US Senate report details price-gouging by pharmaceutical companies

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A recently-released US Senate investigation found that four major pharmaceutical companies operated like hedge funds and followed specific business models to monopolize drugs for rare, life-threatening conditions.

The companies—Turing Pharmaceuticals, Retrophin, Valeant Pharmaceuticals International and Rodelis Therapeutics—targeted decades-old, off-patent drugs, monopolized both their production and distribution, and held dying patients and their health care providers hostage as they hiked prices, often overnight, by tenfold or greater. All four companies were headed by veteran hedge fund traders and were run as such.

The investigation by the Senate Special Committee on Aging began in November 2015, encompassing three hearings, numerous interviews, and the review of more than one million pages of documents subpoenaed from the companies. The companies adhered to a basic five-point business model to maximize profits, acquiring the rights to produce these drugs only if they met specific criteria which would guarantee profits.

First, all the drugs had to have only one manufacturer in the US, so that monopoly production could be guaranteed. Second, all the drugs had to be the best available treatment for their condition, so that physicians would be compelled to prescribe them even in the face of massive price-hikes. Third, the drugs had to serve only small, isolated patient populations incapable of organizing effective opposition to the price-gouging.

The companies then manipulated the markets by controlling access to the drugs to prevent competitors from obtaining samples from which they could develop generic drugs, or cornering high-value patients with highly restrictive “patient assistance programs” that would leave competitors only the least attractive patients, the poor and uninsured. The companies confidently hiked the prices of these drugs, raking in net profits in excess of tens or hundreds of millions of dollars in a single year. None of the four companies invested a penny into the further research and development of the drugs they acquired.

In one case, the pharmaceutical company in question monopolized both the best available treatment for a disease and its best alternative treatment. In 2010, Valeant Pharmaceutical acquired both Cuprimine (penicillamine) and Syprine (trientine hydrochloride), the two best available treatments for Wilson disease, a rare genetic disorder—there are 3,000 cases at most in the US—that renders the body unable to process copper. If untreated, Wilson disease can cause severe brain damage, liver failure and death. The prices of a month’s supply for the two drugs in 2010 were $445 and $652, respectively. By the end of July 2015, the price rocketed to $26,200 and $21,300, respectively—price increases of over 3,000 percent.

Families, faced with rising health care costs as insurance companies increase premiums and out-of-pocket costs, are forced to skip doses or hoard pills in fear of the next price-hike or other disaster. Charitable grants could run dry, financial aid applications to the company-run patient assistance programs could be denied, and insurance companies could simply drop coverage of the drug from their plans. Some patients and physicians expressed their fear that speaking out would lead to the companies to stop manufacturing the drugs entirely.

One of the victims of this price-gouging was Patrick Melvin, a young father diagnosed with Wilson disease in July 2014. He had lived a normal life taking Syprine until his health insurance company reduced coverage of the drug and left him with a co-pay of $20,000 for a month’s supply. Melvin went without the drug for weeks, impairing his cognitive function and ultimately crippling him, forcing him out of employment and onto disability benefits. He had to delegate to his mother the task of submitting financial aid applications to Valeant’s patient access program, which was complicated by his changing employment status. Melvin died in September 2015 after suffering a massive stroke.

Then-CEO of Valeant, Michael Pearson, admitted to a Senate committee hearing that his “free market system” of holding patients’ lives hostage was a factor in the company’s decision to acquire and spike the price of

Syprine.

Many of the companies were headed by Wall Street alumni. Retrophin and Turing Pharmaceuticals were both led by Martin Shkreli, a former hedge fund manager and self-described “capitalist”. Shkreli’s hand-picked successor at Turing was Ron Tilles, another investment broker who had worked with Shkreli in Retrophin, before Tilles was ousted by Retrophin for raiding company resources to enrich himself and pay off investors from a previous hedge fund.

In the case of Rodelis Therapeutics, the Senate’s investigation admitted that the boundaries between it and its largest investor, Avego Healthcare Capital, were “practically invisible.” The companies even shared a mailing address at one point. Senior management used an Avego email address to negotiate drug acquisition, and analyses on Rodelis’s target markets were ordered under Avego’s name.

The companies were operated like hedge funds, presenting analyses to investors describing how well the drugs they targeted fit each aspect of their five-point business model. Shkreli, in an email to investors regarding Turing’s overnight price-hike of Daraprim (pyrimethamine), wrote, “I think it [revenue] will be huge. We raised the price from $1,700 per bottle to $75,000. … So 5,000 [patients] paying [for] bottles at the new price is $375,000,000—almost all of it is profit, and I think we will get 3 years of that or more. Should be a very handsome investment for all of us.”

Daraprim was developed in 1953 and treats toxoplasmosis, an infection that can lead to brain and organ damage, blindness and death in infants and adults with compromised immune systems, such as AIDS sufferers. Turing sells Daraprim for $750 a pill. Outside of the US, it can cost as little as 10 cents a dose. Turing’s analysis of the drug reported that physicians would be “at a loss to think of an appropriate alternative” to Daraprim. Another pre-acquisition report stated that the drug could generate 30 times their annual revenue, an estimated $180 million.

Pharmaceutical companies established patient assistance programs in calculated efforts to control and maximize market share, running these programs like customer retention departments. For example, vouchers were distributed to insured patients to help cover their insurance co-pays, discouraging patients from publicly criticizing the drugs’ inaccessibility and ensuring continued revenue from the insurance company, which picked up the rest of the bill. The pharmaceutical industry spent $7 billion on co-pay assistance in 2015, compared to $1 billion in 2010. In Valeant’s case, their patient assistance program actively monitored social media to mitigate negative publicity.

Pharmaceutical companies skirted federal regulations that require them to provide discounted prices to certain pharmacies and other health care providers that serve patients on state-funded health care programs, such as Medicaid and Medicare. Turing executive Michael Smith instructed employees to start disputing such claims for Daraprim. Rodelis commissioned a presentation from the consulting firm Avalere Health, which gave advice on “limiting 340B exposure”.

Nearly 60 percent of Americans, and 90 percent of seniors, many of whom are on fixed income, take prescription drugs. In 2016 alone, $328 billion was spent on prescription drugs, with $50 billion in patient out-of-pocket costs. Spending on prescription drugs increased by 11.5 percent in 2012, in contrast to the average 1.8 percent annual increases in the previous nine years. Hospitals, also burdened with rising drug prices, have been forced to experiment with alternative treatments and develop new protocols as they stock less of their preferred drugs. Not-for-profit hospitals have been forced to cut community health programs to offset budget shortfalls, or to close entirely.

The report ends with toothless proposals to “keep the marketplace competitive” by establishing an expedited process to approve generic drugs, or to allow certain drugs to be imported temporarily. None of the companies or their executives have been found criminally liable for financially—and in some tragic cases, physically—crippling hundreds of the sick and dying.

Generic drugs, which make up 89 percent of the prescriptions dispensed in the US, are also not immune from price-hikes from pharmaceutical companies. At least 300 generic drugs doubled in price from 2009 to 2014, and 48 of those drugs increased in price by at least 500 percent.