

HEPATITIS C AND VETERANS

HEARING

BEFORE THE

COMMITTEE ON VETERANS' AFFAIRS

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HEPATITIS C AND VETERANS

WEDNESDAY, DECEMBER 3, 2014

U.S. SENATE,
COMMITTEE ON VETERANS' AFFAIRS,
Washington, DC.

The Committee met, pursuant to notice, at 11:34 a.m., in room SR-418, Russell Senate Office Building, Hon. Bernard Sanders, Chairman of the Committee, presiding.

Present: Senators Sanders, Hirono, Burr, and Moran.

OPENING STATEMENT OF HON. BERNARD SANDERS, CHAIRMAN, U.S. SENATOR FROM VERMONT

Chairman SANDERS. My apologies to everybody. There were some votes that were announced yesterday that Senators had to be at, so we pushed back the hearing, so we appreciate everybody being here.

Today's hearing is dealing with a very, very important subject. It contains, I think, some very good news and some news which is not so good, and that is what we are going to discuss.

The good news is that for the very first time, there is now available on the market an effective, fast working, and life-saving drug to treat a very, very serious illness in this country, which is Hepatitis C. Hepatitis C impacts some three-to-five million Americans, and disproportionately affects veterans. So, the good news is that we have a drug now which replaces other less effective treatment, which can have terrible side effects, with a much, much better drug, and that is very welcome news.

The bad news is that this particular drug, called Sovaldi, manufactured by a company called Gilead, is so expensive—it is on the market for about \$1,000 a pill with a course of treatment at about \$84,000—that while this drug is terribly valuable, the reality is that many people cannot afford it.

I became aware of this issue when, as Senator Burr will remember, a number of months ago, VA came to us with a request for the funds they needed to deal with the problems in the VA, and there was a line item for \$1.3 billion just for Hepatitis C treatment, which made me aware of the problem.

So, the question that we are going to be exploring today is the impact of a drug to treat Hepatitis C. Because VA negotiates drug prices with the pharmaceutical industry, it was able to get a substantial discount for the drug, yet, it is still very, very expensive. And if the VA is going to spend billions of dollars for one drug to treat one illness, the reality is that there is less money available to deal with the many other problems facing the VA.

One of the issues that Senator Burr and I are working on, which is a very terrible issue, is suicide rates and mental health issues among veterans, and I want to see VA do a better job and provide treatment for more people. It is an expensive proposition to treat mental illness. But, because VA may have to spend outrageous sums of money for one drug, there is less money available to deal with other issues, like treating mental illness.

Prior to the manufacturing of these new drugs from Gilead, the primary method for treating Hepatitis C was Interferon, an injectable medication that has many side effects that are emotionally and physically painful for most patients. Additionally, many patients require additional medical intervention, including liver transplants. These treatments are expensive. According to research by Dr. John Gaetano of the University of Chicago, who has special expertise in hepatitis, it is estimated that costs for a person with liver damage over a 10-year period can exceed \$270,000, and the average liver transplant in 2011 cost \$577,000. Therefore, if we can get cost-effective treatment to people with Hepatitis C and prevent these very, very costly procedures, in the end VA, Medicare, Medicaid, and the American people save substantial sums of money. So, we have to figure out how we get treatment to these people in the most cost-effective way.

Gilead, the manufacturer of Sovaldi, is, as I indicated, providing this drug at a treatment cost of \$84,000. We invited Gilead to be with us today to answer the questions as to why their product is so very, very expensive and I am upset that they have chosen not to be here. Apparently, as they told us, all of their executives seem to be traveling all over the world and were unable to be here today to answer our questions.

No one denies the appropriateness of companies that do research and development to make a decent profit on their product. That is the way the system works. But, what we are looking at here with Gilead is not a decent profit. What we are looking at is very clearly a very, very excessive profit and a lot of that profit is going to be paid for by the taxpayers of this country.

Gilead purchased Pharmasset, the company that developed the drug now known as Sovaldi, for \$11 billion. According to some estimates, Gilead is expected to make more than \$200 billion on the sale of Sovaldi. Let me repeat that. They purchased the company that developed the product for \$11 billion. It is estimated that they will make \$200 billion on that one product.

So, the issue that we are really dealing with today is not only the impact of the cost of this drug on VA, Medicaid, and Medicare, it is a moral issue—how many people in this country will suffer, and how many will die very painful deaths because they can not access the drugs they need because of the excessive costs. I am pleased we have some great witnesses here today who are going to help us explore this issue.

While this is a national issue—I mentioned a moment ago that some four million people in this country are suffering with Hepatitis C—VA currently has 174,000 veterans receiving care for Hepatitis C, and the estimate is that an additional 42,000 veteran patients have not yet been tested to see if they, too, have the disease.

A full 25 percent of VA patients with Hepatitis C have advanced liver disease, which is also called cirrhosis of the liver, and in the last 10 years, the number of veterans with liver cancer, a common side effect of Hepatitis C among the veteran population, has increased ten-fold. This is especially true of Vietnam-era veterans.

And, the one point that I also want to make is a lot of people in this country, including veterans, inadvertently got this virus by walking into a hospital and getting treatment before we knew how Hepatitis C was spread. Maybe they got a blood transfusion from a needle that was previously used and they ended up with Hepatitis C through no fault of their own.

Another point I want to make is that, according to *Bloomberg News*, Gilead is working on deals with generic drug makers to sell Sovaldi to about 80 developing countries for a tiny, tiny fraction of the cost for which they are selling that product to Americans. Now, I happen to think it is a good thing that people in Egypt, where Hepatitis C is very prevalent, and in other developing countries around the world, that people get this drug at an affordable price, but it should not be the case that the taxpayers, consumers, or patients in this country have to subsidize that affordability. So, I think it is important that people get it at a price they can afford it, but Americans should get it at a price they can afford as well.

So, let me conclude by saying that I appreciate the work VA has done to move rapidly to provide the most up-to-date treatment for veterans with Hepatitis C, but it is deplorable that due to the high price tag, VA might not be able to offer this treatment to all who qualify. I fear we are going to see significant rationing among the VA population. In fact, we are already seeing rationing in the Medicaid population all over this country, because States do not have the money to provide this new treatment. And we must address the moral issue were. Are we comfortable with a situation in which a company is making extraordinary profits while people suffering with Hepatitis C cannot access the treatment that they need?

So, that is the framework of today's discussion. We have some great panelists to help us explore that issue, and with that, let me give the microphone over to Senator Burr.

**STATEMENT OF HON. RICHARD BURR, RANKING MEMBER,
U.S. SENATOR FROM NORTH CAROLINA**

Senator BURR. I thank the Chairman. I will try to be brief, Mr. Chairman, and I would encourage our colleagues, to put their opening statements in the record, perhaps rather than give them, so we can get right to the witnesses.

The one take-away that I have so far is that innovation is expensive. We have known that. Every time we innovate a new therapy, a new drug, a new device, there is a recovery cost, and many times it is government that drives the cost up because we lengthen the approval time; therefore, we shorten the patent lifetime, or individuals question exactly what the recovery period is going to be like and the cost of the capital they need to make it through the "valley of death." Research and advanced development and slow trials cost much more than what the innovator thought to begin with. So, if you are going to hold companies responsible, then you have got to

hold venture capitalists responsible and everybody in the chain of financing innovation.

Yet, I think one thing that we agree on is that we do not want to give up innovation. While much of the discussion is focused on the cost of these new therapies, particularly Sovaldi, I think it is important that we not lose sight of the promise that breakthroughs hold for Hepatitis C patients. While I am concerned that veterans may not have access to the particular drugs they need and about the increases in general spending governmentwide, in this case, I believe the attention has been misplaced.

I believe the price of this specific drug is to be looked at on a macro level. We should examine the long-term benefits groundbreaking therapies bring to our veterans as well as the long-term savings it could bring to the VA and to taxpayers by replacing the need for more risky and costly treatments, such as liver transplants.

The benefit to the veterans is obvious, however. Since FDA approved Sovaldi only a year ago, it may be too early to truly understand the benefits to VA. This drug is a game changer in treating veterans with Hepatitis C and all Americans. For the first time, there is a drug on the market with a proven record of curing Hepatitis C in only 12 weeks, without the debilitating side effects of previous treatments. This drug will put veterans on a sounder long-term path and vastly change their quality of life.

Prior to this drug, Hepatitis C patients faced up to 48 weeks of daily pills and weekly injections. The treatment came with severe flu-like side effects and a very limited cure rate. When we look at the cost of the drug, we need to take into consideration the role the drug plays in meeting the needs of the patient and the role they have on improving patients' quality of life.

On one level, I understand why the Chairman chose this Committee to hold a hearing on the cost of Hepatitis C treatments. Because of the battlefield blood transfusions that took place in Vietnam, Hepatitis C is more prevalent in VA's population than in the general population. In fact, in 2013, 174,000 veterans were estimated with Hepatitis C, or about 3 percent of the VA's unique patient population, compared to less than 1 percent of the general population diagnosed with Hepatitis C.

But, you cannot make a comparison between what the VA pays and what others pay for a prescription drug. Under current law VA is mandated a discount on the prescription drug price. The law directs the manufacturers of certain drugs to enter into an agreement with VA under which the price paid by VA for those drugs is no more than 76 percent of the average non-Federal manufacturer's price.

Now, let me just stop there and say the general population is subsidizing everything that we put into the VA population. The general population is subsidizing what we take into the VA population. Maybe that is the right thing to do. It is what we have adopted. But, it does make it more expensive for the general population.

Because VA is mandated to pay a certain price, it cannot be assumed that government controls on drug prices will yield the best medicines in the future. Mandating drug prices would reduce the

amount of money drug manufacturers invest in research and development and ultimately adversely impact innovation.

Today's hearing marks the second hearing in the past month the Chairman has convened to look at various drug pricing issues. As I have said before, we are not going to do right by the American people if all we look at is drug pricing in a vacuum and then proceed to ignore how greater government involvement by this Congress and the Federal Government more broadly adversely impacts the very innovation patients waiting for a cure depend on. It is my hope that we will look at this in the context of how innovation actually saves the taxpayers long-term money over the long term, but most importantly, increases the quality-of-life of our Nation's veterans immediately.

I thank the Chair.

Chairman SANDERS. Thank you, Senator Burr.
Senator Hirono.

**STATEMENT OF HON. MAZIE K. HIRONO,
U.S. SENATOR FROM HAWAII**

Senator HIRONO. Thank you, Mr. Chairman, and thank you to our witnesses for being here today.

Earlier this year, Senator Kirk and I introduced the Viral Hepatitis Testing Act of 2014. Our bill would increase surveillance, education, and testing programs for viral hepatitis. Our bill also directs HHS to identify populations considered high risk. I believe that our veterans' population, given the rate of infections at three times higher than the general population, is one such population. Thirty percent of all VA veterans suffering from hepatitis-related liver disease reside in rural areas, so that presents its own set of concerns and challenges.

It is important to increase surveillance within the VA population to help prevent the spread of Hepatitis C as well as ensure that veterans are getting treatment in a timely manner. Given the impact it has on veterans and the issues surrounding the cost of treatment options, this hearing is, of course, timely.

Many individuals infected with Hepatitis C are unaware that they have it, and this is a highly contagious infectious disease. So, individuals can live for many years without symptoms and during this time may unknowingly transmit the virus to others.

Previous treatments for Hepatitis C were debilitating for many patients, with lots of bad side effects. Fortunately, recent medical advances have provided easier treatment options for those infected with Hepatitis C. Unfortunately, as has already been stated, the treatment options are very expensive—estimates range from around \$80,000 to \$100,000 for a course of treatment—and there is still no way to prevent new cases of Hepatitis C.

These new treatments claim to cure hepatitis in over 90 percent of all cases, and to-date for Hawaii, 35 patients at Hawaii VA have benefited from this new treatment. The high cure rate combined with the ability of patients to tolerate the new treatment make these new drugs highly desirable for those with Hepatitis C. So, the VA has prioritized those with advanced liver disease for the treatment in an effort to control costs.

Despite the drug discount and the prioritization of patients, it is estimated that the VA will spend \$1.3 billion over the next 2 years just on this Hepatitis C treatment. It is not sustainable. It will strain VA resources at a time when veterans are increasing in number and complexity of conditions.

I look forward to hearing from the panel about the cost of Hepatitis C treatment and how the VA is managing the veterans' treatment. I am also interested in hearing how the VA proposes to continue providing the treatment while ensuring no loss of service for other health care concerns. Thank you.

Chairman SANDERS. Thank you very much, Senator Hirono.

OK. Now, let us bring up our first panel, if Mr. Valentino and Dr. Ross can join us. We are pleased to have these very knowledgeable folks to discuss this issue with us.

Michael Valentino is Chief Consultant of VA's Pharmacy Benefits Management Services, and he is accompanied by Dr. David Ross, Director of the HIV, Hepatitis C, and Public Health Pathogens Program at the Department of Veterans Affairs. We thank both of you very much for joining us for this important discussion.

Mr. Valentino, please begin.

STATEMENT OF MICHAEL VALENTINO, R.Ph., MHSA, CHIEF CONSULTANT, PHARMACY BENEFITS MANAGEMENT SERVICES, U.S. DEPARTMENT OF VETERANS AFFAIRS; ACCOMPANIED BY DAVID ROSS, M.D., Ph.D., MBI, DIRECTOR, HIV, HEPATITIS C, AND PUBLIC HEALTH PATHOGENS PROGRAM, OFFICE OF PUBLIC HEALTH/CLINICAL PUBLIC HEALTH, VETERANS HEALTH ADMINISTRATION

Mr. VALENTINO. Thank you very much. Good morning, Chairman Sanders and Ranking Member Burr. Thank you for the opportunity to discuss VA's commitment and actions to provide Hepatitis C virus care for veterans. I am accompanied today by Dr. David Ross, Director of VA's HIV, Hepatitis, and Public Health Pathogens Program.

All veterans, including those with Hepatitis C, have earned and deserve health care that is sensitive to their unique service exposures and health risks. Acknowledging this fact, VA added Hepatitis C drugs to its drug formulary and also developed prescribing guidance to assist providers to care for the 174,000 veteran patients who are known to have been infected with the Hepatitis C virus, also known as HCV. VA is the largest single HCV provider in the United States and has had a comprehensive national HCV program in place since 2001.

Historically, like other health care providers, VA has only been able to treat a portion of veterans for HCV due to the low efficacy and high toxicity of older drug therapies. Fortunately, the recent approval of newer drugs is making HCV treatment and cures easier to achieve.

VA's primary goal for formulary management has been and remains the provision of safe, high quality drug therapy by a reliance on robust evidence to guide medication use. Drug formularies are not new components of the health care delivery systems in either the public or private sectors. VA was a pioneer in this area, employing drug formularies as early as 1955.

In VA, the simple drug lists of earlier times have been augmented with clinical protocols designed to assist clinicians in using drugs safely, effectively, and efficiently. This is accomplished using evidence-based drug reviews, actively managing drug utilization, leveraging VA's purchasing power, streamlining supply chain distribution, and, importantly, by integrating clinical pharmacists into the medication-use process.

In the past 3 years, significant gains have been made in the options available to cure HCV infection, with additional options expected to be approved in the very near future. In late 2003 [sic], the U.S. Food and Drug Administration approved two antiviral medications for use as part of combination regimens. These drugs offer shorter treatment durations, decreased side effects, and increased cure rates over older treatments. Other new agents and combinations of agents are expected to receive FDA approval in 2014 and 2015, making additional treatment regimens available to veterans.

As part of its comprehensive HCV treatment program, when better HCV treatments become available, VA will continue to move aggressively to treat patients, making it possible to cure an ever-increasing number of HCV-infected veterans. VA moved rapidly to deploy the new, more effective, less toxic HCV treatments, and consistent with its goal as a steward of taxpayer dollars, negotiated significant discounts for these therapies. For example, VA negotiated the \$1,000 per dose commercial price of Sofosbuvir down to \$594 per dose. Similarly, the commercial price of \$790 per dose for Simeprevir was negotiated down to \$413.

In fiscal year 2014, VA treated over 5,400 veterans with these new treatments and spent approximately \$275 million in drug costs alone on these treatments. Despite the significant discounts VA negotiated, it will still be a challenge to ensure adequate funding is in place to provide these medications in the future. This is the reason then-Acting Secretary Gibson requested an additional \$1.3 billion to fund these treatments in fiscal years 2015 and 2016.

As the largest single provider of care for HCV infection in the United States, VA is charged with addressing an epidemic of life-threatening complications among veterans with HCV infection. This challenge is increased by the likelihood that some veterans with HCV infection remain undiagnosed while others will not accept treatment or may not be able to undergo treatment because of coexisting medical conditions. Introduction of very costly, highly effective, less toxic, and easier to administer antiviral therapies holds the promise of eradicating this disease in HCV-infected veterans.

Mr. Chairman, VA is committed to helping veterans by providing the highest quality of care, including medication therapy. We are dedicated to providing evidence-based care to ensure the continual improvement of care for veterans with HCV infection. We recognize our future work to improve the quality of HCV care will be based in large part on understanding and addressing variation in HCV care structures, processes, and outcomes, and by doing all we can to reduce the cost of these therapies.

My colleague, Dr. Ross, and I are happy to respond to any questions you and the Committee Members might have.

[The prepared statement of Mr. Valentino follows:]

PREPARED STATEMENT OF MICHAEL VALENTINO, VHA CHIEF CONSULTANT FOR PHARMACY BENEFITS MANAGEMENT, U.S. DEPARTMENT OF VETERANS AFFAIRS (VA)

Thank you for the opportunity to discuss VA's commitment and efforts in providing timely access to high-quality Hepatitis C Virus (HCV) care for Veterans, including their pharmaceutical treatment. I am accompanied today by David Ross, M.D., Ph.D. Director of VA's HIV, Hepatitis, and Public Health Pathogens Program.

VA has approximately 174,000 Veterans in care with HCV, making it the largest single HCV provider in the U.S. VA has had a comprehensive national HCV program since 2001. Like the rest of the country, VA has treated only a portion of Veterans for HCV because treatment and cures have been difficult to achieve due to low efficacy and high toxicity of standard drug therapies.

OVERVIEW

Chronic infection with hepatitis C virus (HCV) is the most common blood-borne infection in the world and is a major public health problem facing not only the Veterans Health Administration (VHA) but the United States in general. Complications that may result from untreated HCV infection include progressive liver damage leading to cirrhosis (also known as Advanced Liver Disease, ALD), hepatocellular carcinoma (HCC), and other life-threatening conditions. Although many of these complications are treatable or even preventable, they may occur because only half of the individuals with HCV infection in the U.S. are aware they are infected. The epidemic of HCV in the U.S. has also affected VA, and we are capitalizing on the availability of new therapies to improve access to and quality of HCV care.

VHA is a leader in the U.S. in HCV infection care, including screening, treatment, and prevention. Between 2002 and 2013, the percentage of Veterans in VHA care with at least one outpatient visit who had ever received screening for HCV infection more than doubled from 26.9 percent to 56.0 percent. Individuals born between 1945 and 1965 are at higher risk for HCV infection due to exposure to the virus; as of 2013, almost two-thirds of Veterans in VHA care born between these years have been screened for HCV infection. VHA is also developing an electronic clinical reminder to improve screening rates among Veterans in the 1945–1965 birth cohort and others with risk factors. Similar improvements were seen in confirmatory testing after an initial positive screening result, which increased to 96 percent across the system by 2013. VHA's HCV care is implemented at VA medical facilities across the country and uses a comprehensive approach that includes:

- Universal assessment for risk of hepatitis C infection
- Testing and counseling for those at risk, particularly those in the 1945–1965 birth cohort
- Education for patients and their families
- Giving providers access to the best available information about hepatitis C
- Excellence in clinical care
- Support for research to improve clinical care
- Ongoing quality improvement

SCREENING FOR HCV

Increased screening for HCV is a critical component of early identification and linkage to care. Under VHA Handbook 1120.05, Coordination and Development of Clinical Preventive Services, screening is defined as an examination or testing of a person with no symptoms of the target condition to detect disease at an early stage when treatment may be more effective, or to detect risk factors for disease or injury. The current VA HCV screening policy recommends offering HCV testing to any Veteran born between 1945–1965, to any Veteran who has a risk factor for HCV infection such as Vietnam-era service (defined by dates of service in 1964–1975,) or a blood transfusion or organ transplantation prior to 1992, or to any Veteran wishing to be tested. This policy closely follows the 2013 US Preventive Services Task Force recommendation for screening for HCV in persons at high risk for infection and also offering one-time screening for HCV infection to adults born between 1945 and 1965 (B recommendation).

As most Veterans with HCV infection were infected decades ago and fewer than 22,000 new HCV infections in the U.S. occur annually, the increase in the number of HCV-infected Veterans in VHA care largely represents expanded screening and identification of individuals with pre-existing HCV infection rather than new infections. Entry of previously diagnosed patients into VHA care may also have contributed to this increase. It is important to remember that the cohort of HCV-infected

Veterans in VHA care changes from year to year due to new diagnoses, deaths, and Veterans with HCV infection moving into or out of VHA care.

TREATMENT FOR HCV

In the past three years, significant gains have been made in the therapeutic options available to cure HCV infection, with further gains expected in the very near future. In 2013, the U.S. Food and Drug Administration (FDA) approved two antiviral medications for use as part of combination regimens which offer shorter treatment durations and decreased side effects in addition to increased cure rates. Several other new agents and combinations of agents are expected to receive FDA approval in 2014–15, making additional treatment regimens available for patients. The evolution of management and treatment of HCV infection will make it possible to cure an increasing proportion of HCV-infected Veterans with fewer side effects.

VHA has moved rapidly to deploy new, more effective, less toxic HCV treatments and has been able to negotiate significant discounts for these newer therapies. For example, VA has negotiated a price of \$594 per dose for Sofosbuvir (the commercial price is \$1000 per dose) and \$413 per dose for Simeprevir (the commercial price is \$790 per dose). When the VA Pharmaceutical Prime Vendor negative distribution fee of 9.15% is factored in, VA's net price for Sofosbuvir is \$539 per dose and is \$375 per dose for Simeprevir. In FY 2014, VHA treated over 5,400 Veterans with HCV with these new treatments. VA spent over \$370 million in drug costs alone on these new treatments in FY 2014. VA is actively planning for the deployment of more effective HCV treatments becoming available in later this year and we plan to move aggressively to treat patients with these drugs, based on clinical need.

Veterans infected with HCV in VHA care receive primary care through their local VHA medical center or VHA community-based outpatient clinic. However, some Veterans may need to travel to another VHA facility to receive the full spectrum of specialized HCV care. Increasingly, telemedicine platforms, such as telehealth and Specialty Care Access Network-Extension for Community Outcomes (SCAN-ECHO), are being used to deliver care to Veterans in remote areas or to Veterans with conditions that limit mobility.

CURRENT CHALLENGES AND FUTURE DIRECTIONS

As the largest single provider of care for HCV infection in the U.S., VHA is charged with addressing an epidemic of life-threatening complications among Veterans with HCV infection. The challenge is increased by the likelihood that some Veterans with HCV infection remain undiagnosed, while others do not accept treatment or may not be treatment candidates because of co-existing medical conditions. The introduction of very costly, highly effective and less toxic anti-viral therapies, which are easier to administer than older treatments, holds the promise of eradicating this disease in infected Veterans. VA redirected funding for the increased cost of the newer medications for Fiscal Year 2014 and is doing so in 2015. For future budget submissions, VA will incorporate the cost of these new therapies into the Enrollee Health Care Projection Model (EHCPM) estimates. However, addressing the cost of these agents remains a major challenge. In addition, the synthesis of a population health approach to HCV infection with system redesign will improve access to high-quality HCV care for Veterans. System redesign refers to analysis of barriers that may affect patients' access to care, followed by design and execution of changes to overcome such barriers. VHA is currently developing a VISN-centered system redesign approach that will coordinate care of HCV and its complications across a wide area. The application of system redesign principles to HCV diagnoses, treatment, and care promises to substantially improve access to, quality of, and efficiency of care. Finally, the experience, expertise, and dedication of VHA providers and pharmacists will allow VA to deliver the excellent care that Veterans with HCV deserve.

CONCLUSION

VHA is committed to providing evidence-based care to ensure the continual improvement of VHA care for Veterans with HCV infection. We recognize that our future work to improve the quality of HCV care will be based in large part on understanding and addressing variation in HCV care structures, processes, and outcomes. We are happy to respond to any questions you may have.

Chairman SANDERS. Thank you very much.

So, how many veterans do you estimate are suffering with Hepatitis C?

Mr. VALENTINO. Right now, it is 174,000, approximately, who are known to have been infected.

Chairman SANDERS. And, of that 174,000, I know that not every one of them can necessarily be treated by this drug, but what is your guess, if we could snap our finger and have that drug and treatment available, how many of those veterans could be helped by this drug?

Mr. VALENTINO. Well, let me first say to any veterans or loved ones who are listening who are affected by this, it is our goal that you come into VA, talk with your provider, and together decide when the time is right to be treated.

Chairman SANDERS. I am just trying to get an overview here. How many—

Mr. VALENTINO. Right.

Chairman SANDERS. If we did all—and I know you guys do a pretty good job, probably better than anyone else in screening—

Mr. VALENTINO. Yes, sir.

Chairman SANDERS [continuing]. And that is a very positive thing, but if we could snap our fingers today, how many folks are out there who could be treated with this new drug, if you would guess?

Mr. VALENTINO. I would defer to Dr. Ross to answer that question.

Chairman SANDERS. Dr. Ross, what is the answer?

Dr. ROSS. Sure. Thank you for that question, Mr. Chairman. Although we are talking about large numbers, I am going to give you a specific answer. I think it is important to remember, it ultimately comes down to a discussion between patient and physician.

Chairman SANDERS. Right.

Dr. ROSS. Certainly, that was true with the older, more toxic—

Chairman SANDERS. All I am asking for is your guess.

Dr. ROSS. OK. I would say there are patients who have simultaneous medical conditions that need to be dealt with first, and that could be anywhere from one-half to two-thirds of patients where we need to work on those first, either for a short period of time or a longer period of time.

Chairman SANDERS. One-half or two-thirds of the 174,000?

Dr. ROSS. Yes, and that is an off-the-top-of-my-head number.

Chairman SANDERS. Yes, I understand. So, that is about 75,000 or 100,000 people. How many people right now—when the Secretary asked for \$1.3 billion, how many—if he had that check in his hand right now, how many patients would he be treating?

Mr. VALENTINO. It is a very dynamic process with the pricing, but I can give you an answer based on what we know now.

Chairman SANDERS. OK.

Mr. VALENTINO. I would estimate that to be somewhere in the neighborhood of 25,000 to 30,000 patients.

Chairman SANDERS. So, Dr. Ross is suggesting—and, I understand, these are rough estimates—that maybe we need to be treating 100,000, and this \$1.3 billion would treat 25,000?

Mr. VALENTINO. Twenty-five to 30,000.

Chairman SANDERS. OK. So, these numbers suggest to me that if we continue the current pricing, and if you guys do a good job

in outreach, that \$1.3 billion may go up by two to three times. Is that a fair piece of arithmetic, or—

Mr. VALENTINO. As I—yes, although there are some changes in the marketplace that could impact—

Chairman SANDERS. All right. I want to get to that—

Mr. VALENTINO. OK.

Chairman SANDERS [continuing]. In a second.

Mr. VALENTINO. Yes, sir.

Chairman SANDERS. Explain to us, because I have known about VA negotiating prices. You do this with all drugs.

Mr. VALENTINO. Yes, sir.

Chairman SANDERS. And, you are one of the few government entities who can do this. Medicare, for example, does not negotiate prices by law, but you do, and you have got lower prices because of those negotiations. Am I correct that you are paying \$540 a pill for Sovaldi?

Mr. VALENTINO. After all discounts, yes.

Chairman SANDERS. OK, \$540. How come it is not \$386 or \$240? How did you come up to \$540?

Mr. VALENTINO. Well, as was mentioned earlier, there is a statutory discount, and that is really where we start. It was just the result of intensive negotiations with the manufacturer.

Chairman SANDERS. All right. Let me ask you this. Very interestingly, and maybe we can explore that more in the second panel, Gilead is making this drug available to countries like Egypt, which have very, very serious problems with Hepatitis C. My understanding is that they are selling the product in Egypt for just a few dollars a pill. Is that correct? Do you know anything about that?

Mr. VALENTINO. I personally do not. Dr. Ross—

Chairman SANDERS. Dr. Ross, are you aware what they are?

Dr. ROSS. I am aware that—

Chairman SANDERS. My understanding is it is \$10 a pill.

Dr. ROSS. I could not speak to the specifics of—

Chairman SANDERS. OK. We will get more into that in the second panel, perhaps. Why do you think it is the case that they are selling it to a general American consumer who walks in with Hepatitis C for \$1,000, they are selling it to a huge Federal agency, the VA, which treats more Hepatitis C patients than anybody else in the country at \$540, but they are selling it in Egypt for \$10? How does that happen? How come they negotiated a better price than you did?

Mr. VALENTINO. I cannot answer that question. I do not know what Gilead's business model is. I do not know how that was able to be achieved. You know, those—a lot of other countries have different regulatory processes—

Chairman SANDERS. They sure do, which results in the United States paying, by far, the highest prices in the world for prescription drugs.

And, this may be outside of your portfolio in a sense, but if the VA is going to spend billions of dollars—\$1.3 billion now and maybe more later—to treat one illness, is it fair to suggest that will mean we have less money available to take care of veterans' needs in other areas? Is that a fair supposition?

Mr. VALENTINO. Well, we did ask for more money—

Chairman SANDERS. Right—

Mr. VALENTINO [continuing]. And, so, you know, VA is undergoing a lot of changes now with—

Chairman SANDERS. I am a strong supporter of VA and would like to put more money into the system, but there is a limit to what can be done. All that I am saying, if you are spending billions of dollars in one area, common sense suggests that you may not be able to spend in other areas. Is that maybe a fair supposition?

Mr. VALENTINO. I would not disagree with that.

Chairman SANDERS. OK.

Senator Burr.

Senator BURR. Mr. Valentino, I am going to direct my questions to Dr. Ross—

Mr. VALENTINO. Yes, sir.

Senator BURR. If, for some reason, you want to chime in, feel free. I am going to give you another chance to answer Senator Sanders' first question, which is with an unlimited pot of money, of 174,000 people infected with Hepatitis C, how many would you give Sovaldi to?

Dr. ROSS. Let me just ask you to clarify, and I appreciate the chance to address this question in more detail. We are talking about at this instance, or over—

Senator BURR. Say you have all the money that would buy all the Sovaldi you want.

Dr. ROSS. So—

Senator BURR. You have got 174,000 people who are infected and all 174,000 people have been consulted and they would like to take the drug.

Dr. ROSS. OK.

Senator BURR. Could you give it to all of them?

Dr. ROSS. At this—on this date, no, because it is not clinically indicated for a number of patients. That but, let me—

Senator BURR. And, the clinical indication would be the treatment consideration report found on the Web site, which says VA providers are directed to use the new drug therapy on those veterans with advanced liver disease, such as cirrhosis, liver cancer, and those waiting for a liver transplant. The report also recommends that veterans with less serious conditions wait to receive the treatment. Is that—

Dr. ROSS. Yes, and I actually—my office authored that report, so let me—

Senator BURR. So, what do you say to the ones that you say, well, you have got Hepatitis C and eventually you will have cirrhosis, eventually you could have liver cancer, but you have to wait—

Dr. ROSS. No—

Senator BURR [continuing]. Because we are not going to give you the drug now.

Dr. ROSS. No, Senator—

Senator BURR. Are they going to get cured another way?

Dr. ROSS. No. If I may clarify—

Senator BURR. Sure.

Dr. ROSS. The reason for that was not because we were saying, you have to wait. If somebody said, "I want to be treated now," and

I have patients in my clinic where we have had that discussion, we would treat them now. But, these therapies that were approved by the FDA in 2013 still required, in many instances, the use of these toxic drugs that the Chairman referred to. So, what we have done is we have said——

Senator BURR. Do you have a conditional approval?

Dr. ROSS. I am sorry?

Senator BURR. The approval for Sovaldi was conditional upon having gone through other therapies first?

Dr. ROSS. No. No, sir, that patients getting Sovaldi—the FDA approved it in combination with Interferon and Ribavirin or Ribavirin by itself. Both of these are toxic drugs. So, the choice for patients, whether they have advanced liver disease or not, is yes, you can start now, or we feel very, very confident that in some months, new drugs that do not require Interferon or Ribavirin are going to be available and you may want to wait for those less toxic and, according to clinical trials, more effective drugs. It is not a question of you have to wait.

Senator BURR. It is promising. Do you think any of those drugs are going to be cheaper?

Dr. ROSS. I look at are they more effective and are they safer.

Senator BURR. OK. So, let me ask you this, and since Sovaldi is the only product that we have got right now, what are the long-term savings to VA in dollars for curing Hepatitis C? Mr. Valentino, have you done that study?

Mr. VALENTINO. I have not done that study.

Senator BURR. I would specifically ask, on behalf of the Committee, that the VA do that study. What is the long-term savings if we cure Hepatitis C, and I will not limit it to Sovaldi. I will leave it open for other therapies that are going to come along. But, what do we save in the long-term care of that veteran? We are shoving quality of care for the veteran aside. We are purely looking at how much we would spend as taxpayers to take care of that person with the toxic treatment that is today versus a cure that happens in a matter of weeks.

Mr. VALENTINO. I think that is an excellent suggestion and it is something that we would love to look into. I think the issue is, how long would it take for us to have sufficient data to really answer that question? Right now, it is clearly too soon. I do not know at what point we would have sufficient numbers, sufficient information, because, as you know, this is a disease that progresses over decades so——

Senator BURR. Mr. Valentino——

Mr. VALENTINO. Yes, sir.

Senator BURR [continuing]. I would be satisfied if you would look at it and you make your calculation based upon here is what it costs us over the lifespan of a veteran who has Hepatitis C to treat them under what was the conventional treatment. Now, all of a sudden, we have got Sovaldi and it costs us X; and if we treat it and cure, we do not have this continued cost. What do the two look like? So, I realize there may be something in between, but I am looking at either/or, and I think it is important that we look at the dollars and ask ourselves—because once we get there, then we can

put a value on what the quality-of-life is that we are providing to veterans.

We cannot do that today. Therefore, we dumb ourselves down to only being focused on how much Sovaldi costs, and you have to ask yourself, if we were paying \$10, would you have a staple of new therapies that might be coming out that do not require additional toxic products to go with? The answer is, probably, we would not, because a market has to have the capital to do research and development. It has to have the marketplace.

And, as you and we know, the marketplace on Hepatitis C is rather defined. It probably would be considered an orphan product, almost, because of the size of the population. Is that about right, Dr. Ross? Maybe a little bit over the orphan drug designation?

Dr. ROSS. I am not familiar with the specific definition of an orphan drug, but it is a smaller population than—it is a large population in terms of chronic bloodborne effects. It is the largest population with bloodborne effects in the country. It is smaller than, obviously, other conditions, such as high blood pressure.

Senator BURR. My time has run out. The Chairman has been patient and I thank both of you.

Chairman SANDERS. Senator Burr raised some really interesting questions that I hope we will explore later on.

Senator HIRONO.

Senator HIRONO. Thank you.

I found the Chairman's information regarding the varied costs of this particular drug to the general public, to the VA patient, and in places such as Egypt really fascinating. I am all for innovation and not stifling innovation, but on the other hand, if the general non-VA Hepatitis C patient is charged \$1,000 for this pill, clearly, that person is not, I do not think, paying for it. It is insurance, that person's medical insurance that is paying for this drug. Is that generally the case?

Mr. VALENTINO. I would think so, yes.

Senator HIRONO. So, if that is the case—either one of you can answer—what would be the incentive for the drug companies who are getting reimbursed by insurance for these \$1,000 pills to be innovative and come up with less costly, effective drugs?

Mr. VALENTINO. I am not sure I totally understand the question, but I can say this. We do our best to lower the cost of these drugs when there is sufficient competition, when there are clinically acceptable alternatives, and I think the incentive for other companies to enter the market is to gain a portion of that market share.

Senator HIRONO. Well, we are probably already talking about a relatively small market share for people with, albeit hundreds of thousands of people, but maybe in the scheme of things, this is a relatively small market. So, why would a company enter a market where there is already a company there who can charge a lot of money and get reimbursed by health plans?

Mr. VALENTINO. I cannot tell you why, but I can tell you that there are companies doing just that. We expect another drug is going to be approved later this month and others are going to be approved in 2015. So—

Senator HIRONO. That is good to know, and these companies that are coming up with alternative treatments, is their testing being supported through tax credits and other incentives?

Mr. VALENTINO. I cannot—

Senator HIRONO. Do you know?

Mr. VALENTINO [continuing]. Comment on that, Senator. I do know that a lot of the basic work that leads to some of these discoveries is, in fact, initially funded that way, but I certainly cannot comment on to what extent.

Dr. ROSS. Senator—

Senator HIRONO. Yes.

Dr. ROSS. If I could just add on to Mr. Valentino's points, I think part of it is also what proportion of patients might switch over to a newer therapy. For example, to go back to Senator Burr's question about the treatment considerations document, we gave physicians and providers the choice of deferring therapy with Sovaldi because we knew that for genotype 1 patients, one of the major strains, the most common strain. But, later on in that document, we said, if you have genotype 2 or 3 infection, we know that there are not better drugs likely to be approved soon for those particular strains and, therefore, we said, there is no reason to wait.

So, the question is, is something better coming along, and while I cannot speak from the pharmaceutical companies' perspective, as a provider, I am going to say, is this drug going to work better and be less toxic for my patient, the one that is coming along, so I might wait. If not, then I am going to say, well, it is more important to start treatment now.

Senator HIRONO. I think my series of questions has to do with whether the marketplace really can—is operating in a way that there is more competition for different kinds of treatments that are effective and much less costly. So, is there a way to prevent Hepatitis C, because once one is infected, there is a progression to the disease. So, what are we doing on the prevention side?

Mr. VALENTINO. Do you want to address that?

Dr. ROSS. OK. Briefly, there is no vaccine for Hepatitis C. Transmission for most people occurred decades ago. There are about 20,000 or so new infections every year. The number is actually going up, almost entirely because of sharing of needles among injection drug users.

So, things that we are doing within VA are focusing—and this is done as part of Hepatitis C care—is to help treat people with substance use disorders. We also are doing things—and, again, this is integrated with their medical care—to try and reduce exposures that could also damage the liver, particularly thinking of alcohol use, and an integrated care approach is much more effective about getting people ready for treatment.

One brief anecdote. I have a patient who I saw yesterday who—we started him on methadone maintenance about 6 months ago and he is now ready for treatment. In other words, he will be able to reliably undergo treatment.

Senator HIRONO. So, do these prevention methods that you are utilizing, do they—are they working? I realize it is not that easy to determine whether something you are doing is actually preventing—

Dr. ROSS. It is a matter of keeping people from getting it in the first place, but it is also a question of getting people ready for treatment. Work done in VA has shown that if you take people who have these barriers to treatment because of other diseases, frequently substance abuse or alcohol use, and you give them integrated psycho-social care in the same clinic—this was work that was done at Minneapolis VA, and, I should mention, this is the model that is being used at the Matsunaga VA in Honolulu—

Senator HIRONO. Oh, right.

Dr. ROSS [continuing]. They are more likely to complete therapy and be cured than people who do not have those problems in the first place but do not get that kind of supportive care.

Senator HIRONO. Thank you. Thank you, Mr. Chairman.

Chairman SANDERS. Just in the nick of time. Senator Moran, it is your turn.

**STATEMENT OF HON. JERRY MORAN,
U.S. SENATOR FROM KANSAS**

Senator MORAN. Mr. Chairman, thank you. I am happy to be here in the nick of time.

Let me ask a question somewhat unrelated to the topic today, but it is my opportunity to again send a message to the Department of Veterans Affairs. On November 13, a large group of Senators requested information from the VA. That letter has not been responded to. It is related to the Reform Act. It is our continual question about implementation, particularly related to the 40 miles for a VA facility. I have a number of questions. We asked for the Secretary and officials from the Department of Veterans Affairs to meet with us. And, I would just ask if you, on your return, would raise this topic with those who might be able to facilitate this meeting.

The topic, from my perspective, is, so, you have a facility within 40 miles, but it does not provide the service that you, as the veteran, need. Does that count as a facility within 40 miles? I have great interest in trying to get community mental health centers involved in providing services and the question of whether or not they would be able to provide services has been unanswered. And, finally—although not finally—finally in this list, the issue of is there going to be required advance approval, prior approval by the VA, before you go see an outside provider, and if that is required, is that going to be required every time you make a visit such that we are back to having a bureaucracy again that you have got to go through before you get to go see the outside provider.

I apologize. I know you are here on a different topic. It is an important topic. But, these are awfully important issues in all aspects of veteran health care, and thank you for the nod of your head, which suggests to me that you will—you are going to do what I have asked.

Mr. VALENTINO. Yes, sir.

Senator MORAN. Thank you very much.

Mr. VALENTINO. Absolutely.

Senator MORAN. Mr. Chairman, thank you.

Chairman SANDERS. Thank you very much.

Senator Burr, do you have any other questions?

Senator BURR. No.
Chairman SANDERS. OK. Thank you very much.

RESPONSE TO POSTHEARING QUESTIONS SUBMITTED BY HON. MAZI HIRONO TO MICHAEL VALENTINO, VHA CHIEF CONSULTANT FOR PHARMACY BENEFITS MANAGEMENT, U.S. DEPARTMENT OF VETERANS AFFAIRS

1. The current VA policy recommends offering testing for Hepatitis C. Is there any advantage to making testing standard for all vets when they enter the VA system? If not, would there be an advantage to screening Veterans in high-risk categories?

VA Response: Current VA policy calls for a hepatitis C virus infection (HCV) risk screening at least once on all patients in VHA care, as well as HCV testing for those who are identified as being at high-risk for HCV infection. This policy is consistent with recommendations by the Centers for Disease Control and Prevention (CDC) as well as the U.S. Preventive Services Task Force (USPSTF). This approach maximizes and targets the application of VA resources. Testing all Veterans for HCV on entry to VA care would mean testing both low-risk and high-risk populations. Testing Veterans who are at low-risk would potentially yield a large number of false-positive test results but an extremely small number of true-positive tests. At the same time, testing low-risk Veterans would require substantial monies, both to perform the initial testing and to exclude actual infection among Veterans with false-positive results. Such testing would create anxiety for Veterans who have false-positive tests without providing any benefit. Thus, testing low-risk Veterans would require expenditure of considerable funds without any significant improvement in care.

There are clear advantages to limiting testing to high-risk Veterans for HCV:

- Maximizes efficient use of resources;
- Minimizes false-positive test results; and
- Allows prevention efforts to focus on Veterans who test negative but remain at high risk because of active substance use or other risk factors.

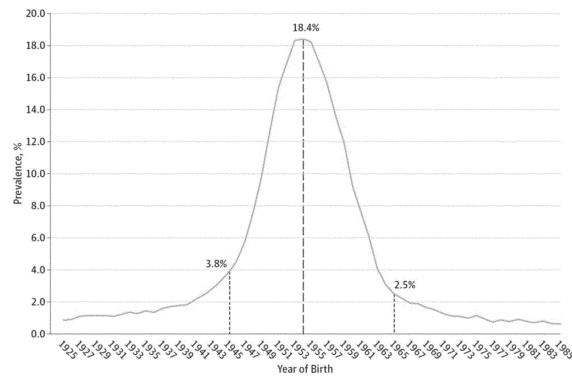
The VA policy on HCV risk factor screening and laboratory testing includes the following specific recommendations:

- 1) Perform HCV risk factor screening at least once on all patients in VHA care.
- 2) Perform laboratory testing if the Veteran desires testing, or if screening identifies any of the following risk factors:
 - Born between 1945-1965;
 - Prior or current intravenous drug use;
 - Blood transfusion or organ transplantation prior to 1992;
 - Hemodialysis;
 - Vietnam-era Veteran, defined by dates of service from 1964 through 1975;

- Health care, emergency medical care, emergency medical and public safety workers after a needle stick injury or mucosal exposure to HCV-positive blood;
- Tattoos or body-piercings obtained in non-regulated settings;
- Intranasal drug users who have shared paraphernalia;
- 20 or more lifetime sex partners;
- Past sexual exposure to an HCV-infected partner;
- Current or past sexual partners of HCV-infected persons;
- HIV infection;
- History of hemophilia and received clotting factor concentrates prior to 1987;
- History of unexplained liver disease or abnormal liver function test;
- Diagnosis of alcoholic hepatitis or alcohol abuse or dependence;
- Born to a mother with HCV; or
- Incarceration.

Efforts are underway to increase testing among the birth cohort (1945-65) and other Veterans at risk. VHA's current guidelines follow the CDC 2012 recommendation for one-time testing for those born between 1945-1965 as this group accounts for approximately three fourths of those currently infected with HCV in the United States. The figure below illustrates the high risk for Veterans in this 1945-65 birth cohort.

Hepatitis C Virus Testing and Prevalence among U.S. Veterans in Department of Veterans Affairs Care



JAMA Intern Med. 2013; 173(16):1549-1552.

2. Would a national surveillance program for viral hepatitis help reduce the number of new cases at the VA?

VA Response: National surveillance for viral hepatitis is important to reducing viral hepatitis, and related morbidity and mortality in VA and the U.S. as a whole.

VA currently has a robust surveillance program for HCV (see question 4 for discussion of hepatitis B surveillance). Components of the surveillance program are as follows:

- Screening of all Veterans for HCV risk factors
- Testing of all Veterans who are at high risk or who desire testing
- Automatic (reflex) follow-up confirmatory testing to identify which patients with positive test results actually have chronic HCV
- Entry of patients with laboratory-confirmed chronic HCV into facility-level electronic HCV Clinical Case Registries (CCRs) by CCR coordinators at each VA facility
- Daily aggregation of data from facility-level CCRs into the VA's national HCV CCR
- Annual report generation on numbers of HCV patients in VA care, along with detailed characteristics of the population of patients in VHA care with confirmed HCV (demographics, disease status, treatment status, and other factors of interest)
- Weekly and monthly generation of reports as needed for operational purposes (e.g., numbers of VA HCV patients treated with new anti-viral drugs)

Currently, there are approximately 17,000 persons newly infected with HCV annually in the U.S., with fewer than 1,000 persons newly infected with HCV in VA care. Virtually all of these new infections are related to injection drug use combined with needle sharing. VA's guidelines on HCV testing (see response to Question 1, above) are designed to identify patients who may become newly infected through this route. If a patient is HCV-negative but remains at risk for infection because of behaviors such as injection drug use, the negative result is an ideal opportunity to work with the patient to modify his or her behavior to decrease the risk of infection.

3. The VA estimates that 30% of VHA patients with Hepatitis C-associated liver disease reside in rural areas. In Hawaii, many veterans face geographical barriers when seeking specialty care. What areas can VA improve in providing Hepatitis C or liver disease-related treatment for veterans in rural areas? Could you describe

VHA's efforts to utilize telehealth services for our veterans suffering from chronic Hepatitis C or liver disease?

VA Response: Expertise in treatment of HCV has traditionally been concentrated at VA Medical Centers, particularly those affiliated with academic medical centers. This model, while useful, creates a barrier to access for Veterans with HCV who are located far from such Medical Centers. While this issue is a particular concern for Veterans living in rural or highly rural areas, it can also be a problem in urban areas for Veterans facing mobility or transportation challenges. VA can improve access for such patients by building on a number of mechanisms, which are currently in use at various facilities across the system:

- Increasing the number of providers trained to deliver HCV care, particularly at outlying VA Community-Based Outpatient Clinics (CBOCs) affiliated with VA Medical Centers.
- Expanding its already robust programs in teleconsultation and telehealth services in the area of HCV care.
- Employing a "circuit rider" approach in which trained clinicians come to a location convenient for the patient.

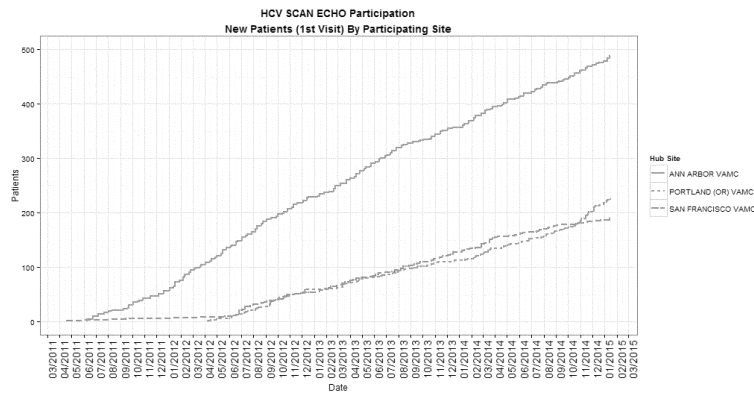
To increase the number of trained providers, VA has intensively trained hundreds of new providers over the last few years. These include primary care physicians, clinical pharmacists, nurse practitioners, and physician's assistants. VHA Pharmacy Benefits Management Services and Public Health have collaborated on a series of "boot camps" that train clinical pharmacists – who are extremely well-suited via their professional education and experience – to serve as HCV treatment specialists.

Training of primary care providers via teleconsultation has been of particular interest in VA because of the overlap between primary care expertise and the conditions seen in many Veterans in care with HCV that may affect treatment candidacy, such as depression, alcohol use disorders, and substance use disorders. In addition, the manageable toxicity profile and greatly increased simplicity of newly available regimens makes it practical to train primary care clinicians to deliver high-quality HCV treatment in a relatively short period of time.

To accomplish this, VA uses a teleconsultation model called VA National Specialty Care Access Network-Extension of Community Healthcare Outcomes (SCAN-ECHO) to increase access to care for Veterans with chronic HCV and/or liver disease in rural or geographically challenging areas. VHA's Office of Specialty Care Services partnered with other VHA offices including Public Health, Primary Care, Telehealth, Nursing Service, Pharmacy Benefits Management Services, and Rural Health to develop an effective teleconsultation platform. SCAN/ECHO focuses on hepatitis C care at five

regional sites nationwide. It is a provider-to-provider capacity building model that uses video conferencing technology to mentor primary care providers in the provision of high quality HCV care. Primary care providers at VA CBOCs engage in case-based education on HCV with experts at VA medical centers, gaining the skills and experience to treat patients with HCV. Providers at any VA CBOC can participate, using a secure video over Internet link to present patients to VA HCV experts at a VA medical center hub. Published non-VA data and internal VA data show that outcomes achieved via this program are similar to those achieved by treatment directly at a hub medical center. SCAN-ECHO has simultaneously increased the number of Veterans who can be safely treated at rural or underserved sites, while developing the future capacity of health care providers in those sites to independently provide HCV treatment and care. Specialist skills, knowledge, and resources are amplified across the system, rural Veterans are better able to access high quality HCV care without having to travel long distances, and rural VA providers receive professional development and institutional support.

The figure below shows the numbers of patients provided care through three of SCAN-ECHO hubs.



In some situations, telehealth care for HCV may be preferable to a teleconsultation model. For example, a VA HCV patient living far from a VA Medical Center may need to be evaluated directly by a HCV expert because of a complex clinical situation or the unavailability of a primary care provider trained in HCV care. In this setting, telehealth encounters (i.e., provider-patient encounters rather than the provider-provider model used in SCAN/ECHO) is being increasingly used within VA to provide access to HCV

treatment expertise without subjecting patients to prolonged travel. A number of VA Medical Centers, such as the San Francisco VA Health Care System, are treating remote patients via video-teleconference. A guide to the effective implementation of Liver Telehealth was published in 2013 and disseminated widely (<http://vawww.hepatitis.va.gov/pdf/liver-telehealth-manual.pdf>).

Finally, in states with appropriate geography such as Hawaii, a “circuit-rider” approach is used involving travel of an experienced HCV provider to CBOCs, again allowing access to high-quality HCV care while minimizing patient travel.

4. What is the VA doing about Hepatitis B among veterans? What tools and resources are needed to implement screening, education, and treatment programs?

VA Response: The prevalence of hepatitis B virus infection (HBV) among Veterans in VA care is significantly higher than among the general U.S. population, based on a recently completed VA study that has been submitted for publication. To address this, VA has taken the following actions in four areas:

- Screening/testing
 - Revised and updated VA risk factor screening/laboratory testing guidelines for HBV to align with recommendations from the CDC and the U.S. Preventive Services Task Force.
 - Continued funding of initiatives at local VHA facilities to screen and diagnose Veterans at high-risk for HBV.
- Treatment/prevention
 - Recommended that patients with chronic hepatitis B be referred to an infectious disease specialist or hepatologist to assess for hepatitis B treatment candidacy. Anti-viral treatment is indicated based on appropriate clinical and laboratory markers, according to national guidelines.
 - Added all FDA-approved treatments for HBV infection to the VA National Formulary.
 - Expanded use of tele-health and SCAN-ECHO to leverage existing specialist care in HBV and expand its reach to VHA facilities in rural or underserved areas.
 - Revised its guidelines for immunization against HBV.
 - In addition, screening for hepatocellular cancer is recommended for Veterans with chronic hepatitis B infection with appropriate clinical criteria.

- Education and outreach
 - Published an Information Letter for VHA clinicians to provide background on HBV in VHA and detailed standards on prevention, diagnosis, and treatment of HBV among Veterans in care.
 - Developed educational materials on HBV for providers and patients.
 - Provided Webcasts for VHA clinicians on diagnosis and treatment of HBV.
 - Developed social marketing campaigns to promote awareness of HBV among Veterans in care and VHA clinicians.
- Surveillance
 - Worked with existing VA data sources to develop HBV surveillance capabilities.
 - Launched investigations into the epidemiology of HBV in VA, including:
 - Analysis of HBV testing rates among Veterans in VA care;
 - Analysis of the contribution of HBV infection to advanced liver disease among Veterans in care;
 - Analysis of testing and treatment among Veterans at risk for reactivation of HBV infection due to immunosuppressive therapy.

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Chairman SANDERS. The next panel, please. [Pause.]

It is my pleasure to introduce John Rother, who is President and Chief Executive Officer of the National Coalition on Health Care and the leader of the Campaign for Sustainable Prescription Drug Pricing.

Second, we will hear from Robert Weissman, who is President of Public Citizen.

Gilead has chosen not to be here today.

Mr. Rother.

STATEMENT OF JOHN ROTHER, PRESIDENT AND CHIEF EXECUTIVE OFFICER, NATIONAL COALITION ON HEALTH CARE AND THE LEADER OF THE CAMPAIGN FOR SUSTAINABLE PRESCRIPTION DRUG PRICING

Mr. ROTHER. Mr. Chairman, Ranking Member Burr, thank you for the opportunity to be here. I am John Rother. I am the President and CEO of the National Coalition on Health Care, and the Coalition is the sponsor of something called the Campaign for Sustainable Rx Pricing, which has been active now for over 6 months, has focused particularly on the issue of Sovaldi, but is actually concerned with a broad category of specialty drugs and their affordability.

You have my full statement. I would ask that it be put in the record. I would like to just make, really, three points in the time before we get to the questions.

I do think that we have a huge fiscal challenge ahead of us, not just in the VA, in health care generally, and it is driven in large part by the price of new specialty drugs. Sovaldi is really just the canary in the coal mine that indicates the kind of challenge ahead

of us. So, I do not think we can talk just about Sovaldi without looking at what is coming at us, which are going to be even more expensive drugs, raising more difficult fiscal challenges in the VA, in Medicaid, in Federal health programs in general, and in the private sector.

Our coalition is made up of purchasers, providers, consumer groups, uniformly deeply concerned about this, and uniformly believe that the path we are on in terms of pricing here is unsustainable, that we need a new approach, certainly one that supports innovation, but not one that is going to result in people not being able to afford the very cures that innovation produces.

So, my first point is that this is not just a matter of \$1,000 a pill. This is a matter, primarily, of a drug that is potentially beneficial to three to five million people. So, it is not an orphan drug at all. It is a drug that would be appropriate for a large number of Americans. The problem is the total cost of treatment, not so much the individual pill price.

Inevitably, as your question earlier suggested, this kind of cost is going to force tradeoffs with other necessary treatment within the VA, within Medicaid, within prisons, within private health insurance. We are seeing this every day today and it is a deep concern, because in many cases, the services not delivered are the very preventative type of services that have the greatest return on investment, and if we neglect those, then we are just making the problem more difficult down the road.

So, the first point is, this is the canary in the coal mine and it is a matter not only of price, but of the number of people.

The second point is that there are many new specialty drugs in the FDA pipeline. They could soon overwhelm our health financing system generally. Therefore, I do think we need new approaches to rewarding innovation, to making sure that we have drugs that are not only effective, but also affordable. There are several ways in which we could ensure that we continue to have the innovation we need, but at more affordable prices, and in my testimony, I indicate several.

My third point is that there are several first steps that I think would be constructive that are consistent with what we are doing in health care generally, moving toward transparency, moving toward a value basis for reimbursement. Those same ideas could be applied to pharmaceuticals. There are several ways in which we could ask companies to be more transparent about how they arrived at prices, about what their value calculation is, and about how they believe that value could be enhanced for the largest number of Americans, not just for the individual.

I regret that Dr. Martin is not here. I have had several conversations with him. He has made some statements in public. I think we have a very clear idea of how they came to the pricing, which, frankly, had nothing to do with value. It had everything to do with the prior cost of treatment to a much smaller number of people. I call that escalator pricing and I think that we need to change the escalator.

We need a better way of doing this and I applaud the Committee for having this hearing. I think this is a very difficult, complicated subject, and I do think it is urgent, not, again, just because of Hep-

atitis C, not just because of Sovaldi, but because of the large number of very expensive specialty drugs that are likely to be in front of us in the very near future.

Thank you.

[The prepared statement of Mr. Rother follows:]

PREPARED STATEMENT OF JOHN ROTHER, PRESIDENT AND CEO, NATIONAL COALITION ON HEALTH CARE ON BEHALF OF THE CAMPAIGN FOR SUSTAINABLE RX PRICING

HOW VETERANS ARE AFFECTED BY THE HIGH COST OF SPECIALTY DRUGS

I. INTRODUCTION

Chairman Sanders, Ranking Member Burr, and Members of the Committee, I am John Rother, President and CEO of the National Coalition on Health Care (NCHC). I appreciate this opportunity to testify on behalf of the Campaign for Sustainable Rx Pricing regarding the high cost of specialty drugs and how our Nation's veterans are affected by this growing problem.

The NCHC launched the Campaign for Sustainable Rx Pricing in May 2014 to call attention to high-priced prescription drugs—most notably, specialty drugs—and the impact these prices are having on consumers, employers, and taxpayers. The Campaign is supported by the more than 90 stakeholder members of the NCHC. Our member organizations include medical societies, businesses, unions, health care providers, faith-based associations, pension and health funds, insurers, and groups representing consumers, patients, women, minorities, and persons with disabilities. Collectively, our organizations represent more than 100 million Americans.

The goal of the Campaign for Sustainable Rx Pricing is to foster a national dialog on the pricing of high-cost biopharmaceutical therapies, some of which are now priced at \$1,000 or more per dose with total treatment costs of \$100,000 or more. Prices at that level threaten access to care and result in much higher out-of-pocket costs, higher premiums, and higher taxes. We believe there needs to be a better approach to pricing that recognizes value and balances the interests of innovator drug companies with the interests of society and our health care system. We are calling on the leaders of the biopharmaceutical industry to engage with us in a dialog about market-based solutions for ensuring that the U.S. health care system can sustainably pay for the innovation that is so vital to our health and well-being.

My testimony for today's hearing focuses on three broad topics: (1) the challenges caused by rising health care prices; (2) the role of specialty drug prices as a major component of the health care cost problem; and (3) market-based solutions, including a stronger commitment to transparency, that are needed to address this growing problem.

II. RISING HEALTH CARE COSTS ARE A CHALLENGE FOR ALL STAKEHOLDERS

The high cost of health care is a significant and ongoing challenge for consumers, businesses, and government programs, including the Department of Veterans Affairs (VA) health care system.

According to the most recent data¹ from the Centers for Medicare & Medicaid Services (CMS), national health expenditures in 2014 are projected to total \$3.057 trillion (a 5.6 percent increase over 2013), with \$290.7 billion spent on prescription drugs (a 6.8 percent increase). Total national health spending in 2014 accounts for 17.6 percent of the Nation's gross domestic product (GDP) and translates into per capita spending of \$9,596. CMS further projects that national health spending will increase at an average annual rate of 5.7 percent over the 2013–2023 time period, with per capita spending reaching a level of \$14,944 by 2023.

Rising health care costs are presenting challenges on multiple fronts. Working families and seniors face difficult choices when their budgets are pressured by medical expenses. Many businesses, both large and small, find that health care costs are undermining their ability to hire new employees, expand their operations, and compete in the global economy. Federal, state, and local governments—facing budget constraints driven by continually increasing health care costs—are forced to limit the resources they devote to other priorities such as infrastructure, education, and public safety.

¹CMS National Health Expenditure Data, September 2014. <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html>

The VA health care system—which serves nearly 9 million enrollees, with an annual budget approaching almost \$60 billion²—also is impacted by rising health care costs. Because the VA serves patients whose medical needs tend to be greater than those of the broader U.S. population, its budget is disproportionately impacted by high health care costs, including new specialty drugs with extremely high price tags.

III. SPECIALTY DRUG PRICES ARE A LARGE COMPONENT OF THE PROBLEM

Spending on specialty drugs represents a growing share of overall prescription drug spending and is increasing at a rapid and unsustainable rate. Addressing these cost trends is critically important to ensuring a sustainable health care system and achieving affordability for businesses and consumers.

Specialty drugs generally are defined as drugs that are structurally complex and often require special handling or delivery mechanisms. While these drugs have been ground-breaking in the treatment of cancer, rheumatoid arthritis, multiple sclerosis, and other chronic conditions, the cost of treating a patient with specialty drugs can exceed \$100,000 annually. Their high costs and extended use are placing a significant strain on our health care system.

While only 4 percent of Americans take a specialty drug, the spending associated with these drugs represents a quarter of all drug spending in the United States, according to a 2013 report³ by CVS Caremark. In a separate 2014 report,⁴ CVS Caremark concluded that spending on specialty drugs increased by 15.6 percent in 2013, compared with only a 0.8 percent increase in spending on traditional medications. A similar trend was reported⁵ by Express Scripts, which has projected that spending on specialty drugs will increase 63 percent between 2014 and 2016. Additional research⁶ by the PricewaterhouseCoopers Health Research Institute projects that specialty drug spending will increase from \$87 billion in 2012 to \$402 billion in 2020—a 361 percent increase in eight years.

The role of specialty drugs as a major driver of drug spending is a direct result of their growing presence in the pharmaceutical market. In 2010, specialty drug approvals by the Food and Drug Administration (FDA) exceeded traditional drug approvals for the first time, a trend that has continued each year since. In 2013, 19 of the 28 drugs approved by the FDA—more than two-thirds—were specialty drugs.⁷

Examples: Sovaldi and Harvoni

Within the past year, two new specialty drugs for treating patients with the Hepatitis C virus—Sovaldi and Harvoni—have entered the marketplace. These drugs provide important and effective breakthrough therapies for the treatment of Hepatitis C patients. But the manufacturer, Gilead Sciences, is demanding unaffordable prices that pose a serious threat to the pocketbooks of consumers, employers, government programs (including the VA health care system), and taxpayers.

Sovaldi, approved by the FDA in December 2013, is priced at \$1,000 per pill and costs \$84,000 for a 12-week course of treatment. Because Sovaldi is often prescribed in concert with other drugs, the total treatment cost sometimes approaches \$150,000 for a single patient.

Harvoni, which received FDA approval in October 2014, is priced at \$1,125 per pill and costs \$94,500 for a 12-week course of treatment. This drug also is combined with other treatments for many patients.

Sovaldi is on pace to become the highest grossing drug in history, having generated sales of \$2.27 billion in the first quarter of 2014 and \$3.48 billion⁸ in the second quarter. If this sales trend continues, Gilead essentially will recover its total investment in Sovaldi in the first year. Pharmasset, the company that carried out the research and development on Sovaldi, intended to price the drug at 43 percent

² U.S. Department of Veterans Affairs, President's Budget Request for Fiscal Year 2015. <http://www.va.gov/budget/products.asp>

³ CVS Caremark, 2013 Insights, Specialty Trend Management. <http://www.cvshealth.com/sites/default/files/Insights%202013.pdf>

⁴ CVS Caremark, 2014 Insights, 7 Sure Things. <http://investors.cvshealth.com/~media/Files/CVSVS-IR/reports/2014-cvs-caremark-insights-report.pdf>

⁵ Express Scripts, Industry Updates, April 8, 2014. <http://lab.express-scripts.com/insights/industry-updates/report-specialty-drug-spending-at-lowest-rate-since-2007>

⁶ PwC's Health Research Institute, Medical Cost Trend: Behind the Numbers 2015, June 2014. http://www.pwc.com/en_US/us/health-industries/behind-the-numbers/assets/hri-behind-the-numbers-2014-chart-pack.pdf

⁷ "Specialty Drug Approvals in 2013." Express Scripts Insights. March 26, 2014. <http://lab.express-scripts.com/insights/drug-options/specialty-drug-approvals-in-2013>

⁸ *Wall Street Journal*, Hepatitis C Pill Rockets Gilead Into Big Leagues, July 24, 2014.

of what Gilead is now charging.⁹ Did Gilead purchase the company knowing it could more than double the price and pay for its investment in one year? Has an incentive for innovation been abused at the expense of taxpayers and patients?

We are concerned that the exorbitant price tag assigned to this drug reflects an abuse of the market power that is granted to pharmaceutical manufacturers under Federal law. Under the Hatch-Waxman Act,¹⁰ manufacturers receive the exclusive right to manufacture and sell their products for a period of time so that they can be rewarded for their innovation and recover the costs associated with developing important new therapies. This system generally has worked well, producing effective treatments for many illnesses that were once untreatable. However, when a new medicine is considered more effective than previous therapies, the high demand for that product, combined with the market exclusivity, allows the manufacturer a great deal of market power in setting the price. In the case of Sovaldi, we believe that market power has been abused.

Implications for Veterans

The Committee has indicated that the VA currently provides health care services to more than 170,000 veterans who have the Hepatitis C virus, and that tens of thousands of additional veterans are estimated to have Hepatitis C but have not been tested.

Recognizing that the VA serves a large number of veterans who may benefit from either Sovaldi or Harvoni, we are seriously concerned about the impact the unreasonable prices for these drugs will have on access to care for our Nation's veterans. At a time when almost all government programs are facing tight budget constraints and operating with limited resources, it is critically important to ensure that the essential health care services we owe to the men and women who have served in uniform are not underfunded because the VA is forced to pay excessive prices for new specialty drugs.

Looking at the overall impact of the costs associated with Sovaldi and Harvoni, we have serious concerns that new specialty drugs with unusually high prices may place an unsustainable burden on the VA health care system, result in many patients not receiving needed treatments and therapies due to budget constraints, and create the potential for even greater dysfunction down the road if they establish a pattern for future pricing strategies.

The Sovaldi and Harvoni Price Tags Are Not Sustainable

Innovative new drugs are not sustainable if the health care system cannot afford them.

The IMS Institute for Healthcare Informatics has estimated that the total cost of purchasing Sovaldi for all 3.2 million Americans who are infected with Hepatitis C would approach \$300 billion. This figure is roughly equal to the total amount spent in 2013 on all other brand name prescription drugs combined. *Kaiser Health News*¹¹ describes the problem with this explanation: "If all 3 million people estimated to be infected with the virus in America are treated at an average cost of \$100,000 each, the amount the U.S. spends on prescription drugs would double, from about \$300 billion in one year to more than \$600 billion."

The increase in the number of exceptionally high-priced drugs threatens the sustainability of our health care system. This is particularly true for public programs, including the VA health care system, which serve disproportionately sicker populations who are more likely to need these new medications and are already straining under the cost of existing high-priced new medications currently on the market. With additional specialty drugs prepared to come down the pipeline, and without pressure on pharmaceutical companies to change their behavior, the health care system will not be able to withstand the coming onslaught of six-figure therapies.

IV. MARKET-BASED SOLUTIONS ARE NEEDED TO MAKE SPECIALTY DRUGS MORE AFFORDABLE

The Campaign for Sustainable Rx Pricing is advocating market-based solutions for making specialty drugs more affordable. New approaches to rewarding innova-

⁹*The Fiscal Times*, The \$1,000 Pill That Could Cripple the VA's Budget, by Erik Pianin, October 8, 2014, <http://finance.yahoo.com/news/1-000-pill-could-cripple-104500188.html>

¹⁰CRS Report for Congress, The "Hatch-Waxman" Act: Selected Patent-Related Issues, April 1, 2002. <http://congressionalresearch.com/RL31379/document.php?study=The+Hatch+Waxman+Act+Selected+Patent-Related+Issues>

¹¹Kaiser Health News, Who Should Get Pricey Hepatitis C Drugs, May 5, 2014. <http://kaiserhealthnews.org/news/sovaldi-who-should-get-pricey-drug/>

tion and pricing drugs based on their value—along with a strong emphasis on transparency—are important first steps toward achieving this goal.

One solution is to encourage alternative payment and incentive structures for rewarding innovation in the development of new drugs and technologies. These types of payment strategies can improve access to new drugs while at the same time generating additional evidence on the value to patients of these new medications. As part of a broader value-based purchasing strategy, these alternative arrangements—such as outcomes-based contracting or reimbursing providers a flat fee for obtaining drugs, rather than a percentage of the drug’s total cost—provide enhanced financial incentives for manufacturers of new drugs that are linked to standards for quality care, performance, and health outcomes. Greater use and availability of comparative effectiveness data is a key element in the future growth of these innovative payment arrangements.

On another front, we support enhanced flexibility for the VA to conduct pilot programs to explore new ways of assessing and pricing drugs based on their value. For example, the VA should be authorized to use the findings of comparative effective research to provide information to patients and providers about which drug regimens and treatments deliver the most value and which are less effective. Such information is highly beneficial to both patients and providers. Additionally, the use of value-based insurance design can help promote better outcomes and quality of care, while discouraging low-value, high-cost care through the use of financial incentives. By building on best practices in the private sector, the VA can improve access to high-quality and cost-effective treatments based on the best available medical evidence and clinical guidelines.

Promoting greater transparency in the pharmaceutical industry is another strategy that offers significant promise for improving the affordability of specialty drugs. Recognizing that a competitive market is the best place to create value and determine price, we believe that the drug manufacturing industry should commit to the following common sense principles for health care sustainability which would benefit patients and the entire health care system:

1. Drug Manufacturers Claiming a Value Proposition for Their Products Should Provide Documentation of Such Claims. Manufacturers should provide a clear basis for claims they make that drugs reduce costs elsewhere in the health care system. Such reporting should include the net effect of any savings relative to the cost of the drug. If the manufacturer is claiming system-wide savings relative to existing alternative treatments, for example, it should clearly define the populations and treatment alternatives for which they are claiming savings and provide substantiating data that can be independently validated. Studies by independent researchers also are needed to provide a more comprehensive assessment of the value of new products.

2. Drug Manufacturers Should Make Price Increases More Predictable to Benefit Patients and the Health System as a Whole. Price inflation of existing drugs has become a serious problem, with manufacturers routinely demanding double-digit price increases year after year and throughout a plan year. A robust discussion of drug price predictability needs to take place, with a particular focus on the impact to consumers.

3. Drug Manufacturers Attempting to Launch New Products Should Disclose Likely Populations Served, Launch Price, and Any Value Proposition, in as Timely a Manner as Possible. Manufacturers currently withhold this information until nearly the minute the drug hits the market, which unnecessarily impedes the ability of patients and the health care system to react to a drug’s indications, value, and pricing. Providing this information earlier will allow the market to function more efficiently.

4. Drug Manufacturers, Working with FDA, Should Make Available All Clinical Data to Help Third-party Researchers Examine Comparative Effectiveness and Value. Various organizations, including the American Medical Association, have called on drug manufacturers to work with the FDA to make this information available. Facilitating another government agency (such as the Patient-Centered Outcomes Research Institute), or other responsible third party, to assess the impact a newly introduced drug would have on public and commercial costs in relation to the drug’s ability to improve patient health would be beneficial for patients without resorting to distortionary government intervention into price setting. Rather, adding a non-binding “cost effectiveness” component to a government agency’s or other organization’s mission would provide a credible assessment of a drug’s overall value.

5. Drug Manufacturer Participation in Organizations that Influence Coverage Decisions Should Be Transparent and Free from Conflict of Interest. Many organizations play a role in influencing coverage, such as the drug compendia entities and United States Pharmacopeia (USP). To the extent that drug manufacturers and oth-

ers influence data availability, selection of indications, and interpretation of evidence in drug compendia, they are also setting the standards for drug use and coverage. Critical, independent reviews should be required of the information submitted by drug manufacturers and any potential conflicts of interest should be disclosed to the public and resolved in advance of the review process.

V. CONCLUSION

Thank you again for the opportunity to testify on this important issue. As we continue to work with stakeholders in the private sector, the Coalition looks forward to continuing a dialog with the Committee about market-based strategies for ensuring that veterans—along with the broader U.S. population—have access to affordable specialty drugs.

Chairman SANDERS. Thank you, Mr. Rother.
Mr. Weissman.

STATEMENT OF ROBERT WEISSMAN, PRESIDENT, PUBLIC CITIZEN

Mr. WEISSMAN. Thank you very much, Mr. Chairman, Mr. Burr.

Unfortunately, \$84,000 treatments are not atypical any more in our medical system, and they are not sustainable. What is unusual about Sovaldi is the patient population that it is intended to treat, which is a large patient population, at least 3.2 million people in the United States. If you combine that level of price with that size of population, we know what we are going to get, because we are already getting it, which is rationing. Now, from my point of view—and I think it should be the point of view of all Americans—that is unacceptable, particularly in the circumstances where we are talking about a life-saving drug and the rationing is entirely avoidable.

I want to make three points to elaborate on that general commentary. The first point is that this level of pricing is already, with the modest sales of Sovaldi and related products, severely taxing private and public payers; we are, in fact, having rationing right now. Medicaid systems across the country right now are rationing the product. Private insurers are not making the product available to people for whom it is clinically indicated, and they are not going to be able to.

The math is extraordinary. Now, the pricing is going to evolve over time, but if you just look at Sovaldi, \$84,000 for a course of treatment, 3.2 million people in America with the disease, we are talking about \$268 billion—\$268 billion for one pharmaceutical treatment.

Now, in the course of the debate over the Affordable Care Act, there was a lot of discussion about the ethics of rationing of care. This is a case where we are not talking about theoretical rationing. It is happening now, and it is a certainty that it will continue in a worse way with this level of pricing.

Now, it is one thing to have rationing where there is an objective basis for costs. Hospitals cost money. Doctors cost money. Nurses cost money. Sophisticated medical technology costs money. There is nothing about the manufacturing cost of Sovaldi that costs anything like \$84,000. So, this is a choice we are making. It is not determined by any objective reason, and to me, I think that is just unacceptable. Our country can do better and it must do better.

Now, some have held out hope that new treatments will lead to price competition, or that hard bargaining by payers, of which the

VA is the best, will be able to yield sufficient price reductions, and I think that is misguided. Based on prior experience, new drugs do not necessarily come in at a lower price. In fact, they often come in at a higher price. In general, brand name competitors try not to compete on price. And, when you have a starting point price of \$84,000, even if we have substantial reductions in price due to negotiations, we are still going to be stuck with a super-high price, just because the starting point was so high.

However, we do have solutions available to us, and really fundamental solutions. Now, we should say, I think it is correct—I agree with many of the things you said, Senator Burr, about both the importance of innovation and looking at government policy. The reason for this price level, as both of you have asked, is a single thing, which is Gilead has a monopoly. Gilead does not have a market created monopoly, they have got a government granted monopoly, a patent monopoly, a monopoly that comes from their exclusivities.

If we choose to address that monopoly through government policy, since we, the people, gave the monopoly in the first place, we can bring the price down. We know we can bring it down to less than 1 percent, at least at the manufacturing level, leaving aside whatever fair compensation we need to pay to Gilead, because of the price reductions that already exist in developing countries, as you referenced, Senator Sanders.

Two methodologies we might pursue to reduce price. One, we might have just government use of the product, government use of the patent and other related technologies and know-how. In that case, we could source the product from generic competitors and pay Gilead a royalty. If we pay Gilead a royalty of \$5,000 per patient, we would actually still have cut the price overall by 90 percent. We have got existing statutory authority to do that under 28 U.S.C. Section 1498.

A different approach might be to look to buy out Gilead's patent altogether. We could do that in one way, which would be to say, we are just going to give Gilead as much money as we anticipate the company will make by the virtue of its patent monopoly. Why would we do that? Well, we would do that because we are already going to pay them that much money, but we could then provide treatment to everyone, whereas under the current system, we are going to pay all that money and have rationing.

I would not advocate doing that. I think we could adjust down significantly what we pay for a patent buy-out. But, it is another method we might consider to provide treatment for all, which really ought to be our objective, providing treatment for all at some reasonable price and with a reasonable compensation for Gilead.

As a concluding note, and to agree with Mr. Rother, this is a unique story in some cases because of the high price, the large patient population, and the unique value of this drug, but it is typical in terms of what we have already on the marketplace and, really, what else is going to come. We are going to have these kinds of high prices, and they are unsustainable. So, we need not seek a solution just for Sovaldi, but, really, systemic solutions. I think that involves looking at new forms of compensation for innovation, overcoming monopolies, and looking also at return on the government investment and R&D. Senator Sanders, you have introduced legis-

lation in this regard. I think there are many other important ideas and it is time for a debate on these new approaches.

[The prepared statement of Mr. Weissman follows:]

PREPARED STATEMENT OF ROBERT WEISSMAN, PRESIDENT, PUBLIC CITIZEN

Mr. Chairman and Members of the Committee, Thank you for the opportunity to testify today on issues related to Hepatitis C among veterans. I am Robert Weissman, president of Public Citizen. Public Citizen is a national consumer advocacy public interest organization with 350,000 members and supporters. For more than 40 years, we have advocated with some considerable success to advance public health, to ensure access to safe and affordable medicines, and to protect taxpayers against corporate plunder of the public treasury.

Hepatitis C is a serious liver disease that is widely prevalent, and takes about 15,000 lives annually in the United States. Infection rates with the Hepatitis C virus are far higher among veterans than the general public—as much as five times higher—making Hepatitis C treatment a priority matter for the Department of Veterans Affairs (VA).

The good news is that new drug treatments for Hepatitis C have become available over the past year, and more seem set to become available in the near future. It is important to be cautious about claims of the efficacy of these new treatments, because they have been subjected only to minimal clinical testing and there has been only a short period of use in the general public. But with that cautionary note in mind, these new drugs appear to offer much higher cure rates—up to 95 percent—than previously existing therapies, with much less severe side effects.

But these new drugs, which include Gilead's sofosbuvir (brand name Sovaldi), Gilead's drug combining sofosbuvir with ledipasvir (brand name Harvoni), Johnson & Johnson's simeprevir (brand name Olysio) and likely a new drug from Abbvie, are extraordinarily expensive. By way of example, Gilead is charging \$1,000 a pill for sofosbuvir, or \$84,000 for a 12-week course of treatment.

These prices are intolerably high and imposing unsustainable costs on consumers, insurers and taxpayers.

As a result, public and private payers are moving to rationing.

This would be unfortunate but somewhat unavoidable if the drugs were extraordinarily expensive to manufacture, or if research-and-development costs had been unusually high. But neither is the case. The prices are so high because Gilead and other manufacturers have monopoly pricing power, and are choosing to use that power to price gouge.

The government is not helpless to respond, but even price negotiations will fail to bring prices down sufficiently. The VA obtains Sovaldi and Harvoni for a roughly 44 percent discount, but this still leaves treatment at sky-high rates.

A sustainable solution to the pricing of the new Hepatitis C drugs must involve a government-mandated license or acquisition of rights to make the drugs, so that generic suppliers can enter the market, with a determination of what constitutes fair compensation to Gilead or other brand-name suppliers for the mandated license. With generic production, prices will fall by more than two orders of magnitude, so that drug costs will be less than 1 percent of what Gilead and other manufacturers are charging (potentially excluding royalty payments).

While ensuring fair compensation for Gilead and other brand-name manufacturers, the priority goal of government policy in this area should be to ensure that treatment is made available to all for whom it is clinically indicated. This principle should be overriding: Patients should not be subjected to avoidable rationing of a critically important medicine.

Because of prevalence rates among veterans, it is reasonable to analyze the Hepatitis C drug pricing problem as a VA problem. It might reasonably be considered a particular problem of the multiple Federal agencies that provide health insurance coverage or direct treatment of patients. Ultimately, however, it is a societal problem, and the best solutions will cover all Americans. In this testimony, I highlight VA-specific issues and opportunities, but in the main I address the drug pricing problem as a national issue.¹

¹To be sure, with more than 150 million people infected with Hepatitis C virus globally (see HK Mohd, J Groeger, AD Flaxman, ST Wiersma, "Global epidemiology of hepatitis C virus infection: new estimates of age-specific antibody to HCV seroprevalence," *Hepatology*. 2013 Apr;57(4):1333–4), the problem is worldwide. Here, too, the key to lowering price is to enable generic competition, and Gilead has agreed to license generic manufacturers, at least to sell in 91 countries. (Gilead, "Gilead Announces Generic Licensing Agreements to Increase Access to

Continued

The first section of this testimony provides a brief overview of Hepatitis C incidence, treatment, and treatment cost. The second section underscores that rationing at current prices is both inevitable and already occurring. The third section notes that research and development expenses cannot possibly justify the price for sofosbuvir. The fourth section considers whether competition among brand-name products may lead to sufficient price reductions for Hepatitis C treatment, and concludes it will not. The fifth section makes the case for non-voluntary licensing of the new Hepatitis C drugs, or for a mandated government buyout of the key patent and related rights. The testimony concludes by noting that the problems posed by the new Hepatitis C drugs are endemic to the pharmaceutical sector, and urges consideration of new approaches for paying for drugs and incentivizing pharmaceutical research and development.

I. HEPATITIS C: INCIDENCE, TREATMENT, COST

Hepatitis C is a liver disease that results from infection with the Hepatitis C virus (HCV). Persons newly infected with HCV are usually asymptomatic, so acute Hepatitis C is rarely identified or reported.

Approximately 75–85 percent of people infected with HCV develop chronic Hepatitis C, according to the Centers for Disease Control and Prevention (CDC). Sixty to 70 percent of those infected will develop chronic liver disease; 5–20 percent will develop cirrhosis over a period of 20–30 years. One to five percent will die from chronic infection, due to liver cancer or cirrhosis.²

The CDC estimates that the number of HCV-infected people in the United States is 3.2 million,³ though some believe the figure may be more on the order of 5.2 million.⁴ Approximately 15,000 people die annually in the United States from HCV-related conditions.⁵ Although injection drug use is presently the primary means of HCV transmission, infection rates are highest among those born between 1945 and 1965.

HCV infection rates are far higher among veterans than the general population, perhaps five times the rate among non-veterans. Researchers have estimated infection rates among veterans in the 5.4 to 6.1 percent range, as compared to a national estimated incidence rate of 1.2 percent.⁶ Among veterans born between 1945 and 1965, the infection rate is on the order of 10 percent.⁷ In 2011, 5.4 million veterans had outpatient visits. More than 2.8 million were screened for HCV infection. More than 170,000 of those vets were found to be HCV infected.⁸

There are other subpopulations with elevated rates of HCV infections, notably prisoners. As many as one in three prisoners are infected with HCV.⁹

Not long ago, treatment options for HCV were relatively poor, but this situation has changed dramatically in recent years. In the late 1990s, the development of interferon plus antiviral therapy and then pegylated interferon-based therapy—a difficult to tolerate and expensive treatment, with a 50–80 percent cure rate—marked a major step forward.¹⁰ Within the last year, however, a new and appar-

Hepatitis C Treatments in Developing Countries,” September 15, 2014, available at: <http://www.gilead.com/news/press-releases/2014/9/gilead-announces-generic-licensing-agreements-to-increase-access-to-hepatitis-c-treatments-in-developing-countries>.) Establishing a fair global licensing system poses unique issues that I do not discuss in this testimony.

²Centers for Disease Control and Prevention, “Hepatitis C FAQs for Health Professionals,” available at: <http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm#>.

³Centers for Disease Control and Prevention, “Hepatitis C FAQs for Health Professionals,” available at: <http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm#>.

⁴E Chak, AH Talal, KE Sherman, ER Schiff, S Saab, “Hepatitis C virus infection in USA: an estimate of true prevalence,” *Liver Int.* 2011 Sep;31(8):1090–101.

⁵“The increasing burden of mortality from viral hepatitis in the United States between 1999 and 2007.” K. Ly, et al. *Annals of Internal Medicine*, 2012. 156(4): p. 271–278.

⁶JA Dominitz, et. al. “Elevated prevalence of hepatitis C infection in users of United States veterans medical centers,” *Hepatology*. 2005 Jan;41(1):88–96; Lisa I. Backus, Pamela S. Belperio, Timothy P. Loomis, Troy Shahoumian, Larry A. Mole, “Hepatitis C Virus Screening and Prevalence Among Veterans in Department of Veterans Affairs Care in 2012,” November 3, 2013, available at: <http://www.publichealth.va.gov/docs/populationhealth/hepatitis/AASLD-2013-HCV-screen-oral-11-03-2013.pdf#>.

⁷Lisa I. Backus, Pamela S. Belperio, Timothy P. Loomis, Troy Shahoumian, Larry A. Mole, “Hepatitis C Virus Screening and Prevalence Among Veterans in Department of Veterans Affairs Care in 2012,” *Epidemiology of viral hepatitis*. *Hepatology*, 2013. 58: 216A–219A.

⁸Lisa I. Backus, Pamela S. Belperio, Timothy P. Loomis, Gale H. Yip, Larry A. Mole, “Hepatitis C Virus Screening and Prevalence Among US Veterans in Department of Veterans Affairs Care,” *JAMA Intern. Med.* 2013;173(16):1549–1552.

⁹Centers for Disease Control and Prevention, “Correctional Facilities and Viral Hepatitis,” available at: <http://www.cdc.gov/hepatitis/Settings/Corrections.htm>.

¹⁰Centers for Disease Control and Prevention, “Hepatitis C FAQs for Health Professionals,” available at: <http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm#>; HCV Advocate, “A Brief History of

ently far superior treatment has emerged. The drug manufacturer Gilead obtained Food and Drug Administration (FDA) approval to market the oral antiviral sofosbuvir (brand name Sovaldi), which evidence suggests offers an 80–95 percent cure rate in most patients after 12–24 weeks of treatment.¹¹

Treatment options for Hepatitis C appear to be fast evolving. In October of this year, the FDA approved a new drug combining sofosbuvir with ledipasvir, sold by Gilead under the brand name Harvoni. The combination product is approved for treatment of Hepatitis C in people with HCV genotype I, the most common type in the United States, and is the first treatment for people with this genotype that does not also require interferon or the antiviral ribavirin.¹² Other products and other combination products are likely to come on the market soon.

Along with apparently exceptional cure rates and low side effects, the other exceptional feature of Sovaldi and Harvoni is the exceptionally high prices that Gilead is charging. The company is charging \$1,000 for each sofosbuvir pill, meaning the cost of a 12-week course of treatment is \$84,000. Gilead's price for Harvoni is \$1,125 a pill, or \$94,500 for a 12-week course of treatment.¹³ Individuals may be prescribed different courses of treatment, so costs may be lower (\$63,000 for a shorter course of Harvoni); and in many cases may be much higher either because of a longer duration of treatment or combination with certain other medications (\$150,000 for sofosbuvir in combination with Johnson & Johnson's simeprevir (brand name Olysio)).

The Veterans Administration is, of course, the best Federal Governmental model of pharmaceutical procurement. Thanks to a multi-pronged procurement system that includes statutorily mandated price reductions and the ability of the agency to negotiate with suppliers and to adjust its formulary,¹⁴ the VA is commonly able to obtain drugs at a price that is 40 percent or more below published wholesale prices.¹⁵

The VA has negotiated an arrangement with Gilead to obtain sofosbuvir at a more than 40 percent price discount—a significant cut, but still leaving the drug costing \$594 per pill. The price for Harvoni is \$829 per pill.¹⁶ The Federal Bureau of Prisons is able to obtain the same discounts as the VA; state prisons, which house a majority of the incarcerated in the United States, are not.¹⁷

Prices in the range of \$84,000 for a course of pharmaceutical treatment are, unfortunately, becoming increasingly common, especially for cancer drugs and biologics. In most cases, however, drug makers charge such extraordinary prices for products that serve limited patient populations.

Hepatitis C is a different case altogether. There is a very large patient population—at least 3.2 million, and perhaps many more.

Neither private nor public payers—nor the health care system overall—can afford to provide an \$84,000 per patient treatment to every person with HCV.

The math is quite startling:

$$3.2 \text{ million patients} \times \$84,000/\text{patient} = \$268.8 \text{ billion.}$$

For the VA alone, assuming a price of \$50,000 per patient, the cost just to treat those currently under VA care and diagnosed with Hepatitis C would be \$8.5 billion (170,000 patients \times \$50,000/patient). Assuming 1 million veterans with HCV (a low

Hepatitis C,” available at: http://hcvadvocate.org/hepatitis/factsheets_pdf/Brief_History_HCV.pdf; and U.S. Department of Veterans Affairs, “Interferon and Ribavirin Side Effects,” available at: <http://www.hepatitis.va.gov/provider/reviews/treatment-side-effects.asp>.

¹¹Centers for Disease Control and Prevention, “Hepatitis C FAQs for Health Professionals,” available at: <http://www.cdc.gov/hepatitis/HCV/HCVfaq.htm#>.

¹²Food and Drug Administration, “FDA Approves First Combination Pill to Treat Hepatitis C,” October 10, 2014, available at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm418365.htm>.

¹³Andrew Pollack, “Harvoni, a Hepatitis C Drug From Gilead, Wins F.D.A. Approval,” *New York Times*, October 10, 2014, available at: http://www.nytimes.com/2014/10/11/business/harvoni-a-hepatitis-c-drug-from-gilead-wins-fda-approval.html?_r=0.

¹⁴Gretchen A. Jacobson, Sidath Viranga Panangala, and Jean Hearne, “Pharmaceutical Costs: A Comparison of Department of Veterans Affairs (VA), Medicaid, and Medicare Policies,” A Congressional Research Service Report for Congress, January 19, 2007, available at: <https://www.hsdl.org/?view&did=713133>.

¹⁵National Committee to Preserve Social Security and Medicare, “Price Negotiation for the Medicare Drug Program: It is Time to Lower Costs for Seniors,” October 2009, available at: http://www.ncpssm.org/pdf/price_negotiation_part_d.pdf; Austin Frakt, Steven D. Pizer, Roger Feldman, “Should Medicare Adopt the Veterans Health Administration Formulary?” *Health Economics*, April 2011, available at SSRN: <http://ssrn.com/abstract=1809665>.

¹⁶U.S. Department of Veterans Affairs, “Pharmacy Benefits Management Services,” available at: <http://www.pbm.va.gov/PBM/PharmaceuticalPrices.asp>.

¹⁷Peter Loftus, “New Hepatitis Drugs Vex Prisons,” *Wall Street Journal*, April 24, 2014, available at: <http://online.wsj.com/articles/SB10001424052702304311204579510054146055222>.

estimate of 4 percent prevalence among approximately 25 million veterans), the cost to provide treatment to all of them would be \$50 billion.

These are rough numbers, of course, because of the uncertainty over the exact size of the patient population and varying possible per patient costs. But the rough numbers are sufficient to show how Gilead's pricing precludes universal treatment.

Now, it is important to emphasize that sofosbuvir treatment for HCV infection is still in its early days, so it is too soon to have complete confidence that the drug is as efficacious as early results seem to suggest, and too soon to suggest that everyone with HCV should receive the treatment, irrespective of genotype and how their condition has progressed.

Yet there is some reason to believe that treatment should be universal and immediate, and Gilead itself is making this claim. "Gilead and some doctors make the case that even if liver damage is not serious, people with a chronic virus infection can have various other health problems, including an increased risk of heart attack. Treating the disease early is better, they argue, because it avoids liver damage to begin with."¹⁸

Without making any claims here about the validity of this view, it is important to analyze its implications and appropriate policy options.

II. RATIONING IS HERE

The price of sofosbuvir and the size of the patient population guarantees one thing: The treatment will be rationed.

Insurers and physicians will try to ration the drug on a priority basis, making it available only to the sickest patients, but there is absolutely no doubt that it will be rationed.

Indeed, rationing is already underway. Although some formulary and prescribing decisions are being made against the backdrop of the remaining uncertainty over the efficacy of sofosbuvir, prescribing restrictions are explicitly informed by the unmanageable cost of the drug.

Explained the National Association of Medicaid Directors in a recent statement: "The potential for eliminating hepatitis C is an exciting one. However, the high cost of sofosbuvir (branded Sovaldi), at \$1,000 a pill, requires careful consideration of how to responsibly decide how to best use this new treatment option, especially in light of the three million people currently diagnosed with hepatitis C in the United States. * * * However exciting these new treatments are, the unprecedented nexus of cost and widespread demand threaten to disrupt the health care landscape in the near term."¹⁹ The statement was released in conjunction with a report reviewing and raising questions about the published studies on sofosbuvir.

States are limiting access to the drug, with cost considerations narrowing availability beyond the criteria suggested by treatment guidelines. In Illinois, Medicaid will provide sofosbuvir only to patients meeting 25 separate criteria, including that they have advanced Hepatitis C and no evidence of recent substance abuse or treatment.²⁰ In Idaho, Medicaid treatment guidelines require patients to have advanced liver disease and no indication of substance abuse within the last six months.²¹

Summarizes Reuters in a news account describing the national scene: "Some insurers have already put conditions on who can get the drug, and states including California and Texas have slowed or put treatment on hold while they study what to do."²²

¹⁸ Andrew Pollack, "Harvoni, a Hepatitis C Drug From Gilead, Wins F.D.A. Approval," *New York Times*, October 10, 2014, available at: http://www.nytimes.com/2014/10/11/business/harvoni-a-hepatitis-c-drug-from-gilead-wins-fda-approval.html?_r=0.

¹⁹ National Association of Medicaid Directors, "Evidence-Based Reporting Critical to Decisions on Sofosbuvir and Health Care Innovations," May 20, 2014, available at: http://MedicaidDirectors.org/sites/MedicaidDirectors.org/files/public/namd_statement_med_project_report_140520_3.pdf.

²⁰ Illinois Department of Healthcare and Family Services, "Prior Authorization of Sovaldi and Other Medications for the Treatment of Chronic Hepatitis C," August 8, 2014, available at: <http://www.hfs.illinois.gov/assets/080814n2.pdf>.

²¹ Idaho Department of Health and Welfare, "Idaho Medicaid—Prior Authorization Therapeutic Criteria for Sofosbuvir (Sovaldi)," May 23, 2014, available at: <http://www.healthandwelfare.idaho.gov/Portals/0/Medical/PrescriptionDrugs/HepatitisCAgentsGuidelines.pdf>.

²² Caroline Humer and Deena Beasley, "Insurers Scrutinize Drug Costs After \$84,000 Sovaldi Surprise," *Reuters*, May 29, 2014, available at: <http://www.reuters.com/article/2014/05/28/usa-healthcare-hepatitis-c-insight-graphic-idUSL1N00D1F820140528>. See also Julie Appleby, "There's a Life-Saving Hepatitis C Drug. But You May Not Be Able to Afford It," *Kaiser Health News*, March 3, 2014, available at: <http://kaiserhealthnews.org/news/insurers-debate-who-should-get-costly-hepatitis-c-drug/>; Drew Armstrong, "Hepatitis C Drug Price Limiting State Medicaid Approvals," *Bloomberg*, March 5, 2014, available at: <http://www.bloomberg.com/news/2014-03-05/hepatitis-c-drug-price-limiting-state-Medicaid-approvals.html>; Jonathan D. Rockoff, "Sales Soar

When the Congress debated the Affordable Care Act, there was a heated national discussion about rationing of health care. Well, rationing is already upon us, and it has nothing to do with the Affordable Care Act. It does have a great deal to do with government policy, however. Gilead is able to impose outrageous prices because it possesses a government-granted monopoly, through the grant of patents and other exclusivities. The government has in its power the ability to overcome these monopoly barriers, and it should. I discuss mechanisms to do so below.

It is worth noting the specific nature of the rationing of sofosbuvir that is now occurring and will continue as long as prices remain in the current range. This is not rationing because of the real and unavoidable cost of providing care—of paying for doctors and nurses, maintaining hospitals, operating sophisticated medical equipment, or even the expense of developing new drugs. It is rationing imposed because of artificial monopolies—something far more objectionable, and much more easily addressed.

III. RESEARCH AND DEVELOPMENT: NO JUSTIFICATION FOR SOVALDI PRICING

Big Pharma typically justifies the high price of medicines by referencing research and development (R&D) costs. Pharmaceutical R&D is costly, risky and characterized by delayed payouts, the argument goes, so prices must be high to incentivize investment and reward success. But the income stream from Sovaldi is so extraordinary that the R&D rationalization holds no water.

A new study by the industry-funded Tufts Center for the Study of Drug Development pegs the cost of developing a new molecular entity at \$2.6 billion.²³ This figure, which relies on secret industry data, has been widely ridiculed for being too high; but it is important to note that it is risk adjusted and takes into account the cost of capital—in other words, that figure is intended to represent the cost not just of successfully developing a drug, but of the failures incurred along the way, as well as time costs. Gilead practically covered this cost in just the first quarter of revenues from Sovaldi!²⁴

We know something as well about Gilead's actual costs. The company acquired the patents to sofosbuvir through its acquisition of the firm Pharmasset for \$11 billion in 2011. Gilead will cover that expense with roughly a year's revenue from Sovaldi.

Pharmasset's key assets were its rights to the product that became sofosbuvir. The product was amidst Phase II tests and just beginning Phase III tests for some genotypes at the time Gilead acquired Pharmasset.²⁵ Gilead was willing to pay so much for the firm because it saw the potential for the drug candidate that became sofosbuvir. The \$11 billion purchase price had nothing to do with Pharmasset's R&D investment in what became sofosbuvir. That investment in the three years prior to Gilead's acquisition, as detailed in Pharmasset's 10-K filings, was a very modest \$62.4 million (\$6.891 million in 2009, \$16.431 million in 2010 and \$38.332 million in 2011; total does not include lesser expenses not attributed to any particular project).²⁶ By way of comparison, Gilead is earning roughly \$200 million every week from sales of Sovaldi.

Gilead has not tried to justify its pricing for Sovaldi through the tried-and-true reference to R&D costs, because even under Big Pharma's trumped up claims about R&D costs, Sovaldi revenue far exceeds any potential claim to reasonable return on investment.

The company has instead chosen to rely primarily on the claim that sofosbuvir offers value for money, in the sense that an \$84,000 course of treatment is cheaper than the cost of a liver transplant or other late-stage interventions necessary for some people with Hepatitis C. This is a creative rationale for an industry that typically disdains such cost-benefit analyses, insisting that patients should be entitled to treatment without regard to any financial cost-benefit analyses.

for Pricey Hepatitis Drug Sovaldi," Wall Street Journal, March 31, 2014, available at: <http://online.wsj.com/articles/SB10001424052702303978304579473273033614530>; Troyen Brennan and William Shrank, "New Expensive Treatments for Hepatitis C Infection," JAMA 2014;312(6):593-594.

²³ Tufts Center for the Study of Drug Development. "Cost to Develop and Win Marketing Approval for a New Drug Is \$2.6 Billion," November 18, 2014, available at: http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study.

²⁴ Gilead, "Gilead Sciences Announces First Quarter Results," April 22, 2014, available at: <http://investors.gilead.com/phoenix.zhtml?c=69964&p=irol-newsArticle&ID=1920785>.

²⁵ Gilead, "Gilead Sciences to Acquire Pharmasset, Inc. for \$11 Billion," November 21, 2011, available at: <http://investors.gilead.com/phoenix.zhtml?c=69964&p=irol-newsArticle&ID=1632335&highlight=>

²⁶ Pharmasset, Inc. Form 10-K, November 14, 2011, available at: <http://www.sec.gov/Archives/edgar/data/1301081/000119312511311300/d225717d10k.htm>.

In any case, the ultimate refutation of this claim is simple: The price is just too much. The system can't, and won't, pay—at least not for everyone who potentially needs treatment.

IV. BRAND-NAME COMPETITION OFFERS NO CURE

What then is to be done? Some have held out hope that competition from new Hepatitis C products will lower prices, either through direct price competition or by enabling payers to negotiate prices down. But there is very little chance that competition from new products will lower prices anywhere near enough.

A new combination regimen from Merck and including sofosbuvir has recently failed to show good results.²⁷

However, Abbvie is seeking approval for a new product that may show greater promise and constitute a legitimate alternative to sofosbuvir for patients with HCV genotype 1, the most common type in the United States.²⁸ But even assuming Abbvie's product, and perhaps others in the pipeline, do gain marketing approval and offer comparable benefits to sofosbuvir for certain patients, they are unlikely to bring steep drops in price.

Brand-name companies do not generally engage in robust competition over price while their products remain on patent, instead behaving more as oligopolists. New entrants into a class not infrequently peg their prices above those of existing sellers. This has been notably true in the instance of HIV/AIDS drugs, where new drugs in class typically sell at prices comparable to, or, not infrequently, more than earlier entrants; new classes of antiretrovirals are commonly priced above prior ones; and prices tend to increase annually throughout the entire market.²⁹ The Congressional Budget Office (CBO) has found these trends to be generally true: In four out of five therapeutic classes examined by the CBO, the breakthrough product price continued to rise even after the introduction of me-too, brand-name competitors.³⁰

By contrast, generic competition does lower price, but—in keeping with the experience with limited competition among brand-name suppliers—prices tend to fall only modestly with one or a few competitors. The steep price reductions from generic competition are realized only with large numbers of competitors in the market.³¹

Indeed, although there has been considerable talk about a potentially lower price from Abbvie for its competitor product, there is little reason to expect dramatic price reductions. Investment analysts are now speculating that the company may price its drug 10–20 percent below Gilead.³² For a product as expensive as Sovaldi, this would represent a non-trivial savings on the order of \$15,000 per patient. But such

²⁷ Bill Berkrot, “Merck Four-Week Hep C Regimen with Gilead’s Sovaldi Comes Up Short,” Reuters, November 9, 2014, available at: <http://www.reuters.com/article/2014/11/10/us-merck-co-hepatitis-idUSKCN0IU00K20141110>.

²⁸ Abbvie, “AbbVie Submits New Drug Application to U.S. FDA for its Investigational All Oral Interferon Free Therapy for the Treatment of Hepatitis C,” April 22, 2014, available at: <http://abbvie.mediaroom.com/2014-04-22-AbbVie-Submits-New-Drug-Application-to-U-S-FDA-for-its-Investigational-All-Oral-Interferon-Free-Therapy-for-the-Treatment-of-Hepatitis-C>.

²⁹ See James Love and Thiru Balasubramanian, “Price Evolution of Antiretroviral Drugs 1996 to 2002 Maryland Reimbursements for Medicaid Program,” August 28, 2003, available at: http://keionline.org/sites/default/files/ER_James_Love_Thiru_Balasubramanian_Maryland_Medicaid_ARV_prices_20030828.pdf.

³⁰ Congressional Budget Office, “How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry,” July 1998, available at: <http://www.cbo.gov/sites/default/files/pharm.pdf> (see p. 20). Price rises for brand-name drugs after they are first placed on the market are commonplace and can be extraordinary, a reminder that—absent policy interventions—the price for sofosbuvir may well rise considerably in the years ahead. See General Accounting Office, “Brand-Name Prescription Drug Pricing: Lack of Therapeutically Equivalent Drugs and Limited Competition May Contribute to Extraordinary Price Increases,” December 2009, available at: <http://www.gao.gov/new.items/d10201.pdf>; and Robert Langreth, “Big Pharma’s Favorite Prescription: Higher Prices,” Bloomberg BusinessWeek, May 8, 2014, available at: <http://www.businessweek.com/articles/2014-05-08/why-prescription-drug-prices-keep-rising-higher#p2>.

³¹ Congressional Budget Office, “How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry,” July 1998, available at: <http://www.cbo.gov/sites/default/files/pharm.pdf>. (The rising prices of generics in the United States over the last year and the diminished benefit of generic competition is surely due in considerable part to the reduction in number of generic manufacturers, and the growing interconnections between generic and brand-name companies, including through pay-to-delay and other licensing arrangements, as well as the outright brand-name company acquisition of generic firms.)

³² Ed Silverman, “If Abbvie Discounts Its Hep C Drug, Would Pricing Reach a Tipping Point,” Wall Street Journal, October 14, 2014, available at: <http://blogs.wsj.com/pharmalot/2014/10/14/if-abbvie-discounts-its-hep-c-drug-would-pricing-reach-a-tipping-point>.

a price reduction would not be nearly enough to reduce pressure on payers, or to avoid rationing.

If the Abbvie product turns out to be a close substitute of sofosbuvir for patients with HCV genotype 1 and of comparable efficacy, and if Abbvie does evidence an interest in competing on price, then perhaps the VA and other payers willing and able to engage in hard bargaining will be able to reduce prices further. Even so, the extraordinary high starting point established by Gilead makes it almost impossible for negotiations to succeed at lowering price to a tolerable level.³³

V. THE IMPERATIVE OF PUBLIC USE OR ACQUISITION

Ultimately addressing the sofosbuvir pricing problem—and avoiding both unjustified drain on the pocketbooks and treasuries of consumers and private and government insurers, and needless rationing of this apparently important medicine—will require a government licensing or acquisition arrangement. There is no doubt that generic producers can make and profitably sell sofosbuvir at prices that are two orders of magnitude cheaper than the Gilead price. With marginal pricing, the drug can be made available to everyone who is clinically indicated to receive it, while Gilead can be provided some fair compensation.

Gilead has never claimed that its \$84,000 price reflects manufacturing costs. To its credit, the company has announced a discount and licensing arrangement for developing countries. Gilead will make sofosbuvir available in India for \$1,800 for a course of treatment. It has voluntarily licensed seven Indian firms to produce the drug, and there is every reason to expect their price to be far below the \$1,800 level set by Gilead.³⁴

In the United States, there is a well-established method for the government to use patented inventions without permission of the patent owner, via 28 U.S.C. 1498(a).³⁵ Sec. 1498 establishes an absolute right for the government and its contractors to use patented inventions, with the only limitation being that reasonable compensation must be paid.

Sec. 1498 is most commonly used by contractors, notably defense contractors, but its reach extends far beyond the defense sector. Following the spread of anthrax by postal mail in 2001, the use of Sec. 1498 was contemplated to build a stockpile of ciprofloxacin against potential bioterrorist threats. Although Sec. 1498 was not employed, it was against the backdrop of a government use license threat that Bayer, the manufacturer of then-patent protected ciprofloxacin, lowered its price significantly.³⁶

³³Troyen Brennan and William Shrank, “New Expensive Treatments for Hepatitis C Infection,” *JAMA* 2014;312(6):593–594. (From the chief medical officer and chief scientific officer for CVS Caremark: “The ultimate approach to cost will be lower prices, which will occur as more products create competition. However, it will likely entail narrower formularies, in which the physician choice of a particular medication is limited by the deals negotiated by insurers and pharmacy benefit managers. Even then, the costs could still be very high—restrictive formularies have led to discounts of 30% to 40% for branded medications, not the greater than 95% discounts that occur when drug patents expire and generic competitors enter.”)

³⁴Gilead, “Gilead Announces Generic Licensing Agreements to Increase Access to Hepatitis C Treatments in Developing Countries,” September 15, 2014, available at: <http://www.gilead.com/news/press-releases/2014/9/gilead-announces-generic-licensing-agreements-to-increase-access-to-hepatitis-c-treatments-in-developing-countries>. Gilead’s licensing deal for developing countries has been subject to considerable criticism (see Ketaki Gokhale, “Gilead Licenses Hepatitis Therapy in India Amid Price Criticism,” Reuters, available at <http://www.bloomberg.com/news/2014-09-15/gilead-licenses-sovaldi-to-mylan-others-for-developing-markets.html>), not without reason, but the company should be given credit for putting forward a legitimate licensing scheme that will likely make sofosbuvir available in poor countries for a price 1 percent or less of what is charged in the United States.

³⁵“Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner’s remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture.”

³⁶In 2001, in the midst of the anthrax scare, Secretary of Health and Human Services Tommy Thompson, at the urging of Senator Charles Schumer, began discussion of exercising Sec. 1498 authority to ensure the government was able to build emergency reserves of ciprofloxacin to prepare for the possibility of a bioterrorist attack. (Matt Fleischer-Black, “The Cipro Dilemma—In the Anthrax Crisis, Tommy Thompson Distorted Patent Law to Save Public Health. Good Move?” *The American Lawyer*, January 2002, available at: <http://www.cptech.org/ip/health/cl/cipro/americanlawyer012002.html>.)

Sen. Schumer argued, “[f]irst, Bayer can only produce so much Cipro, and we should not put our best response to anthrax in the hands of just one manufacturer. Second, buying Cipro only from Bayer—who charges a lot more than generic manufacturers would—means we spend a lot

Continued

It is also worth noting other contexts in which the government issues non-voluntary licenses on pharmaceutical inventions, particularly in the context of efforts to overcome anti-competitive practices. Licenses have been issued to overcome collusive deals between brand-name and generic firms to delay generic competition (pay-to-delay cases) and to mitigate the anti-competitive impact of mergers.

What would a government use license look like for sofosbuvir and related products?

Under a traditional government use license approach, the Federal Government would authorize generic manufacturers to make and sell the product for its use—in this case, for distribution to patients under its care.

The scope of the license could vary considerably. The license could be to treat patients served only by a particular agency—the Department of Veterans Affairs, for example, or the Federal Bureau of Prisons. It could cover all government programs, including Medicaid and Medicare. It could also be designed to cover all Hepatitis C patients in the United States, if the U.S. Government were to create a program to provide pharmaceutical treatment for all Hepatitis C patients for whom treatment is clinically indicated. The Ryan White HIV/AIDS program is an example of a disease-specific Federal insurance and treatment program, though it is a means-tested program.³⁷

With the ability to negotiate scaled-up purchases from generic makers anywhere in the world that satisfy quality considerations, the government could likely obtain a course of a treatment at a cost of several hundred dollars per patient.

On top of the cost of purchase, reasonable compensation would need to be provided to Gilead. There is a fairly rich case law in determining fair compensation under Sec. 1498, which looks to a wide range of factors, including licensing practices within the industry. Within the pharmaceutical sector, licenses are common, and aggregate around 5 percent, though rates often rise considerably higher. In this instance, Gilead would have a good claim for a much higher royalty. A royalty rate of 100 percent would double the price of the product, but likely still keep costs well below \$1,000. Even if Gilead were paid a royalty of \$1,000 per patient, costs might be as little as \$1,200 per patient. Even with a per patient royalty of \$5,000, the calculus of providing treatment would be revolutionized.

It's worth underscoring just how revolutionary would be such a price reduction. At \$1,200 per patient, the cost to treat 3.2 million patients would be \$3.84 billion—as compared to \$268 billion at the \$84,000 price. For the VA, the price to treat 170,000 patients would be \$204 million—as compared to \$8.5 billion at the current discount price. For a veteran patient population of 1 million, the cost would be \$1.2 billion—as compared to \$50 billion.

With a \$5,000 per patient royalty, the costs would be \$16.6 billion for the entire U.S. population, \$884 million for 170,000 vets and \$5.2 billion for a veteran population of 1 million.

Apart from the political will to pursue such an approach, there would be significant issues to address. These include:

- Establishing a fair and reasonable royalty that satisfies a reviewing court if challenged by Gilead. Courts tend to look at a wide range of factors, including royalty rates for comparable licenses, the licensor's policy to maintain its patent monopoly, the advantage of the patented invention over alternatives, and the outcome

more and receive a lot less. Hopefully, we won't even need to use the Cipro we already have on hand, but if we make arrangements to purchase it from multiple generic drug manufacturers, we'll have it if we need it." (Randall Willis, "Infringement for the public good?" *Modern Drug Discovery*, May 2005, available at: <http://pubs.acs.org/subscribe/archive/mdd/v05/i05/html/05pap.html>)

HHS had previously negotiated a price of \$1.77 per tablet for Cipro. On October 22, HHS announced a newly negotiated price of \$0.95 per tablet for a purchase of 100 million tablets. Purchasing 100 million tablets at the new price saved the government and taxpayers \$82 million. Furthermore, the negotiated agreement provided the government with the option of making a subsequent purchase of 100 million tablets at \$0.85 per tablet as well as the option of a third 100 million tablets purchase at \$0.75 per tablet. (HHS Press Office, "HHS, Bayer, Agree to Cipro Purchase," October 24, 2001, available at <http://archive.hhs.gov/news/press/2001pres/20011024.html>.) It took less than one week from the first public murmurings of government use for the government to obtain a nearly 50 percent discount.

Also worth noting: In the 1960s, the VA used Sec. 1498 to procure a generic version of the tranquilizer meprobamate at a more than 95 percent discount. (Donald McNeil, "U.S. Weighs the Hidden Cost of its Pharmacy Bill," October 17, 2001, available at: <http://www.freerepublic.com/focus/news/549769/posts>.)

³⁷Health Resources and Services Administration, "About the Ryan White HIV/AIDS Program," available at: <http://hab.hrsa.gov/about/aboutprogram.html>.

of a hypothetical arms-length negotiation, but there is considerable variation in the standard for reasonableness imposed by courts.³⁸

- Overcoming the “data exclusivity” rights that Gilead obtains as the party to have obtained marketing approval for sofosbuvir. These rights prevent generic firms from relying on Gilead’s clinical trials in order to obtain FDA marketing approval, for a period of five years. Government use of the sofosbuvir patents pursuant to Sec. 1498 would not include a right to rely on Gilead’s testing data. The government might solve this problem by using its broad eminent domain authority to acquire a license to rely on the test data.³⁹ It might gain Gilead’s agreement to rely on the test data as part of a negotiation over the price of compensation for the patent license. Or, it could, in theory, if it chose, repeat the clinical trials needed to obtain FDA approval.

A second approach to non-voluntary acquisition of a right to use Gilead’s patents, conceptualized by James Love of Knowledge Ecology International, would be a patent buyout.⁴⁰ Under this approach, the Federal Government would simply purchase from Gilead the entire rights to the sofosbuvir patents, exclusivities and know-how. In practical terms, the primary difference between this approach and a government use license would be that a judgment would be made on the overall compensation to be paid to Gilead for use of its patents and associated rights, rather than making royalty payments on a per pill or per patient basis. But underlying the idea is a different theoretical approach.

See also James Love and Robert Weissman, “A Patent Buy-Out of Hepatitis C Treatments, the Case of the United States,” KEI Policy Note, forthcoming.

At its core, the idea would be to assess how much Gilead is likely to earn from the American market for sales of sofosbuvir, make some modifications as mentioned below, and then pay the company the entirety of that revenue stream. Why would the government do this? Because for almost exactly the same amount of money as Americans are going to pay Gilead for provision of sofosbuvir to a limited pool of patients, the government could provide the drug to everyone for whom it is clinically indicated.

In the first half of 2014, Gilead racked up more than \$5 billion in sales in the United States alone, with sofosbuvir provided to just 70,000 patients.⁴¹ Imagine that this trajectory continues: Sovaldi becomes a \$10 billion seller in the United States, and 150,000 people are treated annually. The drug’s key patents expire in 2025 and 2029. Let’s assume 10 years of monopoly protection for the product. Gilead will earn \$100 billion—just from within the United States—while treatment is rationed.

Here’s how the patent buyout approach might work: Gilead is paid \$100 billion right now. Treatment is made available to everyone who needs it, as soon as suppliers can ramp up. With a marginal cost of production of say, \$200, the cost of providing medicine to each of 3 million patients is only an additional \$600 million.

Now, \$100 billion is an extraordinary sum of money. But the point is, Americans are set to pay this much to Gilead anyway. With Gilead’s current monopoly, we pay that astronomical sum and get rationing; the patent buyout alternative would at least enable us to provide near-immediate treatment for everyone in need, with no rationing.

³⁸ Fifteen frequently referenced “Georgia Pacific factors” were elaborated in *Georgia-Pacific Corp. v. United States Plywood Corp.*, 318 F.Supp 1116, 6 USPQ 235 (SD NY 1970).

³⁹ See U.S. Department of Justice, “History of the Federal Use of Eminent Domain,” available at: http://www.justice.gov/enrd/History_of_the_Federal_Use_of_Eminent_Domain.html as well as discussion at *Kirby Forest Industries, Inc. v. United States*, 467 US 1 at 4–5. If the government were to use its eminent domain powers to obtain a license to rely on Gilead’s data, it would be required to pay “just compensation,” pursuant to the Fifth Amendment. There would be a strong argument that just compensation should be zero, since Gilead would already be paid compensation for a license to use a product otherwise given monopoly protection. An alternative compensation approach would look to the cost of the clinical trials undertaken by Gilead to obtain FDA approval for sofosbuvir, and for the Federal Government to pay a fair share for the cost of those trials. This approach is currently followed for use of pesticide testing data under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). See Robert Weissman, “Public Health Friendly Options for Protecting Pharmaceutical Registration Data,” *International Journal of Intellectual Property Management*, vol. 1, no. 1/2, 2006, available at: <http://www.essentialaction.org/access/uploads/IJIPM1101Weissman-5.pdf>. Since clinical testing costs for sofosbuvir were in the \$100 million range, paying for a portion of these costs would not significantly add to the amount the government would pay Gilead.

⁴⁰ James Love, “Non-voluntary Use of Patents for Drugs to Treat the Hepatitis C Virus in the United States: Mechanisms Available to the Federal Government, State Governments and Private Actors,” July 18, 2014, available at: http://keionline.org/sites/default/files/Non-voluntary_use_HCV_patents_USA.pdf.

⁴¹ Andrew Pollack, “Gilead’s Hepatitis C Drug, Sovaldi, Is On Pace to Become a Blockbuster,” *New York Times*, July 23, 2014, available at: http://www.nytimes.com/2014/07/24/business/sales-of-hepatitis-c-drug-sovaldi-soar.html?_r=0.

Of course, there could be substantial modifications to the \$100 billion figure. In light of the prospect of a competing treatment, we could imagine that Gilead's revenues will diminish over time and that an effective buyer could negotiate lower prices. We might decide that Gilead's current price is simply too high, and impose a fair-pricing reduction. Perhaps these adjustments cut the payment to Gilead in half, perhaps more.

The buyout of Gilead's U.S. patent and related rights could proceed through voluntary negotiation, against the backdrop of a potential use of the government's Sec. 1498 and/or eminent domain authority. If Gilead refused to agree, the government could proceed to exercise those authorities.

The government might choose to shoulder the burden of paying for the buyout on its own, or it might impose a fee on other payers—health insurers and self-insuring employers—to share costs. One can imagine many different ways to allocate costs.

As with the issuance of a government use license, the patent buyout approach plainly presents a series of challenges. Negotiating or determining compensation would be contentious. Apportioning costs to nongovernmental payers would be complicated and likely require legislation. As with issuance of a government use license, the government might choose to create a special program for Hepatitis C coverage, but this would be less necessary because one benefit of the patent buyout approach is that it would make available generic versions of sofosbuvir for the private as well as public sector.

But all of these challenges can be addressed.

And the potential complications and contentiousness of either non-voluntary approach to making sofosbuvir available at marginal cost to all who need it should not obscure more important realities:

1. The present approach whereby we are at the mercy of Gilead's monopoly control over sofosbuvir—a government-granted monopoly, at that—is morally unacceptable, because it requires the needless rationing of an important medical therapy. The same holds for other new Hepatitis C treatments.

2. The deference to Gilead's monopoly pricing for sofosbuvir is fiscally unsustainable. Sky-high prices for medicines with smaller patient populations are unacceptable, but the health care system can more easily absorb them. Gilead's pricing for a product needed by a large patient population is already imposing serious strains on both public and private payers.

3. Market and voluntary approaches to addressing the excessive and intolerable pricing of sofosbuvir are almost certain to fail. There is no reason to believe either brand-name competition or bulk purchasing negotiations by public or private insurers will reduce the price of sofosbuvir or competing medicines to acceptable levels.

4. The Federal Government has the legal tools and the capacity to address these problems through non-voluntary licensing or patent acquisition.

VI. THE BROADER PHARMACEUTICAL POLICY LANDSCAPE

The Hepatitis C story is unusual in that an apparently very effective drug has become available to treat a large patient population.

But the pricing of sofosbuvir and other Hepatitis C treatments is no longer unusual, as high five figure and even six figure drugs become increasingly common.⁴²

The future of pharmaceutical pricing for new drugs is coming into sharper focus: astoundingly high prices that drain public treasuries, impose unmanageable costs on private insurers and stress consumers paying out of pocket beyond their breaking point. This is a future of price gouging, unsustainable health care costs, and routinized rationing.

It's not a future we should welcome, and it's not one that we should tolerate.

We need to find different ways to reward innovators for research and development other than with patent monopolies and marketing exclusivities. Research and development does have real costs, and it is important that it be both supported and incentivized. But monopolies have proven an enormously inefficient way to do so, and now are increasingly being deployed in an unsustainable fashion.

Real solutions are not going to come from the margins, because the pricing system is fundamentally broken. It's past time for a very serious debate about how we leverage the very substantial public investment in medical R&D to ensure more ac-

⁴² See Peter B. Bach, "Could High Drug Prices Be Bad for Innovation," *Forbes*, October 23, 2014, available at: <http://www.forbes.com/sites/matthewherper/2014/10/23/could-high-drug-prices-be-bad-for-innovation>; Alicia Caramenico, "Unaffordable Lifesaving Drugs—The List is Growing," *AHIP* (America's Health Insurance Plans) Coverage blog, September 29, 2014, available at: <http://www.ahipcoverage.com/2014/09/29/unaffordable-lifesaving-drugs-the-list-is-growing>.

cess to treatment.⁴³ And it's time also to talk about a new reward system for innovation, which pays drug developers directly for the public health benefits they confer—for their innovative contribution, and the risks taken—but permits immediate, marginal pricing of new drugs.⁴⁴

It's a great thing that our public and private medical research system is able to develop important new drug treatments. For patients, however, those treatments are useful only if they are accessible, and we've now reached a point where treatments will increasingly be restricted and rationed because brand-name drug companies have used monopolies to price them out of reach. We have to do better, and we can.

Chairman SANDERS. Thank you.

Senator BURR. Mr. Chairman, if I could apologize to the witnesses, I have got a meeting that I cannot miss. I would very much like to be here to ask some questions. I will leave you in sufficient hands.

Chairman SANDERS. Thank you, Senator Burr.

Let me start off by throwing out some information that I believe is accurate, but correct me if you think it is not. My understanding is that Sovaldi was developed by Pharmasset, that Pharmasset was purchased by Gilead for about \$11 billion, is that correct?

Mr. WEISSMAN. Yes.

Chairman SANDERS. My understanding is that in the first year that the product, Sovaldi, is on the market Gilead will make about \$11 billion and get a 100 percent return on their investment for purchasing Pharmasset. Is that your understanding?

Mr. WEISSMAN. Yes.

Chairman SANDERS. Obviously, no one can predict what happens in the future, but there are some estimates that Gilead can make as much as \$200 billion on this one product alone, having bought the company that developed it for \$11 billion. Does that sound roughly accurate?

Mr. WEISSMAN. It could be more.

Chairman SANDERS. It could be more. OK. Both of you raised the moral issue of a company making a huge profit, charging unbelievably high prices which results in a whole lot of people: (A) unable to afford the product; and (B) in the case of government agencies, whether it is VA or Medicaid, spending significant sums of money to buy that product, meaning that they have less money available for other needs.

What is the moral implication of it? Are we comfortable as a nation with a product being available which can save human lives, but either individuals or government agencies are not able to afford that product the company is making unbelievably high profits? Is that a good way to do health care in America?

Mr. ROTHER.

Mr. ROTHER. Senator, we could have a very interesting moral discussion. I believe there are many moral issues raised by not only this situation, but health care in general. I do think that in this country, we have decided that for-profit institutions have a role,

⁴³ See Robert Weissman, "The Role of federally-Funded University Research in the Patent System," testimony before the U.S. Senate Committee on the Judiciary, October 24, 2007, available at: <http://www.judiciary.senate.gov/imo/media/doc/07-10-24WeissmanTestimony.pdf>.

⁴⁴ See, for example, S. 627, the Medical Innovation Prize Fund Act, introduced by Senator Bernie Sanders, which would eliminate patent and other exclusive rights to market pharmaceuticals, and instead pay innovators from a medical innovation prize fund.

particularly in the pharmaceutical arena, and we have to live with that.

For me, the moral issue is not so much the profit as it is are people who need and could benefit from this therapy receiving it or likely to? And if we do not have a system that can assure that, I think that raises a very serious moral question, and we clearly do not in this situation because of the price. Again, I would say profits are part of our system, but at this point, we have to question whether or not we have an ability to serve a real human need.

Chairman SANDERS. Let me ask the same question of Mr. Weissman. Researchers at the University of Liverpool have estimated Gilead's production costs, or Pharmasset's production costs for a full course of treatment is approximately \$150 to \$250 per person. That is less than $\frac{3}{10}$ of 1 percent of the price the company is actually charging, which is \$84,000. We also know that, based on the SEC filings from Pharmasset, the original developers of the drug now known as Sovaldi, they had intended to charge \$36,000, not \$84,000. So, how do we get to \$84,000 when the developer of the drug wanted to charge \$36,000 especially when the full course of treatment—the production cost—is \$150 to \$250? How does this \$84,000 magically appear?

Mr. WEISSMAN. Well, maybe one other number to throw in the mix before answering is the actual R&D expenditure on this product, so—

Chairman SANDERS. It must have been many billions of dollars, was it not?

Mr. WEISSMAN. It was not.

Chairman SANDERS. Oh.

Mr. WEISSMAN. It was probably around \$100 million. We know from Pharmasset's 10(k) filings they spent about \$68 million in the 3 years prior to Gilead's acquisition on their clinical trials.

Chairman SANDERS. Let us repeat that. They spent \$68 million for the research and development to develop the drug, and they are going to make \$11 billion the first year the drug is out and perhaps \$200 billion over the course of the life of the drug?

Mr. WEISSMAN. That is correct. So, I think we are a long way from worrying about fair return on R&D investments. We are untethered from the R&D consideration, and I think—where did the \$84,000 figure come from? Because they can. They did not want to go to six figures, because they thought that was a bad idea. It might look more—give them more trouble than they wanted to take. The nature of a patent monopoly is the monopoly seller chooses the price.

Chairman SANDERS. So, you have a monopoly situation where the person who has a pill that is desperately needed by people all over this country and all over the world can charge anything they want for it?

Mr. WEISSMAN. Right, and it is not like \$36,000 is a fair price. That is just a different price.

Chairman SANDERS. It is not \$94,000, right.

Mr. ROTHER, did you want to comment.

Mr. ROTHER. Senator, if I could, I do think that the traditional justification for high prices in pharmaceuticals is obsolete, and Gilead, to their credit, has not tried to justify price on the basis of

R&D, because they cannot. And, that is probably true for many of the new specialty drugs. The price is divorced from the cost of development.

In earlier public statements, the CEO of the company has clearly stated that they took the existing price, the standard of care pre-existing, and bumped it up and set their price at maybe 20 percent higher. That did not take into account the vast increase in the population that would be appropriate for this. So, they really did not even think about the public consequences or the consequences to health payers, governments, insurers, individual businesses. They just did what I think has become common practice in the industry, which is that escalator pricing—taking the current price and, for a new product, bumping it up regardless of R&D costs.

Chairman SANDERS. I certainly believe that when you have a product that saves lives and eases suffering, you want to get it out as widely as possible. In fact, in Egypt, where Hepatitis C is a very, very serious problem, Gilead is going to sell this product there for \$10 a pill rather than the \$1,000 a pill they are charging in the United States. How does that happen? Should the VA go to Egypt and buy a whole lot of product there?

Mr. ROTHER. There are quite serious considerations among some of my members about sending their infected patients to Egypt.

Chairman SANDERS. Is that something that some of your—

Mr. ROTHER. Absolutely. It is called medical tourism, and—

Chairman SANDERS. Right.

Mr. ROTHER [continuing]. You can save quite a bit of money.

Chairman SANDERS. So that we are clear on this: somebody in the United States who is not in the VA, not in Medicaid, has Hepatitis C.

Mr. ROTHER. Right.

Chairman SANDERS. Today, they have to pay \$1,000 a pill here, or \$84,000 for the treatment. Some of the people you work with are now suggesting that folks go to Egypt to buy that treatment for \$10 a pill. Is that what I am hearing from you?

Mr. ROTHER. Medical tourism has actually been a phenomenon for a while, but this is an extreme situation—

Chairman SANDERS. This is extreme, yes.

Mr. ROTHER [continuing]. Where the differential in the cost is so dramatic that it is hard not to think about this as a serious strategy for health insurers, or public programs, for that matter, who otherwise simply cannot afford this.

Chairman SANDERS. Will—my guess is that they make money on selling it at \$10 a pill in Egypt. Do we think they do?

Mr. WEISSMAN. I am sure they do. I mean, they are doing some interesting things in terms of the licensing in developing countries so that—they are enabling seven Indian manufacturers, also, to sell in 91 countries. They will undercut the Gilead price in Egypt. They will undercut the Gilead price in India, as well. So, yes, at \$800, they will make a profit, or \$900, but they are not trying to make real profits there.

Chairman SANDERS. Yes.

Mr. WEISSMAN. I think what all this speaks to, and even more than guessing what the marginal cost is, we have a system that is not functioning properly. The purpose of granting a monopoly is to

incentivize R&D, and now, as Mr. Rother says—it is correct—we are now incentivizing something else. It is doing something else entirely. And, if we have a rational approach to thinking about this, the idea should be making important medical treatments available to everybody, really, at marginal cost. So, \$200 is the cost of getting it; that is a real cost. That is the cost it should be. We have to incentivize and pay some kind of compensation to create some kind of incentive for R&D—

Chairman SANDERS. Right.

Mr. WEISSMAN [continuing]. But, we should not do it by charging patients super-high prices. We should not do it by making health insurers unable to pay.

Chairman SANDERS. This is a huge issue, which obviously, as I think you indicated, Mr. Rother, goes well beyond Sovaldi. And, the issue here is that, as you both indicated, we have got to come up with an approach which encourages innovation, which rewards innovators, which lets them make good profits, but at the same time, once we have that product which saves lives, we get it out as widely and as cost-effectively as possible throughout this country and throughout the world. Is that essentially the goal of what we are talking about?

And, you indicated, Mr. Weissman, we can offer up with the idea of a prize. In other words, the government says, look, these are the challenges that we face, the illnesses we want to deal with and you are going to come up with a product and make a lot of money, but then it is ours and we are going to distribute it in a cost-effective way. Is that an approach that makes sense?

Mr. ROTHER. I think it is an option that we ought to really consider, but we also need other options that maybe, I believe, are perhaps more attainable in the short term, because I think that is a dramatic—

Chairman SANDERS. You do not think the pharmaceutical industry will be supportive of—

Mr. ROTHER. Somehow, I just doubt that.

Chairman SANDERS. Yes—

Mr. ROTHER. So, anyway, I think that demanding greater transparency, moving them toward value-based pricing would be a big advance. It might not have a huge impact at first, but at least we would have a more informed debate. At least we would be able, then, to have a serious discussion about alternatives and we would have the information that we need, which now is not available.

Chairman SANDERS. Well, in this case, we do have. I think, Mr. Weissman, you indicated that R&D for this product was, what, several hundred million?

Mr. WEISSMAN. One-hundred million.

Chairman SANDERS. One hundred—

Mr. WEISSMAN. This is an unusual case. Yes, we actually have information.

Chairman SANDERS. All right. So, we do know that their profit margin is going to be extraordinary based on R&D. But, your thought is transparency would be helpful throughout the process?

Mr. WEISSMAN. Well, if I can comment, I think there is no question about that. There is this recent study from Tufts where the \$2.6 billion estimate for the cost of developing a new pharma-

ceutical based on secret industry data is not being made available, and I think, you know, I agree with all the points that Mr. Rother made in the testimony.

Chairman SANDERS. So, in other words, we have no reason to believe that that is necessarily accurate?

Mr. WEISSMAN. I would say we have many reasons to believe that is not necessarily accurate. But, as to the point of whether the industry would oppose this, I am sure the industry would oppose your bill at first, Mr. Sanders, but the fact is that the current system is not just leading to immoral outcomes, it is ineffective at incentivizing R&D—both in terms of the irrational outcomes, and we are just not getting very much back. You could—and what actually is incentivizing quite a bit is intensive marketing and expenditures on capitalizing on the monopolies, not actually on the R&D side.

So, I believe, as your legislation proposes, we would have similar amounts or perhaps even larger amounts available for actual R&D than currently is available, and to reward actual results from R&D than is currently done. You just would not take the hide out of consumers to pay for all the marketing of the monopolistically-protected product.

Chairman SANDERS. I recall speaking to physicians on this issue who talk about the absurdity of them writing out prescriptions that are not filled by people who simply cannot afford to fill them, and think about the enormous waste in that, of people who do not get the medicine that they should because they cannot afford it, then end up in a hospital a lot sicker than they should be.

Mr. ROTHER, did you want to—

Mr. ROTHER. Yes. I was actually going to make a point about physicians. We have been talking to many of the leading physicians in the field about this issue and they are deeply troubled. And, I believe we will shortly be able to hold a press conference with them and give voice from the clinical perspective to what they see as an unjustifiable—

Chairman SANDERS. In the sense that there is a product out there that their patients need—

Mr. ROTHER. Right.

Chairman SANDERS [continuing]. But cannot afford, is that the—

Mr. ROTHER. Absolutely. They understand, as well, the kinds of tradeoffs that that kind of a price forces health systems to make because they are the ones then confronted with it. So, I think you will find a very strong clinical voice. Now, of course, there are many physicians who receive money from the pharmaceutical industry, so we have to acknowledge that. But, these people are the acknowledged leaders in the field and I think we will find they believe that the current system is not sustainable and does not work and we need to think about new ways of rewarding—

Chairman SANDERS. So, their frustration is they have patients who can be treated, but they are unable—

Mr. ROTHER. Yes.

Chairman SANDERS [continuing]. To treat them because of the cost of the product.

Mr. ROTHER. That is correct.

Chairman SANDERS. All right. What questions am I not asking?

Mr. ROTHER. Well, I wanted to make a point—I am sorry that Senator Burr is not here—about cost effectiveness, because he was saying we could assume here that if everyone was treated, we would save all this money. In fact, that is not the case. The most authoritative body that studies the cost effectiveness of pharmaceuticals, ICER, has done a study on Sovaldi and they have concluded that the drug is not cost effective given to everyone. It could be cost effective if it is very focused on those people who are the most seriously ill, but that leaves then untreated many people who really are at risk.

So, this group will be meeting once again in just a couple of weeks—I am going to be part of that—to look at the next generation, Harvoni, and will also bring the best independent analysis to whether the drug is worth it at its current cost. Of course, I do not know what the conclusion will be, but I just wanted to put on the record the fact that there has been very careful analysis of cost effectiveness and the conclusions do not support the current pricing of Sovaldi.

Chairman SANDERS. Mr. Weissman, any last thoughts?

Mr. WEISSMAN. Well, I want to thank you for holding the hearing. Again, I think that Sovaldi is a flash point issue, and we should say one reason is because it is such a good drug, or at least appears to be, based on the early results we have, whereas most new medicines are not. But, it is a harbinger of what is to come and even of what we already have. But, because this one has the profile it has, the high price, the large population, and apparent high efficacy, we really need to focus on it and, I think, really push for legislative approaches that deal with this particular problem as a way to get to a bigger discussion, but also for administrative actions. I think the administration has opportunities here to do some things on its own to take care of at least the current patients in various Federal systems, which is the bulk of the population.

Chairman SANDERS. Well, let me conclude by thanking both of you for your excellent testimony. The truth is, this hearing could be held in any number of committees, because it goes well beyond Sovaldi and the fact that veterans have a disproportionately high percentage of Hepatitis C than the general population. The issue here for the Veterans Committee is that with the limited budget, we want to make sure all of our veterans get the health care they need, the quality care they need. But, there is no question in my mind that if we end up spending billions of dollars on this one particular drug, it is going to make it difficult for the VA to provide care in other areas where veterans need it. It is an issue for VA. It is an issue for Medicaid and it is an issue for Medicare. It is really an issue for the entire country.

So, we thank you both very much for being here and look forward to continuing working with you.

This hearing is adjourned.

[Whereupon, at 12:51 p.m., the Committee was adjourned.]