



October 23, 2018

The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Ave, SW
Washington, DC 20301

The Honorable Scott Gottlieb
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Secretary Azar and Dr. Gottlieb:

The Diabetes Advocacy Alliance (DAA) is writing to echo concerns raised in a recent study highlighting accuracy issues with certain blood glucose testing systems furnished to people with diabetes. We urge you to take necessary steps to ensure all people with diabetes have access to safe and accurate blood glucose testing systems.

The DAA is a coalition of 24 diverse member organizations, representing patient, professional and trade associations, other non-profit organizations, and corporations, all united in the desire to change the way diabetes is viewed and treated in America. Since 2010, the DAA has worked to increase awareness of, and action on, the diabetes epidemic among legislators and policymakers. The organizations that comprise the DAA share a common goal of elevating diabetes on the national agenda so we may ultimately defeat diabetes.

A study¹, published in *Diabetes Care* in May 2018, assessed the accuracy of 18 blood glucose testing systems cleared by the U.S. Food and Drug Administration (FDA) which represented 90% of commercially available systems used from 2013-2015. The study found only six of the 18 systems met the accuracy standards in all three of the separate accuracy tests conducted; four systems did not meet the accuracy standards in any of the three studies conducted. It is alarming that so few systems met the accuracy standards in all three tests and that four did not meet the accuracy standards in any of the tests.

As you know, more than 30 million Americans have diabetes including approximately 12 million Medicare beneficiaries (nearly 30 percent). People with diabetes use and rely on blood glucose testing systems to manage their chronic disease to avoid the costly complications of diabetes with the expectation that they are accurate. HHS, and relevant agencies like the FDA and CMS, should strive to ensure that blood glucose testing systems, especially those covered by federal programs like Medicare and Medicaid, consistently meet accuracy and safety standards.

The undersigned organizations strongly urge you to acknowledge the issue of blood glucose testing system accuracy and its potential implications for people with diabetes including seniors with diabetes and take the necessary steps to ensure people with diabetes have access to safe and accurate testing systems. We look forward to continuing to engage with HHS and FDA on this issue. If you have any questions or need additional

¹ Klonoff DC, Parkes JL, Kovatchev BP, Kerr D, et al. Investigation of the accuracy of 18 marked blood glucose monitors. *Diabetes Care* May 2018, dc171960; DOI: 10.2337/dc17-1960.

information, please free to contact one of the DAA's co-chairs: Meghan Riley at mriley@diabetes.org, Meredith Dyer at mdyer@endocrine.org, or Karin Gillespie at kgil@novonordisk.com.

Sincerely,

Academy of Nutrition and Dietetics
American Association of Clinical Endocrinologists
American Association of Diabetes Educators
American Diabetes Association
American Optometric Association
Diabetes Patient Advocacy Coalition
Endocrine Society
Novo Nordisk Inc.