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Can 'Robotic' Pills Replace Injections?

Mir Imran, With Google Backing, Hopes to Change Diabetes Treatment

By Timothy Hay

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The adage "Take two aspirin and call me in the morning" is destined for a futuristic makeover. Doctors may just as easily recommend swallowing sophisticated gadgets instead.

That is the hope of prolific inventor Mir Imran, who has created a robotic pill to replace injectable drugs for chronic conditions such as diabetes. The gadget, in preclinical studies and backed by Google Inc. 's venture-capital unit, consists of an ingestible polymer and tiny hollow needles made of sugar that are designed to safely deliver drugs to the small intestine.

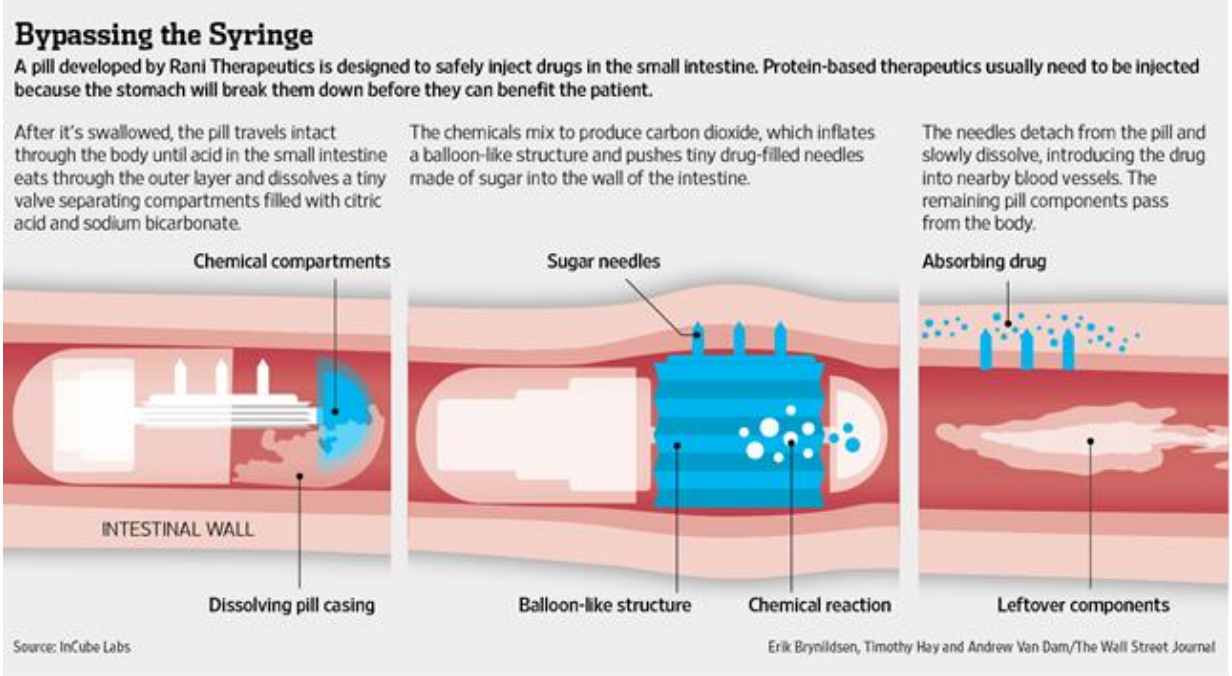
Such a pill would have seemed unthinkable years ago. But advancements in technology and scientific research have recently led to two federally approved robotic pills.

The Food and Drug Administration earlier this month cleared the PillCam, a pill-sized camera from Given Imaging Ltd. that photographs human insides in a hunt for colon polyps. Another company, Proteus Digital Health Inc., received clearance a year and a half ago to put ingestible sensors inside pills to help patients and doctors determine how many they have taken.

Mr. Imran's pill hasn't yet been tested in humans, so it is probably still at least a year away from even seeking federal approval. It also would require substantial financing to manufacture millions of pills. But if it is successful, the gadget has the potential to disrupt a multibillion-dollar market for injectable drugs and make life easier for millions of sufferers of conditions such as diabetes and rheumatoid arthritis.

Mr. Imran is a safer bet than most entrepreneurs. The Indian-born founder of the research lab and business incubator InCube Labs in Silicon Valley has founded more

than 20 medical-device startups, a dozen of which have been acquired by companies such as Medtronic Inc. He owns over 300 patents and helped develop the first implantable cardioverter defibrillator to correct irregular heartbeats.



Rani Therapeutics, the startup formed at InCube Labs to commercialize the robot pill, last year raised funds from Google Ventures and angel-investment fund VentureHealth.

Blake Byers, the Google Ventures general partner who spearheaded the investment, says Mr. Imran may be achieving one of the "holy grails" for biotechnology by figuring out how to deliver protein-based drugs such as basal insulin to the body without the use of a syringe.

"This investment is not exactly in our wheelhouse, but we're open to people who can change our minds," Mr. Byers said. "This one really stood out as a huge clinical need; $110 billion is spent in the U.S. every year on biologics, all of them injectable."

Drugs used to treat a variety of chronic conditions, including diabetes, rheumatoid arthritis, osteoporosis and multiple sclerosis, can't be delivered in pill form because stomach acids break down the proteins.

Mr. Imran's idea is an "autonomic robotic delivery system" that can stay intact in the stomach and small intestine long enough to deliver enough of the drug. The body's natural digestive processes activate the pill to perform a series of functions even without any electronics.

As the pH level, or acidity, builds up in the intestine, the outer layer of the polymer pill casing dissolves, exposing a tiny valve inside the device that separates two chemicals, citric acid and sodium bicarbonate.

When the valve becomes exposed, the chemicals mix together to create carbon dioxide. This acts as an energy source, gently inflating a balloon-like structure that is outfitted with needles made of sugar and preloaded with drugs.

The needles push into the intestinal wall, which has no pain receptors. Once lodged there, they detach from the gadget and slowly dissolve, while the balloon and polymer casing pass from the body.

In numerous attempts over the past 40 years to make insulin and other drugs available in pill form, pharmaceutical companies have been able to create coatings so tough that pills can reach the small intestine. But once there, they are attacked by enzymes, which has compromised the pills and prevented significant amounts of the drug from reaching the patient.

In preclinical studies, Rani Therapeutics has shown that its robotic pill can boost drug absorption at least as high as syringes can, Mr. Imran said.

"I am guardedly optimistic, and I say guardedly because there is still a lot of work left to do," said Elliott Sigal, who several months ago retired from drug maker Bristol-Myers Squibb Co. His 16-year run at the drug maker included top posts in drug discovery and development and a nearly 10-year tenure as the head of research and development.

"Rani's engineering-based approach to this is very innovative," said Mr. Sigal, who doesn't have a financial stake in the business. "He is getting results that I have not seen before. It hasn't been tried in human patients yet, and things do sometimes fail at that level. But if the [trials] data continues, there will be a great deal of pharma interest."

Mr. Imran said pharmaceutical companies, which would license the technology for use with their own drugs, have already expressed interest. He declined to give further details.

Rani Therapeutics will spend another year testing the robot pill, he said, in the hope that it will have definitive clinical data in 2015. If the data back up his claim about the pill, it could not only help millions of patients ditch their syringes and stick-pens, but it could remove another barrier for a range of early-stage treatments that currently have no safe avenue into the body, said Google Ventures' Mr. Byers.