

Sudden Price Spikes in Off-Patent Drugs: Perspectives from the Front Lines

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Senator Claire McCaskill

Opening Statement

Thank you Chairman Collins.

Daraprim, a drug originally developed to treat malaria, is the medicine doctors today use to treat toxoplasmosis—a disease that affects about 22 percent of the U.S. population. While the majority of toxoplasmosis cases do not require treatment, the disease can be deadly for babies and those with compromised immune systems, like patients with cancer or HIV. Daraprim was developed in the 1950s and has no current patent or other exclusivity protections.

In 2005, a patient infected with toxoplasmosis could expect to spend \$70 on a typical course of Daraprim. In 2010, a company named CorePharma, which was later acquired by Impax, purchased the rights to Daraprim and raised the cost of a course of treatment to roughly \$900. In August of this year, the rights to Daraprim were once again sold, this time to Turing Pharmaceuticals. The new price tag for an average course of treatment? \$50,000 - an increase of more than 6000 percent since 2005. At the time, Martin Shkreli [Sh-KRELL-ee], Chief Executive Officer of Turing, declared the new price his company set for Daraprim both “reasonable” and “appropriate.” More recently, at a Forbes healthcare summit last Thursday, Mr. Shkreli lamented that he should have raised the price of Daraprim even higher.

An almost 1200 percent increase in 2010 was bad enough, but an additional 5500 percent price increase on a 62-year old drug shocks the conscience. And this type of price increase in the absence of any improvements to the drug whatsoever is not an isolated incident. In July, I had the chance at a hearing to question another pharmaceutical executive, Howard Schiller of

Valeant Pharmaceuticals, about an 820 percent price increase his company took in February 2015 after acquiring another off-patent drug called Isuprel [EYE-su-prell], which is used to treat cardiac arrest. When I asked Mr. Schiller how Valeant could justify such an increase on Isuprel, a drug to which no improvements had been made post-acquisition, Mr. Schiller could only tell me that Valeant had conducted a “complex” analysis and had concluded that the drug was previously “significantly underpriced.” He further asserted that such a price increase on a Valeant drug was “an anomaly.”

Following that hearing, I submitted questions for the record to Mr. Schiller, requesting additional information from Valeant regarding the company’s decision to hike the price of Isuprel so dramatically, as well as information on Valeant’s 312 percent increase on another off-patent drug called Nitropress, which is also used to treat cardiac arrest. In response, Valeant refused to answer my questions and instead downplayed my concerns, noting that Isuprel and Nitropress are only “two [Valeant] drugs selected out of a portfolio of hundreds of medications.”

Unfortunately, over the past several months, we have learned that Isuprel and Nitropress are not “an anomaly” as Valeant claimed. To the contrary, dramatic price hikes are seemingly business as usual for Valeant. This year alone, Valeant raised prices on its brand-name drugs an average of 66 percent, about five times as much as its closest industry peers. At the same time, as of October 2015, Valeant’s research and development expenditures for the past twelve months were reportedly equal to only three percent of its sales.

The American pharmaceutical industry leads the world in innovation, and we rightly prize a system that allows the discovery of medicines that save and improve lives. But it’s imperative that we find out if that system is being taken advantage of by companies or individuals that seek deep profits while contributing little or nothing to advances in medical

treatment. To me, there's a line at which these huge price increases on prescription drugs go from rewarding innovation to price gouging. In particular, when these price hikes occur without any therapeutic changes or improvements to the drug, it raises troubling questions about whether companies like Turing and Valeant are taking advantage of the patients who depend on their products for survival.

These price increases come at a time when Americans are more worried than ever about the affordability of prescription drugs. And what Daraprim, Isuprel, Nitropress, and the other drugs in our investigation have in common is that they do not have market competition from generic alternatives. Therefore, they were ripe for companies and even investors to swoop in to snatch them up and charge whatever price they want, regardless of the people who desperately rely on these medications every day. So even though these drugs no longer have the legal monopoly granted by a patent, they end up having a de facto monopoly in the marketplace because if you need them, there is only one place you can get them. This is a market failure, and when there's a market failure, the government has a role in addressing it.

I hope that this hearing and the future hearings we are planning can start the process of developing legislative solutions to safeguard the healthcare system, protect the taxpayer, and ensure that patients have access to lifesaving medications at a reasonable price. I also hope to make clear that this is not just an individual pocketbook issue for Americans. If our healthcare system is being cheated, that has consequences for all Americans in the form of higher premiums and higher costs to Medicare and Medicaid. We cannot sustain and improve these valuable programs if some bad actors are taking advantage of the system and extracting billions of dollars without adding value to the lives of patients or the system overall. This sort of action hurts the entire American economy.

Finally, I want to note that I'm lucky to be paired with Susan Collins on this investigation. In my experience, quality congressional work is far easier to do in a cooperative and bipartisan fashion. When the price of your medication quadruples, you don't care whether the folks looking into it are Republicans or Democrats, you just want somebody to fight for you. The best answers are likely to be found when many people are asking questions, and Senator Collins and I both think this is an area that deserves more scrutiny from Congress, the media, and the American public. We all must commit to ensuring that the health of the American public isn't being compromised by companies placing profit ahead of patients.

I thank the witnesses for being here today, and I look forward to hearing their testimony.