

# Yale SCHOOL OF MEDICINE

## *Department of Internal Medicine*

March 25, 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:

### Section of Endocrinology

ROBERT S. SHERWIN, MD

*C.N.H. Long Professor of Medicine*

*Chief, Section of Endocrinology*

*Director, Yale Center for*

*Clinical Investigation (YCCI)*

*Director*

*Diabetes Endocrinology Research Center*

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*courier*

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We are writing as members of a clinical recommendations panel to ask the Food and Drug Administration (FDA) to expeditiously consider and adopt the enclosed draft guidance on artificial pancreas systems, which is based on recommendations we developed over several months last fall. This document was created by a broad spectrum of leading experts in the field of diabetes research and clinical care and we believe its recommendations, if adopted, will enable testing of artificial pancreas systems to proceed safely and without delay. It is essential that we move forward the development of safe and effective systems that provide critically needed improvements in the treatment of patients with type 1 diabetes.

The Clinical Recommendations Panel on Closed Loop Systems, chaired by Robert Sherwin, MD, was convened at the request of the Juvenile Diabetes Research Foundation (JDRF) to address key questions developed by JDRF, FDA, the National Institutes of Health, and private industry that would help shape the design of further studies and make recommendations on key design elements for future home use studies for the artificial pancreas. The panel held a series of in depth meetings, beginning on August 24, 2010 in Washington, DC and proceeding into the fall, to consider and make recommendations for each key question related to artificial pancreas development. Panel representatives presented at a November 10<sup>th</sup> public workshop sponsored by FDA and NIH and provided a detailed briefing to FDA staff in January.

Now we believe it is time for FDA to act quickly to adopt these recommendations in the form of a guidance document. Researchers need detailed information from FDA about the expectations for the artificial pancreas studies and the ultimate products, which would enable studies deemed safe to go forward without delay. For instance, it is necessary for researchers to have guidance now in order to move safely from inpatient to outpatient settings and choose which patients should be included in these studies.

Diabetes has now reached epidemic proportions in this country. For patients with type 1 diabetes, maintaining control of blood glucose levels is extremely difficult with today's tools, resulting in both acute medical emergencies and the development of life threatening complications. Artificial pancreas systems have the potential to greatly



improve the care of type 1 diabetes, enabling patients to live longer and healthier lives. For all these reasons, we urge you to make adoption of artificial pancreas guidance a top priority.

Thank you for your consideration.

Sincerely,



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Professor of Endocrinology, Yale University School of Medicine  
Director, Yale Center for Clinical Investigation and Diabetes Endocrinology Research Center, Yale University School of Medicine



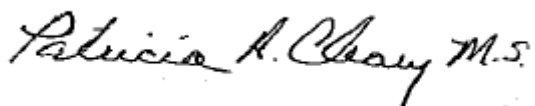
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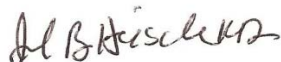
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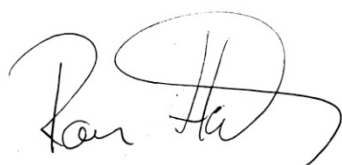
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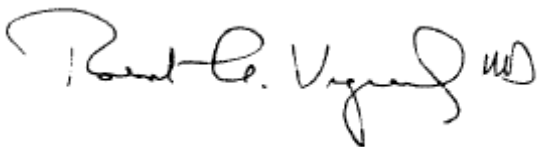
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cc: John M. Taylor III, J.D., Acting Principal Deputy Commissioner, FDA

Jeffrey E. Shuren, M.D., J.D., Director, Center for Devices and Radiological Health, FDA