# MEDICAL INNOVATION: INTEGRATED INSULIN PUMP THERAPY (MEDICAL DEVICE: THERAPEUTIC)

Physicians: Dean Kamen, Al Mann Industry: AutoSyringe, Medtronic Academic: Johns Hopkins University

#### **Situation**

## A complicated and painful treatment regimen

Type 1 diabetes is a chronic disease in which the body fails to produce enough, or any, insulin to regulate proper levels of blood glucose (sugar). Diagnosed mostly in people younger than 40, type 1 diabetes is a relatively common condition – <u>approximately one in 250 Americans</u> suffer from the disease.

People with type 1 diabetes need to follow a complicated and painful regimen several times a day in which they monitor their levels of blood glucose and then inject precise amounts of insulin to maintain proper blood glucose levels in their body. Not doing so can lead to major health problems including diabetic comas, heart disease, blindness, kidney damage and even death.

Diabetes also accounts for a huge financial toll: <u>direct costs of managing the condition amount to hundreds of billions of dollars worldwide, and a far higher sum is spent on indirect costs attributable to poor management of the disease in the form of lost workdays, restricted activity days, mortality and permanent disability. Total spending on type 1 and 2 diabetes accounts for over a hundred billion dollars each year in the United States alone.</u>

### **Physician-Industry Collaboration**

#### A truly "smart" system for managing insulin levels

Until very recently, <u>diabetics had no alternative than to follow this cumbersome regimen of monitoring and injecting insulin manually</u>, resulting in imprecise treatment that could often lead to fainting spells, lowered productivity, and restrict the activities they could engage in.

The idea for an automatic insulin pump that would replace this manual process circulated among diabetes specialists for years before the first version was created by Dean Kamen in the late 1970s. Called the Auto-Syringe, the infusion pump was carried in a large backpack by the diabetic, so it was not very practical. Following Kamen's pioneering work, Alfred E. Mann, then the CEO of Pacesetter Systems, formed a team in 1980 to develop an wearable insulin pump in conjunction with NASA and the Applied Physics Laboratory at Johns Hopkins University. The team became Pacesetter Systems Infusion Division, later becoming MiniMed, and now a division of Medtronic.

In 1983 at the American Diabetes Association convention, the company introduced its first insulin pump, little more than a rudimentary product, but soon followed by other smaller and programmable devices. Today, Medtronic produces a truly "smart" insulin pump and glucose monitoring system no larger than a pager that monitors a diabetic's blood levels, and automatically transmits a glucose value to the pump that injects the proper insulin dosage. And fully implantable pumps – the next frontier – already exist and are awaiting FDA approval.

#### **Innovation Benefits**

#### Greater productivity, higher employment retention

Properly controlling blood glucose levels is both life-saving and cost effective. A recent study confirmed that insulin pumps are more effective than multiple daily insulin shots at helping control glucose levels, and can lower the total daily insulin dose that type 1 diabetics need. Patients with well-controlled diabetes report higher employment retention rates, greater productive capacity, less absenteeism and fewer bed-ridden or restricted-activity days, easily saving hundreds of millions of dollars in the U.S. each year.

#### **Patient Benefits**

#### Realizing her dream

As she related to AdvaMed's <u>Profiles in Progress You Can See</u>, Nicole Johnson was elated as she stood on the podium being crowned Miss America 1999. What most people didn't know is that only a few years earlier, Nicole learned she had type 1 diabetes, forcing her to drop out of college and almost abandon her dream of competing in beauty pageants.

Treating her disease manually was difficult to do – in the Miss Virginia competition in 1997, Nicole collapsed on stage and fell into a diabetic coma. She knew there had to be a better way to live with this chronic disease. "It was my best and worst day," she said. "I knew I had to make a decision about living with type 1 diabetes."

Following that experience at age 23, Nicole started using an insulin pump, and she has never looked back. Nicole was able to resume competing in pageants, and realized her dream of becoming Miss America less only two years later. She has not had any complications and has improved her levels of blood glucose over time.

Now, as a diabetes educator, and a motivational speaker and journalist, Nicole strives to inform people about the importance of taking charge of their diabetes. "I want people to know that diabetes does not have to limit anyone...The technologies available today have allowed me to achieve my personal and professional dreams," she said.