

Why people with diabetes can't buy generic insulin

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Credit: Darren Lewis/public domain

A generic version of insulin, the lifesaving diabetes drug used by 6 million people in the United States, has never been available in this country because drug companies have made incremental improvements that kept insulin under patent from 1923 to 2014. As a result, say two Johns Hopkins internist-researchers, many who need insulin to control diabetes can't afford it, and some end up hospitalized with life-threatening complications, such as kidney failure and diabetic coma.

In a study published March 19, 2015, in the *New England Journal of Medicine*, authors Jeremy Greene, M.D., Ph.D., and Kevin Riggs, M.D., M.P.H., describe the history of [insulin](#) as an example of "evergreening," in which pharmaceutical companies make a series of improvements to important medications that extend their patents for many decades. This keeps older versions off the generic market, the authors say, because generic manufacturers have less incentive to make a version of insulin that doctors perceived as obsolete. Newer versions are somewhat better for patients who can afford them, say the authors, but those who can't suffer painful, costly complications.

"We see generic drugs as a rare success story, providing better quality at a cheaper price," says Greene, an associate professor of the history of medicine at the Johns Hopkins University School of Medicine and a practicing internist. "And we see the progression from patented drug to generic drug as almost automatic. But the history of insulin highlights the limits of generic competition as a framework for protecting the public health."

More than 20 million Americans have diabetes, in which the body fails to properly use sugar from food due to insufficient insulin, a hormone produced in the pancreas. Diabetes can often be managed without drugs or with oral medications, but some patients need daily [insulin injections](#). The drug can often cost from \$120 to \$400 per month without prescription [drug](#) insurance.

"Insulin is an inconvenient medicine even for people who can afford it," says Riggs, a research fellow in general internal medicine and the Berman Institute of Bioethics at Johns Hopkins. "When people can't afford it, they often stop taking it altogether." Patients with diabetes who are not taking their prescribed insulin come to Riggs' and Greene's Baltimore-area clinics complaining of blurred vision, weight loss and intolerable thirst—symptoms of uncontrolled diabetes, which can lead to

blindness, [kidney failure](#), gangrene and loss of limbs.

The two doctors decided to find out why no one makes generic insulin. A University of Toronto medical team discovered insulin in 1921, and in 1923, the university, which held the first patent, gave [drug companies](#) the right to manufacture it and patent any improvements. In the 1930s and 1940s, [pharmaceutical companies](#) developed long-acting forms that allowed most patients to take a single daily injection. In the 1970s and 1980s, manufacturers improved the purity of cow- and pig-extracted insulin. Since then, several companies have developed synthetic analogs.

Biotech insulin is now the standard in the U.S., the authors say. Patents on the first synthetic insulin expired in 2014, but these newer forms are harder to copy, so the unpatented versions will go through a lengthy Food and Drug Administration approval process and cost more to make. When these insulins come on the market, they may cost just 20 to 40 percent less than the patented versions, Riggs and Greene write.

Provided by Johns Hopkins University School of Medicine

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