

# Congress of the United States

Washington, DC 20515

April 15, 2011

The Honorable Margaret A. Hamburg, M.D.  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Dr. Hamburg:

We are writing to express our strong interest in the development of the artificial pancreas, which is at a critical point in the regulatory process at your agency. Your continued leadership is essential. This technological development has the potential to dramatically improve the health and quality of life for those who have diabetes. Building on that leadership and recognition of the potential innovation, we encourage your agency to quickly take into account guidance put forth by leading experts in the field regarding the artificial pancreas so that this promising technology may be made available to those with type 1 diabetes in the near future.

As you are well aware, diabetes is a burdensome, dangerous, and debilitating disease. Nearly 26 million Americans have diabetes, and one in three American children born today will develop the disease. Diabetes is the leading cause of kidney failure and adult-onset blindness. Moreover, diabetes increases the risk of heart attack deaths by two to four times, and causes more than 80,000 amputations each year. People with diabetes are also at risk for seizures, comas, and sudden death. One third of every Medicare dollar is spent on people with diabetes and estimates show that diabetes costs the U.S. economy \$174 billion annually. Simply put, people with diabetes desperately need better tools to manage their disease and prevent its life-threatening and costly complications.

The timely approval of an artificial pancreas could help improve health outcomes for those with type 1 diabetes. As shown in a landmark study in February 2010, a first generation artificial pancreas system can improve diabetes control and even lower the risk of blood glucose emergencies. Specifically, it will be a combination of two external devices: an insulin pump and a continuous glucose monitor (CGM) to enable a person with diabetes to maintain normal glucose levels by automatically providing the correct amount of insulin at the appropriate time.

We appreciate that the Food and Drug Administration has played a pivotal role in moving the research of the artificial pancreas forward by approving clinical trials in hospital settings and making the artificial pancreas one of its Critical Path initiatives. We encourage your agency to move forward in the development of this transformational technology by quickly providing clear and reasonable guidance so that outpatient artificial pancreas studies can proceed as soon as

possible. We look forward to working with you and your agency as the regulatory process advances.

Sincerely,

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Ed Whitfield  
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