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

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

Medicaid and Prescription Drug Purchasing

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

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

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

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

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

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

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

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

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

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

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

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

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

[453] *Id.*

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

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

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

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

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

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

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

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

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

According to NAMD, during its first year on the market, states were largely unsuccessful in securing supplemental rebates for Sovaldi. In its letter to Congress, NAMD wrote, "states are not well positioned to secure meaningful supplemental rebates for Sovaldi. . . . To date, supplemental rebates states have secured for Sovaldi are minimal, with any further concessions predicted on unrestricted access to the drug."[461] In fact, just five state Medicaid programs reported that they reached supplemental rebate agreements with Gilead for Sovaldi in 2014.[462]

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

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

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

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

[461] *Id.*

[462] *See* Appendix A.

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

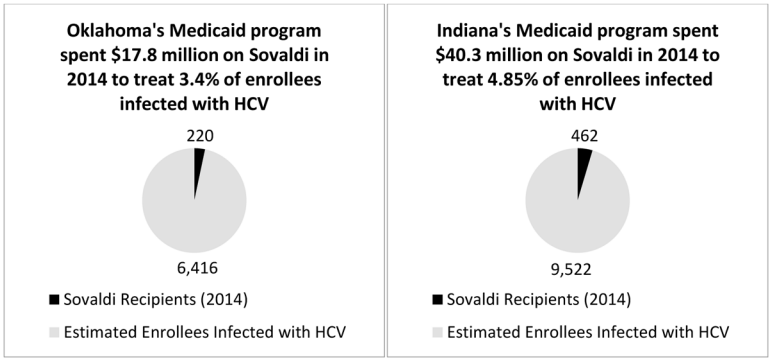
[464] Appendix D, Ex. 2, Letter from Darin J. Gordon and Thomas J. Betlach, National Association of Medicaid Directors, to Congress (Oct. 28, 2014) at 4.

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

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

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

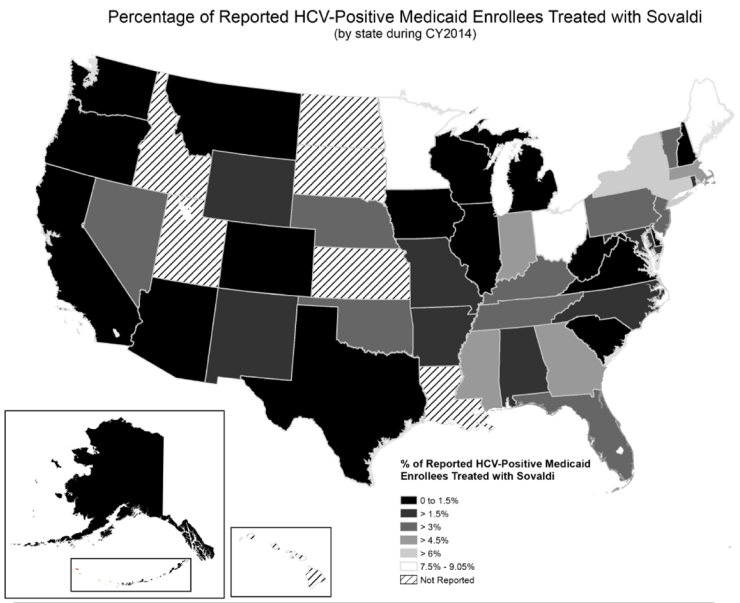
Graph 1 – HCV Spending and Percentage of Medicaid Enrollees treated in Oklahoma and Indiana (CY 2014)



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

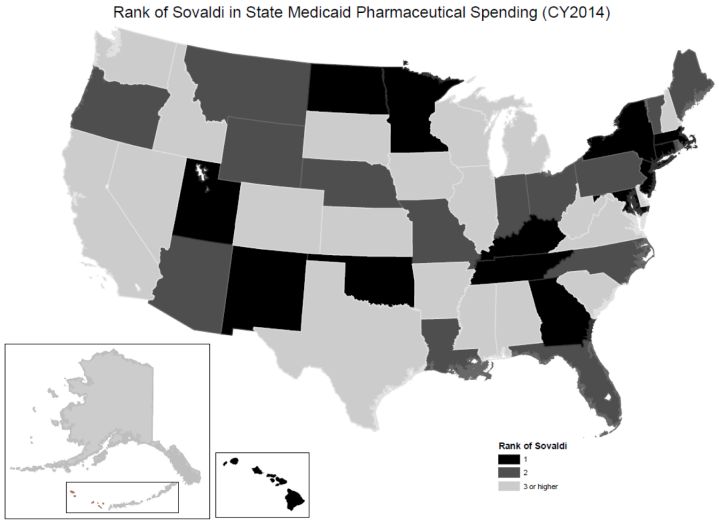
[466] The estimate of 698,000 enrollees was derived from data reported by states to staff. The actual number of Medicaid enrollees infected with HCV is likely significantly higher, because seven states did not provide estimates—Hawaii, Idaho, Louisiana, North Dakota, Ohio, South Dakota, Utah. *See* Appendix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

Map 1



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

Map 2



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

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

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

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

Investigative staff received responses from 48 state programs to the question regarding supplemental rebates, and only five reported reaching a supplemental rebate agreement with Gilead during 2014.[473] This illustrates that Gilead's supplemental rebate terms for Sovaldi were not accepted by the vast majority of state Medicaid programs. The states that reached agreement with Gilead estimated having roughly 15,000 enrollees infected with HCV, less than 2.2% of Medicaid enrollees believed to be infected with the disease.[474] As referenced above and discussed in more detail below, in the absence of acceptable rebate offers, many states reacted to the high cost of Sovaldi and Harvoni by restricting access to the sickest patients and requiring that patients be under the care of hepatologists or other specialists prior to receiving the drugs.

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

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

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

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

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

[470] Colorado, Illinois, Kansas, South Dakota. *See* Appendix A.

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

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

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

[474] *See* Appendix A.

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

- Georgia reported to investigative staff that $30.4 million was spent to treat 329 patients with Sovaldi during 2014.[476] The patients treated with Sovaldi represented less than 6% of the estimated 6,000 enrollees who have been diagnosed with HCV.[477] In an August presentation to the state legislation, the Georgia Department of Community Health reported that $40.8 million had been spent on Harvoni through the first six months of 2015 and projected that $80 million would be spent on hepatitis C drugs during FY2016 with an expectation that the budget impact would continue through FY2017.[478]
- Pennsylvania estimated that “the cost could range from $2.87 billion to $3.05 billion paid to the dispensing providers, or $1.58 billion to $1.73 billion after the federal drug rebates are collected.” [479] There are an estimated 31,000 enrollees in Pennsylvania’s Medicaid program diagnosed with HCV.[480]
- New York’s MCOs and FFS alone spent more than $363 million on Sovaldi.[481]

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

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

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

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

[477] *See* Appendix A.

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

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

[480] *See* Appendix A.

[481] *See* Appendix A.

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

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

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

Continued

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

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

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

The letter went on to say:

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

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

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

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

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

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

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

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

[487] *Id.* at 4.

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

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

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

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

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

With the assistance of the Oregon Health & Sciences University's Center for Evidenced-based Policy ("OHSU"), investigative staff examined how the PAs were structured for Sovaldi, and later, Harvoni and Viekira Pak.[491] OHSU conducted an initial survey of publicly available data on state Medicaid programs' approval of Sovaldi between May 30, 2014 and September 24, 2014.[492] Within this period—roughly six and nine months after introduction of Sovaldi, respectively—OHSU found:

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

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

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[489] Appendix D, Ex. 10, Letter from Samantha McKinley to the Honorable Charles E. Grassley and the Honorable Ron Wyden, (Oct. 21, 2015), at 2.
[490] *Id.*
[491] *See* Appendix B.
[492] *See* Appendix B, tables 1(a) and 1(b).
[493] *See* Appendix B.
[494] *Nucleotide Analog NS5B Polymerase Inhibitor (Sovaldi© -sofosbuvir) Prior Authorization Criteria, available at* https://nebraska.fhsc.com/Downloads/NEcriteria_Sovaldi-201409.pdf.
[495] Texas Medicaid/CHIP Vendor Drug Program, *Medicaid Fee-For-Service Prior Authorization Criteria and Policy (Antiviral Agents for Hepatitis C Virus)* (Mar. 2015), *available at* https://paxpress.txpa.hidinc.com/hepc_initial_request.pdf.

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

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

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

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

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

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

[496] Appendix B, tables 2(a) and 2(b).
[497] Appendix B, tables 2(a) and 2(b).
[498] Appendix D, Ex. 11, Letter from Andy Vasquez to the Honorable Ron Wyden & the Honorable Charles E. Grassley (Aug. 14, 2015), at 2.
[499] *See id.* at 3.
[500] Appendix A, table 1.
[501] Sebastian Schneeweiss et al., *The Effect of Medicare Part D Coverage on Drug Use and Cost Sharing Among Seniors Without Prior Drug Benefits,* 28 Health Affairs w305, w305–w316 (2009), *available at* http://content.healthaffairs.org/content/28/2/w305.full.

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

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

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

The plans themselves are also unique. Medicare sets a standard drug benefit design but allows for individual plans to vary the structure so long as the plan meets certain actuarial equivalence tests. Low-income beneficiaries also receive even greater cost-sharing protection than provided by the standard benefit. In 2015, the standard benefit includes a $320 deductible; coverage for 75% of drug expenses up to a benefit level of $2,960; and a catastrophic coverage for costs above a total drug spending threshold of $7,061.76.[507] Above the latter level, a beneficiary is required to pay 5% of the costs of drugs, with 95% borne by the Medicare program.[508] As a result, the higher an enrollee's annual drug spend, the greater the proportion of their costs will be paid for by Medi-

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

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

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

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

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

[507] Medpac, *Part D Payment System,* at 1–2.

[508] *Id.*

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

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

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

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

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

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

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[509] *Id.*

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

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

[512] *Id.* at 27.

[513] *Id.*

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

Sovaldi, Harvoni, and the Impact on Medicare

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

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

Data analyzed by investigative staff shows that in the 18 months since Gilead's HCV drugs gained FDA approval, Medicare spent nearly $8.2 billion on pre-rebate spending on Sovaldi and Harvoni. (See Graph 2 below, and Appendix C for corresponding tables). Part D's spending before rebates on Sovaldi in 2014 was greater than any individual drug paid for by Medicare's Part D or Part B programs during 2013 and the same can be said for pre-rebate spending Harvoni through the first six months of 2015.[517]

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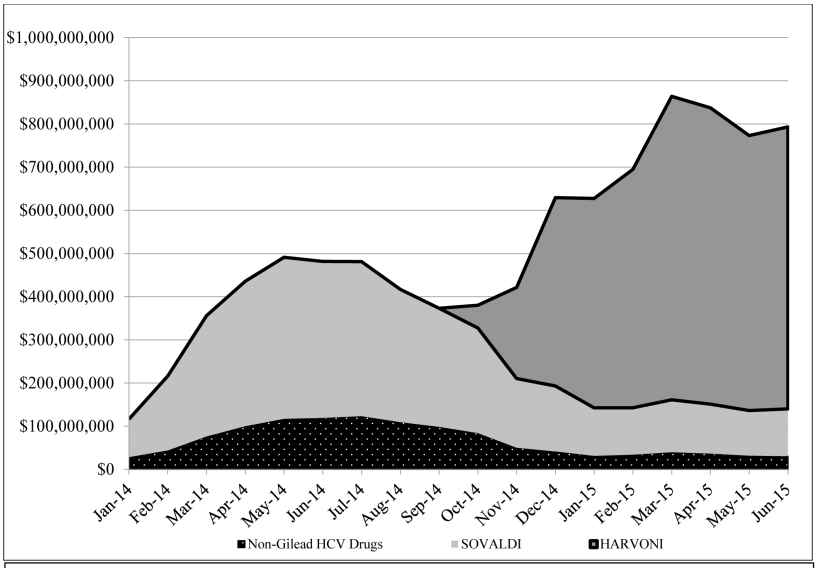
[514] The Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, *2015 Annual Report,* at 106, *available at* http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2015.pdf.

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

[516] *Id.*

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

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



Source: CMS
Notes: Harvoni was approved by the FDA on October 10, 2014; "Other" includes Olysio, Viekira Pak, Copegus, Pegasys, Pegasys Proclick, Moderiba, Intron-A w Diluent, Victrelis, Intron-A, Rebetol, Rebetron, Peg-Intron, Sylatron, Peg-Intron Redipen, Ribavirin, Virazole, Infergen, Ribatab, Ribapak, Ribasphere, Incivek, Ribasphere, and Ribapak

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

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

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

[518] *See* Appendix C.
[519] *See* Appendix C.
[520] *Id.*
[521] *Id.*

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

Sovaldi and Harvoni's Effect on the Federal Prison System

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

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

Table 4—Bureau of Prisons Spending on HCV Medications

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

Source: *Federal Bureau of Prisons*

[522] *Id.*
[523] U.S. Department of Justice, Office of the Inspector General, *The Federal Bureau of Prison's Efforts to Manage Inmate Health Care, Audit Report 08–08* (Feb. 2008), *available at* https://oig.justice.gov/reports/BOP/a0808/final.pdf.
[524] Data provided by Federal Bureau of Prisons (Nov. 12, 2015).
[525] Eric Chak et al., *Hepatitis C Virus Infection in USA: An Estimate of True Prevalence,* 31 Liver Int'l 1090, 1090–1101 (Sept. 2011), *available at* http://www.ncbi.nlm.nih.gov/pubmed/21745274; Centers for Disease Control and Prevention, *Prevention and Control of Infections with Hepatitis Viruses in Correctional Settings* (Jan. 2003), *available at,* http://www.cdc.gov/mmwr/PDF/rr/rr5201.pdf.

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

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

Source: *Federal Bureau of Prisons*

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

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

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

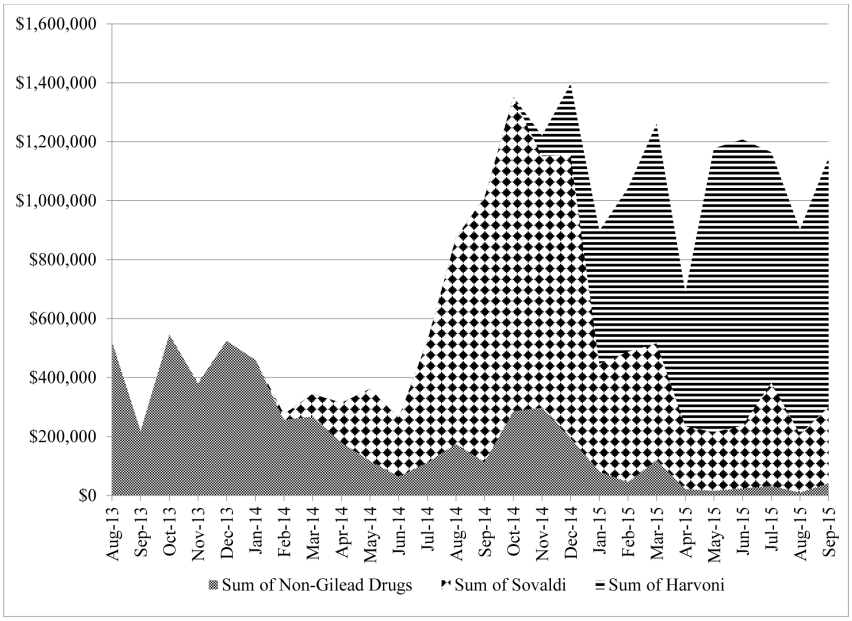
Several agencies, including the BOP, are required to maintain a Department of Veterans Affairs (VA) Schedule contract as a condition of receiving payment. The Veterans Health Care Act of 1992[528] authorizes the VA to negotiate drug prices on behalf of many government agencies, including the BOP. The VA's National

[526] Federal Bureau of Prisons, *Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection* (July 2015), *available at* https://www.bop.gov/resources/pdfs/hepatitis_c.pdf.
[527] *Id.* at 7.
[528] 38 U.S.C. § 8126.

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

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

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



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

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

Access Restrictions by Non-Public Payers

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

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

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[530] *See* Appendix B, Table 1b.
[531] *Id.*
[532] *Id.*
[533] *Id.* At the time of the survey, no publicly available criteria were found for United Health Care, another major payer.
[534] *See* Appendix D.
[535] Appendix F, Gilead Sciences, Inc., Response to Chairman Wyden/Senator Grassley letter dated July 11, 2014, narrative answer to question 20 (Sept. 9, 2014).
[536] *Id.*
[537] *Id.*
[538] *Id.*
[539] Appendix E, Ex. 40, Email from Kevin Young to Jim Meyers, Coy Stout, Re: ADAP and Sofosbuvir (Nov. 19, 2013), GS–0020802.

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

> [P]atients who are insured and who do not meet their payer's coverage criteria will no longer be eligible for support via Gilead's Patient Assistance Program. Patients who fall within the category of "Insured and Did Not Meet Payer Criteria" are patients whose insurance providers limit access to Sovaldi/Harvoni based on, but not limited to, the following:
>
> - Fibrosis score restrictions
> - Preferring or exclusively covering another product on formulary (i.e., Viekira Pak preferred)
> - Limiting coverage to a maximum treatment duration or denying subsequent treatment after a patient has failed therapy
> - Step-therapy requirements
> - Clinical criteria (e.g., psychiatric requirements, drug and alcohol testing)
>
> It is important to note that a very small number of patients fall into this category. Support Path experts will continue to treat each patient case individually and consider a number of variables when assessing patients for our free drug program.

The company justified the changes as followed:

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

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

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

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

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

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

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

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

- More than half of the states are limiting coverage to the sickest patients (i.e. F3–F4)
- Additional strict criteria including one per lifetime treatment, patient certifications, and drug/alcohol testing
- Budget concerns driving strict management through [prior authorization] requirements
- Staffing for [prior authorization] requirements has also impacted coverage decisions (i.e. IL Medi)
- Appeals require court hearings in WI, AR, IL[543]

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

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

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

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

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

[544] *Id.*

[545] *Id.* at GS–0019108.

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

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

Concerns Before and Shortly After FDA Approval

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

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

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

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

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

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

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

[549] Telephone interview with Lynda Dee (November 2014).

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

[551] *Id.*

> that it's going to be cost-effective, but that scale of what's cost-effective is I think an unreasonable way to look at it.
>
> I mean, if the price of telaprevir[552] and boceprevir[553] I think is already exorbitant. I mean, if you could price it even close to what those drugs are, I think that would be reasonable under the circumstances, and you'd still make a fortune. The volume that you're going to get for this is I think it's outstanding. . . .
>
> [T]hank you for the good work and I hope we can get this drug out to people and as many people that need it as possible.[554]

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

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

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

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

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

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

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

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

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

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

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

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

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

> We should remind you of our original warning that, even though new DAAs are a major improvement that may be cost-effective in the long run, our healthcare system lacks this particular downstream thinking. Both government and industry payer programs operate under short-term budget constraints that are incapable of absorbing the costs of Sovaldi for every patient they cover who needs access to this medication.
>
> We had hoped Gilead would be satisfied with cornering the larger volume market. By all accounts, Gilead will dominate the DAA market for years to come. This has made Sovaldi's price all the more unconscionable. Gilead is already close to recouping the Pharmasset purchase price of Sovaldi, even before the fixed-dose combination with ledipasvir is on the market. We still hope Gilead will consider a larger volume market strategy—one that will make

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[558] *Id.* at GS–0020134.

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

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

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

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

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

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

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

Controversy After the Price Was Set

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

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

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[562] *Id.*

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

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

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

> known generically as sofosbuvir, would be $28,000 for four week—or $1,000 per daily pill. That translates to $84,000 for the 12 weeks of treatment recommended for most patients, and $168,000 for the 24 weeks needed for a hard-to-treat strain of the virus. "This is unbearable to the health care system and it is completely unjustified," said Michael Weinstein, president of the AIDS Healthcare Foundation, which runs treatment clinics in the United States and abroad and has previously clashed with Gilead on the price of its drugs for H.I.V. The Initiative for Medicines, Access and Knowledge, a legal group based in New York, recently filed a motion to try to block patenting of the drug in India. If it succeeds, generic manufacturers in India will be able to manufacture cheap copies of the drug for distribution there and in some other developing countries. Gilead said the price was fair given the drug's higher cure rate and that the total cost for the 12-week regimen was "consistent with, and in some cases lower than" the cost of some other regimens for hepatitis C. It said it would offer financial assistance to some patients.[566]

Ten days later, the *Columbus Dispatch* (Ohio) reported:

> The advances come at a high cost. Sovaldi carries a wholesale-price tag of $1,000 a pill, or $84,000 for a full course. How much insurers will cover remains uncertain, as does when they'll pay for it. People can live normally with the virus and without serious liver damage. But once it starts to damage the liver—and especially after the onset of cirrhosis—treatment becomes more difficult. "People will want to get rid of hep C because it's there, but whether everybody is going to be offered treatment at this cost, we don't know," [said Dr. William M. Lee, a hepatitis C expert and clinical professor of internal medicine at Ohio State University's Wexner Medical Center.][567]

On December 30, 2013, *National Public Radio* produced a story about Sovaldi titled *"$1,000 Pill For Hepatitis C Spurs Debate Over Drug Prices,"* in which reporter Richard Knox interviewed Alton and Camilla Graham, a former Vertex executive and hepatitis C specialist at Beth Israel Deaconess Hospital in Boston:

> RICHARD KNOX: Graham, who's at Beth Israel Deaconess Hospital in Boston, notes that Gilead paid $11 billion to acquire a smaller company that developed Sovaldi. She thinks Gilead should be allowed to recoup that investment. But . . .
>
> CAMILLA GRAHAM: You only need about 150,000 people to recover that cost. And so, you know, if you're treating two million people, once you've recovered your cost, then I think—I don't want to say it's unfair, but it does start feeling more exploitative.

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[566] Andrew Pollack, *New Hope in Hepatitis As F.D.A. Allows Pill,* N.Y. Times, Dec. 7, 2013, at B1.

[567] Misti Crane, *New Drugs Close in on Hep C Cure,* Columbus Dispatch, Dec. 16, 2013, at 1A.

> RICHARD KNOX: She thinks once Gilead has recovered its investment cost, it ought to cut the price of Sovaldi.
>
> GREGG ALTON: That's very unlikely that we would do that. I appreciate that thought.
>
> RICHARD KNOX: Again, that's Gregg Alton of Gilead Sciences.
>
> GREGG ALTON: Really you need to look at the big picture. Those who are bold and go out and innovate like this and take that risk, there needs to be more of a reward on that. Otherwise it would be very difficult for people to make that investment.
>
> RICHARD KNOX: Alton says Gilead will help U.S. patients pay for Sovaldi if they can't afford it and will charge far less for a course of the drug in places such as India, Pakistan, Egypt, and China, where most people with hepatitis C live.
>
> GREGG ALTON: I don't think we'll be able to get it into the low hundreds. But I think we can get it into an affordable range for them. It'll be from the high hundreds to low thousands for these types of markets.
>
> RICHARD KNOX: It took more than 10 years before many people in developing countries got access to life-saving HIV drugs. Advocates hope it won't take anywhere near that long to start curing hepatitis C.[568]

On January 6, 2014, the pharmaceutical trade publication *FierceBiotech* wrote:

> Thomas Wei of Jefferies & Co. had initially figured that Gilead would have to hit a peak sales estimate of $4 billion to justify the cost of Sovaldi. Analysts have recently been settling in around $7 billion after calculating the returns on a pill that will cost $1,000 a day—or $84,000 for a 12-week course. But winning here has come at a cost that may be hard to calculate. Already whipped up by Gilead's steep prices on HIV drugs like the newly approved *Stribild,* some prominent nonprofits immediately took a swipe at Gilead's pricing strategy.[569]

On July 11, 2014, Gregg Alton, Gilead's Executive Vice President, Corporate and Medical Affairs, acknowledged, during an American Enterprise Institute forum, that the price of the drug had caused controversy and a "challenge" to the nation's medical system:

> A lot of what's happening here is we have a breakthrough, a quantum leap in the ability to treat Hepatitis C. We can do something today that we couldn't do last year and there's a cost associated with that. And I think that has

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[568] Richard Knox, *$1,000 Pill For Hepatitis C Spurs Debate Over Drug Prices,* National Public Radio, Morning Edition (Dec. 30, 2013) (transcript available on LexisNexis).

[569] John Carroll, *Sovaldi: Gilead Hits Pay Dirt with a Breakthrough Hep C Drug,* FierceBiotech (Jan. 6, 2014), *available at* http://www.fiercebiotech.com/special-reports/sovaldi-gilead-hits-pay-dirt-breakthrough-hep-c-drug.

challenged our system. But what I really want to say in closing is that despite all the challenges and some of the criticism that you may be hearing, and the friction, and I guess the shrill tone of the conversation, there's a positive side to this, which is we're going to cure more people of hepatitis C this year than we ever have before.[570]

Responses From Medicaid Programs to Gilead

Following the launch of Sovaldi, Medicaid programs in states across the country were wrestling with the combination of Gilead's high cost and the flood of patients who wanted to take advantage of the shorter treatment regimen.

In recent years, a growing number of states have joined "pools," in which several Medicaid programs join forces to increase their market power. There are three primary pools—National Medicaid Pooling Initiative (NMPI), Top Dollar (TOP$), and Sovereign States Drug Consortium (SSDC).[571] Both NMPI and TOP$ are administered by Provider Synergies, LLC, a subsidiary of Magellan Health Services and the SSDC is administered by the member states.

On May 11, 2014, Gilead offered three tiers of supplemental rebates to the Medicaid pools—6%, 8%, and 10%—that had been approved by the company's legal department.[572] Each tier was tied to requirements that increased patient access, i.e., the higher the discount, the more access was to be provided:

- **6% discount—Unique Position 1.** Any PA [prior authorization] criteria imposed is consistent with and no more restrictive than the FDA approved label. Additional restriction for fibrosis score (Metavir) of F2–F4 [fibrosis levels two through four] is permissible. PA criteria may require prescriptions be written by Specialists (hepatologists or gastroenterologists, for example).
- **8% discount—Unique Position 2.** Any PA criteria imposed is consistent with and no more restrictive than the FDA approved label. PA criteria may require prescriptions be written by Specialists.
- **10% discount—Unique Position 3.** Any PA criteria imposed is consistent with and no more restrictive than the FDA approved label. Any PA criteria imposed shall not require prescriptions by Specialists. Of note, Gilead has stated that they are not detailing their hepatitis portfolio to non-Specialists.[573]

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[570] American Enterprise Institute, Discussion transcript, *How Will We Pay for the Price of Cures?,* at 35 (July 11, 2014), *available at* http://www.aei.org/wp-content/uploads/2014/07/-cost-of-cures_154738513625.pdf.

[571] For more details, *see Pharmaceutical Bulk Purchasing: Multi-State and Inter-Agency Plans,* Nat'l Conf. of State Legis., http://www.ncsl.org/research/health/bulk-purchasing-of-prescription-drugs.aspx (last updated Jan. 2015).

[572] Appendix D, Ex. 17, Email from William Dozier, Senior Manager, National Accounts, Gilead Sciences, Inc., to Douglas M. Brown, Senior Director, Pharmacy Pricing & Value Based Solutions, Magellan Health Services (May 11, 2014).

[573] Appendix D, Ex. 18, Email from Douglas M. Brown, Senior Director, Pharmacy Pricing & Value Based Solutions, Magellan Health Services to Matthew D. Lennertz, Magellan Health Services (May 19, 2014). Brown told investigative staff that "not detailing their hepatitis portfolio to non-Specialists" meant that Gilead was not promoting Sovaldi to general practice doctors.

The relatively small discounts, coupled with requirements to reduce restrictions for treatment, made the rebates difficult for states to accept because of the potential budgetary impact. Magellan's Douglas Brown, who negotiated on behalf of NMPI and TOP$, made reference to the dynamic when he shared the offer with states on May 19th:

> I'm happy to have this offer in place for those states that cannot otherwise manage utilization in this category and are experiencing a sharp increase in total spend. However, I expect most states to forgo this offer and continue to actively manage this category. Our negotiations with Gilead continue, especially for those states that require fibrosis scores of F3 or greater as well as other PA criteria.[574]

Less than three weeks later on June 5, 2014, Brown gave an update to Gilead's William Dozier, a senior manager of national accounts, warning of the backlash from state Medicaid programs:

> I would say that 20 of 25 states have no interest in the offer. [Connecticut] looks to take the 10% offer. The other four are debating the offer (but not rushing their decision).[575]

Gilead officials also directly met with and received written correspondence from representatives of individual state Medicaid programs, who indicated that access restrictions would follow and that some were already occurring. The Ohio Medicaid program raised concerns about the price of Sovaldi in a teleconference with National Accounts Manager David Kaufman and National Accounts Director Justin Crum on June 26, 2014. Price concerns were again raised in an in-person meeting that included the state's Medicaid director, John McCarthy, on September 24, 2014. The second meeting included Associate Director for Government Affairs Rebecca O'Hara, Associate Director for Medical Sciences Paul Miner and outside counsel Joshua R. Sanders.[576]

In addition to his meeting with Ohio Medicaid officials, meeting minutes show that Miner was in attendance on July 8, 2014 when the Michigan Medicaid's pharmaceutical and therapeutics committee reviewed Sovaldi. Minutes show that Vanita Pindolia, the vice president, of ambulatory clinical pharmacy programs-pharmacy care management for Health Access Plan (HAP) of Michigan, spoke directly to the price of Sovaldi:

> Dr. Pindolia from HAP testified on behalf of the Michigan Association of Health Plans. She addressed the impact this medication will have on insurance premiums for both private and government programs and the review done by the Institute for Clinical and Economic Review (ICER) for California Technology Assessment Forum (CTAF). In the ICER report the cost effectiveness is addressed in terms of "cost per additional Sustained Viral Response (SVR)". Per

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[574] *Id.*

[575] Appendix D, Ex. 19, Email from Douglas M. Brown, Senior Director, Pharmacy Pricing & Value Based Solutions, Magellan Health Services, to William Dozier, Senior Manager, National Accounts, Gilead Sciences, Inc. (June 5, 2014).

[576] Appendix D, Ex. 20, Letter from John B. McCarthy, Director, Ohio Department of Medicaid, to Peter Gartrell (Aug. 7, 2015).

> ICER, if Sovaldi is reserved to patients with advanced liver disease then the cost of the drug is recouped as total healthcare savings at the 20 year mark; however if Sovaldi was used to treat all patients with positive HCV, only 66% of drug cost is recouped with total healthcare savings at 20 year.[577]

The CTAF report Pindolia cited, was issued in March 2014, concluding:

> A majority of the CTAF Panel rated the new treatments as "low value" compared with older drugs due to the magnitude of the potential impact on health care budgets of treating large numbers of patients with these high-priced drug regimens. Because the financial impact of using these new drugs to treat all eligible patients with hepatitis C is untenable, policy makers should seek avenues to achieve reductions in the effective price of these medications. Panel members and outside experts nearly all agreed that for both clinical and cost reasons, not every patient with hepatitis C needs to be immediately treated with the new drugs. Informed, shared decision-making about the timing of treatment should be encouraged. Given the circumstances, it is reasonable to consider prioritizing treatment with the new drugs for patients who need urgent treatment and have some evidence of liver fibrosis but do not have advanced liver disease.[578]

Two days later, on September 9, 2014, Janet Zachary-Elkind, deputy director of the Division of Program Development and Management and a top official from New York State's Medicaid program, sent an email to Gilead's Vice President for Government Affairs Kacy Hutchinson that included a table that quantified the impact that Sovaldi was expected to have on the state's Medicaid program.[579] The email reads:

> As you can see, if all beneficiaries with CHC were to be treated with Sovaldi, our total spend (amount paid to pharmacies) would be greater than the total annual pharmacy spend in the NY Medicaid program (~$4.5B). The second chart identifies those beneficiaries that would meet the standardized criteria that we've developed. If all beneficiaries that meet our standardized criteria were to be treated, our total spend for Sovaldi would be equal to approximately 67% of our total annual pharmacy spend. While we can't predict the total number of people that will be treated with Sovaldi, we estimate that it will be somewhere between 10 and 20% of 35,010 (the number of members identified in the second chart) for this calendar year.[580]

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[577] Meeting Minutes, Michigan Pharmacy and Therapeutics Committee (July 8, 2014), *available at* https://michigan.fhsc.com/Downloads/PTMinutes-20140708a.pdf.

[578] Institute for Clinical and Economic Review, California Technology Assessment Forum, *The Comparative Clinical Effectiveness and Value of Simeprevir and Sofosbuvir in the Treatment of Chronic Hepatitis C Infection,* at ES9 (Apr. 15, 2014), *available at* http://ctaf.org/sites/default/files/u119/CTAF_Hep_C_Apr14_final.pdf.

[579] Appendix D, Ex. 21, Email from Janet Zachary-Elkind to Kacy Hutchison (Sept. 9, 2014).

[580] *Id.*

On August 6, 2014 four company officials—Vice President for Government Affairs Kacy Hutchinson, Vice President of Managed Markets Coy Stout, National Account Director Justin Crum, and National Accounts Executive Manager Tyler Hunter—met with the Texas Health and Human Services Commission (HHSC):

> HHSC's former Executive Commissioner, Dr. Kyle Janek, expressed his displeasure with Gilead's pricing. He reminded the Gilead executives and representatives of the impact of their drug to the state budget. Given the size of the Texas Medicaid population, Dr. Janek also asked for a discounted rate. He referenced the Drug's availability at a fraction of the price in other countries and the likelihood that it would be cheaper for Texas to fly Medicaid recipients to those countries for treatment than to treat them in the U.S. Gilead executives and representatives explained that the company limited access to the drug in other countries to citizens of those countries and then defended their pricing model.[581]

The next month, Stephanie Tran, Gilead's Associate Manager for Medical Information, received a letter from the Texas Health and Human Services Commission requesting clinical data for Sovaldi and the drug that would eventually be marketed as Harvoni. The state was seeking more information as it considered clinical edits for HCV patients. "With such a significant impact on the state health care budget, there is very little room for error," Andy Vasquez, the state's director for vendor drug programs wrote.[582] ". . . [T]here is still data that would be crucial to providing the most accurate representation of cost-effective treatment, based on available clinical evidence."[583]

In addition to the August meeting and letter to Tran, company officials had seven more meetings with Texas officials between October 21, 2014 and January 16, 2015 to discuss Gilead's rebate offers for Harvoni and Sovaldi. In addition to Crum, Hunter and Stout, additional participants included Associate Director for Medical Science Michelle Puyear, Associate Director of Government Affairs Erin Smith, and Director for Government Contracts and Pricing Kimberly Hawkins.[584] In all, Texas raised concerns about pricing with at least eight different Gilead officials, yet, as cited above, the state's P&T Committee eventually designated Viekira Pak as the preferred therapy for HCV because "AbbVie submitted more aggressive rebates."[585]

During a forum in October 2014 at The Brookings Institution in Washington D.C., advocate Ryan Clary bookended criticism of access restrictions imposed by commercial insurers and state Medicaid programs with criticism about Sovaldi's price. He called for lower prices for future HCV therapies, noting that they were a contributing factor to Medicaid programs restricting access to patients.

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[581] Appendix D, Ex. 11, Letter from Andy Vasquez, Deputy Director, Vendor Drug Program, Medicaid/CHIP, Texas Health and Human Services Commission, to Hon. Ron Wyden and Hon. Charles E. Grassley at 2 (Aug. 14, 2015).
[582] *Id.*, Attachment 1.
[583] *Id.*
[584] *Id.*, Attachment 2.
[585] *Id.* at 2.

Clary, the executive director of the National Viral Hepatitis Roundtable, an advocacy sponsored by several pharmaceutical companies, including Gilead,[586] delivered his remarks while sitting next to Gilead's Chief Operating Officer, John Milligan:

> The public programs, the state Medicaids, that's a different story. These are programs who are not in the business to make a profit off of health care; they are in the business to provide health care to low income people, many in vulnerable populations, who are in a safety net program and do the best they can with strapped budgets. And they are having a real hard time providing access to Hep C treatment. They don't pay $84,000, they get significant price relief, but they are still having issues. The problem with the state Medicaids is they reacted so quickly to the P.R. campaign and the misinformation and quickly implemented really harmful—not all Medicaids, many—harmful restrictions, that are blanket restrictions, that are discriminatory particularly toward people who either currently or have recently injected drugs—and those are folks who probably would like to be cured of Hepatitis C and not be transmitting to others—so that needs to be dealt with. And as far as the price, my organization and our colleagues have been on record, the price of Sovaldi is expensive, it is too high. The rationale makes sense, but when you look at the sheer number of people who have Hepatitis C, who we know have Hepatitis C, and you look at the cost of treating everybody and curing everybody, we are not going to do it in the next couple years, we know that—time to get through that misinformation—but that's a really high cost. And we've encouraged lower prices, we're hoping that the next wave of prices—and it's not just Gilead, we have other companies coming on board—really look at the access problems we're having, understand that price does play a factor treatment access and make decisions based on that. It's a fantastic drug. This all comes from the spirit and the hope that we can cure everyone with Hepatitis C who wants to be treated. I vote for the option of treating everyone with Hepatitis C.[587]

Congress Raises Concerns

In addition to the letter sent by Senators Wyden and Grassley that began this investigation, Gilead's CEO received a letter in March 2014 from three senior members of the House Energy and Commerce Committee, Henry A. Waxman, Frank Pallone, Jr., and Diana Degette. The letter raised concern about the cost of Sovaldi, and its use with Olysio, in an attempt by providers to avoid the use of interferon:

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[586] National Viral Hepatitis Roundtable, *Sponsors, available at* http://nvhr.org/content/members/sponsors (last visited July 16, 2015).

[587] The Brookings Institution, Event, The Cost and Value of Biomedical Innovation: Implications for Health Policy (Oct. 1, 2014), *available at* http://www.brookings.edu/events/2014/10/01-cost-and-value-biomedical-innnovation-hep-c#/full-event/.

> These costs are likely to be too high for many patients, both those with public insurance and those with private insurance. Because Hepatitis C is "concentrated in low-income, minority patients," the affordability problems are likely to be particularly acute for state Medicaid programs and those patients served by these programs. Colorado and Pennsylvania have already announced that their Medicaid programs will be limiting use of the new drug to "only the sickest patients," such as those already suffering from liver disease. California's Medicaid program is still considering how and when to reimburse for the drug. The large pharmacy benefit manager Express Scripts has said it is "encouraging some doctors in its networks to delay prescribing Sovaldi." Even in cases where public or private insurers pay for the medication, it will impose substantial costs on taxpayers and could cause premium increases for those with employer or individual coverage.[588]

All told, officials from Gilead received communications from a number of policy makers, advocates, providers, and payers regarding concerns about the high price of Sovaldi and that because of the price, patients who could benefit would not receive the drug. In addition, many noted their concerns about the impact that its high price would have on public payers. While Gilead had predicted that a negative response from patients and advocacy groups was "very likely" at the price point it selected, it may have ultimately underestimated the extent of concerns. Investigative staff found that this negative response was directly communicated to Gilead from 2013 through the present.

[588] Appendix D, Ex. 22, Letter from Hon. Henry A. Waxman et al., to Dr. John C. Martin, Chief Executive Officer, Gilead Sciences, Inc. (Mar. 20, 2014).

Section 6: A Competitor Drug Enters the Market

The emergence of an effective competitor—AbbVie's Viekira Pak—altered the market for HCV drugs, as evidenced by Gilead entering into substantial discounts with some payers. However, even with Viekira Pak's entrance, some state Medicaid programs asserted that Gilead continued to draw a hard negotiating line and did not offer steep enough discounts. Thus, concerns regarding price and access restrictions remain, and regulatory agencies have taken various actions that may further affect the market for HCV drugs.

Gilead's products, Sovaldi and Harvoni, were the most widely used HCV treatments in the United States the year following FDA approval of Sovaldi in late 2013. The primary competitor to Sovaldi was Olysio, although the Johnson & Johnson drug was more frequently used as an off-label, interferon-free combination with Sovaldi than as a stand-alone treatment.[589] Following Harvoni's approval by the FDA in October 2014, use of Olysio sharply declined, most likely because Harvoni provided an interferon-free single-pill treatment for genotype 1 patients that was significantly less expensive than the Sovaldi-Olysio combination.[590] As the company prepared to release Harvoni, it was contemplating a similar contracting strategy to what it had employed for Sovaldi—a 4% supplemental discount for being listed on the preferred drug list, and generally 8% for allowing prescriptions for patients with F2–F4 fibrosis scores and 10% for allowing authorization to the FDA label (i.e., all patients).[591]

On December 19, 2014, the FDA approved Viekira Pak, manufactured by AbbVie.[592] As discussed in Section 3 of this report, Gilead had expected Viekira Pak to bring competition to genotype 1 patients, the largest segment of the U.S. HCV market. Like Harvoni, Viekira Pak can be used without interferon, and clinical trials demonstrated that Viekira Pak offered comparable cure rates to Harvoni.[593] However, unlike Harvoni, Viekira Pak is a multi-tablet regimen, rather than a single-pill treatment. CVS Pharmacy noted that a single-tablet regimen gave Gilead products the "best clinical profile," but that "there was not an appreciable clinical superiority of one product over another." [594]

Three days following Viekira Pak's approval, Express Scripts Holding Co., the nation's largest pharmacy benefit manager (PBM), announced that it would make Viekira Pak its preferred treatment

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[589] Appendix D, Ex. 23, Troyen A. Brennan et al., CVS Health Corp., Analysis of "Real World" Sovaldi® (sofosbuvir) Use and Discontinuation Rates, September 2014, at Table 1.

[590] Michelle Fay Cortez & Cynthia Koons, *Johnson & Johnson Forecasts Profit Decline on Competition,* Bloomberg (Jan. 20, 2015), *available at* http://www.bloomberg.com/news/articles/2015-01-20/johnson-johnson-earnings-beat-estimates-on-prescription-sales.

[591] Appendix E, Ex. 52, Gilead Sciences, Inc., HCV Wave 2 Contracting Recommendations, September 9, 2014, GS–0019058, at GS–0019112.

[592] Press Release, U.S. Food and Drug Administration, FDA approves Viekira Pak to treat hepatitis C, *available at* http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm427530.htm.

[593] American Association for the Study of Liver Diseases and Infections Disease Society of America, HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C: Initial Treatment of HCV Infection, *available at* http://www.hcvguidelines.org/full-report/initial-treatment-hcv-infection (last updated Aug. 7, 2015).

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

for genotype 1 and would no longer cover Sovaldi and Harvoni for these patients.[595] The deal was the result of AbbVie offering discounted pricing for Viekira Pak that exceeded discounts Gilead had offered up to that point.[596] *Reuters* reported at the time that "AbbVie narrowed the price gap to resemble what Western European countries pay for Sovaldi, which runs from $51,373 in France to $66,000 in Germany."[597]

Gilead responded in January and February by entering into discounting agreements for Harvoni and Sovaldi with CVS,[598] Anthem,[599] Humana,[600] Aetna,[601] and UnitedHealth Group.[602] Cigna[603] struck agreements with Gilead for Harvoni only. Investigative staff could not verify the discount amounts because agreements between PBMs and drug manufacturers are confidential. However, in February 2015, Gilead announced that its "gross-to-net" deductions[604] for HCV products increased from 22% in 2014 to 46% in 2015, as a result of "the recent and ongoing round of negotiations with payers and PBMs."[605] Peter Wickersham, then-senior Vice president at Prime Therapeutics, LLC, a PBM representing 26 million people, described the sudden, steep discounting as unprecedented: "Wickersham said in his 20 years in the industry he had never seen prices for a brand-name drug cat-

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[595] Caroline Humer, *Express Scripts drops Gilead hep C drugs for cheaper AbbVie rival,* Reuters (Dec. 22, 2014), *available at* http://www.reuters.com/article/2014/12/22/us-express-scripts-abbvie-hepatitisc-idUSKBN0K007620141222.

[596] *Id.*

[597] *Id.*

[598] Robert Langreth & Caroline Chen, *Gilead Makes Exclusive Deal With CVS For Hepatitis C Drugs,* Bloomberg Business (Jan. 5, 2015), *available at* http://www.bloomberg.com/news/articles/2015-01-05/gilead-makes-exclusive-deal-with-cvs-for-hepatitis-c-medicine.

[599] Robert Langreth, *Gilead Strikes Hepatitis C Deal With Anthem,* Bloomberg Business (Jan. 8, 2015), *available at* http://www.bloomberg.com/news/articles/2015-01-08/gilead-strikes-hepatitis-c-deal-with-anthem.

[600] Bob Herman, *Humana Opts For Gilead In Hepatitis C Drug Battle,* Modern Healthcare (Jan. 14, 2015), *available at* http://www.modernhealthcare.com/article/20150114/NEWS/301149943.

[601] Linda A. Johnson, *Aetna Chooses Gilead Sciences Hepatitis C Drugs Over AbbVie's,* San Jose Mercury News (Jan. 16, 2015), *available at* http://www.mercurynews.com/business/ci_27337565/aetna-chooses-gilead-sciences-hepatitis-c-drugs-over.

[602] Caroline Humer, *UnitedHealth Backs Gilead's Harvoni As Preferred Hepatitis C Treatment,* Reuters (Jan. 28, 2015), *available at* http://www.reuters.com/article/2015/01/28/us-unitedhealth-gilead-hepatitisc-idUSKBN0L12JP20150128.

[603] Press Release, Cigna Corporation, Cigna Signs Agreement With Gilead to Improve Affordability of Hepatitis C Treatment for Customers and Clients (Feb. 4, 2015), *available at* http://newsroom.cigna.com/NewsReleases/cigna-signs-agreement-with-gilead-to-improve-affordability-of-hepatitis-c-treatment-for-customers-and-clients.htm.

[604] Since filing its first Annual Report as a public company in 1996, Gilead has recognized and reported its net revenue by deducting from gross revenue three major items: "estimated product returns, cash discounts, and government programs and rebates." Gilead Sciences, Inc., Annual Report (Form 10–K) at 30 (Mar. 25, 1997), *available at* http://www.sec.gov/Archives/edgar/data/882095/0000912057-97-009728.txt. Gilead defined net product sales as sales "net of estimated mandatory and supplemental discounts to government payers, in addition to discounts to private payers, and other related costs," in its annual report for fiscal year 2014. Gilead Sciences, Inc., Annual Report (Form 10–K) at 58 (Feb. 25, 2015), *available at* http://www.sec.gov/Archives/edgar/data/882095/000088209515000008/a2014form10-k.htm. In 2013, Gilead forecast gross-to-net revenue deductions 17.9% for sofosbuvir during 2014, which included an 8.1% deduction for mandatory discounts (such as Medicaid discounts), a 4.8% deduction for supplemental discounts (such as discounts made per the terms of commercial contracts), and a 5% deduction for "Other" discounts, including IMA fees, prompt payment discounts, the Medicare "donut hole," and copay coupons. Appendix E, Ex. 36, Gilead Sciences, Inc., Sofosbuvir Pricing and Market Access Assessment, Response to Follow Up Questions (Aug. 26, 2013), GS–0013857, at GS–0013881, GS–0013883.

[605] Gilead Sciences, Inc., Fourth Quarter 2014 Gilead Sciences Earnings Conference Call, Webcast (Feb. 3, 2015), *available at* http://investors.gilead.com/phoenix.zhtml?p=irol-eventDetails&c=69964&eventID=5178585.

egory plummet so quickly after a competing drug was introduced."[606]

CVS told investigative staff that successfully negotiating with drug manufacturers typically depends on market competition, stating, "When single source drugs come to market, it is difficult to negotiate a lower cost because there is no market competition," but that "[t]he entrance of alternative drugs in a class generally increases manufacturers' willingness to negotiate with payors."[607] CVS, like Express Scripts, found that "as new drugs came on to the market like Viekira Pak, we were able to negotiate discounts."[608]

Some states also reached agreements with HCV drug manufacturers. In January 2015, Texas' Pharmaceutical and Therapeutics Committee selected Viekira Pak as the program's preferred drug, both because it viewed the drug as equally effective and "because AbbVie submitted more aggressive rebates . . . Viekira Pak was more cost effective."[609] Texas was one of 13 state Medicaid programs that OHSU researchers identified as having selected Viekira Pak as the preferred drug as of May 5, 2015. By comparison, 12 state Medicaid programs selected Harvoni as their preferred drug.[610]

Despite the benefits of competition, many state Medicaid programs remained concerned about the cost of new HCV therapies (and the resulting costs). "Through our multi-state rebate contract negotiating pool we have engaged HCV product manufacturers for various pricing level considerations. However, these efforts have been met with little to no success," Samantha McKinley, the pharmaceutical director for Kentucky's Medicaid program, wrote to Senators Wyden and Grassley on October 21, 2015.[611]

State Medicaid programs reported that obtaining suitable discounts from Gilead remained difficult even after Viekira Pak's entrance in the market. On October 2, 2015, Theodore Dallas, the Secretary of Human Services for Pennsylvania wrote that even with competition, Gilead's prices were not sufficiently reduced, and that the state has retained tight control over approving prescriptions:

> Initially, Gilead offered a very modest supplemental rebate for Sovaldi on the condition of a guarantee of unfettered access: no prior authorization, and no requirements for prescriptions to be written by, or in consultation with a medical specialist. When Gilead introduced Harvoni and AbbVie introduced Viekira Pak to the market, Gilead claimed willingness to negotiate supplemental rebates but negotiations were unproductive. Currently, Viekira Pak is designated as preferred on the [fee-for-service preferred

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[606] Robert Langreth, *Hepatitis Drug Prices Fall So Low, No Exclusives Needed*, Bloomberg Business (Jan. 12, 2015), *available at* http://www.bloomberg.com/news/articles/2015-01-12/prime-covers-both-gilead-and-abbvie-liver-drugs-as-prices-plunge.

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

[608] *Id.*

[609] Appendix D, Ex. 11, Letter from Andy Vasquez to Hon. Ron Wyden and Hon. Charles E. Grassley at 2 (Aug. 14, 2015).

[610] Appendix B, Table 2a.

[611] Appendix D, Ex. 10, Letter from Samantha McKinley to Hon. Ron Wyden and Hon. Charles E. Grassley at 2 (Oct. 21, 2015).

> drug list]; Harvoni, Sovaldi, Daklinza and Technivie are designated as non-preferred. They are covered and available when determined to be medically necessary. All of the drugs, including Viekira Pak, require prior authorization.[612]

On November 5, 2015, Andrew M. Slavitt, Acting Administrator for CMS, published a blog post concerning access, affordability, and innovation for prescription drugs in which he singled out the high cost of new, highly effective HCV drugs as an ongoing challenge.[613] Slavitt wrote:

> A recent example of a much discussed, highly-effective drug is a therapy used by Hepatitis C patients. Hepatitis C, a debilitating and life threatening infection that leads to chronic conditions of the liver, has undergone a revolutionary improvement in cure rates with innovative new medicines. These medicines are changing the lives of many individuals, but they are also expensive, costing tens of thousands of dollars, sometimes even more than one hundred thousand dollars, per patient. These costs have strained personal as well as public budgets, particularly state health care budgets. Because state budgets generally need to be balanced every year, new drug treatments can surprise states with tens or hundreds of millions of dollars in new spending. As these costs often necessarily compete with other state programs like K–12 education, transportation, law enforcement, and public health programs, some states have made tough choices, including limiting access to these therapies.[614]

However, as Slavitt also noted, states have an obligation to provide treatment. CMS simultaneously issued a notice to all state Medicaid directors specifically related to HCV drug access to reinforce the point.[615] As Slavitt explained in his post:

> Our notice to state Medicaid directors reminds states of their obligation to provide access to these promising therapies (consistent with section 1927 of the Social Security Act) based on the medical evidence, and that they have tools available to manage their costs.[616]

The Agency also sent letters to HCV drug companies, Gilead, Johnson & Johnson, Merck & Company, Inc., and AbbVie, in which Slavitt wrote:

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[612] Appendix D, Ex. 6, Letter from Theodore Dallas, Secretary, Department of Human Services, Commonwealth of Pennsylvania, to Hon. Ron Wyden and Hon. Charles E. Grassley at 3 (Oct. 2, 2015).

[613] Andrew M. Slavitt, "Prescription Drugs: Advancing Ideas to Improve Access, Affordability, and Innovation," *The CMS Blog* (Nov. 5, 2015), *available at* http://blog.cms.gov/2015/11/05/prescription-drugs-advancing-ideas-to-improve-access-affordability-and-innovation.

[614] *Id.*

[615] Department of Health and Human Services, CMS, Release No. 172, Medicaid Drug Rebate Program Notice, Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs (Nov. 5, 2015), *available at* http://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-172.pdf.

[616] Andrew M. Slavitt, "Prescription Drugs: Advancing Ideas to Improve Access, Affordability, and Innovation," *The CMS Blog* (Nov. 5, 2015), *available at* http://blog.cms.gov/2015/11/05/prescription-drugs-advancing-ideas-to-improve-access-affordability-and-innovation.

> Manufacturers also have a role to play in ensuring access and affordability. The agency believes it is important that state Medicaid agencies have access to the lowest available manufacturer prices in the market. Additionally, they should be given the opportunity to participate in discount or value-based purchasing arrangements offered by manufacturers.[617]

Additional factors may affect the U.S. market for HCV therapies. For example, as demonstrated this year by FDA safety warnings that were issued for Sovaldi and Viekira Pak. On March 24, 2015, the FDA warned "that serious slowing of the heart rate can occur when the antiarrhythmic drug amiodarone is taken together" with Harvoni or Sovaldi in combination with other direct-acting antiviral HCV drugs such as Olysio or daclatasvir.[618] The warning advised to avoid such co-prescriptions.[619] On October 22, 2015, the FDA issued a warning that Viekira Pak and Technivie (approved for treatment of genotype 4 patients) "can cause serious liver injury mostly in patients with underlying advanced liver disease."[620] The FDA required new safety warnings reflecting the risk to the drugs' labels.[621] While these warnings have not resulted in any of the drugs being pulled from the market at the time of this report, it is not known what impact they could have on practices and attitudes of patients, health care providers, and payers, which could affect competition in the market.

As such, the market for HCV therapies continues to evolve. Even as competition appears to have mitigated some of the pricing concerns discussed throughout this report, concerns about cost burden and access remain. In addition, future warnings or regulatory actions could further affect the HCV market.

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[617] Department of Health and Human Services, CMS, HCV Communication, Assuring Medicaid Beneficiaries Access to Hepatitis C (HCV) Drugs (Nov. 5, 2015), *available at* http://medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/hcv-communication.html.

[618] FDA, FDA Drug Safety Communication: FDA warns of serious slowing of the heart rate when antiarrhythmic drug amiodarone is used with hepatitis C treatments containing sofosbuvir (Harvoni) or Sovaldi in combination with another Direct Acting Antiviral drug (Mar. 24, 2015), *available at* http://www.fda.gov/Drugs/DrugSafety/ucm439484.htm.

[619] *Id.*

[620] FDA, FDA Drug Safety Communication: FDA warns of serious liver injury risk with hepatitis C treatments Viekira Pak and Technivie (Oct. 22, 2015), *available at* http://www.fda.gov/Drugs/DrugSafety/ucm468634.htm.

[621] *Id.*

Section 7: Conclusions and Questions

This report is a case study of one company's experience in bringing a breakthrough therapy to market. Although it may have implications for other companies and other products, this report focuses only on the facts and circumstances of Gilead Sciences' introduction of sofosbuvir-based HCV drugs. Given that, despite the company's assurances of cooperation, Gilead failed to produce all relevant documents and supporting materials related to pricing, the staff's analysis of pricing decisions and strategies is necessarily based only on the documents and interviews that were provided by the company and from outside sources.

Gilead acquired access to its sofosbuvir-based drugs through a multi-billion dollar acquisition and spent hundreds of millions of dollars more completing clinical trials and FDA approvals. While there were extensive discussions regarding return on those investments while Gilead was considering the acquisition of Pharmasset, there is scant evidence that return on these investments played a significant role in determining the pricing of these drugs. Similarly, the cost of manufacturing Sovaldi, which was nominal, played no part in establishing the price. In an interview, Gilead executive Jim Meyers, who played a lead part in making the pricing recommendation did not know the cost of manufacturing the drug.

During the investigation, Gilead asserted that its primary concern in developing and marketing Sovaldi was to treat the largest number of HCV patients possible. For example, Gilead claimed that it shifted the emphasis of Sovaldi's Phase 3 trials to focus more heavily on treating genotype 1 patients, which Meyers told investigative staff was done to help as many patients as possible—as many as 5 million people are infected with HCV in the U.S., of which roughly 70% are carrying genotype 1. In reality, Gilead's marketing, pricing, and contracting strategies were focused on maximizing revenue—even as the company's analysis showed a lower price would allow more people to be treated—not only for Sovaldi, but more importantly for its follow-on sofosbuvir-based product pipeline. Significantly, when confronted with the widespread initiation of access restrictions, Gilead refused to offer substantial discounts and did not significantly modify its contracting strategy to improve patient access.

A key consideration in Gilead's decision-making process to determine the ultimate price of Sovaldi was setting the price such that it would not only maximize revenue, but also prepare the market for Harvoni and its even higher price. To that end, Gilead's goal throughout its pricing decision process appears to have been to identify the price just below the level where payers would place significant restrictions on patient access. Although it knew there would be some patient loss in the $80,000 to $85,000 per standard dosage range, Gilead's internal analysis indicated that it was a viable level for the majority of payers, and would also help secure what the company later referred to as "market share leader-

ship"[622] for Harvoni as a preferred future therapy and baseline price for the next wave of HCV drugs. The response to the launch price by payers appears to have been more severe than Gilead's expectations.

While Gilead claimed in interviews with investigative staff that payers readily accepted the proposed $80,000 to $85,000 price range during its pre-marketing surveys and focus groups, not a single one of the states, payers, or pharmacy benefits managers interviewed by staff investigators told us that it communicated assent in such surveys, nor did its organization. To the contrary, several experts and entities privately and publicly warned Gilead about the consequences of excessive pricing before introduction.

Even though Gilead assumed that the final price recommendation of $84,000 would not result in significant patient access restrictions, it quickly became apparent that this assumption was incorrect as many public and private payers quickly reacted and adopted restrictions. Ultimately, these restrictions reduced the number of patients who could have received treatment.

When presented with these access restrictions and pleas by both public and private payers for supplemental rebates or discounts to reduce the cost of HCV treatment for their respective patient populations, Gilead offered supplemental rebates and discounts of minimal value (on the order of 10% if all restrictions were lifted for Medicaid, for example). Only a handful of payers accepted these additional reductions. When payers proposed additional discounts, Gilead rejected them.

When launching Harvoni, Gilead essentially executed the same revenue maximizing methodology that it used for Sovaldi, even though it was aware that such an approach could cause similar access challenges. Gilead always intended to extract a premium for this follow-on, all oral drug. Its acquisition advisor, during the run-up to Gilead's purchase of Pharmasset, called it a "convenience bump." By elevating the price for the new standard of care set by Sovaldi, Gilead intended to raise the price floor for all future HCV treatments, including its follow-on drugs and those of its competitors. Its expectations were confirmed when AbbVie entered the market with its multi-drug, all oral Viekira Pak for genotype 1 at a base treatment price of $83,319, marginally below Gilead's prices. Gilead was able to maintain pricing power until Express Scripts, a major pharmacy benefits manager, entered into an agreement with AbbVie to make Viekira Pak its preferred genotype 1 HCV drug. Gilead quickly entered into its own agreements with other major benefits managers and payers including CVS Caremark and Anthem with what appear to have been substantial discounts. Industry sources have estimated these discounts to be on the order of 40% from the list price, although due to their confidential nature, those discounts have not been confirmed.

[622] Appendix E, Ex. 45, Gilead Sciences, Inc., 2015–2016 HCV Commercial Plan (Apr. 22, 2014), GS–0014083, at GS–0014085.

Potential Areas for Committee Consideration

The evidence collected for this report presents the Senate Finance Committee with a warning for critical policy areas under its jurisdiction. The federal government has responsibility for billions of dollars in payments for pharmaceuticals through the Medicare and Medicaid programs. However the federal government is not the direct payer for either. In Medicare, payments for pharmaceuticals are made through prescription drug plans sponsors. In Medicaid, each state program is responsible for payments, with the federal government reimbursing a state-specific percentage, or "match." The Finance Committee is responsible for policies that govern these programs and the intermediaries making payments on behalf of the federal government.

The narrative in the case of Sovaldi is fairly straightforward: Pharmasset developed the drug that ultimately became known as Sovaldi. Gilead purchased Pharmasset and shepherded Sovaldi through the completion of the FDA approval process. Gilead engaged in a complex process in determining the price of Sovaldi, ultimately settling on a price that underestimated the reaction from both private and public payers. When the payer community reacted negatively to the price of Sovaldi during its initial period of monopoly pricing power, Gilead provided only limited price flexibility, which led to implementation of widespread treatment restrictions that limited access to the sickest patients. Roughly a year later, AbbVie received approval for its drug, Viekira Pak, and competition through third parties—Express Scripts and CVS Caremark—immediately extracted rebates and discounts from the previously set list prices of both products.

One could argue that the system "worked," in that a new entrant into the market impacted the negotiated cost of the "first to market," or breakthrough, drug. In other words, competition worked to lower the cost of pharmaceuticals. Gilead's ability to set and hold the price for Sovaldi at a point that clearly caused stress to the payer community lessened with the entrance of a competitor. However, even as competition lowered prices for therapies, this report documents that concerns remain, particularly in the public payer community, about high costs for treating millions of people in the U.S. infected with HCV.

There is no question that Viekira Pak's entrance into the market changed the status quo. It is true that aspects of the system worked, in this case, because AbbVie came to the market with a competitor drug roughly a year after Sovaldi's release. However, only looking at that one event in a vacuum ignores the impact of the efforts that Gilead had undertaken to change the HCV market as a whole.

Sovaldi was a significant breakthrough for those diagnosed with HCV. However, comparing the drug with the previous standard of care is like comparing apples to oranges. At the most basic level, patients' ability to tolerate it meant that more patients could take it. This dramatic increase in market size and resulting revenue to Gilead was anticipated by the company. However, when payers attempted to extract rebates or discounts to ease cost concerns given the higher numbers of patients being treated, Gilead rebuffed those

efforts. The result was that patients who could benefit from these drugs did not receive them due to the high cost. Those patient populations remain at risk and will, for the most part, still require treatment in the future.

Accordingly, the public and private payer community continue to face a higher cost for the prevailing (new) standard of care, and higher overall costs because the new generation of HCV drugs is better tolerated and will most likely be far more widely prescribed.

Understanding the significance of AbbVie's entrance into the market is critical. If no other company had developed a breakthrough competitor with similar clinical results, Gilead's de facto control of the market could have lasted much longer. The average time between a single source innovator entering the market and a generic manufacturer producing its equivalent product and bringing it to market is 12.6 years.[623] Without successful competition, the costs to the public and private payers could have caused much more significant disruptions and access restrictions for years.

While it is premature to make specific legislative recommendations, several specific questions warrant public discussion:

1) What are the effects of a breakthrough, single source innovator drug on the marketplace?

Among other things, this report reflects the reality that federal health care programs—notably Medicare and Medicaid—have little to no policy levers at their disposal to significantly impact the price of a single source innovator drug. This report found that not until reasonable competition entered the marketplace did Gilead's pricing incentives and behavior change. Not all expensive innovator drugs face competition so soon after launch, and thus the next expensive innovator drug could potentially create significant budgetary pressures for federal payers and lead to access restrictions for an extended timeframe. In light of Gilead's abrupt change in behavior when faced with competition, what policy levers are available to increase competition with a single source innovator or otherwise ensure single source breakthrough drugs are available to those who would benefit clinically?

2) Do the payers in the programs have adequate information to know the cost, patient volume, and increases in efficacy of a new treatment regimen?

With respect to Sovaldi, cost drove much of the negative reaction to the introduction of the drug. Gilead argued that the price point for Sovaldi was less than that of the total cost associated with the previous treatment regime. The payers argued that the cost of Sovaldi was greater than any single treatment previously considered for HCV. What is clear is that payers were caught off guard by the price of the treatment regimen, especially when Sovaldi was used in combination with Olysio, driving the cost of treatment to approximately $150,000.

With respect to volume, HCV impacts millions of Americans, the full count of which is unknown. In the case of Sovaldi, payers were

[623] Henry Grabowski et al., *Recent Trends in Brand-Name and Generic Drug Competition,* 17 J. Med. Econ. 207, 207–14 (Dec. 10, 2013), *available at* http://informahealthcare.com/doi/abs/10.3111/13696998.2013.873723.

overwhelmed by the cost of the drug in conjunction with the volume of patients now eligible for treatment. The volume was further driven by patients being warehoused in anticipation of new drugs, as well as aggressive marketing by Gilead and other manufacturers. Again, payers clearly did not anticipate the demand for Sovaldi, and it is possible Gilead itself was caught off-guard. However, if the latter is true, the company decidedly did not take action to self-correct, and instead remained committed to securing its original price from public and private payers alike, regardless of volume.

While the Committee does not have jurisdiction over the approval process of drugs, the Committee's role as a significant payer cannot be ignored. If the payers do not have the opportunity to know what is coming and react accordingly with their plans and pricing, that is a problem. The Committee should explore ways to provide greater transparency in this area.

3) What role does the concept of "value" play in this debate, and how should an innovative therapy's value be represented in its price?

The Committee should consider that cost, patient volume, and increases in efficacy ultimately speak to the concept of value. The Committee has worked exhaustively to inject the concept of value into the reimbursement regimes in Medicare. While the Committee has worked with value-based purchasing largely in Medicare Parts A and B, the Committee should turn its attention to ensuring that the program is getting value for the spending in Part D. The Congressional Budget Office has already shown that spending increases for Part D can lead to decreases in Parts A and B spending. But in the future, the Committee will also have to consider whether the payers in Medicare and Medicaid are doing enough to ensure that innovative drugs produce additional value that supports their additional expense.

4) What measures might improve price transparency for new higher-cost therapies while maintaining incentives for manufacturers to invest in new drug development?

The Committee should explore the degree to which transparency could put downward pressure on pricing without exposing confidential, proprietary information about a new drug's scientific development. When confronted by dramatically higher costs, many payers restricted access. The Committee should examine ways to support manufacturers that direct their efforts toward expanding access to their cures.

The process which a payer of health care services, whether it be an employer or the federal government, must go through to determine the exact price it will pay for pharmaceuticals is long, complicated, and often opaque. While most drug manufacturers publicly announce the "price" of their drugs, the actual amount paid by individual payers is kept secret for a variety of potentially legitimate reasons. However, there are reasons to believe that increased transparency in actual prices paid would better inform the public as well as help policy makers make more informed decisions. On the latter point, the public may be surprised to learn that members

of Congress are forbidden by law[624] to have access to information regarding price discounts and rebates agreed to by drug manufacturers as part of the Medicare and Medicaid programs. Congress and payers alike need more complete information on the ultimate prices paid.

5) What tools exist, or should exist, to address the impact of high cost drugs and corresponding access restrictions, particularly on low-income populations and state Medicaid programs?

The data contained in this report provides estimates of the number of Medicaid enrollees infected with HCV, the number of enrollees who received treatment, and the cost of that treatment to taxpayers. More often than not, states responded to the high need for—and high cost of—HCV treatments by imposing access restrictions leading to a fraction of the infected population actually receiving treatment. In addition, as shown in the report, this high cost, high need situation is expected to continue to strain state Medicaid budgets and affect decision-making around access. The Committee should explore the tools that states and the federal government can employ, or should be able to employ, to appropriately manage their patient populations, ensure timely access to medically necessary treatments, and address the financial constraints of new cures that enter the market.

[624] 42 U.S.C. § 1396r–8(b)(3)(D).