

Date: March 4, 2016

To: Senators Ron Wyden and Charles Grassley  
Report\_Feedback@finance.senate.gov

From: Kathleen Salvia



Re: Patient Response to Your Letter of January 21, 2016

Gentlepersons:

Thank you for the opportunity to contribute to your study of the development, pricing, marketing, and sales of Sovaldi and Harvoni. I applaud you for seeking ways to make sure that the public payer system is not blind-sided in the future by the predatory marketing practices related to breakthrough drugs in general. As someone not yet in the public payer system, having recently fought a losing battle with my insurance company to obtain the drug Harvoni, I also strongly support your efforts to ascertain the impact of these practices on our general citizenry and other payers as well.

We all know that competition is an integral part of a capitalist society, yet in any political system, equal access to healthcare should be every individual's right. It is especially shameful that in a developed country as rich as the United States, this is not the case. How does one govern greed? Unchecked, as we have seen with mortgage and securities industries, it can cripple the entire world economically. As our healthcare system as it exists today cannot stand up to repeated assaults by "single source innovator" greed, your willingness to tackle this problem is gratefully acknowledged. My responses to your questions follow.

1. *What are the effects of a breakthrough, single source innovator drug on the marketplace? What policy levers are available to increase competition or to ensure availability to those who would benefit clinically?*

a. The effect in my case was that my insurance company refused to cover Harvoni, and it was further complicated because the plan was self-insured and the employer was not covered by ERISA. There literally was no recourse other than a lawsuit. Ultimately, Gilead chose to give me Harvoni treatment at no cost, even though I did not qualify in terms of income level. I was one of the lucky ones as I was able to negotiate the labyrinthine system; a sick person should not have to be a pretend lawyer in order to obtain healthcare.

b. Making these types of drugs the same price for everyone could streamline the system for all payers and make it more fair for everyone, including patients, insurance carriers, Medicare, and Medicaid. This would preclude companies from competing in terms of price, which I know is against the grain of capitalism, but it does address the question of equalizing access and allowing insurance companies to remain viable. In a perfect world, companies could decide to

compete by offering better service and easier access to their client-bases in order to garner a larger share of the market.

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? Payers were caught off guard because of the large number of patients now able to be treated, so even though the cost of Sovaldi vs previous treatment was about the same (except when they added Olysio), the sheer numbers of patients was overwhelming. Can there be a warning system?*

a. I suggest that the FDA drug approval process could contain a flagging mechanism when such a breakthrough is promising or imminent, much like our green, yellow, red security system.

b. Electronic health record keeping offers the opportunity to automate an anonymous reporting process to collect statistics for any type of condition from treating physicians. It would also seem that payers could notice the numbers of patients suffering from Hep C or any disease, and what stage (or not) of treatment they are in by doing periodic analyses of the diagnoses on the bills they are paying; adding new codes to cover “warehousing” might be possible. All patients would require a consistent identifying, but confidential, number that would follow them through the system and from treater to treater in order to avoid duplication in the statistics.

3. *What role does the concept of ‘value’ play in this debate, and how should an innovative therapy’s value be represented in its price?*

Value is a relative term, as it does not mean the same thing in terms of a civilized society, a corporation, or a political system. It is complicated by other terms like “humanitarian” and “economic”. You cannot put a price on humanitarian value, so I will assume you are asking about economic value. That said, I respectfully submit that there should be no reward other than the usual reward a company expects for creating any product worth its making whether it is a useful drug, a gun, or a car. This is not to say that there shouldn’t be incentives to encourage discovery, and this is addressed in your question #4.

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

a. Make the drug the same price for everyone. I believe that the current form of negotiating prices between different payers is actually more expensive in term of bureaucratic time and effort. It is also not fair to the consumers. It should not be difficult to amortize the desired financial end equally based on the estimated number of patients, and price the drugs the same for everyone.

b. This category of drug needs to be regulated. The questions of “how much is enough” and “what is sufficient financial incentive” can be answered by a percentage-type formula calculating desired net profit on a sliding scale based on anticipated net. Companies then can compete within that stricture. If anticipated net exceeds or falls short of forecasts, adjustments could be made on a regularly scheduled basis in line with the customary corporate quarterly financial reporting schedule.

c. Creation of regulation and computational models should involve stakeholders, and not be used as a political football. Create a volunteer commission of interested parties from all sides to study and create a recommended regulation formula. People being people, most prospective members would be looking after their own interests, so creation of a volunteer commission should be possible, as it would behoove all stakeholders to participate. There would need to be a congressional mandate that the commission WILL make regulation recommendations, and in a timely manner. It could be comprised of treating physicians, public and private insurance financial executives, health advocates, and impartial economists. Other stakeholders may be identified, but they must be non-partisan. The economists would be chosen from top business school graduates, and they could serve their country in this way while receiving reductions in their student loans. Much of the expense of meeting could be avoided by teleconferencing. If Congress could not provide minimal funding for expenses, perhaps healthcare industry leaders could fund the pot, with equal shares coming from all stakeholders.

d. Incentives to innovators could be provided in at least two ways. With pricing being unilaterally applied, the client base will increase and profit will be provided in terms of sheer numbers, i.e. demand. In addition, in exchange for making drugs more affordable, the company could be granted tax credits on that particular product for a set number of years; the loss of tax revenue could be calculated in such a way as to be offset by the reduction in funds paid out by MediCare.

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?*

I think accepting the protocol set by independent experts (such as the that set by the AALSD and IDSA) is a good triage effort from a health perspective, but from an economic perspective, the ultimate cost to the payer due to the consequences of delaying treatment must also be considered and I am not sure there is a tool for this at the present time. For instance, a patient who is “not sick enough” to merit the treatment immediately is not precluded from needing ongoing care or even a liver transplant at some point in the future. Low-income individuals in particular can become discouraged by the system and give up, resulting in more serious illness with the passing of time. Finding a way to measure economic impacts would help complete the picture.

I hope you find this information helpful and I thank you again for the opportunity to contribute.

Kathleen E. Salvia