpoints-clinical-trials-investigating-antidiabetic-drugs-and-biological

16. Kröger J, Siegmund T, Schubert-Olesen O, et al. AGP and Nutrition - Analysing postprandial glucose courses with CGM. Diabetes Res Clin Pract. 2021;174:108738. doi:10.1016/j.diabres.2021.108738

17. Willis HJ, Henderson MSG, Zibley LJ, JaKa MM. "Now I can see it works!" Perspectives on Using a Nutrition-Focused Approach When Initiating Continuous Glucose Monitoring in People with Type 2 Diabetes: Qualitative Interview Study. JMIR Diabetes. 2025;10(1):e67636. doi:10.2196/67636

18. Basiri R, Cheskin LJ. Enhancing the Impact of Individualized Nutrition Therapy with Real-Time Continuous Glucose Monitoring Feedback in Overweight and Obese Individuals with Prediabetes. Nutrients. 2024;16(23):4005. doi:10.3390/nu16234005

19. Galloway F. Data-Driven Insights | 20 Years of FDA Leadership in Novel Cancer Drug Approvals. Friends of Cancer Research. February 6, 2025. Accessed March 13, 2025. https://friendsofcancerresearch.org/blog/20-years-of-fda-leadership-in-novel-cancer-drug-approvals/

20. Downing NS, Aminawung JA, Shah ND, Braunstein JB, Krumholz HM, Ross JS. Regulatory Review of Novel Therapeutics — Comparison of Three Regulatory Agencies. N Engl J Med. 2012;366(24):2284-2293. doi:10.1056/NEJMsa1200223

21. Van Norman GA. Drugs and Devices: Comparison of European and U.S. Approval Processes. JACC Basic Transl Sci. 2016;1(5):399-412. doi:10.1016/j.jacbts.2016.06.003

22. Joppi R, Bertele V, Vannini T, Garattini S, Banzi R. Food and Drug Administration vs European Medicines Agency: Review times and clinical evidence on novel drugs at the time of approval. Br J Clin Pharmacol. 2020;86(1):170-174. doi:10.1111/bcp.14130

23. Ni K, Tampe CA, Sol K, Richardson DB, Pereira RI. Effect of CGM Access Expansion on Uptake Among Patients on Medicaid With Diabetes. Diabetes Care. 2023;46(2):391-398. doi:10.2337/dc22-1287

24. Fusco N, Sils B, Graff JS, Kistler K, Ruiz K. Cost-sharing and adherence, clinical outcomes, health care utilization, and costs: A systematic literature review. J Manag Care Spec Pharm. 2023;29(1):4-16. doi:10.18553/jmcp.2022.21270