Scott Gottlieb, MD
Commissioner, Food and Drug Administration
Janet Woodcock, MD
Director, Center for Drug Evaluation and Research
Lisa Yanoff, MD
Director, Division of Metabolism and Endocrinology Products
William Chong, MD
Deputy Director, Division of Metabolism and Endocrinology Products
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

February 15, 2019

Dear Dr. Gottlieb, Dr. Woodcock, Dr. Yanoff, and Dr. Chong:

The members of the diabetes and cardiovascular community signed below would like to thank the FDA for revisiting the 2008 Guidance for Industry on evaluating cardiovascular risk in new therapies for type 2 diabetes. This guidance has yielded critical insights into and improvements to diabetes care over the past decade and has ensured the safety of diabetes treatments regarding cardiovascular risk. As advocates for people with diabetes, we applaud the FDA's ongoing commitment to making patient outcomes and safety its chief priorities.

This letter's primary purpose is to emphasize that revising the guidance in a thoughtful way must be a priority. Since the 2008 Guidance was released, there have been significant advancements in diabetes care. Given the evolution of diabetes care since 2008, these guidelines are not efficient for bringing safe, effective diabetes therapies to market. We urge the FDA to carefully consider the implications of revising this process so that bringing compounds to market does not become overly burdensome, particularly given the pattern of manufacturers leaving the diabetes field (Amgen, BMS, Gilead, GSK, and Takeda) or reducing investment in diabetes substantially (J&J, Novartis, and multiple others).

With a revised guidance, the FDA and broader community can together continue to improve the lives of people with diabetes, which includes combatting their increased risk of cardiovascular disease – as people with diabetes are four times more likely to die of cardiovascular disease than people without diabetes.

The FDA's revision of the 2008 guidance strongly fits with its existing priorities, including:

- Innovation in chronic disease.
- Exploring real-world evidence while maintaining the highest standards of rigor and methodology.
- Streamlining processes without sacrificing safety or efficacy.

- Collaborating with other stakeholders to increase access to, and affordability of, life-saving therapies.

As the FDA's 2018 Strategic Policy Roadmap so aptly asserts: "A missed chance to promote public health through new innovation can hurt patients and increase overall health care costs. For these reasons, we should seek a predictable and efficient development process for innovative products while also taking new steps to strengthen FDA's gold standard for product review."

A thoughtful update to the guidance would allow the priorities of the FDA and CDER to be realized in a patient population that reaches 30 million nationally and is growing. As the diabetes community has discussed in depth recently, there are outcomes in addition to A1C (which remains a very important measure) that are significant for the daily experience of living with diabetes. As a very important example, we applaud the FDA for recognizing the importance of cardiovascular outcomes for people with diabetes and for prioritizing these considerations in the guidance revision process. We recommend FDA consider ways to incorporate additional outcomes into the type 2 diabetes medication development and approval process. We also strongly encourage FDA to continue its commitment, in particular, to monitor these novel therapies in minority communities that are disproportionately affected by diabetes and underrepresented in clinical trials.

Finally, we urge you to provide ample opportunity for the diabetes and cardiovascular community to comment on the revised guidance as it emerges. The revision of this guidance will directly impact the diabetes community, which is poised to provide valuable insight and feedback. We are grateful for the opportunity to participate in this process and look forward to collaborating in any way possible. With additional notice, an even greater number of organizations and individuals will be able to participate in and collaborate further with the FDA – given our very heterogeneous population, this is increasingly important.

We thank the FDA for its commitment to patient outcomes, as well as to access and innovation. As organizations that represent millions of people with diabetes as well as their family members, loved ones, and health care professionals, we are eager to work together on this most important issue. Please let us know how we can bring you insights from stakeholders less frequently heard from, particularly patients and healthcare professionals.

Sincerely,

Alliance for Aging Research
American Association of Clinical Endocrinologists
American Association of Diabetes Educators
American Diabetes Association

American Pediatric Medical Association, Inc.
Association of Black Cardiologists, Inc.
Diabetes Patient Advocacy Coalition
Healthcare Leadership Council
JDRF
National Hispanic Medical Association
The diaTribe Foundation

For follow-up, please contact:
Kelly Close
Founder, The diaTribe Foundation
kclose@diatribe.org
(415) 518-5336