



October 17, 2011

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

Dear Commissioner Hamburg:

Since taking office, you have made advancing regulatory science at FDA a top priority. We are writing today to highlight an opportunity for the agency to adopt recommendations from JDRF and leading clinical experts which would transform the care of people with type 1 diabetes in the United States and provide tangible evidence of your commitment for FDA to innovate and lead the world in bringing the most promising medical treatments to patients. Each of our organizations produces clinical guidelines for diabetes care. Together, we represent tens of thousands of clinicians specializing in diabetes care. We know quite well what a toll type 1 diabetes can take on individuals and their families and how important it is for them to have the tools they need to improve safety and prevent devastating complications.

We are pleased the FDA has committed to release artificial pancreas guidance by December 1st but are writing today to underscore that it is essential that such guidance include recommendations made by the experts on the Clinical Recommendations Panel on Closed Loop Systems to the FDA earlier this year. Many of our organizations are concerned by guidance proposed by the FDA in June for Low Glucose Suspend systems, which created many unnecessary obstacles to the evaluation of those systems. We want to ensure that the artificial pancreas guidance avoids similar shortcomings that would be so detrimental to the well-being of millions of Americans. We urge you to ensure that the final FDA artificial pancreas guidance contains the following key items:

1. A firm commitment to use continuous glucose monitor (CGM) data in evaluation of artificial pancreas systems. The clinical community recognizes that use of CGM data to evaluate the systems is the only practical way to conduct these studies. To suggest anything less than a full commitment to this in the guidance will significantly delay artificial pancreas systems getting to patients.
2. Reasonable study progression. To gain a reasonable assurance of the safety and effectiveness of artificial pancreas systems, a short-term in-hospital study to demonstrate only the robustness and responsiveness of the system will be needed with an outpatient study of no more than three months duration unless study sponsor deems a longer period to be scientifically required.

3. Flexibility with respect to endpoints, patient population, and safety elements.
 - a. Endpoints: The sponsor should have the flexibility to include the primary and secondary endpoints most appropriate for their particular system and study design.
 - b. Patient population: The sponsor should have the flexibility to enroll the intended population in a pivotal study within a broad spectrum of parameters.
 - c. Safety elements: Each study should be designed with the elements that will maximize patient safety for the particular system (e.g., frequency of contact with study subjects and system design features) without jeopardizing quality of life.

4. Policies to encourage system improvements. FDA guidance should encourage expeditious testing of updated components, to encourage advances in patient care.

In our view, without all these provisions, the guidance will be inadequate. The artificial pancreas has the potential to have more impact on diabetes care and patient health than any development since the discovery of insulin. We hope you will give our comments serious consideration.

Thank you.

Sincerely,



Yehuda Handelsman M.D., F.A.C.P., F.A.C.E., F.N.L.A.
President
American Association of Clinical Endocrinologists



Robert R. Henry, M. D.
President, Medicine and Science
American Diabetes Association



Elizabeth Mayer-Davis, MSPH, PhD, RD
President, Health Care and Education
American Diabetes Association



Lana Vukovljak
Chief Executive Officer
American Association of Diabetes Educators



Janet E. Hall, M.D.
President
The Endocrine Society

Cc: Senator Jeanne Shaheen (D-NH), Co-Chair of the Senate Diabetes Caucus
Senator Susan Collins (R-ME), Co-Chair of the Senate Diabetes Caucus
Representative Ed Whitfield (R-KY), Co-Chair of the Congressional Diabetes Caucus
Representative Diana DeGette (D-CO), Co-Chair of the Congressional Diabetes Caucus