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March 1, 2016

Via email

United States Senate
Committee on Finance
Washington, DC 20510-6200

RE: Report on Gilead Pricing of Sovaldi and Additional Questions

Dear Senator Wyden and Senator Grassley:

Blue Shield of California appreciates the opportunity to provide a response to the Senate Finance Committee's groundbreaking report on the price of Sovaldi and its impacts on the U.S. healthcare system. Blue Shield is a nonprofit health plan that offers health benefits coverage to individuals and groups throughout the State of California. Our mission is to ensure that all Californians have access to high quality care at an affordable price. In 2011, Blue Shield was the first, and remains the only, health plan to voluntarily place a cap on its earnings. Since then, we have limited our net income to 2 percent of our annual revenue.

As a nonprofit, Blue Shield's mission is to increase the number of insured Californians, improve health care quality, and provide higher-value care at an affordable price. One of the biggest challenges in providing affordable coverage is the rising cost of prescription drugs. Your report highlights the significant impact that a single drug had on the U.S. health care system. However, as has been well documented, high-cost "specialty" drugs and unsustainable price increases are becoming the norm in the U.S. This has increasingly put a strain on governments, both federal and state, who are forced to choose between spending on education and infrastructure, or pharmaceutical products. As the report notes, Gilead generated $26.6 billion in sales of Sovaldi in the first 21 months, $20.6 billion of which was from U.S. consumers. California set aside $228 million in its state budget last year just to help offset the costs of Sovaldi. For that amount, California could have hired more than 5,000 teachers.

The Committee's report conclusively demonstrates that the market for drugs in this country is broken. Drug manufactures frequently set prices with only one goal in mind—maximizing profits—regardless of the impacts on public payers or the public health. The current trend is unsustainable for our economy and skews the priorities for our country.

While the Finance Committee does not have jurisdiction over the drug approval process, it has been left with the consequences of this broken market. We applaud the rigorous

staff work that went into the report and the commitment of Senators Wyden and Grassley in pursuing this issue. We look forward to working with the Committee as they begin their work developing solutions to this national problem.

Provided below are specific responses to your additional questions. We would be happy to provide any additional information that you may need.

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

Your report provides ample evidence of the impact of a breakthrough single-source drug on the marketplace. As your report documents, the company that actually developed Sovaldi, Pharmasset, projected selling the drug for $36,000 per treatment regimen. The ultimate price set by Gilead more than doubled that estimate. The difference in the pricing can be attributed solely to the market power of a single source drug and the willingness of a pharmaceutical company to exploit their market power to maximize profit. As the report notes on page 39, the ability to set an initial price sets a benchmark for the market which lasts even after competition is introduced. Documents cited in your report noted that "Gilead's [drug] has the first mover advantage with Wave 1, which gives the possibility to set a higher price reference for the market." While competition has worked to reduce the cost of Hepatitis C drugs, no manufacturer is currently selling the drug close to what Pharmasset had originally cited as its target price. Gilead's strategy in setting a high reference price for the market therefore appears to have worked. More needs to be done to either curtail unrestrained launch prices or to introduce competition more quickly when new entrants are close behind in the approval process.

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

Additional information about drug pricing, patient volume and efficacy would certainly help payers price more accurately. Blue Shield and other payers would support and welcome such measures. However, transparency to payers would do little to limit the cost burdens on all enrollees who bear the burden of high-cost drugs in increased premiums. Blue Shield's commitment is to make the health care system sustainable, not just to protect our own balance sheet, but to make health care affordable to our members. Similarly, the Finance Committee's jurisdiction includes ensuring stable financing of public programs. To support this goal, additional transparency related to drug pricing is required for the public, not just payers. The current pricing system for drugs is notably opaque. Policymakers and market participants are provided minimal clarity around the actual prices of drugs, the costs of R&D used to justify these prices, or the amount or frequency of price increases. Drug manufactures should be required to disclose and justify their proposed prices and price increases to the Committee and to the public. Additional transparency similar to that of any other functioning market is required if the United States is going to receive better value for our health care dollars.

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

There is no debate among stakeholders that the health care system needs to drive towards higher value, particularly in the debate over prescription drugs. However, there is much less consensus as to how to define that "value." Sovaldi is unquestionably a breakthrough drug that offers a cure to a potentially life-threatening disease. However, the value cannot be completely detached from the cost of developing the drug and the cost to the system. In short, value is still dependent on price.

The recent controversy over Daraprim has shown that pricing based exclusively on the "value" to patients without any other context leads to absurd results. While the patent on Daraprim expired long ago and it is sold by GSK in England and other countries for $0.99 a pill,[1] the drug will still save someone's life. Daraprim is therefore extremely high value to certain patients. When Martin Shrkeli bought the rights to Daraprim and raised the cost to $750 a pill, he said that was the fair value based on pricing for pharmaceuticals. "You only need less than 100 pills so at the end of the day, the price for treatment – to save your life – was only $1,000. These days, in modern pharmaceuticals, cancer drugs can cost $100,000 or more, rare disease drugs can cost half a million dollars. Daraprim is still underpriced, relative to its peers," he said.[2] This shows that we cannot talk about "value" in isolation.

To tether pricing based on "value" to a sustainable health care system, the impact to sustainability of the overall health care system has to be a key factor. We believe that independent third-party entities like ICER, which ties its analysis of value to a price that would prevent an excessive cost burden on the health care system, are critical in this analysis. The government as a payer must take a much more active role in supporting independent review, like ICER, based on objective criteria. Additionally, Blue Shield of California has more than 1,600 drugs on our formulary. While value-based payments may be a part of the solution, it is only realistic for a small subset of drugs and does not obviate the need for objective analysis and criteria.

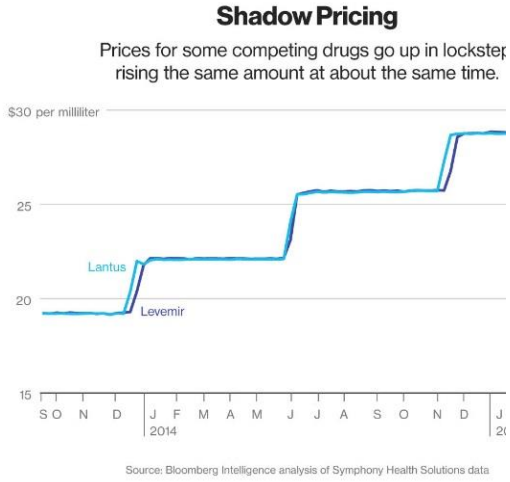
4) What measures might improve price transparency for new higher-cost therapies while maintaining incentives for manufacturers to invest in new drug development?

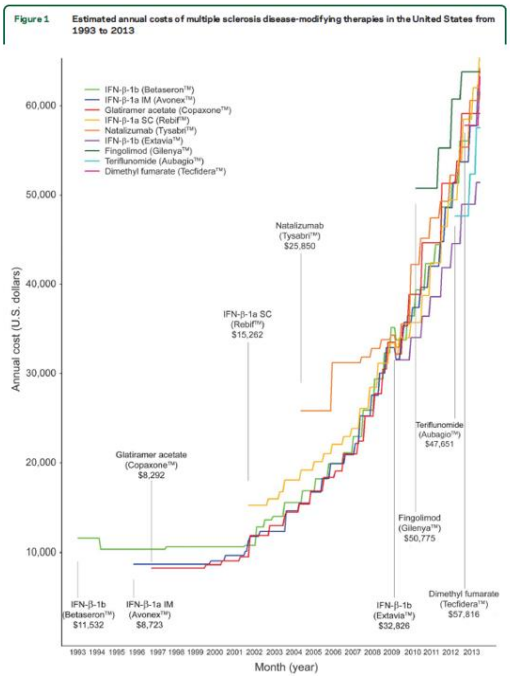
California has introduced and debated transparency legislation that would require additional information related to high cost drugs to help make the market function better. The bill, AB 463, would have required increased disclosure of R&D costs (including taxpayer investments in R&D), manufacturing costs, marketing expenses, and expected profits. Similar bills have been introduced in several states as public payers grapple with the growing problem of high-cost drugs. Interestingly, despite protests from

[1] Reuters, "Transatlantic Divide: How U.S. Pays Three Times More for Drugs," Oct. 12, 2015.
[2] Bloomberg, "Drug Goes from $13.50 to $750 Overnight," Sept. 21, 2015.

manufacturers like Gilead that this information was not available, we were able to model a transparency report for Sovaldi based on the information provided in your report. This shows that additional transparency is not burdensome and the information is readily available to manufacturers.

Additional transparency is needed both around launch prices and price increases. For launch prices, your report demonstrates that pricing for high-cost drugs often has no relation to R&D costs and that it is instead based on maximizing profits. Requiring some public scrutiny of initial pricing would bring downward pressure on these costs. Additionally, transparency should be required for price increases. Bloomberg has documented the price increases for "competing" drugs for diabetes and multiple-sclerosis.[3] As shown in the chart below (left), prices for the major competing insulin drugs have largely increased in lockstep. The price increases for these drugs have also been unjustifiable. The New York Times recently showed that from 2010 to 2015, the price of Lantus (made by Sanofi) went up by 168 %; the price of Levemir (made by Novo Nordisk) rose by 169 %; and the price of Humulin R U-500 (made by Eli Lilly) soared by 325 %.[4] Additionally, prices for old established drugs for multiple-sclerosis (chart right, below) have increased to match newer innovative drugs.





As Dr. Peter Bach and others have noted, this behavior is unique among pharmaceutical manufacturers.[5] While virtually every other participant in the health care system—from

[3] Bloomberg, "Hot Drugs Show Sharp Price Increases in Shadow Market," May 6, 2105.
[4] Dr. Kasia Lipska, "Break up the Insulin Racket," New York Times, Feb. 20, 2016.
[5] Dr. Peter Back, "How the U.S. Could Cure Drug Price Insanity," Fortune, Sept. 17, 2015.

insurers to hospitals and physicians—must provide significant transparency on their costs (particularly related to outlier behavior), the pharmaceutical sector is completely exempt. This seems difficult to justify when their costs are increasing at a rate that far exceeds any other part of the health care dollar.

Even minimal transparency would likely have a significant impact on the market. For example, while insurers must publicly justify any rate increase, pharmaceutical manufacturers can raise prices at any time and for any amount without any public scrutiny. The only way policymakers and the public learned about outrageous price increases related to several drugs that have led to Congressional inquiries was entrepreneurial reporting (Daraprim) or self-interested short-selling hedge-funds (Valeant). Simply requiring manufacturers to disclose price increases of over 10 percent in a calendar year would provide the ability for the Finance Committee and other public payers to perform much more systematic and sustainable oversight. These steps would not in any way curtail incentives to invest in cures, but they would restore some balance to the market.

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

As your report conclusively demonstrates, states have struggled to balance the need for access to breakthrough therapies and sustainability of the health care system. But what your report also revealed is that Gilead knew that it pricing decision would lead to access restrictions. Instead of treating access to a cure to Hepatitis C as a public health issue and maximizing revenue through expanded access, Gilead chose to maximize the price and force states and their Medicaid program into an ethical dilemma. As you wrote, "Thus, in order to manage the costs of Sovaldi and Harvoni, which made up the majority of pharmaceutical spending to treat HCV, state Medicaid programs developed access restrictions to control costs in a constrained budget environment, pitting patients seeking therapy against those agencies weighing complex ethical questions, scientific evidence and public health needs to maximize appropriate access to new treatments." The best tool to promote access and minimize the burden of high-cost drugs is therefore to convince manufacturers to lower the cost of these drugs.

However, much more can be done to allow increased competition to drive down federal and state payment for drugs. The Congressional Budget Office has long noted that giving Medicare the authority to negotiate drug prices will have little actual effect on prescription drug spending. The reason for this conclusion is important—the federal rules related to formularies and access to drugs are so restrictive that drug manufacturers have little incentive to bargain. These rules need to be re-examined to provide more leverage for payers to negotiate with manufacturers, while preserving protections for beneficiaries.

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In particular, protected class restrictions and prior authorization limitations have eliminated leverage for payers to negotiate between competing products even where they do on commercial formularies. When CMS signals to payers that they will provide little leverage to manage their drug costs, manufacturers know they don't have to offer significant discounts. State Medicaid programs face many of the same restrictions. While states should have significant leverage as major payers, federal rules diminish their bargaining power. Additional independent research into the value of new drugs, coupled with additional formulary flexibility to support payers rewarding high-value drugs and sustainable pricing, would help restore a viable balance in the market for drugs.

Thank you for the opportunity to comment on your commendable report. We would welcome the opportunity to discuss any of these issues with you at your convenience.

Sincerely,

Andy Chasin
Policy Director