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April 10, 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:

The American Association of Diabetes Educators (AADE) wishes to voice its support for the draft guidance document proposed by the Juvenile Diabetes Research Foundation (JDRF) for artificial pancreas systems. We ask the FDA to move expeditiously in accepting the document in order that the much needed outpatient clinical trial studies can move forward quickly. This is an important step in moving us all closer to helping and educating people with type 1 diabetes about how to more effectively control glucose levels with an artificial pancreas.

AADE is a multi-disciplinary professional membership organization dedicated to improving diabetes care through education. With more than 12,000 professional members including physicians, nurses, dietitians, pharmacists, and others, AADE has a vast network of practitioners involved in the daily treatment of diabetes patients.

As educators in the treatment of people with diabetes, we know the role the artificial pancreas system can potentially play as it relates to this terrible and dangerous disease in improving glucose control. Despite many advances in technology, patients across this country are still in desperate need of better tools to help in the daily self-management of the disease and prevent its life-threatening and costly complications, thus reducing the burden on the healthcare system.

We ask the FDA to recognize the importance of this proposed guidance and its role in moving forward to the ultimate goal in delivering the artificial pancreas to people with diabetes. The time to act is now.

Sincerely,

A handwritten signature in black ink that reads "Lana Vukovljak". The signature is written in a cursive style.

Lana Vukovljak
CEO

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