WE ARE DPAC
DIABETES PATIENT ADVOCACY COALITION
SAFETY QUALITY ACCESS

Lack of FDA Post-Marketing Oversight on Meter Accuracy Puts Diabetes Patients' Lives at Risk

DPAC's Statement

The Diabetes Patient Advocacy Coalition (DPAC) is an alliance of people with diabetes, caregivers, patient advocates, health professionals, disease organizations and companies working collaboratively to promote and support public policy initiatives to improve the health of people with diabetes. DPAC's guiding principles focus on 3 key areas:

- *Safety (enforce established safety standards on devices, medications and practices for diabetes care)*
- *Quality (advance the standards of care for diabetes management)*
- *Access (access to health care and quality diabetes products for all 29MM Americans with diabetes)*

Given the rising costs of diabetes in America, it is critical that Americans have access to **ALL** components of diabetes training and treatment programs to prevent costly hospitalizations and complications. Yet many patients are facing increasing cost burdens for their diabetes treatment regimens and are choosing to use lower cost self-monitoring blood glucose testing systems (SMBG). Medicare has implemented the competitive bidding program that severely limits patient choice and access for SMBG and has led to a plethora of low-cost blood glucose systems that Medicare patients are forced to use.

Various studies have shown the importance of SMBG in a patient's diabetes disease management program[1][2][3][4][5] and is even more critical for those patients that use insulin, as it is used for dosage calculation and prevention/detection of hypoglycemia and hyperglycemia[6]. Inaccurate glucose

[1] Diabetes Control and Complications Trial Study Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. N Eng J Med 1993;329:977-986.
[2] Polonsky WH et al. Structured self-monitoring of blood glucose significantly reduces A1C levels in poorly controlled, noninsulin-treated type 2 diabetes: results from the Structured Testing Program study, Diabetes Care 2011;34;262-267.
[3] Franciosi M et al. ROSES: role of self-monitoring of blood glucose and intensive education in patients with Type 2 diabetes not receiving insulin. A pilot randomized clinical trial. Diabet Med 2011;28:789-796.
[4] KempfK et al. ROSSO-in-praxi: a self-monitoring of blood glucose-structured 12-week lifestyle intervention significantly improves glucometabolic control of patients with type 2 diabetes mellitus. Diabetes TechnolTher 2010;12:547-553.
[5] Bailey TS, Grunberger G, Bode BW, et al. American Association of Clinical Endocrinologists and American College of Endocrinology 2016 Outpatient Glucose Monitoring Consensus Statement. EndocrPract 2016;22:231-61.
[6] Breton MD, Kovatchev BP. Impact of blood glucose self-monitoring errors on glucose variability, risk for hypoglycemia, and average glucose control in type 1 diabetes: an in silico study, *J Diabetes SciTechnol*. 2010;4(3):562-570.

information can lead to severe consequences. Patients who use continuous glucose monitoring (CGM) also are impacted by inaccurate blood glucose monitoring systems as they are required to calibrate CGM devices through SMBG systems and dose insulin based on their CGM readings.

After a self-monitoring blood glucose system is approved for use by the FDA, there is currently no systematic follow-up process that monitors for ongoing product quality and compliance with international accuracy standards. The Diabetes Technology Society established a surveillance program for self-monitoring blood glucose systems in May 2014[7]. This surveillance program assessed the accuracy of 18 self-monitoring blood glucose systems (SMBG) marketed in the USA and representing approximately 90% of the commercially available systems[7]. Twelve systems failed to meet the accuracy standards, yet these products are still on the market[7] and 2 of them (Prodigy, Embrace) account for over 40% of the Medicare market[8].

Even though the FDA was engaged in the development of the protocol for the SMBG surveillance program and was listed as co-authors of the summary paper[7], it is not clear why the FDA has not more aggressively regulated the market for SMBG systems. For 510k approval, the FDA relies on data generated and submitted by the manufacturer and does not independently evaluate the device[9]. Once the product is approved and in the market, the FDA has limited resources to conduct manufacturing inspections, especially overseas. Many of the manufacturers of the low-cost brands also do not provide medical device reports (MDRs), which makes it difficult for the FDA to track post-market performance.

While DPAC applauds cost-containment efforts for patients, we do not advocate such measures at the expense of patient safety and poor patient outcomes. We support efforts that require the FDA to more rigorously monitor the post-market performance of self-monitoring blood glucose systems and provide black-box warning labels for those systems that do not meet international accuracy standards.

[7] Klonoff D et al. Diabetes Technology Society. Blood Glucose Monitoring System Surveillance Program. Accessed September 18, 2017, from https://www.diabetestechnology.org/surveillance.shtml.
[8] Office of the Inspector General. Medicare Market Shares of Mail-Order Diabetes Test Strips From October Through December 2016. Accessed August 20, 2017 from https://oig.hhs.gov/oei/reports/oei-04-16-00473.pdf.
[9] Klonoff DC, Reyes JS. Do currently available blood glucose monitors meet regulatory standards? 1-day public meeting in Arlington, Virginia. J Diabetes Sci Technol.2013;7(4):1071-1083.