2017 Innovation & Technology Award winner: Enable Injections

The global biologics market is expected to more than double between now and 2024, and Evendale-based Enable Injections Inc. is on track to revolutionize the growing field.

Enable developed a wearable auto-injector that allows patients to self-inject prescription drugs with the touch of a button. The device, which still needs to get approval from the U.S. Food and Drug Administration, would enable patients to self-administer high-volume biologics, a pharmaceutical category expected to grow from $209 billion in 2016 to $480 billion by 2024, according to Transparency Market Research.

Enlarge

Enable Injections is working to change biologics delivery.

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Biologics are used to treat a variety of conditions, including cancer and hemophilia. Because they are viscous and must be given in large doses, they are typically administered intravenously in a clinic. The Enable injector, which is about the size of an Oreo cookie, attaches to a patient's abdomen with adhesive. When the patient presses a button, the device administers the drug subcutaneously. After the drug has been delivered, the button pops out and the patient removes the device and throws it away. Because the system, which can deliver as much as 50 milliliters of a drug, is worn discreetly under a patient's clothing, patients can go about their daily lives while receiving treatment.

In addition to convenience, the technology offers several other important benefits for pharmaceutical companies, payers and patients. Pharmaceutical manufacturers benefit because the device can automatically mix drugs that come in a powdered form using a two-vial system and can be used with their existing drug containers. Payers benefit because self-administered drugs would do away with the need for expensive visits to infusion clinics. Patients benefit because the device is designed to make treatment more comfortable and convenient.

Last fall Enable, which currently employs 60 and plans to add 90 more employees by late 2018, secured $30 million in Series A funding from a venture capital group that included Hong Kong-based ORI Healthcare Fund, CincyTech, Cintrifuse, the Ohio Innovation Fund and Cincinnati Children's Hospital Medical Center.

Enormous though the market potential for Enable may be, CEO Michael Hooven notes there are plenty of hoops to jump through before the technology can be used in the United States. The FDA classifies the drug delivery device as a "combination product." As such, it doesn't require a single approval but instead has to earn FDA approval in combination with each individual drug that it will be used to deliver.

"It's much more expensive, complex and time consuming to get the drug and the device approved together," says Hooven. But there is an upside: Given the arduous approval process, "once we get approved we build customer loyalty because pharmaceutical companies would have to repeat the whole process to get approved to use another delivery system."

Enable has tested the device with saline and will undertake its first clinical trial in combination with an actual drug sometime in the next year, Hooven says. He expects to receive approval to sell outside the United States in the next year or so and anticipates U.S. approval would likely follow a year later.

After that, he says, expect a sea change in the industry.

“Once devices like this become available, payers will not want to pay for intravenous infusions when they don’t have to,” he says. That will drive broader adoption. “I think we can expect to see real change in about five years, and in 10 years this will become standard of care.”