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### Publication Date

2016-03-18

UC Berkeley Center for Labor Research and Education

March 2016

## Specialty drug prices and the Medi-Cal program

by Ramón Castellblanch

Rising specialty drug costs pose a substantial problem for the California state budget and the problem will continue to grow. Overall, specialty drug spending in the United States in 2016 is expected to hit \$192.2 billion.<sup>1</sup> Current trends suggest that specialty drug spending in the U.S. will total \$400 billion by 2020, which will comprise about 9.1 percent of national health spending.<sup>2</sup> While these trends are of concern to all payers, this brief focuses on the implications for Medicaid, and particularly California's program, Medi-Cal. If California's share of specialty drug spending is proportionate to its share of the U.S. population, and if Medi-Cal's share of state specialty drug spending is proportionate to Medicaid's share of U.S. drug spending, then Medi-Cal will spend approximately \$3 billion on specialty drugs in 2016 and, with current Medi-Cal drug purchasing policy, approximately \$6 billion on specialty drugs in 2020.

Of the specialty drugs that came online in 2014, Sovaldi (sofosbuvir), a treatment for hepatitis C, has gotten the most attention. Hepatitis C now accounts for more disease and death in the United States than does human immunodeficiency virus (HIV)/AIDS.<sup>3</sup> Of every 100 people with chronic hepatitis C, 60–70 of them will go on to develop chronic liver disease; 5–20 will go on to develop cirrhosis over a period of 20–30 years; and 1–5 will die from cirrhosis or liver cancer.<sup>4</sup> In California, from 1994 through 2011, over 500,000 chronic hepatitis C cases were newly reported to the California Department of Public Health.<sup>5</sup> Based on limited clinical trials, Sovaldi appears to represent a breakthrough in hepatitis C treatment. In those trials, more patients with hepatitis C given Sovaldi experience sustained viral response (SVR), likely a cure, compared with the SVR rate observed with trials of prior therapies.<sup>6</sup>

But with an extraordinarily high retail price—a minimum of \$84,000 for a course of treatment—and the number of Americans infected with hepatitis C—at least 3 million—Sovaldi alone appears poised to significantly increase overall healthcare costs. In May 2015, the California governor's revised 2015-2016 budget recognized this cost

impact on Medi-Cal, state prisons, state mental hospitals, and the AIDS Drug Assistance Programs by proposing a \$228 million supplement for high-cost drugs such as Sovaldi.<sup>7</sup> Some of this supplement was to be used to help Medi-Cal managed care organizations (MCOs) pay for drugs like Sovaldi even though boilerplate MCO contracts with Medi-Cal require them to cover all prescribed drugs.<sup>8</sup>

The price of Sovaldi reflects a new approach to drug pricing. Studying how Sovaldi was priced and sold is instructive because it shows new cost pressures that Sovaldi, along with many specialty drugs in the pipeline, places on consumers and the health system as a whole, including Medi-Cal. If the way that Sovaldi was priced and sold is a harbinger, then state policies for covering such drugs may need more than patchwork measures such as state budget supplements.

The recently-released U.S. Senate Finance Committee report reveals how Sovaldi was priced and sold. The Committee used documents obtained from businesses like Gilead; Pharmasset, the business Gilead bought in 2011 along with its Sovaldi patent; and Barclays Capital, one of the banks involved in financing the transaction. The report also documents how the high price of Sovaldi has led to severe rationing of the drug to Medicaid patients. The report recommends that programs like Medi-Cal take over the purchasing responsibility from MCOs and negotiate supplemental rebates on hepatitis C drugs in order to more wisely use taxpayer funds to provide treatment to more hepatitis C patients.

## **Sovaldi priced to maximize revenue**

The Senate Finance Committee documents show that Gilead simply priced the drug at the point at which it would maximize revenue for Sovaldi and the related Gilead drug, Harvoni.

The documents show that those involved in the Gilead acquisition of Pharmasset studied the likelihood that payers, including Medi-Cal, would buy Sovaldi at different prices and found a U.S. price of \$1,000 per pill, or \$84,000 over the course of treatment, would produce the maximum revenue for Gilead.

The Senate Finance Committee found no evidence that the cost of Sovaldi research and development was a factor in setting the price.<sup>9</sup> Instead, to rationalize its price for Sovaldi, Gilead developed a cost-effectiveness calculation that compared its cost to that of alternative treatments for hepatitis C. The Committee, however, found a number of ways in which the comparisons were misleading.<sup>10</sup>

Gilead funded a series of studies to convince the FDA that Sovaldi was an alternative to existing treatments. The Drug Effectiveness Review Project found the studies only provided low confidence that Sovaldi was comparably effective. Problems with many studies Gilead used included lack of head-to-head evidence comparing Sovaldi to the alternatives, small samples sizes, and mostly white patients who were HIV negative and without other liver disease. In addition, some trials included only patients without cirrhosis.<sup>11</sup> Nevertheless, the FDA approved Sovaldi. The FDA's approval process left many important questions unanswered such as what types of hepatitis C cases are best for the new drugs.

The Senate report shows an awareness on the part of Gilead that the \$84,000 price per course of treatment for genotype 1 hepatitis C would make the drug unaffordable to millions, and that Gilead found that consideration to be irrelevant in setting the price.<sup>12</sup> In fact, the \$84,000 figure would be a floor for hepatitis C treatment, as the cost of treating genotype 3 hepatitis C could be up to \$168,000 per course of treatment.

In anticipating public outrage to their Sovaldi price, Gilead executives planned to ignore it. Kevin Young, Gilead's executive vice president for commercial operations, wrote in an e-mail to other Gilead executives, "Let's not fold to advocacy pressure in 2014." He went on to write, "Let's hold our position... whatever the headlines."<sup>13</sup>

## High price of Sovaldi has led to Medicaid rationing

The price makes widespread use of Sovaldi by Medicaid unaffordable. In California, for example, there are an estimated 237,000 people in Medi-Cal who are hepatitis C positive, according to the Senate Finance Committee report. If they were each given Sovaldi at \$84,000 a treatment, it would cost Medi-Cal approximately \$20 billion. This is the equivalent of spending nearly a quarter of the annual Medi-Cal budget on a single drug.<sup>14</sup>

States have therefore instituted a patchwork of guidelines for rationing Sovaldi.<sup>15, 16</sup> In the case of Medi-Cal, the current policy on prescribing the new hepatitis C drugs gives MCOs and physicians wide discretion; it only offers "considerations" for prescribing.<sup>17</sup> But it requires prescribers to get prior authorization when prescribing these drugs,<sup>18</sup> making physicians do extra paperwork with each prescription and throwing up an effective disincentive to prescribing these drugs.

As a result, very few hepatitis C Medi-Cal patients are getting Sovaldi. According to the U.S. Senate Finance Committee, the Medi-Cal fee-for-service (FFS) program spent \$21.9 million to provide 280 patients with Sovaldi in calendar year 2014. That same year, Medi-Cal MCOs provided Sovaldi to 1,359 patients. Unfortunately, the Senate Committee did not report the amount Medi-Cal MCOs spent on Sovaldi because the state was unable to provide those figures.<sup>19</sup> Overall, Medi-Cal provided Sovaldi or Gilead's alternative, Harvoni, to less

than 1% of its hepatitis C population, leaving over 235,000 Medi-Cal hepatitis C patients untreated with either drug.<sup>20</sup> (Viekira Pak, a non-Gilead alternative to Sovaldi, was added to the Medi-Cal drug list in mid-2015 and therefore was not included in the data reported by the Committee.)

In November 2015, the U.S. Center for Medicaid and CHIP Services acknowledged and responded to the patchwork of state Medicaid policies on Sovaldi, encouraging states to "exercise sound clinical judgment and utilize available resources to determine their coverage policies." While it noted that there are "guidelines for states to refer to regarding testing, managing, and treating HCV [hepatitis C virus] put forth by the American Association for the Study of Liver Diseases (AASLD), the Infectious Diseases Society of America (IDSA), and the International Antiviral Society-USA (IAS-USA),"<sup>21</sup> it put forward no more specific guidance and left states with considerable leeway in formulating treatment policies for the new drugs for hepatitis C.

Medicaid enrollees' limited access to Sovaldi not only has consequences for them, but could also affect public health. Hepatitis C is an infectious disease that is commonly transmitted by such activities as sharing needles, syringes, or other equipment to inject drugs. It can also be transmitted by needlestick injuries in health care settings. Less commonly, a person can become infected with the hepatitis C virus through sharing personal care items that may have come in contact with an infected person's blood, such as razors or toothbrushes; or by having sexual contact with a person infected with the virus.<sup>22</sup> The fewer Americans who are effectively treated by hepatitis C, the more who will become infected.

In spite of rationing, Sovaldi and other specialty drugs nonetheless had a significant impact on state and federal Medicaid budgets. Medicaid spending on specialty drugs, including

Sovaldi, rose by 35.8% in 2014.<sup>23</sup> Overall, Medicaid drug costs grew 24% in 2014, up from 4% growth in 2013.<sup>24</sup>

### **Sovaldi is the canary in the coalmine**

There are many more specialty drugs in the pipeline. Specialty drugs recently approved by the FDA include treatments for advanced breast cancer, cystic fibrosis, high cholesterol, and two more for hepatitis C. Others that are likely to be approved this year include treatments for lung cancer, multiple myeloma, and muscular dystrophy.<sup>25</sup>

Vendors of new specialty drugs may use the revenue-maximizing method of Gilead to price their drugs. As it is, the Centers for Medicare & Medicaid Services (CMS) expects drug cost inflation to continue to outstrip overall medical care cost inflation beyond 2020, due primarily to specialty drugs.<sup>26</sup> So, by the next decade, Medi-Cal spending on specialty drugs can be expected to top \$10 billion, assuming no change in Medi-Cal policy on purchasing the new hepatitis C drugs and other specialty drugs. As the slice of the state budget allocated to specialty drugs grows, less money will be available for everything else that the state funds, including hospitals and healthcare professionals paid by Medi-Cal.

Given the potential profits from revenue-maximizing drug pricing, speculators from outside are entering the drug industry, increasing the likelihood that the revenue-maximizing method will be used in pricing new specialty drugs. Hedge fund manager Martin Shkreli's use of Turing Pharmaceuticals to raise the price of the life-saving drug Daraprim from \$13.50 a tablet to \$750 is an example.<sup>27</sup> Unless states take action on the price of specialty drugs, the kind of challenge Gilead's pricing has posed for Medicaid programs' budgets could be repeated as newer specialty drugs come online.

### **California can pay less for the new hepatitis C drugs by negotiating supplemental rebates**

Even with severe Medi-Cal rationing, the projected overrun of state spending for Sovaldi has already reached a level that led the state to provide supplemental state appropriations for the drug to the Medi-Cal program. Now, in addition to the supplement in the 2015-16 state budget for high-cost drugs such as Sovaldi, the 2016-17 budget may also include supplements to the Medi-Cal budget for such drugs.<sup>28</sup>

As it stands, Medi-Cal drug purchasing power that could be used to negotiate discounts on the new hepatitis C drugs is severely underutilized. State Medicaid programs have the authority to negotiate supplemental rebates on behalf of Medicaid MCOs, but the MCOs cannot negotiate them for themselves. In 2014, the state enacted Senate Bill 870 which gives Medi-Cal the power to negotiate supplemental rebates on the new hepatitis C drugs for the MCOs when the state reimburses MCOs through separate capitated rate payments or other supplemental payments. The state has already carved out the costs for hepatitis C treatment from Medi-Cal MCO capitation rates and gives MCOs "kick payments" for the new hepatitis C drugs they buy. But, the state has not yet used its power to negotiate supplemental rebates for the MCOs. While Medi-Cal does negotiate supplemental rebates on hepatitis C drugs, it is only for its FFS program.

Medi-Cal used to combine all of its purchasing power to negotiate large supplemental rebates.<sup>29</sup> But Medi-Cal now makes less use of its purchasing pool, assuming that Medi-Cal MCOs, which cover approximately four-fifths of Medi-Cal beneficiaries, can better handle healthcare costs.<sup>30</sup> In the case of hepatitis C drugs, this assumption appears to be mistaken. Medi-Cal MCOs invoiced the state for hepatitis C treatments, including but not limited to

## State Medicaid Programs' Unique Advantage in Prescription Drug Pricing

In recommending that state Medicaid programs consider supplemental rebates for the new hepatitis C drugs, CMS is reminding them that federal law gives them a distinct advantage over non-federal medical insurance plans, including Medi-Cal MCOs, in getting lower prices for prescription drugs. The law provides that state Medicaid plans get the lowest price that any insurer pays for a drug. That price is commonly known as the “best price.” Importantly, the prices some federal agencies (like the Veterans Administration) pay for drugs are excluded from the “best price” calculation.

This “best price” law makes it difficult for non-federal insurers to get a price lower than “best price” since, under the law, if a non-federal insurer gets a price lower than “best price” that lower price becomes the new “best price” and every Medicaid plan in the U.S. gets it. The resulting cost to the drug-maker is a tremendous disincentive to them giving prices to non-federal insurers that are below “best price.” However, as a federal program, the prices that state Medicaid programs get are exempt from the calculation of “best price.” If one state Medicaid program gets a price below “best price” it only applies to that program. There is therefore much less disincentive to drug-makers giving prices lower than “best price” to state Medicaid plans.

The way that state Medicaid plans get prices below “best price” is through negotiating supplemental rebates. When a drug-maker gives a state Medicaid plan a price lower than “best price” the state plan does not pay the lower price up front but rather gets a subsequent supplemental rebate. Ultimately, the supplemental rebate will make the state’s final cost for the drug lower than the “best price.”

The bargaining power that state Medicaid plans use to get supplemental rebates is their authority to require prior authorization on a drug’s prescription before they pay for it. If a state Medicaid plan requires prior authorization, physicians who want to prescribe the drug will be required to do extra paperwork, creating a disincentive to the drug being prescribed. In this way, a prior authorization requirement reduces the drug’s sales.

When there are two or more drugs of comparable effectiveness to treat the same disease, a state Medicaid program can use its prior authorization authority to negotiate supplemental rebates. For example, if drug-maker A and drug-maker B make drugs of comparable effectiveness to treat the same disease, the state Medicaid program can offer drug-maker A a prior authorization requirement on the drug of drug-maker B in exchange for a supplemental rebate from drug-maker A. That supplemental rebate can make the cost of drug-maker A’s drug lower than the “best price.”

Sovaldi, that averaged \$107,000 per patient over a 16-month period in 2015 and 2016.<sup>31</sup> At the same time, only a very small fraction of their hepatitis C patients were getting these drugs. Since current state policy permits the plans to pass much of their high-cost drug expenses directly to the state, the MCOs have little incentive to negotiate lower prices. Furthermore, the state is missing out on potential price reductions because MCOs are barred from directly negotiating the supplemental rebates which the state has the power to negotiate.

In a November 2015 letter to the states, CMS suggested that the states could go one of two ways in dealing with Sovaldi prices. They could severely ration the drug—which CMS discourages but acknowledges is occurring. Or they could take advantage of the fact that there is now competition to Sovaldi and seek “to negotiate supplemental rebates or other pricing arrangements with manufacturers to obtain more competitive prices for both their FFS and managed care programs, thereby reducing costs.”<sup>32</sup> According to a recent report from the Medicaid and CHIP Payment and Access Commission, several states report they have negotiated supplemental rebates of up to 20 to 30% this way.<sup>33</sup>

To date, Medi-Cal is not using its prior authorization power to get supplemental rebates for any of the high-priced hepatitis C drugs.

This is evident because Medi-Cal requires prior authorization for all three new high-priced drugs for hepatitis C and none of these drugs are on the short list of Medi-Cal preferred prior authorization drugs.<sup>34</sup> In the meantime, states like Georgia, Maine, Minnesota, Vermont, and Wyoming have already gotten supplemental rebates for Sovaldi.<sup>35</sup>

What California can do now to best take advantage of its Medi-Cal purchasing power is to take the advice of CMS and direct the Department of Health Care Services (DHCS) to use SB 870 and negotiate supplemental rebates for these drugs provided to beneficiaries in the Medi-Cal fee-for-service program and in Medi-Cal MCOs. To assure DHCS has the ability to negotiate the largest rebate, the state can provide it with the necessary resources and independently monitor their work. These resources could include an expert panel, such as the one the U.S. Department of Veterans Affairs uses, to regularly and independently review the latest research on hepatitis C treatment.<sup>36</sup> This panel could support negotiators and propose treatment guidelines based on the best available evidence.

There is an impending wave of specialty drugs coming into the market and a great likelihood that their vendors will price them to maximize revenue. California could begin to spend taxpayer money on specialty drugs more wisely by having Medi-Cal negotiate supplemental rebates on hepatitis C drugs. More importantly, reducing prices would support improving access to these drugs for Medi-Cal patients,<sup>37</sup> thereby curtailing the spread of hepatitis C and saving more California lives.

## Endnotes

<sup>1</sup> PwC's Health Research Institute, *Behind the Numbers 2015* (June 2014).

<sup>2</sup> Pew Charitable Trusts, *Specialty Drugs and Health Care Costs* (November 2015).

<sup>3</sup> Klevens, R., Hu, D., Jiles, R., & Holmberg, S. Evolving Epidemiology of Hepatitis C Virus in the United States. *Clinical Infectious Diseases*, 55(S1), S3–9–S3–9. (2012).

<sup>4</sup> U.S. Centers for Disease Control, *Hepatitis C Information* (2015).

<sup>5</sup> *Chronic Hepatitis B and Hepatitis C Infections in California: Cases Newly Reported through 2011*. California Department of Public Health, Sexually Transmitted Diseases (STD) Control Branch (November 2013).

<sup>6</sup> Brennan, T., Lotvin, A., and Shrank, W. "Analysis of "Real World" Sovaldi (sofosbuvir) Use and Discontinuation Rates." *CVSHealth*. (September 2014).

<sup>7</sup> California Governor's budget 2015-16, Revised Summary (May 2015).

<sup>8</sup> California Department of Health Care Services, *Medi-Cal Managed Care Boilerplate Contracts*.

<sup>9</sup> US Senate Finance Committee, *Wyden press release, Investigation Finds Revenue-Driven Pricing Strategy Behind \$84,000 Hepatitis Drug* (December 2015).

<sup>10</sup> Gilead used a price-per-cure evaluation for alternative therapies to compare to a price-per-treatment for Sovaldi, a price that looks lower because it uses a larger denominator. They assumed the price of the alternative would rise 12% in the 4 years between when they made the calculation to when Sovaldi went on the market. They added an 8% "convenience bump" to the 3-times-a-day alternative because Sovaldi was a once-a-day pill. Finally, they calculated alternative's price as 25% higher because it would be sold in the US as opposed to Japan or Europe. For a graph of Gilead's calculation, see page 21 of the senate committee report.

<sup>11</sup> Drug Effectiveness Review Project, *Comparative Effectiveness of Direct-Acting Antiviral Agents for Hepatitis C Infection* (February 2015).

<sup>12</sup> US Senate Finance Committee, *Wyden press release: Investigation Finds Revenue-Driven Pricing Strategy Behind \$84,000 Hepatitis Drug* (December 2015).

<sup>13</sup> US Senate Finance Committee, *The Price of Sovaldi and Its Impact on the US Health Care System*, page 58 (December 2015).

<sup>14</sup> Medi-Cal spending is projected at \$85.1 billion in 2016-2017. California Governor's Budget Summary 2016-2017 (January 2016).

<sup>15</sup> Barua S. et al, *Restrictions for Medicaid Reimbursement of Sofosbuvir for the Treatment of Hepatitis C*

Virus Infection in the United States, *Annals of Internal Medicine* 163(3) (August 2015).

<sup>16</sup> US Department of Health & Human Services, Center for Medicaid & CHIP Services, Alissa Mooney DeBoy, Medicaid Drug Rebate Program Release No. 172 (November 2015).

<sup>17</sup> California Department of Health Care Services, Treatment Policy for the Management of Chronic Hepatitis C (July 2015).

<sup>18</sup> Medi-Cal, Contract Drugs List, State of California.

<sup>19</sup> US Senate Finance Committee, *Data Behind the Sovaldi Report* (December 2015).

<sup>20</sup> US Senate Finance Committee, *The Price of Sovaldi and Its Impact on the US Health Care System*, Appendix A (December 2015).

<sup>21</sup> US Department of Health & Human Services, Center for Medicaid & CHIP Services, Alissa Mooney DeBoy, Medicaid Drug Rebate Program Release No. 172 (November 2015).

<sup>22</sup> US Centers for Disease Control, Hepatitis C FAQs for the Public (October 2015).

<sup>23</sup> Express Scripts, *The 2014 Drug Trend Report: Medicaid* (March 2015).

<sup>24</sup> Martin A.B, et al, National Health Spending in 2014: Faster Growth Driven By Coverage Expansion And Prescription Drug Spending, *Health Affairs* 35(1). (2016).

<sup>25</sup> Tharaldson A., Specialty Pipeline Highlights, *Specialty Pharmacy Times* (October 2015).

<sup>26</sup> Keehan S.P. et al, National Health Expenditure Projections: 2014-24, *Health Affairs* No. 8 (2015).

<sup>27</sup> Pollack A., Drug Goes From \$13.50 a Tablet to \$750, Overnight, *New York Times* (September 2015).

<sup>28</sup> US Senate Finance Committee, Letter from Dooley re: newly available hepatitis C drugs (October 2015).

<sup>29</sup> California State Auditor, Pharmaceuticals: State Departments That Purchase Prescription Drugs Can Further Refine Their Cost Savings Strategies (May 2005).

<sup>30</sup> 9.65 million enrollees were in managed care, out of 11.66 million total Medi-enrollees (excluding those who are undocumented), according to analysis of California Department of Health Care Services data as of May 2015.

<sup>31</sup> Bartalone, Pauline, California Doles Out Millions to Insurers for Hepatitis C Drugs, *KQED State of Health* (January 27, 2016).

<sup>32</sup> US Department of Health & Human Services, Center for Medicaid & CHIP Services, Alissa Mooney DeBoy, Medicaid Drug Rebate Program Release No. 172 (November 2015)

<sup>33</sup> Medicaid and CHIP Payment and Access Commission (MACPAC), Issue Brief: Medicaid Spending for Prescription Drugs (January 2016)

<sup>34</sup> Medi-Cal, Contract Drugs List, State of California.

<sup>35</sup> US Senate Finance Committee, *The Price of Sovaldi and Its Impact on the US Health Care System*, Appendix A (December 2015).

<sup>36</sup> US Department of Veterans' Affairs, Chronic HCV Infection: Treatment Considerations (December 2015).

<sup>37</sup> Chatal H.S. et al, Cost-effectiveness of Early Treatment of Hepatitis C Virus Genotype 1 by Stage of Liver Fibrosis in a US Treatment-Naive Population, *JAMA Intern Med* 176(1). (2016).



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### ACKNOWLEDGEMENTS

I would like to thank Beth Capell and Betsy Imholz for their helpful comments. I also like to thank Laurel Lucia for her review of this brief and Jenifer MacGillvary for her help in preparing the brief.

*The views expressed in this research brief are those of the author and do not necessarily represent the Regents of the University of California, the UC Berkeley Institute for Research on Labor and Employment, or collaborating organizations or funders.*