

Executive summary

Introduction

The following bipartisan report is the result of an 18-month investigation launched by Senate Finance Committee Ranking Member Ron Wyden, D-Ore., and Senator Chuck Grassley, R-Iowa, a senior member of the Finance Committee. The inquiry sought information on how Gilead Sciences, Inc. determined the price for its breakthrough Hepatitis C drugs, Sovaldi and Harvoni in order to understand the impact of that pricing decision on the United States health care system.

At the end of 2013, Gilead brought to market Sovaldi, also known as sofosbuvir, which fundamentally changed the standard of care for individuals with Hepatitis C (HCV), a blood-borne virus that affects as many as 5.2 million Americans by attacking the liver. Until recently, the most common treatment for HCV was built around interferon, a drug that many people could not tolerate because of its severe side effects. In addition, the cure rate for interferon was not high enough to justify widespread treatment for the HCV population. The result was a practice known as “warehousing” in which diagnosed individuals were told to wait for treatment until they were very sick or more effective drugs were developed. By the time Sovaldi entered the market, there was pent-up demand for an effective treatment. Although Sovaldi still required the limited use of interferon for many patients, Gilead’s new class of drugs was the first to offer more effective treatment, and it priced its treatment regimen at a premium.

Findings

Gilead’s own documents and correspondence show its pricing strategy was focused on maximizing revenue—even as the company’s analysis showed a lower price would allow more patients to be treated. This applied to Sovaldi as well as its follow-on drug Harvoni, which is now viewed as the simplest treatment for HCV on the market today because of its one-pill-a-day regimen. Over the eight months Gilead spent determining the price of Sovaldi, the company repeatedly made clear its primary focus was outmaneuvering potential competitors to ensure its drugs had the greatest share of the market, for the highest price, for the longest period of time. And the investigation found that before and after the introduction of Sovaldi to the market, Gilead underestimated the reaction to its price, the number of people who would be treated, and the cost to public and private payers. During its pricing process, Gilead also considered what price it could set without risking “external factors,” such as public outrage, media attention, and congressional inquiries—potentially diminishing the drug’s reputation or revenue potential.

Gilead acquired its sofosbuvir-based drugs through the multi-billion dollar acquisition of Pharmasset, Inc. in 2012, and spent hundreds of millions of dollars more completing clinical trials and FDA approvals. Review of company documents reveals that the return on investment for acquiring Pharmasset and additional research and development were not key considerations in determining the pricing of these drugs.

The \$84,000 price tag significantly affected patient access. Many public and private health care payers adopted substantial restrictions. At least 27 state Medicaid programs—including Iowa and Oregon—restricted Sovaldi’s use to only the sickest patients because of the drug’s price and the cumulative cost of treating HCV patients. Likewise, private insurers instituted strict access controls for the drug.

When presented with these substantial access restrictions and requests by both public and private payers for increased rebates or discounts to reduce the cost of HCV treatment for their respective patients, Gilead offered supplemental rebates and discounts of minimal value (on the order of 10% if all access restrictions were lifted

for Medicaid, for example, which would have resulted in challenging budget choices for many states). Only a handful of payers accepted these additional reductions. When payers sought additional discounts from the company, Gilead rejected them.

Additionally, while Sovaldi has significantly improved cure rates for the most common variety of Hepatitis C, genotype 1, for other genotypes, rates were lower and required much longer treatment, at a wholesale price as high as \$168,000. Gilead did not take meaningful steps to price or discount its drugs to help those individuals.

When launching Harvoni, Gilead essentially executed the same revenue-maximizing strategy it used for Sovaldi, even though it was aware that such an approach could cause similar access challenges. Company documents show Gilead always intended to extract a premium for this follow-on, all oral drug. By elevating the price for the new standard of care set by Sovaldi, Gilead intended to raise the price floor for all future HCV treatments, including its follow-on drugs and those of its competitors.

Gilead's expectations were confirmed when AbbVie entered the market with its similarly effective drug Viekira Pak just below Gilead's prices. Gilead was able to maintain pricing power until major pharmacy benefits manager Express Scripts entered into an agreement with AbbVie to make Viekira Pak its preferred HCV drug. Gilead quickly entered into its own agreements with other major benefits managers and payers, including CVS Caremark and Anthem, with what appear to have been substantial discounts. Industry sources have estimated these discounts to be on the order of 40% from the list price, although due to their confidential nature, those discounts have not been confirmed.

Impact and Next Steps

Despite the increased discounts in 2015, the costs to America's health system have been dramatic. In the first nine months of 2015, Gilead had \$10.1 billion in sales from Sovaldi and Harvoni in the U.S. alone. Already, that is almost more than what was spent on all HCV drug treatment in all of 2014. In the 18 months following Sovaldi's approval, Medicare spent nearly \$8.2 billion before rebates on Gilead's HCV drugs. Medicare Part D spent more on these drugs in the first six months of this year than it did in all of 2014. With respect to Medicaid programs, 29 states said Sovaldi was the most or second most costly pharmaceutical outlay for their programs. The result was treatment for just 2.4% of Medicaid enrollees believed to have HCV in 2014.

The findings of the report highlight several challenges facing the U.S. health care system and pharmaceutical drugs. As such, Senators Wyden and Grassley have raised the following policy questions for public debate, with the goal of improving wider access to effective and affordable drug treatments:

- 1) What are the effects of a breakthrough, single source innovator drug on the marketplace?
- 2) Do the payers in the programs have adequate information to know the cost, patient volume, and increases in efficacy of a new treatment regimen?
- 3) What role does the concept of "value" play into this debate, and how should an innovative therapy's value be represented in its price?
- 4) What measures might improve price transparency for new higher-cost therapies while maintaining incentives for manufacturers to invest in new drug development?
- 5) What tools exist, or should exist, to address the impact of high cost drugs and corresponding access restrictions, particularly on low-income populations and state Medicaid programs?