Health Feature / By Amy Klein

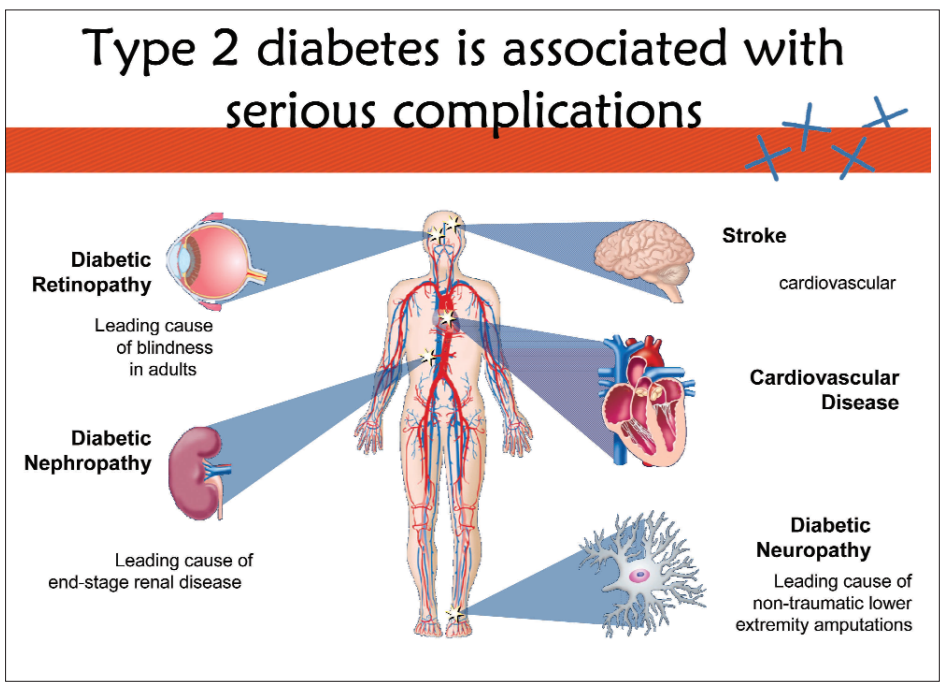
Her Last Shot

Israeli scientist Dr. Miriam Kidron has discovered an insulin capsule to replace injections for people with diabetes.

Dr. Miriam Kidron had no personal motive for researching diabetes — it's not as if someone she was close to suffered from the disease. The Israeli biochemist and pharmacologist simply found the study of diabetes "fascinating."

Kidron, now 70 years old, a religious mother of four and grandmother of 13 — found it so fascinating, in fact, that since earning her PhD. in biochemistry at Hebrew University 35 years ago, she studied the disease at Hadassah University Medical Center in Jerusalem until 2006.

That's when she realized that she and Professor Hanoch Bar-On, the head of the hospital's Diabetes Unit, might be onto what many scientists call the ultimate prize of diabetes research: an insulin pill — capsule, actually — that could replace injections for those in the early stages of Type-2 diabetes, and help others in the later stages or with Type-1. Kidron, Bar-On and her son Nadav then formed the company Oramed Pharmaceuticals to push forward federal drug trials of the pill and get it to the market. Hadassah University Medical Center is part owner. (Bar-On died that year). In May, Israel approved a patent for their capsule's technology.



What Is Diabetes?

Diabetes is a disorder of metabolism — the way our bodies use digested food for energy. Most of the food we eat is broken down into glucose, the body's main source of fuel. After digestion, glucose enters the bloodstream, going to cells throughout the body, used for energy. For glucose to enter the cells, the body must have insulin, a hormone produced by the pancreas. Normally, the pancreas automatically produces the right amount of insulin to move glucose from blood into the cells. But diabetes develops when the pancreas doesn't make enough insulin, or the cells in the muscles, liver and fat do not use insulin properly, or both. As a result, the amount of glucose in the blood increases while the cells are starved of energy.

Injectable insulin was made available on the market as of 1922. But over the years, there have been attempts to find a needle substitute. Other attempts to replace the insulin shot include an inhalable insulin, much like an asthma inhaler. But various problems with inhalables — including possible lung cancer, low profitability — forced it off the market, while research continues. (Diabetics eagerly await Generex Biotechnology's Ora-Lyn inhalable, which uses a mist spray.)

In the past, insulin pills failed because the digestive track breaks down insulin before it can be absorbed into the blood stream and used effectively to process glucose. A successful pill must withstand acid attacks during digestion in the stomach and pass the filter of the gut wall to reach the liver.

According to the World Health Organization, by 2030 there will be 366 million people worldwide affected by diabetes. The American Diabetes Association estimates that more than 25 million Americans currently have diabetes, and 79 million have prediabetes.

Israel ranks first in mortality rates for diabetes and kidney failure, compared to the U.S. and Europe, a 2011 Israeli Health Ministry report found.

Increasing obesity around the world, sugar-laden diets and lack of exercise doesn't help. Over time, high blood glucose levels damage nerves and blood vessels, leading to complications such as heart disease and stroke, the leading causes of death among people with diabetes. Uncontrolled diabetes can eventually lead to other health problems, such as vision loss, kidney failure and amputations.

On the Road to a Solution

Oramed's capsule has a unique drug delivery technology which significantly enhances the absorption of peptides and proteins across the intestinal wall when delivered orally without modifying the active compounds. The capsule contains antiprotease, which guards the protein from the proteolysis enzymes that allow it to process through the digestive tract without being broken down by acids, and reach the liver. The drug-delivery technology can be used in the future on other medications as well, Dr. Kidron says. For example, a future application of the technology could be in flu shots.

The power of Oramed's capsule is to prevent early-stage patients from even taking insulin injections.

A Type-2 Diabetes diagnosis has three phases: In the beginning, patients will simply change their diet and lifestyle. Next, they take a pill that helps the body produce more insulin. But the body's reserves will eventually run out — and that is when they need to start taking insulin shots. But most people put off taking the shots for as long as they possibly can.

If patients in the early stages of the disease could take Oramed's capsule, they would probably never proceed to *needing* insulin shots. (The capsule might help those people who already take insulin shots, but cannot replace the shots right now).

Oramed has begun trials around the world with much success. In the U.S. they are beginning the FDA's Investigational New Drug (IND) program, and hope to have the drug on the market by 2015, and earlier in other countries such as China and Russia.

The Race Continues

A number of other companies are also on the quest for the pill, including Pharma Giant NovoNordis, which is spending $2 billion on their pill, but whose research in the U.S. is only at phase 1 of FDA trials. A handful of smaller companies are also searching for the pill, including Diasome Pharmaceuticals Inc. of Pennsylvania, and Diabetology Ltd in the Channel Islands.

But competition doesn't bother Dr. Kidron. "Personally, at the end of the day, I am not afraid," she says, noting that there will probably be a few options. "There is no one medication good for 100% of the population."

Analysts believe the market for a successful pill is from $5-$10 billion dollars.

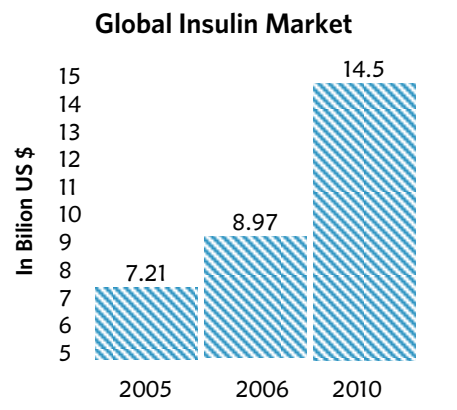
But it's not the money that excites Dr. Kidron. "Money is not my motivation. My children are all married [except OraMed CEO Nadav], and I have what I need. Maybe if it was 50 years ago..." she muses. Money probably would have helped her, as a full-time scientist, wife and mother raising four children, working a non-traditional 9-5 job (or 8-4 in Israel).

But what really drives the Jerusalem grandmother is simple: "I will be happy when people will have oral insulin," she says.

That's all? After devoting so many years of her life to this?

"You see, in science, it's very exciting. You plan something and you do the trials and you don't always have a success — you don't publish the failures. But all of a sudden — and 25 years is not all of a sudden — you have a success. And once you have that success, it's like having a baby," she says. "I feel like it's my baby. I hope it will become a grownup!"

DIABETES: A GROWING GLOBAL EPIDEMIC



The total insulin market was estimated at $14.5 BILLION worldwide in 2010.

25.8 MILLION people suffer from diabetes In the U.S. alone.

There are 346 MILLION diabetics worldwide.