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**COLLINS, SHAHEEN WELCOME PROMPT RELEASE OF FDA
GUIDANCE ON ARTIFICIAL PANCREAS**

Device could improve the lives of millions of Americans living with diabetes

(Washington, D.C.) — U.S. Senators Susan Collins (R-ME) and Jeanne Shaheen (D-NH), co-chairs of the Senate Diabetes Caucus, welcomed news that the Food and Drug Administration (FDA) released guidance today that will allow outpatient clinical trials to begin on the artificial pancreas, a device that could improve the lives of millions of Americans living with diabetes. In a hearing before Collins and Shaheen earlier this year, the FDA promised to issue this guidance by December.

"I am pleased that FDA kept its commitment to issue, in a timely manner, the guidance necessary to take the clinical trials of a truly autonomous artificial pancreas from a hospital inpatient setting to an outpatient basis," said Collins. "At a hearing I chaired this past June, I urged FDA to issue these guidelines by December 1st so that this revolutionary breakthrough in diabetes care may not be further delayed. This technology has seen very positive results in an inpatient setting and is already undergoing outpatient testing in many countries in Europe. An artificial pancreas has the potential to dramatically improve the health and quality of life for individuals with diabetes, and it is time that it be tested in real-life scenarios in our country."

"This technology has life-changing possibilities for millions of Americans, many of them children," Shaheen said. "I have met with so many children and families whose heartbreaking stories convey the urgency of approving this technology. I am glad the FDA has lived up to its commitment to issue this guidance. I will continue to work with them and the many families dealing with this disease to see that this process moves forward, so that we can make this crucial device available to the public as soon as safely possible."

The artificial pancreas combines medical devices that already exist – insulin pumps and continuous glucose monitors – to control blood sugar levels automatically. For people living with diabetes, it would mean the end of burdensome frequent blood tests and injections.

The draft guidance issued today will allow developers of the device to begin outpatient trials. Senators Collins and Shaheen said they will work with stakeholders to review the draft guidance to ensure it is clear, reasonable, and flexible. Data collected from outpatient trials can help lead to final FDA approval of the device for public use.