



# American Association of Clinical Endocrinologists

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April 4, 2011

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

**Re: Draft Guidance for Industry and FDA Staff on Artificial Pancreas Systems**

Dear Dr. Hamburg:

It gives me pleasure to write to you on behalf of more than 6,000 clinical endocrinologists, members of the American Association of Clinical Endocrinologists (AAACE), and lend our **enthusiastic and strong support** to the proposed guidance on artificial pancreas systems you received on March 10, 2011 from the Juvenile Diabetes Research Foundation (JDRF). We had a chance to review the guidance and our members, all practicing endocrinologists, had an opportunity to actively participate in drafting the final version of the document. The document you received does indeed contain some important elements suggested by AAACE members. Given the fact that it will be our members who will most likely actively participate in both designing and actually carrying out the clinical trials of the artificial pancreas it is logical that we are involved in that worthy effort from the very start.

It is high time we took the next practical steps in safely implementing this promising technology and finally have the clinical tools in place to reduce the devastating burden poorly controlled diabetes has on the patients suffering from this incurable disease, their families, and our entire society. The AAACE members stand ready to lend whatever assistance you might need in implementing the Guidance. Thank you very much for your consideration.

Sincerely yours,

George Grunberger, MD, FACP, FACE  
Member, Board of Directors, American Association of Clinical Endocrinologists  
Chair, AAACE Task Force on Insulin Pump Therapy

cc: *John M. Taylor III, JD, Acting Principal Deputy Commissioner*  
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