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Sovaldi: The Greatest Threat Yet to Sustainable Drug Pricing

Sovaldi, an important new treatment for hepatitis C, has sparked outcries from patient advocates, physicians, lawmakers, and public and private payers because of its unusually high price tag. While steep prices for “orphan” drugs used in small populations are not unusual, the pricing of Sovaldi, for which the patient population numbers in the millions, has raised alarms across the health care sector. Sovaldi alone threatens to change the math on prescription drug costs.

Sovaldi – Most Profitable Drug of All Time?

Gilead, Sovaldi’s manufacturer, has priced a 12-week course of treatment at \$84,000, or \$1,000 per pill. Even this cost under-estimates the real costs of treatment, since Sovaldi is often prescribed in concert with other drugs that can easily raise the cost to \$150,000 for a 12-week course.ⁱ

Sovaldi is on pace to become the highest grossing drug ever, outshining Lipitor – considered the best-selling drug in history. Used to treat high cholesterol, Lipitor was prescribed to more than 29 million people in the United States and has generated \$140 billion in cumulative revenues.^{ii,iii} At its peak, Lipitor reached \$13 billion in annual sales, but only in 2006 after a decade on the market.^{iv,v} *Sovaldi, at \$1000 per pill, is 200 times more expensive than Lipitor. It is estimated that Sovaldi will achieve close to \$10 billion in sales in 2014 alone.*^{vi} Gilead reported Sovaldi sales of \$2.27 billion in the first quarter of 2014, beating Wall Street analysts’ estimates by more than \$1 billion; Gilead reported profits of \$2.2 billion over the same time period, compared to \$722.2 million in the same quarter a year earlier.^{vii} *If this sales trend continues, Gilead will essentially recoup its total investment in Sovaldi in the first year.*^{viii}

On Course for Disaster

To put these numbers in perspective, if all individuals infected with hepatitis C in America – an estimated 3.2 million people^{ix} - were treated with Sovaldi, the cost of the Sovaldi alone *would exceed the annual spend on all other brand name drugs combined.*^x The U.S. Centers for Disease Control and Prevention (CDC) estimates that 75 percent of those who are infected with hepatitis C are unaware of their status.^{xi} To help ensure that those infected know they have it and take appropriate action to combat it, the CDC recommends that those who are at increased risk get tested;



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further, it recently issued new guidelines to recommend that all baby boomers – those born between 1945 and 1965 – be screened.^{xii}

Improving rates of detection is an absolutely critical first step towards helping those with hepatitis C, but it is equally important from a public health perspective that we ensure that Americans who are infected have access to appropriate treatment. At the current price, Sovaldi is outright unaffordable for most Americans. With the U.S. median household income at \$53,046,^{xiii} paying for Sovaldi eats up almost 2 years' worth of income.

Americans are the only consumers who are faced with this high price. Gilead is pricing Sovaldi more cheaply in other well-developed nations; for instance, it reported a 12-week course of treatment is priced at \$66,000 in Germany.^{xiv}

It is the norm that Americans often pay the highest prices for prescription drugs of any nation, including well-developed nations, despite many of the manufacturers, including Gilead, being based in the U.S.

Sovaldi is not the first drug to cause sticker shock when it comes to market, but it is the first drug to be priced at such a premium for such a broad population. In fact, insurers and pharmacy benefits managers (PBMs) are reporting that Sovaldi is in their top 5 in spending in the first quarter of 2014, even though it has not yet been widely prescribed.

Spending on high cost drugs, such as “specialty drugs” used to treat complex, often less common conditions, is rising rapidly, year by year, even as spending on “traditional” drugs slows.^{xv} Over the past few years, spending on specialty medications has continued to increase 15-20 percent each year.^{xvi} Spending on specialty drugs in the U.S. in 2012 was about \$87 billion and is estimated to quadruple by 2020, reaching about \$400 billion, or 9.1 percent of national health spending.^{xvii} Currently, only 4 percent of Americans take a specialty drug, but the spending associated with these drugs represents a quarter of all drug spending in the U.S. It is estimated that specialty drug spending will rise to be 50 percent of overall drug spending by 2020.^{xviii}

A growing proportion of drugs that are awaiting FDA approval or that are in development are specialty drugs, and experts expect that many will approach or even surpass Sovaldi's \$84,000 price tag. In fact, some already are: four specialty drugs approved by the FDA in 2012 have an annual cost of more than \$200,000 per patient.^{xix}

The rise of specialty drugs is changing the way we manage chronic disease and Sovaldi is in many ways a harbinger of the impact high-cost specialty drugs will have



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on the health care system in the long term. Once used to treat rare conditions, specialty drug treatments have grown to include more common, chronic conditions. Fifteen years ago, there were 10 specialty drugs on the market; today there are 300.^{xx} In 2008, 25 percent of drugs approved by the FDA were considered specialty drugs; today, 50 percent of the new drugs approved by FDA are specialty drugs.^{xxi}

Sovaldi differs dramatically from other high-cost specialty drugs that predominantly target rare diseases. It also does not require special handling or administration as is the case with most specialty drugs – it's a pill. In fact, it is estimated to cost only a few hundred dollars to manufacture.^{xxii} The only thing that makes it different from any other mass-marketed drug is its inflated price tag. So, why are Americans forced to pay \$84,000 for a course of treatment?

Essentially, drug pricing is based on market power. U.S. patent law gives manufacturers the exclusive right to manufacture and sell their products for a period of time so that they may reap the reward of their innovation. That system has generally worked well, producing effective treatments for many illnesses that were once untreatable. However, when a new medicine is considered more effective than previous therapies there is considerable demand and that, combined with the exclusivity, allows the manufacturer a great deal of market power in setting the price. *In some cases, as with Sovaldi, that market power is abused.*

The Risk to Our Pocketbooks

Sovaldi will be paid for, in some form or another, by most Americans, either through higher insurance premiums or through taxes that fund federal and state health care programs. Sovaldi is not priced so that the average American could afford it, without using their insurance. So, having insurance becomes vital for people who need access to Sovaldi, but insurance also masks the real cost of the drug. With out-of-pocket limits for most people in the \$6,000 range, the majority of the \$84,000 is paid by a consumer's insurance company and state and federal health care programs.

But of course, their share of the costs is ultimately funded by consumers' premiums and taxes. These additional costs for Sovaldi that are being borne by insurers and government health programs are already taking a toll – Medicaid managed care plans are asking for additional state funds to pay these costs, and Medicare Part D plan premiums are expected to increase next year. In month and years to come, not just those with Hepatitis C, but every segment of the American public will be impacted by Sovaldi and other high-cost treatments.

In the private sector, one study estimated that in order to pay for every person infected with hepatitis C to get Sovaldi, premiums would have to increase by \$600 a year.^{xxiii}



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The Medicare program too will face serious costs from Sovaldi's excessive price. The baby boomers now swelling the program face increased risk for Hepatitis C due to blood transfusions that occurred before the blood supply was regularly screened for Hepatitis C, further contributing to Medicare's financial challenges.

Finally, the financial impact of hepatitis C on Medicaid, the state-federal program which serves children, the disabled, seniors in nursing care and the poor, could be even more serious. A substantial portion of hepatitis C-infected individuals are eligible for Medicaid; however, with Medicaid already consuming 16 percent of state budgets,^{xxiv} and states already strapped for cash, it is not clear where funding for Sovaldi will come from. Covering Sovaldi for states means that other services will be impacted – either within the Medicaid budget or from other public programs.

Together, these impacts represent a real burden to American health care and the American economy. Yet all the while, pharmaceutical manufacturers enjoy double-digit profits, with no accountability to the American taxpayer.

Wanted: Sustainable Innovation

Gilead has argued that Sovaldi offsets other health care costs. However, the evidence suggests otherwise. A recent study by the California Technology Assessment Forum (CTAF) attempted to understand the savings, or budgetary offsets, that payers might see from patients receiving Sovaldi. After five years (assuming 50 percent of those with hepatitis C were treated) the report estimates we would only see *only a 10-20 percent offset in savings* from the cost of the drug. Even after 20 years the report estimates the drug would still fall short of offsetting its initial cost.^{xxv} In fact, the higher the percentage of the population that is treated the worse the budget picture looks. Because of its high cost and the potentially catastrophic impact to the state Medicaid budget, the CTAF recommended that provider organizations and payers consider prioritizing patients who have some evidence of liver fibrosis.

Conclusion

Because of its exceptionally high price, its importance to public health, and its broad patient population, the new hepatitis C medication, Sovaldi, has called into question the sustainability of drug pricing.

Health care innovation, in all its forms, is critically important in order to improve our Nation's health. The development of a new medicine, device, or treatment option for those facing the burden of disease promises hope for a better, healthier future. However, for progress to be sustainable it can't come at a prohibitively high price. There is a delicate social contract in place that allows drug manufacturers to reap



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significant financial rewards, but they must sometimes exercise restraint if that contract is to remain in place.

The advent of the Sovaldi era forces us to ask ourselves how we can foster an environment that creates innovative medicines and technologies to improve the lives of Americans, but in a way that achieves equitable access to these live-saving treatments without punishing the rest of the health care system or diverting money away from other important national priorities.

Hepatitis C Background

Hepatitis C is an infectious disease caused by the hepatitis C virus (HCV). It is the most chronic blood borne infection in the U.S. and the CDC estimates 3.2 million Americans are living with chronic hepatitis C.^{xxvi} Worldwide an estimated 130-150 million people are infected.^{xxvii} Left untreated, the infection leads to scarring of the liver that can cause liver cirrhosis and cancer; approximately 12,000 die annually from HCV-related liver disease in the U.S.^{xxviii} Hepatitis C infection is the most common cause for liver transplants in the U.S.^{xxix}

Hepatitis C is divided into six distinct genotypes with multiple subtypes in each genotype class. A genotype is a classification of a virus based on the genetic material in the RNA (Ribonucleic acid) strands of the virus. In general, patients are only infected with one genotype, but each genotype is actually a mixture of closely-related viruses called quasi-species. These quasi-species have the ability to mutate and become immune to current treatments making chronic Hepatitis C difficult to treat.^{xxx}

Genotype 1 is the most common type of hepatitis C genotype in the United States and the most difficult to treat. Identifying the genotype is helpful in making treatment recommendations. Genotypes 2 and 3 respond better to treatment regimens with alpha interferon or the combination of alpha interferon and ribavirin. Duration of treatment is also dictated by genotype. Genotypes do not change during the course of treatment, so once identified, it is not necessary to be tested again.^{xxxi}

Sovaldi is the first drug in a new wave of breakthrough treatments of hepatitis C. In 2013, the FDA approved Sovaldi to treat hepatitis C virus infections in individuals diagnosed with HCV infections.^{xxxii,xxxiii} Sovaldi is effective in treating individuals with HCV genotypes 1, 2, 3, or 4 infections, including those with hepatocellular carcinoma (awaiting liver transplantation) and those with HCV/HIV-1 co-infection.

Sovaldi is considered a direct-acting agent, meaning that it interferes directly with the hepatitis C virus life cycle by suppressing viral replication. When taken as prescribed, Sovaldi has been shown to cure 90 percent of HCV infections, far



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exceeding cure rates for established treatments (60 percent cure rates). The fact that Sovaldi can be used as an interferon-free therapy substantially reduces the potential side effects associated with current HCV treatments that include interferon.

The majority of infected persons are unaware of their infection status because they do not feel ill. Symptoms of liver disease and other HCV-related diseases may not appear until decades after initial exposure. However, infected individuals unknowingly serve as a source of transmission of hepatitis C. It is recommended that anyone at high risk for exposure be screened for HCV infection. In 2013, both the U.S. Preventive Services Task Force and CDC recommended HCV screening for adults born between 1945 and 1965; it is thought this group had a high risk of HCV exposure in the 1970s and 1980s.

ⁱHumer C. "Insurers, Medicaid fear multibillion HepC price tag." Reuters, Mar. 4, 2014. Available at: <http://www.reuters.com/article/2014/03/04/us-health-hepatitis-idUSL1N0M10Z720140304>. Accessed on: May 16, 2014.

ⁱⁱPfizer, Inc. "About Lipitor." Available at: <http://www.lipitor.com/about>. Accessed on: May 16, 2014.

ⁱⁱⁱLabban M. "Is Sovaldi the new Lipitor?" IMS Healthcare and Pharma Blog, Apr. 16, 2014. Available at: <http://healthcare.blogs.ihs.com/2014/04/16/is-sovaldi-the-new-lipitor/>. Accessed on: May 16, 2014.

^{iv}See Labban M. "Is Sovaldi the new Lipitor?" IMS Healthcare and Pharma Blog, Apr. 16, 2014. Available at: <http://healthcare.blogs.ihs.com/2014/04/16/is-sovaldi-the-new-lipitor/>. Accessed on: May 16, 2014. Also see, Loftus P. "Lipitor: Pfizer aims to sell over-the-counter version." The Wall Street Journal, Mar. 2, 2014. Available at: <http://online.wsj.com/news/articles/SB10001424052702304071004579410930136742414>. Accessed on: May 16, 2014.

^vCenterWatch. Lipitor. Available at: <https://www.centerwatch.com/drug-information/fda-approved-drugs/drug/1194/lipitor-atorvastatin-calcium>. Accessed on: May 18, 2014.

^{vi}Peterson K. "Gilead's blockbuster sales leave investors stunned." CBS News, Apr. 22, 2014. Available at: <http://www.cbsnews.com/news/gileads-blockbuster-sales-leave-investors-stunned/>. Accessed on May 16, 2014.

^{vii}Barber J. "Gilead Sciences first-quarter profit nearly triples on better-than-expected sales of Sovaldi." First Word Pharma, April 22, 2014. Available at: <http://www.firstwordpharma.com/node/1204849?tsid=33>. Accessed on: May 16, 2014.

^{viii}The development rights to Sovaldi were purchased by Gilead, which paid \$11 billion to purchase Pharmasset, the company that held those rights. See Heavey, S. "Drug industry group defends rights of Gilead hepatitis drug." Reuters, Apr. 10, 2014. Available at: <http://www.reuters.com/article/2014/04/10/us-hepatitis-gilead-pharma-idUSBREA391I220140410>. Accessed on: May 18, 2014.

^{ix}The U.S. Centers for Disease Control and Prevention. "Hepatitis C information for health professionals." Available at: <http://www.cdc.gov/hepatitis/HCV/Index.htm>. Accessed on: May 16, 2014.

^xIMS estimates that 2013 prescription drug spending in the U.S. was \$329 billion with brands accounting for 71% of that total, or \$233.59 billion. 3.2 million estimated infected individuals treated by Sovaldi at a price of \$84000 would total \$268 billion. Available at http://www.imshealth.com/deployedfiles/imshealth/Global/Content/Corporate/IMS%20Health%20Institute/Reports/Secure/IIHI_US_Use_of_Meds_for_2013.pdf page 40.

^{xi}The U.S. Centers for Disease Control and Prevention. "New CDC vital signs: hepatitis C testing." CDC News Room. Available at: http://www.cdc.gov/media/dpk/2013/dpk-vs-hepatitisC_testing.html. Accessed on: May 19, 2014.

^{xii}Ibid.

^{xiii}U.S. Census Bureau. State and County Quick Facts. Available at: <http://quickfacts.census.gov/qfd/states/00000.html>. Accessed on: May 16, 2014.

^{xiv}<http://www.reuters.com/article/2014/03/21/gilead-sovaldi-idUSL2NOM10UP20140321>

^{xv}"Specialty drugs" do not have a universally accepted definition. They are typically used to treat complex, often chronic, medical conditions, such as autoimmune diseases, and cancer; derived from biologic (cell-based) sources as opposed to chemical compounds; present challenges to administer or store; and, have a high per unit cost (\$600 to greater than \$1,200/month).



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- ^{xviii} "NASP EXPO speakers project strong growth for specialty pharmaceuticals through 2020." Specialty Pharma Journal.com. Available at: <http://www.specialtypharmajournal.com/medical-news/business-news/4895-nasp-expo-speakers-project-strong-growth-in-specialty-pharmaceuticals-through-2020>. Accessed on: May 18, 2014.
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- ^{xxii} <http://www.npr.org/blogs/health/2013/12/30/256885858/-1-000-pill-for-hepatitis-c-spurs-debate-over-drug-prices> and <http://freepdfhosting.com/d4a7e2bba6.pdf>
- ^{xxiii} http://www.ctaf.org/sites/default/files/u119/CTAF_Hep_C_Apr14_final.pdf
- ^{xxiv} <http://www.cbpp.org/cms/?fa=view&id=2783>
- ^{xxv} "The Comparative Clinical Effectiveness and Value of Simeprevir and Sofosbuvir in the Treatment of Chronic Hepatitis C Infection." The Institute for Clinical and Economic Review report for the California Technology Assessment Forum, Apr. 15, 2014. See pages ES6 and ES7. Available at: http://www.ctaf.org/sites/default/files/u119/CTAF_Hep_C_Apr14_final.pdf. Accessed on: May 18, 2014.
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