

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 SOC’s, the impact of expected competition on the market for HCV therapies, the increased cost for SOC’s 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.

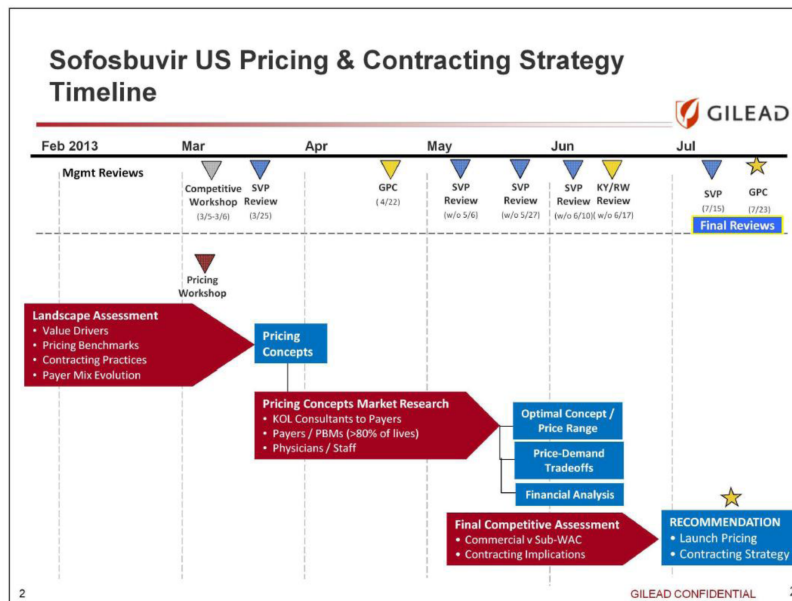
¹³⁴ *Id.* at GS-0013492—GS-0013502.

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.

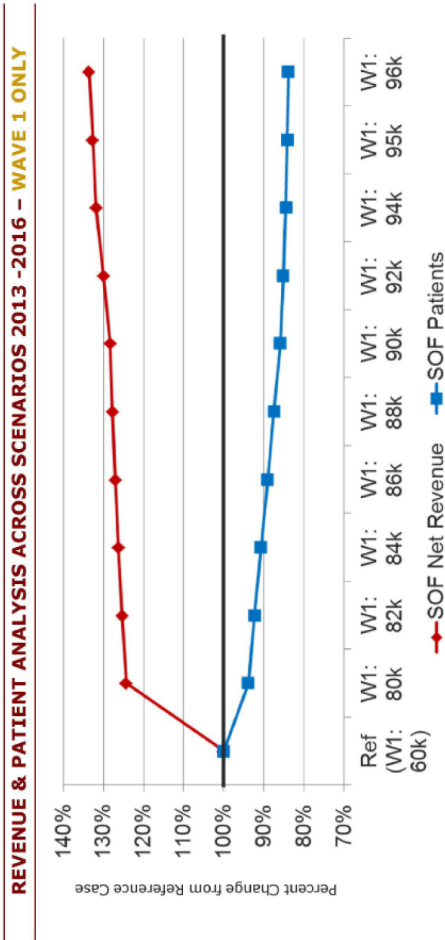
The slide presentation included analysis of the expected tradeoffs of increasing the price of Sovaldi—revenue would rise but the number of patients receiving the drug would decline. (See slide below). It also showed that Gilead was aware it was in a position to create clear savings for payers, but chose 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.*

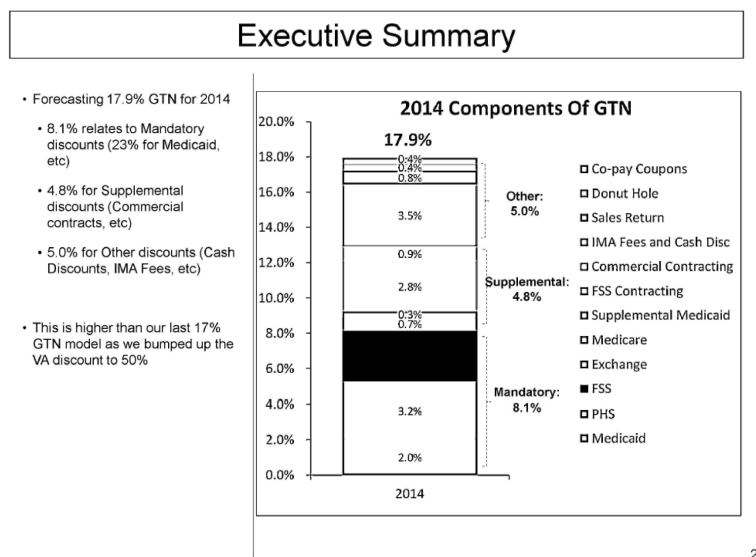
²⁹³ *Id.* at GS-0013862.

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 review. 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, 19, 26/8/14)	ASB914 FDC (G11, 19, 18, 12/14)	ASV + DCV (G11b, 1E, 24/14)

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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

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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.

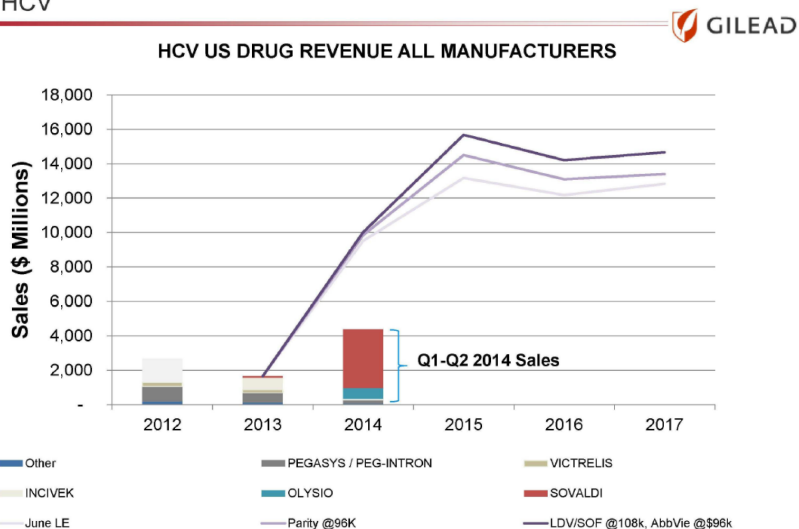
³⁴⁷ Appendix E, Ex. 49, Gilead Sciences, Inc., Updated Slides—Wave 2 Pricing, GS–0018965, at GS–0018992.

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 (\$94.5k 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%

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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

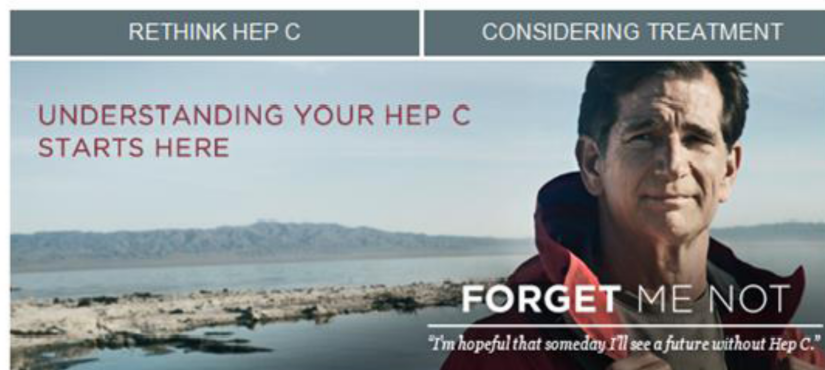
On the website, clicking "learn more about a treatment option for Hepatitis C" links to a website advertising Harvoni. According to an advertising industry website, a Gilead commercial that advertises the HepCHope phone number and website had aired at least 9,816 times as of November 18, 2015.⁴¹⁵

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

Nearly 9 out of 10 patients with genotype 1 were able to say...

I am
HEPATITIS Cured

Important Safety Information

What is the most important information I should know about SOVALDI?
SOVALDI combination therapy with ribavirin 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 ends. Talk to your doctor about forms of birth control.

If you or your partner can become pregnant, you must have a pregnancy test before starting treatment with SOVALDI combination therapy, every month while being treated, and for 6 months after your treatment ends.

Tell your healthcare provider right away if a pregnancy occurs while taking or within 6 months after you stop taking SOVALDI combination therapy. You or your healthcare provider should contact the Ribavirin Pregnancy Registry. If you are also infected with HIV and taking medicines to treat your HIV infection, an Antiretroviral Pregnancy Registry is also available. For contact information see Brief Summary of Full Prescribing Information.

You should not take SOVALDI alone. SOVALDI should be used together with ribavirin 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®, Rilteva®, Raltegravir), 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
SOFCOSBUVIR

Gilead Sciences, Inc. All rights reserved. SV0000017 01/14

*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 (ribavirin) and weekly injections (peginterferon alfa).

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.