

Testimony of Pam K. Sagan

Hearing Witness

Panel II

At the Hearing titled:

**“FDA Medical Device Regulation: Impact on
American Patients, Innovation and Jobs”**

Wednesday, July 20, 2011, 10:30 a.m.

Before the

House Committee on Energy & Commerce

Subcommittee on Oversight and Investigations

2322 Rayburn House Office Building

Washington, D.C.

Chairman Stearns, Ranking Member DeGette and Members of the Committee: Thank you for asking me to testify before you today. My husband and I have three children; the youngest of whom, our daughter Piper, was diagnosed with type 1 diabetes at the age of two in 1989. She has lived over 20 years with this constant, frightening, deceptive and malicious disease. I come before you not only as a parent, but as an advocate for tools and technology for my daughter and others with diabetes, and with my enduring hope for a cure.

Piper has always been prone to hypoglycemic – low blood sugar – events. They seem to come on hard and fast. I remember her almost drowning as a youngster after becoming unconscious from low blood sugar while taking a bath. College also brought one or two incidents a year where she slept into hypoglycemia and didn't wake up the next morning, requiring emergency medical care. There is a chilling term that is the worry of every parent of a child with diabetes called "dead in bed". Kids are found dead in the morning after a completely normal evening the night before. Most of the time, it is due to severe hypoglycemia. I do not want this to happen to my daughter or anyone else with diabetes. So you can understand where my fire comes from.

Just this past winter, Piper, now a 24-year old, had another severe hypoglycemic incident. While working at a retail store, the last thing she remembers is closing the front door of the shop as she left to walk the 10 blocks to her apartment. My cell phone rang, and she slurred to me that she was locked out of her apartment. Upon further conversation, I realized that she was "low". She had wandered her way home in a semi-conscious state – she had crossed busy city intersections at rush hour, she had fallen and scraped her hands as she walked, and she had lost bladder control. She finally ended up at her apartment, the keys were in her purse, but she did not know what they were. She pulled out her cell phone and pushed the #1 – my cell phone number. All this time, her continuous glucose monitor was alarming, but her blood sugar was too low to take action, and her insulin pump continued to pump insulin into her body, lowering her blood sugar even more.

This is life with type 1 diabetes. Type 1 diabetes occurs when the body's immune system attacks the cells in the pancreas that produce insulin. Insulin regulates glucose in one's body and without it a person with type 1 diabetes cannot live. There is no cure for this disease and it imposes an enormous physical, emotional, and financial burden. On average, a child with diabetes will have to take over 50,000 insulin shots or infusions in a lifetime. Every hour of every day for the rest of her life she will have to balance insulin, food, and activity to try to prevent low and high blood sugars, and the devastating and costly complications: seizures, comas, kidney failure, heart disease, blindness, and amputations. It astounds me that diabetes costs our nation more than \$174 billion a year and one in three Medicare dollars is spent to care for people with diabetes.

Because of these burdens, people with diabetes and their loved ones need timely access to innovative, life-saving technologies to help better manage the disease. Some breakthrough tools and technologies that protect against dangerous diabetes episodes are already available all over the world, but not available here in the United States.

I do not claim to be an expert on the regulatory process at the U.S. Food and Drug Administration, but as a parent with a daughter with diabetes, I am extremely frustrated that better technologies to help people with diabetes are delayed here in the United States.

Low glucose suspend systems have been approved for nearly three years and used safely in over 40 countries worldwide, but they are not available here in the U.S. This technology is one critical example where our nation is lagging behind in the approval of devices that would make living with this disease much safer.

As background, these pumps stop delivering insulin automatically when a monitor indicates that the body's glucose levels are low. With this kind of pump, my daughter wouldn't receive more insulin when she's already low, causing her blood sugar to drop further and potentially causing a seizure, coma, and even death. With the present FDA approval process, it will require a clinical trial conducted in this country, and a delay of years to conduct the study and compile the data before a decision is made. Kids are dying from hypoglycemia now. I want, and my daughter needs, this system available in the U.S. today.

Likewise, if the pattern continues, the next generation of these systems may be available in other countries years before they are available in America. The low glucose suspend technology is the first phase of an artificial pancreas, a combination of a continuous glucose monitor and an insulin pump with software that communicates between the two to automatically monitor glucose levels and administer insulin doses. Unlike the low glucose suspend pump, the artificial pancreas would address both high and low blood sugar levels.

In 2006, I was thrilled that the FDA recognized the importance of this technology and placed the artificial pancreas on its Critical Path Initiative. Since then, with funding from JDRF and the Special Diabetes Program, for which I am so grateful for this Committee's tremendous support, the artificial pancreas was tested favorably in a hospital setting. Now key trials are on hold until the FDA provides a roadmap for outpatient studies. Clinical experts provided a draft roadmap in March to help the process along. I am so grateful that a bipartisan majority of the House provided strong support for this effort with letters, led by Representatives DeGette and Whitfield in the House and several Members of this distinguished Committee, encouraging the FDA to move forward quickly to consider this proposal. The FDA announced recently that it will publish draft artificial pancreas guidance by December. It should not have to take this long. This technology could revolutionize diabetes care. It is imperative that the FDA provide reasonable guidance immediately, not later as we've seen with low glucose suspend systems.

I implore Congress to continue to urge the FDA to move forward urgently on next steps relating to low glucose suspend systems and the artificial pancreas, so that people with diabetes will remain healthier and safer until a cure is found. I want very badly to be an advocate for the work of FDA. And I would lead the chorus of applause for the FDA when real progress happens, but it has to happen very soon. My daughter's life is depending on it.

Thank you, Members of the Committee, for allowing me to testify on an issue so close to home. I am pleased to answer questions you may have.