US Senate report details high prices of Hepatitis C drugs

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A US Senate report released on Tuesday criticized US drugmaker Gilead's pricing strategy of its hepatitis C drug, Sovaldi.

The report is the result of an 18-month investigation based on 20,000 pages of internal company documents, dozens of interviews, and data from Medicaid programs.

According to internal company documents, Gilead looked at a price range for a single treatment of Sovaldi of between $55,000 and $115,000, finally settling on $84,000 or $1,000 per pill.

This price was set to establish a floor for its next wave of even higher-priced drugs, such as its combination hepatitis C treatment Harvoni, priced at $94,500 for a course of treatment. As a company document states, "value capture opportunity is in Wave 1," and "Wave 2 access will be enhanced with a high Wave 1 price."

In the 18 months following Sovaldi's approval by the FDA in December 2013, Medicare spent nearly $8.2 billion before rebates on Sovaldi and Harvoni (approved in October 2014), resulting in a sixfold increase in spending on hepatitis C treatments. The company reported $20.6 billion in sales after rebates in the 21 months after the introduction of Sovaldi.

According to company documents, Gilead estimated that worldwide spending on hepatitis C treatments in 2008 was $2.4 billion; by 2014, sales of Gilead's hepatitis C drugs alone stood at $12.4 billion.

The prices of these drugs were set in order to maximize revenue for the company—at the highest prices the company thought the market would bear—with no regard to patient access. Even when the company was made aware of significant restrictions to patient access due to the price, the company refused to offer substantial discounts.

For example, although Medicaid programs spent $1.3 billion before rebates in 2014 on the medication, less than 2.4 percent of the estimated 700,000 Medicaid enrollees with hepatitis C were treated with Sovaldi.

"Gilead pursued a calculated scheme for pricing and marketing its hepatitis C drug based on one primary goal, maximizing revenue, regardless of the human consequences," said Senator Ron Wyden on the release of the report.

"There was no concrete evidence in emails, meeting minutes or presentations that basic financial matters such as R&D costs or the multibillion-dollar acquisition of Pharmasset, the drug's first developer, factored into how Gilead set the price. Gilead knew these prices would put treatment out of the reach of millions and cause extraordinary problems for Medicare and Medicaid, but still the company went ahead," Wyden said.

Hepatitis C (HCV), the most common blood-borne virus in the US, attacks the liver and can result in cirrhosis, liver cancer and liver failure. It affects as many as 5.2 million people in the United States. According to the Centers for Disease Control, 19,368 Americans died from HCV in 2013.

After HCV was first identified in 1989, it was treated with interferon-alpha, and later in combination with the antiviral drug ribavirin, approved in 1998. However, only about half of HCV patients could tolerate the side effects of the therapies.

This was followed by the development of direct-acting antiviral (DAA) drugs, including Victrelis (boceprevir) and Incivek (telaprevir), approved in 2011, and Olysio (simeprevir) and Sovaldi (sofosbuvir), approved in 2013. These drugs improved the sustained virological response of patients and reduced the required treatment time for most patients, allowing for less interferon use.

Both Sovaldi (sofosbuvir) and Harvoni (a combination of sofosbuvir and ledispavir) reduced treatment time and increased the likelihood that patients would be cured. Harvoni eliminated the need for interferon completely for patients with a particular genotype of the disease.

Sovaldi was largely developed in the labs of the biotech company Pharmasset, located on the outskirts of Atlanta, Georgia. The company was launched in 1998 by medical researchers from Emory University and signed licensing agreements for drug candidates discovered by university scientists. Between 2008 and 2011, Pharmasset spent $62.4 million researching and developing Sovaldi, known then as PSI-7977.

Gilead Sciences, a large biotech company founded in Foster, City California in 1987, began acquisition talks in 2011 and eventually acquired Pharmasset in 2012 for $11.2 billion, largely based on the promise of Sovaldi as a revolutionary new HCV treatment.

Gilead placed its own R&D costs for sofosbuvir-based regimens at $880.3 million. This figure is higher than the actual costs associated with Sovaldi because it also includes the costs of three other related compounds under testing. Gilead refused to provide the costs associated with Sovaldi alone, despite repeated requests from Senate investigators.

According to papers filed with the Securities and Exchange Commission in 2011, Pharmasset planned to sell Sovaldi for $36,000 per treatment (and no higher than $55,000), significantly lower than Gilead's $84,000 price tag. The Senate report found that Gilead believed that its purchase of Pharmasset would be profitable if the drug was priced at $65,000—$20,000 less than the ultimate selling price.

The exorbitant pricing of Sovaldi and Harvoni follow the general trend of drug pricing by the pharmaceutical industry.

According to the latest research report published by the American Association of Retired Person's Public Policy Institute, the prices for 115 specialty prescription drugs widely used by older Americans increased by 10.6 percent in 2013, well above the general inflation rate of 1.5 percent.