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# Sovaldi: Pricing of New Products and Consequences

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**Abstract**. This case provides students with a specific example of a new product introduction, hepatitis C treatment, Sofosbuvir (brand name Sovaldi), introduced by Gilead to market in 2013, at a price of $1,000 per pill. The 12-week course of treatment amounted to the total cost of $84,000 and captured a lot of public and regulatory attention. Most of public criticism directed at Gilead was focused on lack of fairness in pricing as well as lack of transparency. As a result of this public attention, the U.S. Senate conducted public hearings in 2015, resulting in the company's internal and confidential documentation becoming publicly available. This case relies on these disclosed documents and the Senate Hearing Report. It provides students with an example of how prices in prescription drug markets are shaped in the context of the prescription drug industry, its various forces, stakeholders, and regulations. It further shows arguments and dynamics weighted by Gilead's management in deciding to proceed with a premium pricing strategy. This case can be used alone or in combination with a reading, "A Lecture on the Pharmaceutical Industry in the United States".

**Keywords:** prescription drug pricing, cost-effectiveness analysis (CEA), cost-benefit analysis (CBA), health technology assessment (HTA), hepatitis C, Sovaldi, Gilead Sciences

## 1. Introduction

The pricing of prescription drugs is one of the most important decisions pharmaceutical companies make when introducing new drugs in the markets. Pricing of prescription drugs has recently captured a lot of regulatory and public attention and has been criticized on account of lack of transparency and fairness. A case in point is Sofosbuvir (brand name Sovaldi) from Gilead Sciences, a breakthrough in hepatitis C treatment.[1]

When Sovaldi was introduced to markets in 2013, Gilead Sciences charged around $1,000 per pill, which amounted to approximately $84,000 for a 12-week course of treatment, making it the highest-grossing drug launch in history (Loftus

1. Our case is heavily based on the U.S. Senate hearings documentation available at https://www.finance.senate.gov/ranking-members-news/wyden-grassley-sovaldi-investigation-finds-revenue-driven-pricing-strategy-behind-84-000-hepatitis-drug

2014). Unlike other antiviral drugs that manage and slow the progression of the disease, Sovaldi in combination with other drugs cured 90% of the patients in 12 weeks (McQuaid, Savini and Seyedkazemi 2015). This new treatment regimen significantly increased patients' quality-adjusted life-years (QALYs) as one of the measures used in this industry to assess patients' utility. Based on QALYs, billions of savings could be generated in the long run (Rein, Wittenborn, Smith, *et al.* 2015).

The information regarding the marketing and pricing process of a prescription drug is typically kept confidential. However, due to its extremely high price, the Senate investigation by Democrat Ron Wyden of Oregon and Republican Charles Grassley of Iowa (U.S. Senate Committee on Finance 2015) gave the public a rare chance to examine Gilead Sciences' pricing process of Sovaldi. Relying on the Senate Hearing Report and the company's internal documents disclosed during this investigation, this case examines Sovaldi's pricing and the specifics of pricing in the prescription drug markets.

The learning objectives ask that students apply their knowledge of prescription drug markets, their dynamics, various stakeholders and regulations to the analysis of Sovaldi's pricing policy, as one of the most important market outcomes. This case can be used alone or in combination with the following reading, "A Lecture on the Pharmaceutical Industry in the United States". We first present the background and the context of important factors in the hepatitis C disease and its treatment in the U.S. Next, we present processes and methods used by Gilead resulting in the premium price at the point of introducing Sovaldi to the market and finish with the conclusion.

## 2. Sovaldi: Background and Market for Hepatitis C Treatment

An estimated 2.7 to 3.9 million people in the U.S. have hepatitis C (CDC 2016). Left untreated, it can lead to liver cancer and liver failure. It is the leading cause of liver transplants in the U.S. (CDC 2016). There are seven different genotypes of the hepatitis C virus. Depending on the genotype, it requires different treatment regimens and medications (Murphy *et al.* 2015). About 70% of hepatitis C patients in the U.S. are genotype one. For decades, Interferon was the only treatment available. It had a low success rate, required weekly injections, and came with many side effects. In the late 90s, antiviral drugs were being discovered and approved by the FDA, though the success rate was still low, and available treatments had similar side effects.

In 2007, Michael Sofia, working at a small biotech company, Pharmasset, developed Sovaldi, a chemical originally discovered for HIV treatment (Gounder 2013). Pharmasset was founded in 1998 by scientists from Emory University in Atlanta. Its main research focused on HIV and hepatitis viruses. Sovaldi was approved by the FDA to treat genotypes 1, 2, 3 and 4, either alone or often in