

114TH CONGRESS }
1st Session }

COMMITTEE PRINT

{ S. PRT.
114-20 }

**THE PRICE OF SOVALDI
AND ITS IMPACT ON THE
U.S. HEALTH CARE SYSTEM**

PREPARED BY THE STAFFS OF RANKING MEMBER RON
WYDEN AND COMMITTEE MEMBER CHARLES E. GRASSLEY

COMMITTEE ON FINANCE
UNITED STATES SENATE

ORRIN G. HATCH, *Chairman*
RON WYDEN, *Ranking Member*



DECEMBER 2015

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Note

This inquiry began as a Senate Committee on Finance investigation when Senator Wyden was Chairman and Senator Grassley was a member of the Committee's Minority. During the course of the investigation, leadership on the Committee changed in January 2015. Both senators instructed their staffs to continue the investigation and produce a staff report to the Finance Committee. All references to "investigative staff" or "staff" refer to the current Minority staff of the Finance Committee and the staff of Senator Grassley.

Introduction

Hepatitis C (HCV) is the most common blood-borne virus in the United States, affecting as many as 5.2 million people.¹ The virus attacks the liver, resulting in inflammation, scarring and cirrhosis, while increasing the risk of liver cancer. Left untreated, HCV can cause serious illness; the disease is the leading cause of liver transplants in the United States. The aggressiveness of the virus makes it a potent public health issue in the United States. The virus is disproportionately concentrated among Americans who are likely to receive health coverage from public payers including Medicaid, Medicare, the Veterans Administration, and the State and Federal prison system.² The high cost of HCV drugs sold by Gilead Sciences, Inc., continues to put tremendous strain on these public payer systems, creating difficult decisions about how to provide medically necessary drugs to patients while staying within budgets. As a result of the high cost of these drugs, many public and private payers adopted access restrictions to control HCV treatment costs, which reduced the number of patients eligible for treatment.

Gilead brought two drugs to market in recent years, Sovaldi and Harvoni, which have improved therapies to cure HCV. Sofosbuvir—the drug that would ultimately reach the market as Sovaldi and used in combination with ledispavir to create Harvoni—was largely developed by Pharmasset, Inc., a pharmaceutical company that was based in Princeton, New Jersey. Gilead acquired Pharmasset in January 2012.

¹Eric Chak et al., *Hepatitis C Virus Infection in USA: An Estimate of True Prevalence*, 31 *Liver Int'l* 1090, 1090–1101 (Sept. 2011), available at <http://www.ncbi.nlm.nih.gov/pubmed/21745274>.

²*Id.* at 1096, Table 6.

Sovaldi and Harvoni have reduced the time needed for treatment to a fraction of what it was five years ago. In addition, the effectiveness of treatment, that is, the probability that a patient will be cured, has increased. The new drugs have resulted in more patients being able to receive HCV therapy with limited or no use of interferon, an injectable drug that complicates treatment because it typically requires visits to a health care provider, and is often accompanied by difficult side effects.

Progress in therapeutics has come at a high cost for both the public and private sectors. Concurrent with drug price increases, greater numbers of providers and patients have been drawn to these new drugs, leading to increased outlays for HCV treatment. In the run-up to launching Sovaldi, Gilead estimated that worldwide spending on HCV treatment in 2008 totaled \$2.4 billion.³ By 2014, Gilead alone reported net product sales of \$12.4 billion for its HCV drugs, primarily from sales in the United States and Europe.⁴ A competitor drug developed by Johnson & Johnson, known as simeprevir, or Olysio, generated sales of \$2.3 billion in 2014,⁵ primarily due to “off label”⁶ co-prescriptions with Sovaldi.⁷

Gilead’s recent financial results show that the company has generated an additional \$14.3 billion in net product sales from its HCV drugs through the first nine months of 2015, bringing its 21-month total for its HCV drugs to \$26.6 billion, \$20.6 billion of which was from sales to U.S. consumers.⁸

An analysis by the consulting firm IMS Institute for Healthcare Informatics (IMS Institute) showed that U.S. spending on Sovaldi in 2014 was \$7.9 billion, and from 2010 to 2013 U.S. spending on all HCV drugs totaled \$7.8 billion. Sovaldi alone accounted for 64% of U.S. HCV drug spending in 2014, which totaled \$12.3 billion, and more than a third of the \$20.3 billion spent that year on new pharmaceutical treatments.⁹ HCV treatments also caused a jump in spending for “specialty therapies,” which the IMS Institute defines in part as “mostly used by specialists and include treatment for cancer and other serious conditions.”¹⁰ According to the IMS Institute, U.S. “specialty medicine spending increased by 26.5% to

³Appendix E, Ex. 1, Gilead Sciences, Inc., *Gilead Liver Disease Therapeutics Strategy Overview: Board of Directors Review* (2011), GS-0019261, at GS-0019265—GS-0019266 (2011).

⁴Gilead Sciences, Inc., Annual Report (Form 10-K), at 59 (Feb. 25, 2015), available at <http://www.sec.gov/Archives/edgar/data/882095/000088209515000008/a2014form10-k.htm>.

⁵Johnson & Johnson, Annual Report (Form 10-K), Exhibit 13, at 5 (Feb. 23, 2015), available at <http://www.sec.gov/Archives/edgar/data/200406/000020040615000004/ex13-form10k20141228.htm>.

⁶The practice of a health care provider prescribing a drug or combination of drugs in a manner outside of what has been officially approved (in the U.S., by the Food and Drug Administration).

⁷Chris Hepp, *Drug Sales Bolster J&J’s Bottom Line*, Phila. Inquirer (Apr. 21, 2014), available at http://articles.philly.com/2014-04-21/business/49268459_1_olysio-gilead-sciences-sovaldi.

⁸Gilead Sciences, Inc., Third Quarter 2015 Financial Results (Form 8-K), Exhibit 99.1 (October 28, 2015), available at

<http://www.sec.gov/Archives/edgar/data/882095/000088209515000031/exhibit991earningspressrel.htm>; Gilead Sciences, Inc., Fourth Quarter and Full Year 2014 Financial Results (Form 8-K), Exhibit 99.1 (Feb. 3, 2015), available at

<http://www.sec.gov/Archives/edgar/data/882095/000088209515000003/exhibit991earningspressrel.htm>.

⁹IMS Institute for Healthcare Informatics, *Medicines Use and Spending Shifts: A Review of the Use of Medicines in the U.S. in 2014*, at 1, 8 (2015) [hereinafter IMS Institute for Healthcare Informatics, *Medicines Use and Spending Shifts*].

¹⁰*Id.* at 8.

\$124.1 billion in 2014; the increase was 16.3% excluding hepatitis C treatments.”¹¹

After the introduction of Sovaldi at end of 2013, millions of Americans had a potentially viable path to a cure, but the price and cumulative cost on the health care system caused roadblocks for many. In response to treatment access and cost issues, Senators Ron Wyden and Charles Grassley sent a letter to Gilead on July 11, 2014, requesting documents and information about how the company determined the price for Sovaldi, the first of its two HCV drugs.

For over a year, investigative staff reviewed more than 20,000 pages of internal company documents provided by Gilead, as well as documents obtained from the Federal Trade Commission (FTC), Food and Drug Administration (FDA), state Medicaid programs, the Centers for Medicare and Medicaid Services (CMS), the Federal Bureau of Prisons (BOP), and other companies. In addition, investigative staff interviewed more than 100 people with expertise in HCV, or who had interacted with Gilead regarding Sovaldi and/or Harvoni. Lastly, investigative staff collected data from Medicaid programs in 50 states and the District of Columbia that provide important information about the breadth of HCV infection for one segment of public payers, and the cost that states faced in order to treat the disease.

Based on all of the information reviewed, it appears that in pricing its line of HCV drugs Gilead may have underestimated the warnings of patient groups, insurers, health care providers, and other organizations about the potential impact that price would have on access. Such warnings were made not only through the media, but directly to company officials, both in private correspondence and various public forums. While publicly saying it prioritized patient access, Gilead set Sovaldi’s price at a level where ultimately many patients would not receive treatment. Sovaldi was on the market for almost a year without serious competitors, allowing Gilead to maintain a high effective price despite efforts by many payers to negotiate volume or treatment discounts or rebates.

The costs incurred by Gilead to bring the drugs to market included its \$11.2 billion purchase of Pharmasset in 2011. Pharmasset performed the initial development of the drug and began the process of FDA approval, which Gilead then completed following the acquisition. Several months after Gilead agreed to buy Pharmasset, a Gilead executive described the acquisition as a “bargain.”¹² The company failed to provide sufficient information to determine how much additional cost it incurred to complete the development, finish the FDA approval process, and bring the drug to market.

This report describes how Gilead set the price for Sovaldi and its follow-on drug, Harvoni. In addition, this report discusses and analyzes the financial and budgetary impacts of Gilead’s pricing decisions on payers—public and private—as well as the resulting access restrictions imposed due to Sovaldi’s cost. And finally, the re-

¹¹*Id.*

¹²Appendix E, Ex. 2, Email from John McHutchison to Matthew Young, Re: Bristol-Inhibitex (Jan. 7, 2012), GS-0010634.

port describes Gilead's response to resultant market forces, including payer access restrictions and competition.

Appendices

Several appendices to the report provide additional information and documents related to the investigation.

Appendix A contains data collected by investigative staff from state Medicaid programs showing the amount of money spent on Sovaldi and Harvoni in 50 states and the District of Columbia, as well as the estimated number of Medicaid clients with HCV in states where the information was available.

Appendix B presents a review of prior authorization restrictions put in place by state Medicaid programs for Sovaldi and Harvoni, as well as a sample of other payers. The study was completed by researchers at the Oregon Health and Sciences University.

Appendix C presents data provided by the Centers for Medicare & Medicaid Services (CMS) on Medicare spending on Sovaldi, Harvoni, and other HCV drugs.

Appendix D contains correspondence and other documents received by the Senators or investigative staff regarding Sovaldi or Harvoni.

Appendix E contains all Gilead documents cited in this report.

Appendix F contains all narrative answers cited in this report from Gilead in response to questions in the July 11, 2014 letter from Senators Wyden and Grassley.

Section 1: Hepatitis C, its Human Toll, Treatment, and the Effect of “Warehousing” on Pharmaceutical Markets

Hepatitis C and Its Human Toll

In 2013, HCV was listed as the cause of death for 19,368 people in the United States.¹³ This number likely underestimates the number of HCV deaths. CDC researchers have found that fewer than 20% of HCV-infected decedents have HCV listed on their death certificates, even though at least 75% of HCV-infected decedents had pre-mortem evidence of serious liver disease.¹⁴ Despite the likely undercounting, a 2012 study reported that the number of HCV-associated deaths was greater than the number of human immunodeficiency virus (HIV)-associated deaths in the United States between 1999 and 2007.¹⁵ This trend has continued in recent years. The virus is a killer not just in the United States, but across the world. Globally, between 130 million and 150 million people have chronic HCV; annually, the virus and related liver disease kill 704,000 people worldwide.¹⁶ In comparison, the World Health Organization (WHO) estimated that in 2010, malaria caused 660,000 deaths, and that in 2011, tuberculosis caused 1.4 million deaths and HIV caused 1.7 million deaths.¹⁷

Prior to the virus’s identification in 1989, HCV was frequently spread through unscreened blood transfusions.¹⁸ The virus is disproportionately concentrated among baby boomers born from 1945 through 1965. In 2011, about 75% of HCV deaths in the United States were among forty-five to sixty-four-year-olds.¹⁹ The CDC estimates that 3.2% of baby boomers are positive for HCV, five times higher than people born prior to 1945 or after 1965. Consequently, in 2012 and 2013, the CDC and the U.S. Preventative Services Task Force recommended that all people born from 1945 through 1965—more than 60 million people—be tested for the virus.²⁰ The virus is most commonly transmitted in the United States through the use of unsanitary needles, leaving intravenous drug users at

¹³Centers for Disease Control and Prevention (CDC), *Surveillance for Viral Hepatitis—United States, 2013*, Table 4.5, at 58, available at <http://www.cdc.gov/hepatitis/statistics/2013surveillance/commentary.htm>.

¹⁴Reena Mahajan et al., *Mortality Among Persons in Care With Hepatitis C Virus Infection: The Chronic Hepatitis Cohort Study (CHeCS), 2006–2010*, 58 *Clinical Infectious Diseases* 1055, 1055–61 (2014).

¹⁵Kathleen N. Ly et al., *The Increasing Burden of Mortality From Viral Hepatitis in the United States Between 1999 and 2007*, 156 *Annals of Internal Medicine* 271, 271–78 (2012).

¹⁶GBD 2013 Mortality and Causes of Death Collaborators, *Global, regional, and national age-sex specific all-cause and cause-specific mortality for 240 causes of death, 1990–2013: a systematic analysis for the Global Burden of Disease Study 2013*, 385 *Lancet* 9963, 117–71 (2015).

¹⁷World Health Organization, *Global Policy Report on the Prevention and Control of Viral Hepatitis in WHO Member States* (2013), available at http://apps.who.int/iris/bitstream/10665/85397/1/9789241564632_eng.pdf?ua=1.

¹⁸Q.L. Choo et al., *Isolation of a cDNA clone derived from a blood-borne non-A, non-B viral hepatitis genome*, 244 *Science* 359, 359–62 (1989).

¹⁹CDC, *Number and Rate* of Deaths with Hepatitis C Listed as a Cause of Death, by Demographic Characteristic and Year—United States, 2007–2011*, available at <http://www.cdc.gov/hepatitis/Statistics/2012Surveillance/Table4.4.htm>.

²⁰Bryce D. Smith et al., CDC, *Recommendations for the Identification of Chronic Hepatitis C Virus Infection Among Persons Born During 1945–1965* (2012), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6104a1.htm>; U.S. Preventative Services Task Force, *Hepatitis C: Screening*, (June 2013), available at <http://www.uspreventiveservicestaskforce.org/Page/Topic/recommendation-summary/hepatitis-c-screening>.

high risk for contracting the disease.²¹ With a growing number of people who inject intravenous drugs, such as heroin or other opiates, rates of HCV infection are increasing, as the recent HCV outbreak reported in Indiana illustrates.²²

Distinct Genotypes Across the World Create Distinct Markets

There are seven different genotypes of HCV and within each genotype, there are sub-genotypes.²³ Each genotype and sub-genotype reacts differently to treatment, and the FDA has approved drug regimens for specific HCV genotypes and sub-genotypes, rather than the entire spectrum of HCV. The current generation of HCV drugs, including Sovaldi and Harvoni, are not “full spectrum” drugs that can treat all genotypes, and they are not an equally effective treatment against all sub-genotypes.

The prevalence of specific genotypes and sub-genotypes varies among different regions of the world. About 70% of HCV cases in the United States are genotype 1, the majority of which are sub-genotypes 1a and 1b. Genotypes 2 and 3 are estimated to account for 16% and 12% of cases in the United States, respectively, while genotypes 4, 5 and 6, in total, account for fewer than 4% of cases in the United States.²⁴ Conversely, in many Middle Eastern and African countries, genotype 4 accounts for more than 90% of HCV infections.²⁵ Genotype 5 is almost entirely contained within South Africa and select countries in Europe and the Middle East.²⁶ Drug manufacturers have concentrated their focus on selling HCV drugs that treat genotypes with prevalence in developed countries.²⁷

HCV Symptoms

A major challenge associated with HCV is its tendency to go undiagnosed, due to its slow progression and tendency to remain asymptomatic for years. These attributes have earned HCV the moniker “the silent killer,” and have contributed to poor surveil-

²¹Centers for Disease Control and Prevention, *Viral Hepatitis Surveillance, United States, 2013*, at 6 (last updated Oct. 19, 2015), available at <http://www.cdc.gov/hepatitis/statistics/2013surveillance/pdfs/2013hepsurveillancerept.pdf> (“HCV is transmitted primarily through percutaneous (parenteral) exposure that can result from injection drug use, needle stick injuries, and inadequate infection control in health-care settings.”); *id.* at 52 (“Of the 955 case-reports that had information about injection drug use, 61.6% (n=588) indicated use of injection drugs.”).

²²Centers for Disease Control and Prevention, CDC Health Alert Network, *Outbreak of Recent HIV and HCV Infections Among Persons Who Inject Drugs* (Apr. 24, 2015), available at <http://www.bt.cdc.gov/han/han00377.asp>.

²³Donald G. Murphy et al., *Hepatitis C Virus Genotype 7, a New Genotype Originating from Central Africa*, 53 *J. Clinical Microbiology* 967, 967–72 (2015).

²⁴See e.g., Jane P. Messina et al., *Global Distribution and Prevalence of Hepatitis C Virus Genotypes*, 61 *Hepatology* 77, 77–87 (2015); M. Michele Manos et al., *Distribution of Hepatitis C Virus Genotypes in a Diverse U.S. Integrated Health Care Population*, 84 *J. Med. Virology* 1744, 1744–1750 (2012), available at <http://www.ncbi.nlm.nih.gov/pubmed/22997077>.

²⁵Sanaa M. Kamal & Imad A. Nasser, *Hepatitis C Genotype 4: What We Know and What We Don't Yet Know*, 47 *Hepatology* 1371, 1371 (2008), available at <http://webhome.weizmann.ac.il/home/liorg/HCV.pdf>.

²⁶N. Antaki et al., *HCV Genotype 5: An Orphan Virus*, 18 *Antiviral Therapy* 263, 263–69 (2012), available at <http://www.ncbi.nlm.nih.gov/pubmed/23111702>.

²⁷Appendix E, Ex. 3, Pharmasset, Board of Directors Meeting, Princeton, NJ (July 21, 2011), GS-0004488; Appendix E, Ex. 4, Gilead Sciences, Inc., Gilead to Acquire Harry (Nov. 19, 2011), GS-0009179, at GS-0009187; Jane P. Messina et al., *Global Distribution and Prevalence of Hepatitis C Virus Genotypes*, 61 *Hepatology* 77, 77–87 (2014), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4303918/>.

lance of the disease.²⁸ A recent study estimated that half of people in the U.S. with chronic HCV are aware they are infected.²⁹ When HCV symptoms do develop, they include easily bleeding or bruising, itchy skin, fluid accumulation in the abdomen (ascites), swelling in the legs, weight loss, confusion, drowsiness, slurred speech (hepatic encephalopathy), and development of spider-like blood vessels on the skin (spider angiomas).³⁰ Approximately 20% of chronic HCV patients, if untreated, will develop cirrhosis.³¹

Hepatitis C remains the leading primary indication for people receiving or waiting for liver transplants.³² The most recent available federal data show that 1,402 patients received transplants in 2012, and 4,612 patients were on waiting lists.³³

Advancing Treatment for Hepatitis C

There is no vaccine for HCV, unlike for Hepatitis A and Hepatitis B. However, in recent years, significant progress has been made in improving standards of care (SOC). The effectiveness of a drug is primarily measured by the speed of viral reduction (early virologic response, or EVR, and rapid virologic response, or RVR) and the percentage of cured patients. A patient is considered cured when blood tests do not detect the virus twelve or twenty-four weeks after treatment, which is called sustained virologic response (SVR).³⁴ Each successive SOC has simplified and shortened treatment regimens, increased effectiveness, and minimized side effects.

HCV treatment relied on interferon for nearly twenty-five years. It is a naturally occurring protein that cells secrete when they are attacked by a virus and was first identified in 1957. Interferon exists in three different forms—alpha, beta, and gamma—and each is used to treat numerous diseases, including cancer, multiple sclerosis, AIDS, and genital warts.³⁵ Interferon works by boosting the immune system to effectively block new cell sites to which a virus could attach. However, interferon has drawbacks, especially when used for prolonged treatment. Interferon treatment requires injections, necessitating weekly or semi-weekly visits to a provider's office or regular access to other health care services. Additionally, interferon causes side effects, including flu-like symptoms, such as

²⁸ Patrick Strudwick, *Hepatitis C: Hunting the Silent Killer*, The Guardian (Feb. 25, 2015), available at <http://www.theguardian.com/society/2015/feb/25/hepatitis-c-hunting-the-silent-killer>.

²⁹ Baligh R. Yehia et al., *The Treatment Cascade for Chronic Hepatitis C Virus Infection in the United States: A Systematic Review and Meta-Analysis*, PLoS ONE (July 2, 2014), available at <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0101554>.

³⁰ Mayo Clinic, *Diseases and Conditions: Hepatitis C* (Jan. 15, 2015), <http://www.mayoclinic.org/diseases-conditions/hepatitis-c/basics/definition/con-20030618?p=1>.

³¹ David H. Spach, *HCV Epidemiology in the United States*, University of Washington, Hepatitis C Online (June 16, 2014), available at <http://www.hepatitisc.uw.edu/go/screening-diagnosis/epidemiology-us/core-concept/all#hcv-incidence-prevalence>.

³² United States Department of Health & Human Services, Organ Procurement & Transplantation Network, Scientific Registry of Transplant Recipients, 2012 Annual Data Report: Liver, at 69, 75 (Table 1.3) and 81 (Table 4.7), available at http://srtr.transplant.hrsa.gov/annual_reports/2012/flash/03_liver_13/v2files/assets/downloads/publication.pdf.

³³ *Id.*

³⁴ H. Nina Kim & David H. Spach, *Virologic Responses During Treatment of Hepatitis C*, University of Washington, Hepatitis Web Study, (last updated Oct. 1, 2012), available at <http://depts.washington.edu/hepstudy/hepC/mgmt/viroresponse/discussion.html> (last updated Oct. 1, 2012).

³⁵ *Interferon*, Encyclopedia Britannica Online (Aug. 7, 2009), available at <http://www.britannica.com/EBchecked/topic/290230/interferon>.

fever, fatigue, muscle aches, and myalgia.³⁶ Patients have likened the side effects to having the flu throughout treatment. Many patients cannot tolerate interferon, and thus did not have a viable treatment option.³⁷

Researchers began testing the effectiveness of interferon-alpha (interferon) therapies for HCV in the mid-1980s before the virus was identified and was still known as non-A-non-B hepatitis.³⁸ After the virus' identification in 1989, interferon became the first SOC for those that could tolerate it. Interferon, as a standalone SOC, has a poor SVR rate. A twenty-four-week regimen has an SVR of only 6%, and a forty-eight-week regimen increases the SVR to 16%.³⁹ In 1998, the FDA approved ribavirin, an antiviral drug, for use in combination with interferon for treatment of HCV.⁴⁰ The combination improved the effectiveness of treatment; a twenty-four-week regimen resulted in an SVR of 34%, and a forty-eight-week regimen resulted in an SVR of 42%. Ribavirin further increased the SVR to 54% when combined with pegylated interferon, which combines polyethylene glycol (PEG) with interferon.⁴¹

The next major advance in treatment was the development of direct-acting antiviral (DAA) drugs, which work by attacking specific viral proteins encoded within the virus's RNA. These viral proteins include enzymes such as the NS5B polymerase and NS3/4A protease, as well as the NS5A protein, which is involved in the HCV replication complex. In 2011, the FDA approved two DAAs, boceprevir (Victrelis) and telaprevir (Incivek).⁴² In 2013, the FDA approved two additional DAAs, simeprevir (Olysio) and sofosbuvir (Sovaldi).⁴³ Each successive DAA advanced HCV treatment by maintaining or improving SVR, while also reducing treatment time for most patients, thereby reducing the use of interferon.

The introduction of drugs that could treat patients without interferon critically advanced HCV treatment. Although the FDA approved Sovaldi for use without interferon for genotype 2 and genotype 3 patients, the primary cohort of genotype 1 patients still required the use of interferon and ribavirin with Sovaldi. However,

³⁶Mary L. Filipi et al., *Nurses' Perspective on Approaches to Limit Flu-Like Symptoms During Interferon Therapy for Multiple Sclerosis*, 16 Int'l J. of MS Care 55, 59 (2014), available at <http://ijmsc.org/doi/pdf/10.7224/1537-2073.2013-006>.

³⁷*Id.*

³⁸Jay H. Hoofnagle et al., *Treatment of Chronic Non-A, Non-B Hepatitis with Recombinant Human Alpha Interferon: A Preliminary Report*, 315 New Eng. J. Med. 1575, 1575–1578 (1986), available at <http://www.ncbi.nlm.nih.gov/pubmed/3097544>.

³⁹Doris B. Strader & Leonard B. Seef, *A Brief History of the Treatment of Viral Hepatitis C*, 1 Clinical Liver Disease 6, 6 (2012), available at <http://onlinelibrary.wiley.com/doi/10.1002/cld.1/epdf> [hereinafter Strader & Seef, *A Brief History of the Treatment of Hepatitis C*].

⁴⁰Press Release, Schering-Plough Corp., Schering-Plough Announces FDA Approval of Rebetron(TM) Combination Therapy for Previously Untreated Hepatitis C Patients; Rebetron Combination Therapy Now Approved for Use in Both Previously Untreated and Relapse Hepatitis C Patients (Dec. 9, 1998). Ribavirin was discovered in 1972 and, in addition to treating HCV, treats other RNA viruses. Shane Crotty et al., *Ribavirin's Antiviral Mechanism of Action: Lethal Mutagenesis?*, 80 J. Molecular Med. 86, 86 (2001), available at <http://www.liaa.org/files/Ribavirin-Crotty.pdf>. Ribavirin does not effectively treat HCV as a monotherapy because it does not reduce the production of HCV RNA, although it does significantly reduce liver damage. *Id.* at 91.

⁴¹Strader & Seef, *A Brief History of the Treatment of Hepatitis C*, at 6.

⁴²VICTRELIS Prescribing Information (2011), available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/202258lbl.pdf; INCIVEK Prescribing Information (2011), available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/201917lbl.pdf.

⁴³OLYSIO Prescribing Information (2013), available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/205123s001lbl.pdf; SOVALDI Prescribing Information (2013), available at <http://www.accessdata.fda.gov/spl/data/24e7ec0a-9f1b-4b63-8e48-53a63cd7c46f/24e7ec0a-9f1b-4b63-8e48-53a63cd7c46f.xml>.

in January 2014, the American Association for the Study of Liver Disease (AASLD) recommended that providers combine Sovaldi with Olysio for patients who could not tolerate interferon-based therapies. This off-label combination comprised approximately one-third of all Sovaldi-based treatments by the second quarter of 2014.⁴⁴ The off-label drug combination further increased the cost of treatment for a portion of the patient population, primarily genotype 1 patients who could not tolerate interferon.

In October 2014, nine months after the AASLD recommendation, the FDA approved Gilead's ledipasvir-sofosbuvir (Harvoni), the first FDA-approved interferon-free HCV therapy for genotype 1 patients.⁴⁵ In November 2014, the FDA approved Johnson & Johnson's application for the AASLD-recommended Olysio-Sovaldi combination,⁴⁶ but use of these drugs and their combination has fallen due to market competition from Viekira Pak and Harvoni⁴⁷ (see slide below).⁴⁸ In December 2014, the FDA approved another interferon-free regimen, consisting of a combination of drugs—ombitasvir, paritaprevir, ritonavir, and dasabuvir (Viekira Pak).⁴⁹ Notably, Harvoni is a single-tablet therapy, whereas Viekira Pak is a multi-tablet therapy.

⁴⁴ Appendix E, Ex. 5, Gilead Sciences, Inc., Miscellaneous powerpoint slides (2014), GS-0019034, at GS-0019036.

⁴⁵ HARVONI Prescribing Information (2014), available at <http://www.accessdata.fda.gov/spl/data/a3f06ce8-e0c0-4d41-9126-c43c94e4c87c/a3f06ce8-e0c0-4d41-9126-c43c94e4c87c.xml>.

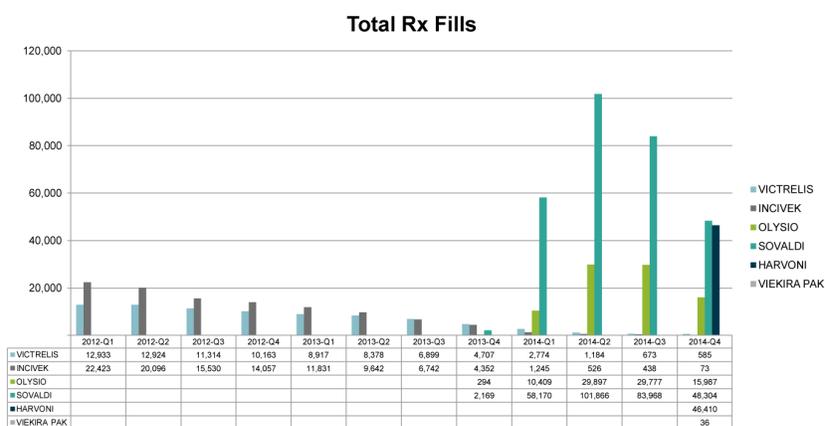
⁴⁶ Anna Edney, *J&J Wins U.S. Approval for Hepatitis C Combo with Gilead*, Bloomberg (Nov. 5, 2014), available at <http://www.bloomberg.com/news/articles/2014-11-05/j-j-wins-u-s-approval-for-hepatitis-c-combo-with-gilead>.

⁴⁷ Olysio generated revenue of \$234 million during the first three months of 2015, an annualized pace of \$936 million, compared to \$2.3 billion in sales during the full year 2014.

⁴⁸ Appendix D, Ex. 1, Email from Ann Walker-Jenkins, Director, Federal Government Affairs, CVS Health Corp., to Peter Gartrell (Mar. 9, 2015), attaching written response to investigative staff, at 6.

⁴⁹ VIEKIRA PAK Prescribing Information (2014), available at <http://www.accessdata.fda.gov/spl/data/045ddc2b-403e-7db2-b3e1-9627632ab3d7/045ddc2b-403e-7db2-b3e1-9627632ab3d7.xml>.

Industry HCV Treatment Trend



Source: IMS data Jan 2012 to Dec 2014

CVSHealth 1

Even after competition entered the genotype 1 market, Sovaldi was the only drug that the FDA had approved to treat genotypes other than genotype 1—its label included indications for the treatment of genotypes 1, 2, 3, and 4 patients. Consequently, Gilead did not face significant competition in the U.S. for genotype 2 or 3 treatments besides the interferon-ribavirin combination, which has significantly worse side effects and, in some genotypes, worse outcomes. On July 24, 2015, the FDA approved daclatasvir (Daklinza) for treatment of genotype 3; however, its label indicates that it should be used in combination with Sovaldi,⁵⁰ which means there remains no standalone competitor. The AASLD has added the Daklinza-Sovaldi combination to its recommended treatment regimens for genotype 1 and 2 patients. In addition, the FDA has approved a combination of ombitasvir, paritaprevir, and ritonavir (Technivie) for genotype 4 patients without cirrhosis.⁵¹

Fibrosis and Patient “Warehousing”

The severe side effects of interferon-based regimens coupled with the anticipation of new, more tolerable treatment regimens, and the slow progression of HCV, caused many providers to advise their HCV patients to wait until more tolerable and effective therapies came to market. This practice is known as “warehousing.” Providers warehoused patients based in part on fibrosis scores, which correspond with declining liver function and range from 0 (no fibro-

⁵⁰ DAKLINZA Prescribing Information (2015), available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/206843Orig1s000lbl.pdf.

⁵¹ TECHNIVIE Prescribing Information (2015), available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2015/207931Orig1s000lbl.pdf.

sis) to 4 (severe fibrosis or cirrhosis).⁵² Warehousing can result in sharply increased demand when an anticipated treatment comes to market. Fibrosis scores played two key roles in the recent debate over HCV treatment in part because low fibrosis scores are an indicator of a patient's ability to forestall treatment. Patients with early stages of the disease (fibrosis scores of 0, 1 or 2) were frequently advised to wait until new drugs were released before beginning treatment. The rationale was that there would be better outcomes for patients who could medically afford to wait on new treatments with shorter durations, higher cure rates, and fewer side effects.

Warehousing had previously occurred in 2000, in anticipation of the FDA's approval of pegylated interferon, and again in 2010, leading up to the approval of DAA medications. Warehousing has been a focus of pharmaceutical makers, Wall Street analysts, and the financial press because pent up demand materially affects revenue when regulatory approvals for improved treatments are anticipated. Such warehousing with HCV medications was noted in 2000 ahead of regulatory approval of pegylated interferon:

One issue is a study released in late October showing that Schering-Plough Corp.'s experimental hepatitis drug Peg-Intron is more effective than the standard treatment for hepatitis C when the drug is combined with ICN's ribavirin. The study compared the combination to the standard therapy of ribavirin and Intron A, a combination sold by Schering-Plough as Rebetron. The study results "have led to some speculation that doctors may be warehousing their patients instead of giving them Rebetron now as they wait for approval of Peg-Intron and ribavirin," Smith said. If that's true, that could lead to a temporary weakness in ribavirin sales, Smith said.⁵³

Again in 2010, warehousing occurred leading up to approval of the first DAA medications:

At Fred Poordad's bustling hepatitis C clinic in the heart of Los Angeles, one in every five patients receives no treatment. They are waiting for a wave of new drugs, expected in the next 18 months, that may boost their chance at a cure by as much as 10-fold. The medicines also may bolster the prospects of Merck & Co., Vertex Pharmaceuticals Inc. and Johnson & Johnson, the companies in a race to get the first new treatment to the market in a decade. About half of patients can't tolerate the side effects of existing therapies, which generate \$2 billion annually in sales. The new drugs could expand the market to \$10 billion in five years,

⁵²Marc G. Ghany et al., *Diagnosis, Management, and Treatment of Hepatitis C: An Update*, 49 *Hepatology* 1335 (2009), available at <http://onlinelibrary.wiley.com/doi/10.1002/hep.22759/abstract>.

⁵³Karen Fessler, *Panic Abandons Plan to Sell 50,000 ICN Shares*, L.A. Times (Dec. 14, 2000), available at <http://articles.latimes.com/2000/dec/14/business/fi-47>.

said Geoff Porges, an analyst for Sanford C. Bernstein & Co. in New York.⁵⁴

With the expected introduction of new, more effective HCV drugs, Pharmasset noted the projected effect of warehousing on the market in financial filings after Gilead announced its intention to buy the company: “Warehousing in 2012 and 2013 results in the 2011 treatment rate being halved for these years. The treatment rate then accelerates in 2014 to twice the 2011 treatment rate and remains stable through the end of the forecast period.”⁵⁵ In a 2013 New York Times article, Dr. Scott Friedman explained the rationale behind the patient warehousing that occurred in anticipation of Sovaldi:

Many doctors are now “warehousing” their hepatitis C patients—urging them to forgo treatment until the new drugs are approved. “There’s no way I’m going to put them on an interferon regimen when we’re a year away from having interferon-free regimens,” said Dr. Scott Friedman, the chief of liver diseases at the Icahn School of Medicine at Mount Sinai. “It’s rare you have to pull the trigger and get them on treatment in that period of time.” Gilead estimates that only 58,000 Americans with hepatitis C are now undergoing treatment, a small fraction even of those who know they are infected. Wanting to avoid interferon’s side effects, some patients without symptoms try to monitor their liver and start treatment only if it shows signs of deterioration. But with the new more tolerable treatments, some experts say, it makes sense to treat early-stage disease to prevent cirrhosis and the accompanying risk of liver cancer.⁵⁶

⁵⁴ Michelle Cortez & Naomi Kresge, *Warehoused Hepatitis C Patients May Boost Merck, J&J*, Bloomberg (Apr. 19, 2010), available at <http://www.bloomberg.com/news/articles/2010-04-18/warehoused-hepatitis-c-patients-may-boost-sales-for-merck-j-j-vertex>.

⁵⁵ Pharmasset, Inc. Amendment No. 2 to Solicitation/Recommendation Statement Under Section 14(d)(4) of the Securities Exchange Act of 1934 (Schedule 14D-9), at 9 (Dec. 20, 2011), available at <http://www.sec.gov/Archives/edgar/data/1301081/000119312511347237/d270458dsc14d9a.htm>.

⁵⁶ Andrew Pollack, *Hepatitis C, A Silent Killer, Meets Its Match*, N.Y. Times (Nov. 4, 2013), available at http://www.nytimes.com/2013/11/05/health/hepatitis-c-a-silent-killer-meets-its-match.html?pagewanted=all&_r=0.

Section 2: Gilead's Acquisition of Pharmasset and the Final Approval Phase for Sovaldi

Pharmasset's Path From University Labs to Hepatitis C Front-Runner

Pharmasset was launched by four medical researchers in 1998, with its first headquarters in a suburb of Atlanta. Soon thereafter, the company signed licensing agreements for drug candidates discovered during university-based research and signed additional agreements with several pharmaceutical companies.⁵⁷

As Pharmasset prepared to become a publicly traded company in 2006, it focused on the clinical development of drugs to treat HIV, Hepatitis B, and HCV.⁵⁸ By 2008, Pharmasset's financial filings showed that it began spending money on pre-clinical studies for PSI-7977, which Gilead would eventually market as Sovaldi, and include as a component of Harvoni.⁵⁹ Between 2008 and 2011, Pharmasset spent \$62.4 million researching and developing PSI-7977.⁶⁰ Those research funds included a federal grant of \$244,479.25 awarded under the Qualifying Therapeutic Discovery Program for development of PSI-7977.⁶¹

Pharmasset executives understood PSI-7977's potential as a drug candidate. More than a year before acquisition talks began with Gilead, Pharmasset executives informed their board of directors that the drug's safety and efficacy profile proved promising in clinical trials, and that PSI-7977 "is less risky than other drugs at this stage of development."⁶² Pharmasset received unsolicited buyout offers from other pharmaceutical companies, prompting the company to engage Morgan Stanley as an advisor.⁶³

Pharmasset executives also continued to press the board for supplemental budget approvals to carry on development of PSI-7977.⁶⁴ Executives discussed and explored ways to turn a small firm focused on research into a company that sold HCV drugs internationally.⁶⁵ According to an internal slide presentation, the FDA told the company on August 18, 2011 that PSI-7977 "could enable [a] rapid transition away from interferon AND ribavirin," and that agency officials "were supportive of a rapid move to monotherapy in order to eliminate both interferon and ribavirin."⁶⁶ On November 6,

⁵⁷ Pharmasset, Inc., Registration Statement (Form S-1), at F-21 (May 8, 2006), available at <http://www.sec.gov/Archives/edgar/data/1301081/000119312506103750/ds1.htm>.

⁵⁸ *Id.*

⁵⁹ Appendix F, Gilead Sciences, Inc., Response to Chairman Wyden/Senator Grassley letter dated July 11, 2014, narrative answer to question 6a (Sept. 9, 2014).

⁶⁰ *Id.*

⁶¹ *Qualifying Therapeutic Discovery Project Grants for the State of New Jersey*, Internal Revenue Service (May 7, 2015), available at <http://www.irs.gov/Affordable-Care-Act/Affordable-Care-Act-Tax-Provisions>.

⁶² Appendix E, Ex. 6, Pharmasset, Board of Directors meeting packet (July 21, 2010), GS-0014970 at GS-0015031—GS-0015039.

⁶³ Pharmasset, Inc. Solicitation/Recommendation Statement Under Section 14(d)(4) of the Securities and Exchange Act of 1934 (Schedule 14D-9) (Dec. 6, 2011), at 8-12, available at <http://www.sec.gov/Archives/edgar/data/1301081/000119312511331226/d265035dsc14d9.htm>.

⁶⁴ Appendix E, Ex. 7, Pharmasset, Board of Directors Memorandum (Sept. 16, 2011), GS-0017760.

⁶⁵ Appendix E, Ex. 8, *Global Commercialization Strategy Update to Pharmasset Board of Directors* (2011), GS-0003852.

⁶⁶ Appendix E, Ex. 9, PSI-7977 Phase II Clinical Trial Data Review (Oct. 3, 2011), GS-0011638, at GS-0011640.

2011, just two weeks before announcing its acquisition by Gilead, Pharmasset publicly unveiled the results of a Phase 2 FDA trial dubbed “ELECTRON,” which showed that PSI-7977 effectively cured all 40 of the genotype 2 and 3 participants, including 10 who had not used interferon.⁶⁷

Jim Meyers, Gilead vice president of North American commercial operations, told investigative staff that the data release was better than Gilead expected. It provided a better view and a more bullish view of all of the variables that came into play, including assumptions about the drug’s launch year, its eventual market penetration, overall disease prevalence and geographic distribution.⁶⁸

Pharmasset’s Phase 2 success with PSI-7977 came against a backdrop of stiff competition. In 2011, the first drugs that directly attacked HCV had been released, and a herd of pharmaceutical companies was racing to be the first with an interferon-free therapy, as described in a 2010 memo from Pharmasset’s executives to its board:

[M]ost big pharmaceutical companies with antiviral franchises are expecting HCV to be the next big antiviral market and are placing a strong emphasis on quickly establishing market leadership through the use of direct acting antivirals to improve the efficacy of current therapy with the hope of decreasing the duration of interferon therapy. This will be quickly followed by combinations of direct acting antivirals in hopes of eliminating interferon therapy.⁶⁹

Given the promising data from clinical trials and the potential market for improved HCV therapies, Pharmasset’s PSI-7977 was well-positioned to be a market leader. Gilead was aware of this potential.

Gilead’s Concern About a Weak Product Pipeline

Gilead was not only concerned about ensuring it could acquire Pharmasset’s promising molecule, it was aware that it could move too slowly and miss the chance to purchase the company in a highly competitive industry. Gilead and its bankers code-named the acquisition “Project Harry,” with the companies named after characters from the children’s novel *Harry Potter*—Pharmasset was referred to as “Harry” and Gilead was “Gryffindor.” In a presentation titled “Introduction to Project Harry” on July 21, 2011, Gilead COO John Milligan stated that “Harry is the best, and most timely, way to bring a nucleotide to Gilead’s portfolio,” and the company was “unlikely to be available a year from now” because it is an “[a]ttractive acquisition for several companies.”⁷⁰

Presentations to Gilead’s board suggest that absent its own promising drug compounds, the purchase of Pharmasset was the

⁶⁷ *Twelve Weeks Interferon-Free PSI-7977 Regimen Cures 100 Percent Hep C Genotype 2/3*, Hep Mag (Nov. 6, 2011), available at http://www.hepmag.com/articles/psi7977_svr_hcv_2501_21405.shtml.

⁶⁸ Interview with Jim Meyers, Senior Vice President, North America Commercial Organization, Gilead Sciences, Washington, D.C. (Dec. 1, 2014).

⁶⁹ Appendix E, Ex. 6, Pharmasset, Board of Directors meeting packet (July 15, 2010), GS-0014970, at GS-0015031–0015042.

⁷⁰ Appendix E, Ex. 10, Gilead Sciences, Inc., *Introduction to Project Harry* (July 21, 2011), GS-0019211, at GS-0019214.

primary route for the company to compete in the HCV market. Barclays summarized the strategic rationale in the days before the acquisition was announced:

- Diversifies Gryffindor’s business outside of **HIV** while leveraging Gryffindor’s area of expertise
- Harry acquisition accelerates Gryffindor’s development program in the treatment of **HCV**
- Harry’s nucleotide analog PSI-7977 and portfolio of nucs have demonstrated potency and effectiveness in 700+ patients without safety or resistance concerns
- Gryffindor’s expertise in anti-viral therapies positions it as the company uniquely capable of maximizing Harry’s **HCV** commercial opportunity⁷¹

More than a year before acquisition talks began, Pharmasset executives presented a case study to the company’s board that succinctly summarized their view of Gilead’s difficulties in HCV drug development:

Today, Gilead is left wondering what to do in HCV. As a result of their lack of success in HCV, they hired John McHutchison to head their Hepatitis development efforts in June 2010. The very clear signals from Gilead and John are that they will be making some strategic moves in HCV.⁷²

The expectation of a strategic move was partially due to Gilead’s own difficulties in developing an HCV drug. As negotiations with Pharmasset began in September 2011, Gilead announced another setback for one of its HCV drugs, GS-9190, forcing the company to alter study protocols after patients in two studies reported adverse side effects.⁷³ A presentation to Gilead’s board of trustees in October 2011 showed that as late as 2010, Gilead had been aiming for a “broad genotypic oral antiviral” in 2020, but that “the competitive nature of the field and speed of development has now compacted the timelines” to within just a few years.⁷⁴ Another presentation showed that Gilead’s advisory board expected an all-oral therapy “very soon,” that “[development] [t]imelines are shrinking rapidly,” and that the “[f]ield is moving very fast; faster than anyone anticipated.”⁷⁵ The presentation stated that Pharmasset was recruiting patients to its clinical trials faster than any other company, and concluded that the company “has established the fastest pathway forward with the simplest regimen that is furthest along.”⁷⁶ These presentations made clear that Gilead’s lack of success in its HCV

⁷¹Appendix E, Ex. 11, Barclays, Description of Fairness Opinion (Nov. 13, 2011), GS-0011877, at GS-0011880 (emphasis in original).

⁷²Appendix E, Ex. 6, Pharmasset, Board of Directors meeting packet (July 15, 2010), GS-0014970, at GS-0015031—0015061.

⁷³Press Release, Gilead Sciences, Inc., Gilead Amends Study Design for Ongoing Hepatitis C Clinical Trials That Include GS 9190, Pegylated Interferon and Ribavirin, and Another Direct-Acting Antiviral Agent (Sept. 4, 2011), available at <http://www.gilead.com/news/press-releases/2011/9/gilead-amends-study-design-for-ongoing-hepatitis-c-clinical-trials-that-include-gs-9190-pegylated-interferon-and-ribavirin-and-another--directacting-antiviral-agent>.

⁷⁴Appendix E, Ex. 12, Gilead Sciences, Inc., *Gilead Liver Disease Franchise: BOD Strategic Review* (2011), GS-0019275, at GS-0019285—0019286.

⁷⁵Appendix E, Ex. 13, Gilead Sciences, Inc., *Harry Update* (Oct. 7, 2011), GS-0019236, at GS-0019239.

⁷⁶*Id.* at GS-0019246.

pipeline and its desire to remain competitive increased both the value and importance of acquiring Pharmasset's promising therapies.

The \$11.2 Billion Acquisition of Pharmasset

On January 17, 2012, Gilead Sciences, Inc., announced the completion of its \$11.2 billion purchase of Pharmasset, Inc. Gilead executives were confident in Pharmasset's HCV drug candidate, which was entering the final phase of testing for regulatory approval. However, when the acquisition was first announced on November 21, 2011, it triggered a selloff of Gilead stock, and was panned by financial analysts who deemed the deal as extremely risky:

Investors balked at the deal on Monday, with shares of Gilead falling 9 percent on the announcement. "For Gilead to give up effectively one-third of their value for an unproven asset still subject to significant ongoing clinical risk seems remarkable," Geoffrey Porges, biotechnology analyst at Sanford C. Bernstein & Company, wrote in a note Monday. Thomas Wei of Jefferies & Company estimated that Gilead's sales of hepatitis C drugs would have to reach \$4 billion a year—difficult, but not impossible—to justify the purchase price.⁷⁷

Despite doubts among analysts and investors, Gilead executives were confident that Pharmasset was developing a molecule that would revolutionize HCV treatment by potentially removing interferon from therapy in the future. Furthermore, executives were willing to pay a premium because, as noted above, Gilead's own efforts at developing HCV drugs were not succeeding and were not progressing as quickly as needed to keep up with competitor companies.

Although a company executive told investigative staff that Gilead was taking an extraordinary risk in buying Pharmasset,⁷⁸ documents provided by the company suggest that executives were very confident in sofosbuvir's ability to gain FDA approval. Gilead slides highlighted an "[e]xcellent safety profile (no measureable side effects in any patients to date)" headed into Phase 3 testing as well as high cure and response rates for genotype 1 patients with and without interferon.⁷⁹ The confidence stemmed from months that Gilead, in conjunction with advisors from Barclays and Bank of America, had spent studying the global HCV market and potential revenue streams from a hypothetical "Harry-Gryffindor" acquisition. The acquisition team had studied proprietary financial and research data provided by Pharmasset under non-disclosure agreements, and provided regular reports to executives and the Board of Directors at Gilead.

⁷⁷ Andrew Pollack & Michael J. De La Merced, *Gilead to Buy Pharmasset for \$11 Billion*, N.Y. Times (Nov. 21, 2011), available at <http://dealbook.nytimes.com/2011/11/21/gilead-to-buy-pharmasset-for-11-billion/>? r=0.

⁷⁸ Interview with Jim Meyers, Senior Vice President, North America Commercial Organization, Gilead Sciences, Inc., in Washington, D.C. (Oct. 30, 2014).

⁷⁹ Appendix E, Ex. 13, Gilead Sciences, Inc., *Harry Update* (Oct. 7, 2011), GS-0019236 at GS-0019240.

The information left Gilead's leadership sufficiently convinced of PSI-7977's promise, that the company increased its offer 37% during the 11 weeks spent negotiating the deal—from \$100 per share to the final offer price of \$137 per share.⁸⁰ That was a 59% premium to the all-time high price for Pharmasset stock.⁸¹

John McHutchison, who would be an important player in the eventual pricing of Sovaldi, was deeply involved in the acquisition process. A medical doctor and well-known HCV researcher, McHutchison had been a consultant to Pharmasset before joining Gilead as senior vice president, liver disease therapeutics, and a member of the company's executive team.⁸² Shortly before the deal closed, McHutchison described the purchase of Pharmasset as a "bargain" in an email to Matthew Young at Barclays, which served as Gilead's acquisition advisor. In the same email, dated January 7, 2012, McHutchison wrote that Bristol-Myers Squibb acted in "desperation" when the company paid \$2.5 billion to purchase another small biotechnology firm developing a different HCV drug.⁸³

In 2014, the first year that Gilead marketed Sovaldi and Harvoni, the company reported \$12.4 billion in worldwide HCV sales,⁸⁴ more than three times the amount that Jefferies & Company projected being needed to justify the purchase of Pharmasset. The company expects sales of its HCV drugs to grow in 2015, having reported net product sales of \$14.3 billion during the year's first nine months.⁸⁵

Pharmasset Expected 12-Week HCV Treatment to Cost \$36,000

Gilead's eventual selling price for Sovaldi was substantially higher than what Pharmasset expected to charge. Specifically, after the acquisition was announced, Pharmasset filed with the Securities and Exchange Commission on December 6, 2011, showing it projected to sell PSI-7977 for \$36,000 per treatment regimen in the United States, with discounted prices in the European Union.⁸⁶ Gilead ultimately set the price of Sovaldi at \$84,000 for a single 12-week treatment course, more than twice as high as Pharmasset's public projection at the time the acquisition was announced.

Gilead claims that Pharmasset actually projected a higher selling price than \$36,000. In particular, Gilead's outside counsel directed

⁸⁰ Pharmasset, Inc. Solicitation/Recommendation Statement Under Section 14(d)(4) of the Securities and Exchange Act of 1934 (Schedule 14D-9) (Dec. 6, 2011), at 8–12, *available at* <http://www.sec.gov/Archives/edgar/data/1301081/000119312511331226/d265035dsc14d9.htm>.

⁸¹ Press Release, Gilead Sciences, Inc., Pharmasset, Inc., Gilead Sciences to Acquire Pharmasset, Inc. for \$11 Billion (Nov. 21, 2011), *available at* <http://www.sec.gov/Archives/edgar/data/882095/000119312511317734/d259746dex991.htm>.

⁸² Press Release, Gilead Sciences, Inc., John G. McHutchison, MD, to Join Gilead Sciences as Senior Vice President, Liver Disease Therapeutics (June 8, 2010), *available at* <http://investors.gilead.com/phoenix.zhtml?c=69964&p=irol-newsArticle&ID=1436018>.

⁸³ Appendix E, Ex. 2, Gilead Sciences, Inc., Emails between Matthew Young, Barclays Capital, and John McHutchison (Jan. 7, 2012), GS-0010634.

⁸⁴ Gilead Sciences, Inc. Annual Report (Form 10-K) (Feb. 25, 2015), *available at* <http://www.sec.gov/Archives/edgar/data/882095/000088209515000008/a2014form10-k.htm>.

⁸⁵ Press Release, Gilead Science, Inc., Gilead Sciences Announces Second Quarter 2015 Financial Results (July 28, 2015), *available at* <http://www.sec.gov/Archives/edgar/data/882095/000088209515000022/exhibit991earningspressrel.htm>.

⁸⁶ Pharmasset, Inc. Solicitation/Recommendation Statement Under Section 14(d)(4) of the Securities and Exchange Act of 1934 (Schedule 14D-9) (Dec. 6, 2011) at 32, *available at* <http://www.sec.gov/Archives/edgar/data/1301081/000119312511331226/d265035dsc14d9.htm>.

investigative staff to Pharmasset's amended 14-D filing, which projects a price range of \$36,000 to \$72,000 for U.S. customers, filed on December 20, 2011.⁸⁷ Investigative staff's review of documents provided during the course of the investigation show that Pharmasset's executives and board of directors were presented with this price range immediately before the acquisition was announced, but the \$72,000 price did not appear to play a role as the company considered selling to Gilead.

Documents show that the \$72,000 price for PSI-7977 first appeared on November 18, 2011, three days before the acquisition was announced. That day, Pharmasset CEO Schaefer Price emailed a presentation to the company's board of directors. The presentation states that the "price for 7977 + RBV ranges from \$36,000 (Victrelis only) to \$72K (Incivek + SOC). This does not reflect any price premium or cost savings to payers."⁸⁸ The presentation also states that the then-current cost to treat patients with protease inhibitors ranged from "\$65K to \$74K based on length" of treatment. Importantly, though, the price increases were not included in the presentation's forecast model.⁸⁹

On the same day as the Price email, Morgan Stanley presented slides to the Pharmasset board containing a matrix titled "Pricing Sensitivity—Mgmt. Case."⁹⁰ In this matrix, unit pricing of \$72,000 translates to a price of \$290 per share.⁹¹ This amount per share is more than twice the purchase price the board approved from Gilead less than 72 hours later. This suggests that Pharmasset did not view \$72,000 as a realistic price. Moreover, in that presentation, all of the management cases—downside, base, and upside—used \$36,000 as the price for PSI-7977. The management case "represents management's view of the most probable scenario in light of recent developments in the Hepatitis C landscape."⁹²

Other documents from earlier in the year further demonstrate that Pharmasset had not contemplated pricing PSI-7977 nearly as high as Gilead would eventually price Sovaldi. One document contains a presentation prepared by Morgan Stanley with financial analysis prepared in its advisory role to Pharmasset. These presentations contained a matrix like the one below estimating the per-

⁸⁷ Pharmasset, Inc., Amendment No. 2 to Solicitation/Recommendation Statement Under Section 14(d)(4) of the Securities Exchange Act of 1934 (Schedule 14D-9) (Dec. 20, 2011), available at <http://www.sec.gov/Archives/edgar/data/1301081/000119312511347237/d270458dsc14d9a.htm>.

⁸⁸ Appendix E, Ex. 14, Email from Schaefer Price to Herb Conrad, et al., "FW: Forecast Assumptions," November 18, 2011, GS-0018378; Appendix E, Ex. 15, Pharmasset, Inc., "Adjustments to Forecast Assumptions, Based on Learnings from AASLD" (Nov. 18, 2011), GS-0018379 at GS-0018380. At the time, clinical guidelines recommended using Victrelis (boceprevir) in combination with peg-interferon/ribavirin for 24 to 44 weeks; guidelines recommended that Incivek be used for 12 weeks in combination with peg-interferon/ribavirin, with an additional 12 to 36 weeks of peg-interferon/ribavirin. See Table 2 in Mark G. Ghany et al., *An Update on Treatment of Genotype 1 Chronic Hepatitis C Virus Infection: 2011 Practice Guideline by the American Association for the Study of Liver Diseases*, 54 *Hepatology* 1433, 1433-44 (Oct. 2011), available at <http://doi.org/10.1002/hep.24641>.

⁸⁹ Appendix E, Ex. 15, Pharmasset, Inc., "Adjustments to Forecast Assumptions, Based on Learnings from AASLD" (Nov. 18, 2011), GS-0018379, at GS-0018380.

⁹⁰ A management case is typically the financial model that executives believe is most likely reflective of a company's business on a go-forward basis or the model that management is using to make planning decisions.

⁹¹ Appendix E, Ex. 16, Morgan Stanley, Project Royal Discussion Materials (Nov. 18, 2011), GS-0018382, at GS-0018396.

⁹² *Id.* at GS-0018393.

share value of Pharmasset correlated with the expected prices for PSI-7977 and another drug candidate, PSI-938:⁹³

Pricing Sensitivity - Base Case

\$ / Share

		Price per Unit - 7977		
		\$24,000	\$36,000	\$50,000
Price per Unit - 938	\$24,000	\$84	\$123	\$168
	\$36,000	\$93	\$131	\$177
	\$50,000	\$103	\$141	\$186

The above pricing sensitivity matrix suggests that if Pharmasset expected PSI-7977 to sell for \$50,000, the company would have expected its market value to range from \$13.7 billion to \$15.2 billion—between 22.6% and 35.7% higher than the price that was actually garnered from Gilead.⁹⁴ Similarly, presentations in May 2011 and July 2011 show that the highest price points being discussed in modeling were \$24,000 and \$36,000, the latter of which was dubbed the “management case.”

Lastly, a presentation from September 2011 shows the price of manufacturing PSI-7977 in relation to the price of therapy. While the drug was being manufactured for testing, Pharmasset calculated the production cost to be \$32,000 per kilogram, or \$1 per 1,200-milligram caplet.⁹⁵ Pharmasset expected production costs to be cut by almost two-thirds to \$11,000 per kilogram when commercial-scale operations began.⁹⁶ The presentation shows that manufacturing costs for Pharmasset would be de minimis compared to

⁹³ Appendix E, Ex. 17, Morgan Stanley, Project Royal Discussion Materials (Oct. 6, 2011), GS-0002762.

⁹⁴ To determine this estimate, investigative staff compared the tender price Gilead offered Pharmasset shareholders when the 2011 transaction took place (\$137/share) with the Morgan Stanley pricing sensitivity matrix. *Id.* The matrix projected different share prices for Pharmasset based on prices for PSI-7977 and PSI-938. The column in which PSI-7977 was priced at \$50,000 had a range of share prices as low as \$168 (with PSI-938 at \$24,000) and \$186 (with PSI-938 at \$50,000), which are 122.6% and 135.7% of the tender price. Staff used those percentage differences to multiply the final purchase Gilead paid for Pharmasset (\$11.2 billion) to arrive at a range of \$13.7 billion and \$15.2 billion.

⁹⁵ Appendix E, Ex. 18, Pharmasset, Untitled Presentation by Pharmasset Executives (Sept. 2011), GS-0011557 at GS-0011588.

⁹⁶ *Id.* at GS-0011581.

the revenue each course of therapy would generate—ranging from 0.9% for a \$50,000 course to 1.5% for a \$30,000 course:⁹⁷

PSI-7977 12 week Regimen Cost of Goods

Price per Course of Therapy

API Cost/kg		\$50,000	\$40,000	\$30,000
	\$32,000	2.3%	2.9%	3.9%
	\$11,000	0.9%	1.1%	1.5%

Assumptions:

- Every patient (all genotypes) is treated with 12 week 400mg QD regimen – 84 caplets
- Regimen manufacturing cost (84 caplets) is \$370 @ \$11,000/Kg and \$1075 @ \$32,000/Kg
- Drug product cost is ~\$1 per 400mg caplet
- API cost and price of therapy indicated above

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Thus, it appears that, based on internal presentations given between five months and three days before the announcement of Gilead's acquisition of Pharmasset, Pharmasset did not intend to sell PSI-7977 for prices exceeding \$50,000. In particular, the range that was presented to the board while the acquisition was in its final stages indicate that the financial impacts of the higher end of the drug price range would have meant Pharmasset was substantially undervaluing itself.

**Gilead Did Not Contemplate a Price Above \$75,000
Leading up to Acquisition**

On November 13, 2011, less than two weeks before the deal was announced, Barclays gave a presentation to Gilead that suggests Gilead was considering a price range of \$55,000 to \$75,000 for Sovaldi treatment to ensure suitable financial returns. The presentation referenced a gross price per patient in the United States of \$65,000 and included sensitivity analysis showing the revenue effect of increasing or decreasing the price by \$10,000 (resulting in the \$55,000 to \$75,000 range).⁹⁸ It is important to recognize that the figures in the presentation were projected gross prices, which is the price point before discounting to payers which results in a net price.

⁹⁷*Id.* at GS-0011590.

⁹⁸Appendix E, Ex. 19, Barclays Capital, *Revenue/Valuation Models: Project Harry* (Nov.13, 2011), GS-0013466, at GS-0013467, GS-00013474.

These figures were developed over the course of several months by Barclays in close partnership with a Gilead project team. Emails show that the pricing model had been through numerous iterations with Gilead's employees studying the model for market assumptions with respect to infection rates, cure rates, market share and other data points related to the HCV population domestically and abroad.⁹⁹

Jim Meyers told investigative staff that the molecule's ultimate price was not a major consideration during the run-up to the purchase of Pharmasset.¹⁰⁰ Gilead had a rough but conservative estimate for drug prices, primarily based on the Barclays model.¹⁰¹ Treatment rates, flow of patients and flow of diagnosis were the company's primary concern at that point.¹⁰² Price was not unimportant, but the number of patients was more important to making the deal acceptable.¹⁰³

Meyers referred investigative staff to the last page of a presentation from July 20, 2011, and a summary of assumptions, including an \$80,000 "price-per-cure" (the total cost of prescribing drugs divided by the number of cured patients results in an average price per cured patient), which was based on the price of telaprevir and boceprevir.¹⁰⁴ Price per cure is higher than the price of these drugs because some number of patients taking the drug would not be cured, and the initial treatment regimen required the use of interferon and/or ribavirin to also be administered.¹⁰⁵ That presentation assumed that the gross price of DAA drugs would start at \$63,500, equaling a price per cure of \$80,000.¹⁰⁶ The pricing assumption model showed that the cost-per-cure was projected to increase 3% annually, and assumes an 8% "convenience bump" in pricing when an all-oral, single-tablet drug came to market.¹⁰⁷ This appears similar to the strategy, detailed later in this report, which Gilead employed when it priced Sovaldi and Harvoni. Lastly, Barclays expected that American patients would be charged a premium for HCV treatments, compared to patients in Japan and Europe (see slide below).¹⁰⁸

⁹⁹ Appendix E, Ex. 20, Email from John McHutchison to Jonathan Piazza, Re: Project Pyramid Assumptions (June 21, 2011), GS-0004809; Appendix E, Ex. 21, Gilead Sciences, Inc., *Project Harry—Model Discussion* (Aug 16, 2011), GS-0005511.

¹⁰⁰ Interview with Jim Meyers, Senior Vice President, North America Commercial Organization, Gilead Sciences, Inc., in Washington, D.C. (Dec. 1, 2014).

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ *Id.*

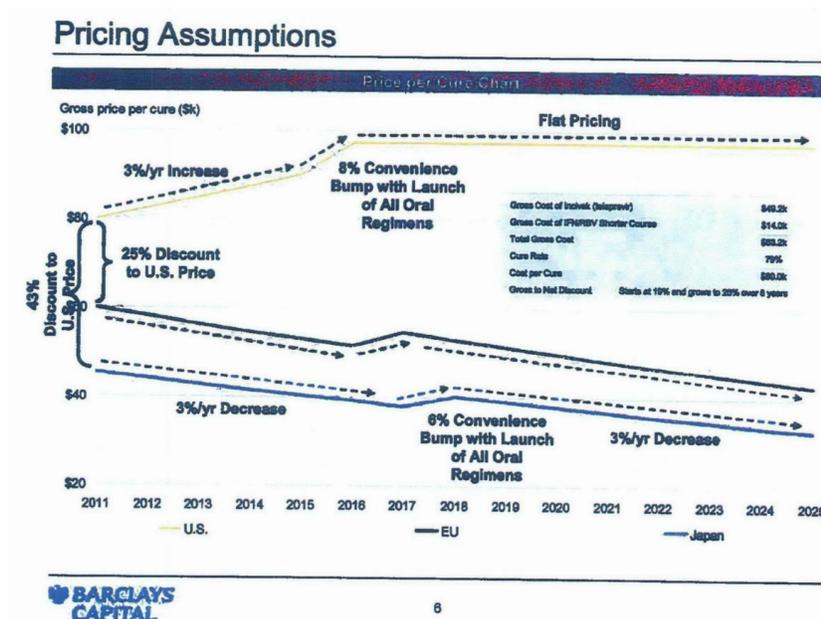
¹⁰⁴ Appendix E, Ex. 22, Gilead Sciences, Inc., *Project Harry—Barclays Deck Backgrounder* (July 20, 2011), GS-0000207, at GS-0000228.

¹⁰⁵ *Id.* at GS-0000214.

¹⁰⁶ *Id.* at GS-0000219.

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*



In sum, as the deal between Pharmasset and Gilead entered its final phase, Gilead executives believed that the purchase of Pharmasset would be profitable if the drug were sold for a gross price ranging from \$55,000 to \$75,000 before sales discounts were applied. A presentation one year after the sale suggests the company expected prices to be at the midpoint—i.e., \$65,000.¹⁰⁹ This was approximately \$20,000 less than what Gilead ultimately chose as the selling price.

Complete R&D Costs for Gilead's Completion of the Approval Process for Sovaldi Were Not Provided

Gilead provided R&D spending data for “sofosbuvir-based regimens,” which include “any compound in R&D that uses sofosbuvir or is combined in development with sofosbuvir.”¹¹⁰ Thus, the spending data may overstate the R&D costs associated with bringing Sovaldi to market because the data includes three compounds in addition to sofosbuvir as a single-agent drug.¹¹¹ Gilead failed to provide costs attributable solely to the development of Sovaldi, despite repeated requests to do so.

¹⁰⁹ Appendix E, Ex. 23, Gilead Sciences, Inc., *Hepatitis C and GS-7977 Development Update*, “HCV Strategy Review,” November 5, 2012, GS-0019442, at GS-0019461–GS-0019462.

¹¹⁰ Appendix F, Gilead Sciences, Inc., Response to Chairman Wyden/Senator Grassley letter dated July 11, 2014, narrative answer to question 12 (Sept. 9, 2014).

¹¹¹ These four combinations were GS-7977 (sofosbuvir as a single-agent drug); GS-7977 in combination with GS-5885 (which would eventually become Harvoni); GS-7977 in combination with GS-5816; and GS-7977 in combination with GS-9813. Appendix E, Ex. 24, Gilead Sciences, Inc., *2012–2018 Financial Forecast* (Nov. 2012), GS-0019394 at GS-0019413.

Gilead said that its estimated R&D costs for sofosbuvir-based regimens would be \$880.3 million between 2012 and 2014.¹¹² The R&D costs that Gilead provided are detailed in table 1 below:

Table 1—Gilead Sciences’ Research and Development Costs for Sofosbuvir-based Drug Regimens

	2012	2013	2014 (estimated)
Personnel Costs *	\$45,195,000	\$51,770,600	\$74,765,423
Clinical Studies/Contract Research Organization Costs **	\$136,942,698	\$238,986,739	\$242,830,400
Milestones/Licenses	–	\$4,117,281	(\$2,907,678)
Overhead Allocations/Facilities Costs/Materials and Supplies	\$27,859,182	\$29,339,061	\$31,367,638
Total	\$209,996,871	\$324,213,681	\$346,055,782
Total 2012–2014			\$880,266,334

Source: Gilead Sciences, Inc.

* Gilead does not track expenses related to personnel costs, overhead allocation, facilities costs, and materials and supplies by therapeutic product candidate. Gilead estimated expenses by allocating based on a percentage of total employee headcount.

** Section 14.1 of Sovaldi’s FDA label states “The safety and efficacy of SOVALDI was evaluated in five Phase 3 trials in a total of 1724 HCV mono-infected subjects with genotypes 1 to 6 chronic hepatitis C (CHC) and one Phase 3 trial in 223 HCV/HIV-1 co-infected subjects with genotype 1, 2 or 3 CHC.”¹¹³

As noted above, Pharmasset spent \$62.4 million between 2008 and 2011 researching and developing PSI-7977. Combined, this totals \$942.4 million. Gilead did note in its response to the senators’ letter that additional costs were expected for post-market release studies, but Gilead failed to detail those costs.¹¹⁴

By comparison, while negotiating its eventual sale to Gilead, executives for Pharmasset presented the company’s expected drug development costs for fiscal year 2012 (which began October 1, 2011):

Our budgeted development program expenses are \$125.0 million for fiscal 2012, up \$72.7 million from \$52.3 million in fiscal 2011. The main drivers of this substantial increase in our development expenses is the advancement of PSI-7977 into four Phase 2b studies (including the Phase 2b QUANTUM study), as well as 3 Phase 3 studies, and the advancement of PSI-938 into the QUANTUM study.¹¹⁵

¹¹² Appendix F, Gilead Sciences, Inc., Response to Chairman Wyden/Senator Grassley letter dated July 11, 2014, narrative answer to question 12 (Sept. 9, 2014).

¹¹³ SOVALDI Prescribing Information, Section 14.1 (2013), available at <http://www.accessdata.fda.gov/spl/data/24e7ec0a-9f1b-4b63-8e48-53a63cd7c46f/24e7ec0a-9f1b-4b63-8e48-53a63cd7c46f.xml>.

¹¹⁴ Appendix F, Gilead Sciences, Inc., Response to Chairman Wyden/Senator Grassley letter dated July 11, 2014, narrative answer to question 12 (Sept. 9, 2014).

¹¹⁵ Appendix E, Ex. 25, Pharmasset, Inc., Board of Directors Packet (Oct. 11, 2011), GS-0017925, at GS-0017956.

Specifically, development costs for PSI-7977 were budgeted by Pharmasset to be \$90.5 million.¹¹⁶ In the same presentation, Pharmasset executives projected that the Phase 3 studies for PSI-7977—the final clinical development needed for regulatory approval that Gilead was primarily engaged in after the merger—would total \$125.6 million.¹¹⁷

The spreadsheet on the following page provides specific, quarterly costs that Pharmasset budgeted for these studies.

¹¹⁶*Id.*

¹¹⁷*Id.* at GS-0017966.

	FQ1 '12 Budget	FQ2 '12 Budget	FQ3 '12 Budget	FQ4 '12 Budget	F '12 Budget	F '11 Actuals	Diff Ov (Und)	Total Study Costs
Development Programs								
PSI-7977								
DMPK, Tox & Other	\$ 963	\$ 943	\$ 766	\$ 587	\$ 3,259	\$ 3,117	\$ 142	
Phase 1 & Clin Pharm	2,339	1,101	1,288	900	5,628	4,765	863	
Phase 2b - early studies	1,185	754	534	330	2,803	9,215	(6,412)	
Phase 2b - ATOMIC	2,615	1,670	1,156	693	6,134	9,465	(3,331)	
Phase 3 - Study 1	3,769	7,102	7,492	8,094	26,457	743	25,714	\$ 54,077
Phase 3 - Study 2	428	3,124	5,624	6,588	15,764	-	15,764	\$ 36,286
Phase 3 - Study 3		428	3,672	7,146	11,246	-	11,246	\$ 35,278
Phase 3b - Rollover				500	500	-	500	
Phase 3b - Health Economics				500	500	-	500	
API	7,251	4,088	5,137	1,729	18,205	10,339	7,866	
	<u>18,550</u>	<u>19,210</u>	<u>25,689</u>	<u>27,067</u>	<u>90,466</u>	<u>37,644</u>	<u>52,852</u>	
PSI-938								
DMPK, Tox & Other	792	303	418	616	2,129	2,145	(16)	
Phase 1 & Clin Pharm	2,540	2,223	3,669	2,911	11,343	5,035	6,308	
Phase 2b - QUANTUM	3,421	4,541	4,205	5,678	17,845	2,251	15,594	\$ 49,480
API	1,557	1,605	31	31	3,224	3,966	(742)	
	<u>8,310</u>	<u>8,672</u>	<u>8,323</u>	<u>9,236</u>	<u>34,541</u>	<u>13,397</u>	<u>21,144</u>	
PSI-661								
	-	-	-	-	-	1,289	(1,289)	
Total	<u>\$ 26,860</u>	<u>\$ 27,882</u>	<u>\$ 33,992</u>	<u>\$ 36,303</u>	<u>\$ 125,037</u>	<u>\$ 52,330</u>	<u>\$ 72,707</u>	

Gilead's Development Timeline Benefited from FDA Policies

Sovaldi was one in a series of HCV therapies that benefited from FDA policies designed to shorten the R&D process and broaden access to potentially lifesaving therapies (See Table 2). In the case of Sovaldi, the compressed timeline meant Gilead was afforded an opportunity to sell its therapy in the U.S. with minimal competition in the genotype 1 market for nearly a year.

Little more than a month before acquiring Pharmasset in 2011, Gilead executives reported to the board that changes to FDA standards regarding HCV testing protocols would benefit the purchase of Pharmasset and speed up the eventual approval of sofosbuvir. The agency would no longer require SVR to be tested 24 weeks after treatment ended. Instead, it would require an SVR follow-up at just 12 weeks.¹¹⁸ Furthermore, studies using placebo-controlled trials would be accepted. As a result, Phase 3 studies would be “simpler and faster.”¹¹⁹ Gilead executives believed that the probability of successfully reaching the market increased along with the “truncated timelines for approval.”¹²⁰

By November 2012, McHutchison reiterated to the board that “the timelines have shortened considerably for both GS-7977 as a single agent and GS-7977 combinations,” in a presentation that referred to additional conversations with the FDA (when Gilead acquired Pharmasset, the PSI-7977 became GS-7977). A presentation made on the same day first referenced the company's expectation that a new drug approval (NDA) for GS-7977 would be submitted by April 2013, and approval achieved by December of that year.¹²¹

In 2013, the FDA granted GS-7977 both “breakthrough therapy designation”¹²² and GS-7977 “priority review”¹²³ status. The priority review, granted in June 2013, expedited the approval of Sovaldi.¹²⁴ The breakthrough status broadened the label's treatment indication, as Martin explained in a memo that was drafted for the board of directors:

As highlighted by John McHutchison and Bill Symonds during our meeting last month/earlier this month, the FDA granted Sovaldi a Breakthrough Designation, which

¹¹⁸ Appendix E, Ex. 26, Gilead Sciences, Inc., *Harry Update: Board Meeting* (Oct. 24, 2011), GS-0019309, at GS-0019311.

¹¹⁹ *Id.*

¹²⁰ Appendix E, Ex. 13, Gilead Sciences, Inc., *Harry Update: Board Meeting* (Oct. 7, 2011), GS-0019236, at GS-0019244.

¹²¹ Appendix E, Ex. 23, Gilead Sciences, Inc., *Hepatitis C and GS-7977 Development Update*, November 5, 2012, GS-0019442, at GS-0019443, GS-0019469.

¹²² The agency implemented the process based on instruction in the Food and Drug Administration Safety and Innovation Act of 2012 to “implement more broadly effective processes for the expedited development and review of innovative new medicines intended to address unmet medical needs for serious or life-threatening diseases,” Pub. L. No. 112-144, § 901(a)(1)(C), 126 Stat. 993.

¹²³ Authorized by the Prescription Drug User Act (PDUFA) of 1992, Pub. L. No. 102-571, priority review allows the FDA to act on an NDA within six months of submission, as opposed to the standard 10-month period. The FDA can grant priority review status if the NDA “treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness.” Food and Drug Administration, *Guidance for Industry: Expedited Programs for Serious Conditions—Drugs and Biologics*, at 7 (2014), available at <http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm358301>.

¹²⁴ Press Release, Gilead Sciences, Inc., Gilead Announces U.S. FDA Priority Review Designation for Sofosbuvir for the Treatment of Hepatitis C (June 7, 2013), available at <http://www.gilead.com/news/press-releases/2013/6/gilead-announces-us-fda-priority-review-designation-for-sofosbuvir-for-the-treatment-of-hepatitis-c>.

allowed us to submit data from two additional Phase 3 studies beyond the four Phase 3 trials submitted with the initial New Drug Application.¹²⁵

Martin appeared to be referring to the VALENCE and PHOTON-1 studies.¹²⁶ The FDA’s summary review explained, “VALENCE provided data to support a 24-week treatment duration for GT3 subjects to improve relapse rates and PHOTON-1 provided data to support regimens for HCV/HIV-1 co-infected subjects along with an interferon-free regimen for GT1 subjects.”¹²⁷

Under section 506(a) of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended, breakthrough designation is provided:

if the drug is intended, alone or in combination with 1 or more other drugs, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on 1 or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development.¹²⁸

When considering a breakthrough therapy designation request, the FDA evaluates the quantity and quality of the clinical evidence submitted, available alternative therapies to that drug, and magnitude of treatment effects shown.¹²⁹ For Gilead, expanding the label’s indication meant that Sovaldi would be a viable therapy for more patients, expanding the market for the drug.

Financial documents filed a month after the Gilead-Pharmasset acquisition was announced show that Pharmasset’s management expected that the drug would be launched in the U.S. sometime between the fourth quarter of 2013 and the second quarter of 2015.¹³⁰ The actual December 2013 FDA approval was at the front-end of these projections. The importance of this timing shift is underscored in pricing documents discussed in detail later in this report showing that Gilead officials believed a lack of competition would inform the eventual price for Sovaldi.

Table 2 shows the HCV drugs that received FDA approval.

¹²⁵ Appendix E, Ex. 27, Gilead Sciences, Inc., Email from Cara Miller to Gregg Alton (Nov. 22, 2013), GS-0020826.

¹²⁶ Food and Drug Administration Center for Drug Evaluation and Research, Clinical Pharmacology and Biopharmaceutics Review(s): Application Number: 204671Orig1s000, at 2 (Nov. 22, 2013), available at http://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204671Orig1s000ClinPharmR.pdf.

¹²⁷ *Id.* at 8.

¹²⁸ Food and Drug Administration Safety and Innovation Act Pub. L. No. 112–114, § 902(a)(3), 126 Stat. 995 (2012).

¹²⁹ Center for Health Policy at Brookings, *Breakthrough Therapy Designation: Exploring the Qualifying Criteria* (2015) [hereinafter Brookings, *Breakthrough Therapy Designation*], available at http://www.brookings.edu/~media/events/2015/04/24-fda-breakthrough-therapy-designation/breakthrough-therapy-designation_final.pdf.

¹³⁰ Pharmasset, Inc., Amendment No. 2 to Solicitation/Recommendation Statement Under Section 14(d)(4) of the Securities Exchange Act of 1934 (Schedule 14D–9) (Dec. 20, 2011), available at <http://www.sec.gov/Archives/edgar/data/1301081/000119312511347237/d270458dsc14d9a.htm>. Pharmasset, Inc.

Table 2—HCV Drugs That Received FDA Approval

Drug	Approval Date	Breakthrough Therapy Designation for Approved Indication(s)	Priority Review (Y/N)	Indication(s) Approved
Daklinza (daclatasvir) NDA 206843.	July 24, 2015	No	Yes	For the treatment of hepatitis C virus (HCV) genotype 3 in combination with sofosbuvir.
Technivie (ombitasvir, paritaprevir, and ritonavir) NDA 207931.	July 24, 2015	Yes	Yes	For use in combination with ribavirin for the treatment of hepatitis C virus (HCV) genotype 4 infections in patients without cirrhosis.
Viekira Pak (ombitasvir, paritaprevir, and ritonavir; dasabuvir) NDA 206619.	December 19, 2014	Yes	Yes	For use with or without ribavirin to treat patients with chronic hepatitis C virus (HCV) genotype 1 infection.
Harvoni (ledipasvir and sofosbuvir) NDA 205834.	October 10, 2014	Yes	Yes	For the treatment of chronic hepatitis C (CHC) genotype 1 infection.
Sovaldi (sofosbuvir) NDA 204671	December 6, 2013	Yes	Yes	For the treatment of chronic hepatitis C (CHC) infection as a component of a combination antiviral treatment regimen. [Labeling specifies efficacy established in genotype 1, 2, 3 or 4]
Olysio (simeprevir) NDA 205123	November 22, 2013	No	Yes	For the treatment of chronic hepatitis C (CHC) genotype 1 infection as a component of a combination antiviral treatment regimen.
Incivek (telaprevir) NDA 201917	May 13, 2011	No *	Yes	In combination with peginterferon alfa and ribavirin, the treatment of genotype 1 chronic hepatitis C (CHC) in adult patients with compensated liver disease, including cirrhosis.
Victrelis (boceprevir) NDA 202258.	May 13, 2011	No *	Yes	For the treatment of chronic hepatitis C (CHC) genotype 1 infection, in combination with peginterferon alfa and ribavirin, in adult patients with compensated liver disease, including cirrhosis.

Source: FDA.

Note: *Prior to Food and Drug Administration Safety and Innovation Act and creation of the Breakthrough Therapy designation.

Section 3: The Pricing of Sovaldi

Shortly after Gilead bought Pharmasset, the company's senior officials began to prepare for the release of what they expected to be a blockbuster drug. The documentation reviewed shows that Gilead considered a number of factors in determining a price point for Sovaldi, including costs for the existing standard of care for HCV treatment and setting a high baseline for the next wave of HCV drugs. In addition, during the pricing process, Gilead looked at a range of impacting factors to gauge the likelihood of various "softer issues" at different pricing points, ranging from professional societies including price "asterisks" in their therapy recommendations, to protests from the AIDS Health Foundation or Fair Pricing Coalition, to losing "key opinion leader" endorsements, and even the likelihood of congressional hearings or letters concerning the price of Sovaldi.¹³¹ (See slide below)

The Gilead pricing team concluded that while pricing Sovaldi at \$80,000 to \$85,000 would generate an outcry from advocacy groups and payers, "[t]his price will allow Gilead to capture value for the product without going to a price where the combination of external factors and payer dynamics could hinder patient access to uncomfortable levels."¹³² Ultimately, Gilead was mistaken in some of its key assumptions as many public and private payers quickly reacted and adopted access restrictions.

Gilead did not produce all relevant documents and supporting materials related to pricing as requested, despite the company's assurances of cooperation. Therefore, the staff's analysis of pricing decisions and strategies that follows is necessarily based only on the documents and interviews that were provided by the company and from outside sources.

¹³¹Appendix E, Ex. 28, Gilead Sciences, Inc., Sofosbuvir Pricing and Market Access Assessment, Final Recommendations—July 31st, 2013, GS-0014018, at GS-0014047.

¹³²*Id.* at GS-0014044, GS-0014047—GS-0014050, GS-0014053.

Aside from payer access and physician demand, there are a number of softer issues that could affect Gilead's final pricing decision



Stakeholders	Wave 1 Regimen	\$60,000	\$70,000	\$80,000	\$90,000	\$105,000	\$125,000
	Wave 1 SOF product (12 wks)	\$50,000	\$60,000	\$80,000	\$80,000	\$95,000	\$115,000
	Wave 2 FDC (8 wks or 12 wks?)	\$70,000	\$80,000	\$100,000	\$100,000	\$115,000	\$135,000
Payers	Likelihood of applying directly observed therapy due to high price	Unlikely	Possible	Possible	Possible	Likely	Likely
Physicians	Likelihood of delay treatment of GT-1 TN patients due to pricing	Unlikely	Possible	Possible	Possible	Likely	Likely
	Likelihood of losing some KOL endorsement/support as price too high	Very Unlikely	Unlikely	Possible	Possible	Likely	Likely
	Likelihood of getting rejection on TE patients and delay treatment for all due to misconception of restriction for SOF	Possible	Possible	Possible	Possible	Possible	Possible
Patients and Advocacy groups	Likelihood of AHF, FPC and other advocacy groups reacting negatively to price, and affecting public opinion	Likely	Likely	Very Likely	Very Likely	Very Likely	Very Likely
	Higher out-of-pocket costs (not offset by patient support) could drive patient choice away from SOF, especially AbbVie has great patient support programs	Very Unlikely	Very Unlikely	Unlikely	Unlikely	Unlikely	Possible
	Likelihood of AHF, FPC and other advocacy groups promote AbbVie products due to the relationship and lower price	Unlikely	Unlikely	Possible	Possible	Possible	Likely
Treatment Guidelines	Likelihood of AASLD develop treatment pathway to prioritize (staging) patients (per KOLs or/and professional community request)	Possible	Possible	Possible	Possible	Possible	Possible
	Likelihood of a "price mention or asterisk" in AASLD (per KOLs or/and professional community request)	Unlikely	Unlikely	Possible	Possible	Possible	Likely
Others	Likelihood of public outcry if SOF revenue exceed \$2B as government trying to control healthcare cost	Possible	Possible	Possible	Possible	Likely	Very Likely
	Likelihood of a letter from congress on SOF price	Possible	Likely	Likely	Likely	Likely	Likely
	Likelihood of a congressional hearing if SOF revenue exceed \$2B	Unlikely	Unlikely	Unlikely	Unlikely	Unlikely	Possible

Early Pricing Strategy

By October 2012, the company had Phase 3 trials well underway, and was turning its attention to how it would market Sovaldi. That same month, Gilead laid out objectives for its commercial launch in a working document titled "Gilead HCV U.S. BPOA."¹³³ The document detailed potential customer groups, advertising strategies to reach baby boomers, and "critical success factors for

¹³³ Appendix E, Ex. 29, Gilead Sciences, Inc., Gilead HCV U.S. BPOA (Oct. 2012), GS-0013489, at GS-0013489.

launch.”¹³⁴ As it would for the next 14 months, the company was largely focused on expanding the patient pool that would be treated with sofosbuvir.

In a November 2012 a presentation titled “HCV Strategy Review,” Kevin Young, the company’s executive vice president for commercial operations, referenced a U.S. price of “\$58k vs. \$65k (likely at parity for launch).”¹³⁵ The price in the EU would be “discount to U.S. \simeq 25%.”¹³⁶

On March 25, 2013, Gilead management met and reviewed the results of market data that had been collected in a senior vice president briefing titled “Sofosbuvir U.S. Pricing & Contracting Strategy.”¹³⁷ This meeting was the first of eight scheduled meetings leading to a recommendation to a group of senior executives known as the “global pricing committee” or GPC.¹³⁸

Gilead’s key pricing considerations at this time, as reflected in the documents provided, were comparisons to the costs of existing HCV SOCs, the impact of expected competition on the market for HCV therapies, the increased cost for SOCs longer than the 12-week regimen for genotype 1 patients, and an initial discussion of contracting strategies. The slide on the following page indicates Gilead’s contracting and pricing timeline.

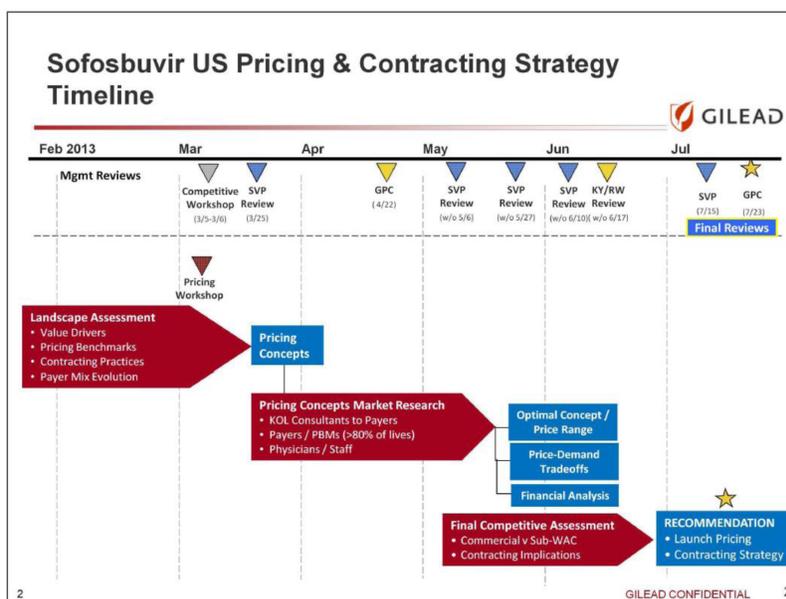
¹³⁴ *Id.* at GS-0013492—GS-0013502.

¹³⁵ Appendix E, Ex. 23, Gilead Sciences, Inc., *Hepatitis C and GS-7977 Development Update*, “HCV Strategy Review,” November 5, 2012, GS-0019442, at GS-0019460, GS-0019462.

¹³⁶ *Id.* at GS-0019462.

¹³⁷ Appendix E, Ex. 30, Gilead Sciences, Inc., *Sofosbuvir U.S. Pricing & Contracting Strategy*, SVP Briefing, March 25, 2013, GS-0019128.

¹³⁸ Gilead failed to provide documents related to the GPC meeting scheduled for April 22 or July 21. Only one SVP review was provided for the month of May, and none in June. The “KY/RW Review,” which stands for Kevin Young and Robin Washington, both senior officials at the company, is referred to on page GS-0019129 of Exhibit 30, but was not provided. *See id.* at GS-0019129. In a letter dated September 30, 2014, Senators Grassley and Wyden asked Gilead’s outside counsel, Mark R. Paoletta, to certify all documents related to these meetings had been provided. Gilead’s counsel failed to certify that the document production had been completed, indicating that many documents remained, and that the request would likely “incorporate hundreds of thousands of emails and documents.” Gilead also failed to provide any documentation of a “SOF Launch Meeting” that the HCV Sales Team was scheduled to convene in November 2013 (referred to in Appendix E, Ex. 31, Gilead Sciences, Inc., *U.S. HCV Launch Update*, August 1, 2013, GS-0014059, at GS-0014068).



According to Meyers, the GPC is a critical intra-corporate body that determined the final price of Sovaldi and other drugs.¹³⁹ The committee typically meets when a material product, such as Sovaldi, is being priced. The GPC is made up of top executives at the company including:

- John Martin, CEO
- Robin Washington, CFO
- John Milligan, COO
- Jim Meyers, Senior Vice President for Commercial Operations, North America
- Kevin Young, Executive Vice President, Commercial Operations (now retired)
- Norbert Bischofberger, Executive Vice President, Research and Development Chief Scientific Officer
- John McHutchison, Executive Vice President for Clinical Research.¹⁴⁰

By the time of the March 2013 presentation, the company had Phase 3 testing data and had begun taking steps to understand the drug's place in the market.¹⁴¹ The company was gathering data relevant for pricing determinations taking into consideration what was currently being paid for similar drugs, discounting, and the concentration of the payer market share. The pricing process was based on four different factors: clinical attributes, value determination, market research with payers, and the cost of current product

¹³⁹ Interview with Jim Meyers, Senior Vice President, North America Commercial Organization, Gilead Sciences, Inc., in Washington, D.C. (Dec. 1, 2014).

¹⁴⁰ *Id.*

¹⁴¹ *Id.*

regimens.¹⁴² The 58-page slide deck prepared for management touched on all of these points and data, while noting that “sofosbuvir will likely rank among the largest launches ever (year 1 sales), driving a doubling in payers’ HCV class expenditures in 2014.”¹⁴³

As part of pricing considerations, Gilead aimed to gain a thorough understanding of how similar drugs on the market were priced.¹⁴⁴ Gilead focused on the genotype 1 market because it makes up roughly 70% of HCV patients in the United States and was a focal point for competing drug companies. As discussed in Section 1 of this report, two protease inhibitors, telaprevir (Incivek developed by Vertex) and boceprevir (Victrelis developed by Merck), had already received FDA approval in 2011. However, Sovaldi was expected to have an edge because clinical studies showed it would provide faster, more effective treatment and reduced time on, or outright elimination of, interferon injections.¹⁴⁵

Gilead used the prices of Incivek and Victrelis as a baseline and evaluated how to price sofosbuvir at a premium to existing therapies.¹⁴⁶ Company officials surmised that its drug had a “value premium” because of increased efficacy and tolerability, shorter treatment duration, and its potential to ultimately be part of an all-oral regimen (as it ultimately would be in combination with ledipasvir in Harvoni).

In a slide titled “Premium Based on Explicit Savings from P/R Duration,” the company used the approximate price of Incivek (\$55,275) as a pricing baseline. Incivek required using interferon/ribavirin for 24 to 48 weeks. Gilead calculated Incivek’s average Wholesale Acquisition Cost (WAC) based on 36 weeks of interferon/ribavirin would be \$82,496.¹⁴⁷ Using this model, Gilead’s clinical and projected “real world” cure rates could justify prices ranging between \$82,000 and \$121,000 for a 12-week course of the drug.¹⁴⁸

The next step was to evaluate competition. Because Incivek and Victrelis would be sidelined by next generation drugs, Gilead anticipated two primary competitors, simeprevir (Olysio) and the “second wave” all-oral drug combination being developed by AbbVie (later launched as Viekira Pak).¹⁴⁹

Another key concern was the timing and order of competitor drug release dates. For example, AbbVie’s all-oral regimen could affect uptake for sofosbuvir, which still relied on interferon and ribavirin, if Gilead’s all-oral offering, Harvoni, had not yet received approval. The presentation also left open the question about what weight Gilead should give to “actual or assumed competitive pricing.”¹⁵⁰ Importantly, the group also weighed how Harvoni’s eventual pricing should affect pricing for the launch of Sovaldi.¹⁵¹

¹⁴² *Id.*

¹⁴³ Appendix E, Ex. 30, Gilead Sciences, Inc., Sofosbuvir U.S. Pricing & Contracting Strategy, SVP Briefing, March 25, 2013, GS-0019128, at GS-0019156.

¹⁴⁴ *Id.* at GS-0019143.

¹⁴⁵ *Id.* at GS-0019133.

¹⁴⁶ *Id.* at GS-0019172, GS-0019173.

¹⁴⁷ *Id.* at GS-0019143.

¹⁴⁸ *Id.* at GS-0019174—GS-0019175.

¹⁴⁹ *Id.* at GS-0019133.

¹⁵⁰ *Id.* at GS-0019136.

¹⁵¹ *Id.*

The clinical data that was included in the presentation showed that Sovaldi would perform better clinically in genotype 1 patients than Olysio, which would be Sovaldi's primary head-to-head advantage until the FDA approved interferon-free regimens.¹⁵² Looking ahead to competition, Gilead recognized that AbbVie's yet-to-be-approved Viekira Pak had shown similar clinical efficacy as Gilead's interferon-free Harvoni (which also was in clinical trials). However, Gilead was confident that the simplicity of its eventual drug—Harvoni would require taking only a single pill per day whereas Viekira Pak required multiple pills—would be more popular with providers and payers.¹⁵³

Gilead surmised that “price and/or contracting may be an important competitive differentiator” for Olysio and Viekira Pak.¹⁵⁴ The company planned to focus on a series of strategic questions over the coming months:

- Is our objective to maximize revenue or volume/share?
- What nominal price range for sofosbuvir should we consider? Are today's PIs [protease inhibitors] a valid reference point?
- How should we think about articulating sofosbuvir's price—in terms of price per cure? Other more or less sophisticated metrics?
- How can we best manage value perceptions of sofosbuvir for those patient groups for which SVR% is lower? Should we evaluate strategies that offer guarantees, e.g., price-per-cure, blended pricing maximum across genotypes?¹⁵⁵

The last of these questions touched in part on the treatment of people with genotype 2 and 3, for which sofosbuvir would be the only DAA to gain FDA approval until the July 2015 approval of Daklinza. The FDA label that was eventually issued recommended that genotype 3 patients use the drug for twice as long as for genotype 1 patients—24 weeks.¹⁵⁶ Using the drug longer meant paying twice as much—a \$168,000 WAC price before additional costs for ribavirin—and an increased likelihood of side effects such as pruritus and asthenia.¹⁵⁷ The March 2013 presentation shows that Gilead anticipated that the headline number for cures—more than 90%—would set a higher expectation for many patients whose actual outcomes were significantly more uncertain.¹⁵⁸ Some patients taking Sovaldi would pay more for a drug that had a lower probability of curing their particular HCV genotype or sub-genotype.¹⁵⁹

Gilead's clinical data showed that the outcomes for genotype 3 patients, particularly those with cirrhosis or who had undergone

¹⁵² *Id.* at GS-0019167, GS-0019168.

¹⁵³ *Id.* at GS-0019166.

¹⁵⁴ *Id.* at GS-0019135.

¹⁵⁵ *Id.* at GS-0019178.

¹⁵⁶ SOVALDI Prescribing Information (2013), available at <http://www.accessdata.fda.gov/spl/data/24e7ec0a-9f1b-4b63-8e48-53a63cd7c46f/24e7ec0a-9f1b-4b63-8e48-53a63cd7c46f.xml>.

¹⁵⁷ *Id.* at Table 3.

¹⁵⁸ Appendix E, Ex. 30, Gilead Sciences, Inc., Sofosbuvir U.S. Pricing & Contracting Strategy, SVP Briefing, March 25, 2013, GS-0019128, at GS-0019167, GS-0019178, GS-0019182.

¹⁵⁹ One of the company's strategic questions in the presentation was: “How can we best manage value perceptions of sofosbuvir for those patient groups for which SVR% is lower? Should we evaluate strategies that offer guarantees, e.g., price-per-cure, blended pricing maximum across genotypes?” *Id.* at GS-0019178.

previous treatment for HCV (“treatment experienced” or “TE”) were far less certain than, for example, patients with genotype 1 who were non-cirrhotic and had never received treatment (“treatment naive” or “TN”).¹⁶⁰ The concerns about treating genotype 3 patients was especially true in March 2013, when Gilead’s pricing team only appeared to be evaluating results for 12 weeks of treatment, which had an SVR of just 56% for genotype 3 patients who were treatment-naive.¹⁶¹ Treatment-experienced genotype 3 patients showed an even lower SVR for 12 weeks—30%—and just 62% for 16 weeks.¹⁶²

Gilead also would have been aware that its drug faced shortfalls in other patient populations. People with subtype genotype1b and cirrhosis had lower SVR rates (82% and 80%, respectively) than those with subtype genotype1a and non-cirrhotic (both at 92%).¹⁶³ For patients facing a liver transplant, the FDA label recommended using Sovaldi with ribavirin for 48 weeks. However, clinical trials showed SVR of just 64% following a transplant.¹⁶⁴ The cost of Sovaldi for those patients alone would be \$336,000 at wholesale prices.¹⁶⁵

Gilead considered adjusting the price downward for patients with genotypes 2 and 3, but ultimately set a single price, regardless of genotype or clinical effectiveness. Meyers would raise this issue with senior executives less than a month before sofosbuvir received FDA approval:

It will be important for us to have a coordinated cross-functional characterization of the price of SOF at launch, regardless of who we’re speaking to (advocacy groups, physicians, payers, Wall Street, etc.). Part of that characterization (not by any means all of it) will be addressing concerns about patients who may require 24 weeks of SOF and thus be subjected to 2X the cost (GT-3 patients, HIV/HCV co-infected patients, etc.). If not handled effectively, this concern could dominate the narrative at launch.

As you know, I raised this concern proactively with some of our closest advisors at AASLD. Below was the helpful advice from Nid Afdhal (which was very similar to that of Ira Jacobson) on how to speak to the fact that some patients may need 24 weeks [sic]

SOF has been developed for a therapy duration of 12 weeks or less, now and in the future. For the first year of launch, there are some patient segments that may benefit from 24 weeks of SOF. We are hopeful that having an FDA approved indication for a longer duration of therapy in

¹⁶⁰ Appendix E, Ex. 32, Gilead Sciences, Inc., 2013–2015 HCV Launch Commercial Plan, April 4, 2013, GS–0013503, at GS–0013509.

¹⁶¹ Appendix E, Ex. 30, Gilead Sciences, Inc., Sofosbuvir U.S. Pricing & Contracting Strategy, SVP Briefing, March 25, 2013, GS–0019128, at GS–0019176.

¹⁶² Appendix E, Ex. 32, Gilead Sciences, Inc., 2013–2015 HCV Launch Commercial Plan, April 4, 2013, GS–0013503, at GS–0013508. The FDA ultimately approved using Sovaldi for 24 weeks in genotype 3 patients.

¹⁶³ SOVALDI Prescribing Information (2013), available at <http://www.accessdata.fda.gov/spl/data/24e7ec0a-9f1b-4b63-8e48-53a63cd7c46f/24e7ec0a-9f1b-4b63-8e48-53a63cd7c46f.xml>.

¹⁶⁴ *Id.*

¹⁶⁵ The wholesale price for Sovaldi is \$84,000 for 12 weeks, and a 48-week prescription would cost four times as much, excluding additional costs for interferon and/or ribavirin.

these subgroups will induce payers to cover SOF and leave a modest cost burden to the patient (that Gilead can cover) [sic]¹⁶⁶

In addition to the wholesale price, the presentation showed the company beginning to consider the question of its contracting strategy with private and public payers. Gilead's data showed that commercial payers accounted for 52% of Victrelis payments and 63% of Incivek payments during the fourth quarter of 2012, with the remaining split among various public payers.¹⁶⁷ Furthermore, as Gilead observed of Incivek and Victrelis: “[t]hrough PIs have been widely contracted, discounts have been relatively small and geared mostly to provide access rather than preferred status.”¹⁶⁸ That led Gilead to ask additional strategic questions:

- Do payers anticipate historic increases in HCV expenditures? If so, how do they intend to control them?
- What should Gilead do to assuage payers' concerns?
- Is contracting a cost of entry in HCV? Should we contract from “day one”? Should our contracting strategy be proactive or reactive? Do we think it's going to be a nominal contract?
- Should we make any “guarantees” to create greater predictability of expenditures for payers?¹⁶⁹

Just as importantly, Gilead recognized that because the Affordable Care Act (ACA) substantially expanded the number of people who qualify for Medicaid, “the percentage of HCV-infected [individuals] with public coverage, specifically Medicare and VA, will grow substantially.”¹⁷⁰ Even at that early stage, Gilead viewed the shift to public payers “as important targets for policy engagement and contracting.”¹⁷¹ The company also was concerned that its average sales price could face “significant downward pressure” due to the Medicaid expansion and transition of baby boomers onto Medicare.¹⁷² The company questioned whether the WAC should incorporate the expectation that prices would be subject to pressure, and whether Gilead would need to engage in “more proactive in contracting with government payers.”¹⁷³

May 2013: The Second Pricing Check-in

Gilead continued its pricing discussions on May 10, 2013, when the Sofosbuvir Pricing & Contracting Strategy Working Team met for “SVP Check-in II.” The meeting was scheduled to last 90 minutes, and included presentations from Abby Ginsberg, a senior manager of marketing sciences at Gilead, and three representatives

¹⁶⁶ Appendix E, Ex. 33, Email from Jim Myers to David L. Johnson, et al., Characterization of SOF pricing at Launch (Nov. 8, 2013), GS-0020772, at GS-0020772—GS-0020773.

¹⁶⁷ Appendix E, Ex. 30, Gilead Sciences, Inc., Sofosbuvir U.S. Pricing & Contracting Strategy, SVP Briefing, March 25, 2013, GS-0019128, at GS-0019159–60.

¹⁶⁸ *Id.* at GS-0019156.

¹⁶⁹ *Id.* at GS-0019157.

¹⁷⁰ *Id.* at GS-0019161.

¹⁷¹ *Id.*

¹⁷² *Id.* at GS-0019163.

¹⁷³ *Id.*

from the consulting firm IMS—Steve Swanson, Tom Baker, and Kevin O’Leary.¹⁷⁴

Based on the documentation reviewed, this pricing check-in was dominated by the results of a study conducted by IMS that was intended to determine an access-optimizing pricing strategy for the drug. The significant themes from this presentation involved Sovaldi’s ability to influence the price of future HCV products; that a price point of \$80,000—\$90,000 would be acceptable in terms of access, even without significant contracting; and pricing concerns for genotype 3 patients and non-standard SOC regimens.

By the time of the May 10 meeting, a strong sentiment had emerged within the company that there was a “clinically justified reason for premium pricing,” according to internal interviews that were highlighted in the presentation.¹⁷⁵ Other views discussed internally included:

- Optimize price for G1 and develop strategies for dealing with G2/3
- Penetrate the market upfront to maximize sofo experience
- Exploring price per cure messaging is critical
- Leave plenty of room in the gross to net assumptions for Wave 2¹⁷⁶

Several anonymous quotes from company officials were included in the presentation slide, such as “Vertex moved the conversation with managed to care [sic] to pricing per cure and I think that we can make that argument better.”¹⁷⁷ That statement likely reflects that until the introduction of protease inhibitors to the market, there had not been a sufficiently effective cure against which a reasonable pricing method could be justified. Now that Gilead was on the cusp of introducing a more effective cure for genotype 1 patients than had previously been introduced, the internal view was that Gilead should follow other companies in using a price-per-cure method (rather than a price-per-regimen method), which would ultimately justify higher unit pricing.

To further pinpoint a price for the product’s market introduction, IMS was hired to “determine the access-optimizing price point for its novel HCV therapy sofosbuvir in support of the brand’s U.S. launch,” with a goal “to anticipate payer access and management strategies for sofosbuvir in order to determine the access-optimizing pricing strategy.”¹⁷⁸ It was charged with gauging the product’s value for providers and payers, developing the expected mix of private and public payers with which Gilead would interact, and prioritizing the most important accounts, both for market access and contracting strategies.¹⁷⁹

¹⁷⁴ Appendix E, Ex. 34, Gilead Sciences, Inc., Sofosbuvir Pricing & Contracting Strategy Working Team, SVP Check-in II, May 10, 2013, GS-0013972, at GS-0013973.

¹⁷⁵ *Id.* at GS-0013976.

¹⁷⁶ *Id.*

¹⁷⁷ *Id.*

¹⁷⁸ *Id.* at GS-0013981.

¹⁷⁹ *Id.*

Meyers told investigative staff that IMS contacted over 90 payers and asked them what value they saw in the proposed label.¹⁸⁰ The communications were made in a double-blind fashion—the client was not aware of the payers’ identities, and vice-versa.¹⁸¹ Payers were presented with clinical attributes and other information about a given drug, but were not provided the name or company developing it.¹⁸²

IMS began its portion of the presentation by highlighting an Express Scripts report that showed drugs used to treat HCV made up less than 1% of Express Scripts’ PMPY (per-member-per-year) drug spending in 2012. With a PMPY of \$7.82, HCV was behind the four most expensive therapy classes—inflammatory conditions (\$50.62), multiple sclerosis (\$37.98), cancer (\$31.93), and HIV (\$20.78).¹⁸³ The relatively low spending on HCV drugs fit into Gilead’s view that HCV was being undertreated and was a potent commercial opportunity. Express Scripts was a bellwether because it is the largest pharmacy benefit manager, as measured by market share.

IMS asked payers not only about Sovaldi, but also anticipated products, Harvoni and AbbVie’s Viekira Pak. In the presentation, IMS described Sovaldi as the first wave of a two-step drug release strategy for Gilead. The second wave would be Harvoni, which would be interferon-free and would compete with Viekira Pak.¹⁸⁴ In the executive summary, IMS laid out top level results of the surveys, first from a clinical point of view:

- Wave 1 sofosbuvir was seen to be a clear winner over the current standard of care in GT-1 and GT-2, while GT-3 was generally not well-received (at least in treatment naive patients)
- AbbVie’s regimen was highly valued, despite the complicated regimen burden, and was favored by payers over IFN-containing regimens, including sofosbuvir Wave 1
- Wave 2 was the unanimously preferred regimen over all profiles tested and was driven by a multitude of clinical factors, including co-infected data, limited side effects, once daily oral dosing, and SVR¹⁸⁵

IMS noted that Managed Medicaid payers “did appear slightly less enthusiastic” about Sovaldi’s clinical attributes.¹⁸⁶ Likewise, while payers recognized a “significant step for advancing HCV treatment,” the expectation of a high price was flagged by three payers that “immediately cited their **concerns that the product would be expensive** due to all the improvements relative to the current treatment options.”¹⁸⁷

The executive summary then laid out “Wave 1 Pricing Strategy,” for Sovaldi:

¹⁸⁰ Interview with Jim Meyers, Senior Vice President, North America Commercial Organization, Gilead Sciences, Inc., in Washington, D.C. (Dec. 1, 2014).

¹⁸¹ *Id.*

¹⁸² *Id.*

¹⁸³ Appendix E, Ex. 34, Gilead Sciences, Inc., Sofosbuvir Pricing & Contracting Strategy Working Team, SVP Check-in II, May 10, 2013, GS-0013972, at GS-0013979—GS-0013980.

¹⁸⁴ *Id.* at GS-0013983.

¹⁸⁵ *Id.*

¹⁸⁶ *Id.* at GS-0013985.

¹⁸⁷ *Id.* at GS-0013986 (emphasis in original).

- Pricing potential varied across payer segments although acceptable pricing with equal access was widely achievable at up to \$80-90K; access will always have a PA [prior authorization] to the label in HCV and a hard step through current products was seen to be quite difficult
- Gilead could feasibly influence AbbVie's pricing by capturing a high price with Wave 1, which is most likely to be the price reference for AbbVie at the time of their launch¹⁸⁸

IMS suggested that pricing at "\$80-90K" was "acceptable" and would provide "equal access."¹⁸⁹ IMS also assumed that AbbVie would enter the market at a high price and that Gilead could capture that price point by entering high as well.¹⁹⁰ The potential price point for AbbVie appears to be a building block for the price Gilead ultimately would use for Sovaldi:

- If AbbVie launches before Wave 2, it will become the new price reference and drive payer reactions to Wave 2 list prices
- Despite the significantly better clinical perception, Wave 2 will likely need to be within a 10-15% price range to AbbVie's regimen to avoid being disadvantaged on access because of equal SVR
- For Wave 2, contracting could be valuable with payers who might prefer AbbVie's 3-DAA based on a lower price; the goal would be to allow Gilead to have equal market access and compete among docs¹⁹¹

The presentation then turned its attention to "Wave 2 Pricing Strategy," for what would eventually be called Harvoni. IMS was even more explicit about the opportunity Gilead had to set a high price if Sovaldi was brought to the market first, and the pricing downside the company faced if it was beaten to the market by AbbVie:

- Gilead's [drug] has the first mover advantage with Wave 1, which gives the possibility to set a higher price reference for the market
- If AbbVie's 3-DAA comes to the market before Wave 2, it will become SoC and Wave 2 will not be able to command a premium over it if equal market access is the goal¹⁹²

These suggested strategies show the importance that market competition likely had on Gilead's approach to pricing and contracting its HCV drugs. The presentation also delved into cost issues regarding non-genotype 1 patients. Although genotype 2, 3, and 4 patients make up a minority (20-25%) of HCV patients in the United States, treatment costs would be much higher given the additional amount of time needed for treatment. For example, at the time, the only other FDA-approved treatment for genotype 3 pa-

¹⁸⁸ *Id.* at GS-0013983.

¹⁸⁹ *Id.*

¹⁹⁰ *Id.*

¹⁹¹ *Id.*

¹⁹² *Id.* at GS-0013992.

tients was 24 weeks of pegylated interferon and ribavirin, which had a wholesale cost of \$18,150; whereas Sovaldi plus pegylated interferon and ribavirin for genotype 3 patients required 24 weeks, pushing the wholesale cost of treatment above \$168,000—more than nine times the previous SOC. This price increase was in the face of concern from payers that genotype 3 trials demonstrated only slight improvements to the then-current standard of care, interferon and ribavirin; the slide characterized the data from trials as “seen to be **weak relative to IFN/Ribavirin alone.**”¹⁹³

IMS added additional detail to its preliminary conclusions regarding how Gilead should engage in a contracting strategy throughout 2014. First, IMS said that “contracting was not seen to be mandatory for sofosbuvir in Wave 1,” and that “access will likely be achieved without active payer engagement via contracting.”¹⁹⁴ Contracting also should only be undertaken as a “sign of good faith.”¹⁹⁵ It suggested a potential contracting approach in which Gilead “[c]ontract only with the high level of control payers that may block Wave 1 at high prices and only implement traditional rebate +/- performance kickers.”¹⁹⁶

Furthermore, for Wave 2, i.e. Harvoni, the potential contract approach was to “[c]ontract selectively only with payers preferring AbbVie to gain equal access and compete for physicians, who will likely prefer Gilead’s easier regimen.”¹⁹⁷ IMS told Gilead that “[p]layers expect significant contracting opportunities when both AbbVie and Wave 2 are on the market due to comparable SVR, which drives payers to see interchangeability,” although “[p]layers would, however, expect Gilead to have to offer less given the improved pill burden.”¹⁹⁸

The IMS consultation may have reinforced the internal view that Gilead’s line of drugs should be sold at a premium price. IMS reported that payers evaluating SVR data had a “very **strong perception of GT-2 data . . . GT-1** was also well-received to nearly all payers though **slightly less so than the GT-2 data,**” and that the “improved dosing/duration” were “very favorable drivers of value.”¹⁹⁹ IMS also reinforced the company’s expectation that it would not compete on price, but instead on its ability to treat patients. Lastly, it shows that Gilead expected the price it set for Sovaldi to be a benchmark from which per-unit prices could increase.

IMS also presented analyses of how Gilead could approach setting a price from a “regimen pricing argument” similar to Gilead’s first SVP Check-In two months earlier. For genotype 1 patients using Incivek, the FDA called for up to 48 weeks of pegylated interferon/ribavirin. The new sofosbuvir regimen would only require 12 weeks—a potential savings of more than \$27,000 at wholesale costs. Instead of passing the potential savings onto payers, IMS suggested an approach in which the savings would be added to sofosbuvir’s topline revenue. IMS calculated that the Incivek reg-

¹⁹³ *Id.* at GS-0013993 (emphasis in original).

¹⁹⁴ *Id.*

¹⁹⁵ *Id.*

¹⁹⁶ *Id.*

¹⁹⁷ *Id.*

¹⁹⁸ *Id.*

¹⁹⁹ *Id.* at GS-0013985 (emphasis in original).

imen would cost \$95,766²⁰⁰ of which roughly \$35,000 could be attributed to interferon and ribavirin. That left roughly \$25,000 of “potential savings capture” from the shorter regimen of interferon and ribavirin that could be added to sofosbuvir’s price. On the slide, IMS noted:

- Sofosbuvir will clearly benefit from **comparison to the current triple regimen cost** because of shorter duration and less INF/ribavirin [sic]
- Payer price sensitivity toward regimen costs **compels a choice** of pricing strategy **that maximizes revenue for a single regimen**
- Generally, payers will look at the **cost of single agents** in terms of PMPM²⁰¹ **for underwriting purposes**, but the **P&T**²⁰² will certainly consider course of therapy²⁰³

The potential \$85,000 price was included in tables with three other price benchmarks—less than \$67,000, \$100,000, and more than \$120,000—showing how commercial, Medicaid, and Medicare payers might restrict access at different price points. Across each of the payer categories, access for genotype 1 patients became increasingly restrictive as the price rose. However, IMS concluded that “most payers are willing to accept at least \$85k for GT-1 before considering additional access restrictions over the current PIs.”²⁰⁴ Payers were more reluctant to accept that cost for genotype 2 and 3 patients where data showed relatively minor improvements in terms of cure rates.²⁰⁵ As IMS summarized, “GT-2/3 posed more difficulties to payers at the tested price points, and GT-3 in particular pushed many payers to look for heavy restrictions or block sofosbuvir completely.”²⁰⁶

In a third table summarizing potential prices for Harvoni’s eventual release, IMS concluded “[s]ofosbuvir in Wave 2 was widely seen as achieving a \$100K price point although the competitive implications of AbbVie pricing will clearly influence achievable pricing.”²⁰⁷

The IMS view on pricing strategy was built at least partly on the experience that other drug companies had in introducing earlier HCV treatments, which IMS used as a case study.²⁰⁸ For example, in 1998 the Schering Corporation introduced Rebetron, which combined interferon and ribavirin in a single package.²⁰⁹ IMS observed that “through aggressive price increases, Schering doubled the cost

²⁰⁰ IMS used 12 weeks of Incivek plus 48 weeks of ribavirin and interferon as a reference. See *id.* at GS-0014017.

²⁰¹ “Per Member Per Month” is a calculation of the monthly average cost of services provided to individuals.

²⁰² “Pharmacy and Therapeutics Committees” are made up of physicians, pharmacists, and other health professionals, who together manage and update a provider’s formulary, and set policies for use of different drugs.

²⁰³ Appendix E, Ex. 34, Gilead Sciences, Inc., Sofosbuvir Pricing & Contracting Strategy Working Team, SVP Check-In II, May 10, 2013, GS-0013972, at GS-0013988 (emphasis in original).

²⁰⁴ *Id.* at GS-0013989.

²⁰⁵ *Id.* at GS-0013990.

²⁰⁶ *Id.* at GS-0013990.

²⁰⁷ *Id.* at GS-0013991.

²⁰⁸ *Id.* at GS-0013995—GS-0013999.

²⁰⁹ Lauran Neergaard, *FDA Approves Potent Hepatitis C Drug*, Associated Press (June 3, 1998).

of HCV therapy over 3–4 years following Rebetron launch.”²¹⁰ Rebetron was reported to cost between \$15,600 and \$17,300 for a yearlong therapy, or \$1,300 to \$1,440 a month.²¹¹

July 2013: The Final Pricing and Access Recommendations

On July 31, 2013, Gilead’s pricing team gave Meyers final pricing and access recommendations. The documentation from the July timeframe indicated a belief that price sensitivity would begin at \$90,000 and a recognition of potential public payer restrictions. There were also deep concerns about wave 2 pricing because of prospective competition and a continued confidence in the clinical efficacy of the drug in comparison to the prices for existing regimens and other factors justifying a higher price. At the time, the contracting strategy began to take more detailed shape.

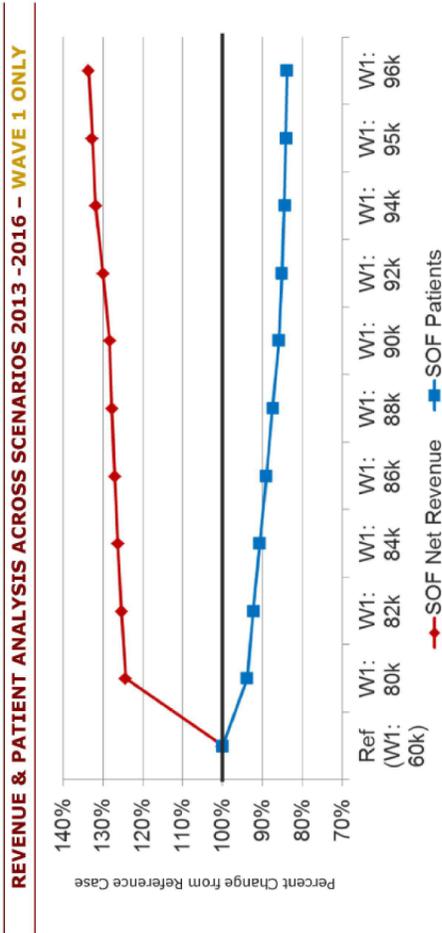
The slide presentation included analysis of the expected tradeoffs of increasing the price of Sovaldi—revenue would rise but the number of patients receiving the drug would decline. (See slide below). It also showed that Gilead was aware it was in a position to create clear savings for payers, but chose to pursue a “regimen neutral” price justified by “cost-per-cure” calculations that resulted in greater revenue per treatment than previous DAAs. The company had received feedback from payers that “[g]iven the significant improvements in efficacy and tolerability and high level of physician demand, SOF enjoys substantial pricing freedom in Wave 1,” that “price sensitivity begins at \$90k for subset of payers [sic],” and “that even at a high price differential it is unlikely they would impose step edits through inferior regimens (PIs or simeprevir).”²¹²

²¹⁰ Appendix E, Ex. 34, Gilead Sciences, Inc., Sofosbuvir Pricing & Contracting Strategy Working Team, SVP Check-In II, May 10, 2013, GS-0013972, at GS-0013996.

²¹¹ Denis Grady, *Group Finds a Way to Offer a Hepatitis C Drug for Less*, N.Y. Times (June 30, 1999), available at <http://www.nytimes.com/1999/06/30/us/group-finds-a-way-to-offer-a-hepatitis-c-drug-for-less.html>.

²¹² Appendix E, Ex. 28, Gilead Sciences, Inc., Sofosbuvir Pricing and Market Access Assessment, Final Recommendations—July 31st, 2013, GS-0014018, at GS-0014026.

Preliminary findings from the financial modeling – Wave 1 only
 Impact of Wave 1 Price on Demand and Net Revenues

The financial analysis shows that with in the \$80k-\$95K range patient impact increases as price is increased but not enough to offset Revenue Gains.

The presentation predicted that 24% of the payers it had surveyed would institute access restrictions of some sort for genotype 1 patients if Sovaldi were priced at \$75,000, and that 47% would institute restrictions at \$90,000.²¹³ For genotype 2 patients, 33% of payers were predicted to institute restrictions at a price of \$75,000, and 43% at \$90,000; for genotype 3 patients, restrictions at the two price points were expected to be 37% and 51%, respectively.²¹⁴

²¹³ *Id.* at GS-0014029.

²¹⁴ *Id.* at GS-0014029—GS-0014030.

The presentation concluded that “[t]he optimal range for Wave 1 pricing based on revenue/uptake trade-offs is likely \$85–\$95K, though other softer factors must be considered,” and ultimately recommended that the price be “between \$80K to \$85K per course of therapy.”²¹⁵ The presentation picked up on other themes that had been discussed and analyzed in previous presentations, including:

1. Gilead has **considerable pricing potential with sofosbuvir in Wave 1** without major access consequences, but the pricing potential for future launches will be constrained by competition
2. Long term sofosbuvir franchise value will be driven by **a high price capture opportunity in Wave 1 and a volume capture in Wave 2 and beyond**²¹⁶

As noted above, one of Gilead’s considerations for Wave 1 prices, i.e., Sovaldi, was the potential to achieve a high price for Wave 2, i.e., Harvoni. The “value capture opportunity is in Wave 1,” the presentation stated, and “Wave 2 access will be enhanced with a high Wave 1 price.”²¹⁷ It went on to say that “[a]t any price, access for Wave 2 improves as the price for Wave 1 is increased, suggesting that Wave 1 will set a price benchmark against which Wave 2 will ultimately be evaluated.”²¹⁸ It also noted that the introduction of market competition would change the pricing environment. The “[c]ompetitive threat from AbbVie and [Bristol-Myers Squibb] will be critical factors for the Wave 2 market access strategy as these regimens could drive payers to disadvantage sofosbuvir under select scenarios, especially if efficacy is comparable among all the regimens and there is a large price differential.”²¹⁹

There was particular concern about competition posed by Bristol-Myers Squibb’s drug candidate, daclatasvir, “being used to break up the sofosbuvir [single tablet regimen].”²²⁰ Bristol-Myers was singled out several times in the presentation as a constraining factor for the eventual pricing of Harvoni, underscoring the need that it was important Sovaldi “[e]stablishes high benchmark for Wave 2.”²²¹ Gilead believed the Bristol-Myers Squibb combinations, with fewer pills, could pose a market share risk to AbbVie, and “could be a threat to Gilead depending on price,”²²² limiting Gilead’s ability to charge a premium for Harvoni. The presentation stated, “[w]ave 1 pricing will impact the imputed sub-WAC value of ledipasvir, therefore determining the value capture opportunity for a sofosbuvir + daclatasvir combination” and “[t]hese considerations re-enforce the limitations on taking a premium in Wave 2, as a large difference between the two regimens would make NS5A substitution significantly more appealing to payers.”²²³ As noted above, the FDA approved a Daklinza-Sovaldi combination for geno-

²¹⁵ *Id.* at GS-0014053.

²¹⁶ *Id.* at GS-0014053 (emphasis in original).

²¹⁷ *Id.* at GS-0014026.

²¹⁸ *Id.*

²¹⁹ *Id.*

²²⁰ *Id.* at GS-0014027.

²²¹ *Id.* at GS-0014052.

²²² *Id.* at GS-0014027.

²²³ *Id.*

type 3 patients on July 24, 2015 that was submitted by Bristol-Myers Squibb.

The presentation sought to assure executives that Gilead would have ample justification to price its HCV drug at a premium level. Gilead had weathered criticism for pricing decisions in the recent past, coming under scrutiny for its decision to charge \$28,500 for the AIDS drug Stribild. One activist derided Stribild's price at the time of FDA approval as "shockingly irresponsible,"²²⁴ and 13 congressmen expressed concern in a letter to CEO John Martin about the effects of Gilead's drug-pricing decisions on the AIDS Drug Assistance Program.²²⁵ The presentation stated "HCV is very much unlike HIV and, while exercising caution based on the Stribild launch is understandable, sofosbuvir is quite different."²²⁶ It went on to detail the "sofosbuvir opportunity relative to Stribild," with the following lists:

Sofosbuvir Wave 1 is . . .	Implications
<ol style="list-style-type: none"> 1. Substantially better than standard of care across metrics. 2. In a therapy area where there is significant unmet need. 3. In a therapy area where prior authorizations are the norm. 4. Being researched with more rigor than the Stribild launch. 	<ul style="list-style-type: none"> • Market access in HIV is significantly different than market access in HCV • Prescribing physicians are comfortable with prior authorizations and recognize that they are part of "standard operating procedures" • Stribild is not viewed by payers as having substantially better efficacy than current products and view it largely as a convenience value story • Sofosbuvir demonstrates substantially better data in both efficacy and convenience as well as other metrics that are important to payers and represents significant clinical value²²⁷

Gilead remained confident that Sovaldi's ability to increase SVR for most patients, coupled with reduced time on interferon and ribavirin, was ample justification for increased pricing: "A price of \$80–\$85K does represent >30% premium to Incivek on a molecule price [sic], however, the product is delivering better outcomes for those dollars."²²⁸ The presentation touched on how payers might end up justifying paying for multiple rounds of treatment with some patients: "[p]ayers are currently paying significantly more than the price of Incivek to achieve an outcome, so regimen cost is critical."²²⁹ The company also included "future market considerations" justifying their pricing:

- Healthcare reform has incentives to pay for value, which aligns with what sofosbuvir will deliver (even if it is not the least expensive agent)
- While it is true that budgets are not infinite, higher cost products can be preferred if actually demonstrating strong real world outcomes²³⁰

²²⁴ Andrew Pollack, *F.D.A. Approves Once-A-Day Pill for H.I.V.*, N.Y. Times (Aug. 27, 2012), available at http://www.nytimes.com/2012/08/28/business/fda-approves-once-a-day-pill-for-hiv.html?_r=0.

²²⁵ Press Release, Office of U.S. Representative Alcee Hastings, Hastings Expresses Concern over HIV Drug Price Increases, ADAP (Aug. 1, 2012), available at <http://alceehastings.house.gov/news/documentsingle.aspx?DocumentID=327935>.

²²⁶ Appendix E, Ex. 28, Gilead Sciences, Inc., Sofosbuvir Pricing and Market Access Assessment, Final Recommendations—July 31st, 2013, GS-0014018, at GS-0014021.

²²⁷ *Id.* (emphasis in original).

²²⁸ *Id.* at GS-0014022.

²²⁹ *Id.*

²³⁰ *Id.*

Gilead presented multiple pricing scenarios for Sovaldi, numbered one through five—\$50,000, \$60,000, \$80,000, \$95,000, and \$115,000 (the company assumed each would have an additional \$10,000 worth of interferon/ribavirin).²³¹ Those prices were compared to the price for Incivek plus interferon/ribavirin “at launch” (\$81,000) and “today” (\$99,000).²³² The company concluded that “[r]elative to the current cost of Incivek, sofosbuvir would most likely provide *savings* to payers at molecule prices <\$80k.”²³³ The company relied on a cost-per-cure justification for a higher price— “[s]avings are still likely at a sofosbuvir product cost of \$95K, especially considering sofosbuvir’s superior SVR and the significant rates of treatment failure/abandonment associated with Incivek.”²³⁴

The company also considered the effect of selling to substantial government payers, such as Medicaid, 340B, and the VA, which it termed “sub-WAC channels,” where pricing would be “substantially lower than the Commercial market.”²³⁵ The company expected the payer mix for treatment of HCV to be heavily weighted toward various public payer insurance programs, growing from 34% in 2012 to as much as 58% by 2016.²³⁶

Like their commercial counterparts, Gilead expected most Medicaid and Medicare payers would likely provide “preferred access” to Sovaldi if the drug were priced below \$80,000. Above that price, all three payer categories were expected to begin implementing some sort of restrictions on access, particularly for patients with genotype 2 or genotype 3.²³⁷

For other payer groups, Gilead recognized that “[n]on-traditional segments widely vary in price sensitivity and some degree of contracting is likely required regardless of price” to secure access.²³⁸ For the VA, that meant “discount for access.”²³⁹ For integrated delivery networks (IDN) such as Kaiser Permanente, “these price levels will likely not provide access and demand contracts.”²⁴⁰ For Departments of Corrections, “possible discount for access, though may not be a Gilead target.”²⁴¹ A key consideration for the company was that Gilead would be “generally pushing the upper comfort level for IDN payers.”²⁴²

This presentation was the first in which Gilead discussed contracting strategy in detail and its unwillingness to discount from the WAC price to gain access on payers’ formularies and/or preferred drug lists. The company planned to limit its contracting because “[r]eactive contracting with low rebates should be sufficient in many channels although proactive strategies will be required elsewhere.”²⁴³

²³¹ *Id.* at GS-0014024.

²³² *Id.*

²³³ *Id.* (emphasis in the original).

²³⁴ *Id.*

²³⁵ *Id.* at GS-0014025.

²³⁶ *Id.* at GS-0014028.

²³⁷ *Id.* at GS-0014033—GS-0014035.

²³⁸ *Id.* at GS-0014036.

²³⁹ *Id.*

²⁴⁰ *Id.*

²⁴¹ *Id.*

²⁴² *Id.*

²⁴³ *Id.* at GS-0014037.

To determine where to contract, Gilead identified “market influencers” in different payer categories that were tightly managing access to HCV drugs already on the market.²⁴⁴ In the commercial space the market influencers included companies like Aetna, Regence, and Blue Cross Blue Shield Michigan; in Medicare Part D, Coventry and Emblem Health; and in managed Medicaid states, such as Missouri, Illinois, Louisiana, and California.²⁴⁵ For Department of Corrections and Medicaid fee-for-service payers, the primary target was California, which represented “~12% of the overall DOC payer segment,” and “~10% of channel,” respectively.²⁴⁶ Gilead planned to use a “proactive approach” with Kaiser Permanente and the VA.²⁴⁷ In all cases, the company planned to offer 5% to 10% discounts off the WAC price.²⁴⁸

The company examined the implications of pricing Sovaldi at various levels, and how different prices would affect the company’s standing amongst stakeholders, the value to shareholders and reputational risks. The lowest prices posed the least risk, but the least financial upside.²⁴⁹ Gilead determined that “[w]hile pricing at \$50–60K would promote preferred status, it will result in significant unrealized revenue.”²⁵⁰ It continued:

- Pricing at \$50K
 - PROS: Gilead could build substantial “good will” with the payer community and will gain widespread “preferred” market access across nearly every payer segment in the market
 - CONS: What Gilead could achieve at \$50K would also be achievable at much higher prices, suggesting significant foregone revenue; despite pricing at this level, activists are still likely to voice dissatisfaction with the strategy
- Pricing at \$60K
 - PROS: Gilead very unlikely to face any access issues from the major market segments and will be enabling payers to pay substantially less per patient on a regimen basis relative to incumbent products
 - CONS: Gilead not realizing a substantial revenue amount and Wave 1 price would fall below the access-optimizing price; furthermore, achieving more than an \$80K Wave 2 price will be unlikely, eroding shareholder value²⁵¹

At the next price level, \$80,000, the company identified “external considerations” to be the primary risk, that is, how consumer groups would react to the price.²⁵² Gilead concluded “[a]t \$80K, widespread parity access will be the norm, with strong physician

²⁴⁴ *Id.* at GS-0014031—GS-0014037.

²⁴⁵ *Id.* at GS-0014033, GS-0014035.

²⁴⁶ *Id.* at GS-0014037.

²⁴⁷ *Id.*

²⁴⁸ *Id.* at GS-0014031—GS-0014037.

²⁴⁹ *Id.* at GS-0014047.

²⁵⁰ *Id.* at GS-0014048.

²⁵¹ *Id.*

²⁵² *Id.* at GS-0014049.

and patient preferences driving significant uptake.”²⁵³ It then considered the effects on four different groups:²⁵⁴

- Payer Considerations
 - Given that SOF will be cheaper than most PIs on a regimen basis, payers are highly unlikely to manage access at \$80K (beyond PA to label), instead placing it at parity to current treatments and leaving the decision to physicians
- Physician/Patient Considerations
 - SOF will be the clear favorite of physicians and patients considering its equivalent (or cheaper) total cost, significantly improved SVR, decreased duration, and reduced side effect burden relative to PIs
- Competitive Considerations
 - An aggressive pricing strategy for [simeprevir] could create some challenges for SOF in some high control accounts, but a low price strategy would be value-destroying for Janssen
- External Considerations
 - As with all prices, advocacy groups will criticize pricing, likely focusing on the product cost without accounting for the total regimen discount
 - While a select subset of KOLs (key opinion leaders) will be vocal about their concerns, a change in guidelines is highly unlikely at this price²⁵⁵

At \$95,000, which the company had identified earlier in the document as an “inflection point,” risks from physicians, patients, and competing companies increased. Gilead summarized the landscape: “[p]layer pushback is more likely . . . but strict management will remain difficult to the significantly improved clinical profile.” More specific considerations included:²⁵⁶

- Payer Considerations
 - The majority of payers are still unlikely to impose anything above a soft step at \$95K, although certain high-control plans such as the VA and Kaiser may require additional contracting or cost-effectiveness data to ensure access
- Physician/Patient Considerations
 - Given the strength of the profile and modest premium to PIs, physician preferences will remain largely unchanged
 - Patients will continue to prefer sofosbuvir, with most OOP (out-of-pocket) issues easily addressable via co-pay programs

²⁵³ *Id.*

²⁵⁴ The abbreviations include PA (prior authorization, which payers can use to restrict access), PIs (protease inhibitors), SIM (simeprevir, a.k.a. Olysio), and KOLs (key opinion leaders). “Janssen” refers to Johnson & Johnson’s pharmaceutical arm that developed Olysio.

²⁵⁵ Appendix E, Ex. 28, Gilead Sciences, Inc., Sofosbuvir Pricing and Market Access Assessment, Final Recommendations—July 31st, 2013, GS-0014018, at GS-0014049.

²⁵⁶ OOP is Out of Pocket expenses; 3-DAA is triple direct-acting antiviral; BMS is Bristol-Myers Squibb.

- Competitive Considerations
 - At this price, an AbbVie premium for 3-DAA would break the \$100K threshold, which they may elect to avoid
 - Irrespective of Wave 2 price, as Wave 1 price rises, the capturable [sic] opportunity for BMS expands²⁵⁷
- External Considerations
 - Advocacy group criticism will intensify but overall impact will be similar
 - While increasing numbers of KOLs may voice concern, guideline modification remains unlikely given the modest premium to PI regimens vs. the significant clinical improvements²⁵⁸

Finally, the company considered the highest end of its proposed price range—\$115K. At that point, external risks were considered to be at their highest (as denoted by a circle filled with red).²⁵⁹ Other factors registered high risk, but their respective circles were only two-thirds red, indicating less concern.²⁶⁰ Gilead expected “[s]trict management and guideline restrictions may appear at \$115K, with usage in GT-2 and GT-3 presenting a potential target for payers.”²⁶¹ More specifically:

- Payer Considerations
 - At \$115K, many payers will attempt to disadvantage sofosbuvir through tier differentials and soft steps; while hard steps are possible, it will remain extremely difficult to step patients through an inferior regimen
- Physician/Patient Considerations
 - Physicians will still prefer sofosbuvir to PI regimens, but a limited number may reduce usage or consider warehousing
 - Usage in GT-3 and, to a lesser extent, GT-2 will become increasingly difficult to justify, particularly for TN patients
- Competitive Considerations
 - Competitor pricing would be informed by Gilead’s access experience, and risks of discounts rise
 - This price translates into \$38K reduction in SOF costs if Wave 2 is only 8 weeks, heightening price pressure from BMS
- External Considerations
 - High levels of advocacy group criticism and negative PR/competitive messaging could be expected at \$115K and it would be increasingly difficult to manage at these levels

²⁵⁷ This observation refers to Gilead’s concern about daclatasvir being paired with other companies’ drugs, including sofosbuvir.

²⁵⁸ Appendix E, Ex. 28, Gilead Sciences, Inc., Sofosbuvir Pricing and Market Access Assessment, Final Recommendations—July 31st, 2013, GS-0014018, at GS-0014050.

²⁵⁹ *Id.* at GS-0014051.

²⁶⁰ *Id.*

²⁶¹ *Id.*

- Select KOLs may intensify their push for guideline modification²⁶²

With a price range established for senior management to consider, the company's pricing team summarized what Gilead should expect if the drug were priced at \$80,000 to \$85,000, including the expectation that certain patients would have problems accessing the drug, and that contracting would be necessary for certain payers:

- Sofosbuvir will have a PA to the label, which will mean very limited, if any, access for treatment experienced patients; naives will be accessible
- Gilead will need to contract with the VA, Kaiser, and likely additional plans on the fringes who may restrict sofosbuvir
- Advocacy groups will be vocal at any price and a minority of KOLs may voice concern²⁶³

It also set an action plan with priorities for Gilead:

- While restrictions based on fibrosis score are unlikely, Gilead needs to be prepared to answer questions about which patients and why
- It will be critically important to communicate to payers the clinical value that SOF creates and to be prepared in advance to answer questions regarding in which patients SOF should be used
- Gilead should proactively identify key accounts and develop a plan for messaging to them immediately following launch to ensure access
- Ensure that payers understand the population Gilead is aiming to treat and to reinforce that the population is not in the millions, as some believe²⁶⁴

This presentation shows that Gilead set a price as high as it thought acceptable before significant access restrictions would be imposed. Its analysis indicated that pricing in the \$80,000 to \$85,000 range would deliver this result for the majority of genotype 1 patients, though not for other patient groups. As discussed later in this report, Gilead's analyses were ultimately incorrect on this point as many payers adopted access restrictions at the final price of \$84,000. Even when the scope of these restrictions became manifest in mid-2014, Gilead did not alter its approach.

The presentation's final slide was devoted to patient support programs such as co-pay coupon programs, donations to two independent non-profit patient assistance foundations, and patient assistance programs (PAP). These programs were designed to "ensure there is no gap in coverage and impact from pricing & contracting decisions."²⁶⁵

In its April 2015 report, *Medicines Use and Spending Shifts*, the IMS Institute states "[m]anufacturers commonly provide coupons when their brand is not covered on a formulary," and

²⁶² *Id.* at GS-0014051.

²⁶³ *Id.* at GS-0014054.

²⁶⁴ *Id.*

²⁶⁵ *Id.* at GS-0014058.

“[i]ncreasingly, coupons are being used around the launch of an innovative brand to eliminate barriers to patients considering new medicines.”²⁶⁶ Any loss on co-payment (typically a small percentage of a drug’s price) is made up by the insurance company’s portion. Industrywide, co-pay coupons were used for 8% of total prescriptions in 2014 compared to 3% in 2011, 5% in 2012 and 6% in 2013.²⁶⁷ However, co-pay coupons may not be used for federally funded health care programs.²⁶⁸

The copay coupons, used to pay the deductibles or coinsurance for commercial customers, were expected to cost the company between \$10 million and \$15 million, depending on the WAC price (\$60,000 to \$100,000).²⁶⁹ The Foundation support would cost \$100 million at \$60,000, with costs growing about \$5 million for every incremental price increase of \$10,000.²⁷⁰ The PAP did not add additional costs, but instead was foregone revenue—it was a cost of goods sold for 6,000 uninsured patients and 6,000 pre-transplant patients.²⁷¹ Although this presentation outlined the company’s initial approach to its patient support programs, the strategy of providing such benefits evolved as payer access restrictions began to be imposed, as discussed in section 4 of this report.

The timeline in the March presentation discussed above indicates that the pricing and access recommendations would next have been provided to the GPC for a final review. However, interviews and documents that Gilead provided to investigative staff do not clearly indicate whether the GPC was involved in a final review.

August 2013: The Board is Briefed on Sovaldi’s Launch and Pricing

On August 1, 2013, the day after the final pricing team recommendation, Meyers and Bill Symonds, Gilead’s vice president for liver diseases, presented “an update on the status of the clinical trials involving sofosbuvir and . . . the preparations taken for the anticipated U.S. launch of sofosbuvir.”²⁷² Meyers’ presentation, “U.S. HCV Launch Update,” gave a high-level overview of the market, pricing and Gilead’s launch timeline to the board of directors.²⁷³ During the meeting, members of the board “asked a number of questions that were answered by management.”²⁷⁴ After Meyers and Symonds left the room, the board and Kevin Young, the executive vice president for commercial operations, “further discussed the anticipated launch of sofosbuvir.”²⁷⁵

²⁶⁶ IMS Institute for Healthcare Informatics, *Medicines Use and Spending Shift*, at 25.

²⁶⁷ *Id.*

²⁶⁸ Office of the Inspector General, U.S. Department of Health and Human Services, *Special Advisory Bulletin: Pharmaceutical Manufacturer Copayment Coupons*, September 2014, available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/SAB_Copayment_Coupons.pdf.

²⁶⁹ Appendix E, Ex. 28, Gilead Sciences, Inc., Sofosbuvir Pricing and Market Access Assessment, Final Recommendations—July 31st, 2013, GS-0014018, at GS-0014058.

²⁷⁰ *Id.*

²⁷¹ *Id.*

²⁷² Appendix E, Ex. 35, Gilead Sciences, Inc., Minutes of Regular Meeting of Board of Directors, August 1, 2013, GS-0019671, at GS-0019672.

²⁷³ Appendix E, Ex. 31, Gilead Sciences, Inc., U.S. HCV Launch Update, August 1, 2013, GS-0014059.

²⁷⁴ Appendix E, Ex. 35, Gilead Sciences, Inc., Minutes of Regular Meeting of Board of Directors, August 1, 2013, GS-0019671, at GS-0019672.

²⁷⁵ *Id.*

The presentation by Meyers and Symonds began with a review of the market, specifically, Gilead's estimate that there were 4.1 million people in the United States with HCV, but that only 1.7 million were diagnosed. In addition, the presentation noted that of the 1.7 million diagnosed with HCV, 381,000 were being cared for by a health provider, and just 73,000 were currently being treated with drugs.²⁷⁶ The presentation underscored the need to boost marketing efforts around HCV and disease awareness; "HCV-infected patients account for only ~17% of the patient volume of HCV treaters," which "[i]ncreases the importance of implementing a broad disease awareness/medical education platform and of increasing patient awareness of new treatment options."²⁷⁷

Meyers reiterated the need for sofosbuvir to be established as the SOC and "backbone of HCV therapy at initial launch," because the more that physicians waited for interferon-free therapies for genotype 1 patients, "the less established SOF will be at the time of competitive IFN-free launches."²⁷⁸ Broad market access, growing the pool of patients seeking therapy, and deploying disease awareness advertising were also deemed "critical success factors."²⁷⁹ The board also was guided through disease awareness and branded marketing materials that would accompany Sovaldi at launch, and was informed that Gilead's U.S. sales force of 144 people was 30% larger than the next closest competitor, Vertex.²⁸⁰

The next topic for Myers was payer access restrictions and pricing comparisons, emphasizing the need to set a high price for Sovaldi in order to set a price platform from which to launch Harvoni. The presentation stated that Gilead would be "[b]etter off pricing SOF at initial launch for GT-1 patients, as there will be varying degrees of access restrictions for GT-2/3 patients regardless of where we price," and that "[w]herever we want to end up in terms of pricing for SOF/LDV, we have to get most of the way there in the initial pricing of SOF."²⁸¹ The "[l]argest incremental gain in SVR is at initial launch, and this is what payers value."²⁸² The company would "need to keep prescribing in the hands of physicians, not payers, and to contract for open/parity access only when necessary."²⁸³

August 2013: Answering Follow-up Questions

On August 26, 2013, a presentation was given entitled "Sofosbuvir Pricing and Market Access Assessment: Response to Follow Up Question." The presentation built on the July 31st presentation where Meyers was provided a final recommendation from Gilead's pricing team to senior management.²⁸⁴

²⁷⁶ Appendix E, Ex. 31, Gilead Sciences, Inc., U.S. HCV Launch Update, August 1, 2013, GS-0014059, at GS-0014061.

²⁷⁷ *Id.* at GS-0014063.

²⁷⁸ *Id.* at GS-0014067.

²⁷⁹ *Id.* at GS-0014067.

²⁸⁰ *Id.* at GS-0014069—GS-0014071.

²⁸¹ *Id.* at GS-0014076.

²⁸² *Id.*

²⁸³ *Id.* at GS-0014076.

²⁸⁴ Appendix E, Ex. 36, Gilead Sciences, Inc., Sofosbuvir Pricing and Market Access Assessment: Response to Follow Up Question, August 26, 2013, GS-0013857.

The presentation delved into “the potential impact of discounting on demand into the financial modeling.”²⁸⁵ It studied payer, patient, and provider reactions to a gross-to-net price that reflect contracted discounts.²⁸⁶ The impact of discounting did “not change the overall conclusion from the financial analysis: [w]ithin a \$70K–\$95K SOF price range patient impact increases as price is increased but not enough to offset revenue gains.”²⁸⁷ It continued, “[a]ssuming a gross SOF price between \$75K and \$90K the current budgeted level of mandatory and supplemental discounting could theoretically support enough contracting to regain the majority of the predicted patient losses.”²⁸⁸ But, “[g]iven the competitive timing executing these contracts in a timely manner may be challenging . . . assum[ing] supplemental discounts could be in place by Q3.”²⁸⁹

Gilead assumed its discounts for HCV drugs would be lower than for other product lines—17% for HCV drugs versus a range of 20% to 41% for its other units.²⁹⁰ The presentation assumed that supplemental discounts would be offered only to “the most price sensitive accounts” in Medicare, Medicaid, and commercial payer segments.²⁹¹ The presentation used several percentages for projected discounts for each payer segment.²⁹² Subsequent tables and graphs show that the patient impact, i.e., lost patient starts, would be reduced by discounting across all price levels, and that revenue would increase during Wave 1. “Incorporating the impact of discounting on patients [sic] demand increases the forecast and reduces estimated patient loss significantly,” the presentation states.²⁹³ At an \$85,000 price point, with a 6% supplemental discount applied, Gilead projected patient losses of 10% in 2014, 8% in 2015, and 11% in 2016 compared to a \$65,000 price point.²⁹⁴ An “alternative version” at the end of the presentation shows that implementing 15% supplemental discount for commercial payers would have reduced patient start at a WAC price of \$85,000 to 5% in 2014, 2% in 2015, and 3% in 2016; revenue in each of those years was expected to remain higher than without discounting.²⁹⁵

However, as detailed in Sections 4 and 5 of this report, very few payers agreed to Gilead’s discount offers for Sovaldi. The discount offers were viewed negatively because of their small size and because they were tied to loosening access restrictions to treatment that would have increased patient volume, offsetting any cost savings for the payer.

A note at the bottom of the page appears to show how the company’s assumptions about discounting had evolved from the “June Forecast” price of \$60,000. Discounts appear to be lower, meaning a greater share of the gross price would be captured in the net price:

²⁸⁵ *Id.* at GS-0013858.

²⁸⁶ *Id.* at GS-0013860.

²⁸⁷ *Id.* at GS-0013859.

²⁸⁸ *Id.*

²⁸⁹ *Id.* at GS-0013859.

²⁹⁰ *Id.* at GS-0013880.

²⁹¹ *Id.* at GS-0013861.

²⁹² *Id.*

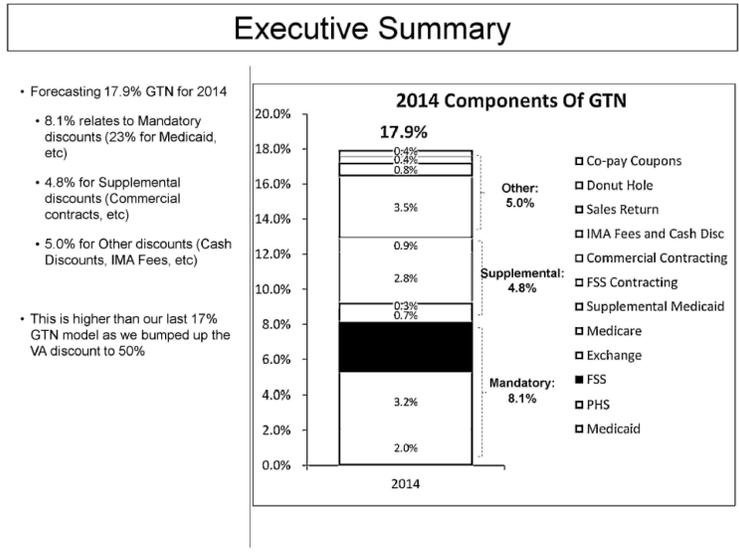
²⁹³ *Id.* at GS-0013862.

²⁹⁴ *Id.* at GS-0013861, GS-0013863.

²⁹⁵ *Id.* at GS-0013887.

Gross to Net in June forecast was ~22% in 2014; updated gross-to-net assumptions of ~13% in 2014 are used for all scenarios with Wave 1 pricing at or below \$60K and ~17% for all scenarios with Wave 1 pricing about \$60K²⁹⁶

Two slides in the presentation’s appendix (see below) further detail how Gilead calculated its gross-to-net assumptions.²⁹⁷ Mandatory discounting for government programs would account for the majority of the discounts (8.1%). Supplemental discounts to commercial payers and others would account for 4.8%, and other discounts (for example, cash discounts and inventory management agreements, which are referred to as IMAs) would account for 5% of the discounting. References to FSS apply to the Federal Supply Schedule, the contracting system for the VA, Department of Defense, and other federal agencies such as the Bureau of Prisons (see Section 4).²⁹⁸ The slides also reinforce that Gilead planned to limit supplemental discounting except with certain key accounts.



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²⁹⁶ *Id.* at GS–0013862.

²⁹⁷ *Id.* at GS–0013881 and GS–0013882.

²⁹⁸ U.S. Department of Veterans Affairs, *available at VA Federal Supply Schedule Service: General FAQs*, <http://www.fss.va.gov/faqs/general.asp#q001> (last visited Sept. 1, 2015).

Mandatory & Supplemental Discounts

Supplemental Rationale:

- **Medicaid** – Proactive contracting to occur at launch for California with increasing supplemental beginning in Q2'14 as a result of competition from AbbVie's FDC
 - Q4'13/Q1'14 supplemental based off assumed CA population per 2012 census of 11% of total US at 10% discount = ~1% effective Medicaid Supplemental
- **Exchange** – No proactive contracting anticipated. Assumes contracting beginning in Q2'14, 1 quarter in advance of AbbVie's launch
- **Medicare** – No proactive contracting anticipated. Assumes ramp-up of contracting beginning in Q1'14 and not right at launch due to timing of payer formulary reviews. Assumes slightly longer review timing than HIV since HCV is not a protected class
- **PHS** – No proactive contracting
- **Inmates** – Proactive contracting for CA DOC (12% of overall DOC population * 10% = ~1% effective discount). Assumes not effective until Q1'14 due to formulary review timing and contracting activities
- **FSS** – Proactive contracting to match total discount offered by existing PIs (Bocepravir 44-61% and Telaprevir 42-48%)
- **Commercial** – Proactive contracting with Kaiser and increasing reactive contracting starting in Q2'14 towards "Market Influencers" in advance of competitor launches
 - Kaiser: 10% of volume at 10% discount = ~1% effective discounting on overall commercial

	Mandatory Discount	Quarterly Supplemental Discount				
		Q4'13	Q1'14	Q2'14	Q3'14	Q4'14
Medicaid	23%	1%	1%	3%	4%	5%
Exchange				5%	8%	10%
Medicare			2%	4%	5%	5%
PHS	23%					
Inmates	23%		1%	1%	1%	1%
FSS	25%	25%	25%	25%	25%	25%
Commercial		1%	1%	2%	2%	2%

Competitor Launches:	Simeprevir (G11, 1N, 26/28 WA)	ASB91a FDC (G11, 1N, 1E, 12 WA)	ASV + DCV (G11b, 1E, 24 WA)
			ASV + DCV + P/R (G11, 1E, 24 WA)

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The presentation examined what it considered the “highly unlikely” scenario of Johnson & Johnson pricing simeprevir at \$20,000 per course of treatment, its impact on Gilead’s revenue from Sovaldi, and how it “would put negative attention on SOF at the recommended price.”²⁹⁹ Focusing on Sovaldi’s price, the presentation concluded that if simeprevir were priced at \$20,000, Gilead would need to triple the number of patient starts in 2014 to 37,500 people in order to achieve the same revenue as it would if simeprevir were priced at \$60,000.³⁰⁰ Similarly, the presentation concluded that “[o]ur Wave 1 goal of a high price remains consistent”—and Harvoni “Wave 2 strategy may require more caution.”³⁰¹

November 2013: Sovaldi’s Price is Set by Top Executives

One of the final pricing documents provided by Gilead is the “Sofosbuvir Pricing and Market Access Recommendation,” dated November 15, 2013. This presentation recommended that Sovaldi be priced at \$81,000 or \$27,000 per bottle.³⁰² This is the price that Meyers and Young would provide to the company’s senior management three days later for final approval.

This presentation is light on details compared to previous presentations, and very little new information is presented, save for the following:

²⁹⁹ Appendix E, Ex. 36, Gilead Sciences, Inc., Sofosbuvir Pricing and Market Access Assessment: Response to Follow Up Question, August 26, 2013, GS–0013857, at GS–0013865.

³⁰⁰ *Id.* at GS–0013866.

³⁰¹ *Id.* at GS–0013867.

³⁰² Appendix E, Ex. 37, Gilead Sciences, Inc., Sofosbuvir Pricing and Market Access Recommendation, November 2013, GS–0014079, at GS–0014079.

- The optimal range for Wave 1 pricing based on revenue/uptake trade-offs is likely \$85–\$95K, though other softer factors must be considered
- If we price lower it opens up a window for competitors to pair up with SOF and come in at a lower regimen cost than our FDC
- Even if we priced lower, such as \$70k, it would not mitigate the high cost of a 24 week regimen (message points being developed), and therefore we recommend we address this on a case by case basis on a sub-WAC level³⁰³

It is clear that Gilead was concerned about competition. The threat of competition worked in two ways—the efficacy of AbbVie’s drug combination complicated the decision-making process to price the product and the potential of a daclatasvir-sofosbuvir combination put upward pressure on the price. Lastly, the company recognized the weakness of its drug in treating genotype 3 patients versus the interferon/ribavirin SOC.

The final pricing recommendation was addressed as follows:

- We recommend pricing sofosbuvir Wave 1 at \$81K (\$27k/bottle) per course of 12 week therapy and contract selectively for access at target payers:
- For the VA we recommend negotiating up to a 50% discount on their volume (vs the original 40% discount) to make up for the higher cost of treating co-infected and IFN-ineligible patients which account for about 60% of their population
- For Kaiser we recommend negotiating up to a 10% discount for access
- Other plans will be evaluated on a one off basis³⁰⁴

On November 18, 2013, Young received a slide from Meyers and forwarded it to company officers later that night (see slide below). In the body of the email, Young stated, “[o]ur recommendation for your discussion and approval is \$27,000 per 28 tablet bottle” (\$81,000 for 12W).³⁰⁵

³⁰³ *Id.*

³⁰⁴ *Id.*

³⁰⁵ Appendix E, Ex. 38, Email from Kevin Young to John Martin et al., Re: COMPANY CONFIDENTIAL (Nov. 18, 2013), GS-0020800.

Sofosbuvir (SOF) Pricing

Target Price	SOF price per bottle (\$)	SOF price per pill (\$)	Cost of 12 weeks of SOF (\$)	Cost of 24 weeks of SOF (\$)	Cost of SOF + PEG/RBV for 12 weeks	Cost of SOF + RBV for 12 weeks	Cost of SOF + RBV for 24 weeks
\$70,000	\$23,333	\$833	\$70,000	\$140,000	\$79,640	\$70,990	\$141,980
\$75,000	\$25,000	\$893	\$75,000	\$150,000	\$84,640	\$75,990	\$151,980
\$80,000	\$26,666	\$952	\$80,000	\$160,000	\$89,640	\$80,990	\$161,980
\$85,000	\$28,333	\$1,012	\$85,000	\$170,000	\$94,640	\$85,990	\$171,980
\$90,000	\$30,000	\$1,071	\$90,000	\$180,000	\$99,640	\$90,990	\$181,980

Genotype / Patient type	SOF-based regimen	Cost of SOF-based regimen (\$)	Cost of current SOC (\$)
GT-1 (Option A)	SOF + PEG/RBV for 12 weeks	\$89,640	\$95,074*
GT-1 (Option B)	SOF + RBV for 24 weeks	\$161,980	\$95,074*
GT-2	SOF + RBV for 12 weeks	\$80,990	\$19,279
GT-3	SOF + RBV for 24 weeks	\$161,980	\$19,279
HIV/HCV co-infection	SOF + RBV for 24 weeks	\$161,980	n/a

* Range from \$85,435 to \$104,714

Business Proprietary Information – Confidential Treatment Requested

GILEAD CONFIDENTIAL

GS-0020801

On November 23, 2013, less than two weeks before Sovaldi received FDA approval and went on the market in the U.S., Young sent an email to Cara Miller, the company's senior director for public affairs stating, "The amount to drop into the U.S. Sovaldi press release, when you do final review is '\$28,000.'"³⁰⁶ The price appears to have been set during an offsite meeting held in the days prior with the company's leadership team—CEO John Martin, President and COO John Milligan, Chief Scientific Officer Norbert Bischofberger, CFO Robin Washington, Executive Vice President for Corporate and Medical Affairs Gregg Alton, and Young.³⁰⁷ No notes or further record of this meeting has been provided.

On November 24, 2013, Young was in Tokyo, Japan and exchanged emails with Martin, who noted the per-bottle price of \$28,000 would be "be easy from the press release, from 28 days and \$28,000."³⁰⁸ Young responded, "I think \$28,000 is right. Its [sic] where I wanted to be and I think we all collectively circled this price point. What I've really appreciated is how we have stepped carefully through this with the Board and [the leadership team] over two years."³⁰⁹ Martin ended the back-and-forth saying "I'm pleased where we are too."³¹⁰

³⁰⁶ Appendix E, Ex. 39, Email from Kevin Young to Cara Miller, Re: CONFIDENTIAL (Nov. 24, 2013), GS-0020946, at GS-0020947.

³⁰⁷ *Id.*; Appendix E, Ex. 38, email from Kevin Young to John Martin et al., COMPANY CONFIDENTIAL (Nov. 18, 2013), attaching Sofosbuvir (SOF) Pricing chart, GS-0020800, GS-0020801.

³⁰⁸ Appendix E, Ex. 39, Email from Kevin Young to Cara Miller, Re: CONFIDENTIAL (Nov. 24, 2013), GS-0020946.

³⁰⁹ *Id.*

³¹⁰ *Id.*

Those emails appear to be the final decision points in a pricing process. During that time, company officials engaged in a series of presentations that examined a complex matrix of tradeoffs regarding revenue, volume, marketing, reactions from payers, patients, and advocates, potential market competition, and how Sovaldi's price ultimately would affect pricing of Gilead's successor drug, Harvoni. Staff repeatedly requested documentation regarding the final pricing decision, but Gilead refused such requests. Accordingly, it was not clear what factors ultimately influenced the final decision to increase the price from the final recommendation of \$27,000 per bottle to \$28,000 per bottle.

However, it was clear that as senior leadership finalized the price for Sovaldi, the company was already anticipating protests over the price. "Let's not fold to advocacy pressure in 2014," Young wrote in an email on November 19, 2014, to Meyers, the company's chief spokesman, Coy Stout, and Kristie Banks, a senior director for business development and contract compliance.³¹¹ "Let's hold our position whatever competitors do or whatever the headlines."³¹²

International Pricing of Sovaldi Was Significantly Lower Than in the United States

As noted in the senators' July 2014 letter to Gilead, the pricing strategy for Sovaldi in non-U.S. markets contemplated significant lower prices than what would be set for U.S. consumers. For example, the senators noted that Gilead had reportedly reached an agreement with Egypt to sell Sovaldi for roughly \$900 per course of treatment.

In a written response to the senators, Gilead explained that it engaged in separate pricing approaches for developed- and less-developed countries. In developed countries, Gilead negotiated with individual countries and payers. Based on information provided by Gilead, Table 3 shows the wholesale price for Sovaldi in those developed countries was at significant discount to the U.S. price (per 12-week course of treatment).³¹³

³¹¹ Appendix E, Ex. 40, Email from Kevin Young to Jim Meyers et al., Re: ADAP and Sofosbuvir (Nov. 19, 2013), GS-0020802, at GS-0020802.

³¹² *Id.*

³¹³ Appendix F, Gilead Sciences, Inc., Response to Chairman Wyden/Senator Grassley letter dated July 11, 2014, narrative answer to question 21 (Sept. 9, 2014).

Table 3—Wholesale Price of Sovaldi in Developed Countries Outside the United States

Country	Price
Austria	\$63,189.70
Canada	\$50,525.00
Denmark	\$56,449.40
Finland	\$54,381.20
France	\$72,508.00
Germany	\$63,198.70
Luxembourg	\$62,149.90
Norway	\$53,043.90
Sweden	\$51,453.60
Switzerland	\$59,594.80
United Kingdom	\$57,100.20

Source: *Gilead Sciences, Inc.*, Response to Chairman Wyden/Senator Grassley letter dated July 11, 2014, narrative answer to question 21, September 9, 2014 (Appendix F)

In formulating its strategy for pricing for European countries, Gilead’s commercial pricing team sought to achieve “the highest price we can get accepted in early launch markets (UK, Germany, France).”³¹⁴ At the time, the team expected the United Kingdom to set the European price floor and Germany to set the ceiling,³¹⁵ although Gilead put great weight on negotiating an early European price point with the French Temporary Authorization of Use (ATU) program at \$74,000 in October 2013.³¹⁶ This program allows access to drugs for serious illness prior to final marketing authorization approval,³¹⁷ and was seen as an important benchmark for European negotiations.³¹⁸ Under this program, companies are granted a price premium, averaging 12%.³¹⁹ However, even at this price, a senior Gilead official cautioned that “. . . we should be careful saying that the price is comparable with existing treatment. It’s actually at a significant premium (although entirely justifiable on its merits.)”³²⁰

In less-developed countries, Gilead employed a different set of strategies. Initially, it followed a “tiered pricing structure based on a country’s health care and other resources and the severity of the HCV prevalence within that country.”³²¹ How these factors were weighted was not explained, but Gilead confirmed that it had signed a treatment agreement with the Egyptian government in

³¹⁴ Appendix E, Ex. 41, Gilead Sciences, Inc., “EAME SOF Price Recommendations” (Gilead slide presentation), September 11, 2013, GS–0019913, at GS–0019914.

³¹⁵ *Id.*

³¹⁶ Appendix E, Ex. 42, Email from Kevin Young to Jim Meyers and Derrell Porter (Oct. 19, 2013), GS–0020285, at GS–0020285.

³¹⁷ A. Degrossat-Theas et al., Abstract, *Temporary authorization for use: does the French patient access programme for unlicensed medicines impact market access after formal licensing?*, 31 *PharmacoEconomics* 335, 335–43 (April 2013), available at <http://www.ncbi.nlm.nih.gov/pubmed/23529210>.

³¹⁸ Appendix E, Ex. 42, Email from Kevin Young to Jim Meyers and Derrell Porter (Oct. 19, 2013), GS–0020285, at GS–0020285—GS–0020287.

³¹⁹ A. Degrossat-Theas et al., Abstract, *Temporary authorization for use: does the French patient access programme for unlicensed medicines impact market access after formal licensing?*, 31 *PharmacoEconomics* 335, 335–43 (April 2013), available at <http://www.ncbi.nlm.nih.gov/pubmed/23529210>.

³²⁰ Appendix E, Ex. 43, Email from Paul Carter to Cara Miller (Oct. 11, 2013), GS–0020212, at GS–0020212—GS–00200213.

³²¹ Appendix F, Gilead Sciences, Inc., Response to Chairman Wyden/Senator Grassley letter dated July 11, 2014, narrative answer to question 21 (Sept. 9, 2014).

July 2014 at a list price equivalent to \$908.04 per course of treatment.³²²

As Gilead noted in its written response, it also was pursuing a parallel strategy for these same less-developed-country markets based on the licensing of generic production and marketing of sofosbuvir-based drugs. Indeed, shortly after the response was provided, Gilead entered into licensing agreements with seven Indian pharmaceutical companies to produce and market sofosbuvir (Sovaldi) and ledipasvir/sofosbuvir single tablet regimen (Harvoni) in 91 developing countries.³²³ As explained by Meyers and Andy Rittenberg, corporate counsel for Gilead, in the October 30th interview, this model also has been used by Gilead for HIV/AIDS drugs. According to Mr. Rittenberg, these generic manufacturers would be licensed to manufacture and sell these drugs even in countries in which Gilead had previously reached pricing agreements.³²⁴

The generic manufacturers would set their own prices even to the point of undercutting Gilead's own country-specific price agreement—a point reiterated in the company's fact sheet, which states that "(t)he generic drug companies may set their own prices. . . ." ³²⁵ The license agreement for these generic manufacturing arrangements posted by Gilead on its website establishes a 7% royalty to be paid to Gilead Sciences Limited, an Irish corporation, on net sales of products in these 91 countries.³²⁶ According to the most recent version of the company's fact sheet, these generic licensing agreements have now been expanded to include 11 Indian companies for distribution in 101 developing countries.³²⁷

The cost of these drugs outside of the U.S. is significantly below the U.S. price—a fact that was actively considered by Gilead in pricing them in Canada. In a presentation prepared by the Gilead Sciences Canada, the company concluded that the expected Canadian wholesale price of \$55,000 would not draw cross border patients and that the structure of the Gilead distribution system would limit the risk of mail order arbitrage.³²⁸ Gilead concluded that U.S. patients would not cross the border to incur a final expected out-of-pocket expense of some \$64,000.³²⁹

³²² *Id.*

³²³ Press Release, Gilead Sciences, Inc., Gilead Announces Generic Licensing Agreements to Increase Access to Hepatitis C Treatments in Developing Countries, (Sept. 15, 2014), *available at* <http://www.gilead.com/news/press-releases/2014/9/gilead-announces-generic-licensing-agreements-to-increase-access-to-hepatitis-c-treatments-in-developing-countries>.

³²⁴ Interview with Jim Meyers, Senior Vice President, North America Commercial Organization, Gilead Sciences, Inc., in Washington, D.C. (Oct. 30, 2014).

³²⁵ Gilead Sciences, Inc., Fact Sheet, Chronic Hepatitis C Treatment Expansion: Generic Manufacturing for Developing Countries, August 2015, *available at* <http://www.gilead.com/-/media/files/pdfs/other/hcvgenericagreementfactsheet.pdf?la=en>.

³²⁶ Gilead Sciences, Inc., License Agreement, Execution Copy, September 15, 2014, (Section 4.1, page 8), *available at* http://gilead.com/-/media/files/pdfs/other/2014_original_hcv_licensing_agreement.pdf?la=en.

³²⁷ Gilead Sciences, Inc., Fact Sheet, Chronic Hepatitis C Treatment Expansion: Generic Manufacturing for Developing Countries, August 2015, *available at* <http://www.gilead.com/-/media/files/pdfs/other/hcvgenericagreementfactsheet.pdf?la=en>.

³²⁸ Appendix E, Ex. 44, Gilead Sciences, Inc., Canadian Sofosbuvir Pricing Considerations, September 30, 2013, GS-0020086, at GS-0020087.

³²⁹ *Id.* at GS-0020091.

Sticking to the Plan: Harvoni Builds on the Price Set for Sovaldi

After the successful launch of Sovaldi, Gilead turned its attention to pricing Harvoni, the second wave of HCV drugs involving sofosbuvir. In a series of presentations, Gilead described how it would “[s]ecure market share leadership, while growing the market,” through “[e]ffective portfolio management/prioritization in wake of successive launches, [r]esponding to competitors’ attempts to fragment the market *through scientific dialogue* with prescribers, [e]nsuring parity access in a payer environment that desires market fragmentation,” and “[a]ccelerating Market Development efforts to grow the market.”³³⁰ The ultimate goal for the time period was to “[m]aximize [t]otal [f]ranchise [v]alue.”³³¹

As it considered pricing Harvoni at \$96,000 for a 12-week course of therapy, which the majority of patients was expected to need, the company projected that its HCV drugs would generate more than \$30 billion in net revenue between 2015 and 2018.³³² The company ultimately set Harvoni’s price at \$94,500.³³³

Harvoni was expected to face competition that would make large price jumps difficult. One of the challenges was to “[p]rotect against price erosion from Wave 1→2, and 2→3.”³³⁴ As it set out to price Harvoni, the company viewed its position as one of “modest pricing power for the LDV/SOF, although avoiding restrictions with all accounts will be difficult to achieve.”³³⁵ The company also was loath to offer broad discounts, because they “do not offer offsetting share benefits for Gilead; however, this does not mean there are not some payers where discounting will be profitable.”³³⁶

Gilead’s main selling point for Harvoni has been that for certain patients—specifically, those who were treatment-naïve and free of cirrhosis—it would be a single-pill, interferon-free therapy that could be curative in eight weeks. However, Gilead expected that just 21% to 46% of patients using its drugs would fit in that category and receive the eight-week therapy.³³⁷ Gilead expected 14% to 32% of its Harvoni revenue to come from eight-week patients.³³⁸ The remainder would be on 12 weeks (45% to 70%) or in the case of treatment experienced patients with cirrhosis, 24 weeks (9%).³³⁹ Gilead has repeatedly said that Harvoni lowered the cost of treatment, but it did so only for the least sick, i.e., those with the lowest viral load counts and the healthiest livers.³⁴⁰ In terms of sticker prices, Gilead would now be charging \$94,500 for a 12-week treat-

³³⁰ Appendix E, Ex. 45, Gilead Sciences, Inc., 2015–2016 HCV Commercial Plan, April 22, 2014, GS–0014083, at GS–0014085 (emphasis in original).

³³¹ *Id.* at GS–0014086 (emphasis in original).

³³² Appendix E, Ex. 46, Gilead Sciences, Inc., Topics for Discussion—LDV/SOF U.S. Pricing, August 4, 2014, GS–0019000, at GS–0019026.

³³³ Stephanie M. Lee, *Is \$1,125 Hepatitis Pill from Bay Area Drugmaker Worth It?*, San Francisco Chronicle (Oct. 11, 2014), available at <http://www.sfgate.com/health/article/Is-1-125-hepatitis-pill-from-Bay-Area-drugmaker-5815341.php>.

³³⁴ Appendix E, Ex. 45, Gilead Sciences, Inc., 2015–2016 HCV Commercial Plan, April 22, 2014, GS–0014083, at GS–0014097.

³³⁵ Appendix E, Ex. 47, Gilead Sciences, Inc., U.S. HCV Pricing Update, SVP Update Meeting, July 21, 2014, GS–0018861, at GS–0018862.

³³⁶ *Id.*

³³⁷ *Id.* at GS–0018878.

³³⁸ *Id.* at GS–0018894—GS–0018895.

³³⁹ *Id.* at GS–0018878.

³⁴⁰ *Id.*

ment, up from \$84,000 for Sovaldi, and more than 30% higher than the price of Incivek.

In addition to boosting awareness of sofosbuvir and gaining access to payers' formularies, the company would seek to "[e]ducate governments about economic advantages of investments in HCV cure and of HCV budget increases in 2015–2016," and "[a]ccelerate patient flow through the HCV waterfall."³⁴¹ In other words, ensure patients were tested and received treatment at an earlier disease stage, "to drive longer term sustainable growth."³⁴² Specifically, the company was seeking to "[e]ncourage a shift towards more patients being candidates for treatment" to "drive rapid SOF uptake across all indicated patient types."³⁴³

Gilead was aware of "[n]egative noise regarding price and potential access limitations."³⁴⁴ It also knew that "[b]udget impact" would "shape reimbursement decisions in certain markets, with growing desire to prioritize care" amongst patients.³⁴⁵ Gilead singled out Medicaid, noting that "[w]hile this will grow to ~15% of the treated population, coverage may continue to be challenging based on state-level budget constraints," and that the program was "[h]ighly cost constrained and predominately cost-focused."³⁴⁶ Gilead expected HCV treatment "to drive a significant increase in 2015 federal Medicare Part D spending and annual individual beneficiary premiums."³⁴⁷ It also was aware that "[t]he Wave 2 launches will add significantly to the total spend on HCV," with its projections topping \$15 billion in 2015, alone, compared to less than \$2 billion in 2013 (see slide below).³⁴⁸ Gilead stated in a slide titled "PR Considerations" presented in July that "[g]iven that the LDV/SOF is >\$1000/pill for all scenarios under consideration, negative stakeholder reactions and media scrutiny can be expected to continue in the months prior to AbbVie's launch."³⁴⁹ Similar to its approach with Sovaldi, Gilead examined how different prices would affect "soft" factors ranging from negotiations with insurers, to the possibility that "[d]iscussions of U.S. government price controls gain traction."³⁵⁰

³⁴¹ Appendix E, Ex. 45, Gilead Sciences, Inc., 2015–2016 HCV Commercial Plan, April 22, 2014, GS–0014083, at GS–0014095 (emphasis in original).

³⁴² *Id.*

³⁴³ Appendix E, Ex. 48, Gilead Sciences, Inc., 2014–2015 U.S. HCV Franchise BPOA (Draft), GS–0014143 at GS–0014146.

³⁴⁴ *Id.*

³⁴⁵ Appendix E, Ex. 45, Gilead Sciences, Inc., 2015–2016 HCV Commercial Plan, April 22, 2014, GS–0014083, at GS–0014088.

³⁴⁶ Appendix E, Ex. 48, Gilead Sciences, Inc., 2014–2015 U.S. HCV Franchise BPOA (Draft), GS–0014143 at GS–0014157.

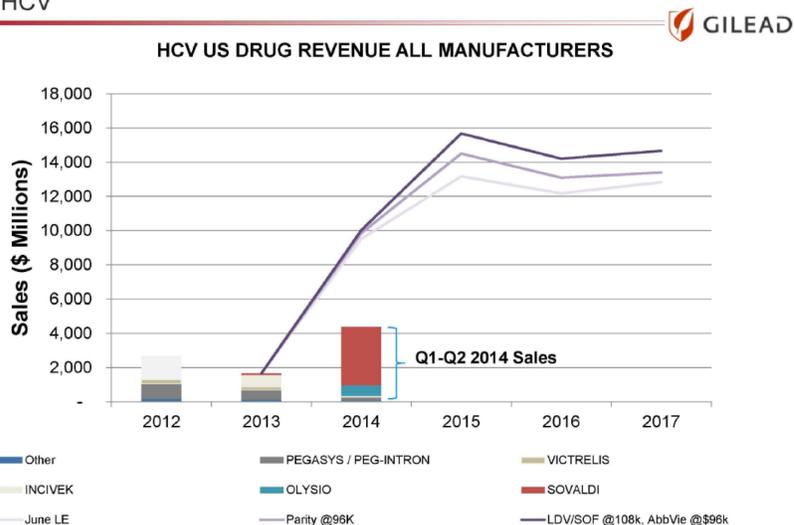
³⁴⁷ Appendix E, Ex. 49, Gilead Sciences, Inc., Updated Slides—Wave 2 Pricing, GS–0018965, at GS–0018992.

³⁴⁸ Appendix E, Ex. 47, Gilead Sciences, Inc., U.S. HCV Pricing Update, SVP Update Meeting, July 21, 2014, GS–0018861, at GS–0018891.

³⁴⁹ *Id.* at GS–0018906 (emphasis omitted).

³⁵⁰ Appendix E, Ex. 46, Gilead Sciences, Inc., Topics for Discussion—LDV/SOF U.S. Pricing, August 4, 2014, GS–0019000, at GS–0019013.

The Wave 2 launches will add significantly to the total spend on HCV



Source: IMS MIDAS US HCV SALES, Note: Merck is not included in the sales figures but does impact share calculations

In addition, Gilead received direct feedback from payers such as CVS/Caremark, Molina Healthcare, Atrius Health, California Medicaid, UnitedHealth Group, and Blue Cross Blue Shield of Michigan, all of which had representatives on Gilead's payer advisory board.³⁵¹ In October 2014, “[a]dvisors found Sovaldi and LDV/SOF’s clinical profile compelling; however, the cost per population and impact on the plan’s budgets [sic] are large concerns for advisors,” which the presentation listed under “similarities” with previous advisory boards.³⁵² And as Gilead was seeking to expand the number of patients, Joel Brill, the CEO of Predictive Health LLC, warned “[t]here is a need to narrow the patient population, because if you tell us that all patients need to be treated, our budgets cannot afford that,” which was put under a category in the presentation of “budget sustainability.”³⁵³

Gilead recognized that Sovaldi had fundamentally changed the HCV market in 2014. It estimated that, based on 120,000 new patients and an average treatment cost of \$89,300, “[o]verall additional spending on HCV treatments in the U.S. in 2014 is estimated \$10.7 [billion],” which “[r]eflects a 280% increase in national HCV [per member per month] spending from \$0.87 in 2013 to \$4.2 in 2014,” while “[a]nnual increases in PMPM have typically ranged from 3% to 4%.”³⁵⁴ In addition, the company expected HCV spending to push down earnings-per-share by double-digit percentages

³⁵¹ Appendix E, Ex. 50, Gilead Sciences, Inc., Managed Markets Hepatitis C Virus (HCV) Payer Advisory Board Final Report, October 3, 2014, GS-0018760, at GS-0018768—GS-0018769.

³⁵² *Id.* at GS-0018774.

³⁵³ *Id.* at GS-0018777.

³⁵⁴ Appendix E, Ex. 47, Gilead Sciences, Inc., U.S. HCV Pricing Update, SVP Update Meeting, July 21, 2014, GS-0018861, at GS-0018908.

for the largest health insurers, UnitedHealth, WellPoint, Aetna and Humana, which “could drive payers to push back on cost or change coverage going forward.”³⁵⁵ The slide below summarizes Sovaldi’s financial impacts to private payers during 2014.³⁵⁶

Major payers have been actively adjusting forecasts and working with their state partners to prepare for expected increased HCV spend



PAYER	COMMENTARY
Express Scripts	<ul style="list-style-type: none"> Specialty spend is forecasted to increase +63% over the next three years HCV is expected to be a key driver of this increased spend
Humana	<ul style="list-style-type: none"> EPS was lower than the second quarter of last year due to HCV drug costs Working with states (e.g., Florida, Illinois, Virginia) to fund HCV exposures
Aetna	<ul style="list-style-type: none"> Medical cost trends continue to be moderate and consistent with previous range of projections despite HCV cost pressures
WellPoint	<ul style="list-style-type: none"> More than doubled HCV costs in pricing for 2014 compared to 2013 and added \$100M to that outlook in Q1 2014 Working with states to incorporate full expected HCV costs into reimbursement rates
Centene	<ul style="list-style-type: none"> Net cost impact of HCV in Q2 2014 was \$13.7M (compared to \$4.2M in Q2 2013 and \$7.3M in Q1 2014) Working with states to include full expected HCV costs into reimbursement rates
United Health Group	<ul style="list-style-type: none"> Q2 spend for HCV was “in line with” revised expectations after Q1
WellCare	<ul style="list-style-type: none"> HCV drugs have had a meaningful short term budget impact (\$0.30 per share in expenses) Florida is the first state to provide a specific reimbursement agreement for the managed Medicaid lives

Source: Payers’ Q2 Earnings Calls, via RBC -32-

Gilead prioritized outreach to certain health care providers based on the number of HCV patients they were seeing and treating. For providers who were already prescribing Sovaldi, the company’s “[b]ehavioral [o]bjective” was to continue and expand use of the drug.³⁵⁷ For providers who were not using Sovaldi, the company planned to initiate sales calls and urge them to begin prescribing.³⁵⁸

The company also broke down consumer and patient groups into high, medium and low priorities. Within the high priority category were diagnosed patients whose average age was 50 and were employed, insured, “more educated” and with an annual income of \$60,000.³⁵⁹ Gilead’s “behavioral objective” with these patients was to “[e]ngage patients to re-think their Hep C, [a]ctivate urgency to treat, [d]rive linkage to treating specialists, [a]sk provider for treatment by name.”³⁶⁰ Community service providers and allied health care providers in clinical settings were designated a “low-medium” priority.³⁶¹ Gilead estimated that there were 9,000 community health clinics that would need to be engaged to ensure the com-

³⁵⁵ *Id.* at GS-0018908—GS-0018909.

³⁵⁶ *Id.* at GS-0018891.

³⁵⁷ Appendix E, Ex. 48, Gilead Sciences, Inc., 2014–2015 U.S. HCV Franchise BPOA (Draft), GS-0014143, at GS-0014151—GS-0014153.

³⁵⁸ *Id.*

³⁵⁹ *Id.* at GS-0014154.

³⁶⁰ *Id.*

³⁶¹ *Id.* at GS-0014155.

pany's treatments were used.³⁶² It expected that "[t]o activate [community health workers, Gilead would] need to educate about evolving treatment paradigm, cure, importance of linkage to HCV care."³⁶³

Finally, Gilead ranked payers, with commercial, Medicare, and VA rated as "high" priorities, and Medicaid as a "medium" priority. Corrections were rated as a "low-med" priority, as were integrated delivery networks like Kaiser Permanente "depending on risk."³⁶⁴ Payers participating in exchanges were "low" priority, with the company noting that "[o]nly 6% of treated patients will come from exchange plans by 2016," and that while coverage was similar to commercial and managed care Medicaid plans, exchanges are "generally more restrictive, and with higher cost-sharing."³⁶⁵ Two months later, the company would observe that payers would be reluctant to block access to new HCV drugs, "instead, payers may pick two 'winners' and generate rebates off the volume."³⁶⁶

In regards to determining the price point for Harvoni, Gilead studied \$84,000, \$115,000 and \$145,000. Notably, Gilead labeled the \$145,000 price point as "unacceptably expensive."³⁶⁷ In a survey of payers, \$84,000 was viewed as "reasonable," while \$115,000 was viewed as "at the top end of value alignment" and "pushing the upper limit."³⁶⁸ However, like when it priced Sovaldi, Gilead was aware that market competition, particularly for genotype 1 patients, would restrict the company's ability to capture higher prices with its second wave drug, Harvoni.

Gilead was concerned that since Bristol-Myers Squibb was exploring a combination of its own drug with sofosbuvir that it would create competition over price and possibly undercut Harvoni if priced it too high: "As a consequence, if LDV/SOF is priced at a significant premium to the alternative, physicians will allocate a substantial share of prescriptions to the DCV+SOF combination."³⁶⁹ Likewise, the company spent a significant amount of effort comparing its price to different price points for AbbVie's Viekira Pak, and the trade-offs between market access and revenue maximization.³⁷⁰

It also studied what Wall Street analysts expected in terms of a price for Harvoni, and the "potential impact on estimate earnings," which would affect equity investment.³⁷¹ Documents show that the company had had an interest in analysts' opinions on Harvoni's price during the lead-up to Sovaldi's release. On October 31, 2013, Robin Washington received a lengthy "buy-side survey" from health care analyst Mark Schoenebaum that contained financial and pric-

³⁶² *Id.*

³⁶³ *Id.*

³⁶⁴ Appendix E, Ex. 45, Gilead Sciences, Inc., 2015–2016 HCV Commercial Plan, April 22, 2014, GS–0014083, at GS–0014157.

³⁶⁵ Appendix E, Ex. 48, Gilead Sciences, Inc., 2014–2015 U.S. HCV Franchise BPOA (Draft), GS–0014143, at GS–0014156—GS–0014157.

³⁶⁶ Appendix E, Ex. 47, Gilead Sciences, Inc., U.S. HCV Pricing Update, SVP Update Meeting, July 21, 2014, GS–0018861, at GS–0018865.

³⁶⁷ *Id.* at GS–0018866.

³⁶⁸ *Id.*

³⁶⁹ *Id.* at GS–0018863.

³⁷⁰ *Id.* at GS–0018869.

³⁷¹ Appendix E, Ex. 46, Gilead Sciences, Inc., Topics for Discussion—LDV/SOF U.S. Pricing, August 4, 2014, GS–0019000, at GS–0019009—GS–0019010.

ing predictions that had been collected from 203 respondents.³⁷² These analysts expected that the gross price for a 12-week regimen of Sovaldi would be \$85,400; the price of Harvoni was expected to be \$94,000.³⁷³

On September 9, 2014, the company discussed its contracting strategy with a price of \$94,500, specifying specific discounts for various payer groups and payers:³⁷⁴

Segment	Discount	Approach	Commentary
Kaiser Permanente	20%	Proactive	
Integrated Delivery Networks (Geisinger, University of Pittsburgh Medical Center, Selective, Henry Ford)	8%–10%	Proactive	Henry Ford is reactive only
Departments of Corrections (CA, FL, NY, OH, MI, AZ & University of Texas Medical Branch)	10%–20%	Proactive	Contract with listed State DOC's at a discount of 10–20%. UTMB will receive 340B pricing and a 15% supplemental discount on eligible utilization (10% on Commercial utilization)
FFS Medicaid Medicaid Pools Magellan and SSDC Independent States: Magellan Independent States: FL, MO, TN, TX, VA All other independent states: CA, CO, GA, IL, IN, MA, OH	4–10%	Proactive	Independent states will be negotiated if they are listed as "select payers" or reactive, as needed Discounts will be tiered based on the coverage levels (fibrosis level) – Listed on preferred drug list (4%) – F2–F4 (8%) – Prior Authorization to Label (10%)
Managed Medicaid	See Commentary	PROACTIVE for PerformRx and Envision Rx REACTIVE FOR ALL OTHER MMCO ACCOUNTS ACCORDING TO GUIDELINE CRITERIA	– At launch, for Type A accounts, proactively extend rebates for SOF/LDV at 4%–5% – At formulary review/competitor launch, rebates for the Type A accounts in 5%–7% range – For Type B accounts, either half of rebate available to account capped at 7% or rebate range of 5%–7% – For Type C accounts, discounts will be considered based on guideline criteria
VA/DOD	10% (plus 26% statutory discount)	Proactive	VA discounts will be proactively submitted via TPR

³⁷² Appendix E, Ex. 51, Email from Mark Schoenebaum to Robin Washington, FINAL data from gild/bmy (and sort of MRK/ROG) buy-side survey, (Oct. 31, 2013), GS–0020496, at GS–0020496—GS–0020497.

³⁷³ *Id.*

³⁷⁴ Appendix E, Ex. 52, Gilead Sciences, Inc., HCV Wave 2 Contracting Recommendations, September 9, 2014, GS–0019058, at GS–0019060—GS–0019063.

Segment	Discount	Approach	Commentary
340B	Statutory Discounts	Proactive	All 340B accounts will receive statutory discounts with the exception of UTMB and Puerto Rico DOH
Healthcare exchanges	Equal to commercial discounts	Proactive	Exchange utilization will be included in commercial account contracts at the commercial discount rate

Source: Appendix E, Ex. 52, Gilead Sciences, Inc., HCV Wave 2 Contracting Recommendations, September 9, 2014, GS-0019058, at GS-0019060—GS-0019063

Gilead further broke down its priority accounts by tier. Standing alone at the top tier was Express Scripts, which Gilead estimated had 233,900 HCV patients.³⁷⁵ The second tier included Humana (43,700 HCV patients), Optum Rx (78,900 HCV patients), WellPoint (76,520 HCV patients), and CVS Caremark (22,035 HCV patients).³⁷⁶ With most of the largest national accounts, Gilead planned to begin contracting negotiations at a 5% rebate, generally maxing out at between 8% and 12%.³⁷⁷ These highest priority accounts were followed by eight pages of tables with dozens more accounts that, because of size or other reasons, were deemed a lower priority by Gilead.³⁷⁸ Rebate strategies varied widely, ranging from no rebate to 12% (see slide below).³⁷⁹

**Contracting Recommendations and Rationale
Overview of Tiered Rebate Approach**

Below are the rebate recommendations for each account tier. Due to their size and influence, ESI, CVS Caremark, Humana, UnitedHealthcare, and WellPoint are considered "must win" accounts.

	Accounts	Max Rebate (S94.5k WAC for 12 wk regimen)
Tier 1	EXPRESS SCRIPTS®	8% - 12%
Tier 2	National: Humana, OPTUMRx, WELLPOINT	8% - 12% (Humana: 12% - 15%)
Tier 3	aetna, CVS CAREMARK, WellCare, PRIME	8% - 12%
Tier 4	Key Regionals: blue of california, Harvard Pilgrim HealthCare, ...and others	10%
Tier 4	Kaiser: KAISER PERMANENTE	20%
Tier 4	Other IDNs: selecthealth, GEISINGER, UPMC	8-10%
Tier 5	High Potential, High Control: Rebate 5%	5%
Aggregate Rebate		7% - 10%

GILEAD

³⁷⁵ *Id.* at GS-0019069.

³⁷⁶ *Id.*

³⁷⁷ *Id.*

³⁷⁸ *Id.* at GS-0019068—GS-0019078.

³⁷⁹ *Id.*

The company appears to have been strict in its limits for rebate negotiations. For example, while the company was willing to provide Kaiser Permanente with a higher discount than other payers (20%), Kaiser had “articulated expectations of a rebate as high as 30% to 49%.”³⁸⁰ In notes on the contracting approach for Kaiser, the company states “the rebate may be extended by BU and Executive Leadership above 20%.”³⁸¹ It is not clear who or what “BU” is in this instance. Similar notations can be found for other accounts, as well.

Gilead estimated that about 360,000 of the 1.2 million-person state prisoner population were infected with HCV, but the company planned to limit its contracting approach to the most populous state systems. The company had already secured contracts with California and Texas and would seek to contract with only the five largest Departments of Corrections that remained, because the company saw diminishing benefits in smaller prison systems. The five states—Florida, New York, Ohio, Michigan, and Arizona—represented “~42% of non-contracted inmate lives.”³⁸² In focusing on the prison population, Gilead saw an “[a]bility to treat inmates before they are released and potentially treated through Medicaid.”³⁸³ Risks included “[s]pillover to other non-contracted state DoCs,” and potentially “miss[ing] out on treatment opportunities arising from public policy changes.”³⁸⁴ The company noted it would “[s]upport HCV treatment in DoC segment by providing reduced price which will stretch the existing DoC budgets.”³⁸⁵

Gilead also studied what factors payers and physicians would focus on when making a conclusion as to what price point was palatable. Payers appeared to provide the company with some conflicting views with respect to the price of Harvoni. For example, the company expected that for “scenarios with the same net price, access is more favorable for a high WAC/high discount approach,” than lower WAC and lower rebates.³⁸⁶ However, a key finding with its payer advisory board indicated that SVR rates were a focal point; “[a]llthough advisors initially responded negatively to the cost of the regimen, most advisors responded positively to data presented as cost per SVR.”³⁸⁷ As an example, when members of Gilead’s payer advisory board were asked during a May 2014 meeting to “price each regimen based on the clinical profile as if they were the manufacturer,” the average was \$102,855, with a range of \$84,000 to \$126,000.³⁸⁸ William Cardarelli, director of pharmacy at Atrius Health, believed the controversy over the drugs’ prices would be short-lived: “The best thing you can do is help us figure out who gets treated and not position yourselves as treating everyone at diagnosis. This too will pass, the hysteria will die down;

³⁸⁰ *Id.* at GS-0019082.

³⁸¹ *Id.*

³⁸² *Id.* at GS-0019094.

³⁸³ *Id.* at GS-0019098.

³⁸⁴ *Id.* at GS-0019096.

³⁸⁵ *Id.* at GS-0019098.

³⁸⁶ Appendix E, Ex. 47, Gilead Sciences, Inc., U.S. HCV Pricing Update, SVP Update Meeting, July 21, 2014, GS-0018861, at GS-0018910.

³⁸⁷ Appendix E, Ex. 50, Gilead Sciences, Inc., Managed Markets Hepatitis C Virus (HCV) Payer Advisory Board Final Report, October 3, 2014, GS-0018760, at GS-0018772.

³⁸⁸ *Id.* at GS-0018797.

there's something new every year. The government has the attention of a 2-year-old.”³⁸⁹

Notably, physicians did not assign great importance to the price of the drug, which Gilead was keenly aware of throughout its process of pricing Sovaldi and Harvoni. A survey of payers ranked net cost as the second most important issue for management of therapies.³⁹⁰ Physicians, meanwhile, ranked five clinical attributes ahead of cost: SVR, tolerability, adverse events, treatment duration, and ease of administration ahead of a patient's out-of-pocket expenses.³⁹¹ Such divergence was one of the reasons that Gilead was focused on keeping decisions in the hands of providers.

Gilead's Marketing to Doctors and Patients

Part of Gilead's strategy was to seed demand by having patients approach their health care providers (HCPs) for treatment, and to convince providers of the drug's merits so they would “expand their definition of ‘treatment candidates’ so that they reengage untreated patients for SOF.”³⁹² At the same time, the company needed “access and advocacy” to eliminate “barriers” to treatment and medical society treatment guidelines, as well as KOLs (key opinion leaders) to advocate on behalf of the products.³⁹³ To that end, the company's top goal was to quickly establish sofosbuvir as the standard of care for all genotype 1, genotype 2, and genotype 3 patients, and to “sustain launch trajectory by growing treated patient pool,” specifically, increasing treated patients 73% beginning in November 2013.³⁹⁴

As Gilead began to consider how to price its soon-to-be-approved drug, the company refined its commercial pitch to ensure that it would be financially successful. A 44-page presentation on April 4, 2013 titled “2013–2015 HCV Launch Commercial Plan,” shows that Gilead wanted to maximize the opportunities, and minimize the threats through a combination of advertising, brand placement, lobbying, public relations and marketing, developing supporters in the medical and patient advocacy communities, targeted speeches at medical conferences, published articles in medical journals, and extensive salesforce training on a country-by-country basis taking into account national requirements. These initiatives would be led by the company's Commercial Planning and Operations department, whose job it would be to marshal the resources of employees in departments ranging from public affairs to research and development, medical affairs and sales.³⁹⁵

In order to prepare the market for sofosbuvir's launch, Gilead planned to court providers using a branded campaign to sell “HCV Treaters, Past Treaters and high potential Non-Treaters” on the clinical efficacy of Sovaldi through in-office visits, journals, and on-

³⁸⁹ *Id.* at GS-0018773.

³⁹⁰ Appendix E, Ex. 47, Gilead Sciences, Inc., U.S. HCV Pricing Update, SVP Update Meeting, July 21, 2014, GS-0018861, at GS-0018926.

³⁹¹ *Id.* at GS-0018926, GS-0018943.

³⁹² Appendix E, Ex. 29, Gilead Sciences, Inc., Gilead HCV U.S. BPOA, October 2012, GS-0013489, at GS-0013493.

³⁹³ *Id.* at GS-0013493.

³⁹⁴ *Id.* at GS-0013490.

³⁹⁵ Appendix E, Ex. 32, Gilead Sciences, Inc., 2013–2015 HCV Launch Commercial Plan, April 4, 2013, GS-0013503, at GS-0013527—GS-0013534.

line material.³⁹⁶ Each category of “treater” was prioritized based on the potential for providers to take up “target behaviors” to “quickly adopt sofosbuvir as SOC, re-engage untreated patients in their practice and discuss sofosbuvir with them, [and] become advocates for sofosbuvir and increasing treatment rates.”³⁹⁷ The company further analyzed the groups in terms of the number of patients, prescriptions for interferon, and speed with which they began using previous protease inhibitors. The most valuable “customer group” for the company’s sales force were 660 “high value current PI (protease inhibitor) treaters.” Based on prescription data for other HCV drugs, the company estimated that these providers had an average of 26 patients per provider—more than five times as many as the next category of 4,452 “Community PI Rxers.”³⁹⁸ One goal was to ensure that Gilead’s sales resources were being used to convince providers to prescribe sofosbuvir.

In addition, a cornerstone of Gilead’s strategy to court the medical community was its “[s]peaker [f]aculty and [t]raining.”³⁹⁹ Gilead recruits, trains and retains third-party health care professionals that are part of a “Speakers Bureau” to communicate on behalf of the company’s products and the diseases they treat. In order to incentivize experts to speak on behalf of their products, Gilead will pay speaking fees and reimburse travel expenses for the speakers.⁴⁰⁰ Gilead reported paying speaking fees of \$2.1 million for Harvoni and \$2.9 million for Sovaldi in 2014.⁴⁰¹ An analysis by investigative staff shows that Gilead made 2,630 payments to 293 providers in 46 states for “compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program,” related to Sovaldi or Harvoni.⁴⁰² The average payment was \$1,379, and the median payment was \$2,500.⁴⁰³

These speakers use materials, slides and handouts that have been approved and are tightly controlled by Gilead:

Speakers may not edit, reorder, or hide any slides or otherwise modify the content emphasis, balance or context of the material in the slides. Speakers must move through the on-label deck, displaying every slide. They need not verbalize all content on every slide but should address points of interest or relevance for the particular audience or setting. A substantial portion of the presentation must be devoted to the presentation and discussion of this slide deck. Speakers may only use their own slides in excep-

³⁹⁶ *Id.* at GS-0013494.

³⁹⁷ *Id.* at GS-0013497.

³⁹⁸ *Id.* at GS-0013498.

³⁹⁹ Appendix E, Ex. 48, Gilead Sciences, Inc., 2014–2015 U.S. HCV Franchise BPOA (Draft), GS-0014143, at GS-0014163.

⁴⁰⁰ Gilead Sciences, Inc., 2009 *Pocket Guide to Gilead’s Business Conduct Manual*, at 17–19, available at <http://phx.corporate-ir.net/External.File?item=UGFyZW50SUQ9MjE0MjI8Q2hpbGRJRDR0tMXxUeXBIPtM=&t=1> [hereinafter Gilead, 2009 Pocket Guide].

⁴⁰¹ Gilead Sciences, Inc., *Sunshine Act/Open Payments Compliance: Reporting Period: January 1 to December 31, 2014*, available at <http://www.gilead.com/responsibility/sunshinepercent20actpercent20openpercent20paymentspercent20compliance> (last visited Sept. 10, 2015).

⁴⁰² Data available from Gilead Sciences, Inc., 2014 Non-Research Speaker Payments (spreadsheet), available at <http://goo.gl/iTu3Ld> (accessed July 14, 2015).

⁴⁰³ *Id.*

tional circumstances and if they are pre-approved by Gilead.⁴⁰⁴

Gilead aimed to conduct 2,500 to 2,750 speaker programs related to its HCV treatments with as many as 400 speakers onboard by the third quarter of 2014.⁴⁰⁵ Presentations promoting Harvoni were approved by the company within two days of the FDA's approval of the drug, and speeches began within two weeks after approval.⁴⁰⁶

Convincing providers was only part of the equation for Gilead as the company wanted patients who had long been told to wait for development of more effective cures to go to their providers seeking help. These combined efforts would “need to drive more patients into care and increase referral rates,” and “overcome inertia towards non-treatment.”⁴⁰⁷

Gilead recognized that years of warehousing had shrunk the annual number of people receiving HCV treatment to 56,000 annually.⁴⁰⁸ To combat the low number of patients, Gilead calculated that Sovaldi, and its would-be competitor, Olysio, needed to increase the number of annual treatments to be viable: “Sofosbuvir and simeprevir launch must increase treated pool by 41K patients to be consistent with forecast.”⁴⁰⁹ The document does not indicate that Gilead ever expected the two drugs to be used in an off-label combination as AASLD ultimately recommended for patients who could not tolerate interferon.

To foster demand, the company planned to use a non-branded disease awareness advertising campaign to target baby boomers to ask providers about new HCV treatments.⁴¹⁰ The working document had many components ranging from geography (“20 states capture 75% of Baby Boomer population”) to effective types of media (“TV, Internet, and radio have the highest reach to Boomers”) to potential advantages to using a spokesperson (“Credible individual that baby boomers can relate to (e.g. Sally Field for Boniva”).⁴¹¹ The company would measure the campaign's success based on rating points and other tracking metrics, response to the campaign demonstrated by seeking out more information, and, finally, action as demonstrated by provider visits and drug prescriptions.⁴¹²

While not explicitly discussed in this presentation, one example of the awareness campaign includes the website *www.hepchope.com*, which Gilead set up in addition to a toll-free phone number 1-844-4HepcHope. The toll-free number is staffed from 9 a.m. to 9 p.m. by health educators employed by Gilead in Foster City, California, where the company is based. When calling, the caller is asked to provide an email or physical mailing address with which Gilead and its partner companies can send educational

⁴⁰⁴ Gilead, *2009 Pocket Guide*, at 17–19.

⁴⁰⁵ Appendix E, Ex. 48, Gilead Sciences, Inc., 2014–2015 U.S. HCV Franchise BPOA (Draft), GS-0014143, at GS-0014163.

⁴⁰⁶ *Id.* at GS-0014163—GS-0014165.

⁴⁰⁷ Appendix E, Ex. 29, Gilead Sciences, Inc., Gilead HCV U.S. BPOA (Oct. 2012), at GS-0013492, GS-0013493.

⁴⁰⁸ *Id.* at GS-0013490.

⁴⁰⁹ *Id.*

⁴¹⁰ *Id.* at GS-0013499.

⁴¹¹ *Id.* at GS-0013500.

⁴¹² *Id.* at GS-0013499—GS-0013502.

information about HCV (see below), strategies for finding a provider and discussing the disease, and information about Gilead's HCV treatments.

The caller is further asked how they heard about the hotline/website, and are advised that, while their privacy will be protected, Gilead may use their information for market research. Callers can be transferred to Gilead's "Support Path" program, which is designed to help "patients get started on therapy and move toward treatment completion," through on-call nurses, financial assistance for drug purchases, and prepared forms such as "letters of medical necessity" that providers send to insurers.⁴¹³ Like HepCHope, the program provides valuable and detailed market intelligence for Gilead. For example, a presentation in September 2014 analyzing Medicaid fee-for-service programs says a "majority of states are managing HCV with strict criteria," pointing to "953 unique patients on Support Path."⁴¹⁴

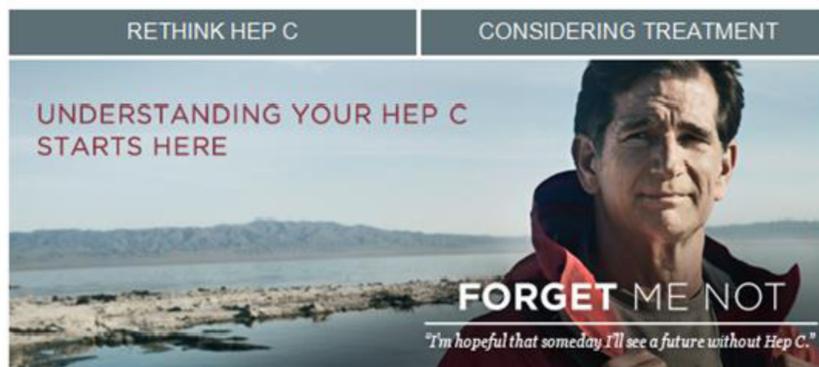
On the website, clicking "learn more about a treatment option for Hepatitis C" links to a website advertising Harvoni. According to an advertising industry website, a Gilead commercial that advertises the HepCHope phone number and website had aired at least 9,816 times as of November 18, 2015.⁴¹⁵

⁴¹³ Gilead Sciences, Inc., Support Path, available at <http://www.mysupportpath.com/> (accessed Nov. 10, 2015).

⁴¹⁴ Appendix E, Ex. 52, Gilead Sciences, Inc., HCV Wave 2 Contracting Recommendations, September 9, 2014, GS-0019058, at GS-0019104.

⁴¹⁵ Gilead Sciences, Inc., *HepCHope.com TV Commercial, "Forget Me Not,"* available at <http://www.ispot.tv/ad/7Ba0/hepchope-com-get-me-not> (accessed Nov. 18, 2015).

HEP C HOPE.COM



Welcome [REDACTED]

We are so glad you've joined Hep C Hope. We understand that, at times, your hepatitis C (Hep C) may not be your first priority. Maybe you pushed it aside because you haven't had any symptoms. Or perhaps your Hep C specialist has said your Hep C isn't that bad or you don't need treatment now.

YOU HAVE NOT BEEN FORGOTTEN. That's why we're here. Hep C Hope is designed to provide you with information and resources to help you rethink your Hep C so that, when you're ready, you can have a better conversation with your [Hep C specialist](#).

THIS IS AN EXCITING TIME. Many people like you are rethinking their Hep C. In fact, there are treatment options that may help cure your Hep C. Cure means the Hep C virus is not detected in the blood when measured 3 months after treatment is completed.

We are looking forward to helping you learn more about Hep C and your treatment options.

Sincerely,
The Hep C Hope Team

We're here to give you information and support to help you move forward.

IN THE COMING WEEKS, YOU CAN EXPECT TO

- Receive more information and resources
- Get tips on how to have a better conversation with your Hep C specialist
- Learn about different treatment options

Learn more about Hep C and your **treatment options**.

Meyers told investigative staff that the company never launched a branded campaign for Sovaldi on television. Instead, the company provided visual materials to physicians and advertised in medical journals. Meyers said the print campaign started in February 2014 and lasted roughly a month-and-a-half, at which point the company

noted an unexpected volume surge.⁴¹⁶ Examples of print advertisements for Sovaldi can be found in the July 2014 and September 2014 issue of Esquire magazine.⁴¹⁷ The purpose of the ads was to build disease awareness, Meyers said, but Gilead was experiencing such large volume that it was not deemed necessary.⁴¹⁸

Gilead has advertised a great deal for Harvoni—ads for the drug have aired 8,224 times as of November 18, 2015.⁴¹⁹

Changing Hep C with a groundbreaking treatment called SOVALDI.*

SOVALDI is a prescription medicine used with other antiviral medicines to treat chronic (lasting a long time) hepatitis C (Hep C) infection in adults. SOVALDI should not be taken alone. It is not known if SOVALDI is safe and effective in children under 18 years of age.

For the most common type of Hep C (genotype 1), SOVALDI is designed and proven to work quickly with just 12 weeks of treatment in combination with other prescription medicines. One SOVALDI pill is taken once daily along with another oral medicine and a weekly injection. In a clinical study nearly 9 out of 10 patients were cured. All patients received SOVALDI once daily for 12 weeks along with another oral medicine (sofosbuvir) and weekly injections (peginterferon alfa).

Cure means the Hep C virus is not detected in the blood when measured 3 months after treatment is completed.

They're calling this Hep C treatment a breakthrough. They got that right. Imagine being Hep C free after just 12 weeks of treatment.

Don't wait for your liver disease to progress. Talk to your gastroenterologist today and visit sovaldi.com or call 844-4-SOVALDI.

Important Safety Information

What is the most important information I should know about SOVALDI?
SOVALDI combination therapy with sofosbuvir or peginterferon alfa and ribavirin can cause birth defects or death of your unborn baby. If you or your sexual partner is pregnant or plans to become pregnant, do not take these medicines. You and your sexual partner must use 2 effective forms of birth control and should not become pregnant while being treated with SOVALDI combination therapy and for 6 months after your treatment is over. Talk to your doctor about forms of birth control.

You should not take SOVALDI alone. SOVALDI should be used together with sofosbuvir in combination with peginterferon alfa and ribavirin to treat chronic Hep C infection.

What should I tell my healthcare provider before taking SOVALDI?

- If you have liver problems other than hepatitis C infection, had a liver transplant, severe kidney problems or are on dialysis, HIV, any other medical condition or if you are breastfeeding or plan to breastfeed. You and your healthcare provider should decide if you will take SOVALDI or breastfeed. You should not do both.
- If you take rilpivirine (Rilpivirine, Ripster®), St. John's wort or a product that contains St. John's wort. Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Other medicines may affect how SOVALDI works.

What are the most common side effects of SOVALDI?

For SOVALDI used in combination with peginterferon alfa and ribavirin they include tiredness, headache, nausea, difficulty sleeping, and low red blood cell count.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

SOVALDI
SOFOSBUVIR

*In a study of 287 patients who had no prior Hep C treatments, 89% of those with genotype 1 were cured. All patients received SOVALDI once daily for 12 weeks along with another oral medicine (sofosbuvir) and weekly injections (peginterferon alfa).

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Please see Brief Summary of full Prescribing Information on the following page.

In addition, the company needed to ensure that policymakers were aware of HCV as a public health issue, so it would be a higher priority for government outlays. The company planned to boost government awareness by “creating tools necessary to engage policymakers in advocating and elevating HCV as a major public health issue and increase budgets accordingly.”⁴²⁰ To that end, before launching the drug, Gilead planned to “articulate the unmet needs and disease burden of HCV to multiple stakeholders including physicians, health policy makers, payers, and advocates,” and “develop evidence of HCV disease burden and a plan for raising HCV as a national health priority.”⁴²¹

Gilead believed sofosbuvir’s shortening and simplification of treatment for genotype 1 patients would be appealing to providers, who in turn would be more likely to prescribe the drug than they had been with predecessor therapies. However, because relatively few physicians routinely prescribed drugs for HCV, the company

⁴¹⁶ Interview with Jim Meyers, Senior Vice President, North America Commercial Organization, Gilead Sciences, Inc., in Washington, D.C. (October 30, 2014).

⁴¹⁷ Gilead Sciences, Inc., *Sovaldi* (advertisement), Esquire Magazine, at 44–45 (July 2014 Esquire Magazine (Sept. 2014), at 128–129.

⁴¹⁸ Interview with Jim Meyers, Senior Vice President, North America Commercial Organization, Gilead Sciences, Inc., in Washington, D.C. (October 30, 2014).

⁴¹⁹ Gilead Sciences, Inc., *Harvoni TV Commercial*, “I am Ready,” available at <http://www.ispot.tv/ad/786d/harvoni-i-am-ready#moreData> (accessed Nov. 18, 2015).

⁴²⁰ Appendix E, Ex. 32, Gilead Sciences, Inc., 2013–2015 HCV Launch Commercial Plan, April 4, 2013, GS–0013503, at GS–0013533.

⁴²¹ *Id.* at GS–0013519.

would need to convince more providers to pursue treatment for their patients. By increasing the number of prescribing providers, more patients would become potential consumers. To that end, the company would “strive for rapid inclusion in guidelines” from medical organizations that would raise its profile in the medical community.⁴²² The company planned to target the Conference on Retroviruses and Opportunistic Infections (CROI), the European Association on the Study of the Liver (EASL), the International Society for the Pharmacoeconomics and Outcomes Research (ISPOR), the Asian Pacific Association for the Study of the Liver (APASL), and the American Association for the Study of Liver Disease (AASLD).⁴²³

As the drug was launched, Gilead wanted to “ensure payers and national health authorities are supportive of the value offered by SOF-based regimens,” and its goal was “from the outset, SOF-based regimens should be considered first for all GT2/3 and GT1 TN patients.”⁴²⁴

The goal following launch would be to “maintain SOF value and eliminate access barriers with payers,” by working to “protect price erosion in advance of SOF/LDV launch, and maintain value in GT2/3,” and “work to ensure restrictions are not imposed in key markets.”⁴²⁵ At the same time, the push for patients would be sharpened with efforts to “increase the numbers of patients accessing treatment,” and “encourage treating physicians to initiate SOF-based regimens in the majority of patients for whom previously no treatment was offered.”⁴²⁶ Over the course of three years, the company wanted to “increase referral of diagnosed patients to treating physicians,” and “support efforts to increase delivery of HCV care beyond specialists who treat today.”⁴²⁷

At the same time that Gilead was laying out plans to maximize sales of sofosbuvir, it also recognized potential commercial threats, including:

- HCPs (health care providers) may wait for IFN-free regimens in GT1
- Apathy for Tx (treatment/treating) early disease due to limited data on benefits of treating earlier
- Payers may limit access and force declining value
- Potential for market fragmentation with launches of competitive regimens
- Low government prioritization of HCV in many countries⁴²⁸

The company planned to prioritize targeting sofosbuvir for genotype 1 patients in Europe and the U.S. as that genotype was predominant in both regions. In the U.S., as well as in France, Germany, and Italy, secondary emphasis would be given to genotype 2 patients, reflecting the second largest bloc in the countries’ re-

⁴²² *Id.* at GS-0013510.

⁴²³ *Id.* at GS-0013528.

⁴²⁴ *Id.* at GS-0013519.

⁴²⁵ *Id.* at GS-0013522.

⁴²⁶ *Id.*

⁴²⁷ *Id.*

⁴²⁸ Appendix E, Ex. 32, Gilead Sciences, Inc., 2013–2015 HCV Launch Commercial Plan, April 4, 2013, GS-0013503, at GS-0013510.

spective patient populations. Similarly, for Spain and the United Kingdom, the company would focus on genotype 3 patients, based on the number of prospective prescriptions.⁴²⁹ Gilead also singled out two “special populations” to target: pre-transplant patients (of which the company estimated to be 6,400 in the U.S., and 4,800 in the EU) who would receive up to 48 weeks of sofosbuvir, and patients with both HIV and HCV, of which there were an estimated 55,000. As the company noted, most of these patients were already under the care of specialists, and had “fewer barriers to initiating treatment vs mono-infected” patients with only HCV.⁴³⁰

In its April 4th commercial plan, Gilead had defined its commercial opportunity, strategy, and initiatives. Its success in the U.S. ultimately would be measured post-launch by “key metrics” on a monthly and quarterly basis.⁴³¹ These metrics included “ex-factory units,” i.e., sales directly from the factory to distributors, total prescriptions of Sovaldi, revenue, and “forecast attainment.”⁴³² No other documentation of this meeting has been provided, despite repeated requests that Gilead provide supporting documents.

Once the drug was launched, a series of metrics would be used to measure success in the United States and across the world. The company planned to “establish and communicate unified launch success metrics,” and “track success metrics” that would be communicated monthly.⁴³³ Among those metrics were physician surveys to determine brand awareness; profile constructs of patients being prescribed the drug; message testing; tracking various prescription data, including new-to-brand prescriptions, new proscriptions, total prescriptions, and longitudinal (i.e., geographic) prescriptions;⁴³⁴ revenues, respectively; factory-to-distributor sales; monitoring the prescriber base; and attaining forecast goals.⁴³⁵ Many of these same metrics would be repeated in the “EAME” market comprising Europe, Asia, and the Middle East.⁴³⁶

Impact of AASLD/IDSA HCV Treatment Recommendations

In late January 2014, on the heels of Sovaldi’s 2013 launch, an advisory committee under the auspices of the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) issued guidance on the treatment of HCV.⁴³⁷ The panel declared sofosbuvir as the “recommended” regimen for treatment-naïve genotype 1 patients who were eligible to receive interferon regardless of subtype.⁴³⁸ Simeprevir, a drug manufactured by Gilead’s competitor Johnson & Johnson as Olysio, was declared “acceptable” for subtype 1b and some subtype 1a patients.⁴³⁹ The endorsement effectively rendered Sovaldi the new

⁴²⁹ *Id.* at GS-0013511—GS-0013513.

⁴³⁰ *Id.* at GS-0013511—GS-0013514.

⁴³¹ *Id.* at GS-0013537.

⁴³² *Id.*

⁴³³ *Id.* at GS-0013532.

⁴³⁴ These were referred to in the presentation as NBRx, NRx, TRx, LRx, respectively.

⁴³⁵ Appendix E, Ex. 32, Gilead Sciences, Inc., 2013–2015 HCV Launch Commercial Plan, April 4, 2013, GS-0013503, at GS-0013536—GS-0013537.

⁴³⁶ *Id.* at GS-0013538.

⁴³⁷ American Association for the Study of Liver Disease & Infectious Diseases Society of America, *HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C* (2014), available at <http://www.hcvguidelines.org>.

⁴³⁸ *Id.* at 18.

⁴³⁹ *Id.* at 19.

standard of care for HCV. It should be noted that the FDA labels required interferon to be administered with both Sovaldi and Olysio for genotype 1 patients, though for shorter periods than previous therapy regimens.

In addition, the panel made a recommendation that sofosbuvir (Sovaldi) and simeprevir (Olysio) could be administered together for genotype 1 patients who could not tolerate interferon.⁴⁴⁰ This recommendation was based largely on a single phase 2 clinical trial of 167 patients known as COSMOS. This combination was not officially approved by the FDA until October 2014 and did not conform to the FDA label for either drug until then.⁴⁴¹ Nonetheless, an increasing number of physicians prescribed this off-label regimen in order to address the continuing treatment obstacles to interferon. By some estimates, the combination represented upwards of 1/3 of all Sovaldi prescriptions by the end of the 2nd quarter of 2014.⁴⁴² When faced with the expert panel's recommendation, many payers accepted the off-label regimen, but then faced the double cost of two expensive HCV drugs being co-prescribed. The wholesale price of the two together was roughly \$150,000.⁴⁴³

Gilead pointed to this off-label use as a major factor in payers' growing complaints about the cost of Sovaldi during 2014. In its written response to the senators' letter, Gilead stated that it opposed the recommendation of using the two drugs together.⁴⁴⁴ While it is true that a significant number of patients were given the Sovaldi/Olysio combined regimen, it appears that this was done by physicians to address one of the drawbacks inherent in Sovaldi, which was its continued reliance on interferon for the largest cohort of HCV patients, i.e., those with genotype 1. With the advent of the all-oral Harvoni and Viekira Pak products, use of the combination decreased dramatically.⁴⁴⁵

Finally, it is important to note that without the AASLD/IDSA expert panel recommendation, the combination off-label use would not likely have occurred at the levels of use seen in 2014.

Potential conflicts of interest could have played a role in the AASLD/IDSA's recommendations for Sovaldi and the Sovaldi/Olysio combination, and a number of panel members reported that they received compensation and/or research funding from the two manufacturers.⁴⁴⁶ However, we located no direct evidence of influence on

⁴⁴⁰ *Id.* at 18.

⁴⁴¹ Johnson & Johnson's Janssen division applied to the FDA for approval to use the two in combination on May 7, 2014, citing the COSMOS study. Press Release, Johnson & Johnson, Janssen Submits Supplemental New Drug Application to U.S. FDA for Olysio™ (Simeprevir) for Once-Daily Use in Combination with Sofosbuvir for 12 Weeks for the Treatment of Adult Patients With Genotype 1 Chronic Hepatitis C (May 7, 2014), available at <http://www.investor.jnj.com/releasedetail.cfm?releaseid=846096>. FDA approved the combined use on November 5, 2014. Anna Edney, *J&J Wins U.S. Approval for Hepatitis C Combo With Gilead*, Bloomberg (Nov. 5, 2014), available at <http://www.bloomberg.com/news/articles/2014-11-05/j-j-wins-u-s-approval-for-hepatitis-c-combo-with-gilead>.

⁴⁴² Hepatitis C Online, Medications to Treat HCV, Simeprevir (Olysio), <http://www.hepatitisc.uw.edu/page/treatment/drugs/simeprevir-drug> (last visited Nov. 11, 2015).

⁴⁴³ *Id.*

⁴⁴⁴ Appendix F, Gilead Sciences, Inc., Response to Chairman Wyden/Senator Grassley letter dated July 11, 2014, narrative answer to questions 17, 18d (Sept. 9, 2014).

⁴⁴⁵ *Id.*

⁴⁴⁶ Appendix F, Gilead Sciences, Inc., Response to Chairman Wyden/Senator Grassley letter dated July 11, 2014, narrative answer to questions 18a, 18b (Sept. 9, 2014); American Association for the Study of Liver Diseases & Infectious Diseases Society of America, *Recommendations*

panel members and, as noted above, the recommendation on the Sovaldi/Olysio combination was contrary to Gilead's longer-term interests and its corporate position as explained in its written response. Members of the panel interviewed indicated that their primary concern in making the recommendation was addressing the need for improved treatment regimens that did not rely upon interferon and providing better outcomes compared to the prior regimens.

Section 4: The Financial Burden of Treating HCV and Resulting Access Restrictions

Investigative staff closely examined how Sovaldi, Harvoni, and other recent therapies for HCV affected three different federal public payer programs—Medicaid, Medicare, and the Bureau of Prisons. These programs have a disproportionate population of the nation’s HCV patients and are an important part of the nation’s health care system. As noted at various points in this report, Gilead’s two drugs have dramatically increased the amount spent on HCV care. These programs combined to spend at least \$5.2 billion for Gilead’s HCV therapies in calendar year 2014 before rebates—\$4.4 billion attributable to Sovaldi and more than \$800 million to Harvoni, which only gained FDA approval in mid-October of that year.⁴⁴⁷ Through the first six months of the year, Medicare reports having paid \$4.4 billion, before rebates, for Gilead’s HCV therapies, compared to just \$200 million for all other drugs approved to treat the disease. As a result, these public payers, as well as traditional insurance plans, adopted access restrictions to limit the number of patients who could benefit from this new class of HCV therapies. The nature and extent of these restrictions appear to go well beyond what Gilead anticipated in its pricing process.

Medicaid and Prescription Drug Purchasing

Medicaid is a jointly funded state-federal program that provides health insurance to over 72.4 million low-income Americans.⁴⁴⁸ In order to receive federal financial participation, states must establish and administer their Medicaid programs within broad federal guidelines under which states have flexibility to determine the type, amount, duration, and scope of services they provide.

States generally provide a comprehensive set of benefits consisting of mandatory benefits such as inpatient and outpatient hospital care and physician services as well as optional services including prescription drugs.⁴⁴⁹ While prescription drug coverage, including coverage for HCV treatments, is considered an optional benefit, every state has chosen to cover outpatient prescription drugs for nearly all of their Medicaid enrollees.⁴⁵⁰ As a result, due to the unique structure of the Medicaid drug program, state Medicaid programs can be particularly sensitive to the cost of drugs.

The Medicaid Drug Rebate Program was created by the Omnibus Budget Reconciliation Act of 1990 to help offset the cost of certain

⁴⁴⁷ The pharmaceutical spending data collected from Medicare Part D and state Medicaid programs represent outlays before mandatory (Medicaid) or voluntary/supplemental (Medicaid and Part D) rebates were applied. Federal law limits the disclosure of pricing information in a form that discloses the identity of a specific manufacturer or wholesaler, subject to limited exceptions. See 42 U.S.C. §§ 1395w-102, 1395w-104, 1396r-8.

⁴⁴⁸ Department of Health and Human Services, Centers for Medicare & Medicaid Services, *Medicaid & CHIP: August 2015 Monthly Applications, Eligibility Determinations and Enrollment Report* at 2 (2015) [hereinafter HHS, *Medicaid & CHIP Report*], available at <http://medicaid.gov/medicaid-chip-program-information/program-information/downloads/august-2015-enrollment-report.pdf>.

⁴⁴⁹ *Benefits*, Medicaid.gov, available at <http://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/medicaid-benefits.html>.

⁴⁵⁰ *Prescription Drugs*, Medicaid.gov, available at <http://www.medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/prescription-drugs.html>.

outpatient drugs.⁴⁵¹ Under the program, drug manufacturers are allowed to enter into a national rebate agreement with the Secretary of the Department of Health and Human Services to offer certain rebates to states' Medicaid programs in exchange for guaranteed state Medicaid coverage of FDA-approved drugs sold by the drug manufactures. The basic Medicaid rebate for brand name drugs is the greater of: (1) the difference between the drug's average manufacturer price (AMP) during the drug's rebate period—typically the previous calendar quarter—and the drug's best price or (2) 23.1% of the drug's AMP.⁴⁵² Under the Medicaid Drug Rebate Program, drug manufactures would owe an additional rebate on brand name drugs when they raise prices faster than the inflation rate.⁴⁵³ According to the Centers for Medicare & Medicaid Services (CMS), approximately 600 drug manufactures are currently participating in the Medicaid Drug Rebate Program, including Gilead.⁴⁵⁴ In addition to the basic and additional Medicaid drug rebate, state Medicaid programs collaborate through purchasing pools to negotiate supplemental drug rebates with drug manufactures.⁴⁵⁵

Medicaid has faced significant costs for treating individuals infected with HCV. Historically, Medicaid eligibility was limited to certain low-income children, pregnant women, parents of dependent children, the elderly, and individuals with disabilities.⁴⁵⁶ However, under the Affordable Care Act of 2010, states were provided with enhanced federal funding to extend coverage to low-income adults—many of whom were previously uninsured.⁴⁵⁷ As a result of this policy, enrollment in Medicaid has ballooned by more than 12 million since October 2013 to a total of more than 71 million enrollees today.⁴⁵⁸ Medicaid is now the single largest health insurer in the country, covering more individuals than Medicare or any other private insurer.

As a result of the sheer size and complex health needs of the Medicaid population and the program's unique drug rebate program, the impact of Sovaldi and Harvoni on state Medicaid programs has been particularly deep. The impact can be best seen when examining state Medicaid budgets and program coverage policies.

State Medicaid programs typically pay for outpatient drugs in one of two ways—either through a fee-for-service (FFS) payment made directly to the pharmacist, or through a capitated payment made directly to a managed care organization (MCO), which then manages payment to the pharmacist.⁴⁵⁹ In both cases, upon enter-

⁴⁵¹ Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, § 4401, 104 Stat. 1388.

⁴⁵² *Medicaid Drug Rebate Program*, Medicaid.gov, available at <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Medicaid-Drug-Rebate-Program.html>.

⁴⁵³ *Id.*

⁴⁵⁴ *Id.* (see link to Drug Manufacturer Contact Information file).

⁴⁵⁵ See, e.g., *NMPI—National Medicaid Polling Initiative*, Provider Synergies, available at <http://www.providersynergies.com/services/medicaid/default.asp?content=NMPI>.

⁴⁵⁶ Julia Paradise, Kaiser Family Foundation, The Kaiser Commission on Medicaid and the Uninsured, *Medicaid Moving Forward 2* (2015), available at <http://kff.org/health-reform/issue-brief/medicaid-moving-forward>.

⁴⁵⁷ Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).

⁴⁵⁸ HHS, *Medicaid & CHIP Report*, at 2.

⁴⁵⁹ Brian Bruen & Katherine Young, Kaiser Family Foundation, The Kaiser Commission on Medicaid and the Uninsured, *Paying for Prescribed Drugs in Medicaid: Current Policy and Upcoming Changes* 1, 3 (2014), available at <https://kaiserfamilyfoundation.files.wordpress.com/2014/05/8593-paying-for-prescribed-drugs-in-medicaid-current-policy-and-upcoming-changes.pdf>.

ing the market, Sovaldi had a demonstrable financial impact described with greater detail in the following pages.

The Outsized Impact of Gilead’s HCV Drugs on State Medicaid Drug Spending

The financial impact of Gilead’s line of HCV drugs on state Medicaid programs has been dramatic. Shortly after Harvoni was approved by the FDA, the National Association of Medicaid Directors (NAMD) wrote to Congress on October 28, 2014 that “the challenge Sovaldi and other new hepatitis C medications pose for the Medicaid program is the intersection of a high-cost therapy and a potentially large population eligible for therapy.”⁴⁶⁰

According to NAMD, during its first year on the market, states were largely unsuccessful in securing supplemental rebates for Sovaldi. In its letter to Congress, NAMD wrote, “states are not well positioned to secure meaningful supplemental rebates for Sovaldi. . . . To date, supplemental rebates states have secured for Sovaldi are minimal, with any further concessions predicted on unrestricted access to the drug.”⁴⁶¹ In fact, just five state Medicaid programs reported that they reached supplemental rebate agreements with Gilead for Sovaldi in 2014.⁴⁶²

Thus, in order to manage the costs of Sovaldi and Harvoni, which made up the majority of pharmaceutical spending to treat HCV, state Medicaid programs developed access restrictions to control costs in a constrained budget environment,⁴⁶³ pitting patients seeking therapy against those agencies “weighing complex ethical questions, scientific evidence and public health needs to maximize appropriate access to new treatments.”⁴⁶⁴ A recent study of HCV patients in four Mid-Atlantic states showed that Medicaid recipients were more likely than those with Medicare or commercial insurance to have their prescriptions for DAAs rejected, or have their treatment delayed.⁴⁶⁵

To better quantify and qualify the financial impacts of these drugs on individual state programs, investigative staff requested quantitative and qualitative data from Medicaid programs in all 50 states and the District of Columbia regarding a series of issues related to HCV infections, pharmaceutical spending, interactions with Gilead, and the financial impact of Sovaldi and Harvoni on state Medicaid spending. State Medicaid programs were asked to provide:

- Total spending (pre-rebate) on Sovaldi and Harvoni in CY2014
- The number of prescriptions filled for Sovaldi and Harvoni during CY2014

⁴⁶⁰ Appendix D, Ex. 2, Letter from Darin J. Gordon and Thomas J. Betlach, National Association of Medicaid Directors, to Congress (Oct. 28, 2014) at 3.

⁴⁶¹ *Id.*

⁴⁶² See Appendix A.

⁴⁶³ See Appendix B for a compilation of access restrictions supplied by the Oregon Health & Sciences University.

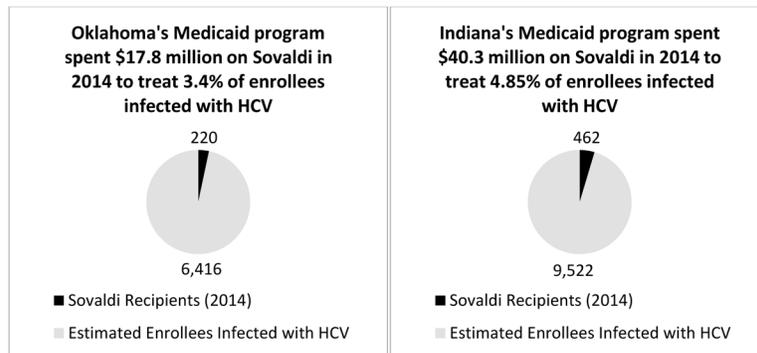
⁴⁶⁴ Appendix D, Ex. 2, Letter from Darin J. Gordon and Thomas J. Betlach, National Association of Medicaid Directors, to Congress (Oct. 28, 2014) at 4.

⁴⁶⁵ Vincent Lo Re, et al., American Association for the Study of Liver Diseases (AASLD) Abstract, *Incidence and Determinants of Denial of DAA Treatment for Chronic HCV Infection by Insurance Type During the First 6 Months of the Modern HCV Treatment Era*, 62 *Hepatology* 1382A (2015) available at <http://www.aasld.org/sites/default/files/TLM-2015-LakeBreakingAbstracts.pdf>.

- The number of unique recipients who were dispensed Sovaldi and Harvoni during CY2014
- The top 25 drugs, in terms of aggregate spending, in CY2014
- The rank of Sovaldi and Harvoni in the state's pharmaceutical spending
- The estimated number of enrollees infected with HCV
- The estimated number of enrollees in each state's Medicaid program
- Whether the state signed a supplemental rebate agreement with Gilead in CY2014

All 51 programs responded to the information request, providing valuable data showing how state Medicaid programs were affected by the price of Sovaldi and Harvoni (see Appendix A). State Medicaid programs reported that \$1.3 billion was spent on Sovaldi during CY2014, prior to any statutory or supplemental rebates. For this cumulative outlay for Sovaldi in 2014, state agencies reported that just 16,281 enrollees received the drug, constituting less than 2.4% of at least 698,000 Medicaid recipients nationwide believed to carry the disease (map 1 shows the percentage of enrollees who were treated with Sovaldi during CY2014 on a state-by-state basis).⁴⁶⁶ Oklahoma and Indiana are examples of states that spent heavily on HCV drugs in 2014 to treat small portions of Medicaid enrollees infected with the disease (see graph).

Graph 1 – HCV Spending and Percentage of Medicaid Enrollees treated in Oklahoma and Indiana (CY 2014)

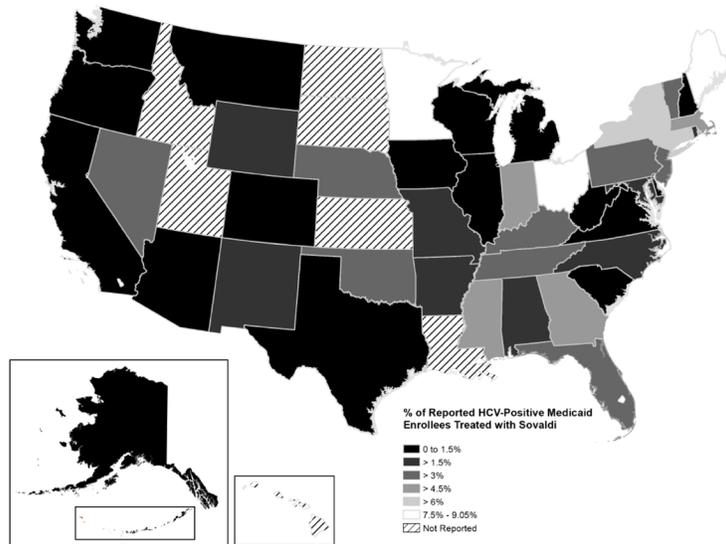


Source: State of Oklahoma, State of Indiana. (Appendix A)

⁴⁶⁶The estimate of 698,000 enrollees was derived from data reported by states to staff. The actual number of Medicaid enrollees infected with HCV is likely significantly higher, because seven states did not provide estimates—Hawaii, Idaho, Louisiana, North Dakota, Ohio, South Dakota, Utah. See Appendix A.

Map 1

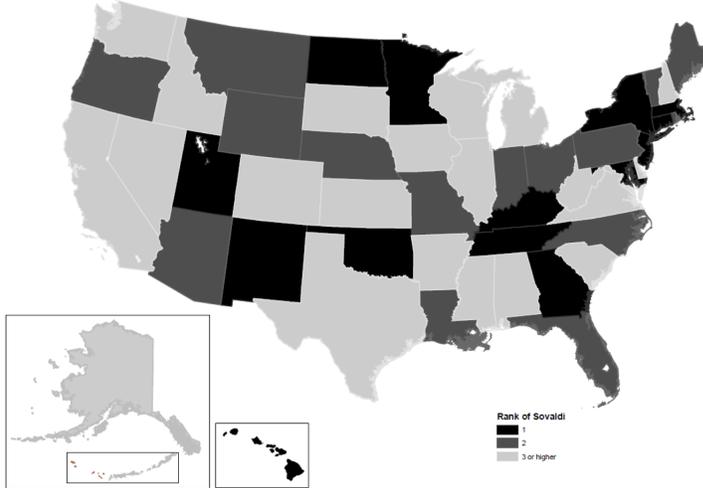
Percentage of Reported HCV-Positive Medicaid Enrollees Treated with Sovaldi
(by state during CY2014)



Source: State Medicaid program data; Appendix A, tables 1 and 2

Map 2

Rank of Sovaldi in State Medicaid Pharmaceutical Spending (CY2014)



Source: State Medicaid program data; Appendix A, table 2

The data collected by investigative staff show that outlays for Sovaldi ranked it among the top five pharmaceutical spending items for 33 different state Medicaid agencies (see map 2).⁴⁶⁷ Fourteen states reported that Sovaldi was the top pharmaceutical cost for their FFS, MCO or combined programs.⁴⁶⁸ Fifteen more reported that Sovaldi was the second highest cost.⁴⁶⁹ Four more states reported that Sovaldi ranked third, fourth or fifth in their pharmaceutical spending for CY2014.⁴⁷⁰

Researchers at the Brigham and Women's Hospital found that spending on Sovaldi accounted for more than 6.6% of the pharmaceutical program budgets for state Medicaid programs in Connecticut, New York and Massachusetts.⁴⁷¹ Oregon's Medicaid program, which spent \$591.2 million in 2014, expected that HCV treatment would make up a significant portion of its future drug spending:

Based on historical utilization and assumptions regarding provider capacity, we concluded approximately 500 patients would be treated annually at a projected cost of \$51 million per year for the first six years.⁴⁷²

Investigative staff received responses from 48 state programs to the question regarding supplemental rebates, and only five reported reaching a supplemental rebate agreement with Gilead during 2014.⁴⁷³ This illustrates that Gilead's supplemental rebate terms for Sovaldi were not accepted by the vast majority of state Medicaid programs. The states that reached agreement with Gilead estimated having roughly 15,000 enrollees infected with HCV, less than 2.2% of Medicaid enrollees believed to be infected with the disease.⁴⁷⁴ As referenced above and discussed in more detail below, in the absence of acceptable rebate offers, many states reacted to the high cost of Sovaldi and Harvoni by restricting access to the sickest patients and requiring that patients be under the care of hepatologists or other specialists prior to receiving the drugs.

The high cost of Sovaldi and Harvoni has exerted a strain on state Medicaid budgets, and is predicted to continue to do so. For example:

- Washington's Medicaid director wrote that "if [the Health Care Authority] were to pay for hepatitis C treatment for all Med-

⁴⁶⁷ See Appendix A. Gilead valued this type of spending rank data. In April 2014, the company requested state-by-state ranks for Sovaldi from Magellan Medicaid Administration, a contractor that negotiated rebates on behalf of 25 state agencies. When a Magellan official questioned the relevance of such data to the company, William Dozier, a senior manager for national accounts, wrote that the data were "relevant to the Gilead pricing committee [sic] because it shows the impact current pricing has on Medicaid." Appendix D, Ex. 3, Email from Eric Kimelblatt to Christopher J. Andrews and William Dozier, "Re: Sovaldi Data" (Apr. 15, 2014).

⁴⁶⁸ Connecticut, Georgia, Hawaii, Kentucky, Maryland, Massachusetts, Minnesota, New Jersey, New Mexico, New York, North Dakota, Oklahoma, Tennessee, Utah. See Appendix A.

⁴⁶⁹ Arizona, Florida, Indiana, Louisiana, Maine, Missouri, Montana, Nevada, North Carolina, Ohio, Oregon, Pennsylvania, Rhode Island, Vermont, Wyoming. See Appendix A.

⁴⁷⁰ Colorado, Illinois, Kansas, South Dakota. See Appendix A.

⁴⁷¹ Joshua M. Liao and Michael A. Fischer, New England Journal of Medicine, Early Patterns of Sofosbuvir Utilization by State Medicaid Programs, September 24, 2015, (figure 1) available at <http://www.nejm.org/doi/full/10.1056/NEJMc1506108>.

⁴⁷² Appendix D, Ex. 4, Letter from Lynne Saxton to the Honorable Ron Wyden and the Honorable Chuck Grassley, (Oct. 19, 2015), at p. 2.

⁴⁷³ Louisiana, South Dakota, and Wisconsin did not provide a response to this question. Georgia, Maine, Minnesota, Vermont, and Wyoming agreed to supplemental rebate terms. See Appendix A.

⁴⁷⁴ See Appendix A.

icaid clients infected with hepatitis C, the cost would be three times the current total pharmacy budget [of roughly \$1 billion].” Taking into account rebates with Gilead, the state anticipates spending more than \$242 million in FY2016 alone to treat eligible Medicaid patients.⁴⁷⁵

- Georgia reported to investigative staff that \$30.4 million was spent to treat 329 patients with Sovaldi during 2014.⁴⁷⁶ The patients treated with Sovaldi represented less than 6% of the estimated 6,000 enrollees who have been diagnosed with HCV.⁴⁷⁷ In an August presentation to the state legislation, the Georgia Department of Community Health reported that \$40.8 million had been spent on Harvoni through the first six months of 2015 and projected that \$80 million would be spent on hepatitis C drugs during FY2016 with an expectation that the budget impact would continue through FY2017.⁴⁷⁸
- Pennsylvania estimated that “the cost could range from \$2.87 billion to \$3.05 billion paid to the dispensing providers, or \$1.58 billion to \$1.73 billion after the federal drug rebates are collected.”⁴⁷⁹ There are an estimated 31,000 enrollees in Pennsylvania’s Medicaid program diagnosed with HCV.⁴⁸⁰
- New York’s MCOs and FFS alone spent more than \$363 million on Sovaldi.⁴⁸¹

In addition, several states wrote to Senators Grassley and Wyden, or otherwise communicated to investigative staff, that they were compelled to undertake unusual financial arrangements with MCOs, seek targeted budgetary authority for the management of costs related to managing HCV treatment, and, in at least one case, enact new legislation. For example:

- The Iowa Department of Human Services “has incorporated the cost of specialty drugs (including HCV medications) in its current and future Medicaid budget requests.”⁴⁸²
- Arizona “added an additional \$30 million in funding to the capitation rates [for managed care organizations] to address the additional costs of Sovaldi and Harvoni, for total funding of \$45 million.”⁴⁸³
- Florida established “kick payments” for HCV drugs in mid-2014 after managed care plans expressed concern that costs for treating the disease would exceed what had been expected at the time capitation rates were set for the year.⁴⁸⁴

⁴⁷⁵ Appendix D, Ex. 5, Letter from MaryAnne Lindeblad to the Honorable Ron Wyden and the Honorable Chuck Grassley (Sept. 23, 2015), at 2.

⁴⁷⁶ Georgia reported spending \$7.5 million on Harvoni and \$6.2 million on Olysio in 2014. See Appendix A.

⁴⁷⁷ See Appendix A.

⁴⁷⁸ Georgia Department of Community Health, *Hepatitis C Overview, Medicaid and SHBP* (Aug. 11, 2015), p. 7–9, available at <http://dch.georgia.gov/sites/dch.georgia.gov/files/Hepatitis%20C%20presentation.pdf>.

⁴⁷⁹ Appendix D, Ex. 6, Letter from Theodore Dallas to the Honorable Ronald L. Wyden and the Honorable Charles E. Grassley, (Oct. 2, 2015) at 2.

⁴⁸⁰ See Appendix A.

⁴⁸¹ See Appendix A.

⁴⁸² Appendix D, Ex. 7, Letter from Charles M. Palmer to Peter Gartrell, (Feb. 9, 2015), at 1.

⁴⁸³ Appendix D, Ex. 8, Letter from Thomas J. Betlach to Peter Gartrell (July 17, 2015), at 2.

⁴⁸⁴ Appendix D, Ex. 9, Letter from Justin M. Senior to the Honorable Orrin G. Hatch and the Honorable Ron Wyden (Oct. 19, 2015), at 2. “A kick payment is a rate mechanism to manage the uncertainty of the number of people who will need high cost Hepatitis C treatment. A kick

- Kentucky reported in a letter to the senators that the state’s “spending related to HCV has increased to about 7 percent of its total Medicaid budget, providing new hepatitis C drugs to a relatively small number of patients.”⁴⁸⁵

Texas sent a letter to the Senators expressing its concern with respect to HCV drug prices:

The state’s experience with second generation HCV drugs prompted the 84th Texas Legislature to pass a rider on the state’s appropriations act in June 2015. The rider requires [The Health and Human Services Commission] to estimate the potential cost of all new outpatient drug products prior to covering the products. All products with an estimated annual cost of greater than \$500,000 must be submitted to the Legislative Budget Board for review. This requirement may increase the amount of time between approval of a new treatment by the FDA and provision of that treatment to Medicaid clients.⁴⁸⁶

The letter went on to say:

The rebate revenue from manufacturers lessens the impact of second generation HCV drugs on the state’s Medicaid budget. However, given the exorbitant price of these medications, the rebates are insufficient and these drugs jeopardize the solvency of the state’s Medicaid and public health programs. Manufacturers lowering the price at which these drugs are sold to providers would be more beneficial than rebates to the Texas Medicaid program and would also benefit its state-funded health program.⁴⁸⁷

In a letter to Senators Wyden and Grassley, Oregon’s Medicaid director stated:

What we face is not a drug cost problem; it is a drug price problem. State Medicaid programs are limited in our ability to control pharmacy benefit expenditure, particularly as federal law requires us to provide a pathway to coverage for all FDA-approved drugs, no matter how minimal the likely benefit per dollar spent. While federally mandated rebates help, they provide limited relief.⁴⁸⁸

Kentucky is preparing to begin HCV screening tests at county health departments, partly due to the rising use of injectable drugs in the state, which has contributed to the spread of the disease:

Given the current cost of the newer treatment options and to remain fiscally responsible we will be forced to make

payment allows the Medicaid program to pay the health plans based on expected costs for each enrollee who is prescribed the drugs for treatment.” *Id.*

⁴⁸⁵ Appendix D, Ex. 10, Letter from Samantha McKinley to the Honorable Charles E. Grassley and the Honorable Ron Wyden (Oct. 21, 2015).

⁴⁸⁶ Appendix D, Ex. 11, Letter from Andy Vasquez to the Honorable Ron Wyden and the Honorable Charles E. Grassley (Aug. 14, 2015), at 3.

⁴⁸⁷ *Id.* at 4.

⁴⁸⁸ Appendix D, Ex. 4, Letter from Lynne Saxton to the Honorable Ron Wyden and the Honorable Chuck Grassley, (Oct. 19, 2015), at 2.

difficult decisions regarding who does and does not get access to treatment medications upon diagnosis.⁴⁸⁹

One of the tools that Kentucky, and many other states, has used to prioritize treatment and manage costs is establishing prior authorization criteria.⁴⁹⁰

Adoption of Prior Authorizations in Response to HCV Drug Pricing by State Medicaid Programs

In light of Sovaldi's high price and an inability to negotiate suitable supplemental rebate terms that would moderate program costs, more than half the nation's state Medicaid programs implemented prior authorization (PA) criteria, which restrict access in order to the drug to control costs.

With the assistance of the Oregon Health & Sciences University's Center for Evidenced-based Policy ("OHSU"), investigative staff examined how the PAs were structured for Sovaldi, and later, Harvoni and Viekira Pak.⁴⁹¹ OHSU conducted an initial survey of publicly available data on state Medicaid programs' approval of Sovaldi between May 30, 2014 and September 24, 2014.⁴⁹² Within this period—roughly six and nine months after introduction of Sovaldi, respectively—OHSU found:

- 27 state Medicaid programs had adopted PA criteria for the drug;
- 24 state Medicaid programs of those that adopted PA criteria adopted PAs based on disease severity as measured by Metavir fibrosis scores;
- 19 of the programs that managed the disease on the basis of fibrosis scores allowed use of the drug for only the most advanced stages of disease with fibrosis scores of F3 or F4; and
- Other PA criteria included prescription by or consultation with a specialist in liver disease, alcohol and drug use screening, interferon-free eligibility, achievement of early viral response to initial treatment, no prior treatment with sofosbuvir, and once-in-a-lifetime access.⁴⁹³

After OHSU's review, some states' programs that researchers listed as not having PAs for Sovaldi or Harvoni subsequently implemented restrictions. For example, Nebraska adopted PA criteria for Sovaldi that limited prescriptions of the drug to patients with a Metavir score of F3 or F4.⁴⁹⁴ Likewise, following FDA approval of Harvoni and Viekira Pak, Texas set PA criteria requiring patients have a F3 or F4 fibrosis score, in addition to other restrictions such as treatment by a specialist and demonstrating sobriety.⁴⁹⁵

⁴⁸⁹ Appendix D, Ex. 10, Letter from Samantha McKinley to the Honorable Charles E. Grassley and the Honorable Ron Wyden, (Oct. 21, 2015), at 2.

⁴⁹⁰ *Id.*

⁴⁹¹ See Appendix B.

⁴⁹² See Appendix B, tables 1(a) and 1(b).

⁴⁹³ See Appendix B.

⁴⁹⁴ *Nucleotide Analog NS5B Polymerase Inhibitor (Sovaldi® -sofosbuvir) Prior Authorization Criteria*, available at https://nebraska.fhsc.com/Downloads/NEcriteria_Sovaldi-201409.pdf.

⁴⁹⁵ Texas Medicaid/CHIP Vendor Drug Program, *Medicaid Fee-For-Service Prior Authorization Criteria and Policy (Antiviral Agents for Hepatitis C Virus)* (Mar. 2015), available at https://paxpress.txpa.hidinc.com/hepc_initial_request.pdf.

OHSU also performed a survey of publicly available state Medicaid program restrictions on the use of Harvoni, which was introduced on October 10, 2014, shortly after the Sovaldi survey was completed.⁴⁹⁶ This second survey also included the use of Viekira Pak, the most direct, all-oral, competing regimen for genotype 1. The OHSU survey of Harvoni/Viekira Pak restrictions was conducted between April 30, 2015 and May 5, 2015, roughly six-to-nine months after introduction. The OHSU survey found:

- 33 state Medicaid programs had adopted criteria governing the use of these two drugs;
- 25 of those that adopted PA criteria also adopted PAs based on disease severity;
- 19 had requirements that patients have fibrosis scores of F3 or F4; and
- Other criteria included alcohol sobriety and drug use screening, prescription or consultation by a specialist, once-in-a-lifetime access, viral response to initial treatment, and informed consent.⁴⁹⁷

Texas was one of 13 state Medicaid programs reported in the survey to have placed Viekira Pak on its preferred drug list (PDL), meaning that it was essentially the default medication unless patients could not tolerate the drug or it was not indicated for use with the patient's HCV genotype. The state's pharmaceutical and therapeutics committee chose Viekira Pak for the PDL "based on the understanding that both Harvoni and Viekira Pak were effective treatments, but because AbbVie submitted more aggressive rebates to HHSC's [Health and Human Services Commission] PDL vendor, Viekira Pak was more cost effective."⁴⁹⁸ Even with the discounts, the state expects spending on HCV therapies will total \$194 million through FY2018.⁴⁹⁹ The program estimates that 17,325 Medicaid enrollees are infected with the virus.⁵⁰⁰

The Medicare Prescription Drug ("Part D") Benefit: An Overview

Prior to the 2003 enactment of the Medicare Modernization Act, the Medicare program lacked a prescription drug benefit. As a result, one-third of all Medicare enrollees lacked prescription drug coverage with many of these beneficiaries deciding to forgo some of their prescribed medications due to high cost.⁵⁰¹ In the year the law was passed, a quarter of Medicare seniors did not fill at least one prescription due to high costs, and a third spent \$100 or more per month on drugs.

The three groups of Medicare enrollees most vulnerable to out-of-pocket drug costs were those without prescription coverage, low-income seniors, and the complex chronically ill (those with three or

⁴⁹⁶ Appendix B, tables 2(a) and 2(b).

⁴⁹⁷ Appendix B, tables 2(a) and 2(b).

⁴⁹⁸ Appendix D, Ex. 11, Letter from Andy Vasquez to the Honorable Ron Wyden & the Honorable Charles E. Grassley (Aug. 14, 2015), at 2.

⁴⁹⁹ See *id.* at 3.

⁵⁰⁰ Appendix A, table 1.

⁵⁰¹ Sebastian Schneeweiss et al., *The Effect of Medicare Part D Coverage on Drug Use and Cost Sharing Among Seniors Without Prior Drug Benefits*, 28 *Health Affairs* w305, w305–w316 (2009), available at <http://content.healthaffairs.org/content/28/2/w305.full>.

more complex conditions). Seniors with access to prescription coverage typically received it from employers, through private, individual purchase of Medigap, Medicare Part C (then Medicare+Choice) plans, or through Medicaid, with the former method prevalent among higher-income seniors, and the latter two more common among the low-income.⁵⁰² Since the creation of Part D, the program has only grown. As of 2014, 37 million Medicare beneficiaries received drug coverage through Part D, roughly 69% of the Medicare program's beneficiaries.⁵⁰³

Part D relies on private insurers, known as Prescription Drug Plans (PDPs), to deliver the prescription drug benefit to beneficiaries.⁵⁰⁴ Medicare Advantage plans can also offer a prescription drug benefit. Medicare beneficiaries choose from a range of PDPs offering benefits in their geographic region, and pay a premium subsidized by Medicare. Medicare covers about 75% of the cost of the drug benefit and the remainder is paid by the beneficiary. However, low-income beneficiaries receive a more substantial subsidy. In each of the 34 regions, PDPs compete based on premiums, the availability of prescription drugs, pharmacy networks, and quality.⁵⁰⁵

The amount Medicare pays a PDP is directly related to bids submitted by each plan to the CMS. A plan's bid is an estimate of its costs to provide the drug benefit to enrollees in the next year.⁵⁰⁶ To determine payment to plans, CMS calculates a national average bid, and each plan then receives a payment equal to that national average. If an individual plan's bid is higher than the national average, the difference is made up by an increase in the size of that plan's premium paid by enrollees. As a result of this payment structure, large increases in projected drug costs not only affects a plan's ability to offer affordable drug coverage, but also affects all Part D enrollees and the overall spending by Medicare.

The plans themselves are also unique. Medicare sets a standard drug benefit design but allows for individual plans to vary the structure so long as the plan meets certain actuarial equivalence tests. Low-income beneficiaries also receive even greater cost-sharing protection than provided by the standard benefit. In 2015, the standard benefit includes a \$320 deductible; coverage for 75% of drug expenses up to a benefit level of \$2,960; and a catastrophic coverage for costs above a total drug spending threshold of \$7,061.76.⁵⁰⁷ Above the latter level, a beneficiary is required to pay 5% of the costs of drugs, with 95% borne by the Medicare program.⁵⁰⁸ As a result, the higher an enrollee's annual drug spend, the greater the proportion of their costs will be paid for by Medi-

⁵⁰² Dana Gelb Safran, *Prescription Drug Coverage and Seniors: Findings From a 2003 National Survey*, Health Affairs W5-152, W5-160 (Apr. 2005), available at <http://content.healthaffairs.org/content/early/2005/04/19/hlthaff.w5.152.short>.

⁵⁰³ Medpac, *Status Report on Part D*, Report to the Congress: Medicare Payment Policy, at 347 (Mar. 2015), available at <http://www.medpac.gov/documents/reports/chapter-14-status-report-on-part-d-%28march-2015-report%29.pdf?sfvrsn=0>.

⁵⁰⁴ Some Medicare Advantage plans also provide drug coverage in addition medical benefits.

⁵⁰⁵ Medpac, *Part D Payment System* (2014), at 2, available at <http://www.medpac.gov/documents/payment-basics/part-d-payment-system-14.pdf?sfvrsn=0> [hereinafter Medpac, Part D Payment System].

⁵⁰⁶ The bid is subsequently adjusted by a number of factors including the enrollees' health statuses.

⁵⁰⁷ Medpac, *Part D Payment System*, at 1-2.

⁵⁰⁸ *Id.*

care. This arrangement is of particular importance in the context of increased utilization of high-cost drugs and their impact on Medicare spending.

The coverage between the \$2,960 and \$7,061.76 thresholds is known as the Part D coverage gap or “donut hole.” Prior to the enactment of the ACA, Part D offered no drug coverage between these two thresholds; the ACA phases out the coverage gap over time. In 2015, 55% of the cost of brand name drugs purchased in the coverage gap will be paid for on behalf of beneficiaries (50% through discounts provided by manufacturers and 5% through a subsidy provided by Medicare).⁵⁰⁹

Unlike FFS Medicare for hospitals and physicians, Part D prices for health services are not set administratively, but rather are set through negotiations between PDPs (or often PBMs on behalf of PDPs) and drug manufacturers. The government is prohibited by law to interfere in these negotiations.⁵¹⁰ The outcome of these negotiations and the size of price discounts PDPs receive from manufacturers are the result of multiple factors including the bargaining power of the PDPs (or PBMs), the level of competition among drug manufacturers, and alternative therapies available to patients.

Part D relies on private negotiations between Part D prescription drug plans and drug manufacturers to establish the price of drugs offered to Medicare beneficiaries. Many factors influence the outcome of these negotiations and the ultimate price of drugs that is borne by both Medicare and Part D enrollees. Two particularly important factors affecting the size of a rebate are: (1) the presence of similar drugs in the market, and (2) the Part D plan’s ability to steer enrollees toward one manufacturer’s drug over another.

In the instance where only one drug is on the market, manufacturers have little incentive to offer price discounts or rebates if the manufacturer is confident the plan will include the drug on its formulary and physicians will prescribe the drug to their patients. This dynamic changes significantly if a competitor enters the market with a drug in the same therapeutic class. In that case, both manufacturers have an incentive to offer price discounts or rebates in the hope that a plan places the manufacturer’s drug on the plan’s formulary. The Congressional Budget Office (CBO) has found, “rebates tend to be higher in therapeutic classes containing more drugs that are close substitutes.”⁵¹¹

Manufacturers also provide price discounts or rebates if a plan adjusts its benefit design to increase the likelihood patients will be prescribed its drug over a competitor’s drugs. The CBO found that “[t]he ability to steer beneficiaries toward preferred drugs gives Part D plan sponsors leverage when negotiating drug prices.”⁵¹² Manufacturers “tend to offer the largest rebates to plan sponsors that actively steer a large share of beneficiaries to their drugs.”⁵¹³ Without multiple, similar drugs on the market, the needed leverage to extract price discounts or rebates from drug manufacturers does

⁵⁰⁹ *Id.*

⁵¹⁰ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108–173, 117 Stat. 2066 (42 U.S.C. § 1395w–111(i)).

⁵¹¹ Congressional Budget Office, *Competition and the Cost of Medicare’s Prescription Drug Problem* (2014), at 28, available at <https://www.cbo.gov/sites/default/files/45552-PartD.pdf>.

⁵¹² *Id.* at 27.

⁵¹³ *Id.*

not exist and as a result, Medicare and Part D enrollees will typically pay for higher drug costs.

Sovaldi, Harvoni, and the Impact on Medicare

Medicare Part D has been lauded as a successful addition to the Medicare benefit. However, recent spending growth and future projections of Part D spending show costs increasing considerably. The 2015 Medicare Trustees report states that Part D spending growth from 2013 to 2014 was 12.1%, compared to 6.5% over the previous eight years.⁵¹⁴ According to the CBO, Part D spending growth will far outpace traditional Medicare fee-for-service spending growth over the next ten years. CBO notes that Parts A and B spending will increase by 89% between 2014 and 2025. Part D will see spending growth over the same time period of 168%.⁵¹⁵

Increased spending growth leads to higher premiums for Part D enrollees and additional fiscal pressure on the federal budget. Because each plan's bid contains the plan's cost of providing drug therapies to expected enrollees and these bids are proprietary, it is difficult to assess an individual drug's impact on plans' bids. However, the Medicare Trustees report specifically notes a projected acceleration in per capita benefits for 2015 because "additional plan spending for several high-cost drugs to treat hepatitis C was not factored into plan bids for the 2014 plan year, resulting in significant reconciliation payments from Part D to plans in 2015."⁵¹⁶

Data analyzed by investigative staff shows that in the 18 months since Gilead's HCV drugs gained FDA approval, Medicare spent nearly \$8.2 billion on pre-rebate spending on Sovaldi and Harvoni. (See Graph 2 below, and Appendix C for corresponding tables). Part D's spending before rebates on Sovaldi in 2014 was greater than any individual drug paid for by Medicare's Part D or Part B programs during 2013 and the same can be said for pre-rebate spending Harvoni through the first six months of 2015.⁵¹⁷

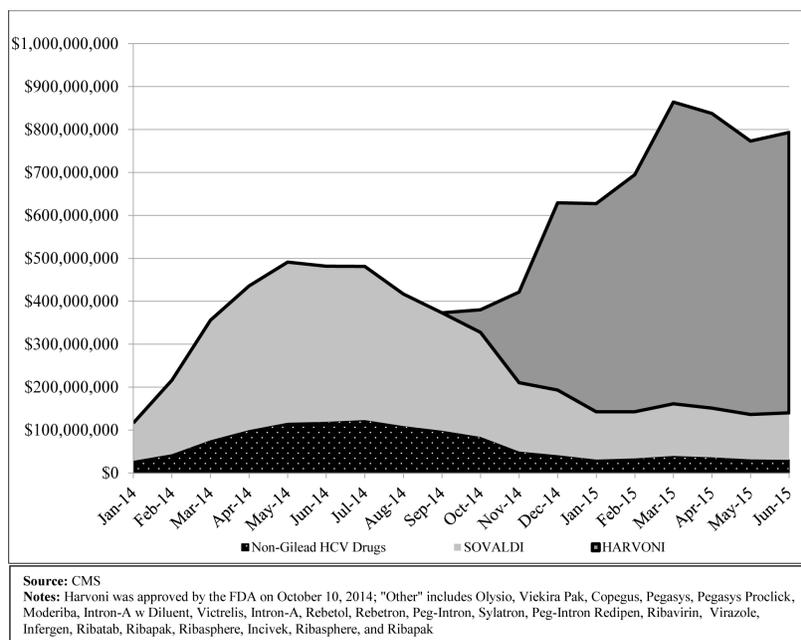
⁵¹⁴The Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, *2015 Annual Report*, at 106, available at <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2015.pdf>.

⁵¹⁵Congressional Budget Office, *March 2015 Medicare Baseline, by Fiscal Year*, (Mar. 9, 2015), available at <https://www.cbo.gov/sites/default/files/cbofiles/attachments/44205-2015-03-Medicare.pdf>.

⁵¹⁶*Id.*

⁵¹⁷Nexium, which is prescribed for treatment of heartburn, was the top drug by total expenditures (before rebates) for Part D at \$2.5 billion; Rituximab, which is used to treat cancer and rheumatoid arthritis, was the top drug by total expenditures for Part B at \$1.5 billion. CMS, *Medicare Provider Utilization and Payment Data: Part D Prescriber*, Part D Prescriber National Summary table, CY 2013, available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Part-D-Prescriber.html>; MedPac, *Report to Congress: Medicare and the Healthcare Delivery System* (June 2015), at 66 (Table 3-1), available at <http://www.medpac.gov/documents/reports/chapter-3-part-b-drug-payment-policy-issues-%28june-2015-report%29.pdf?sfvrsn=0>.

**Graph 2—Monthly Part D Spending on Hepatitis C Drugs
(Jan. 2014–June 2015)**



In 2014, Medicare spent \$4.8 billion on HCV drugs prior to rebates, \$3.1 billion of which was spent on Sovaldi, and nearly \$700 million more on Harvoni, which was on the market for roughly 12 weeks after being approved in October by the FDA.⁵¹⁸ Medicare's spending on HCV drugs through the first six months of 2015 indicates that the aggregate cost of treating the disease is likely to grow. Medicare's pre-rebate spending for HCV drugs in 2015 had already reached \$4.6 billion by the end of June, more than 95% of which was attributable to Gilead drugs (\$3.7 billion for Harvoni; \$669 million for Sovaldi).⁵¹⁹

In the 18 months that Gilead's drugs have been on the market, Medicare's monthly spending on HCV treatments increased more than six-fold from \$116.4 million in January 2014 (Sovaldi, 76%, Olysio, 9%, Other HCV drugs, 15%) to \$793.2 million in June 2015 (Harvoni, 82%; Sovaldi, 14%; Other HCV drugs, 4%).⁵²⁰ Medicare's average pre-rebate monthly spending on HCV drugs grew to \$765 million during the first six months of 2015, more than double the average monthly spend of \$349.5 million.⁵²¹

By way of comparison, Medicare's pre-rebate spending on HCV drugs for calendar year 2013 was \$396 million, of which \$238 mil-

⁵¹⁸ See Appendix C.

⁵¹⁹ See Appendix C.

⁵²⁰ *Id.*

⁵²¹ *Id.*

lion was spent on DAAs (Incivek, Olysio, Sovaldi, Victrelis) according to CMS data analyzed by investigative staff.⁵²²

Sovaldi and Harvoni's Effect on the Federal Prison System

The Bureau of Prisons (BOP) is responsible for delivering medically necessary health care to its inmates in accordance with proven standards of care.⁵²³ As of November 5, 2015, the BOP reported that 9,216 of the system's 198,953 inmates have been diagnosed with HCV.⁵²⁴ The prevalence of HCV infection in prison inmates is substantially higher than that of the general U.S. population, in part due to the prevalence of individuals who have used injectable drugs.⁵²⁵

In fiscal year 2014, the year Sovaldi became available to treat prisoners infected with HCV, the BOP's spending on HCV drugs increased 14%, even though the number of patients treated decreased 52%. By comparison, in fiscal year 2012, before the Gilead pharmaceuticals had been introduced as a viable treatment option, the BOP spent \$4.4 million on treatment of 369 HCV cases (see table 4 below). In fiscal year 2014, after the introduction of Sovaldi, the BOP spent \$5.9 million on the treatment of only 183 HCV inmates. Moreover, in fiscal year 2015 YTD with the use of both Sovaldi and Harvoni as HCV treatment, the BOP has spent nearly \$13.7 million to treat just 222 HCV-diagnosed inmates. In fiscal year 2014, Gilead's drugs accounted for 46% of the BOP's HCV spending; by fiscal year 2015, Gilead's drugs accounted for 91% (see table 5 and graph 3 below).

Table 4—Bureau of Prisons Spending on HCV Medications

Fiscal Year	HCV Medication Purchases	Patients Treated
2012	\$4,378,238	369
2013	\$4,168,807	381
2014	\$5,917,436	183
2015	\$13,665,112	222

Source: Federal Bureau of Prisons

⁵²² *Id.*

⁵²³ U.S. Department of Justice, Office of the Inspector General, *The Federal Bureau of Prison's Efforts to Manage Inmate Health Care, Audit Report 08-08* (Feb. 2008), available at <https://oig.justice.gov/reports/BOP/a0808/final.pdf>.

⁵²⁴ Data provided by Federal Bureau of Prisons (Nov. 12, 2015).

⁵²⁵ Eric Chak et al., *Hepatitis C Virus Infection in USA: An Estimate of True Prevalence*, 31 *Liver Int'l* 1090, 1090–1101 (Sept. 2011), available at <http://www.ncbi.nlm.nih.gov/pubmed/21745274>; Centers for Disease Control and Prevention, *Prevention and Control of Infections with Hepatitis Viruses in Correctional Settings* (Jan. 2003), available at <http://www.cdc.gov/mmwr/PDF/rr/rr5201.pdf>.

Table 5—Annual Spending by Federal Bureau of Prisons on HCV Drugs (by brand name)

Drug	FY 2012	FY 2013	FY 2014	FY 2015
Harvoni	\$0	\$0	\$0	\$6,885,214
Sovaldi	\$0	\$0	\$2,700,783	\$5,556,731
Olysio	\$0	\$0	\$166,802	\$778,636
Pegylated Interferon	\$1,803,072	\$483,808	\$990,854	\$258,574
Viekira Pak	\$0	\$0	\$0	\$92,622
Ribavirin	\$384,057	\$310,715	\$191,671	\$71,049
Daklinza	\$0	\$0	\$0	\$14,399
Victrelis	\$532,772	\$2,115,613	\$1,100,593	\$7,888
Incivek	\$1,658,337	\$1,258,671	\$766,733	\$0
Total	\$4,378,238	\$4,168,807	\$5,917,436	\$13,665,112

Source: Federal Bureau of Prisons

Overall system medical costs have been increasing. According to data provided by the BOP, the BOP's total medical spending in fiscal year 2013 was \$1.062 billion, of which \$82.3 million was for pharmaceuticals; in 2014, total medical spending was \$1.097 billion, of which pharmaceutical spending comprised \$96.1 million; and in 2015, total medical spending was \$1.147 billion, of which pharmaceutical spending was \$108.4 million.

To most effectively deal with the rising cost of HCV treatment, the BOP's Health Services Division (HSD) issued Clinical Practice Guidelines (CPGs) on the Evaluation and Management of Chronic Hepatitis C Virus Infection.⁵²⁶ Based on perceived risk for complications or progression of the disease, these guidelines prioritize inmates into four levels of treatment. According to a 2015 BOP memorandum, inmates with the highest priority (priority 1) have the most advanced HCV with rapidly progressing liver disease including:

- Cirrhosis (end-stage liver disease);
- Liver transplant candidates or recipients;
- Patients with liver cancer or comorbid conditions associated with HCV;
- Patients being cared for with immunosuppressant medications; and
- Prisoners who were receiving treatment when they entered the system.⁵²⁷

Several agencies, including the BOP, are required to maintain a Department of Veterans Affairs (VA) Schedule contract as a condition of receiving payment. The Veterans Health Care Act of 1992⁵²⁸ authorizes the VA to negotiate drug prices on behalf of many government agencies, including the BOP. The VA's National

⁵²⁶ Federal Bureau of Prisons, *Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection* (July 2015), available at https://www.bop.gov/resources/pdfs/hepatitis_c.pdf.

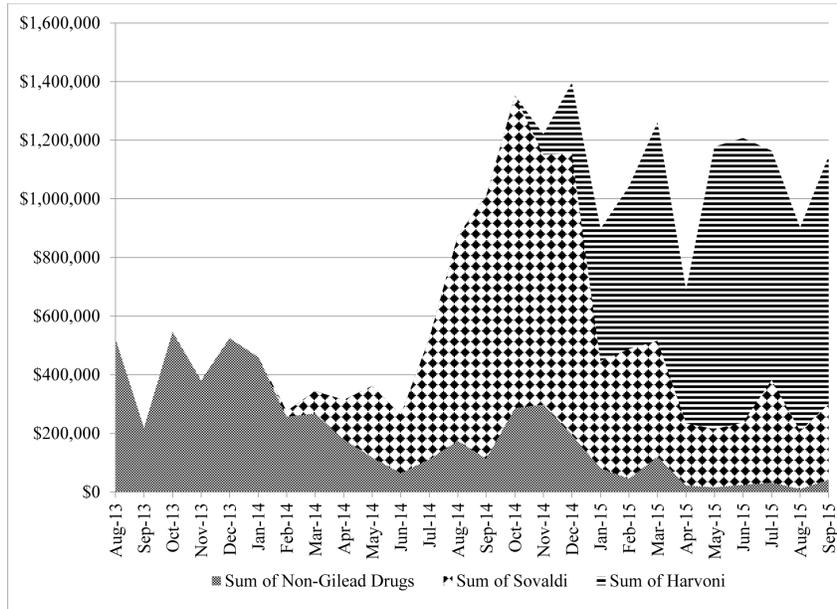
⁵²⁷ *Id.* at 7.

⁵²⁸ 38 U.S.C. § 8126.

Acquisition Center negotiates and establishes Federal Supply Schedule (FSS) prices for the Department of Defense, VA, the Public Health Service, and the U.S. Coast Guard (known as the “Big 4”) receiving at least a 24% discount from the weighted average price of a single form and dosage unit paid by wholesalers to a manufacturer. This price is known as the Federal Ceiling Price (FCP).

Many of the FSS contracts are renegotiated on a five-year period, allowing for contractual modifications as new drugs or generics enter the market, with all covered drug pricing to be renegotiated at the end of every calendar year. If the BOP desires, it can enter into discussions with manufacturers for additional discounts, called Temporary Price Reductions (TPR), based on market share or access, but granting of a TPR to an agency like the BOP is completely discretionary by the manufacturer. The BOP is therefore rarely involved in one-on-one negotiations with individual companies, and has relatively little control over the prices it receives for pharmaceutical products.⁵²⁹

Graph 3—Monthly Hepatitis C Drug Spending by Federal Bureau of Prisons (Aug. 2013–Sept. 2015)



Source: Federal Bureau of Prisons
Note: “Non-Gilead HCV Drugs” include Daklinza, Olysio, Incivek, Victrelis, Pegylated-Interferon, and Ribavirin

⁵²⁹ Telephone interview of BOP staff (Aug. 27, 2015).

Access Restrictions by Non-Public Payers

The OHSU survey conducted between May 30, 2014 and September 24, 2014 included several non-state payers to compare PA restrictions with state Medicaid programs.⁵³⁰ OHSU found that non-state payers adopted similar PA restrictions. Publicly available criteria for Sovaldi used by Aetna, CIGNA, Regence BlueCross BlueShield, and Anthem BlueCross BlueShield were reported in the survey.⁵³¹ All PA restrictions for non-state payers included some level of disease severity, with the two BlueCross Blue Shield plans requiring F3 or F4 scores.⁵³² Aetna required early viral response to initial treatment. Several required alcohol sobriety and drug use screening and patient treatment support and management programs. All required determination of interferon ineligibility.⁵³³ In communications with investigative staff separate from the OHSU survey, state program officials, as well as other payers, indicated that such restrictions were overwhelmingly based on concerns related to the cost impacts of sofosbuvir-based treatment on their programs.⁵³⁴

As described earlier, in order to help patients with private insurance offset the cost of co-pays and other coverage assistance, Gilead budgeted funds for its patient assistance programs. Through the first week of July 2014, Gilead reported providing co-pay coupons, worth an average of \$919, to 18,618 unique patients.⁵³⁵ The money was used to reduce co-payments, which means that patients had a lower cost burden, but does not offset the amount of money that insurers end up paying for the drug.⁵³⁶ Gilead reported providing free product worth \$225 million through the PAP to 3,568 unique patients (an average of \$62,709 per patient), or roughly 5.4% of patients treated with Sovaldi up to that point.⁵³⁷ The company said it did not have access to foundation assistance data, nor did the company disclose the names of the foundations or the amount they were provided. All of the costs related to operating the PAP, including manufacturing costs of the free product provided through it, copay coupons, and a patient support program called MySupportPath, are accounted for as operating expenses (sales and marketing operational expenses). The copay coupons offset Gilead's product revenue.⁵³⁸ The company had already anticipated by late 2013 that the PAP program should be monitored; in the context of Gilead's approach to AIDS Drug Assistance Programs, Young wrote to Meyers, Stout, and Banks, "Let's monitor PAP very carefully. I do worry that people might attempt to stretch applications for PAP. We might see some strange behaviors we need to address early."⁵³⁹

⁵³⁰ See Appendix B, Table 1b.

⁵³¹ *Id.*

⁵³² *Id.*

⁵³³ *Id.* At the time of the survey, no publicly available criteria were found for United Health Care, another major payer.

⁵³⁴ See Appendix D.

⁵³⁵ Appendix F, Gilead Sciences, Inc., Response to Chairman Wyden/Senator Grassley letter dated July 11, 2014, narrative answer to question 20 (Sept. 9, 2014).

⁵³⁶ *Id.*

⁵³⁷ *Id.*

⁵³⁸ *Id.*

⁵³⁹ Appendix E, Ex. 40, Email from Kevin Young to Jim Meyers, Coy Stout, Re: ADAP and Sofosbuvir (Nov. 19, 2013), GS-0020802.

Gilead announced on July 1, 2015 that it would exclude some insured patients from the PAP program. Advocates, including the AIDS Healthcare Foundation, viewed Gilead's denial of patient access to HCV treatment through the PAP program as a "bargaining strategy" or "punitive measure against health insurers," and ultimately an attempt to force payers into further opening access to Gilead's HCV drugs.⁵⁴⁰ In a letter addressed to "Community Partner" from Gilead's Coy Stout, vice president, managed markets, the company detailed its changes:

[P]atients who are insured and who do not meet their payer's coverage criteria will no longer be eligible for support via Gilead's Patient Assistance Program. Patients who fall within the category of "Insured and Did Not Meet Payer Criteria" are patients whose insurance providers limit access to Sovaldi/Harvoni based on, but not limited to, the following:

- Fibrosis score restrictions
- Preferring or exclusively covering another product on formulary (i.e., Viekira Pak preferred)
- Limiting coverage to a maximum treatment duration or denying subsequent treatment after a patient has failed therapy
- Step-therapy requirements
- Clinical criteria (e.g., psychiatric requirements, drug and alcohol testing)

It is important to note that a very small number of patients fall into this category. Support Path experts will continue to treat each patient case individually and consider a number of variables when assessing patients for our free drug program.

The company justified the changes as followed:

In the interest of facilitating patient access in the period immediately following the launch of Sovaldi and Harvoni, the Gilead Patient Assistance Program (PAP) made these medications available to virtually all patients who met financial and other program requirements. Gilead also implemented significant discounts for its HCV therapies across different payer groups. While many payers responded to these discounts by opening access broadly, some payers have continued to restrict access despite the discounts. As a result, our PAP criteria enabled continued restrictions by some payers by providing a generous route for them to deny access and refer patients they have chosen not to cover. While we have approved many of these patients in the past, we feel it is necessary to establish more specific guidelines for patient eligibility. Our PAP was designed to help uninsured patients with the most

⁵⁴⁰Senate Finance Committee Interview of Emalie Huriaux, Director of Federal and State affairs, Project Inform (July 10, 2015); see also *AHF Criticizes Gilead for Blacklisting Hepatitis C Patients from Drug Assistance Programs to Punish Insurers*, Aids Healthcare Foundation (July 23, 2015), available at <http://cqrcengage.com/aidshealth/app/document/8671298?sessionid=gAma-5LojCWfh42hyhRCL98y.undefined>.

need, and changes are necessary to remain true to that mission. We believe these changes also will help increase access among those payers who continue to restrict access.⁵⁴¹

The price of Sovaldi constituted a large burden—notably among state Medicaid programs, Medicare, and the BOP—and triggered access restrictions across public and private payers, thus limiting the number of HCV-infected patients who could access the new treatment options. In response to these restrictions, Gilead stayed firm in its initial contracting strategy by offering only small discounts in return for opening patient access, and limiting its PAP program.

⁵⁴¹ Appendix D, Ex. 12, Letter from Coy Stout, Vice President, Managed Markets, Gilead Sciences, Inc., to Community Partner (July 1, 2015).

Section 5: Patients' and Payers' Reactions to the Price of Sovaldi

Gilead may not have anticipated the scope and depth of the resulting restrictions as it was attempting to price Sovaldi in a way that would not “hinder patient access to uncomfortable levels,”⁵⁴² but it should not have been surprised by negative reactions—particularly after the price was announced—as patient groups, public and private payers, and others began to provide direct feedback on the price, as detailed in this section.

By September 2014, as it considered a price for Harvoni, the company had done its own analysis of access restrictions that state Medicaid programs had put in place for Sovaldi:

- More than half of the states are limiting coverage to the sickest patients (i.e. F3–F4)
- Additional strict criteria including one per lifetime treatment, patient certifications, and drug/alcohol testing
- Budget concerns driving strict management through [prior authorization] requirements
- Staffing for [prior authorization] requirements has also impacted coverage decisions (i.e. IL Medi)
- Appeals require court hearings in WI, AR, IL⁵⁴³

“Extreme budget constraints drive strict criteria for treatment and an unstable formulary review process inhibiting access to Sovaldi,” the presentation concluded.⁵⁴⁴ Furthermore, the company expected that “[h]ighly restrictive criteria to control costs and F3–F4 restrictions will likely remain.”⁵⁴⁵

The presentation shows that Gilead was clearly aware that the cost of providing Sovaldi to Medicaid patients had become—and would continue to be—problematic, even though executives believed \$84,000 was a fair price that would be readily accepted by the marketplace, given their belief in the clinical efficacy of the product. Meyers said that Gilead had spoken to many major payers and received positive feedback, and that negative press about Sovaldi’s price only took off after the spike in the off-label combination of Sovaldi and Olysio.⁵⁴⁶ However, even before the product was introduced to market, Gilead officials were informed of significant concerns about the price.

For many payers, particularly in Medicaid, the combination of price and an influx of patients seeking treatment for HCV was a major part of the concerns—and the warnings—that Gilead received. The material that follows shows that Gilead officials were told, and in some cases repeatedly, about the potential negative consequences that a high price for Sovaldi and future HCV treatments could have on the American health system, public payers,

⁵⁴² Appendix E, Ex. 28, Gilead Sciences, Inc., Sofosbuvir Pricing and Market Access Assessment, Final Recommendations—July 31st, 2013, GS-0014018, at GS-0014020.

⁵⁴³ Appendix E, Ex. 52, Gilead Sciences, Inc., HCV Wave 2 Contracting Recommendations, September 9, 2014, GS-0019058, at GS-0019107.

⁵⁴⁴ *Id.*

⁵⁴⁵ *Id.* at GS-0019108.

⁵⁴⁶ Interview with Jim Meyers, Senior Vice President, North America Commercial Organization, Gilead Sciences, Inc., in Washington, D.C. (Oct. 30, 2014).

private payers, and ultimately, patients who would be denied treatment. The communications—in the form of meetings, phone calls, and written communications—began more than two months before Gilead received its approval for Sovaldi in December 2013, and continue into 2015.

Concerns Before and Shortly After FDA Approval

One of the first warnings about the potential impacts of high HCV drug prices came during a meeting of the FDA’s Antiviral Drugs Advisory Committee.⁵⁴⁷ The administrative hearing, which took place less than two months before the FDA’s approval of Sovaldi, was one of the final steps in the agency’s review process. Gilead was represented at the hearing by John McHutchison, William Symonds, and Diana Brainard, all of whom are either executives or senior managers in the company’s liver disease unit.⁵⁴⁸ The hearing allowed members of the committee to ask questions of the company with respect to its research, and in turn, receive input from the public.

Lynda Dee, a Baltimore attorney who for more than a decade has advocated on behalf of people infected with AIDS and HCV, was among those in attendance. For many years, she led a coalition of advocacy groups that has met with drug companies prior to drugs being released to the market. These advocacy group meetings were intended to provide companies with a “patient perspective” about the positive and negative impacts of drugs on consumers—clinically, financially, socially—and provide a forum to advocate for lower prices.⁵⁴⁹

“[O]h, happy day,” Dee said of Sovaldi’s pending approval, according to a transcript of the meeting.⁵⁵⁰ Dee ticked off the positives of the drug and the company, one by one. The groups she was representing, AIDS Action Baltimore and the Fair Pricing Coalition (FPC), both received grant funding from Gilead. She was supportive of the company’s study protocols. She also had a personal interest in her attendance:

“I’m actually cured of HCV using sofosbuvir, and I’m really elated to see this day come. And I think that most everybody in the HCV community feels that way.”⁵⁵¹ However, she had concerns about price:

I also hope that—you know, it’s America. There are no rules about what you can charge. But it would be a shame that this drug would not be accessible to people because it cost too much. I would urge you. I would say I would beg you to consider pricing this drug reasonably. We all know

⁵⁴⁷U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Meeting Agenda, Antiviral Drugs Advisory Committee Meeting (Oct. 25, 2013), available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AntiviralDrugsAdvisoryCommittee/UCM375281.pdf>.

⁵⁴⁸*Id.* At the time, McHutchinson was Senior Vice President for liver diseases; Symonds was Vice President for liver diseases; and Brainard was Senior Director of liver diseases.

⁵⁴⁹Telephone interview with Lynda Dee (November 2014).

⁵⁵⁰U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Meeting Transcript, Antiviral Drugs Advisory Committee, at 212–216 (Oct. 25, 2013) [hereinafter FDA Meeting Transcript], available at <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AntiviralDrugsAdvisoryCommittee/UCM382913.pdf> (statement by Lynda Dee).

⁵⁵¹*Id.*

that it's going to be cost-effective, but that scale of what's cost-effective is I think an unreasonable way to look at it.

I mean, if the price of telaprevir⁵⁵² and boceprevir⁵⁵³ I think is already exorbitant. I mean, if you could price it even close to what those drugs are, I think that would be reasonable under the circumstances, and you'd still make a fortune. The volume that you're going to get for this is I think it's outstanding. . . .

[T]hank you for the good work and I hope we can get this drug out to people and as many people that need it as possible.⁵⁵⁴

An early call for lower pricing was also made during a day-long meeting between the FPC and Gilead at the company's Foster City, California, headquarters. Gilead was represented by McHutchison, David Johnson, vice president of marketing for the liver diseases business unit, Janice Tam, medical affairs, Coy Stout, vice president for managed markets; Bill Guyer, medical affairs; Cara Miller, medical affairs; and Michele Rest, medical affairs.⁵⁵⁵ The coalition planned to urge Gilead to set the price for Sovaldi at or below the roughly \$60,000 price of Victrelis and Incivek, protease inhibitors that were then the prevailing standard of care.⁵⁵⁶

Gilead's account of the meeting matches the FPC's agenda. Johnson sent a detailed summary of the FPC meeting to many of the company's most senior officials. Johnson described the meeting as a "collaborative" dialogue, noting "they also emphasized that they want both a reasonable price and a comprehensive patient support program," and specifying that "they hope Gilead will price sofosbuvir at or below current SOC (\$60K)."⁵⁵⁷ The email went on to foreshadow concerns that many state Medicaid programs would raise after the approval of Sovaldi and Harvoni:

While they understand the clinical value of sofosbuvir (and believe it is a "very good drug"), they feel the cost-effectiveness argument will not matter in the current environment as states, insurers, physicians and patients are focused on the "right now" costs and not what the potential cost-savings may be down the road. This will be particularly true as more new compounds become available. They also are focused on the potential impact of a high price on VA/Correctional formularies—particularly as they expect Merck and Vertex to significantly lower the price for

⁵⁵²The cost of a 12-week treatment of telaprevir is \$49,200, which does not include the cost of pegylated interferon and ribavirin, which are used in combination with telaprevir. Hepatitis C Online, Medications to Treat HCV, Telaprevir (Incivek), *available at* <http://www.hepatitisc.uw.edu/page/treatment/drugs/telaprevir-drug> (last visited Sept. 28, 2015).

⁵⁵³The cost of boceprevir is \$26,400 for a 24 week course, \$35,200 for a 32 week course, and \$48,400 for a 44 week course. These prices do not include the cost of pegylated interferon and ribavirin, which must be used in combination with boceprevir. Hepatitis C Online, Medications to Treat HCV, Boceprevir (Victrelis), *available at* <http://www.hepatitisc.uw.edu/page/treatment/drugs/boceprevir-drug> (last visited Sept. 28, 2015).

⁵⁵⁴FDA Meeting Transcript at 215–16 (statement by Lynda Dee).

⁵⁵⁵Appendix D, Ex. 13, Meeting Agenda, HCV Fair Pricing Coalition Meeting (Oct. 3, 2013) (prepared by Cara Miller).

⁵⁵⁶Appendix D, Ex. 14, Meeting Agenda, "FPC Gilead 10–3–13 Meeting Agenda (FOR FPC ONLY)" (Oct. 3, 2013) (prepared by Lynda Dee).

⁵⁵⁷Appendix E, Ex. 53, Email from Cara Miller to Gregg Alton, FW: FPC Ad Board Feedback (Oct. 4, 2013), GS-0020133, at GS-0020133—GS-0020134.

boceprevir/telaprevir in advance of our launch. It's possible that when a patient hears a high price, they may immediately assume they can't afford treatment and not pursue any further dialogue with their physicians regarding treatment. Similarly, a physician may make a value judgment as to whether it is worth putting a patient with high-risk behaviors on treatment. Education of both physicians and patients is critical. Patients have to advocate for themselves so educating them on how to/what to ask for will be key. Currently, patients are getting majority [sic] of their information from media, not from their doctors. Additional barriers to care include a lack of federal leadership and policy, and routine testing for HCV.⁵⁵⁸

The email's recipients included high-level Gilead executives.⁵⁵⁹

A month later, according to minutes Dee provided to investigative staff, the coalition held a teleconference on December 6, 2013, the day that FDA approved Sovaldi. The minutes show that coalition members expressed "disappointment" about the \$84,000 list price of the drug. Gilead was represented on the call by Guyer, Johnson, Miller and Stout.⁵⁶⁰

On April 14, 2014, four months after Sovaldi had been approved by the FDA, the FPC sent a follow-up letter to Gilead. The letter was addressed to Stout and Rest, as well as Kristie Banks, senior director for business operations and contract compliance; Jim Drew, director, business operations and contract compliance and Flood.⁵⁶¹ The letter reiterated the coalition's call for the company to lower Sovaldi's price to improve access for HCV patients:

We should remind you of our original warning that, even though new DAAs are a major improvement that may be cost-effective in the long run, our healthcare system lacks this particular downstream thinking. Both government and industry payer programs operate under short-term budget constraints that are incapable of absorbing the costs of Sovaldi for every patient they cover who needs access to this medication.

We had hoped Gilead would be satisfied with cornering the larger volume market. By all accounts, Gilead will dominate the DAA market for years to come. This has made Sovaldi's price all the more unconscionable. Gilead is already close to recouping the Pharmasset purchase price of Sovaldi, even before the fixed-dose combination with ledipasvir is on the market. We still hope Gilead will consider a larger volume market strategy—one that will make

⁵⁵⁸ *Id.* at GS-0020134.

⁵⁵⁹ Coy Stout, Bill Guyer, Cara Miller, Jim Meyers, Kevin Young. *Id.* Other attendees of the meeting were Vice President for Public Affairs Amy Flood, Senior Vice President of Medical Affairs Hans Reiser, and Executive Vice President for Clinical Research and Development Operations Andrew Cheng. The email also was forwarded by Cara Miller to Executive Vice President, Corporate and Medical Affairs Gregg Alton. *Id.*

⁵⁶⁰ Appendix D, Ex. 15, "Gilead 12-6-13 Call Notes" (prepared by Lynda Dee).

⁵⁶¹ Appendix D, Ex. 16, Letter from Murray Penner, Fair Pricing Coalition, to Coy Stout, Vice President, Managed Markets, Kristie Banks, Senior Director, Business Operations & Contract Compliance, Jim Drew, Director, Business Operations and Contract Compliance, Amy Flood, Vice President, Public Affairs, and Michele Rest, Director, Public Affairs, Gilead Sciences, Inc. (Apr. 14, 2014).

a respectable profit for the company, while being priced so that it is accessible for the millions of patients for whom Sovaldi is indicated.⁵⁶²

In all, the FPC's message on pricing was directly communicated to at least a dozen Gilead employees in a private meeting, public forum, phone conference, and letter, in addition to multiple press releases and media interviews given by coalition members that received national press attention.

Early concern about Sovaldi pricing was not limited to patient advocates. On November 5, 2013, exactly a month before the FDA granted approval, Meyers sent an email to 16 people within the company with the "Synopsis of feedback from top HCV advisors at AASLD."⁵⁶³ Meyers subsequently forwarded the email to John Martin, John Milligan, and Norbert Bischofberger.⁵⁶⁴ Over the course of six pages, Meyers summarized discussions with doctors attending the annual meeting of liver experts, which had been held during the first five days of November in Washington, D.C. Portions of the email touched on potential pricing issues the company could face:

Ira Jacobson was approached after the Gilead Symposium by a physician (GI) who works with Empire Blue Cross Blue Shield whom [sic] told him that Empire is "scared to death" by the pending launch of SOF. He indicated they put aside \$500 million for the PI's and ended up spending \$1.1 billion. When Ira asked the payer representative what they'd do with a decompensated cirrhotic who was prescribed 24–48 weeks of SOF + RBV, he replied "we'd cover it for 12 weeks, it's on the patient after that." Ira was very concerned with this response. He went on to say that he was happy to help us in our efforts with payers in any way that he could. Mark Sulkowski volunteered that the buzz at AASLD is that SOF will be the highest priced pill in the history of the pharmaceutical industry. "Everyone is speculating." [sic]⁵⁶⁵

Controversy After the Price Was Set

Following the drug's approval on December 6, 2013, news outlets trumpeted the arrival of Sovaldi and the potential positive benefits for long-suffering hepatitis patients. Multiple outlets, ranging from national newspapers to regional outlets and trade press, noted the high price, the controversy it had created, and the potential barriers it would pose for patients seeking access to the drug. On December 7, the *New York Times* reported:

[T]he greater convenience and effectiveness comes at a price. Gilead said the wholesale cost of Sovaldi, which is

⁵⁶² *Id.*

⁵⁶³ Appendix E, Ex. 54, Email from Jim Meyers to David L. Johnson, et al., Synopsis of feedback from top HCV advisors at AASLD (Nov. 5, 2013), GS-0020776.

⁵⁶⁴ *Id.*; see also *id.* (email from Jim Meyers to John Martin, Synopsis of feedback from top HCV advisors at AASLD (Nov. 14, 2013)); Appendix E, Ex. 55, Email from Jim Meyers to John Milligan, Synopsis of feedback from top HCV advisors at AASLD (Nov. 8, 2013), GS-0020765; Appendix E, Ex. 56, Email from Jim Meyers to Norbert Bischofberger, Synopsis of feedback from top HCV advisors at AASLD (Nov. 7, 2013), GS-0020753.

⁵⁶⁵ *Id.* (included in all emails above).

known generically as sofosbuvir, would be \$28,000 for four weeks—or \$1,000 per daily pill. That translates to \$84,000 for the 12 weeks of treatment recommended for most patients, and \$168,000 for the 24 weeks needed for a hard-to-treat strain of the virus. “This is unbearable to the health care system and it is completely unjustified,” said Michael Weinstein, president of the AIDS Healthcare Foundation, which runs treatment clinics in the United States and abroad and has previously clashed with Gilead on the price of its drugs for H.I.V. The Initiative for Medicines, Access and Knowledge, a legal group based in New York, recently filed a motion to try to block patenting of the drug in India. If it succeeds, generic manufacturers in India will be able to manufacture cheap copies of the drug for distribution there and in some other developing countries. Gilead said the price was fair given the drug’s higher cure rate and that the total cost for the 12-week regimen was “consistent with, and in some cases lower than” the cost of some other regimens for hepatitis C. It said it would offer financial assistance to some patients.⁵⁶⁶

Ten days later, the *Columbus Dispatch* (Ohio) reported:

The advances come at a high cost. Sovaldi carries a wholesale-price tag of \$1,000 a pill, or \$84,000 for a full course. How much insurers will cover remains uncertain, as does when they’ll pay for it. People can live normally with the virus and without serious liver damage. But once it starts to damage the liver—and especially after the onset of cirrhosis—treatment becomes more difficult. “People will want to get rid of hep C because it’s there, but whether everybody is going to be offered treatment at this cost, we don’t know,” [said Dr. William M. Lee, a hepatitis C expert and clinical professor of internal medicine at Ohio State University’s Wexner Medical Center.]⁵⁶⁷

On December 30, 2013, *National Public Radio* produced a story about Sovaldi titled “\$1,000 Pill For Hepatitis C Spurs Debate Over Drug Prices,” in which reporter Richard Knox interviewed Alton and Camilla Graham, a former Vertex executive and hepatitis C specialist at Beth Israel Deaconess Hospital in Boston:

RICHARD KNOX: Graham, who’s at Beth Israel Deaconess Hospital in Boston, notes that Gilead paid \$11 billion to acquire a smaller company that developed Sovaldi. She thinks Gilead should be allowed to recoup that investment. But . . .

CAMILLA GRAHAM: You only need about 150,000 people to recover that cost. And so, you know, if you’re treating two million people, once you’ve recovered your cost, then I think—I don’t want to say it’s unfair, but it does start feeling more exploitative.

⁵⁶⁶Andrew Pollack, *New Hope in Hepatitis As F.D.A. Allows Pill*, N.Y. Times, Dec. 7, 2013, at B1.

⁵⁶⁷Misti Crane, *New Drugs Close in on Hep C Cure*, Columbus Dispatch, Dec. 16, 2013, at 1A.

RICHARD KNOX: She thinks once Gilead has recovered its investment cost, it ought to cut the price of Sovaldi.

GREGG ALTON: That's very unlikely that we would do that. I appreciate that thought.

RICHARD KNOX: Again, that's Gregg Alton of Gilead Sciences.

GREGG ALTON: Really you need to look at the big picture. Those who are bold and go out and innovate like this and take that risk, there needs to be more of a reward on that. Otherwise it would be very difficult for people to make that investment.

RICHARD KNOX: Alton says Gilead will help U.S. patients pay for Sovaldi if they can't afford it and will charge far less for a course of the drug in places such as India, Pakistan, Egypt, and China, where most people with hepatitis C live.

GREGG ALTON: I don't think we'll be able to get it into the low hundreds. But I think we can get it into an affordable range for them. It'll be from the high hundreds to low thousands for these types of markets.

RICHARD KNOX: It took more than 10 years before many people in developing countries got access to life-saving HIV drugs. Advocates hope it won't take anywhere near that long to start curing hepatitis C.⁵⁶⁸

On January 6, 2014, the pharmaceutical trade publication *FierceBiotech* wrote:

Thomas Wei of Jefferies & Co. had initially figured that Gilead would have to hit a peak sales estimate of \$4 billion to justify the cost of Sovaldi. Analysts have recently been settling in around \$7 billion after calculating the returns on a pill that will cost \$1,000 a day—or \$84,000 for a 12-week course. But winning here has come at a cost that may be hard to calculate. Already whipped up by Gilead's steep prices on HIV drugs like the newly approved *Stribild*, some prominent nonprofits immediately took a swipe at Gilead's pricing strategy.⁵⁶⁹

On July 11, 2014, Gregg Alton, Gilead's Executive Vice President, Corporate and Medical Affairs, acknowledged, during an American Enterprise Institute forum, that the price of the drug had caused controversy and a "challenge" to the nation's medical system:

A lot of what's happening here is we have a breakthrough, a quantum leap in the ability to treat Hepatitis C. We can do something today that we couldn't do last year and there's a cost associated with that. And I think that has

⁵⁶⁸ Richard Knox, *\$1,000 Pill For Hepatitis C Spurs Debate Over Drug Prices*, National Public Radio, Morning Edition (Dec. 30, 2013) (transcript available on LexisNexis).

⁵⁶⁹ John Carroll, *Sovaldi: Gilead Hits Pay Dirt with a Breakthrough Hep C Drug*, *FierceBiotech* (Jan. 6, 2014), available at <http://www.fiercebiotech.com/special-reports/sovaldi-gilead-hits-pay-dirt-breakthrough-hep-c-drug>.

challenged our system. But what I really want to say in closing is that despite all the challenges and some of the criticism that you may be hearing, and the friction, and I guess the shrill tone of the conversation, there's a positive side to this, which is we're going to cure more people of hepatitis C this year than we ever have before.⁵⁷⁰

Responses From Medicaid Programs to Gilead

Following the launch of Sovaldi, Medicaid programs in states across the country were wrestling with the combination of Gilead's high cost and the flood of patients who wanted to take advantage of the shorter treatment regimen.

In recent years, a growing number of states have joined "pools," in which several Medicaid programs join forces to increase their market power. There are three primary pools—National Medicaid Pooling Initiative (NMPI), Top Dollar (TOP\$), and Sovereign States Drug Consortium (SSDC).⁵⁷¹ Both NMPI and TOP\$ are administered by Provider Synergies, LLC, a subsidiary of Magellan Health Services and the SSDC is administered by the member states.

On May 11, 2014, Gilead offered three tiers of supplemental rebates to the Medicaid pools—6%, 8%, and 10%—that had been approved by the company's legal department.⁵⁷² Each tier was tied to requirements that increased patient access, i.e., the higher the discount, the more access was to be provided:

- **6% discount—Unique Position 1.** Any PA [prior authorization] criteria imposed is consistent with and no more restrictive than the FDA approved label. Additional restriction for fibrosis score (Metavir) of F2–F4 [fibrosis levels two through four] is permissible. PA criteria may require prescriptions be written by Specialists (hepatologists or gastroenterologists, for example).
- **8% discount—Unique Position 2.** Any PA criteria imposed is consistent with and no more restrictive than the FDA approved label. PA criteria may require prescriptions be written by Specialists.
- **10% discount—Unique Position 3.** Any PA criteria imposed is consistent with and no more restrictive than the FDA approved label. Any PA criteria imposed shall not require prescriptions by Specialists. Of note, Gilead has stated that they are not detailing their hepatitis portfolio to non-Specialists.⁵⁷³

⁵⁷⁰ American Enterprise Institute, Discussion transcript, *How Will We Pay for the Price of Cures?*, at 35 (July 11, 2014), available at http://www.aei.org/wp-content/uploads/2014/07/cost-of-cures_154738513625.pdf.

⁵⁷¹ For more details, see *Pharmaceutical Bulk Purchasing: Multi-State and Inter-Agency Plans*, Nat'l Conf. of State Legis., <http://www.ncsl.org/research/health/bulk-purchasing-of-prescription-drugs.aspx> (last updated Jan. 2015).

⁵⁷² Appendix D, Ex. 17, Email from William Dozier, Senior Manager, National Accounts, Gilead Sciences, Inc., to Douglas M. Brown, Senior Director, Pharmacy Pricing & Value Based Solutions, Magellan Health Services (May 11, 2014).

⁵⁷³ Appendix D, Ex. 18, Email from Douglas M. Brown, Senior Director, Pharmacy Pricing & Value Based Solutions, Magellan Health Services to Matthew D. Lennertz, Magellan Health Services (May 19, 2014). Brown told investigative staff that "not detailing their hepatitis portfolio to non-Specialists" meant that Gilead was not promoting Sovaldi to general practice doctors.

The relatively small discounts, coupled with requirements to reduce restrictions for treatment, made the rebates difficult for states to accept because of the potential budgetary impact. Magellan's Douglas Brown, who negotiated on behalf of NMPI and TOP\$, made reference to the dynamic when he shared the offer with states on May 19th:

I'm happy to have this offer in place for those states that cannot otherwise manage utilization in this category and are experiencing a sharp increase in total spend. However, I expect most states to forgo this offer and continue to actively manage this category. Our negotiations with Gilead continue, especially for those states that require fibrosis scores of F3 or greater as well as other PA criteria.⁵⁷⁴

Less than three weeks later on June 5, 2014, Brown gave an update to Gilead's William Dozier, a senior manager of national accounts, warning of the backlash from state Medicaid programs:

I would say that 20 of 25 states have no interest in the offer. [Connecticut] looks to take the 10% offer. The other four are debating the offer (but not rushing their decision).⁵⁷⁵

Gilead officials also directly met with and received written correspondence from representatives of individual state Medicaid programs, who indicated that access restrictions would follow and that some were already occurring. The Ohio Medicaid program raised concerns about the price of Sovaldi in a teleconference with National Accounts Manager David Kaufman and National Accounts Director Justin Crum on June 26, 2014. Price concerns were again raised in an in-person meeting that included the state's Medicaid director, John McCarthy, on September 24, 2014. The second meeting included Associate Director for Government Affairs Rebecca O'Hara, Associate Director for Medical Sciences Paul Miner and outside counsel Joshua R. Sanders.⁵⁷⁶

In addition to his meeting with Ohio Medicaid officials, meeting minutes show that Miner was in attendance on July 8, 2014 when the Michigan Medicaid's pharmaceutical and therapeutics committee reviewed Sovaldi. Minutes show that Vanita Pindolia, the vice president, of ambulatory clinical pharmacy programs-pharmacy care management for Health Access Plan (HAP) of Michigan, spoke directly to the price of Sovaldi:

Dr. Pindolia from HAP testified on behalf of the Michigan Association of Health Plans. She addressed the impact this medication will have on insurance premiums for both private and government programs and the review done by the Institute for Clinical and Economic Review (ICER) for California Technology Assessment Forum (CTAF). In the ICER report the cost effectiveness is addressed in terms of "cost per additional Sustained Viral Response (SVR)". Per

⁵⁷⁴ *Id.*

⁵⁷⁵ Appendix D, Ex. 19, Email from Douglas M. Brown, Senior Director, Pharmacy Pricing & Value Based Solutions, Magellan Health Services, to William Dozier, Senior Manager, National Accounts, Gilead Sciences, Inc. (June 5, 2014).

⁵⁷⁶ Appendix D, Ex. 20, Letter from John B. McCarthy, Director, Ohio Department of Medicaid, to Peter Gartrell (Aug. 7, 2015).

ICER, if Sovaldi is reserved to patients with advanced liver disease then the cost of the drug is recouped as total healthcare savings at the 20 year mark; however if Sovaldi was used to treat all patients with positive HCV, only 66% of drug cost is recouped with total healthcare savings at 20 year.⁵⁷⁷

The CTAF report Pindolia cited, was issued in March 2014, concluding:

A majority of the CTAF Panel rated the new treatments as “low value” compared with older drugs due to the magnitude of the potential impact on health care budgets of treating large numbers of patients with these high-priced drug regimens. Because the financial impact of using these new drugs to treat all eligible patients with hepatitis C is untenable, policy makers should seek avenues to achieve reductions in the effective price of these medications. Panel members and outside experts nearly all agreed that for both clinical and cost reasons, not every patient with hepatitis C needs to be immediately treated with the new drugs. Informed, shared decision-making about the timing of treatment should be encouraged. Given the circumstances, it is reasonable to consider prioritizing treatment with the new drugs for patients who need urgent treatment and have some evidence of liver fibrosis but do not have advanced liver disease.⁵⁷⁸

Two days later, on September 9, 2014, Janet Zachary-Elkind, deputy director of the Division of Program Development and Management and a top official from New York State’s Medicaid program, sent an email to Gilead’s Vice President for Government Affairs Kacy Hutchinson that included a table that quantified the impact that Sovaldi was expected to have on the state’s Medicaid program.⁵⁷⁹ The email reads:

As you can see, if all beneficiaries with CHC were to be treated with Sovaldi, our total spend (amount paid to pharmacies) would be greater than the total annual pharmacy spend in the NY Medicaid program (~\$4.5B). The second chart identifies those beneficiaries that would meet the standardized criteria that we’ve developed. If all beneficiaries that meet our standardized criteria were to be treated, our total spend for Sovaldi would be equal to approximately 67% of our total annual pharmacy spend. While we can’t predict the total number of people that will be treated with Sovaldi, we estimate that it will be somewhere between 10 and 20% of 35,010 (the number of members identified in the second chart) for this calendar year.⁵⁸⁰

⁵⁷⁷ Meeting Minutes, Michigan Pharmacy and Therapeutics Committee (July 8, 2014), available at <https://michigan.fhsc.com/Downloads/PTMinutes-20140708a.pdf>.

⁵⁷⁸ Institute for Clinical and Economic Review, California Technology Assessment Forum, *The Comparative Clinical Effectiveness and Value of Simeprevir and Sofosbuvir in the Treatment of Chronic Hepatitis C Infection*, at ES9 (Apr. 15, 2014), available at http://ctaf.org/sites/default/files/u119/CTAF_Hep_C_Apr14_final.pdf.

⁵⁷⁹ Appendix D, Ex. 21, Email from Janet Zachary-Elkind to Kacy Hutchison (Sept. 9, 2014).

⁵⁸⁰ *Id.*

On August 6, 2014 four company officials—Vice President for Government Affairs Kacy Hutchinson, Vice President of Managed Markets Coy Stout, National Account Director Justin Crum, and National Accounts Executive Manager Tyler Hunter—met with the Texas Health and Human Services Commission (HHSC):

HHSC’s former Executive Commissioner, Dr. Kyle Janek, expressed his displeasure with Gilead’s pricing. He reminded the Gilead executives and representatives of the impact of their drug to the state budget. Given the size of the Texas Medicaid population, Dr. Janek also asked for a discounted rate. He referenced the Drug’s availability at a fraction of the price in other countries and the likelihood that it would be cheaper for Texas to fly Medicaid recipients to those countries for treatment than to treat them in the U.S. Gilead executives and representatives explained that the company limited access to the drug in other countries to citizens of those countries and then defended their pricing model.⁵⁸¹

The next month, Stephanie Tran, Gilead’s Associate Manager for Medical Information, received a letter from the Texas Health and Human Services Commission requesting clinical data for Sovaldi and the drug that would eventually be marketed as Harvoni. The state was seeking more information as it considered clinical edits for HCV patients. “With such a significant impact on the state health care budget, there is very little room for error,” Andy Vasquez, the state’s director for vendor drug programs,⁵⁸² “. . . [T]here is still data that would be crucial to providing the most accurate representation of cost-effective treatment, based on available clinical evidence.”⁵⁸³

In addition to the August meeting and letter to Tran, company officials had seven more meetings with Texas officials between October 21, 2014 and January 16, 2015 to discuss Gilead’s rebate offers for Harvoni and Sovaldi. In addition to Crum, Hunter and Stout, additional participants included Associate Director for Medical Science Michelle Puyear, Associate Director of Government Affairs Erin Smith, and Director for Government Contracts and Pricing Kimberly Hawkins.⁵⁸⁴ In all, Texas raised concerns about pricing with at least eight different Gilead officials, yet, as cited above, the state’s P&T Committee eventually designated Viekira Pak as the preferred therapy for HCV because “AbbVie submitted more aggressive rebates.”⁵⁸⁵

During a forum in October 2014 at The Brookings Institution in Washington D.C., advocate Ryan Clary bookended criticism of access restrictions imposed by commercial insurers and state Medicaid programs with criticism about Sovaldi’s price. He called for lower prices for future HCV therapies, noting that they were a contributing factor to Medicaid programs restricting access to patients.

⁵⁸¹ Appendix D, Ex. 11, Letter from Andy Vasquez, Deputy Director, Vendor Drug Program, Medicaid/CHIP, Texas Health and Human Services Commission, to Hon. Ron Wyden and Hon. Charles E. Grassley at 2 (Aug. 14, 2015).

⁵⁸² *Id.*, Attachment 1.

⁵⁸³ *Id.*

⁵⁸⁴ *Id.*, Attachment 2.

⁵⁸⁵ *Id.* at 2.

Clary, the executive director of the National Viral Hepatitis Roundtable, an advocacy sponsored by several pharmaceutical companies, including Gilead,⁵⁸⁶ delivered his remarks while sitting next to Gilead's Chief Operating Officer, John Milligan:

The public programs, the state Medicaid, that's a different story. These are programs who are not in the business to make a profit off of health care; they are in the business to provide health care to low income people, many in vulnerable populations, who are in a safety net program and do the best they can with strapped budgets. And they are having a real hard time providing access to Hep C treatment. They don't pay \$84,000, they get significant price relief, but they are still having issues. The problem with the state Medicaid is they reacted so quickly to the P.R. campaign and the misinformation and quickly implemented really harmful—not all Medicaid, many—harmful restrictions, that are blanket restrictions, that are discriminatory particularly toward people who either currently or have recently injected drugs—and those are folks who probably would like to be cured of Hepatitis C and not be transmitting to others—so that needs to be dealt with. And as far as the price, my organization and our colleagues have been on record, the price of Sovaldi is expensive, it is too high. The rationale makes sense, but when you look at the sheer number of people who have Hepatitis C, who we know have Hepatitis C, and you look at the cost of treating everybody and curing everybody, we are not going to do it in the next couple years, we know that—time to get through that misinformation—but that's a really high cost. And we've encouraged lower prices, we're hoping that the next wave of prices—and it's not just Gilead, we have other companies coming on board—really look at the access problems we're having, understand that price does play a factor treatment access and make decisions based on that. It's a fantastic drug. This all comes from the spirit and the hope that we can cure everyone with Hepatitis C who wants to be treated. I vote for the option of treating everyone with Hepatitis C.⁵⁸⁷

Congress Raises Concerns

In addition to the letter sent by Senators Wyden and Grassley that began this investigation, Gilead's CEO received a letter in March 2014 from three senior members of the House Energy and Commerce Committee, Henry A. Waxman, Frank Pallone, Jr., and Diana DeGette. The letter raised concern about the cost of Sovaldi, and its use with Olysio, in an attempt by providers to avoid the use of interferon:

⁵⁸⁶National Viral Hepatitis Roundtable, *Sponsors*, available at <http://nvhr.org/content/members/sponsors> (last visited July 16, 2015).

⁵⁸⁷The Brookings Institution, Event, *The Cost and Value of Biomedical Innovation: Implications for Health Policy* (Oct. 1, 2014), available at <http://www.brookings.edu/events/2014/10/01-cost-and-value-biomedical-innovation-hep-c#/full-event/>.

These costs are likely to be too high for many patients, both those with public insurance and those with private insurance. Because Hepatitis C is “concentrated in low-income, minority patients,” the affordability problems are likely to be particularly acute for state Medicaid programs and those patients served by these programs. Colorado and Pennsylvania have already announced that their Medicaid programs will be limiting use of the new drug to “only the sickest patients,” such as those already suffering from liver disease. California’s Medicaid program is still considering how and when to reimburse for the drug. The large pharmacy benefit manager Express Scripts has said it is “encouraging some doctors in its networks to delay prescribing Sovaldi.” Even in cases where public or private insurers pay for the medication, it will impose substantial costs on taxpayers and could cause premium increases for those with employer or individual coverage.⁵⁸⁸

All told, officials from Gilead received communications from a number of policy makers, advocates, providers, and payers regarding concerns about the high price of Sovaldi and that because of the price, patients who could benefit would not receive the drug. In addition, many noted their concerns about the impact that its high price would have on public payers. While Gilead had predicted that a negative response from patients and advocacy groups was “very likely” at the price point it selected, it may have ultimately underestimated the extent of concerns. Investigative staff found that this negative response was directly communicated to Gilead from 2013 through the present.

⁵⁸⁸ Appendix D, Ex. 22, Letter from Hon. Henry A. Waxman et al., to Dr. John C. Martin, Chief Executive Officer, Gilead Sciences, Inc. (Mar. 20, 2014).

Section 6: A Competitor Drug Enters the Market

The emergence of an effective competitor—AbbVie’s Viekira Pak—altered the market for HCV drugs, as evidenced by Gilead entering into substantial discounts with some payers. However, even with Viekira Pak’s entrance, some state Medicaid programs asserted that Gilead continued to draw a hard negotiating line and did not offer steep enough discounts. Thus, concerns regarding price and access restrictions remain, and regulatory agencies have taken various actions that may further affect the market for HCV drugs.

Gilead’s products, Sovaldi and Harvoni, were the most widely used HCV treatments in the United States the year following FDA approval of Sovaldi in late 2013. The primary competitor to Sovaldi was Olysio, although the Johnson & Johnson drug was more frequently used as an off-label, interferon-free combination with Sovaldi than as a stand-alone treatment.⁵⁸⁹ Following Harvoni’s approval by the FDA in October 2014, use of Olysio sharply declined, most likely because Harvoni provided an interferon-free single-pill treatment for genotype 1 patients that was significantly less expensive than the Sovaldi-Olysio combination.⁵⁹⁰ As the company prepared to release Harvoni, it was contemplating a similar contracting strategy to what it had employed for Sovaldi—a 4% supplemental discount for being listed on the preferred drug list, and generally 8% for allowing prescriptions for patients with F2–F4 fibrosis scores and 10% for allowing authorization to the FDA label (i.e., all patients).⁵⁹¹

On December 19, 2014, the FDA approved Viekira Pak, manufactured by AbbVie.⁵⁹² As discussed in Section 3 of this report, Gilead had expected Viekira Pak to bring competition to genotype 1 patients, the largest segment of the U.S. HCV market. Like Harvoni, Viekira Pak can be used without interferon, and clinical trials demonstrated that Viekira Pak offered comparable cure rates to Harvoni.⁵⁹³ However, unlike Harvoni, Viekira Pak is a multi-tablet regimen, rather than a single-pill treatment. CVS Pharmacy noted that a single-tablet regimen gave Gilead products the “best clinical profile,” but that “there was not an appreciable clinical superiority of one product over another.”⁵⁹⁴

Three days following Viekira Pak’s approval, Express Scripts Holding Co., the nation’s largest pharmacy benefit manager (PBM), announced that it would make Viekira Pak its preferred treatment

⁵⁸⁹ Appendix D, Ex. 23, Troyen A. Brennan et al., CVS Health Corp., Analysis of “Real World” Sovaldi® (sofosbuvir) Use and Discontinuation Rates, September 2014, at Table 1.

⁵⁹⁰ Michelle Fay Cortez & Cynthia Koons, *Johnson & Johnson Forecasts Profit Decline on Competition*, Bloomberg (Jan. 20, 2015), available at <http://www.bloomberg.com/news/articles/2015-01-20/johnson-johnson-earnings-beat-estimates-on-prescription-sales>.

⁵⁹¹ Appendix E, Ex. 52, Gilead Sciences, Inc., HCV Wave 2 Contracting Recommendations, September 9, 2014, GS-0019058, at GS-0019112.

⁵⁹² Press Release, U.S. Food and Drug Administration, FDA approves Viekira Pak to treat hepatitis C, available at <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm427530.htm>.

⁵⁹³ American Association for the Study of Liver Diseases and Infectious Disease Society of America, HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C: Initial Treatment of HCV Infection, available at <http://www.hcvguidelines.org/full-report/initial-treatment-hcv-infection> (last updated Aug. 7, 2015).

⁵⁹⁴ Appendix D, Ex. 1, Email from Ann Walker-Jenkins, Director, Federal Government Affairs, CVS Health Corp., to Peter Gartrell (Mar. 9, 2015), attaching written response to investigative staff.

for genotype 1 and would no longer cover Sovaldi and Harvoni for these patients.⁵⁹⁵ The deal was the result of AbbVie offering discounted pricing for Viekira Pak that exceeded discounts Gilead had offered up to that point.⁵⁹⁶ *Reuters* reported at the time that “AbbVie narrowed the price gap to resemble what Western European countries pay for Sovaldi, which runs from \$51,373 in France to \$66,000 in Germany.”⁵⁹⁷

Gilead responded in January and February by entering into discounting agreements for Harvoni and Sovaldi with CVS,⁵⁹⁸ Anthem,⁵⁹⁹ Humana,⁶⁰⁰ Aetna,⁶⁰¹ and UnitedHealth Group.⁶⁰² Cigna⁶⁰³ struck agreements with Gilead for Harvoni only. Investigative staff could not verify the discount amounts because agreements between PBMs and drug manufacturers are confidential. However, in February 2015, Gilead announced that its “gross-to-net” deductions⁶⁰⁴ for HCV products increased from 22% in 2014 to 46% in 2015, as a result of “the recent and ongoing round of negotiations with payers and PBMs.”⁶⁰⁵ Peter Wickersham, then-senior Vice president at Prime Therapeutics, LLC, a PBM representing 26 million people, described the sudden, steep discounting as unprecedented: “Wickersham said in his 20 years in the industry he had never seen prices for a brand-name drug cat-

⁵⁹⁵ Caroline Humer, *Express Scripts drops Gilead hep C drugs for cheaper AbbVie rival*, *Reuters* (Dec. 22, 2014), available at <http://www.reuters.com/article/2014/12/22/us-express-scripts-abbvie-hepatitisc-idUSKBN0K007620141222>.

⁵⁹⁶ *Id.*

⁵⁹⁷ *Id.*

⁵⁹⁸ Robert Langreth & Caroline Chen, *Gilead Makes Exclusive Deal With CVS For Hepatitis C Drugs*, *Bloomberg Business* (Jan. 5, 2015), available at <http://www.bloomberg.com/news/articles/2015-01-05/gilead-makes-exclusive-deal-with-cvs-for-hepatitis-c-medicine>.

⁵⁹⁹ Robert Langreth, *Gilead Strikes Hepatitis C Deal With Anthem*, *Bloomberg Business* (Jan. 8, 2015), available at <http://www.bloomberg.com/news/articles/2015-01-08/gilead-strikes-hepatitis-c-deal-with-anthem>.

⁶⁰⁰ Bob Herman, *Humana Opts For Gilead In Hepatitis C Drug Battle*, *Modern Healthcare* (Jan. 14, 2015), available at <http://www.modernhealthcare.com/article/20150114/NEWS/301149943>.

⁶⁰¹ Linda A. Johnson, *Aetna Chooses Gilead Sciences Hepatitis C Drugs Over AbbVie's*, *San Jose Mercury News* (Jan. 16, 2015), available at http://www.mercurynews.com/business/ci_27337565/aetna-chooses-gilead-sciences-hepatitis-c-drugs-over.

⁶⁰² Caroline Humer, *UnitedHealth Backs Gilead's Harvoni As Preferred Hepatitis C Treatment*, *Reuters* (Jan. 28, 2015), available at <http://www.reuters.com/article/2015/01/28/us-unitedhealth-gilead-hepatitisc-idUSKBN0L12JP20150128>.

⁶⁰³ Press Release, Cigna Corporation, *Cigna Signs Agreement With Gilead to Improve Affordability of Hepatitis C Treatment for Customers and Clients* (Feb. 4, 2015), available at <http://newsroom.cigna.com/NewsReleases/cigna-signs-agreement-with-gilead-to-improve-affordability-of-hepatitis-c-treatment-for-customers-and-clients.htm>.

⁶⁰⁴ Since filing its first Annual Report as a public company in 1996, Gilead has recognized and reported its net revenue by deducting from gross revenue three major items: “estimated product returns, cash discounts, and government programs and rebates.” Gilead Sciences, Inc., Annual Report (Form 10-K) at 30 (Mar. 25, 1997), available at <http://www.sec.gov/Archives/edgar/data/882095/0000912057-97-009728.txt>. Gilead defined net product sales as sales “net of estimated mandatory and supplemental discounts to government payers, in addition to discounts to private payers, and other related costs,” in its annual report for fiscal year 2014. Gilead Sciences, Inc., Annual Report (Form 10-K) at 58 (Feb. 25, 2015), available at <http://www.sec.gov/Archives/edgar/data/882095/000088209515000008/a2014form10-k.htm>. In 2013, Gilead forecast gross-to-net revenue deductions 17.9% for sofosbuvir during 2014, which included an 8.1% deduction for mandatory discounts (such as Medicaid discounts), a 4.8% deduction for supplemental discounts (such as discounts made per the terms of commercial contracts), and a 5% deduction for “Other” discounts, including IMA fees, prompt payment discounts, the Medicare “donut hole,” and copay coupons. Appendix E, Ex. 36, Gilead Sciences, Inc., *Sofosbuvir Pricing and Market Access Assessment, Response to Follow Up Questions* (Aug. 26, 2013), GS-0013857, at GS-0013881, GS-0013883.

⁶⁰⁵ Gilead Sciences, Inc., *Fourth Quarter 2014 Gilead Sciences Earnings Conference Call, Webcast* (Feb. 3, 2015), available at <http://investors.gilead.com/phoenix.zhtml?p=irol-eventDetails&c=69964&eventID=5178585>.

egory plummet so quickly after a competing drug was introduced.”⁶⁰⁶

CVS told investigative staff that successfully negotiating with drug manufacturers typically depends on market competition, stating, “When single source drugs come to market, it is difficult to negotiate a lower cost because there is no market competition,” but that “[t]he entrance of alternative drugs in a class generally increases manufacturers’ willingness to negotiate with payors.”⁶⁰⁷ CVS, like Express Scripts, found that “as new drugs came on to the market like Viekira Pak, we were able to negotiate discounts.”⁶⁰⁸

Some states also reached agreements with HCV drug manufacturers. In January 2015, Texas’ Pharmaceutical and Therapeutics Committee selected Viekira Pak as the program’s preferred drug, both because it viewed the drug as equally effective and “because AbbVie submitted more aggressive rebates . . . Viekira Pak was more cost effective.”⁶⁰⁹ Texas was one of 13 state Medicaid programs that OHSU researchers identified as having selected Viekira Pak as the preferred drug as of May 5, 2015. By comparison, 12 state Medicaid programs selected Harvoni as their preferred drug.⁶¹⁰

Despite the benefits of competition, many state Medicaid programs remained concerned about the cost of new HCV therapies (and the resulting costs). “Through our multi-state rebate contract negotiating pool we have engaged HCV product manufacturers for various pricing level considerations. However, these efforts have been met with little to no success,” Samantha McKinley, the pharmaceutical director for Kentucky’s Medicaid program, wrote to Senators Wyden and Grassley on October 21, 2015.⁶¹¹

State Medicaid programs reported that obtaining suitable discounts from Gilead remained difficult even after Viekira Pak’s entrance in the market. On October 2, 2015, Theodore Dallas, the Secretary of Human Services for Pennsylvania wrote that even with competition, Gilead’s prices were not sufficiently reduced, and that the state has retained tight control over approving prescriptions:

Initially, Gilead offered a very modest supplemental rebate for Sovaldi on the condition of a guarantee of unfettered access: no prior authorization, and no requirements for prescriptions to be written by, or in consultation with a medical specialist. When Gilead introduced Harvoni and AbbVie introduced Viekira Pak to the market, Gilead claimed willingness to negotiate supplemental rebates but negotiations were unproductive. Currently, Viekira Pak is designated as preferred on the [fee-for-service preferred

⁶⁰⁶Robert Langreth, *Hepatitis Drug Prices Fall So Low, No Exclusives Needed*, Bloomberg Business (Jan. 12, 2015), available at <http://www.bloomberg.com/news/articles/2015-01-12/prime-covers-both-gilead-and-abbvie-liver-drugs-as-prices-plunge>.

⁶⁰⁷Appendix D, Ex. 1, Email from Ann Walker-Jenkins, Director, Federal Government Affairs, CVS Health Corp., to Peter Gartrell (Mar. 9, 2015), attaching written response to investigative staff.

⁶⁰⁸*Id.*

⁶⁰⁹Appendix D, Ex. 11, Letter from Andy Vasquez to Hon. Ron Wyden and Hon. Charles E. Grassley at 2 (Aug. 14, 2015).

⁶¹⁰Appendix B, Table 2a.

⁶¹¹Appendix D, Ex. 10, Letter from Samantha McKinley to Hon. Ron Wyden and Hon. Charles E. Grassley at 2 (Oct. 21, 2015).

drug list]; Harvoni, Sovaldi, Daklinza and Technivie are designated as non-preferred. They are covered and available when determined to be medically necessary. All of the drugs, including Viekira Pak, require prior authorization.⁶¹²

On November 5, 2015, Andrew M. Slavitt, Acting Administrator for CMS, published a blog post concerning access, affordability, and innovation for prescription drugs in which he singled out the high cost of new, highly effective HCV drugs as an ongoing challenge.⁶¹³ Slavitt wrote:

A recent example of a much discussed, highly-effective drug is a therapy used by Hepatitis C patients. Hepatitis C, a debilitating and life threatening infection that leads to chronic conditions of the liver, has undergone a revolutionary improvement in cure rates with innovative new medicines. These medicines are changing the lives of many individuals, but they are also expensive, costing tens of thousands of dollars, sometimes even more than one hundred thousand dollars, per patient. These costs have strained personal as well as public budgets, particularly state health care budgets. Because state budgets generally need to be balanced every year, new drug treatments can surprise states with tens or hundreds of millions of dollars in new spending. As these costs often necessarily compete with other state programs like K–12 education, transportation, law enforcement, and public health programs, some states have made tough choices, including limiting access to these therapies.⁶¹⁴

However, as Slavitt also noted, states have an obligation to provide treatment. CMS simultaneously issued a notice to all state Medicaid directors specifically related to HCV drug access to reinforce the point.⁶¹⁵ As Slavitt explained in his post:

Our notice to state Medicaid directors reminds states of their obligation to provide access to these promising therapies (consistent with section 1927 of the Social Security Act) based on the medical evidence, and that they have tools available to manage their costs.⁶¹⁶

The Agency also sent letters to HCV drug companies, Gilead, Johnson & Johnson, Merck & Company, Inc., and AbbVie, in which Slavitt wrote:

⁶¹² Appendix D, Ex. 6, Letter from Theodore Dallas, Secretary, Department of Human Services, Commonwealth of Pennsylvania, to Hon. Ron Wyden and Hon. Charles E. Grassley at 3 (Oct. 2, 2015).

⁶¹³ Andrew M. Slavitt, “Prescription Drugs: Advancing Ideas to Improve Access, Affordability, and Innovation,” *The CMS Blog* (Nov. 5, 2015), available at <http://blog.cms.gov/2015/11/05/prescription-drugs-advancing-ideas-to-improve-access-affordability-and-innovation>.

⁶¹⁴ *Id.*

⁶¹⁵ Department of Health and Human Services, CMS, Release No. 172, Medicaid Drug Rebate Program Notice, Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs (Nov. 5, 2015), available at <http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-172.pdf>.

⁶¹⁶ Andrew M. Slavitt, “Prescription Drugs: Advancing Ideas to Improve Access, Affordability, and Innovation,” *The CMS Blog* (Nov. 5, 2015), available at <http://blog.cms.gov/2015/11/05/prescription-drugs-advancing-ideas-to-improve-access-affordability-and-innovation>.

Manufacturers also have a role to play in ensuring access and affordability. The agency believes it is important that state Medicaid agencies have access to the lowest available manufacturer prices in the market. Additionally, they should be given the opportunity to participate in discount or value-based purchasing arrangements offered by manufacturers.⁶¹⁷

Additional factors may affect the U.S. market for HCV therapies. For example, as demonstrated this year by FDA safety warnings that were issued for Sovaldi and Viekira Pak. On March 24, 2015, the FDA warned “that serious slowing of the heart rate can occur when the antiarrhythmic drug amiodarone is taken together” with Harvoni or Sovaldi in combination with other direct-acting antiviral HCV drugs such as Olysio or daclatasvir.⁶¹⁸ The warning advised to avoid such co-prescriptions.⁶¹⁹ On October 22, 2015, the FDA issued a warning that Viekira Pak and Technivie (approved for treatment of genotype 4 patients) “can cause serious liver injury mostly in patients with underlying advanced liver disease.”⁶²⁰ The FDA required new safety warnings reflecting the risk to the drugs’ labels.⁶²¹ While these warnings have not resulted in any of the drugs being pulled from the market at the time of this report, it is not known what impact they could have on practices and attitudes of patients, health care providers, and payers, which could affect competition in the market.

As such, the market for HCV therapies continues to evolve. Even as competition appears to have mitigated some of the pricing concerns discussed throughout this report, concerns about cost burden and access remain. In addition, future warnings or regulatory actions could further affect the HCV market.

⁶¹⁷ Department of Health and Human Services, CMS, HCV Communication, Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs (Nov. 5, 2015), *available at* <http://medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/hcv-communication.html>.

⁶¹⁸ FDA, FDA Drug Safety Communication: FDA warns of serious slowing of the heart rate when antiarrhythmic drug amiodarone is used with hepatitis C treatments containing sofosbuvir (Harvoni) or Sovaldi in combination with another Direct Acting Antiviral drug (Mar. 24, 2015), *available at* <http://www.fda.gov/Drugs/DrugSafety/ucm439484.htm>.

⁶¹⁹ *Id.*

⁶²⁰ FDA, FDA Drug Safety Communication: FDA warns of serious liver injury risk with hepatitis C treatments Viekira Pak and Technivie (Oct. 22, 2015), *available at* <http://www.fda.gov/Drugs/DrugSafety/ucm468634.htm>.

⁶²¹ *Id.*

Section 7: Conclusions and Questions

This report is a case study of one company's experience in bringing a breakthrough therapy to market. Although it may have implications for other companies and other products, this report focuses only on the facts and circumstances of Gilead Sciences' introduction of sofosbuvir-based HCV drugs. Given that, despite the company's assurances of cooperation, Gilead failed to produce all relevant documents and supporting materials related to pricing, the staff's analysis of pricing decisions and strategies is necessarily based only on the documents and interviews that were provided by the company and from outside sources.

Gilead acquired access to its sofosbuvir-based drugs through a multi-billion dollar acquisition and spent hundreds of millions of dollars more completing clinical trials and FDA approvals. While there were extensive discussions regarding return on those investments while Gilead was considering the acquisition of Pharmasset, there is scant evidence that return on these investments played a significant role in determining the pricing of these drugs. Similarly, the cost of manufacturing Sovaldi, which was nominal, played no part in establishing the price. In an interview, Gilead executive Jim Meyers, who played a lead part in making the pricing recommendation did not know the cost of manufacturing the drug.

During the investigation, Gilead asserted that its primary concern in developing and marketing Sovaldi was to treat the largest number of HCV patients possible. For example, Gilead claimed that it shifted the emphasis of Sovaldi's Phase 3 trials to focus more heavily on treating genotype 1 patients, which Meyers told investigative staff was done to help as many patients as possible—as many as 5 million people are infected with HCV in the U.S., of which roughly 70% are carrying genotype 1. In reality, Gilead's marketing, pricing, and contracting strategies were focused on maximizing revenue—even as the company's analysis showed a lower price would allow more people to be treated—not only for Sovaldi, but more importantly for its follow-on sofosbuvir-based product pipeline. Significantly, when confronted with the widespread initiation of access restrictions, Gilead refused to offer substantial discounts and did not significantly modify its contracting strategy to improve patient access.

A key consideration in Gilead's decision-making process to determine the ultimate price of Sovaldi was setting the price such that it would not only maximize revenue, but also prepare the market for Harvoni and its even higher price. To that end, Gilead's goal throughout its pricing decision process appears to have been to identify the price just below the level where payers would place significant restrictions on patient access. Although it knew there would be some patient loss in the \$80,000 to \$85,000 per standard dosage range, Gilead's internal analysis indicated that it was a viable level for the majority of payers, and would also help secure what the company later referred to as "market share leader-

ship”⁶²² for Harvoni as a preferred future therapy and baseline price for the next wave of HCV drugs. The response to the launch price by payers appears to have been more severe than Gilead’s expectations.

While Gilead claimed in interviews with investigative staff that payers readily accepted the proposed \$80,000 to \$85,000 price range during its pre-marketing surveys and focus groups, not a single one of the states, payers, or pharmacy benefits managers interviewed by staff investigators told us that it communicated assent in such surveys, nor did its organization. To the contrary, several experts and entities privately and publicly warned Gilead about the consequences of excessive pricing before introduction.

Even though Gilead assumed that the final price recommendation of \$84,000 would not result in significant patient access restrictions, it quickly became apparent that this assumption was incorrect as many public and private payers quickly reacted and adopted restrictions. Ultimately, these restrictions reduced the number of patients who could have received treatment.

When presented with these access restrictions and pleas by both public and private payers for supplemental rebates or discounts to reduce the cost of HCV treatment for their respective patient populations, Gilead offered supplemental rebates and discounts of minimal value (on the order of 10% if all restrictions were lifted for Medicaid, for example). Only a handful of payers accepted these additional reductions. When payers proposed additional discounts, Gilead rejected them.

When launching Harvoni, Gilead essentially executed the same revenue maximizing methodology that it used for Sovaldi, even though it was aware that such an approach could cause similar access challenges. Gilead always intended to extract a premium for this follow-on, all oral drug. Its acquisition advisor, during the run-up to Gilead’s purchase of Pharmasset, called it a “convenience bump.” 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. Its expectations were confirmed when AbbVie entered the market with its multi-drug, all oral Viekira Pak for genotype 1 at a base treatment price of \$83,319, marginally below Gilead’s prices. Gilead was able to maintain pricing power until Express Scripts, a major pharmacy benefits manager, entered into an agreement with AbbVie to make Viekira Pak its preferred genotype 1 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.

⁶²² Appendix E, Ex. 45, Gilead Sciences, Inc., 2015–2016 HCV Commercial Plan (Apr. 22, 2014), GS-0014083, at GS-0014085.

Potential Areas for Committee Consideration

The evidence collected for this report presents the Senate Finance Committee with a warning for critical policy areas under its jurisdiction. The federal government has responsibility for billions of dollars in payments for pharmaceuticals through the Medicare and Medicaid programs. However the federal government is not the direct payer for either. In Medicare, payments for pharmaceuticals are made through prescription drug plans sponsors. In Medicaid, each state program is responsible for payments, with the federal government reimbursing a state-specific percentage, or “match.” The Finance Committee is responsible for policies that govern these programs and the intermediaries making payments on behalf of the federal government.

The narrative in the case of Sovaldi is fairly straightforward: Pharmasset developed the drug that ultimately became known as Sovaldi. Gilead purchased Pharmasset and shepherded Sovaldi through the completion of the FDA approval process. Gilead engaged in a complex process in determining the price of Sovaldi, ultimately settling on a price that underestimated the reaction from both private and public payers. When the payer community reacted negatively to the price of Sovaldi during its initial period of monopoly pricing power, Gilead provided only limited price flexibility, which led to implementation of widespread treatment restrictions that limited access to the sickest patients. Roughly a year later, AbbVie received approval for its drug, Viekira Pak, and competition through third parties—Express Scripts and CVS Caremark—immediately extracted rebates and discounts from the previously set list prices of both products.

One could argue that the system “worked,” in that a new entrant into the market impacted the negotiated cost of the “first to market,” or breakthrough, drug. In other words, competition worked to lower the cost of pharmaceuticals. Gilead’s ability to set and hold the price for Sovaldi at a point that clearly caused stress to the payer community lessened with the entrance of a competitor. However, even as competition lowered prices for therapies, this report documents that concerns remain, particularly in the public payer community, about high costs for treating millions of people in the U.S. infected with HCV.

There is no question that Viekira Pak’s entrance into the market changed the status quo. It is true that aspects of the system worked, in this case, because AbbVie came to the market with a competitor drug roughly a year after Sovaldi’s release. However, only looking at that one event in a vacuum ignores the impact of the efforts that Gilead had undertaken to change the HCV market as a whole.

Sovaldi was a significant breakthrough for those diagnosed with HCV. However, comparing the drug with the previous standard of care is like comparing apples to oranges. At the most basic level, patients’ ability to tolerate it meant that more patients could take it. This dramatic increase in market size and resulting revenue to Gilead was anticipated by the company. However, when payers attempted to extract rebates or discounts to ease cost concerns given the higher numbers of patients being treated, Gilead rebuffed those

efforts. The result was that patients who could benefit from these drugs did not receive them due to the high cost. Those patient populations remain at risk and will, for the most part, still require treatment in the future.

Accordingly, the public and private payer community continue to face a higher cost for the prevailing (new) standard of care, and higher overall costs because the new generation of HCV drugs is better tolerated and will most likely be far more widely prescribed.

Understanding the significance of AbbVie's entrance into the market is critical. If no other company had developed a breakthrough competitor with similar clinical results, Gilead's de facto control of the market could have lasted much longer. The average time between a single source innovator entering the market and a generic manufacturer producing its equivalent product and bringing it to market is 12.6 years.⁶²³ Without successful competition, the costs to the public and private payers could have caused much more significant disruptions and access restrictions for years.

While it is premature to make specific legislative recommendations, several specific questions warrant public discussion:

1) What are the effects of a breakthrough, single source innovator drug on the marketplace?

Among other things, this report reflects the reality that federal health care programs—notably Medicare and Medicaid—have little to no policy levers at their disposal to significantly impact the price of a single source innovator drug. This report found that not until reasonable competition entered the marketplace did Gilead's pricing incentives and behavior change. Not all expensive innovator drugs face competition so soon after launch, and thus the next expensive innovator drug could potentially create significant budgetary pressures for federal payers and lead to access restrictions for an extended timeframe. In light of Gilead's abrupt change in behavior when faced with competition, what policy levers are available to increase competition with a single source innovator or otherwise ensure single source breakthrough drugs are available to those who would benefit clinically?

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?

With respect to Sovaldi, cost drove much of the negative reaction to the introduction of the drug. Gilead argued that the price point for Sovaldi was less than that of the total cost associated with the previous treatment regime. The payers argued that the cost of Sovaldi was greater than any single treatment previously considered for HCV. What is clear is that payers were caught off guard by the price of the treatment regimen, especially when Sovaldi was used in combination with Olysio, driving the cost of treatment to approximately \$150,000.

With respect to volume, HCV impacts millions of Americans, the full count of which is unknown. In the case of Sovaldi, payers were

⁶²³ Henry Grabowski et al., *Recent Trends in Brand-Name and Generic Drug Competition*, 17 J. Med. Econ. 207, 207–14 (Dec. 10, 2013), available at <http://informahealthcare.com/doi/abs/10.3111/13696998.2013.873723>.

overwhelmed by the cost of the drug in conjunction with the volume of patients now eligible for treatment. The volume was further driven by patients being warehoused in anticipation of new drugs, as well as aggressive marketing by Gilead and other manufacturers. Again, payers clearly did not anticipate the demand for Sovaldi, and it is possible Gilead itself was caught off-guard. However, if the latter is true, the company decidedly did not take action to self-correct, and instead remained committed to securing its original price from public and private payers alike, regardless of volume.

While the Committee does not have jurisdiction over the approval process of drugs, the Committee's role as a significant payer cannot be ignored. If the payers do not have the opportunity to know what is coming and react accordingly with their plans and pricing, that is a problem. The Committee should explore ways to provide greater transparency in this area.

3) What role does the concept of "value" play in this debate, and how should an innovative therapy's value be represented in its price?

The Committee should consider that cost, patient volume, and increases in efficacy ultimately speak to the concept of value. The Committee has worked exhaustively to inject the concept of value into the reimbursement regimes in Medicare. While the Committee has worked with value-based purchasing largely in Medicare Parts A and B, the Committee should turn its attention to ensuring that the program is getting value for the spending in Part D. The Congressional Budget Office has already shown that spending increases for Part D can lead to decreases in Parts A and B spending. But in the future, the Committee will also have to consider whether the payers in Medicare and Medicaid are doing enough to ensure that innovative drugs produce additional value that supports their additional expense.

4) What measures might improve price transparency for new higher-cost therapies while maintaining incentives for manufacturers to invest in new drug development?

The Committee should explore the degree to which transparency could put downward pressure on pricing without exposing confidential, proprietary information about a new drug's scientific development. When confronted by dramatically higher costs, many payers restricted access. The Committee should examine ways to support manufacturers that direct their efforts toward expanding access to their cures.

The process which a payer of health care services, whether it be an employer or the federal government, must go through to determine the exact price it will pay for pharmaceuticals is long, complicated, and often opaque. While most drug manufacturers publicly announce the "price" of their drugs, the actual amount paid by individual payers is kept secret for a variety of potentially legitimate reasons. However, there are reasons to believe that increased transparency in actual prices paid would better inform the public as well as help policy makers make more informed decisions. On the latter point, the public may be surprised to learn that members

of Congress are forbidden by law⁶²⁴ to have access to information regarding price discounts and rebates agreed to by drug manufacturers as part of the Medicare and Medicaid programs. Congress and payers alike need more complete information on the ultimate prices paid.

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?

The data contained in this report provides estimates of the number of Medicaid enrollees infected with HCV, the number of enrollees who received treatment, and the cost of that treatment to taxpayers. More often than not, states responded to the high need for—and high cost of—HCV treatments by imposing access restrictions leading to a fraction of the infected population actually receiving treatment. In addition, as shown in the report, this high cost, high need situation is expected to continue to strain state Medicaid budgets and affect decision-making around access. The Committee should explore the tools that states and the federal government can employ, or should be able to employ, to appropriately manage their patient populations, ensure timely access to medically necessary treatments, and address the financial constraints of new cures that enter the market.

⁶²⁴ 42 U.S.C. § 1396r-8(b)(3)(D).

Timeline of Key Events

1987	Gilead Sciences, Inc. (Gilead) is founded in Foster City, California.
1992	Gilead becomes a publicly traded company.
1998	Pharmasset, Inc. (Pharmasset) is founded in Tucker, Georgia.
2006	Pharmasset becomes a publicly traded company.
2008	Pharmasset spends \$770,000 researching PSI-7977, a molecule being developed for the treatment of the Hepatitis C virus (HCV). PSI-7977 would become Sovaldi.
2009	Pharmasset spends \$6.9 million researching PSI-7977.
2010	Pharmasset announces initiation of Phase 2a and 2b studies for PSI-7977. This announcement is the first public acknowledgement that the compound is being developed. The company spends \$16.4 million researching the compound.
May 13, 2011	The Food & Drug Administration (FDA) approves Vertex Pharmaceutical's Incivek (telaprevir) through priority review, for the treatment of Chronic Hepatitis C (CHC) genotype 1 in adult patients with compensated liver disease (including cirrhosis), in combination with pegylated interferon alfa and ribavirin. FDA approves Merck & Company's (Merck) Victrelis (boceprevir) through priority review, for the treatment of CHC genotype 1, in combination with pegylated interferon-alfa and ribavirin, in adult patients with compensated liver disease (including cirrhosis). These drugs are the first direct-acting antivirals (DAA) to receive FDA approval. DAAs work by targeting enzymes within the RNA of HCV.
September 2, 2011	Gilead begins negotiations to acquire Pharmasset. Gilead's initial offer is \$100 per share.
November 1, 2011	Pharmasset initiates Phase 3 trials for PSI-7977.
November 6, 2011	Pharmasset announces results of a Phase 2 trial in which all Hepatitis C (HCV) patients who used PSI-7977 were cured of the disease.
November 21, 2011	Gilead announces agreement to purchase Pharmasset for \$137 per share.
December 16, 2011	Pharmasset halts clinical trials for a second HCV drug, PSI-938. In response to the news, a Gilead spokesman tells the Wall Street Journal , "[s]ince the announcement from Pharmasset regarding PSI-938 does not impact the development of PSI-7977, we do not believe the fundamental value of the deal has been impacted."
January 17, 2012	Gilead completes its purchase of Pharmasset, Inc. for \$11.2 billion. PSI-7977 becomes GS-7977.
March 25, 2013	Gilead begins its evaluation of pricing and access for GS-7977, which would be marketed as Sovaldi.
May 6, 2013	FDA grants Viekira Pak breakthrough therapy designation.
October 10, 2013	FDA grants Sovaldi breakthrough therapy designation. The designation would allow the company to include two additional Phase 3 studies, VALLENCE and PHOTON-1, which provided data supporting treatment of genotype 3 patients, and genotype 1 patients co-infected with HIV, respectively.
November 22, 2013	FDA approves Olysio (simeprevir) through priority review, for the treatment of CHC genotype 1 as a component of a combination antiviral treatment regimen.
November 18–23, 2013	Gilead executives set the price of Sovaldi at \$84,000.
December 6, 2013	FDA approves Gilead's Sovaldi (sofosbuvir) through priority review and with breakthrough therapy designation, for the treatment of CHC infection as a component of a combination antiviral treatment regimen.

Timeline of Key Events—Continued

January 29, 2014	The American Association for the Study of Liver Diseases (AASLD) and Infectious Disease Society of America (IDSA) issue recommendations that health care providers prescribe Sovaldi and Olysio in combination for genotype 1 patients who are not eligible to receive interferon.
July 11, 2014	Senators Wyden and Grassley send a letter to Gilead CEO John Martin seeking information about how the company priced Sovaldi.
August 11, 2014	Vertex Pharmaceuticals notifies providers it will discontinue sales of Incivek in October.
October 10, 2014	FDA approves Gilead's Harvoni (ledipasvir and sofosbuvir) through priority review and with breakthrough therapy designation, for the treatment of CHC genotype 1.
October 28, 2014	The National Association of Medicaid Directors sends letter to Congress raising concerns about the price of Sovaldi and Harvoni.
November 5, 2014	FDA approves Olysio-Sovaldi combination for treatment of patients with CHC genotype 1. The application for the combination was submitted by Johnson & Johnson.
December 19, 2014	FDA approves AbbVie Inc.'s Viekira Pack (ombitasvir, paritaprevir, and ritonavir, dasabuvir) through priority review and with breakthrough therapy designation, for use with or without ribavirin to treat patients with CHC genotype 1.
December 22, 2014	Express Scripts Holding Co., the nation's largest pharmaceutical benefits manager, announces that it has reached a deal to include Viekira Pak on its preferred drug list at a significant, but undisclosed discount. The deal sparks competition between AbbVie and Gilead.
January 20, 2015	Johnson & Johnson announces financial results for full year 2014. Sales of Olysio total \$2.3 billion, largely attributable to co-prescriptions with Sovaldi. The company reports a sharp drop in Olysio sales during the fourth quarter of 2014, compared to the third quarter, which analysts attribute to competition from Harvoni. Merck notifies providers that it will discontinue sales of Victrelis by December 2015.
February 3, 2015	Gilead announces financial results for full year 2014. Net product sales for Sovaldi total \$10.3 billion; net product sales for Harvoni total \$2.1 billion. The company announces that it expects the "gross-to-net" discount for HCV drugs to average 46% in 2015, compared to 22% in 2014. The increase is attributed to recent agreements it has reached with payers. The company also announces a \$15 billion stock buyback program, and initiates a 43-cent-per-share quarterly dividend.
March 24, 2015	FDA issues safety warning that Sovaldi and Harvoni, when used with other direct-acting antiviral drugs such as Olysio, can cause "serious slowing of the heart rate" when used with the arrhythmia drug amiodarone.
July 24, 2015	FDA approves Bristol-Meyer Squibb's Daklinza (daclatasvir) through priority review for the treatment of CHC genotype 3 in combination with Sovaldi. FDA approves AbbVie's Technivie (ombitasvir, paritaprevir, and ritonavir) through priority review and with breakthrough therapy designation, for use in combination with ribavirin for the treatment of CHC genotype 4 patients without cirrhosis.
October 22, 2015	FDA issues safety warning that Viekira Pak and Technivie can cause serious liver injury, "mostly in patients with underlying advanced liver disease."
October 27, 2015	Gilead announces third quarter financial results. For the first nine months of 2015, net product sales for Harvoni total \$10.5 billion; net product sales for Sovaldi total \$3.7 billion.

Timeline of Key Events—Continued

- October 30, 2015** AbbVie announces third quarter financial results. For the first nine months of 2015, net revenue for Viekira Pak totals \$1.1 billion.
- November 5, 2015** The Centers for Medicare & Medicaid Services (CMS) sends a letter to state Medicaid programs expressing concerns about continuing access restrictions for HCV drugs, and encouraging states to negotiate with pharmaceutical companies. On the same day, CMS sends letters to Gilead, Johnson & Johnson, AbbVie, and Merck, seeking information about the companies' negotiating practices.

Glossary of Key Terms

AbbVie, Inc.	Markets and sells Viekira Pak™ and Technivie™.
American Association for the Study of Liver Diseases/Infectious Diseases Society of America (AASLD/IDSA)	Medical societies that have issued clinical practice guidelines and best practices for treatment of hepatitis C.
Bristol Myers-Squibb Co.	Markets and sells Daklinza™.
Cirrhosis	Cirrhosis is a condition in which the liver slowly deteriorates and is unable to function normally due to chronic, or long lasting, injury. Scar tissue replaces healthy liver tissue and partially blocks the flow of blood through the liver. The buildup of scar tissue that causes cirrhosis is usually a slow and gradual process. In the early stages of cirrhosis, the liver continues to function. However, as cirrhosis gets worse and scar tissue replaces more healthy tissue, the liver will begin to fail. Chronic liver failure, which is also called end-stage liver disease, progresses over months, years, or even decades. With end-stage liver disease, the liver can no longer perform important functions or effectively replace damaged cells.
Daklinza™ (daclatasvir)	Developed by Bristol-Meyers Squibb. Approved in July 2015 for treatment of genotype 3 in combination with Sovaldi®.
Direct-acting antiviral drugs (DAA)	DAAs act against HCV by directly inhibiting viral activities including specific enzymes such as polymerase and protease. Among the DAAs are agents which specifically target the NS5A (replication complex), NS5B (polymerase) and NS3/4A (protease).
Early virologic response (EVR)	A significant or complete decline in hepatitis C RNA levels by week 12 of treatment. Failing to achieve an EVR typically means that treatment has failed and a patient will not clear the disease.
Fibrosis	The liver can regenerate most of its own cells when they become damaged. However, if injury to the liver is too severe or long lasting, regeneration is incomplete, and the liver creates scar tissue. Scarring of the liver, also called fibrosis, may lead to cirrhosis.
Genotype	Hepatitis C is divided into distinct strains known as genotypes, which vary in geographic distribution and respond differently to treatment. Also referred to as “GT.”
Genotype 1	The most common strain of hepatitis C in the United States, accounting for roughly 70%–75% of infections.
Genotype 2	The second most common strain of hepatitis C in the United States, accounting for roughly 15%–16% of infections.
Genotype 3	The third most common strain of hepatitis C in the United States, accounting for roughly 10%–12% of infections.
Gilead Sciences, Inc.	Markets and sells Sovaldi® and Harvoni®.
Gross-to-net price	The difference between the gross—wholesale—price of a drug and the net price after deducting mandatory and supplemental discounts to government payers, in addition to discounts to private payers, and other related costs.
Harvoni® (ledipasvir/sofosbuvir)	Developed by Gilead as a fixed-dose, once daily, single tablet regimen of two agents. Approved in October 2014 for treatment of genotype 1 without interferon or ribavirin. First interferon-free therapy. Also referred to as Wave 2 and “SOF/LDV”
Incivek® (telaprevir)	Developed by Vertex. Approved in May 2011 for treatment of genotype 1 in combination with pegylated interferon-alfa and ribavirin. Was among the first two direct-acting antivirals approved to treat hepatitis C, along with Victrelis®.

Glossary of Key Terms—Continued

Interferon-alfa	The first approved therapy for hepatitis C, this injectable drug works by boosting the immune system to effectively block new cell sites to which a virus can attach. It had major drawbacks for patients because it required frequent visits to a health care provider and was often accompanied by difficult side effects. Also referred to as IFN.
Johnson & Johnson	Markets and sells Olysio™.
Merck & Co.	Marketed and sells Victrelis®.
NS5A Inhibitors	Class of drugs including ledipasvir (part of Harvoni®), ombitasvir (part of Viekira Pak™), and daclatasvir (Daklinza™), that inhibit the NS5A part of the virus that is required to create the replication complex. A unique class of antivirals that first allowed for all-oral regimens for hepatitis C.
Olysio™ (simeprevir)	Developed by Johnson & Johnson. Approved in November 2013 to treat genotype 1. The AASLD/IDSA recommended in January 2014 that it be used in combination with Sovaldi for treatment of patients not eligible for treatment with interferon. The FDA approved its use in combination with Sovaldi in November 2014.
Pegylated interferon-alfa	Interferon-alfa linked with polyethylene glycol, which prolongs its effect allowing once weekly injections. Pegylated interferon in combination with ribavirin was the standard of care for the treatment of hepatitis C for over a decade until 2014. Also referred to as PEG IFN or PEG.
Pharmasset, Inc.	Bought by Gilead in 2011, this company was the original developer of PSI-7977, the molecule that would become Sovaldi® and be component of Harvoni®.
Polymerase inhibitors	Class of drugs, including Sovaldi®, Harvoni® and Viekira Pak™ that work by disrupting the polymerase enzyme that mediates hepatitis C RNA replication.
Protease inhibitors	Class of drugs including Olysio™, Victrelis®, and Incivek®, that work by blocking the protease, which cleaves and processes viral polyproteins, an important part of hepatitis C's life cycle.
Rapid virologic response (RVR)	When hepatitis C virus is undetectable at week 4 of treatment. Reaching RVR typically signifies high likelihood that a patient has been successfully cured of the disease.
Ribavirin	An antiviral drug discovered in 1972 used for treatment of RNA viruses including hepatitis C. It was part of the standard of care until 2014 and may be a component of current DAA-based regimens. Also referred to as RBV.
Sovaldi® (sofosbuvir)	Developed clinically by Gilead. Approved in December 2013 to treat genotypes 1, 2, 3 and 4. Also referred to as PSI-7977, GS-7977, SOF, and Wave 1.
Standard of care	Treatment accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals. Also called best practice, standard medical care, and standard therapy.
Sustained virologic response (SVR)	Hepatitis C virus RNA is undetectable a set time after treatment—typically 12 or 24 weeks. Signifies that a patient has likely been cured of the disease.
Technivie™ (obmitasvir/paritaprevir/ritonavir)	Developed by AbbVie. Approved in July 2015 for treatment of genotype 4.
Treatment experienced (TE)	Patient who has received treatment for a disease.
Treatment naive (TN)	Patient who has not yet received treatment for a disease.

Glossary of Key Terms—Continued

Vertex Pharmaceuticals, Inc.	Marketed and sold Incivek®.
Victrelis™ (boceprevir)	Developed by Merck. Approved in May 2011 for treatment of genotype 1 in combination with pegylated interferon-alfa and ribavirin. Was among the first two direct-acting antivirals approved to treat hepatitis C, along with Incivek®.
Viekira Pak™ (obitasvir/ paritaprevir/ritonavir/dasabuvir)	Developed by AbbVie as a fixed-dose regimen of three agents active against HCV. Ritonavir is included as a dose-boosting agent. Approved in December 2014 for treatment of genotype 1 without interferon or ribavirin.
Warehousing	The common, though informal, practice of doctors encouraging their patients to delay treatment close to the release date of a new therapy that is expected to be more effective or less burdensome (in terms of side effects). Typically results in a surge of patients using the new therapy.
Wholesale Acquisition Cost (WAC)	The price of a drug before any discounts, deductions, or other costs.

**Letter from Senators Wyden and Grassley to John Martin,
CEO, Gilead Sciences (July 11, 2014)**

ORRIN G. HATCH, UTAH, CHAIRMAN
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 MIKE CRAPO, IDAHO
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 MICHELLE B. ENZI, WYOMING
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 CHRIS CAMPBELL, STAFF DIRECTOR
 JOSHUA SHEINKMAN, DEMOCRATIC STAFF DIRECTOR

United States Senate
 COMMITTEE ON FINANCE
 WASHINGTON, DC 20510-6200

July 11, 2014

Dr. John C. Martin,
 Chairman and Chief Executive Officer
 Gilead Sciences, Inc.
 333 Lakeside Drive
 Foster City, CA 94404

Dear Dr. Martin:

The Committee on Finance has jurisdiction of matters related to “health programs under the Social Security Act and health programs financed by a specific tax or trust fund,” as provided by Rule XXV of the Standing Rules of the Senate. These federal health care programs include Medicare and Medicaid, which together provide health care to over 100 million Americans and represent nearly \$900 billion in annual federal spending.

The Federal government is the health care industry’s largest customer, and Congress has a responsibility to conduct oversight and ensure that taxpayer dollars are used wisely in a transparent market. Gilead received federal regulatory approval last year for Sovaldi, a drug developed to treat and cure the Hepatitis C virus (HCV). The drug has been hailed as a breakthrough treatment, and its commercial release is a welcome advance in medical research for the 3.2 million Americans infected with HCV and their families.¹

Although Sovaldi has the potential to help people with HCV, at \$ 1,000 per pill, its pricing has raised serious questions about the extent to which the market for this drug is operating efficiently and rationally. While a standard course of treatment for Sovaldi has been widely reported to cost \$84,000 in the United States, Gilead will offer the drug in other countries for a fraction of the price. In Egypt, for example, Sovaldi could be offered for as low as \$900 per course of treatment—a 99 percent discount of the price in the U.S.²

The total cost of a course of this therapy also remains in question. The U.S. Food and Drug Administration dosage approval shows the price could be higher than the \$84,000 for a standard treatment. Some patients with HCV genotypes 1 and 3 will require 24 weeks of treatment.³ The longer treatment regimen roughly doubles the cost-per-patient-per-treatment to \$168,000 for Sovaldi, not including the additional cost of peg-interferon alfa and ribavirin used in combination treatments.⁴ HCV patients with liver cancer could require 48 weeks of treatment.⁵

¹Centers for Disease Control and Prevention, *Hepatitis C FAQs for the Public*, <http://www.cdc.gov/Hepatitis/C/cFAQ.htm#statistics>, accessed July 10, 2014.

²Maggie Fick and Ben Hirschler, Gilead offers Egypt new hepatitis C drug at 99 percent discount, *Reuters*, March 21, 2014, <http://www.reuters.com/article/2014/03/21/us-hepatitis-egypt-gilead-sciences-idUSBREA2K1VF20140321>, accessed July 10, 2014.

³U.S. Food & Drug Administration, *Label for Sovaldi (NDA no. 204671)*, December 6, 2013, http://www.accessdata.fda.gov/drugsatfda_docs/label/2013/204671s000lbl.pdf, accessed July 10, 2014.

⁴Leof, A., et al., (2014). *Sofosbuvir for the treatment of hepatitis C and evaluation of the 2014 American Association for the Study of Liver Diseases treatment guidelines*. Portland, OR: Center for Evidence-Based Policy, Oregon Health & Science University, p. 7–8, http://www.ohsu.edu/xd/research/centers-institutes/evidence-based-policy-center/med/upload/Sofosbuvir_for_HepatitisC_Final_5_19_2014.pdf, accessed July 10, 2014.

⁵*Supra* at note 3.

The large patient population combined with the high price of each individual treatment creates a question as to whether payors of health care, including Medicare and Medicaid, can carry such a load. Health care experts recently estimated that Sovaldi alone could increase Medicare's spending on prescription drugs by \$2 billion between 2014 and 2015 if just 25,000 patients enrolled in the program's prescription drug benefit, known as Part D, receive prescriptions.⁶ That represents "roughly 10 percent of Part D enrollees with the hepatitis C virus and about one-fourth of enrollees who have been diagnosed." If 75,000 Part D enrollees took the drug during the same period, program costs would increase by \$6.5 billion and premiums for all Part D enrollees could jump 8 percent, "a bigger increase than in any year since 2008."⁷

Sovaldi's cost also could dramatically increase the government's spending in other programs, including health care for prisoners with HCV. According to a recent survey, over 1.8 million people with hepatitis C are currently incarcerated.⁸ This represents up to 32.8 percent of the total cases of HCV in the U.S.⁹ The Federal Bureau of Prisons within the Department of Justice has already approved Sovaldi for use in treating prison populations, and it is reported that it receives a 44 percent discount.¹⁰ Even with this discount, American taxpayers could end up paying billions of dollars buying Sovaldi to treat inmates infected with HCV.

Given the impact Sovaldi's cost will have on Medicare, Medicaid and other federal spending, we need a better understanding of how your company arrived at the price for this drug. In order for a marketplace to function properly, it must be competitive, fair, and transparent. It is unclear how Gilead set the price for Sovaldi. That price appears to be higher than expected given the costs of development, and production and the steep discounts offered in other countries. An efficient market needs informed consumers to keep costs down. Consequently, we have directed our staff to investigate issues related to Sovaldi and Gilead's pricing of the drug. As part of this investigation, we are seeking information and documents related to the merger of Gilead Sciences, Inc. and Pharmasset, Inc., the original developer of Sovaldi, that was announced November 21, 2011, and the subsequent pricing of Sovaldi.

The following document requests, questions and statements use "Gilead" to refer to Gilead Sciences, Inc., its board of directors, any subsidiaries and contracted third parties; "Pharmasset" is used to refer to Pharmasset, Inc., its board of directors, any subsidiaries and contracted third parties; "Morgan Stanley" refers to Morgan Stanley & Co., LLC, and all its subsidiaries. "Barclays" refers to Barclays Bank PLC, and all its subsidiaries, including but not limited to Barclays Capital. "Bank of America Merrill Lynch" refers to Bank of America Corporation, and all its subsidiaries, including, but not limited to Merrill Lynch. Any reference to "Sovaldi", "PSI-7977" or "GS-7977" refers to sofosbuvir, a drug used in the treatment of hepatitis C virus, and any other names or codenames used to refer to said drug, its predecessor, and related formulas, compounds, research or development projects. "Supporting documents" refers to, but is not limited to, emails, faxes, notes, minutes, memoranda, reports, forecasts, transcripts, charts, spreadsheets and government forms.

Please answer the following questions and provide the following documents:

1. Please provide copies of all presentations, financial analyses, and supporting documents given to Pharmasset and/or to Gilead from 2010 to present from Morgan Stanley in its role as Pharmasset's financial advisor.¹¹
2. Please provide a copy of the fairness opinion prepared by Morgan Stanley in conjunction with Gilead's final offering price,¹² and all supporting documents

⁶Tricia Neuman, et al., The Cost Of A Cure: Medicare's Role In Treating Hepatitis C, *Health Affairs*, June 5, 2014, <http://healthaffairs.org/blog/2014/06/05/the-cost-of-a-cure-medicare-role-in-treating-hepatitis-c/>, accessed July 10, 2014.

⁷*Ibid.*

⁸Varan, A.K., et al. "Hepatitis C Seroprevalence among Prison Inmates Since 2001: Still High But Declining." *Public Health Reports*, 129, no. 2 (March/April, 2014): 187-195. (<http://www.ncbi.nlm.nih.gov/pubmed/24587554>), accessed July 10, 2014.

⁹*Ibid.*

¹⁰Peter Loftus, New Hepatitis Drugs Vex Prisons, *Wall Street Journal*, April 24, 2014, <http://online.wsj.com/news/articles/SB10001424052702304311204579510054146055222>, accessed July 10, 2014.

¹¹Pharmasset Schedule 14D-9, December 6, 2011, p. 8.

¹²*Ibid.*, p. 12-13.

related to or referencing the fairness opinion, including but not limited to assumptions about the pricing and market for PSI-7977.

3. Please provide copies of the three prospective commercialization forecasts prepared by Pharmasset's management "in and prior to September 2011"¹³ and all supporting documents.
4. Please provide copies of Pharmasset's revised forecasts (prepared before the American Association for the Study of Liver Diseases conference in November 2011)¹⁴ and all supporting documents, including but not limited to assumptions about the pricing and market for PSI-7977.
5. Please provide copies of all communications between Pharmasset's board and its senior management regarding PSI-7977 and all supporting documents, including assumptions about the pricing and market for the drug.
6. In its final annual financial filing with the Securities and Exchange Commission (SEC), Pharmasset reported that its research and development costs totaled \$176.7 million for the fiscal years ending 2009, 2010 and 2011, the period during which PSI-7977 was being developed.¹⁵ Of that total, Pharmasset attributed \$62.4 million directly to the development of PSI-7977.
 - a. Please provide an itemized accounting of Pharmasset's total research and development costs prior to the completion of the merger with Gilead on January 17, 2012.
 - b. Please provide an itemized accounting of Pharmasset's research and development costs directly attributable to the development of PSI-7977 prior to the completion of the merger with Gilead on January 17, 2012.
7. Gilead retained Barclays and Bank of America Merrill Lynch as its financial advisors for the acquisition of Pharmasset.¹⁶
 - a. Please provide copies of all communication between Barclays and Gilead relating to the valuation and acquisition of Pharmasset, including assumptions, projections, analyses, recommendations, and any related supporting documents about the pricing and market for PSI-7977.
 - b. Please provide copies of all communication between Bank of America Merrill Lynch and Gilead, relating to the valuation and acquisition of Pharmasset, including assumptions, projections, analyses, recommendations, and any related supporting documents about the pricing and market for PSI-7977.
8. Please provide all analyses, recommendations, and supporting documents related to the proposed valuation and acquisition of Pharmasset, including assumptions and projections about the price and market for PSI-7977. Please include all documents related to the following:
 - a. The September 2, 2011 meeting between Pharmasset and Gilead to discuss acquisition;
 - b. The October 7, 2011 proposal from Gilead to purchase Pharmasset for \$125 per share;
 - c. The November 17, 2011 proposal from Gilead to purchase Pharmasset for \$135 per share;
 - d. The November 20, 2011 proposal from Gilead to purchase Pharmasset for \$137 per share.
9. Please provide copies of all communications between Gilead and Pharmasset concerning the proposed valuation and acquisition of Pharmasset, including assumptions and projections about the price and market for PSI-7977. Please include all supporting documents related to the following:
 - a. The September 2, 2011 meeting between Pharmasset and Gilead to discuss acquisition;
 - b. The October 7, 2011 proposal from Gilead to purchase Pharmasset for \$125 per share;

¹³ *Ibid.*, p. 29–30.

¹⁴ *Ibid.*, p. 31–32. Referred to as the "Updated Forecast", management assumed PSI-7977 would be launched in the United States no earlier than the third quarter of 2014; that a course of treatment using PSI-7977 would be priced at \$36,000 in the United States, and that European Union pricing would be 60% to 70% of the U.S. price.

¹⁵ Pharmasset, Inc., 10-K for the fiscal year ended September 30, 2011, November 14, 2011, p. 60.

¹⁶ Gilead Sciences, Inc., and Pharmasset, Inc., *Gilead Sciences to Acquire Pharmasset, Inc., for \$11 Billion*, November 21, 2011, <http://gilead.com/news/press-releases/2011/11/gilead-sciences-to-acquire-pharmasset-inc-for-11-billion>, accessed July 10, 2014.

- c. The November 17, 2011 proposal from Gilead to purchase Pharmasset for \$135 per share;
 - d. The November 20, 2011 proposal from Gilead to purchase Pharmasset for \$137 per share.
10. Please provide copies of the analysis of the fair value of the In-Process Research and Development (IPR&D) related to GS-7977 cited in Gilead's 10-Q filed with the U.S. Securities and Exchange Commission (SEC) for the quarter ending March 31, 2012,¹⁷ and all supporting documents related to the preparation of this valuation. Identify and describe the key assumptions in the IPR&D valuation.
 11. Please provide copies of the analysis of the fair value of IPR&D related to sofosbuvir cited in Gilead's 10-K filed with the SEC for the fiscal year ending December 31, 2012,¹⁸ and all supporting documents related to the preparation of this valuation. Identify and describe the key assumptions in the IPR&D valuation.
 12. Please provide an itemized accounting of research and development costs¹⁹ related directly to the development of sofosbuvir that was incurred by Gilead after the completion of the Pharmasset merger on January 17, 2012. This accounting should include separate line items for personnel costs, clinical studies, materials and supplies, licenses and fees, milestone payments under collaboration arrangements, overhead allocations, facilities costs and the value contracts with contract research organizations (CROs) related directly to the development of sofosbuvir.
 13. Before Gilead could complete its acquisition of Pharmasset, both companies were required to file pre-merger notifications with the U.S. Federal Trade Commission (FTC).
 - a. Please provide copies of Gilead's filing with the FTC, all documents provided to the FTC pursuant to 16 C.F.R. § 803.1 and 16 C.F.R. § 803.2, all communications with the FTC related to the filing, and all supporting documents related to the filing.
 - b. Please provide copies of Pharmasset's filing with the FTC, all documents provided to the FTC pursuant to 16 C.F.R. § 803.1 and 16 C.F.R. § 803.2, all communications with the FTC related to the filing, and all supporting documents related to the filing.
 14. Please provide copies of the marketing and pricing plans prepared for, and being used in, the launch of Sovaldi in the U.S. and internationally,²⁰ including all communications and supporting documents related to the preparation of these plans, materials, and prices.
 - a. Looking forward, please describe how the commercial success of Sovaldi, as evidenced by first quarter sales, will affect marketing and pricing plans, including the cost of production, and future prices in the U.S. and internationally. If there will not be any effect, explain why.
 15. Sovaldi is currently prescribed in combination with other medications, which increases the total cost per patient per course of treatment.²¹ Gilead has applied for approval to sell single-dose combinations of Sovaldi with other drugs.
 - a. If approval is granted for a single-dose combination drug, how will it affect the future price of Sovaldi?
 - b. Please provide copies of any pricing plans, marketing plans, or price estimates related to these pending combination drugs, and all supporting documents related to the plans and related forecasts.

¹⁷ Gilead Sciences, Inc. Form 10-Q for the quarterly period ended March 31, 2012, May 4, 2012, p. 16.

¹⁸ Gilead Sciences, Inc., Form 10-K for the fiscal year ended December 31, 2012, February, 27, 2013, p. 105.

¹⁹ Gilead Sciences, Inc., Form 10-K for the fiscal year ended December 31, 2013, February 25, 2014, p. 60.

²⁰ Gilead Sciences, Inc., Form 10-Q for the quarterly period ended March 31, 2014, May 5, 2014, p. 29. Gilead's Selling, General, and Administrative expenses (SG&A) for the quarter ending March 31, 2014, "increased by \$173.8 million or 46%, compared to the same period in 2013, due primarily to a \$113.6 million increase in headcount and other expenses to support the ongoing growth and expansion of our business, which includes ongoing launches of Sovaldi in the United States and internationally as well as the anticipated launch of idelalisib."

²¹ *Supra* at note 3.

16. Please provide copies of Gilead's estimates of the U.S. treatment cost-per-patient and U.S. cost-per-cure for each of the FDA's approved genotype-based treatment regimens for Sovaldi, including itemization of the cost of Sovaldi, the cost of combination drugs, and all supporting documents used in developing such estimates.
17. Looking forward, what are Gilead's expected changes in the treatment cost-per-patient and the cost-per-cure of Sovaldi-based treatment over the next five years for each of the FDA approval regimens for the U.S. HCV populations?
18. Oregon Health & Science University researchers reviewed treatment guidelines for Sovaldi jointly issued by several professional societies, concluding there is a "substantial risk of conflict of interest influencing the recommendations from both individual panel members and funding sources."²² The organizations' website shows 18 of the 27 panel members involved in developing the guidance for the American Association for the Study of Liver Disease (AASLD) and the Infectious Diseases Society of America (IDSA) disclosed either a direct financial relationship with Gilead or received institutional funding from the company.²³ Both groups, and a third collaborating partner, the International Antiviral Society–USA (IAS–USA), have all received funding from Gilead.²⁴
 - a. Please provide an itemized accounting of all payments from 2009 to present between Gilead and/or Pharmasset and the following organizations:
 - i. AASLD
 - ii. IDSA
 - iii. IAS–USA
 - b. Please provide an itemized accounting of all payments from 2009 to present between Gilead and/or Pharmasset and the expert panel members that developed the AASLD/IDSA treatment guidelines for HCV.²⁵
 - c. For each organization or individual identified in (a) or (b), provide:
 - i. Date of payment
 - ii. Payment description
 - iii. Amount of payment
 - iv. Year-end or year-to-date payment total and cumulative total payments for each organization or individual
 - d. Describe any communications between employees of Gilead and the organizations and individuals identified in (a) and (b) regarding the AASLD/IDSA treatment guidelines for HCV. Please provide all supporting documents related to those communications.
19. Gilead's advertising and promotional expenses have increased from \$116.6 million in 2011 to \$216.2 million in 2013.²⁶
 - a. How much money does Gilead plan to spend on advertising and promotional expenses in 2014?
 - b. How much money does the company plan to spend on advertising and promotion of Sovaldi in 2014?
 - c. How much money did the company spend on advertising and promotion of Sovaldi prior to January 1, 2014?
20. Gilead has included Sovaldi in its patient assistance program, which includes coupons for reducing the cost of patient co-pays.²⁷ Gilead estimated that 30,000 patients were treated with Sovaldi during the first quarter of 2014;²⁸
 - a. How many patients have been treated in the United States with Sovaldi to date?

²² *Supra* at note 4, p. 21.

²³ AASLD/IDSA, Recommendations for Testing, Managing, and Treating Hepatitis C, Disclosure Information, http://hcvguidelines.org/disclosure_information, accessed July 10, 2014.

²⁴ See AASLD 2012 Annual Report p. 29, <http://www.aasld.org/aboutus/Documents/2012AnnualReport.pdf>, accessed July 10, 2014; IDSA Industry relations, Grants and Contributions 2010–2014, http://www.idsociety.org/IDSA_Industry_Relations, accessed on July 10, 2014; IAS–USA Cases on the Web Grant Support, <https://www.iasusa.org/cow-grant-support>, accessed on July 10, 2014.

²⁵ AASLD/IDSA, Recommendations for Testing, Managing, and Treating Hepatitis C, Disclosure Information, http://hcvguidelines.org/disclosure_information, accessed on July 10, 2014.

²⁶ *Supra* at note 19, p. 96.

²⁷ Gilead, *Support Path for Sovaldi*, <http://www.gilead.com/responsibility/us-patient-access/support%20path%20for%20sovaldi>, accessed on July 10, 2014.

²⁸ *Supra* note at note 20. p. 27.

- b. How many patients in the United States have been assisted by Gilead's patient assistance program to date?
 - c. What percentage of patients does Gilead expect to be covered under this program?
 - d. What is the average outlay-per-patient in the patient assistance program?
 - e. What percentage of the patient's cost for Sovaldi will the payment assistance program cover for each of the FDA-approved treatment regimens?
 - f. What patients are eligible for this assistance? What patients are ineligible for this assistance?
 - g. There are a number of HCV-infected populations, such as those exposed through intravenous drug use, contaminated blood and those born to someone infected with the virus. Describe the patient populations expected to be covered by the Sovaldi patient assistance program.
 - h. How are the costs of this assistance accounted for within Gilead's financials, e.g. are they deducted as part of the company's Selling, General, and Administrative (SG&A) expenses?
21. Sovaldi is and will be sold in multiple countries, many of which are expected to receive significant discounts compared to the price in the U.S.
- a. Please provide a list of all countries where Sovaldi is or will be sold, and the corresponding price or planned price for each country. Describe how the company reached the price for each country.
 - b. How are the revenue, costs and any discounts associated with international sales, such as Egypt, accounted for within Gilead's financials, e.g. are they deducted as part of the company's Selling, General, and Administrative (SG&A) expenses?

Thank you in advance for your assistance in this matter. Please begin producing documents and information on a rolling basis no later than 14 days—and complete production no later than 60 days—after the receipt of this letter. Please contact our staff as soon as possible to discuss prioritizing the order in which responsive documents and information should be produced.

Please direct any questions about this letter to David Berick, Chief Investigator, or Elizabeth Jurinka, Chief Health Policy Advisor for Chairman Wyden, and to Jason Foster, Chief Investigative Counsel, or Rodney Whitlock, Health Policy Director for Senator Grassley.

Sincerely,
 Ron Wyden,
 Chairman

Charles E. Grassley,
 Member