

October 4, 2024

Dockets Management Staff (HFA-305)  
U.S. Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Re: The diaTribe Foundation Comments to “Discussion Paper: Health Equity For Medical Devices,” Docket No. FDA-2024-N-3616**

To Whom it May Concern:

On behalf of The diaTribe Foundation, thank you for the opportunity to provide input on the Discussion Paper: Health Equity for Medical Devices (Discussion Paper). The diaTribe Foundation applauds the commitment of the Food and Drug Administration’s (FDA) Center for Devices and Radiological Health (CDRH), as outlined in the Discussion Paper to:

- Facilitate availability of and access to medical technologies for all populations;
- Empower people to make informed decisions regarding their healthcare;
- Support innovation of novel and existing technologies that address health inequities; and
- Reduce barriers to increase participation by diverse populations in evidence generation.

Moreover, we appreciate CDRH’s efforts to develop a framework for evaluation of medical devices that incorporates key health equity considerations, with the ultimate goal of eliminating health disparities and improving health outcomes for all Americans.

**About The diaTribe Foundation**

The mission of The diaTribe Foundation 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 national conversation regarding 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 TIR 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*.

### **Health Equity Concerns in Diabetes**

Diabetes has a disproportionate impact on low-income, rural, and racially minoritized communities in America. Among adults, prevalence of diabetes is highest among American Indians and Alaska Natives (13.6%), followed by non-Hispanic Black adults (12.1%), those of Hispanic origin (11.7%), and non-Hispanic Asian individuals (9.1%), with lowest prevalence among non-Hispanic white adults (6.9%).<sup>1</sup> Differences are also observed by education level, an indicator of socioeconomic status: 13.1% of adults with less than a high school education have diagnosed diabetes compared to 9.1% of those with a high school education, and 6.9% of individuals with more than a high school education.<sup>1</sup> Finally, diabetes is more prevalent in rural areas.<sup>1</sup>

The disproportionate impact of diabetes extends to diabetes-related health complications, as well. Black and Hispanic adults with diabetes disproportionately experience microvascular complications compared to white adults and Black and Mexican Americans are less likely to meet targets for cardiovascular risk reduction.<sup>2</sup> Compared with residents of cities, Americans living in small towns have greater risk of hyperglycemia, end-stage kidney disease, myocardial infarction, heart failure, amputation, and other lower-extremity complications.<sup>3</sup> Additionally, rural counties experience persistently higher overall diabetes mortality rates than more urban areas.<sup>4</sup>

### **The Potential for Technology to Mitigate or Exacerbate Health Disparities**

The Discussion Draft raises as a potential consideration in designing studies of medical devices the question of “how might the device technology introduce, exacerbate, or mitigate the potential for different outcomes across the study population?” Given the disproportionate burden of diabetes among minoritized communities, The diaTribe Foundation believes it is critical to understand if data generated by devices intended for disease management by individuals living with diabetes are reliable and comparable across demographic groups. For example, continuous glucose monitoring metrics such as TIR are unbiased data, while a growing body of evidence demonstrates that Hemoglobin A1C (A1C) does not reflect the same average glucose in all individuals, as red blood cell glycation rates vary greatly across individuals.<sup>5-13</sup> Importantly, A1C has been shown to consistently overestimate glycemia in Black people with diabetes,<sup>14-18</sup> with studies also demonstrating A1C inconsistencies in association with commonly co-occurring conditions,<sup>19-24</sup> medication use,<sup>25,26</sup> age,<sup>27</sup> and other factors. Using a device that produces metrics without these discrepancies is essential to avoiding premature or late diagnoses and harmful under- or overtreatment that may exacerbate health disparities and inequities. Thus, in both sponsors’ study designs and CDRH’s evaluation of device safety and effectiveness, The diaTribe Foundation urges that the Agency factor in the potential of the technology to exacerbate—or mitigate—disparities and that any such impacts be transparent for patients and providers.

### **Using Technology to Reduce Barriers to Participation in Evidence Generation**

We value that the Discussion Draft acknowledges the role technologies may play in facilitating more inclusive and representative research, as there are well-established benefits and protocols for the use of tools such as CGMs in generating clinical evidence.<sup>28</sup> As noted above, the commonly-used metric, A1C, is known to be falsely elevated in some sub-groups while CGM data has no known differences in accuracy across sociodemographic groups. Using data without these known biases is

important to avoid misleading conclusions about disease etiology and epidemiology. CGMs can additionally support representative research by reducing the frequency of in-person appointments necessary for data collection, making study participation far more accessible. FDA has acknowledged some of these benefits, noting CGMs provide a more comprehensive assessment of hypoglycemia than self-monitoring of blood glucose (SMBG) by limiting bias, as the devices do not rely on participant effort to measure glucose but rather record all hypoglycemic events—even those that occur while patients are sleeping or in patients with hypoglycemia unawareness.<sup>29</sup> Further, CGM data can provide researchers with rich data on duration of hypo- and hyperglycemic events, glycemic variability, and correlations to exercise and other data in a way not possible with SMBG or A1C-based glycemic monitoring.

### **Ensuring Access to Diabetes Health Technologies**

We also appreciate CDRH’s willingness to accept input on health equity considerations other than those specifically proposed in the Discussion Paper. As noted above, we share CDRH’s priority to facilitate equitable availability of—and access to—medical technologies for all populations. Fundamentally, we know that adequate insurance coverage and payment are inextricably linked to improving access and that better access expands uptake, improves health outcomes, reduces disparities, and advances equity.<sup>30</sup> The benefit of coverage expansions—and sufficient reimbursement rates—are clear: when a regional Medicaid program fully covered CGMs, device uptake increased and glycemic control improved among individuals with both type 1 and type 2 diabetes, with similar levels of improvement amongst all populations.<sup>31</sup> The 2023 coverage expansion of CGMs by Medicare Administrative Contractors provided an estimated additional 1.5 million beneficiaries access to CGMs; a coverage change we advocated and applauded due to its direct impact on improved access and outcomes.<sup>32</sup> Conversely, 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.<sup>33–35</sup>

As the 2024 American Diabetes Association’s Standards of Care recommends that diabetes technologies should be offered to all people with diabetes.<sup>36</sup> The diaTribe Foundation will continue to advocate for expanded public payor and commercial insurance coverage to help ensure access to all FDA-approved medical devices that help individuals manage their disease and improve their health and well-being.

As you continue your focus on advancing health equity, we urge CDRH and the other Centers and Offices within the FDA to work closely with the Centers for Medicare and Medicaid Services (CMS) to ensure that FDA-approved technologies are accessible and affordable for all individuals, particularly those from low-income, minoritized, and rural communities. 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 health technologies and help ensure integration into electronic health records. Without such a department-wide effort, the work of FDA to promote health equity will not result in the intended outcome, which is improving health and well-being for all individuals and communities.

**The diaTribe Foundation Comments**  
**Docket No. FDA-2024-N-3616**

Thank you for the opportunity to comment on the Discussion Draft. We look forward to continued engagement as the CDRH works to integrate health equity considerations into medical device development and review.

Sincerely,



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Chief Executive Officer  
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