

**My Opening Statement from the “Oversight and Investigation” hearing on the “Budget and Spending Concerns at HHS” on Wednesday May 9<sup>th</sup>, 2012.**

*“The purpose of the user fee programs we are here to discuss is to help reduce the time in which FDA can review and make decisions on marketing applications. Lengthy review times for drugs and devices not only affect the industry, but also patients who wait, sometimes entirely too long, for these products to reach the marketplace. One population which is especially reliant on the FDA to move products through the approval pipeline are Americans with diabetes. According to the American Diabetes Association, nearly 26 million Americans have diabetes and, every day, 230 undergo an amputation, 120 enter end-stage kidney disease programs and 55 people go blind from this disease. Diabetes costs our nation more than \$174 billion a year and one in three Medicare dollars is spent to care for people with diabetes.*

*This year’s medical device user fee agreement reached a record almost \$600 million. This large increase in funding from industry to the FDA is meant to augment the staffing, training and expertise FDA brings to bear on the review of all products, but particularly new and innovative technologies that can transform lives. One such technology, the artificial pancreas, is under consideration at FDA and could significantly improve the health and quality of life for those with diabetes.*

*To date, the U.S. has lagged behind other nations in approving state of the art products—such as low glucose suspend systems-- meant to help those with Type 1 diabetes lead healthier, safer, and more productive lives. These pumps stop delivering insulin automatically when a monitor indicates that the body’s glucose levels are already low. Otherwise the continuous delivery of insulin can lead to a seizure, coma or death. This product has been approved and safely in use for almost three years in 40 countries worldwide, but yet the FDA has failed to move it forward in the United States.*

*I hope that many of the provisions included within this package such as the “Investigational Device Exemption” and “Clarification of least burdensome standard” are taken to heart by officials at the FDA and implemented as quickly as possible once this legislation is signed into law. As Vice-Chairman of the Subcommittee on Oversight and Investigations, I plan on working closely with Chairman Stearns and Chairman Pitts and the Subcommittee on Health to ensure that industry and patients are seeing a return on the significant investment of capital and hope that has been made with the FDA.”*