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For cheap generic drug prices, you can thank 40 years of Hatch-Waxman

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Many things about the modern world we take for granted. Personal computers, cellphones, GPS — these things are ubiquitous now but were far less common just a few decades ago.

Here's another item for that list: generic drugs. Today, when you fill a prescription, odds are it's with a generic. In 2021, the Food and Drug Administration reported that 90% of all prescriptions filled in the United States were filled with generics.

That's a great thing for consumers. Generic drugs cost far less than name-brand alternatives, saving patients and taxpayers hundreds of billions of dollars each year. There's a reason generic drugs are so popular. They provide the same benefits as the name brand but at far less cost.

However, generics weren't always so common. In the early 1980s, they constituted a meager 13% of prescriptions. Development was difficult, and regulatory barriers were high.

So, what changed?

Congress recognized there was a problem and acted to solve it.

That solution was the Drug Price Competition and Patent Term Restoration Act, better known as Hatch-Waxman after its principal sponsors, Utah Sen. Orrin Hatch and California Rep. Henry Waxman.

Passed in 1984, Hatch-Waxman achieved that elusive goal that is often necessary for legislation to succeed but difficult to achieve: balance. The law recognized there are two competing interests when it comes to the development of generic drugs that have to be accommodated.

First is the need for drug innovators to recoup the substantial research and clinical costs involved in bringing any new drug to market. Most new drug attempts fail. The research doesn't pan out, the clinical trials don't yield the hoped-for results, or the drug simply doesn't work as expected. And even for those that do, getting the drug to market typically costs hundreds of millions of dollars. That's one reason drug prices are so high — the company has to recoup the cost of development while also making up for the costs of all the other drugs that didn't work.

So, drug innovators need enough financial incentive to bear the risks and costs associated with bringing any drug successfully to market.

The other competing interest is the need for generic manufacturers to have regulatory and litigation certainty as they figure out how to manufacture the drug themselves and prove their generic's equivalence to the name-brand drug. If the barriers to approval or risk of litigation from the name-brand manufacturer are too high, the generic manufacturer will not take the necessary steps to develop and make the lower-cost alternative available.

And so Hatch-Waxman struck a balance. Among other things, it gives drug innovators a period of exclusivity during which the FDA cannot approve a generic version of the drug. This period of exclusivity is separate from any patent rights the innovator has for the drug. The act also extends the life of patents for the drug for a portion of the time the drug was under review by the FDA, thereby helping to ensure that prolonged review does not defeat profitability.

On the generic side of the equation, Hatch-Waxman limits the regulatory burden generic manufacturers must satisfy to obtain approval for the drug and provides a safe harbor from patent infringement claims while the company is pursuing approval. It also provides a streamlined process for adjudicating infringement claims once the generic's new drug application is filed.

So, on the one hand, Hatch-Waxman helps ensure drug innovators have a sufficient period of exclusivity to recoup their substantial investments in bringing the new drug to market. And on the other hand, it provides a pathway for generic manufacturers to seek approval with a lower risk of expensive, uncertain legislation.

And the results speak for themselves. Between 1984, when Hatch-Waxman was passed, and the late 1990s, the percentage of prescriptions that were filled by generics rose from 13% to 50%. It rose again between the late 1990s and early 2010s to 84%. Today, as noted above, the percentage stands at about 90%. At the local level, we've also seen the law's influence in spurring creative initiatives to bring even more affordable, lifesaving generic medications to consumers.

Hatch-Waxman's success cannot be denied. It gave birth to the modern generic drug industry and has saved consumers trillions of dollars since it was enacted.

This year, as we celebrate 40 years of this landmark bill, we should take stock of the lessons it provides for today's Congress and those legislators who, like Hatch and Waxman, are keen to solve pressing problems. We should also take stock of the bill's successes and what can be done to improve the generic approval process. No bill is perfect, and 40 years after the fact, some revisions may be in order.

Hatch, my former boss, was rightly proud of this exceptionally successful law that bears his name. But he was never one to rest on his laurels. And he was constantly committed to improving whatever he could, wherever he found room for refinement. Certainly, he would want us to celebrate 40 years of one of the most important intellectual property laws Congress has ever passed. But he would also want us to take this anniversary as an opportunity to make the law even better. Forty years on, let's keep working to make the pathway for generics as efficient and effective as possible.

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