

May 5, 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 as clinicians and researchers from across the nation, who work with patients with type 1 diabetes to urge the Food and Drug Administration (FDA) to quickly move forward and accept the draft clinical guidance document proposed by the Juvenile Diabetes Research Foundation (JDRF) for artificial pancreas systems.

As experts in the treatment of people with type 1 diabetes and artificial pancreas technologies, we believe the proposed guidance provides a reasonable, safe and scientifically-sound pathway to enable artificial pancreas studies to move to the outpatient settings, the critical next step in delivering this technology to patients. The proposed guidance, based on clinical recommendations from an independent expert panel, serves as a roadmap for not only research but also the industry to develop safe and effective artificial pancreas devices.

Type 1 diabetes is an inherently dangerous disease and despite many advances in technology, patients are still in desperate need of better tools to help in the daily management of the disease and prevent its life-threatening and costly complications. The research completed to date in the clinic has found multiple versions of artificial pancreas systems can improve glucose control. It is now time to test these artificial pancreas devices in more “real world” conditions in order to ensure that the goal is met for patients to maintain proper control of blood glucose levels.

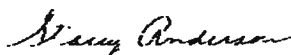
We ask the FDA to recognize the importance of this next step of the ultimate goal in delivering the artificial pancreas to the patients that so desperately need it and to accept the proposed guidance as soon as possible.

We thank you for your consideration and for the FDA's leadership and support of the artificial pancreas.

Sincerely,



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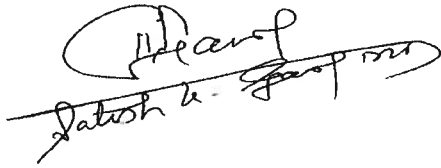


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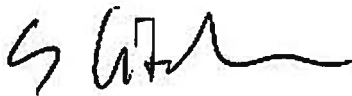
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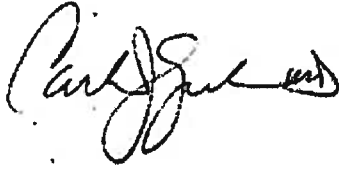
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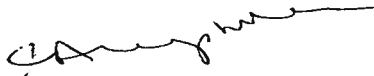
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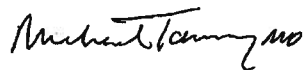
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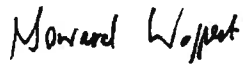
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