

Mr. Patricio Garcia
Center for Devices and Radiological Health
Food and Drug Administration
Bldg. 66, Rm. 1116
10903 New Hampshire Ave., Silver Spring, MD 20993

July 2016

Subject: Docket No. FDA-2016-N-0001
Intended use of Dexcom G5® Mobile Continuous Glucose Monitoring System (CGM)

Dear Mr. Garcia,

Thanks to FDA for considering the views of people whose lives are impacted by diabetes as part of your consideration of the Dexcom G5® labeling application. We were inspired to send this letter by FDA's June 2 webinar on artificial pancreas in which Dr. Courtney Lias encouraged patients sharing views in a mutual communication. FDA's openness in that webinar and this process is greatly appreciated.

We enthusiastically support the application to advance the label for accurate continuous glucose monitoring systems to include therapy adjustments.

As people living with diabetes, we have a unique perspective of risk. Insulin is a very dangerous drug; too much or too little have both immediate and long-term complications. Those who use insulin daily manage dosages to mitigate these risks. We rely on a complex combination of treatment protocols created in collaboration with our healthcare professionals to make rapid self-management steps throughout the day.

We intimately understand there is no perfect diabetes path.

The American Diabetes Association Standards of Care recognize that "one size does not fit all." They go on to emphasize that "for optimal outcomes, diabetes care must be individualized for each patient." We believe that a critical part of optimization is healthcare professionals putting the appropriate tools, with the empowering labels, in the hands of the patient. This proposal expands the tools individuals with their health teams can consider.

All devices, medications and management plans have risks. We accept these tradeoffs as part of the balance of daily life. We seek out high-quality tools to help successfully take careful steps that strike a balance between the possibility of an immediate health emergency from too much insulin and the likelihood of long-term health complications from not enough.

Continuous glucose monitoring (CGM) helps mitigate risk in a way no other device can.

The term used in this application is "replacement for their blood glucose meters and make treatment decisions based on the interstitial fluid glucose concentration reported by the CGM." However bringing CGM and meters "to parity" is perhaps more accurate. Equal footing is essential in making treatment decisions. CGM give us the ability to proactively address some risks of using insulin. You will seek to assess risk by considering a vast array of facts and figures leading to the July 21 hearing.

Facts and figures are important but just as important are the faces of those who live with this risk.

We live the risk of insulin; we know CGM is lifesaving.

Many of us have learned that CGM is as, or more critical, to risk mitigation as any tool available to us. We also know that access to CGM hinges on it coverage providers seeing it as a primary, necessary tool in diabetes care, not adjunctive. Therefore, replacement labeling is critical. CGM is an increasingly valuable tool to mitigate risk for older Americans. And they are at risk. A recent JAMA article estimates that insulin puts ninety-seven thousand Americans in the emergency room each year. That is more ER visits than the government estimates are caused by stimulants, including methamphetamine. That insulin beats "Breaking Bad" is shocking. More shocking is that the vast majority of those ER visits are our Seniors, members of our Greatest Generation.

The benefits of CGM reach across all age ranges. Modern CGM systems facilitate the sharing of glucose data to third parties. In doing so, these tools create the opportunity for an extra layer of safety and protection: a view of our diabetes instrument panel.

Parents can remotely see the glucose of a sleeping child, enhancing safety. Sharing allows any person with diabetes to have the safety of support, at school, at work, and those adults, especially seniors, living alone.

- CGM provides critical insight into both directions and rate of change of sugar values. That helps us be proactive and prevent lows and highs.
- We can set alarms that allow our focus to be on productivity as students, working professionals and in our personal lives.
- CGM automates data collection. That in turn facilitating fine tuning of care plans.

On July 21, we trust that the expert evidence will help you see what we, the people for whom you are attempting to balance risk, already know. CGM is a critical tool, primary in many successful lives with diabetes.

Respectfully,