Appendix D

Exhibit 1

From: Jenkins, Ann **Redacted**
Sent: Monday, March 09, 2015 2:07 PM
To: Gartrell, Peter (Finance)
Subject: Q&A

Peter,

Attached is the Q&A. Please let me know that you received it. Thank you.

Ann Walker-Jenkins
Director, Federal Government Affairs

Redacted

CVS Health

Redacted

CVSHealth

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We are pleased to answer your inquiries regarding some of the internal and external developments related to Gilead, AbbVie and Johnson & Johnson (the "Pharmaceutical Manufacturers") relative to their Hepatitis C (HCV) product offerings. Our desire is to be as open and transparent as possible. Having said that, as you would expect, we have stringent confidentiality obligations in our agreements with the Pharmaceutical Manufacturers to protect our respective proprietary information. As a result, some of the details you have requested we cannot provide.

Question 1: Please describe any negotiations or communications your company had regarding HCV drugs with Gilead, AbbVie, or Johnson & Johnson. When did these communications, meetings or negotiations take place? Any dates, emails or presentations that can substantiate those discussions would be helpful. How did the entrance of a competitor (or at least alternative drugs within the class) change the pharmaceutical makers' behavior?

Answer 1: Consistent with our standard approach to negotiating formulary rebates with manufacturers, we undertook an iterative RFP process which asked each manufacturer to submit competitive financial bids. Our evaluation of those bids was based on many factors including, among other things:

- Clinical considerations
- Acquisition cost of the product
- Net client cost for all Hepatitis C treatments
- Expected current and future distribution of patients between genotypes
- Market share of each product
- Expected average duration of therapy for the various agents
- Factors contributing to medication adherence
- Ability to further control cost through additional utilization management measures

The process began, and typically does begin, in anticipation of the introduction of the products as we seek to obtain additional value.

The entrance of alternative drugs in a class generally increases manufacturers' willingness to negotiate with payors, including PBMs. The degree of clinical differentiation of the products also typically impacts the manufacturers' willingness to negotiate. In this instance, based on the information available to us, our clinical evaluation of the products indicated that there was not material clinical superiority of one product over another. Prior to finalizing our selections, our recommendations were approved by both our internal clinical team and our external Pharmacy and Therapeutics Committee.

Question 2: What discount did Gilead initially offer CVS for Sovaldi and Harvoni? Have those discounts changes over the course of time?

Question 3: What discounts did Abbvie offer CVS for Viekira Pak?

Question 4: What discounts did Johnson & Johnson offer for Olysio?

Answers 2, 3, and 4: Discounts originally offered by each manufacturer were minimal. As the competitive landscape changed, the offered discounts increased. Our negotiations with and the terms offered to us by each manufacturer remain subject to non disclosure agreements and confidentiality obligations. That said, while a critically important component of our evaluation, discounts cannot be considered in isolation and a thorough evaluation must include those factors identified above in addition to the proposed discounts.

Question 5: What was the price point your company was seeking that allowed it to expand coverage of Sovaldi? What was the rationale behind the price point? Is this the same for other HCV drugs?

Answer 5: We negotiated the lowest price point for each product that we were able to achieve based upon the competitive process.

Question 6: Was the decision to grant Gilead's HCV drugs primarily financial? How did clinical information or differences influence choosing one drug over another?

Prior to negotiating on financial terms, we evaluated the clinical information and comparability for each product. Our clinical team, which includes experienced clinical pharmacists, prepared a therapeutic class review following a comprehensive review of available clinical literature. Numerous references and information resources were used to assist in evaluation and review of the medications under consideration for formulary addition. Although we believed that the Gilead products have the best clinical profile (in that it is administered once per day rather than twice, for example), our clinical evaluation indicated that there was not an appreciable clinical superiority of one product over another. As a result of these clinical considerations, cost was a significant factor in our formulary decisions. In addition, our recommendations were approved by an external Pharmacy and Therapeutics Committee after its review of the clinical information. This Committee is an external advisory body of experts from across the United States, composed of 19 independent health care professionals including 16 physicians and 3 pharmacists, all of whom have broad clinical backgrounds and/or academic expertise regarding prescription drugs. A majority of the CVS/caremark National P&T Committee members are actively practicing pharmacists and physicians.

Question 7: Is there a difference between the wholesale prices for Gilead's HCV drugs versus the pharmacy mark-up?

Answer 7: Yes, there is always a difference between wholesale prices and pharmacy mark up.

Question 8: What is the price of treating patients with Sovaldi compared with the cost of the prior treatment cocktail?

Answer 8: It is very difficult to compare the overall cost of the prior treatments to Sovaldi because of the longer course of treatment and relative effectiveness of the new products.

Question 9: There are several different lengths of treatment for Gilead's various HCV drugs, e.g. 8, 12, 24 and 48 weeks. Please provide data about the length (and corresponding cost) of treatment for different time periods of drug usage?

The American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) have recently provided updated Hepatitis C Virus (HCV) treatment guidelines with recommended durations for the various treatments. These durations of treatment range from 8 to 48 weeks based on the HCV genotype (1- 6), the patient's HCV viral load, the patient's level of liver fibrosis, and the patient's other co-morbid diseases. The AASLD/IDSA guidelines indicate that the most common treatment regimen would be the 12-week treatment regimen followed by the 24 week treatment regimen with much lower use of either the 8 week or 48 week treatment regimens. Although very early in the utilization of these very new drugs, CVS/caremark has seen utilization of consistent with the AASLD/IDSA guidelines.

Both Harvoni (ledipasvir/sofosbuvir) and Viekira Pak (paritaprevar/ritonavir/ombitasvir/dasbuvir) are indicated by the United States Food and Drug Administration (FDA) for the treatment of HCV genotype 1 patients or the most common HCV genotype.

<u>HCV genotype 1:</u>

1. Harvoni treatment durations range from an 8-week regimen (in treatment-naïve patients without fibrosis who have a very low viral load) to a 12-week regimen (in treatment-naïve and treatment-experienced patients without fibrosis) and a 24-week regimen for patients with fibrosis.
2. Viekira Pak treatment durations range from a 12-week regimen (in patients with genotype 1a and genotype 1b without cirrhosis) to a 24-week regimen (in patients with genotype 1b with cirrhosis).

HCV genotypes 2-6:

1. A 12-week regimen of Sovaldi (sofosbuvir) and ribavirin therapy is recommended in patients with genotypes 2 and 5.
3. A 24-week regimen of Sovaldi and ribavirin is recommended in patients with genotype 3.
4. A 12-week regimen of either Harvoni or Viekira Pak are recommended in patients with genotype 4 by the AASLD/IDSA guidelines.
5. A 12-week regimen of Harvoni is indicated for patients with genotype 6 by the AASLD/IDSA guidelines.

Lastly, a 48-week treatment regimen is recommended in rare circumstances (in patients who have a history of prior treatment with older HCV treatment regimens or patients with decompensated cirrhosis or hepatocellular carcinoma who are awaiting liver transplantation).

American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (ISDA). December 19, 2014. http://www.hcvguidelines.org/full-report

Question 10: Many payors have discussed the difference between clinical results and "real world" results of Sovaldi and other HCV drugs. Does CVS have any such data for Sovaldi, Harvoni and/or Viekira Pak?

Answer 10: Yes, following is a summary of an analysis we have done on this topic.

Analysis of "Real World" Sovaldi® (sofosbuvir) Use and Discontinuation Rates

Sovaldi was approved in December 2013 and was felt to be a clinical breakthrough as, in clinical trials, it provided a sustained viral response in 95% percent of patients with Hepatitis C, essentially a cure. This compared with the 40 - 50 percent cure rate observed with prior interferon-based therapies and up to a 70 percent cure rate with protease-inhibitor (Victrelis and Incivek) based regimens(1).

Beginning in December 2013, when Sovaldi first became available, there was rapid uptake in the use of the medication, with increasing numbers of patients beginning treatment each month (Fig 1). This was followed by a plateau and then a downward trend* in patients starting treatment with Sovaldi during May – August 2014 as evidenced in CVS Health data (Fig 1). In the nine months following release, 16,560 patients with pharmacy benefits through CVS/Caremark filled prescriptions for the medicine; 65% were for all-oral, interferon-free regimens.

Adherence with Sovaldi regimens treatment was noted to be greater than 90 percent, but was lower than that observed in clinical trials. As noted from an analysis of 1,965 patients who filled Sovaldi regimens in CVS/pharmacy retail locations or CVS/caremark specialty pharmacies, the average discontinuation rate was 8.1 percent compared with 2.0% - 3.6% noted in clinical trials. However, these discontinuation rates were lower than for patients who filled in non-CVS Health-related outlets; discontinuation rate at CVS/Caremark specialty pharmacy was 5.9% compared with 8.5% at non-CVS/Caremark specialty pharmacy**

[*Downward trend may have been due to warehousing of patients given the pending approval of Harvoni and Viekira pak (not due to a lack of coverage)

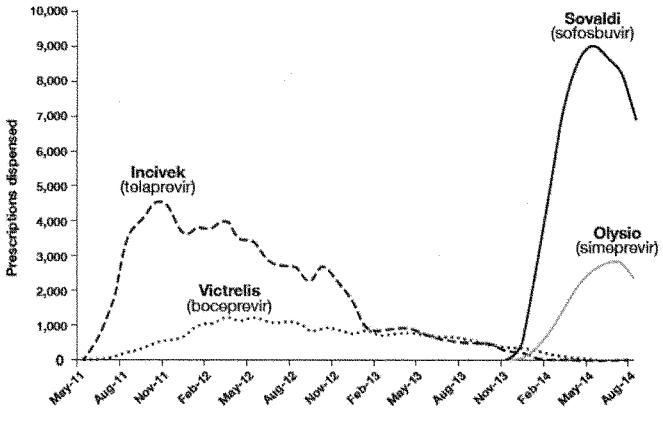
Harvoni Utilization in the Weeks after Launch

The uptake of Harvoni after its launch has been swift and approximately 2.5 times as rapid as that of Sovaldi prescribing after its launch. In the first eight weeks after launch, 7553 prescriptions for Harvoni had been dispensed to CVS/Caremark members compared with 3063 prescriptions of Sovaldi in the first eight weeks after the its launch the previous year (Fig 2).

Following the launch, within eight weeks, the contemporaneous use of Harvoni surpassed that of Sovaldi and weekly prescriptions for Sovaldi started to decrease (Fig 3).

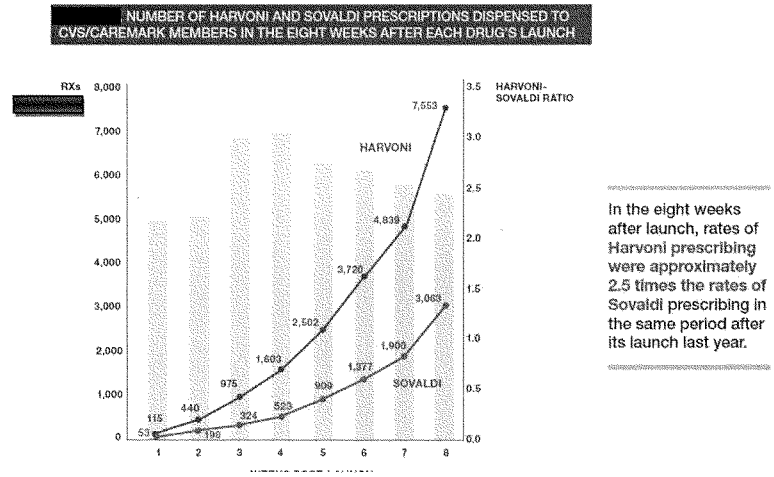
Harvoni use has been noted across all market segments - commercial clients (i.e., employers and health plans) as well as Medicare and Medicaid.

Figure 1: Utilization Trends of Hepatitis C Treatments (May 2011 – Aug 2014)



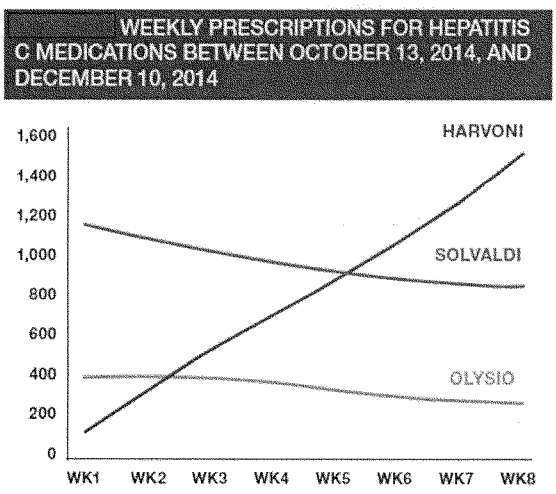
Source: Analysis of "Real World" Sovaldi® (sofosbuvir) Use and Discontinuation Rates
September 2014: Troyen A. Brennan, M.D., Chief Medical Officer, CVS Health; Alan Lotvin, M D., Executive Vice President, CVS/specialty, CVS Health; William Shrank, M.D., Chief Scientific Officer, CVS Health

Fig. 2



Source: Harvoni® Utilization in the Weeks after Launch: Patterns and Implications: Alan Lotvin M.D., Will Shrank M.D. M.S.H.S., Andrew Chang M.P.H, Lora Armstrong Pharm.D., Troyen Brennan M.D., J.D.

Fig. 3

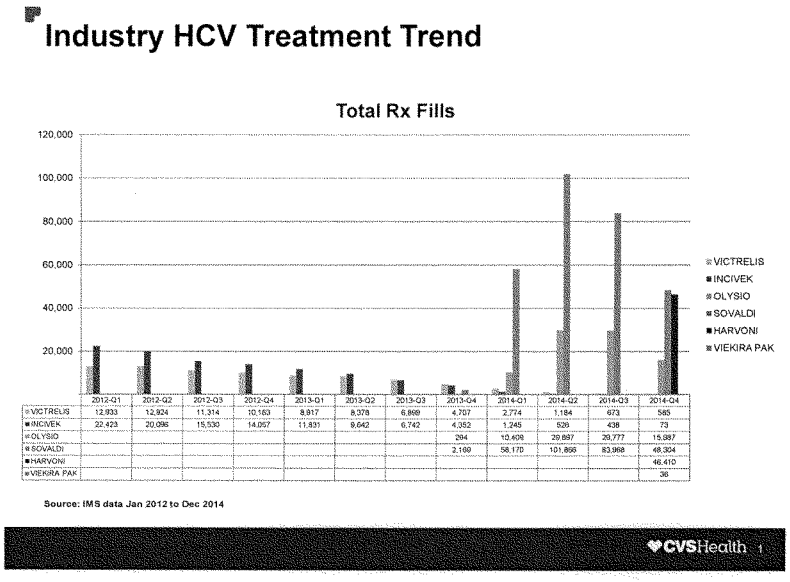


Source: Harvoni® Utilization in the Weeks after Launch: Patterns and Implications: Alan Lotvin M.D., Will Shrank M.D. M.S.H.S., Andrew Chang M.P.H, Lora Armstrong Pharm.D., Troyen Brennan M.D., J.D.

Ref 1: Ghany M, Nelson D, Strader D, et al. AASLD Practice Guideline. An update on treatment of genotype 1 chronic hepatitis C virus infection: 2011 practice guideline by the American Association for the Study of Liver Disease. Hepatology 2011; 54:1433–1444.

Question 11: How does the rate of prescriptions for the drugs that were the standard of care for HCV compare to the rates of prescriptions for the new SOCs starting with Sovaldi?

Answer 11: There has been a dramatic increase in the volume of prescriptions for the newer HCV standard of care medications as compared with prior treatments. The following graph illustrates the volume of prescriptions for earlier treatments, Victrelis and Incivek, as compared with newer treatments, Sovaldi, Olysio, Harvoni and Viekira Pak.



Question 12: Please describe CVS's plans for Part D coverage restrictions in 2015 for HCV drugs. How, if at all, will it differ from the coverage in 2014?

Answer 12: In 2014 we included Incivik and Victarlis on our Medicare Part D formulary and added Sovaldi in June during the 180 review period allowed by CMS for new products. In October 2014, Harvoni was approved by the FDA and in December, Viekira was approved. In early January 2015 we selected one of these new combination drugs to be added to our formulary, which allows us to provide coverage across all genotypes, and expanded the number of options available as compared to our 2014 formulary.

Question 13: To the extent that CVS has Medicaid managed care plans, please describe CVS's plans for state coverage criteria in 2015. How, if at all, will it differ from the coverage in 2014?

Answer 13: We provide support for each of our Medicaid clients to help our clients determine specific coverage criteria for their populations that are consistent with the requirements of the states in which they operate. Although the coverage criteria may impact the availability of formulary rebates, these decisions rest with the plans.

Question 14: Broadly speaking, what are/were the consequences of having a drug priced as high as Sovaldi when it was initially put on the market? How would you address the issues raised by the cost to the health system?

Answer 14: PBMs are skilled at helping its plan sponsors and health care providers manage patient care and lower overall drug costs. They provide services to support patients to help them stay adherent to their medication regimens, for example. The way to lower drug costs is to ensure the drugs are managed by a PBM who understands the clinical tools and competitive marketplace issues to drive to the solution—high quality care at a lower cost. When single source drugs come to market, it is difficult to negotiate a lower cost because there is no market competition. With Sovaldi, ultimately as new drugs came on the market like Viekira Pak, we were able to negotiate discounts and get people the drugs they need at a lower cost.

Question 15: How has Sovaldi been utilized in correlation with Olysio?

Answer 15: The use of Sovaldi with Olysio is an accepted treatment combination with supporting clinical trial results and recommendation in the American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (ISDA) guidelines. This combination use received an FDA indication in 2014 as well. Prior to approval of Harvoni and Viekira Pak, the combination of Sovaldi and Olysio was the only available treatment for patients that could not tolerate interferon. Since the approval of Harvoni and Viekira Pak, the use of Sovaldi with Olysio has slowed and is expected to be used infrequently.

Exhibit 2

NAMD
National Association of Medicaid Directors

October 28, 2014

The Honorable Ron Wyden
Chairman
Senate Committee on Finance

The Honorable Orrin Hatch
Ranking Member
Senate Committee on Finance

The Honorable Tom Harkin
Chairman
Senate Committee on Health, Education, Labor and Pensions

The Honorable Lamar Alexander
Ranking Member
Senate Committee on Health, Education, Labor and Pensions

The Honorable Fred Upton
Chairman
House Committee on Energy and Commerce

The Honorable Henry Waxman
Ranking Member
House Committee on Energy and Commerce

The Honorable Dave Camp
Chairman
House Ways and Means Committee

The Honorable Sander Levin
Ranking Member
House Ways and Means Committee

Dear Senators and Congressmen:

We are writing on behalf of the nation's Medicaid Directors to provide insight on the challenges posed to Medicaid agencies by new and emerging treatments for one of our nation's most pressing public health problems – hepatitis C. We also wish to begin a dialogue with you on federal policies which strike a better balance between appropriate access to new pharmaceutical cures and treatments for consumers and the long-term fiscal health of the Medicaid program which currently covers nearly 70 million low-income, vulnerable individuals and families. Our letter identifies several ideas to ground these conversations.

NAMD is a bipartisan, non-profit organization which represents Medicaid Directors in the fifty states, the District of Columbia and the territories. The Association was created in large part to develop consensus among Directors on critical issues, specifically those that have national policy implications.

444 North Capitol Street, NW, Suite 524 • Washington, DC 20001 • Phone: 202.403.8620 • www.medicaiddirectors.org

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The evolving situation with high-cost breakthrough drugs is an issue that has brought together the state Medicaid Directors. The current experience with hepatitis C has rightly commanded national attention, both for the promise that these new treatments hold, as well as their associated costs.

While the immediate focus and challenges present with hepatitis C treatments, we know this is a harbinger of the promises and challenges that will emerge in the years ahead. Publicly available information indicates that additional specialty drugs are currently moving through the drug pipeline. These are expected to enter the market by 2020 and will treat conditions including new immunotherapy treatments for cancer, cholesterol management, Alzheimer's disease, and multiple sclerosis reversing therapies.

This situation requires an immediate federal solution. We have noted the bipartisan engagement in efforts such as the "21st Century Cures" initiative, which seek to examine the steps federal policymakers can take to accelerate the pace of cures in America. However, we believe Congress has *not* sufficiently addressed the full continuum of issues associated with this process and related drug approval processes. Specifically, policymakers have failed to address the cost and reimbursement issues associated with faster or increased pathways for the development of high-cost therapies and treatments. This is particularly concerning when there is limited information about the evidence base for these products.

Policymakers must begin developing a new framework for conceptualizing the comprehensive costs and value associated with highly effective treatments in public health insurance programs, including Medicaid. In this process, policymakers and the public must also be realistic about the choices and trade-offs involved when taxpayer dollars are used to fund high-cost services and products. This conversation will be difficult, but it is one we believe federal policymakers must immediately begin with states and stakeholders.

The Hepatitis C Situation

In the short term, state Medicaid agencies are deeply concerned about the situation they face with new hepatitis C prescription drugs. As a primary payer for breakthrough treatments for hepatitis C, Medicaid agencies are using the limited tools they have to manage the very serious cost implications of emerging products. They are also weighing complex ethical questions, scientific evidence and public health needs to maximize appropriate access to new treatments.

This situation has several parallels to experiences with other products, namely those for the treatment of HIV/AIDS. As with HIV/AIDS prescription medications, there is sound, but still emerging, scientific evidence, a moral imperative to treat and a high cost based on investment and market dynamics.

However, as compared to HIV/AIDS, experts estimate that hepatitis C affects a much larger population. The Centers for Disease Control and Prevention (CDC) estimates that 3.2 million Americans are infected with hepatitis C. However, most people living with a chronic hepatitis C infection are unaware of their infection status. The CDC describes the disease's progression as "insidious, progressing slowly without any signs or symptoms for several decades." [1]

We anticipate the number of identified infected Americans will increase as more at-risk Americans are tested per CDC and 2012 United States Preventive Services Taskforce (USPSTF) recommendations and Medicare policy. With respect to Medicaid, precise estimates of the Medicaid-specific infected population are not widely available. We do know that experts believe the universe of infected individuals is disproportionately low income, and thus will likely be Medicaid-eligible in the majority of states.

The Challenges for Medicaid Agencies

Of significant concern to state Medicaid programs and other payers is the high cost of a Sovaldi treatment, which at a minimum is $84,000 wholesale acquisition cost per course of treatment, or $1,000 per pill. Still, Medicaid is no stranger to high-cost medications and therapies. Some of the most medically needy and expensive patients in the country are covered by the Medicaid program.

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 the therapy. To date, several states have reported that their first quarter 2014 prescription drug expenditures for hepatitis C treatments has doubled or tripled compared to their entire 2013 spending, which may reflect patients and providers waiting for these new treatments to enter the market. Another hepatitis C combination therapy targeted towards the most common types of hepatitis C infections, Harvoni, was released in mid-October 2014, with an even higher price point of $94,500 per 12 week course of treatment. Other drug manufacturers have signaled that they do not intend to compete on price when they introduce their own breakthrough therapies in 2015. These

[1] http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm#b1

facts suggest that the challenges posed by new hepatitis C therapies are likely to persist over many years.

States have one primary tool, the prior authorization (PA) process, to manage appropriate access to and act as competitive purchasers of prescription drugs. Unlike medical services, states are required to cover any drug which receives FDA approval and for which the manufacturer enters into the mandatory Medicaid drug rebate agreement. While states are employing their PA authority in a range of ways that fit the available evidence and their program structures, this tool is limited and should not be seen as a long term solution for new hepatitis C therapies and similarly-priced products for other diseases and chronic conditions.

For example, states are not well positioned to secure meaningful supplemental rebates for Sovaldi. As mentioned above, Medicaid is required to cover any outpatient drug which receives FDA approval, in return for receiving a mandatory 23 percent rebate from manufacturers. Typically, many states secure supplemental rebates on top of the required rebate by entering into negotiations with manufacturers. But just as Sovaldi is not a typical treatment, these typical approaches have not yielded results for the states.

To date, the supplemental rebates states have secured for Sovaldi are minimal, with any further concessions predicated on unrestricted access to the drug. States, neither individually nor collectively, are sufficiently equipped to secure the concessions required to make Sovaldi-like pricing a sustainable proposition. This is true for this product and for other comparatively priced products moving through the prescription drug pipeline. Though there is potential for more state negotiating power as new drugs enter the market, we cannot speculate as to how effective these negotiations will be in light of the possibility that these drugs will be priced similarly to Sovaldi.

Further, the pricing strategy introduced with Sovaldi is one which is modeled on trading high upfront costs for a believed accrual of savings to the overall healthcare system. This product is priced to reflect the value of its ability to cure, rather than manage, a debilitating infectious disease. As such, the upfront costs of providing Sovaldi are said to be offset by the money saved in not being required to manage the effects of untreated hepatitis C.

This may be true in the aggregate, though Sovaldi is different from prior therapies in that it can potentially benefit a broader range of patients than those who would have needed transplants or other treatments under the prior treatment paradigm. Regardless, this pricing strategy does not comport with the reality we face today. Individuals frequently transition on and off of public health insurance programs, between plans and programs,

or eventually transition from being Medicaid eligible to eligible solely for Medicare or dually eligible for both Medicaid and Medicare.

It is worth noting that Sovaldi's clinical trials were not conducted on patients with co-morbidities, such as HIV/AIDS, that may impact treatment efficacy and effectively lower its overall cure rate. Such populations are more common among Medicaid programs. As a result, there may be significant additional costs to states for patients who are not cured or, for whatever reason, fail to complete the initial full course of treatment and need to be retreated (potentially more than once). Additionally, data are lacking on the long-term "cure" potential of Sovaldi and similar hepatitis C medications. Thus, in the future, patients may potentially need to be maintained on these drugs for longer periods of time.

The long-term pricing strategy applied in this situation – which is also likely to be applied for future breakthrough products – does not align with the underlying Medicaid financing structure. At the state level, Medicaid is financed on an annual or biannual funding cycle, with funding appropriated in the context of balanced budget requirements in all but one state. It is not practical to expect Medicaid programs to finance the significant upfront costs of Sovaldi and other breakthrough hepatitis C treatments, at the expense of providing other needed services, on the promise of seeing savings 10, 20, or 30 years later. In this timeframe, the beneficiary will likely have transitioned to another source of coverage, as discussed above. The potential savings associated with the initial Medicaid purchase of Sovaldi would therefore not accrue to the state's Medicaid program, but rather to another payer. It is not reasonable to expect states to finance the full cost of an expensive treatment whose associated savings likely accrue to another entity decades in the future.

Some reports indicate that while Sovaldi may prove efficacious, its pricing presents a low value proposition to the health care system due to the potentially high costs of treating such a large number of patients with a very expensive medication.[2] We believe further research and analysis is needed to better understand the impact of this and emerging products for Medicaid and the broader health care system.

The Long Term Outlook Calls for Federal Solutions

Simply put, the federal Medicaid statute is not designed to allow states to respond to this new pricing approach for pharmaceuticals. Sovaldi is just the first of many such

[2] California Technology Assessment Forum, "The Comparative Clinical Effectiveness and Value of Simeprevir and Sofosbuvir in the Treatment of Chronic Hepatitis C Infection." http://ctaf.org/sites/default/files/assessments/CTAF_Hep_C_Apr14_final.pdf

exceptionally high-cost "curative" specialty drugs. As more of the specialty drugs that are brought to market adopt this same pricing rationale, new thinking and approaches are required to safeguard the financial integrity of state Medicaid programs and ensure low-income patients are able to access appropriate medical innovations.

We believe federal policymakers must begin to discuss the menu of policy solutions available to address the affordability issue for high-value products. We also urge caution and close inspection of proposed trade provisions to ensure that they do not undermine or limit the ability of states or the federal government to moderate escalating prescription drug, biologic drug and medical device costs in public programs, particularly new costlier drugs or treatments.

Here, we offer an initial list of policy strategies. We anticipate that a more comprehensive and transparent discussion of the issues will generate additional options to ensure this treatment and other high cost treatments are appropriately addressed.

At this time we are not endorsing any single solution on this list. We believe each solution carries advantages and disadvantages, but all merit further exploration by Congress and other federal policymakers and stakeholders.

As a start, we encourage you to solicit other recommendations and begin to evaluate the feasibility of the following:

- **Solutions for all public payers:** Congress can exert downward pricing on Sovaldi and similarly-priced specialty drugs targeting large patient populations. While we recognize that direct price controls would be a politically volatile topic which could be expected to encounter substantial pushback, a strong case can be made for the unique circumstances of hepatitis C in particular. Many of the potential patients for these drugs are covered by federal taxpayer dollars, whether they are covered by Medicare, the federal prison system, the Veterans Health Administration, or Medicaid. There is also a vested public health interest in the potential to eradicate this deadly disease, which is currently responsible for more annual deaths in the country than HIV/AIDS.

- **Mitigating the cost to Medicaid:** Congress could also choose from a menu of policy options that do not directly affect Sovaldi or other breakthrough drug pricing or coverage policies, but would still mitigate state Medicaid programs' exposure. These options include the following:

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- Federal purchasing of the available supply and/or the supply chain, with subsequent discounted distribution of product to the states or a requirement that states pay only the administrative fee (modeled on federal purchasing of vaccines for children and other public health emergency situations);
- Enhanced federal match rates for this, or other such "curative" specialty drugs;
- Mandate additional rebates from a manufacturer, for example one that is triggered if a disease state or condition affects a certain percentage of the Medicaid population;
- Modify the "best price" policies for breakthrough drugs to include the selling price in other countries;
- Risk corridors or other reinsurance approaches, based on subsidizing any state spending in excess of clearly articulated federal projections of coverage and costs;
- A separate federal program created for the sole purpose of financing the provision of this drug to the affected population, similar to the Ryan White and state ADAP programs for HIV/AIDS drugs, with Medicaid serving as a payer of last resort; and
- Allow Medicaid programs to utilize cost-effectiveness research to identify whether or not a particular drug will be included in the program's formulary by granting Medicaid the flexibility to exclude products that are found to not be cost-effective; and
- Create waiver flexibility allowing states to contract with drug manufacturers outside of the Medicaid rebate program structure to allow innovative payment arrangements. For example, allow states to enter into outcomes-based contracts with manufacturers, where payment is made per successful course of treatment rather than per pill.

Sovaldi – both in its medical potential and its price – represents a new frontier for specialty drugs, which are anticipated to enter the market in the near future at increasingly high price points. Federal thinking on Medicaid financing must reflect these developments in order to maintain the fiscal strength of the program in the coming years.

NAMD
National Association of Medicaid Directors

Working through our association, we are prepared to work with you to address the complexities of this critical public health care issue. Please contact NAMD's Executive Director, Matt Salo, to discuss how we can further assist you in this matter.

Sincerely,

Darin J. Gordon
TennCare Director
Department of Finance and Administration
State of Tennessee
President, NAMD

Thomas J. Betlach
Arizona Health Care Cost
Containment System Director
State of Arizona
Vice-President, NAMD

Cc:
Members of the Senate Finance Committee
Members of the Senate Health, Education, Labor and Pensions Committee
Members of the House Energy and Commerce Committee
Members of the House Ways and Means Committee

Exhibit 3

From: Eric Kimelblatt **Redacted**
Sent: Tuesday, April 15, 2014 3:06 PM
To: Andrews, Christopher J.; William Dozier
Cc: Brown, Douglas M.
Subject: Re: Sovaldi Data

At least it would be directional. Other individual states have provided this either publicly or directly to us.
Thanks,
Eric

----- Original Message -----
From: Andrews, Chris **Redacted**
Sent: Tuesday, April 15, 2014 12:03 PM
To: William Dozier
Cc: Eric Kimelblatt; Brown, Douglas **Redacted**
Subject: RE: Sovaldi Data

That ranking would be inaccurate at this point based on how states have been handling Sovaldi dispensing.

Chris

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Thank you.

-----Original Message-----
From: William Dozier **Redacted**
Sent: Tuesday, April 15, 2014 2:36 PM
To: Andrews, Chris
Cc: Eric Kimelblatt
Subject: Re: Sovaldi Data

its relevant to the Gilead.pricing committee because it shows the impact current pricing has on Medicaid.

Best regards,

William

William E. Dozier, MBA
Senior Manager, National Accounts
Strategic Accounts East
Gilead Sciences

Redacted

----- Reply message -----
From: "Andrews, Chris" **Redacted**
To: "William Dozier" **Redacted**
Cc: "Brown, Douglas" **Redacted**
Subject: Sovaldi Data
Date: Tue, Apr 15, 2014 2:19 PM

I don't see how that is relevant to our discussion.

Chris

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-----Original Message-----
From: William Dozier **Redacted**
Sent: Tuesday, April 15, 2014 2:11 PM
To: Andrews, Chris
Cc: Brown, Douglas
Subject: Re: Sovaldi Data

Hi Chris,

Thanks, it will be discussed during a meeting in-house tomorrow.

Linda asked if it is possible to get data on where Sovaldi ranks in top spend by state?

Do you normally gather this or would you need to contact each state?

Best regards,

William

William E. Dozier, MBA
Senior Manager, National Accounts
Strategic Accounts East
Gilead Sciences
Redacted

----- Reply message -----
From: "Andrews, Chris" **Redacted**
To: "William Dozier" **Redacted**
Cc: "Brown, Douglas" **Redacted**

Subject: Sovaldi Data
Date: Tue, Apr 15, 2014 11:01 AM

I've attached the utilization information available to us for hepatitis C products. It is sortable by client and product. Please let us know what the next steps will be.

Chris

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-----Original Message-----
From: Brown, Douglas
Sent: Friday, April 11, 2014 12:16 PM
To: William Dozier
Cc: Andrews, Chris; Brown, Douglas
Subject: RE: Sovaldi Data

William,

We have access to pharmacy claims data but not medical data. The data we'll send to you will be the most recent 3 months of claims data for each customer. In most cases it will be Dec, Jan and Feb. (March data will not be available until the end of April.) We don't have unique recipients in the data set so you'll have to infer that from the utilization.

We'll start there and continue with our discussions.

Doug

-----Original Message-----
From: William Dozier **Redacted**
Sent: Friday, April 11, 2014 11:58 AM
To: Brown, Douglas
Cc: Andrews, Chris
Subject: Sovaldi Data

Hello Doug,

There is a meeting next week to begin discussions on your request.
Is it possible to provide me the following information by next tuesday COB?

Broken out by pool states, most recent data available:

1. Sovaldi utilization for Jan, Feb (March if available) 2. # of patients taking Sovaldi in Jan, Feb (March if available)
3. # of patients diagnosed with HCV

4. Rank in drug spend of Sovaldi year to date

I am copying Chris since you may already be on vacation.

Best regards,

William

William E. Dozier, MBA
Senior Manager, National Accounts
Strategic Accounts East
Gilead Sciences
Redacted

Exhibit 4

OFFICE OF THE DIRECTOR
Kate Brown, Governor

Oregon Health Authority

500 Summer St NE E20
Salem OR 97301
Voice: 503-947-2340
Fax: 503-947-2341
www.Oregon.Gov/OHA
www.health.oregon.gov

October 19, 2015

The Honorable Senator Ron Wyden
The Honorable Senator Chuck Grassley
221 Dirksen Senate Office Building
Washington, DC 20510

Dear Senators Wyden and Grassley:

Thank you for the opportunity to provide updated information on the challenges presented in Oregon by the incidence and prevalence of the Hepatitis C Virus (HCV) and the cost implications for health care reform. Thank you also for your work on this complicated and important issue.

The emerging HCV treatments of Sovaldi, Harvoni and Olysio contribute to the problem of rapidly increasing health care costs. When Sovaldi came to the market, Oregon Medicaid was both eager to provide access to the promising new treatment and shocked by the unpredicted price tag. Since then, we've seen Harvoni and Olysio, and still other new agents are on their way. Even with the promise of added competition, we have no cause to anticipate a lower, sustainable cost for HCV medications. Meanwhile, we struggle to provide appropriate coverage of other new specialty pharmaceuticals that also have high price tags. Some of these show much less promise in terms of meaningful therapeutic benefit.

Much has been said already about Sovaldi and the other recently-released HCV agents. It is a significant concern for all payers, but especially for Medicaid and Medicare. HCV patients are disproportionately beneficiaries of Medicaid or Medicare. This is true nationally, and Oregon is no different. What sets Oregon somewhat apart is that Oregonians have a higher incidence of hepatitis C than the national average. The mortality rate in Oregon from HCV was nearly twice the national average in 2011. Thus, Oregon is especially interested in life-saving, effective treatment, and is especially vulnerable to exceptionally high costs for that treatment.

We previously shared an analysis performed by Dr. Dan Hartung. This analysis identified 10,164 Medicaid clients as of September 2014 who appeared to be good potential candidates for the newly-available HCV treatment.

The gross cost of treatment was estimated to be between $84,000 and $150,000 per patient, depending on the treatment length indicated. Our entire gross drug spend for all drugs in 2014 was $591,191,199. This cost and demand meant that if we treated only half of the potential HCV candidates, we could end up more than doubling the previous year's entire drug spend.

With guidance from experts, we developed a strategy to target and prioritize treatment to those patients identified as the best candidates to successfully complete and benefit from treatment. Prescribing hepatologists and gastroenterologists help ensure treated patients are appropriate and prepared to successfully receive treatment. The Hartung analysis indicated that treating the more advanced patients was cost effective when compared to the previously available treatments. Based on historical utilization and assumptions regarding provider capacity, we concluded approximately 500 patients would be treated annually at a projected cost of up to $51 million per year for the first six years.

Since the new agents came on the market, total expenditure for these new HCV drugs continues to increase. Based on year-to-date expenditures, we expect to exceed $30 million in expenditure for 2015. Again, these appear to be well-tolerated, cost effective therapies that we anticipate will result in a reduction in costs for other services. However, the upfront costs to provide the treatment continue to drive substantial increases in the pharmaceutical budget.

The national attention paid to the new HCV treatments is well-deserved, but the concern over dramatic pharmacy budget increases is not limited to HCV. There are newer treatments for chronic conditions that, unlike the hepatitis drugs, do not provide a cure and will need to be taken by patients every year for the rest of their lives. For example, the PCSK9 inhibitors will be prescribed to treat high cholesterol and will result in a gross cost increase of approximately $14,000 to $29,000 per patient per year. New treatments for cystic fibrosis will exceed $250,000 per year for one patient. The estimated number of patients who meet current FDA-approved indications for the new cystic fibrosis treatment is very small but will still result in a significant financial impact of approximately $4 million per year. With the recent FDA approval of Orkambi (ivacaftor/lumacaftor), and anticipated expansion of FDA-approved indications, many more patients will likely qualify for treatment and the additional annual costs could be as high as $46 million.

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.
This limitation is especially evident for generics, for which we do not have the same rebate protections when the manufacturer raises their average price in excess of the Consumer Price Index.

Again, thank you for your work and attention on the financial impacts of these very expensive pharmaceuticals. Please let me know if you have any questions about this letter or would like further information. I can be reached by telephone at 503-945-6777 or via email at Lynne.Saxton@state.or.us.

Sincerely,

Lynne Saxton

Lynne Saxton
Director

CC: Jeremy Vandehey
Karmen Fore
Drew Johnston

Exhibit 5

STATE OF WASHINGTON
HEALTH CARE AUTHORITY
626 8th Avenue, SE • P.O. Box 45502 • Olympia, Washington 98504-5502

September 23, 2015

The Honorable Ron Wyden
The Honorable Chuck Grassley
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Senator Wyden and Senator Grassley:

Specialty pharmacy drugs have long constituted a portion of total pharmaceutical costs. These medications have historically been used to treat a limited number of medical conditions that affect relatively small numbers of the U.S. population.

More recently, effective, safe and very expensive specialty pharmaceuticals have become available for a wider number of medical conditions. While some of these pharmaceuticals target less common conditions such as cystic fibrosis and multiple sclerosis, others are used to treat very common conditions such as chronic hepatitis C and high cholesterol.

Newer treatments for chronic hepatitis C that have come to market in the last two years have posed especially difficult challenges for payers. Hepatitis C is a chronic infection caused by the hepatitis C virus. It affects one percent of the U.S. population and is the leading cause of cirrhosis, liver cancer and liver transplantation in the U.S.

In Washington State, it is estimated that between 75,000 and 85,000 people harbor the hepatitis C virus; based on available epidemiologic and clinical data, the Washington State Health Care Authority (HCA) estimated that as of July 2014, more than 23,310 Medicaid clients were chronically infected with hepatitis C. The especially high prevalence of hepatitis C in the Medicaid population reflects the increased prevalence of risk factors for hepatitis C in this population.

In November 2013, the Food and Drug Administration (FDA) approved Sovaldi (sofosbuvir) in combination with ribavirin and interferon for the treatment of hepatitis C. Sovaldi, manufactured by Gilead Sciences, represents a major breakthrough in the treatment of hepatitis C because of its effectiveness and lack of toxicity. However, Sovaldi still needed to be used in combination with two older medications – ribavirin and interferon – both associated with a high degree of toxicity.

The State was aware of Sovaldi's impending approval, but had no way of knowing that Gilead would set the price at $1000 per pill (Sovaldi is taken daily for 12 weeks when used in the treatment of the most common type of hepatitis C virus; hence, the cost of treating 1 individual is $84,000, based on Average Wholesale Price at the time). Moreover, the State recognized that within 1 year of Sovaldi's market entrance, additional less toxic and safer hepatitis C regimens would likely become available; these regimens would not require ribavirin and interferon as part of treatment.

The HCA anticipated relatively modest utilization of Sovaldi in 2014 because it needed to be used in combination with more toxic medications; as well, the medical community was eagerly anticipating the availability of much less toxic treatment regiments by early 2015 and "warehousing" patients with the purpose of treating them when the superior regimens became available. Approximately 350 Medicaid patients were treated with Sovaldi in calendar year 2014, a small proportion of those estimated to qualify for treatment. In January 2015 a new less toxic drug, Harvoni was released and HCA has estimated approximately 8,000 individuals will be eligible for treatment.

Taking into account both the federal and Washington State rebate negotiated with Gilead, in FY 2016 alone, the State anticipates spending more than $242 million to treat eligible Medicaid patients ($60,680,000 State; $181,630,000 Federal). Of note, this estimate is based on Medicaid's current clinical policy, which does not provide treatment for those who are infected with hepatitis C and evidence a lower risk of developing severe liver disease or cirhhosis). HCA's current pharmacy budget including Fee for Service and Managed Care is a little over $1 billion. ***If HCA were to pay for hepatitis C treatment for all Medicaid clients infected with hepatitis C, the cost would be three times the current total pharmacy budget.***

The new hepatitis C medications represent the "tip of the iceberg" with respect to the potential impact of new, effective and extraordinarily expensive pharmaceuticals that have recently or will soon come to market. For example, the FDA just approved two new cholesterol-lowering medications. These drugs, known as "PCSK9" inhibitors have been priced at about $14,000 annually. Like the new hepatitis C drugs, these medications treat a common condition; however, whereas people with hepatitis C usually have their hepatitis C virus eliminated with a single 90-day course of treatment, those treated with these new and expensive cholesterol-lowering agents will require treatment on an ongoing basis, i.e. $14,000 will be a recurring annual cost over the course of an individual's lifetime. It is estimated that up to 25 percent of people who need cholesterol lowering treatment cannot tolerate currently available medications (so called "statins," which are pennies per pill). Therefore, the cost implications of the "PCSK9" drugs for payers and national health care costs are staggering.

It is important to note that the new and expensive specialty drugs, while effective in reducing the burden of disease, are priced as such that they do not produce a net savings over time. That is, while treatment costs for the underlying condition will be reduced over time, they are not reduced to the extent that the dollars saved exceed the dollars expended on the drug. While

"cost-effective," these newer agents are NOT cost saving; they will add to the total cost of health care in the U.S.

State Medicaid programs will continue to be challenged to cover these new and emerging treatments. States may be forced to make difficult choices related to coverage for other Medicaid services in order to afford these new and very expensive drugs. We are interested in continuing to work with Congress to find relief for states as more drugs come onto the market.

Please let me know if you have any questions about this letter or would like further information. I can be reached by telephone at (360) 725-1863 or via email at MaryAnne.Lindeblad@hca.wa.gov.

Sincerely,

MaryAnne Lindeblad, BSN, MPH
Medicaid Director
Washington State

cc: Bob Crittenden, Special Assistant, GOV
Peter Gartrell, Committee Staff, U.S. Senate

Exhibit 6

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF HUMAN SERVICES

OCT - 2 2015

The Honorable Ronald L. Wyden
The Honorable Charles E. Grassley
United States Senate
Senate Committee on Finance
Washington, D.C. 20510

Dear Senators Wyden and Grassley:

Thank you for the opportunity to describe Pennsylvania's experience with coverage of the newest Hepatitis C agents in the Pennsylvania (PA) Medicaid program. Sovaldi and Harvoni (manufactured by Gilead), Daklinza (manufactured by Bristol-Myers Squibb), and Viekira Pak and Technivie (manufactured by AbbVie) are all covered under the PA Medicaid program and available in both the fee-for-service (FFS) and the managed care delivery systems. All of the recently-approved drugs for the treatment of Hepatitis C are very costly. The high price of the newer Hepatitis C medications sparked national and international debate over fair pricing which, combined with several unknowns that made overall costs unpredictable, generated significant concern over potential cost of care and indirectly impacted policy decisions on coverage and access.

Cost Concerns and Potential Impact

The Department of Human Service's (Department's) clinical pharmacists routinely monitor the pipeline for new drugs coming to market. They were aware of the anticipated release of each of the new oral Hepatitis C drugs and their promise of higher cure rates with fewer side effects compared to previous treatment options. Like all new drugs, the pharmacists were not aware of costs until the drugs received final approval from the U.S. Food and Drug Administration (FDA) and became available in the market. When the prices were announced, PA Medicaid, like every other public and private third party payer in the nation, experienced "sticker shock."

Concerns about the cost of the new Hepatitis C drugs were exacerbated by a number of unknowns that made total cost unpredictable. The biggest unknown was the size of the target population due to the following:

- Pent-Up Demand – Many people diagnosed with Hepatitis C decided to delay treatment until the newer Hepatitis C drugs were available, as the new drug treatment regimens were entirely oral and were anticipated to increase effectiveness, decrease side effects, and shorten treatment time compared to previously-available regimens.

- Centers for Disease Control (CDC) Recommendation for Testing – In 2012, the CDC recommended that everyone born between 1945 through 1965, also known as baby boomers, get tested for Hepatitis C. People with Hepatitis C often have no symptoms and can live for decades without feeling sick. The only way to know if a person has Hepatitis C is to get tested. The CDC recommended testing for early diagnosis and treatment to help prevent serious health problems, including liver damage, cirrhosis, liver cancer, liver transplants, and even death.

- Direct to Consumer Marketing – Manufacturers used television and magazine advertisements to promote their Hepatitis C drugs, targeting the baby boomer population.

Typically, the expenses associated with high-cost drugs, such as drugs to treat HIV/AIDS and hemophilia, are spread out over time and are predictable. In this case, pent-up demand, increased testing, and greater consumer awareness of the new drugs, combined with a shorter treatment time of 8 to 12 weeks for most patients, creates the potential for a one-time immediate spike in demand for the recently-approved high-cost treatments and challenges traditional fiscal projections and planning.

The PA Medicaid program prepared a rough estimate of the cost impact if every PA Medicaid beneficiary infected with Hepatitis C was treated. According to that estimate, 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. The ranges reflect the difference in paid amounts and net costs and are dependent upon which drug is designated as preferred on the FFS Preferred Drug List (PDL).

The PA Medicaid managed care organizations (MCOs) voiced their concern about the high cost of the drugs and the unpredictability of demand. The Department's actuary included Hepatitis C drug costs when they developed the calendar year 2015 MCO rates. However, the MCOs remain skeptical that the rates are sufficient given the high demand for access to treatment. The Department continues to monitor MCO expenditures in response to MCO demands for further financial adjustment.

PA Medicaid Efforts to Mitigate Cost

Both the PA Medicaid FFS program and the MCOs immediately implemented strategies to manage utilization and mitigate cost impact. Those strategies included prior authorization of the new Hepatitis C drugs and reinforced emphasis on its already robust collection of federal drug rebates on these drugs. The FFS program also worked with its state supplemental rebate contractor to negotiate supplemental rebates for these products. (NOTE: Drugs paid for by PA Medicaid MCOs do not qualify for state supplemental rebates. The MCOs negotiate and collect their own market share

rebates.) 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 FFS PDL; 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.

Current Utilization and Cost

The following chart reflects the current utilization and spend for Hepatitis C drugs in both FFS and managed care in PA Medicaid. The total spend does not account for rebates collected by PA Medicaid.

Hepatitis C Drug Utilization and Spend in PA Medicaid			
January 1, 2014 through August 8, 2015			
	Recipient Count	Claim Count	Spend
Total	2,041	11,969	$186,116,252

Policy Impact

PA Medicaid provides coverage of all FDA-approved drugs of manufacturers who participate in the Federal Drug Rebate Program. Consistent with federal Medicaid requirements, PA Medicaid's policy is to provide coverage for all medically-accepted indications. Both FFS and the Medicaid MCOs rely on package labeling, national and international treatment guidelines, and peer-reviewed medical literature to identify the guidelines to determine medical necessity.

In this case, expert consensus panels published treatment guidelines that shifted the emphasis on determining medical necessity from the clinical merits of these breakthrough treatments to an accommodation of the exorbitant costs. Instead of focusing their guidelines on the clinical merits of the drugs and their medically-accepted indications, treatment guidelines recommended prioritizing treatment for the "sickest" patients due to potential cost and access issues. And, unlike other communicable diseases such as HIV/AIDS, there was no emphasis on reduction in transmission to stem the spread of the disease through education and intervention at the point of transmission. One positive outcome of the concerns about high cost for Pennsylvania was the development and adoption of consistent guidelines to determine medical necessity of the newer Hepatitis C drugs among FFS and all of the PA Medicaid MCOs to ensure equal access across delivery systems.

I hope that this information is helpful. If you need additional information, please contact Mr. Abdoul Barry, Director, Office of Legislative Affairs, at (717) 783-2554.

Sincerely,

Theodore Dallas
Secretary

c: The Honorable Robert P. Casey, Jr.

Exhibit 7

Iowa Department of Human Services

Terry E. Branstad, Governor | Kim Reynolds, Lt. Governor | Charles M. Palmer, Director

FEB 9 2015

Mr. Peter Gartrell
U.S. Senate Committee on Finance
219 Dirksen Senate Office Building
Washington, D.C. 20510
Peter_Gartrell@finance.senate.gov

Dear Mr. Gartrell:

This letter is in response to your recent questions of the Iowa Department of Human Services (DHS) regarding Medicaid pharmaceutical expenditures.

The request was to provide a list of the top twenty-five drugs ranked by total amount paid for calendar year 2014. Additionally, the request was to include claim count, wholesale acquisition cost (WAC), drug quantity, days' supply and the number of unique recipients. It was also requested to include the same information for the drugs Sovaldi® and Harvoni™, if they were not included in the top 25 drugs by amount paid. Iowa Medicaid reimburses pharmacy claims based on a state specific average acquisition cost (AAC) and uses WAC when an AAC is not available. Therefore, the Iowa AAC has also been included in the data where applicable. Please note that both the WAC and AAC can change over time so the average WAC and AAC for calendar year 2014 is provided. The data requested is provided as an attachment.

All prescription drugs are through the fee for service (FFS) program, so the data provided represents all outpatient prescription drug expenditures. Iowa Medicaid currently covers 560,000 Iowans. Approximately 63,000 Medicaid members, or 11 percent of the total population, are covered by an HMO managed care plan (Meridian Health Plan of Iowa); however, pharmacy is carved out of the managed care plan.

Regarding the questions specific to Hepatitis C Virus (HCV), the state estimates 5,406 HCV patients in the Medicaid program. The Iowa DHS has not implemented any special funding provisions (special budget line items, etc.) for coverage of these drugs, but it has incorporated the cost of specialty drugs (including HCV medications) into its current and future Medicaid budget requests.

The Iowa Medicaid program participates in the Sovereign States Drug Consortium (SSDC) for supplemental drug rebates. To date, the program has not accepted a supplemental rebate for any of the HCV medications; however, the rebates offered are under consideration and will be discussed at the April Pharmaceutical and Therapeutics (P&T) Committee meeting.

If you have additional questions, please contact Susan Parker, Pharmacy Director, at sparker2@dhs.state.ia.us or (515)256-4634.

Sincerely,

Charles M. Palmer
Director

CMP:slp

Attachment:
1 – Iowa Medicaid Top 25 Drugs by Paid Amount CY2014

Exhibit 8

AHCCCS
Arizona Health Care Cost Containment System

Douglas A. Ducey, Governor
Thomas J. Betlach, Director

July 17, 2015

Mr. Peter Gartrell
U.S. Senate Committee on Finance
Ranking Member Ron Wyden (Oregon)
219 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Mr. Gartrell:

The AHCCCS Administration submits the requested information in response to your July 8, 2015 correspondence requesting a list of the top 25 drugs ranked by total amount paid for calendar year 2014. The attached spreadsheet includes the following:

Fields requested:	Field descriptions on the excel spreadsheet:
Claim count	Number of Prescriptions
Wholesale acquisition price (WAC)	Health Plan Paid Amount
Drug quantity	Quantity Dispensed
Days of supply	Days Supply
The number of unique recipients	Distinct Members

The first and second tabs on the spreadsheet are the Top 25 Drug by Cost for the Fee-For-Service (FFS) and Managed Care Organizations (MCOs) respectively. The third and fourth tabs are the specific reports for Sovaldi and Harvoni for the Fee-For-Service and Managed Care Organizations (MCOs) respectively.

The current AHCCCS enrollment is 1,746,175 members. Of these members, 1,471,809 are enrolled in MCOs and 116,747 are in the FFS program. An additional 50,483 are in Medicare Savings Programs and 107,136 are in a program that provides emergency services only. Excluding the Medicare Savings Program and emergency services populations, 92.7% of the remainder of the AHCCCS population is enrolled in MCOs and 7.3% is in FFS.

You also requested additional information and the Administration's responses are below.

Has the state agreed to any supplemental rebate with Gilead for Sovaldi or Harvoni? If so, when?

Yes. The effective date of our agreements is January 1, 2015.

Also, many states have had to make special budget line items or other special provisions for Sovaldi and other new HCV drugs because of the cost. Has your agency had to make any special funding provisions that your state has had to request or adopt to cover the cost of these drugs?

There was an existing $15 million in the MCO capitation rates for treatments that Sovaldi and Harvoni are replacing. These dollars were left in the rates to cover a portion of the costs of Sovaldi and Harvoni. Arizona added an additional $30 million in funding to the capitation rates to address the additional costs of Sovaldi and Harvoni, for total funding of $45 million.

Lastly, is there any estimate of the number of HCV patients in the Medicaid program?

There are approximately eighteen thousand identified HCV patients within the AHCCCS program. It should be noted that the national consensus among health care professionals is the number of Hepatitis C patients is understated due to lack of testing.

In the event that you have additional questions, please contact me at your convenience.

Sincerely,

Thomas J. Beltach
Director

Exhibit 9

RICK SCOTT
GOVERNOR

ELIZABETH DUDEK
SECRETARY

October 19, 2015

The Honorable Orrin G. Hatch
Chairman
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Chairman and Ranking Member:

Thank you for asking about the Florida Medicaid Program's experience with the new generation of Hepatitis C drugs that became available beginning in December of 2013.
Florida Statute directs the Agency to implement a Medicaid prescribed-drug spending control program and the Agency utilizes a Preferred Drug List (PDL) as part of that program. The Preferred Drug List (PDL) is a listing of cost effective therapeutic options recommended by the state's Medicaid Pharmacy and Therapeutics Committee. The Pharmacy and Therapeutics Committee is an advisory committee of physicians and pharmacists that ensures that the drugs available on the PDL allow providers a selection that guarantees quality of care and cost containment.

In Florida, most Medicaid recipients are enrolled in the Statewide Medicaid Managed Care (SMMC) program. Under the SMMC program, the Agency negotiated capitation rates and entered into contracts with fully risk bearing health plans to provide services, including prescription drugs, to Medicaid enrollees beginning in May of 2014. Health plans are required to utilize the Agency's PDL and develop prior authorization criteria and protocols, which cannot be more restrictive than that used by the Agency, for reviewing requests for brand name drugs that are not on the Agency's PDL.

The Agency, working with the Pharmacy and Therapeutics Committee, established clinical criteria for the new Hepatitis C drugs as they became available on the market. Below is the original date the criteria was established. Please note, the medications used to treat Hepatitis C are an evolving group and guidelines for treatment may have been modified since the original posting date.

Medication	**Original Date of Criteria**
Harvoni	10/24/2014
Olysio	2/13/2014
Sovaldi	12/17/2013
Viekira Pak	1/20/2015

Medicaid health plans expressed concern that utilization of these new drugs would be high, and if the cost was high, the financial impact would be greater than anticipated in the capitation rates that were negotiated with the Agency. To address the rate impact, Agency staff and the Agency's contracted actuaries established a temporary "kick payment" for Hepatitis C drugs. 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 payment allows the Medicaid program to pay the health plans based on expected costs for each enrollee who is prescribed the drugs for treatment. The goal was to help the plans cover the costs of the treatment until such time as utilization and expenditure data was available to incorporate the cost for these drugs into the capitation rate.

The Agency set new capitation rates for 2015-16 that became effective September 1, 2015 that included coverage for the new Hepatitis C drugs. One of the main drivers of the increase includes prescription drug trends and specialty drug growth. Kick payments for these drugs were discontinued, except for certain enrollees with a diagnosis of HIV/AIDs.

This data below represents expenditures under the fee-for-service program and managed care encounter data relating to the Hepatitis C drugs for the time period of January 1, 2014 – August 7, 2015. Expenditures reported here are gross costs as paid by FFS and as reported paid by the managed care plans; thus do not include offsets for rebates received.

Drug	FFS Claims	MCO claims	FFS Expenditure	MCO Expenditure	Total expenditure FFS + MCO
Harvoni	13	1027	$415,702.00	$31,570,787.99	$31,986,489.99
Olysio	232	309	$5,167,978.11	$6,880,999.86	$12,048,977.97
Sovaldi	958	1617	$26,944,190.01	$45,009,256.10	$71,953,446.11
Viekira	14	85	$394,706.48	$2,349,020.21	$2,743,726.69
Totals	**1,217**	**3,038**	**$32,922,576.60**	**$85,810,064.16**	**$118,732,640.76**

We hope this letter provides you with a high level understanding of Florida Medicaid's experience with the new generation of Hepatitis C drugs.

Sincerely,

Justin M. Senior
Deputy Secretary for Medicaid

JMS/ks

Exhibit 10

CABINET FOR HEALTH AND FAMILY SERVICES
DEPARTMENT FOR MEDICAID SERVICES

Steven L. Beshear
Governor

275 E Main St, 6W-A
Frankfort, KY 40621
www.chfs.ky.gov

Audrey Tayse Haynes
Secretary

Lisa D. Lee
Commissioner

The Honorable Charles E. Grassley
Chairman
Committee on the Judiciary
United States Senate
135 Hart Senate Office Building
Washington, D.C. 20510

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate
221 Dirksen Senate Office Building
Washington, D.C. 20510

October 21, 2015

Re: High Cost Price of HCV Treatment

Dear Senators and Congressmen,

One of the most pressing concerns facing states and the nation's public health is hepatitis C. It is no secret that Kentucky has been challenged with the onslaught of heroin addiction, and we have been very aggressive legislatively with treatment to fight this problem. Heroin not only brings about a public health concern, but also the impact of newer hepatitis C virus (HCV) treatment options on state health care/Medicaid budgets. This is not only a problem for Kentucky but a national public health concern.

Kentucky'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 recipients. Sovaldi® has a list price of $84,000 for a typical 12-week course of treatment. Harvoni®, made by the same company, Gilead Sciences, has a list price closer to $100,000. Newer additions may be available but are also similarly high in cost. Although some manufacturers offer discounts to Medicaid programs, these do little to offset the cost of care.

We are concerned about the sharp rise in costs for Kentucky Medicaid beneficiaries diagnosed with hepatitis C. Our state's opiate problem and the increased testing of people who have injected drugs contribute to the upward trend.

Kentucky will soon start providing hepatitis C screening tests at all its county health departments, just as it does for H.I.V. Although precise estimates of the Medicaid population infected are not readily available, we would expect based upon the available data that the majority of infected individuals are of disproportionately low-income and Medicaid eligible status. Once members are HCV confirmed the question of when to initiate treatment must still be considered. Given the current cost of the newer treatment options and to remain fiscally responsible we will be forced to make difficult decisions regarding who does and does not get access to treatment medications upon diagnosis.

Kentucky is not alone in its concern. 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.

The evolving situation associated with such high cost breakthrough treatments has a great impact upon sensitive and strained health care budgets. Newer HCV products are often acclaimed as curative. Noteworthy here is that clinical trials are rarely focused on co-morbidities found most often among Medicaid recipients which often have a profound impact on treatment efficacy. Although we fully support innovation in treatments, policymakers must begin developing frameworks that address the comprehensive costs and value of treatments in public health insurance programs such as Medicaid. As a primary payer, Kentucky continues to use the limited tools available to manage the cost implications of emerging HCV products, such as prior authorizations, weighing the available scientific evidence to guide access, and continuing to pursue price competition and supplemental rebates despite the fact that the state is not well positioned to secure savings. The price charged by drug companies is the one item where the state has little control.

Drug manufacturers have been reluctant to competitively price these breakthrough therapies as they emerge and we have concerns regarding the increasing challenges which are likely to continue for many years. We welcome any opportunity for open dialogue regarding federal level policies that could create some balance between appropriate access to new treatment options and long-term fiscal sustainability of Medicaid programs.

Thank you for your time and attention to this important issue.

Kindest Regards,

Samantha McKinley, B.S., J.D., D.C., Pharm.D.
Department for Medicaid Services
Pharmacy Director
275 East Main Street, 6W-A, Frankfort, KY 40621
Office (502)564-9444 X 2194
Fax (502) 564-0223
samantha.mckinley@ky.gov

Exhibit 11

TEXAS HEALTH AND HUMAN SERVICES COMMISSION

August 14, 2015

CHRIS TRAYLOR
EXECUTIVE COMMISSIONER

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, D.C. 20510

The Honorable Charles E. Grassley
Senior Member
Committee on Finance
United States Senate
135 Hart Senate Office Building
Washington, DC 20510

Dear Senator Wyden and Senator Grassley:

Thank you for exploring the financial impact that Gilead Sciences, Inc.'s (Gilead) Sovaldi — and other second generation direct acting antiviral medications for the treatment of the Hepatitis C virus (second generation HCV drugs) — has on Medicaid programs. Unfortunately, the high cost of these drugs forced the Texas Health and Human Services Commission (HHSC) to carefully examine which Medicaid beneficiaries are truly in medical need of these products and required HHSC to implement strong prior authorization requirements.

The HHSC Pharmaceutical and Therapeutics (P&T) Committee first reviewed Sovaldi in January of 2014 and recommended a preferred status, contingent upon implementation of prior authorization criteria. HHSC began developing a medical necessity and prior authorization criteria for second generation HCV drugs, based on reliable and appropriate evidence. In July that same year, HHSC requested detailed clinical outcome data from Gilead (see Attachment 1). The associate director for medical sciences for this company, Michelle Puyear, was extremely helpful and provided and explained the data. In addition, HHSC enlisted the services of the Oregon Health Science University Medicaid Evidence Based Decisions Project to help review the data and assist with drafting appropriate prior authorization criteria. Texas Medicaid eventually determined that second generation HCV drugs are medically necessary for beneficiaries if they are diagnosed with the Hepatitis C virus and experience a METAVIR score of F3 or F4. The METAVIR test assesses the level of liver fibrosis on a scale of increasing severity from F0 to F4.

For most of 2014, HHSC program staff focused on the clinical aspects of the drugs, but the high drug cost remained a concern. Because Sovaldi was not yet on the Texas Medicaid formulary, Gilead leadership asked to meet with HHSC executive leadership, and a meeting was conducted on August 6, 2014. The Gilead executives and representatives in attendance were:

- Kacy Hutchison, Vice President of Government Affairs
- Coy Stout, Vice President of Managed Markets
- Justin Crum, Director, National Accounts, Strategic Accounts Central
- Tyler Hunter, Executive Manager, National Accounts

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. Gilead offered no meaningful discounts until January 2015 when two other second generation HCV drugs entered the market: Harvoni (also by Gilead) and AbbVie, Inc.'s (AbbVie) Viekira Pak.

In October 2014, HHSC's Preferred Drug List (PDL) vendor, Magellan Medicaid Administration, sent solicitation letters to all manufacturers of second generation HCV drugs. These letters solicited manufacturers to provide their supplemental rebate offers so the same could be presented to the P&T Committee in its January of 2015 meeting. During this period, but prior to the P&T Committee meeting, HHSC and Gilead discussed coverage criteria and drug price/rebates on multiple occasions. Attachment 2 lists the conversations HHSC held with representatives of Gilead in 2014 and 2015.

In early January 2015, news outlets reported that Express Scripts—the nation's largest pharmacy benefits manager—had signed an exclusive arrangement with AbbVie to make Viekira Pak its sole preferred second generation HCV drug. Shortly after that announcement, and leading up to the January P&T Committee meeting, Gilead met with Texas HHSC again and offered a more substantial supplemental rebate. The deadline for submitting supplemental rebate offers had expired, but HHSC made an exception because of the particular nature of the situation. To be fair, HHSC also allowed AbbVie to revise its offer (post-deadline) and AbbVie did.

Upon completion of their January 2015 review, the P&T Committee recommended Viekira Pak as the preferred product for recipients in both fee-for-service traditional Medicaid and managed care Medicaid. The committee's decision was based on the understanding that both Harvoni and Viekira Pak were effective treatments, but because AbbVie submitted more aggressive rebates to HHSC's PDL vendor, Viekira Pak was more cost effective.

In Texas, almost 90 percent of Medicaid recipients receive benefits through a managed care organization (MCO). When Sovaldi was the only U.S. Food and Drug Administration (FDA)

approved second generation HCV drug, there was much uncertainty about potential expenditures, and calculating an actuarially-sound MCO premium rate that took this drug into account was not possible. Therefore, HHSC was forced to develop an MCO contract amendment and obtain approval from the Centers for Medicare & Medicaid Services to reimburse MCOs for the cost of second generation HCV drugs through a separate non-risk-based payment process. In Texas' managed care Medicaid, second generation HCV drugs are the only products that are "carved-out" of the MCO premium rate. HHSC's policy has consistently required MCOs to assume the risk for all prescription drugs.

Like all states, Texas struggles with the challenge of trying to provide beneficiaries with maximum access to second generation HCV drugs without compromising its Medicaid program's solvency. In Texas, approximately 17,000 Medicaid recipients (primarily adults) were identified with a primary diagnosis of Hepatitis C. Based on HHSC's medical-necessity criteria, product indications, and HCV population demographics, HHSC forecasted potential utilization, and estimates that approximately 1,200 recipients per fiscal year will obtain second generation HCV drugs. The table below provides the estimated net costs per year after all rebates.

	FY 2015 (Apr - Aug)	FY 2016	FY 2017	FY 2018
All Funds*	**$ 20.1**	**$ 65.8**	**$ 53.4**	**$ 54.7**
Federal Funds*	$ 11.7	$ 27.1	$ 23.3	$ 23.9
TX General Revenue*	$ 8.4	$ 38.7	$ 30.0	$ 30.9

Notes

- ** All dollar amounts in millions*
- *Analysis is based on three Hepatitis C treatments: Viekira (12-week), Viekira + Ribavirin (12-week), and Sovaldi (24-week).*
- *Assumed effective date April 2015 with pent-up demand assumed in State Fiscal Year (SFY) 2015.*
- *HHSC System Forecasting, March 2015*

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 HHSC 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.

In January 2015, Texas Medicaid began limited coverage of Sovaldi and Olysio (manufactured by Johnson and Johnson) on an exception basis for recipients with HCV and the most urgent medical needs. In April 2015, Texas Medicaid fully implemented its coverage of the second generation HCV drugs.

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 programs.

HHSC is hopeful that as new HCV and other breakthrough drugs are approved, market forces will reduce costs. Otherwise, Texas and all other states will experience budgetary difficulties that could negatively affect the Medicaid program.

Your exploration of these issues is greatly appreciated. If you would like additional information or have additional questions, please contact me at 512-707-6142 or by email at Andy.Vasquez@hhsc.state.tx.us.

Sincerely,

Andy Vasquez
Texas Health and Human Services Commission
Medicaid/CHIP Deputy Director, Vendor Drug Program

Attachment 1

TEXAS HEALTH AND HUMAN SERVICES COMMISSION

KYLE L. JANEK, M D.
EXECUTIVE COMMISSIONER

July 29,2014

Ms. Stephanie Tran
Associate Manager, Medical Information
Gilead Sciences, Inc.
333 Lakeside Drive
Foster City, CA 94404

Ms. Tran:

We are writing to request clinical data from Gilead Sciences to answer pertinent questions on the Hepatitis C drugs, Sovaldi (sofosbuvir) and the combination drug, ledipasvir/sofosbuvir.

Chronic Hepatitis C is estimated to affect 3.2 million people in the United States and has a high prevalence rate in patients with income below the poverty line. Hepatitis C affects a large number of Texas Medicaid patients and, with the high cost of treatment, it will represent a significant cost to the state of Texas.

The preliminary clinical evidence prompted the FDA to grant Sovaldi a Priority Review and Breakthrough Therapy designation, which it awards products for indicating substantial improvement over available therapies for patients with serious or life threatening diseases, can cut the FDA review time from 10 months to 6 months. The FDA has also granted ledipasvir/sofosbuvir a Breakthrough Therapy designation. There is evidence of the benefits Sovaldi, and by extension ledipasvir/sofosbuvir, will bring to our Hepatitis C patients. However, the full extent of benefits, as well as potential deficits, remains out of reach. The state of Texas is dedicated to providing the most prudent, cost-efficient, and beneficial health care to our Texas Medicaid clients. We have been diligently reviewing clinical information, as well as several guidelines to help form an appropriate clinical edit. As we recommended by our Drug Utilization Board, we have been reaching out to stakeholders for additional input and concerns.

The available guidelines and reviews have been helpful in our draft of a clinical edit. In our review of both the guidelines and the available studies, questions have remained that need to be answered so we can guarantee every step of our clinical edit is founded on the most current and complete information. With such a significant impact on the state health care budget, there is

very little room for error. We appreciate that some information has been published and provided for both products, but there is still data that would be crucial to providing the most accurate representation of cost-effective treatment, based on available clinical evidence.

In order to help us address these items, we are asking Gilead Sciences for the following:

- All data on adverse effects from all studies that have been published, presented, and/or available for both Sovaldi and ledipasvir/sofosbuvir.
- All data to calculate incidence of relapse after SVR12 for all studies that have been published, presented, and/or available for both Sovaldi and ledipasvir/sofosbuvir.
- A flow diagram showing what happened to all people who were initially screened for enrollment in any study studies that have been published, presented, and/or available for both Sovaldi and ledipasvir/sofosbuvir.
    - Study investigators should complete a full CONSORT flow diagram (available at www.consort-statement.org/).
    - For each outcome reported there should be a clear indication of the numerator and denominator for each of the outcomes analyzed.
    - SVR12 and SVR 24 data for all studies that have been published, presented at a meeting, or available to the investigators or manufacturers.
    - Please include data that may have been incomplete from any studies that have been sent to HHSC staff.
- Quality of life data for all studies that have been published, presented, and/or available for both Sovaldi and ledipasvir/sofosbuvir..

We ask that all material be provided in a format that staff can employ to adjust our clinical edit criteria. We appreciate your continued cooperation and timeliness in this matter.

Please let me know if you have any questions or need additional information. Joshua Dominguez Pharm. D., Vendor Drug Pharmacist, serves as the lead staff on this matter and can be reached by telephone at 512-462-6390 or by email at Joshua.Dominguez@hhsc.state.tx.us.

Sincerely,

Andy Vasquez
Medicaid/CHIP Deputy Director, Vendor Drug Program

Attachment 2

Meetings between Health and Human Services (HHSC) staff and Gilead Sciences, Inc. regarding clinical and financial considerations of Texas Medicaid coverage of Sovaldi and Harvoni.

Meeting Date	Description
May 6, 2014	Discuss coverage status of Sovaldi. Gilead representatives include: Tyler Hunter
June 2, 2014	Discuss coverage status of Sovaldi. Gilead representatives include: Tyler Hunter
June 20, 2014	Clinical update on Sovaldi Gilead representatives include: Tyler Hunter, Michelle Puyear
July 29, 2014	HHSC letter to Gilead requesting detailed clinical data
Aug. 6, 2014	Meeting with HHSC executive commissioner requested by Gilead to discuss coverage of Sovaldi Gilead representatives include: Kacy Hutchison, Coy Stout, Justin Crum, Tyler Hunter
Aug. 13, 2014	Detailed discussion of HHSC's clinical data request. Gilead representatives: Michelle Puyear, Tyler Hunter
Oct. 21, 2014	Initial discussion regarding Harvoni; including clinical and rebate considerations Gilead representatives include: Tyler Hunter, Michelle Puyear
Nov. 14, 2014	Discuss Gilead rebate offers for Harvoni and Sovaldi. Note: HHSC conveyed our continued, serious concerns with Gilead's pricing structure and they committed to taking our request to their management with response expected by the next week. Gilead representatives include: Coy Stout, Justin Crum, Tyler Hunter, Erin Smith
Nov. 20, 2014	Discuss enhanced Gilead rebate offer. Gilead offered slight increase from original offer for Harvoni and extended offer to Sovaldi. Gilead representatives include: Justin Crum, Tyler Hunter, Erin Smith (Gilead Government Affairs)
Dec. 4, 2014	Touchbase meeting regarding HHSC evaluation of enhanced rebate offers. Gilead representatives include: Justin Crum, Tyler Hunter
Dec. 17, 2014	Touchbase meeting regarding HHSC evaluation of enhanced rebate offers. Gilead representatives include: Justin Crum, Tyler Hunter
Jan. 7, 2015	Touchbase meeting regarding HHSC evaluation of enhanced rebate offers. HHSC offers extension to supplemental rebate offer submission deadline based on Gilead commitment to submit a new, revised final offer. Gilead representatives include: Justin Crum, Tyler Hunter
Jan. 16, 2015	Pre-P&T Committee meeting discussion regarding Gilead's final, revised offer. Gilead representatives include: Coy Stout, Kimberly Hawkins, Justin Crum

Exhibit 12

GILEAD
Advancing Therapeutics.
Improving Lives.

Wednesday, July 1, 2015

Dear Community Partner,

Gilead has always been an advocate for patient access to therapies in the areas in which we work. I am writing to provide you with an update regarding Support Path, our patient support program for individuals living with chronic hepatitis C.

As you may be aware, Support Path is designed to help patients in the U.S. with high co- pays or who lack adequate insurance access Sovaldi or Harvoni. The Support Path program provides assistance to patients who are uninsured or who need financial assistance to pay for the medicine.

Key components of the program include:

- The Sovaldi and Harvoni Co-pay Coupon Program, which minimizes monthly out-of-pocket costs for eligible patients* to as little as $5 per month
- The Support Path Patient Assistance Program, which will provide Sovaldi or Harvoni at no charge for eligible patients

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 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.

With that in mind, effective July 1, 2015, the following changes will be implemented. Gilead anticipates these changes will not impact the majority of patients helped by our patient support programs.

Specifically, patients 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.

**You are not eligible if you are enrolled in a government healthcare prescription drug program such as Medicaid or Medicare Part D*

For Sovaldi and Harvoni patients who are insured and have been denied coverage by their payer, Support Path can assist patients with the requirements for submitting appeals, peer reviews and understanding the process for in-person hearings if required.

Gilead continues to support open access to hepatitis C therapies – with prescribing decisions made by a physician in partnership with his or her patient. We will continue to work with payers to provide information that conveys the profile of our hepatitis C medications and the benefit of curing individuals living with the virus. We believe that payers should take the responsibility to provide coverage for their insured patients based on the treatment decisions of their healthcare providers.

Through Gilead's Support Path Program, which provides a comprehensive suite of patient assistance resources, we are committed to our mission of helping patients in financial need access our products, and to ensuring our patient assistance program reaches eligible uninsured patients.

As always, we appreciate the ongoing dialogue with our community partners and look forward to continuing to collaborate with you on efforts to expand access to life-saving therapies.

Best regards,

Coy Stout
Vice President, Managed Markets
Gilead Sciences, Inc.

Exhibit 13

HCV Fair Pricing Coalition Meeting
Thursday, October 3, 2013

Gilead Sciences
368 Lakeside Drive
Foster City, CA

9:30 a.m.	**Welcome and Introductions**	David Johnson *Sales and Marketing*
9:45 a.m.	**Sofosbuvir Clinical Update**	John McHutchison *Liver Disease Therapeutics*
10:15 a.m.	**Considerations in the Management of HCV**	Janice Tam *Medical Affairs*
11:15 a.m.	**Payer Landscape in HCV: Considerations for Sofosbuvir**	Coy Stout *Managed Markets*
12:15 p.m.	**Working Lunch**	
1:00 p.m.	**Discussion**	**All**
1:30 p.m.	**Patient Support Landscape**	Jim Drew *Business Operations*
2:15 p.m.	**Discussion**	**All**
3:00 p.m.	**Closing and Next Steps**	**All**

****

Additional Gilead Participants
Bill Guyer
Medical Affairs

Cara Miller
Public Affairs

Michele Rest
Public Affairs

FPC Participants
Bill Arnold
Community Access National Network

Bruce Burkett
Missouri Hep C Alliance

Ryan Clary
National Viral Hepatitis Roundtable

Lynda Dee
AIDS Action Baltimore

Michael Ninburg
Hepatitis Education Project

Murray Penner
NASTAD

Lorren Sandt
Caring Ambassadors

Exhibit 14

FPC Gilead 10-3-13 Meeting Agenda (FOR FPC ONLY)

WAC price of Incivek: $60,470 + $30,000

WAC price of Victrelis: $60,873 + $30,000

Argue only for a lower price than SOC. Arguments for a lower price:

Limited window before inf free DAA regimens are available

We believe Merck and Vertex will be lowering their prices to protect their market share. How low are you willing to go to obtain market share?

It's a new day. ACA Exchanges and other formularies are looking for lowest prices. Provide examples of state and private payer formularies, e.g., Oregon and United Healthcare that is prior authorizing their HIV FDC Stribild because of the cost. Volume, volume, volume is the key to them obtaining the highest market share. Acknowledge the cost-effectiveness of cost per cure, but also argue that pricing themselves out of the market will result in shooting themselves in the foot. What they do now will affect what portion of the market they will corner with their FDC in the future.

AbbVie is going to beat them to the inf free table. How they price sofosbuvir now will determine what their ultimate FDC of 7977 and 5885 will cost if they do the same thing in HCV as in HIV, i.e., charge the same for the component parts of the FDC as for the individual drug. Is that their plan for the HCV FDC? Will they continue to make sofosbuvir available as a stand alone drug?

What Phase IV studies do you have planned for sofosbuvir with other drugs, in the ACTG?

Request an update on their Expanded Access clinical trials, including the number of people enrolled and if they intend to initiate any other EAP trials for other populations, e.g. post-transplant patients and people with bleeding disorders. (Any other populations not now covered.)

Exhibit 15

Gilead 12-6-13 Call Notes

For the FPC: Ryan Clary, Lynda Dee, Michael Ninburg and Lorren Sandt

For Gilead: David Johnson, Bill Guyer, Coy Stout and Cara Miller

Price:

Sovaldi WAC is $84,000 for a 12 week regimen for GT 1, 2 and 4, not including $9,000 for 12 weeks of inf/r. The Sovaldi WAC is less than Olysio + 24 weeks of inf/r. ($84,360).

The price is double for a 24 week GT 3 regimen or $186,000. Gilead stated that they looked at capping the 24 week price, but that this was not possible because they would have had to use only one specialty pharmacy provider. This would mean out of network charges for many patients and an even higher price.

Gilead thinks the broad FDA indications for GT 1, 2, 3 and 4 as well as pre-transplant and co-infected patients and all oral Sovaldi 24 week regimens for inf intolerant patients will be helpful in ensuring payer reimbursement, even for the 24 week regimen, especially if the AASLD promulgates HCV Treatment Guidelines next year, hopefully in January.

Gilead will be shipping Sovaldi on Monday and it will be available in US pharmacies by mid-week, barring unforeseen weather conditions.

In response to disappointment expressed about price, Gilead discussed their access programs at length and said they are working with all payers and will do unbranded education about the need for people to see be tested and be treated. Gilead is speaking with state Medicaids, starting with problem states like Illinois that have budget crises.

Gilead access concessions are as follows: (They gave us every single thing we asked for and more.)

- The SupportPath patient assistance program (PAP) with a $100,000 maximum income requirement for a household of three and 500% of the federal poverty level (FPL) for larger households. See www.supportpath.com or also on the Gilead.com web sight accessible after a few clicks. Contact #: 855-769-7284 (855-7mypath). Gilead will have 40 counselors available for case management/benefits counseling who will investigate insurance options and program eligibility. There will also be warm transfer to other companies' PAPs.

- There will 24/7 nursing support and educational info on their web site.

- They send extensive E-communications to pharmacists regarding directions for Sovaldi ordering and access programs as well as the indications.

- The SupportPath™ Sovaldi™ co-pay coupon program will provide co-pay assistance for eligible patients with private insurance, including Affordable Care Act Marketplace exchange patients, who need assistance paying for out-of-pocket medication costs. Most patients will pay no more than $5 per co-pay. Co-pay assistance of up to 20% of the WAC price or $16,000 for Sovaldi can also be applied toward prescription deductibles and co-insurance obligations. These are huge victories for us!!!

- Gilead has made a substantial contribution to the Patient Access Network (PAN) for co-pay assistance for Medicare Part D clients.

- Gilead has initiated an emergency Sovaldi supply program for patients that may lose their prescriptions ala their HIV PEP program that has a lot of experience shipping HIV antivirals to HIV needle stick patients very quickly.

- Gilead has agreed to ensure access to its PAP or co-pay assistance programs for AIDS Drug Assistance Program (ADAP) patients who are co-infected with HIV, even in states with ADAP programs that will not include Sovaldi on their formularies. Gilead will not be lobbying state ADAPs to add Sovaldi to their formularies at least this year.

- Gilead WILL NOT be working with Harbor Path at this juncture.

Gilead is also working with payers to ensure Sovaldi is included in lower tiers and with the USP to ensure that HCV drugs are included in updated categories since state marketplaces are using them to develop formularies.

Miscellaneous Issues:

Lorren made the points that some states will not be including Sovaldi on their Medicaid formularies and will only be allowing specialists to prescribe Sovaldi. Gilead agreed to look into it this.

Michael asked questions about off-label use and a direct link to PAN on their web site. Gilead stated that while they were not promoting off-label use, they would not require anything but an Rx from a physician to supply a patient with Sovaldi SupportPath access, without requesting what actual regimen a person would be using. They also agreed to look into a PAN link.

I think it was Bill that asked about access for undocumented people. Gilead said although supplying a SSN will make the access process faster, they are not requiring legal alien status, only US residency is required.

Lynda made the point that Gilead needs to go the extra mile to disseminate their SupportPath access programs. She e-mailed them on 12-7-13, asking them to include the underinsured program information on their web site, have their salespeople have written SupportPath info when they visit docs and clinics and include the SupportPath link and contact info and their HIV access program info in their ads.

Gilead ended the call thanking us and agreeing to keep the lines of communication open so that we can continue to discuss future access issues as they occur.

Exhibit 16

FAIR PRICING COALITION

April 14, 2014

Coy Stout, Vice President, Managed Markets
Kristie Banks, Senior Director, Business Operations and Contract Compliance
Jim Drew, Director, Business Operations and Contract Compliance
Amy Flood, Vice President, Public Affairs
Michele Rest, Director, Public Affairs

Gilead Sciences
333 Lakeside Drive
Foster City, CA 94404

Dear Coy, Kristie, Jim, Amy and Michele:

Thank you for the March 25, 2014, call with the Fair Pricing Coalition. Please allow this letter to serve as a follow up to this important discussion, particularly the pressing issue of Sovaldi (sofosbuvir) pricing and access.

We want to address your claim that third-party payers have utilized the media's attention to Sovaldi's exorbitant price to negotiate with Gilead by proxy. We understand that Gilead was not expecting the payer backlash and the furor that has erupted. That said, 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 a respectable profit for the company, while being priced so that it is accessible for the millions of patients for whom Sovaldi is indicated.

To that end, in an effort to keep Sovaldi and Gilead's antiretrovirals affordable and accessible, we urge you to fulfill *all* of the following requests:

- Provide additional rebates for Sovaldi to state Medicaid programs over and above the legally required initial Medicaid rebate offering. Claims that this will slow the Medicaid formulary process are unfounded. We also encourage you to continue rebate agreements with state Medicaid programs for your antiretrovirals, similar to the recent agreement with the New York State Medicaid Director.

- Continue providing additional discounts/rebates to ADAPs over and above those required by the 340B program.

- Refrain from making any changes to current ADAP rebate policies until HRSA can craft sound guidance. We do not need yet another drug access crisis. This is especially relevant for Sovaldi. ADAP clients deserve the chance to access Sovaldi, with its label indication for people coinfected with HIV and HCV, despite Gilead's decision not to promote the inclusion of Sovaldi on ADAP formularies.

- Disclose the number of patients on all your HIV and HCV access programs and your eligibility formula for underinsured patients. This is our second request for this information and it is essential that you be transparent in these matters.

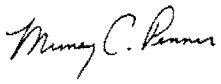
- Provide all underinsured HIV and HCV patients with 100% coverage of all out-of-pocket (OOP) costs, including co-pays, deductibles, co-insurance or any other related prescription costs for all Gilead HIV and HCV prescriptions. We make this request in light of reports from individuals throughout the U.S. who are not taking their medications because they cannot afford the OOP cost(s).

- Provide us with full details of information and data submitted to the Waxman Briefing.

- Institute a price freeze for all HIV and HCV drugs for the next two years and henceforth for a two-year period from the date of FDA approval of all new HIV and HCV drugs.

- Refrain from referring to the FPC when negotiating or discussing your drug prices or access programs. Even though you did not intend to use the FPC for cover, we have heard of your references to early negotiations with this coalition that are being misinterpreted to mean that FPC is supportive of the price established for Sovaldi. The only sure way to avoid this in the future is for you not to refer to the FPC, either publicly or privately, going forward.

Please contact us with your responses as soon as possible and thank you for your anticipated cooperation.



Murray Penner
On behalf of the FPC

Exhibit 17

From: William Dozier **Redacted**
Sent: Sunday, May 11, 2014 6:41 PM
To: Brown, Douglas M.
Cc: Eric Kimelblatt
Subject: Magellan Offer

Importance: High

Hello Doug,

Here are the terms as approved by our legal dept. Though there are minor edits, the structure and terms are exactly the same as we reviewed with you on the phone last week. Our Foster City team will be submitting these exact terms to your FTP site online by Monday morning.

- 6% discount- Parity status on PDL. Any PA criteria imposed on Sovaldi shall be no more restrictive than patients with F2-F4 fibrosis scores.

- 8% discount: Parity status on PDL. Any PA criteria imposed is consistent with and no more restrictive than the FDA approved label.

- 10% discount: Parity status on PDL. 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.

- For all states that accept any discount level, they must immediately remove any current restrictions on Sovaldi that are more restrictive than the corresponding criteria listed above.

Best regards,

William

William E. Dozier, MBA
Senior Manager, National Accounts
Strategic Accounts East
Gilead Sciences
Redacted

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YII=]<https://webmail.gilead.com/OWA/?ae=Item&a=New&t=IPM.Note#>

Exhibit 18

From: Brown, Douglas M.
Sent: Monday, May 19, 2014 3:42 PM
To: Lennertz, Matthew D.
Cc: Brown, Douglas M.; Andrews, Christopher J.
Subject: Sovaldi Supplemental Rebate Offer

Our negotiations with Gilead have produced a supplemental rebate offer on Sovaldi. As states begin to ***actively*** manage access to this drug (with many states including fibrosis scores of F3 or greater and other aggressive criteria) Gilead has come forward with 3 offers. The three offers are as follows:

- **6% discount - Unique Position 1**. Any PA criteria imposed is consistent with and no more restrictive than the FDA approved label. Additional restriction for fibrosis score (Metavir) of F2-F4 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.

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.

For those states that wish to accept the rebate offer, please consult with your contract analyst to commence invoicing and copy Chris Andrews and myself.

Let me know if you have any questions

Thanks,

Doug

Douglas M. Brown R.Ph., MBA
Sr. Director, Pharmacy Pricing and Value Based Solutions
Magellan Medicaid Administration

Redacted

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Exhibit 19

From: Brown, Douglas M.
Sent: Thursday, June 05, 2014 3:07 PM
To: Brown, Douglas M.; William Dozier; Andrews, Christopher J.
Subject: RE: Offer Update

William,

(additional info)

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

Doug

-----Original Message-----
From: Brown, Douglas
Sent: Thursday, June 05, 2014 12:56 PM
To: 'William Dozier'; Andrews, Chris
Subject: RE: Offer Update

CT is 10%. No word from NY.

-----Original Message-----
From: William Dozier **Redacted**
Sent: Thursday, June 05, 2014 12:50 PM
To: Brown, Douglas; Andrews, Chris
Subject: Offer Update

Hello Doug,

Have all states contacted you to accept/decline the offer?

CT accepted at 8% and NY is evaluating, correct?

Best regards,

William

William E. Dozier, MBA
Senior Manager, National Accounts
Strategic Accounts East
Gilead Sciences
Redacted

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e#>

Exhibit 20

Ohio | Department of Medicaid

John R. Kasich, Governor
John B. McCarthy, Director

August 7, 2015

Mr. Peter Gartrell
U.S. Senate Committee on Finance
Ranking Member Ron Wyden (Oregon)
219 Dirksen Senate Office Building
Washington, D.C. 20510

Dear Mr. Gartrell:

In response to your inquiry regarding any records of emails or meetings between Ohio Department of Medicaid (ODM) officials and Gilead where concerns were expressed about the price of the drug please see below:

June 26, 2014 conference call with Gilead and ODM: ODM staff included Margaret Scott, RPh, Michael Howcroft, RPh, Patricia Nussle, RPh, Anam Khan, college intern and Xerox State Healthcare (ODM contractor): Sandra Kapur, PharmD

David Kaufman
Manager, National Accounts
Strategic Accounts Central
Gilead Sciences
Cell: 919.791.8715
Office: 740.474.2142
VM: 800.915.3003 x 5306
david.kaufman@gilead.com

Justin Crum
Director, National Accounts
Strategic Accounts Central
Gilead Sciences
Phone: 650-522-2399
Justin.Crum@gilead.com

Sept. 24, 2014 In-person meeting with ODM Director John McCarthy, David Salisbury, Legislative Liaison, Margaret Scott, RPH, Debbie Saxe, Health Plan Policy Chief and Gilead representatives Rebecca O'Hara, Paul Miner, Justin Crum, local representation Joshua Sanders

Rebecca O'Hara
Associate Director
Government Affairs
Gilead Sciences, Inc.
Phone: 850-339-6211
Rebecca.O'Hara@gilead.com

Joshua R. Sanders, Esq.
Calfee, Halter & Griswold LLP
Phone 614-621-7763
jsanders@calfee.com

Paul Miner, PharmD, Assoc. Director
Medical Sciences
Managed Care & Government Accts.
Gilead Sciences, Inc.
810-333-5818 (c)
paul.miner@gilead.com

Sincerely,

John B. McCarthy, Director

50 W. Town Street, Suite 400
Columbus, Ohio 43215

An Equal Opportunity Employer and Service Provider

Exhibit 21

From: Janet Z Zachary-Elkind (health.ny.gov) **Redacted**
Sent: Tuesday, September 09, 2014 5:25 PM
To: 'Kacy.Hutchison@gilead.com'
Cc: Ttress@ **Redacted** Anthony V Merola (health.ny.gov); Barbara Rogler (health.ny.gov); Michael Colabufo (health.ny.gov)
Subject: Analysis
Attachments: Sovaldi projections.pdf

Hi Kacy:

Attached is our analysis regarding CHC prevalence in NY Medicaid and our estimates regarding number of beneficiaries that could potentially be treated with Sovaldi.

The first chart identifies the total number of beneficiaries with Chronic Hepatitis C (CHC) and anticipated spend, based on the % of beneficiaries potentially treated. 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.

Let me know if you have any questions or would like to discuss further.

Janet

Janet Zachary-Elkind, Deputy Director
Division of Program Development and Management
Office of Health Insurance Programs
NYS Department of Health
Redacted

Pharmacy Fiscal Analysis - Sovaldi
Based on claims with service dates December 13, 2013 through April 30, 2013.
Data Source: Medicaid Data Warehouse - data extracted by SUNY Buffalo on 6/3/14

All Chronic HCV Beneficiaries[1]		
Potential New Chronic Hepatic Infection Treatment	Estimated Number of Beneficiaries with Chronic Hepatitis C Infection (n=57,897)	Estimated Amount Reimbursed to Pharmacies ($)[3]
1%	579	$50,368,086
2%	1,158	$100,736,171
3%	1,737	$151,104,257
5%	2,895	$251,840,428
10%	5,790	$503,680,857
20%	11,579	$1,007,361,714
100%	57,897	$5,036,808,570

Total Possible Members 57,897

Chronic HCV Beneficiaries - Targeted Treatment Group[2]		
Potential New Chronic Hepatic Infection Treatment	Estimated Number of Beneficiaries with Chronic Hepatitis C Infection (n=35,010)	Estimated Amount Reimbursed to Pharmacies ($)[3]
1%	350	$30,457,307
2%	700	$60,914,613
3%	1,050	$91,371,920
5%	1,751	$152,286,533
10%	3,501	$304,573,066
20%	7,002	$609,146,132
100%	35,010	$3,045,730,660

Total Possible Members 35,010

Footnotes:

1. See notes below on how Chronic Hep C was defined. Existing Sovaldi patients(1,754) are included in the totals.
2. Targeted Treatment Group = Patients coinfected with HIV and/or HBV (n=14,070), patients with liver disease have progressed to a stage that requires HCV treatment to prevent further liver
3. Total Cost of treatment calculated to be $86,992. Includes 84 day regiment of Sovaldi, Ribavirin and Peg Interferon at FFS reimbursement. Genotype 1 accounts for approximately 70% (OHSU) of people infected. The remaining 30% could utilize therapy for a longer duration.

Notes:

The 57,897 are patients with a diagnosis of chronic hepatitis C as identified by ICD-9 codes. The medications are only FDA approved for patients with a diagnosis of chronic hepatitis C (CHC). There are no other Compendia-supported indications for the drugs. 57,897 was then reduced to the 35,010 patients (e.g. patients with HIV/AIDS, chronic liver disease or extra hepatic manifestations per the suggested clinical criteria).

Chronic Hep C was identifed using the following codes:

ICD-9	Description
7044	CHRONIC HEPATITIS C WITH HEPATIC COMA
7054	CHRONIC HEPATITIS C WITHOUT MENTION OF H

Exhibit 22

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

March 20, 2014

Dr. John C. Martin, PhD
Chief Executive Officer
Gilead Sciences Inc.
333 Lakeside Drive
Foster City, CA 94404

Dear Dr. Martin:

We are writing to request a briefing from Gilead Sciences Inc. to answer important questions about the pricing of the company's recently approved Hepatitis C drug, Sovaldi.

A breakthrough treatment for Hepatitis C could result in significant public health benefits. Approximately 3.2 million Americans have a chronic Hepatitis C infection, and the illness causes approximately 15,000 deaths in the United States annually.[1] There is no vaccine for Hepatitis C, which causes fatal cirrhosis or liver cancer in up to 5% of affected individuals.[2]

There is evidence that Sovaldi could be a breakthrough treatment. According to FDA, "Sovaldi was effective in treating multiple types of the hepatitis C virus. ... demonstrat[ing] efficacy in participants who could not tolerate or take an interferon-based treatment regimen and in participants with liver cancer awaiting liver transplantation, addressing unmet medical needs in these populations."[3]

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[1] CDC, Hepatitis C FAQs for the Public (2014) (online at http://www.cdc.gov/hepatitis/c/cFAQ.htm#statistics); New York Times, *Awareness: Hepatitis C Death Rate Creeps Past AIDS* (Feb. 27, 2014) (online at www.nytimes.com/2012/02/28/health/research/hepatitis-c-deaths-creep-past-aids-study-finds.html?_r=1&).

[2] CDC, Hepatitis C FAQs for the Public (2014) (online at http://www.cdc.gov/hepatitis/c/cFAQ.htm#statistics); New York Times, *Awareness: Hepatitis C Death Rate Creeps Past AIDS* (Feb. 27, 2014) (online at www.nytimes.com/2012/02/28/health/research/hepatitis-c-deaths-creep-past-aids-study-finds.html?_r=1&).

[3] FDA, FDA Approves Sovaldi for Chronic Hepatitis C (Dec. 6, 2013) (online at http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm377888.htm).

Our concern is that a treatment will not cure patients if they cannot afford it. Reports indicate that Gilead intends to sell Sovaldi at $84,000 per treatment.[4] In cases where Sovaldi is prescribed with other treatments the costs could be even higher. According to a recent Reuters report, "many doctors are requesting a $150,000 combination of Sovaldi ... and Olysio."[5]

These costs are likely to be too high for many patients, both those with public insurance and those with private insurance.[6] 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.[7] 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.[8] California's Medicaid program is still considering how and when to reimburse for the drug.[9] The large pharmacy benefit manager Express Scripts has said it is "encouraging some doctors in its networks to delay prescribing Sovaldi."[10] 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.

The extraordinarily high cost of your drug raises additional concerns because of the role of the federal government in speeding its approval. In April 2013, Gilead submitted a New Drug Application to the Food and Drug Administration for approval of Sovaldi for the treatment of Hepatitis C. As part of the request, Gilead filed for and received a Priority Review and Breakthrough Therapy designation, which reduces the FDA review goal date from ten to six

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[4] Washington Post, *Costly Hepatitis Drug Sovaldi Rattles Industry* (Mar. 1, 2014) (online at http://www.washingtonpost.com/national/health-science/costly-hepatitis-drug-sovaldi-rattles-industry/2014/03/01/86cab0b4-a091-11e3-9ba6-800d1192d08b_story.html).

[5] Reuters, *Insurers, Medicaid fear multibillion-dollar hepatitis C drug tab* (Mar. 4, 2014) (online at www.reuters.com/article/2014/03/04/us-health-hepatitis-idUSL1N0M10Z720140304).

[6] Bloomberg, *At $84,000 Gilead Hepatitis C Drug Sets Off Payer Revolt* (Jan. 27, 2014) (online at http://www.bloomberg.com/news/2014-01-27/at-84-000-gilead-hepatitis-c-drug-sets-off-payer-revolt.html).

[7] Bloomberg, *Hepatitis C Drug Price Limiting State Medicaid Approvals* (Mar. 5, 2014) (online at www.bloomberg.com/news/2014-03-05/hepatitis-c-drug-price-limiting-state-medicaid-approvals.html).

[8] *Id.*

[9] Reuters, *Insurers, Medicaid fear multibillion-dollar hepatitis C drug tab* (Mar. 4, 2014) (online at www.reuters.com/article/2014/03/04/us-health-hepatitis-idUSL1N0M10Z720140304).

[10] Washington Post, *Costly Hepatitis Drug Sovaldi Rattles Industry* (Mar. 1, 2014) (online at http://www.washingtonpost.com/national/health-science/costly-hepatitis-drug-sovaldi-rattles-industry/2014/03/01/86cab0b4-a091-11e3-9ba6-800d1192d08b_story.html).

months.[11] This designation is awarded to medicines that meet certain criteria, including "that the drug may have substantial improvement on at least one clinically significant endpoint over available therapy."[12] The FDA approved Sovaldi on an expedited basis on December 6, 2013.[13]

This history raises many questions about Gilead's approach to pricing this drug and the impact the high cost may have on public health. In order to address these issues, we ask that you brief Committee staff on a number of key questions, including:

(1) The methodology used by Gilead to establish Sovaldi's pricing.
(2) The extent to which Gilead is providing discounts to low-income patients and to key government or private-sector purchasers of the drug.
(3) The value to the company of the expedited review provided under the Priority Review and Breakthrough Therapy designation and how any savings provided by the expedited review factored into pricing decisions for the drug.
(4) The public health impact of insurers' and public health programs' decisions not to cover Sovaldi for all patients with Hepatitis C.

We ask that you provide this briefing no later than April 3, 2014. Please contact Brian Cohen of the Committee staff at (202) 225-3641 if you have any questions.

Sincerely,

Henry A. Waxman
Ranking Member

Frank Pallone, Jr.
Ranking Member
Subcommittee on Health

Diana DeGette
Ranking Member
Subcommittee on Oversight and Investigations

---

[11] Food and Drug Administration, *Regulatory Information* (online at www.fda.gov/regulatoryinformation/legislation/federalfooddrugandcosmeticactfdcact/significantamendmentstothefdcact/fdasia/ucm341027.htm).

[12] *Id.*

[13] Food and Drug Administration, *FDA Approves Sovaldi for Chronic Hepatitis C* (press release) (Dec. 6, 2013) (online at www.fda.gov/newsevents/newsroom/pressannouncements/ucm377888.htm).

Exhibit 23

CVSHealth

Analysis of "Real World" Sovaldi® (sofosbuvir) Use and Discontinuation Rates

September 2014

Troyen A. Brennan, M.D., Chief Medical Officer, CVS Health; Alan Lotvin, M.D., Executive Vice President, CVS/specialty, CVS Health; William Shrank, M.D., Chief Scientific Officer, CVS Health

Background

Sovaldi® (sofosbuvir), a new treatment for Hepatitis C manufactured by Gilead, was launched on December 9, 2013 and immediately generated an intense public debate about cost and value in health care. The medication represents an extraordinary clinical breakthrough; in clinical trials, more than 95 percent of patients with Hepatitis C experience sustained viral response, essentially a cure, compared with the 40 percent cure rate observed with prior interferon-based therapies. Treatment tolerability was a main driver of the stunning improvement in the cure rate, as only two percent of patients discontinued therapy during the trial. Substantially higher discontinuation rates have been observed among patients who used previous Hepatitis C therapies.

Sovaldi is very costly, with a list price (Average Wholesale Price) of approximately $1,000 a pill and $84,000 for a 12-week course. More than three million Americans either have Hepatitis C-caused liver disease or are carriers of the disease, highlighting the enormous possible cost of treating this condition in the U.S. This extraordinary cost has stressed commercial, state and federal budgets. While the drug is extremely effective and may offer value in terms of reducing downstream costs, the short-term monetary outlays are considerable and were largely unexpected. The costs have led to an outcry from payors and policymakers, and resulted in widespread debates about the "fairness" of the medication's pricing.

The debate about Sovaldi's efficacy, price, and value has largely been based on the current price of the medication and the results of several clinical trials. The impressive clinical trial results rely on patients' adherence to the medication, and such adherence is often not replicated in real world settings where patients are not observed as closely and where patients are often sicker, older, or more complex than those participating in clinical trials.

To date, little evidence has been presented publicly that assesses Sovaldi adherence and therapy completion rates in real world populations. Similarly, we know little about correlates of therapy discontinuation. Specifically, there is little evidence to suggest whether patients who were previously treated for Hepatitis C and failed therapy (presumably sicker patients) are more likely to complete therapy than those who are naïve to therapy. We are also unaware of any studies of the relationship between the site of delivery of Sovaldi and rates of adherence to therapy. In this White Paper we present real-world evidence about trends in Sovaldi use, rates of therapy discontinuation, and correlates of non-adherence to treatment. We also discuss expected trends as new products become available in the marketplace.

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Sovaldi Use
In the nearly nine months since Sovaldi's release, 16,560 patients with pharmacy benefits through CVS/caremark filled prescriptions for the medication. More than 65 percent of the Sovaldi regimens prescribed have been interferon-free (Table 1).

Table 1. Utilization of Sovaldi and the Regimens Used

DRUG UTILIZATION (# OF MEMBERS)*	BOOK OF BUSINESS	
	N	%
Sovaldi (sofosbuvir)	16,560	76%
Olysio (simeprevir)	5,194	24%
Total	21,754	100%
Sovaldi utilization in combination with other drugs		
Sovaldi + ribavirin ONLY	7,070	43%
Sovaldi + ribavarin + pegylated interferon	5,599	34%
Sovaldi + Olysio ONLY	3,772	23%
Total	16,441	100%

*Results bases on paid claims data

Discontinuation Rates and Correlates of Discontinuation
To study discontinuation rates, we created a cohort of patients who were continuously eligible with CVS/caremark insurance for 44 months in order to establish previous use of any Hepatitis C regimen. We identified all patients who were continuously eligible and started a Hepatitis C regimen with Sovaldi on or before 5/15/14 in order to assess rates of discontinuation or completion of the regimen. A total of 1,965 patients met this eligibility criteria.

Among those patients who began Sovaldi in combination with other medications, Sovaldi discontinuation rates were approximately four times greater than the rates observed in clinical trials (Table 2): Sovaldi+Peg-IFN+RBV (10.2 percent of patients discontinued), Sovaldi+Olysio (4.2 percent), and Sovaldi+RBV (9.0 percent). Across regimens, treatment-naïve patients were 64 percent more likely to discontinue therapy with Sovaldi than treatment-experienced patients: 8.7 percent treatment-naïve patients discontinued therapy vs. 5.3 percent for treatment-experienced patients ($p<0.05$).

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Table 2: Discontinuation Rates, by Regimen

	N Utilizer*	N Treatment Competed	%	N Treatment Discontinued†	%	Discontinuation Rates in Clinical
Sovaldi+PegIFN/RBV	738	663	89.8%	75	10.2%	2.0%
Treatment-experienced‡	145	134	92.4%	11	7.6%	
Treatment-naïve§	593	529	89.2%	64	10.8%	
Sovaldi+Olysio	547	524	95.8%	23	4.2%	3.6%
Treatment-experienced	115	112	97.4%	3	2.6%	
Treatment-naïve	432	412	95.4%	20	4.6%	
Sovaldi+RBV	680	619	91.0%	61	9.0%	0–2.0%
Treatment-experienced	97	92	94.8%	5	5.2%	
Treatment-naïve	583	527	90.4%	56	9.6%	
All Sovaldi regimens¶	1,965	1,806	91.9%	159	8.1%	
Treatment-experienced	357	338	94.7%	19	5.3%	
Treatment-naïve	1,608	1,468	91.3%	140	8.7%	

*Members who initiated therapy between 12/1/2013 and 5/15/2014, with paid claims and continuous eligibility between 1/1/2011 and 8/24/2014.

†Patients who had refill gaps exceeding the allowable gap period of 15 days were classified as discontinuers.

‡Patients who were treated with a Hepatitis C drug between 1/1/2011 and 11/30/2013

§Patients who were not treated with a Hepatitis C drug between 1/1/2011 and 11/30/2013

¶Treatment-experienced vs. Treatment-naïve; $p<0.05$.

Discontinuation rates also varied by the site of delivery. We evaluated discontinuation rates in the CVS Health organization, where specialty patients receive the same counseling and ongoing patient-centered support services from central specialists whether they access their medications through home delivery or at CVS/pharmacy retail stores through our Specialty Connect™ program. We compared discontinuation rates for patients who filled Sovaldi regimens in CVS/pharmacy retail locations or CVS/caremark specialty pharmacies with patients who filled in non-CVS Health-related outlets. To conduct this analysis, we included members who initiated therapy between 12/1/2013 and 5/15/2014, with paid claims and continuous eligibility between 12/1/2013 and 8/24/2014

In general, discontinuation rates were considerably higher in non-CVS Health outlets. When patients filled their Sovaldi regimens at either CVS/pharmacy retail stores or CVS/caremark specialty pharmacies, through the Specialty Connect™ program, they discontinued their regimens 5.9 percent of the time. Patients who filled outside of CVS Health discontinued 8.5 percent of the time, a 44 percent increased rate of discontinuation compared with CVS Health sites. Discontinuation rates were 8.8 percent for non-CVS/pharmacy retail locations and 8.3 percent for non-CVS/caremark specialty pharmacies. (Table 3)

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Table 3: Discontinuation Rates, by Delivery Channel, Within CVS/caremark Beneficiaries

REGIMEN	PHARMACY CHANNEL	MEMBERS*	TREATMENT DISCONTINUATION BEFORE 12 WEEKS†, N(%)
Sovaldi + PegIFN/RBV	CVS/caremark specialty pharmacy**	1,171	85 (7.3%)
	Non-CVS/caremark specialty pharmacy‡	731	73 (10.0%)
	-Retail	572	*63 (11.0%)*
	-Specialty	129	*9 (7.0%)*
Sovaldi + Olysio	CVS/caremark specialty pharmacy**	768	35 (4.6%)
	Non-CVS/caremark specialty pharmacy‡	552	43 (7.8%)
	-Retail	389	*31 (8.0%)*
	-Specialty	146	*11 (7.5%)*
Sovaldi + RBV	CVS/caremark specialty pharmacy**	1,096	60 (5.5%)
	Non-CVS/caremark specialty pharmacy‡	767	59 (7.7%)
	-Retail	589	*43 (7.3%)*
	-Specialty	133	*14 (10.5%)*
All Sovaldi Regimens[1]	CVS/caremark specialty pharmacy**	3,035	180 (5.9%)
	Non-CVS/caremark specialty pharmacy‡	2,050	175 (8.5%)
	-Retail	1,550	137 (8.8%)
	-Specialty	408	34 (8.3%)

Sovaldi and Olysio launched on December 9, 2013

*Members who initiated therapy between 12/1/2013 and 5/15/2014, with paid claims and continuous eligibility between 12/1/2013 and 8/24/2014.

**Includes both CVS/caremark specialty pharmacy and CVS/pharmacy retail locations through the Specialty Connect program

†Patients who had refill gaps exceeding the allowable gap period of 15 days were classified as discontinuers.

‡ Includes "other" sites: home infusion therapy provider, long term care, and institutional pharmacies

[1]CVS/caremark specialty pharmacy vs. non-CVS/caremark specialty pharmacy; p<0.001

The analysis did not adjust for benefit plan design which may provide different incentives for members to complete treatment.

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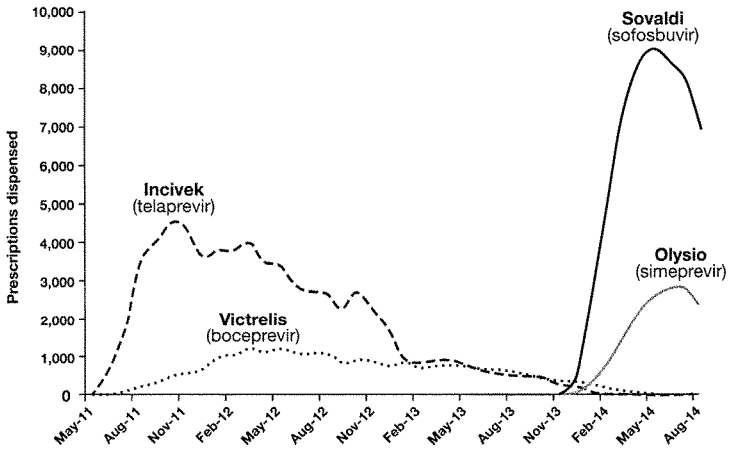
Current and Future Utilization

The practice of "warehousing" patients, waiting to treat until new and improved therapy becomes available, has a rich history in Hepatitis C. In reviewing utilization data over the last four years, it is clear that hepatologists employed an elective approach to the timing of initiation of therapy for those patients without severe sequelae from Hepatitis C. In 2011, when Incivek® (telaprevir) and Victrelis® (boceprevir) were approved for the treatment of Hepatitis C, they represented an important improvement in the ability to treat the disease. As illustrated in Figure 1 below, when these drugs became available in May of 2011 there was a rapid peak in utilization which dissipated when news of the pending availability of a new and improved therapy, Sovaldi, began to circulate. Considering that approximately half of those with Hepatitis C are carriers and unaware they have the disease (approximately 1.5 million Americans) and that the majority of the 1.5 million Americans who are diagnosed with the disease have little or no symptoms, experts suggest that these patterns of peaked use when improved treatments become available will continue.

Figure 1: Utilization Trends of Hepatitis C Treatments (May 2011 – Aug 2014)



Beginning December 2013, when Sovaldi first became available, there was a massive rush to use the medication, with increasing numbers of patients beginning treatment each month (Figure 1). This was due to the fact that in the months leading up to the Food and Drug Administration's approval of Sovaldi, many patients with Hepatitis C who were not experiencing symptoms or adverse health effects had delayed pursuing any treatment until the new, highly effective drug became available. In contrast to the rapid uptake observed initially, CVS Health data show a plateau and then a downward trend in the number of new starters of Sovaldi during May – August 2014.

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Experts anticipate another substantial uptick in use in late September or October 2014, when Gilead, the manufacturer of Sovaldi, releases a new regimen for Hepatitis C that combines Sovaldi and ledipasvir into a single pill that is taken once a day. This regimen confers similar efficacy to multi-pill regimens and requires only an 8-week course of therapy compared with Sovaldi's current 12-week course. Experts believe that many hepatologists have been waiting for the release of this new single pill regimen and will initiate therapy for lower acuity patients when this medication becomes available. The pharmaceutical manufacturer Abbvie plans to release a similar all oral regimen at nearly the same time. The simplicity of these options may further reduce treatment discontinuation rates, although this cannot be determined at present. Additional peaks in use may be seen several months later, when new products from other manufacturers become available, which is likely to drive down costs.

Conclusions

CVS Health followed 1,965 patients who began Sovaldi to treat Hepatitis C during December 2013 – Aug 2014. We found that 8.1% of patients discontinued the drug during the recommended 12-week course, approximately a 4-fold increase in the discontinuation rates observed in clinical trials. Patients with less advanced Hepatitis C disease (those naïve to therapy) were markedly less likely to complete treatment than those who had previously received other Hepatitis C therapies. These findings underscore the well-recognized fact that real world adherence to medication is often poorer than that observed in clinical trials. It is reassuring to note that discontinuation rates were substantially lower in the CVS/caremark specialty pharmacy, where additional counseling and patient support is provided.

Sovaldi is an effective, curative therapy but also a costly one, and Sovaldi treatment discontinuation represents a substantial cost to the health care system without the corresponding clinical benefit and value. Our data suggest that all patients who receive Sovaldi should be followed closely by their providers to support adherence to therapy. Because treatment-naïve patients with less advanced disease discontinued Sovaldi more often, health care providers may choose to prioritize treatment for those who have more advanced disease. We anticipate upcoming spikes in Sovaldi use as new, simpler, and less expensive regimens become available. By anticipating these spikes in use, payors can augment current strategies to improve appropriate adherence in those who initiate therapy, and plan for the substantial cost outlays that will arise.

This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Health.

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This analysis was conducted in accordance with HIPAA and the PBM's business associate agreements.

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Exhibit 24

EDMUND G. BROWN JR.
GOVERNOR

State of California
HEALTH AND HUMAN SERVICES AGENCY

DIANA S. DOOLEY
SECRETARY

Aging
Child Support Services
Community Services and Development
Developmental Services
Emergency Medical Services Authority
Health Care Services
Managed Health Care
Public Health
Rehabilitation
Social Services
State Hospitals
Statewide Health Planning and Development

October 14, 2015

The Honorable Ron Wyden
Ranking Member
Committee on Finance
United States Senate
221 Dirksen Senate Office Building
Washington D.C. 20510

The Honorable Charles E. Grassley
Senior Member
Committee on Finance
United States Senate
135 Hart Senate Office Building
Washington D.C. 20510

Dear Senator Wyden and Senator Grassley:

Thank you for the opportunity to provide comments on California's experience with high-cost drugs, as you explore Gilead Sciences, Inc.'s pricing of the Hepatitis C drug Sovaldi. Our state Medicaid agency, the California Department of Health Care Services, previously provided your staff with more specific utilization and enrollment data for our state Medicaid program, called Medi-Cal, related to newly available Hepatitis C treatments. The purpose of this letter is to provide some context for California's efforts to understand and address the increased costs to the state and to consumers of these Hepatitis C treatments and high-cost drugs more broadly.

In January 2015, our proposed state budget specifically identified the high costs of newly available Hepatitis C treatments and noted that there are thousands of inmates in our state prisons, patients in our state mental hospitals, and participants in Medi-Cal and the AIDS Drug Assistance Programs who are infected with Hepatitis C. This budget proposal provided funding to cover these anticipated increased costs and tasked the California Health and Human Services Agency with convening a workgroup to refine these fiscal estimates and compare practices across our state departments and county governments.

Our agency convened several conversations with an internal workgroup consisting of state departments, county governments, and sheriffs, as well as with an external workgroup consisting of stakeholders representing consumers, organized labor, employers, health plans, providers, and the pharmaceutical industry. We have focused on three areas and have taken preliminary steps in these areas, by considering: what we can do through clinical guidelines, what we can do through procurement policies, and the value equation of high-cost drugs.

We are currently building our proposed budget for the next state fiscal year (July 1, 2016-June 30, 2017), which we will release in January 2016. Fiscal estimates for our departments will continue to account for the impact of these high-cost drugs. In addition, we'll continue to do what we can to manage these costs while providing high quality of care to the individuals in our public programs.

We appreciate your interest in the impact to states of the newly available Hepatitis C drugs, and look forward to continuing to work with our federal partners on these and other issues related to administering Medicaid and other important programs.

Sincerely,

Diana S. Dooley

Diana S. Dooley
Secretary