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Leading Clinical Organizations Urge FDA to Adopt JDRF's
Artificial Pancreas Recommendations

Groups Caution FDA to Avoid Shortcomings Found in Low Glucose Suspend Guidance

Washington, D.C. -- The JDRF applauded leading clinical organizations specializing in diabetes care, who called on the Food and Drug Administration (FDA) to ensure that development of an artificial pancreas, the most revolutionary development in diabetes care since the discovery of insulin, is not delayed by unnecessary regulatory roadblocks.

In a letter sent to FDA Commissioner Margaret Hamburg and leading members of Congress, the American Association of Clinical Endocrinologists, American Association of Diabetes Educators, American Diabetes Association, and the Endocrine Society told the FDA that the final artificial pancreas guidance, due to be released by December 1, needs to avoid the shortcomings of the recently proposed guidance for Low Glucose Suspend System, an artificial pancreas (AP) precursor technology.

“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,” the organizations wrote.

The organizations also noted in the letter that Commissioner Hamburg has “made advancing regulatory science at FDA a top priority” and urged 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.”

The clinician organizations urged the FDA to issue guidance that will allow researchers, scientists and manufacturers to finally move forward with the next phase of outpatient clinical trials for the AP, a technology that researchers and patients believe has the potential to save lives, dramatically transform quality of life for people with type 1 diabetes and reduce preventable medical complications that impose huge costs on our health care system.

In the letter, the clinician organizations asked the FDA to ensure that the final AP guidance contains the following critical elements:

- A firm commitment to use continuous glucose monitor (CGM) data in evaluation of artificial pancreas systems
- Reasonable study progression
- Flexibility with respect to endpoints, patient population, and safety elements
- Policies to encourage system improvements

JDRF, the leading patient group for type 1 diabetes adults, children, and families applauded the letter.

“The FDA will soon release a guidance document which must be properly drafted or it could delay delivery of a highly promising medical technology that will improve or save the lives of millions of Americans living with type 1 diabetes,” said Jeffrey Brewer, President and CEO of JDRF. “This letter from leading clinical organizations reinforces how critical it is for the FDA to issue clear and reasonable AP guidance in December and echoes the concerns and consensus of the broader diabetes community. Failure to issue reasonable guidance will mean that patient access to this life-saving technology will be, at best, delayed, and at worst, prevented entirely.”

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About JDRF

JDRF is the leading global organization focused on type 1 diabetes (T1D) research. Driven by passionate, grassroots volunteers connected to children, adolescents, and adults with this disease, JDRF is the largest charitable supporter of T1D research. The goal of JDRF is to improve the lives of every person affected by T1D by accelerating progress on the most promising opportunities for curing, better treating, and preventing T1D. JDRF collaborates with a wide spectrum of partners who share this goal.

Since its founding in 1970, JDRF has awarded more than \$1.5 billion to T1D research. More than 80 percent of JDRF's expenditures directly support research and research-related education. Past JDRF research efforts have helped to significantly improve the care of people with this disease, and have expanded the critical scientific understanding of T1D. JDRF will not rest until T1D is fully conquered.

For more information, please visit www.jdrf.org.