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Let's Throw a Patent-Burning Party

When a drug goes generic, it's as if society has paid off a mortgage.

By Peter Kolchinsky

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Bottles of Lyrica at a pharmacy in Princeton, Ill., Oct. 23, 2017. PHOTO: DANIEL ACKER/BLOOMBERG NEWS

People used to throw mortgage-burning parties when they paid off their home loans—flame-fed celebrations marking an inflection point toward independence.

It's time to throw a party for Lyrica, Pfizer's Swiss army knife of a blockbuster drug that treats epilepsy, fibromyalgia and several neuropathic-pain-related ailments. Lyrica's patent expires in December. Once it "goes generic," its sales will almost immediately crater as multiple companies begin selling the drug's active ingredient, pregabalin, at steep discounts to Pfizer's brand.

As a society, we've nearly paid the mortgage on Lyrica. It was expensive. The FDA originally approved Lyrica in December 2004, and within three years the drug reached \$1 billion in sales. In 2017 Lyrica's global sales nudged above \$5 billion. Along the way Pfizer used many pharma tricks, legal and illegal, to boost

sales. In 2012 Pfizer won a lawsuit against generics companies that challenged its patents. In 2009 the company paid a record \$2.3 billion fine to the Justice Department for improperly marketing Lyrica.

Pfizer has also imposed its share of price increases. Lyrica's list price has risen 163% since 2012, although net price increases were lower due to the byzantine system of drug rebates. Pfizer has even developed a once-daily pregabalin (regular Lyrica is taken twice-daily). Approved in 2017 as Lyrica CR, and on patent until 2026, it will be a nice-to-have option for those unfazed by the higher copayment.

Because insurance companies saddle patients with high copays, branded drugs like Lyrica are unaffordable to some patients. In the U.S. only 11% of all prescriptions are for branded drugs, the rest for generics. Yet society can afford to make mortgage payments on these assets for our lasting benefit. At about 1.8% of U.S. gross domestic product, payments for branded drugs are a worthy investment. Health insurance in America should be reformed to pay for innovation and allow patients to afford their prescribed treatments.

Lyrica's U.S. patents expire in December but are likely to be extended through June 2019 thanks to a Food and Drug Administration program encouraging companies to demonstrate whether drugs work on children. Until then, Lyrica will help power the biopharma ecosystem with profits. But whether in two months or eight, generic pregabalin will appear on the other side of the ledger, becoming an inexpensive societal resource indefinitely. Pfizer says that more than nine million Americans have been prescribed Lyrica. Over the next several decades, tens of millions more may benefit from generic pregabalin.

Lyrica's mortgage burning is a high-profile manifestation of the fundamental contract the biopharmaceutical industry has with America. Society pays for expensive patented drugs in order to incentivize intrinsically risky and expensive research and development. But patents expire, those expensive drugs become inexpensive generics, and society reaps the rewards forever, or until a better drug comes along on which it's worth paying a new mortgage. That's the ideal.

For the contract to really work, there are kinks to work out. Namely, some pharma companies go too far in trying to extend their drugs' patent lives,

turning justifiable mortgages into unjustifiable rents. Occasionally they even rebrand older, off-patent medicines without any innovative upgrades, which may feel like having your house stolen and sold back to you. And insurers offload too much of the cost of innovative, patented drugs onto patients through onerous cost-sharing structures.

Because human biology is essentially unchanging, many drugs we use today will work as well in a century. Some may even work better with improved diagnostics, delivery technologies and insights into drug combinations. Thus the scientific progress we achieve in our lifetimes will also benefit future generations.

Generics work just as well and meet the same safety standards as original branded drugs, offer huge cost savings almost immediately, and, with few exceptions, remain inexpensive forever. Cholesterol-lowering statins alone have helped decrease deaths from heart attacks and strokes by 50% throughout the developed world over the last few decades. When Pfizer's patent on the best-selling statin Lipitor yielded to generic atorvastatin, the price quickly dropped by 95% and has remained comparatively negligible. Lyrica is likely to experience a similar fate.

Celebrating the end of a drug's patent life—and its new life as an extraordinarily inexpensive societal resource—reminds us why these drugs are so valuable to patients and physicians in the first place. We should celebrate, as a society and an industry, when the best drugs cross the generic threshold. Lyrica's mortgage is nearly paid off, and patients will enjoy the benefits of generic pregabalin for decades to come. Let's light the fire and start the party.

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