

Written Testimony of

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before the

The Committee on Veterans' Affairs
U.S. Senate

On

"Hepatitis C in Veterans"

December 3, 2014



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

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

¹ To 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 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.

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

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

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

⁴ E 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.

⁶ JA 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#>.

⁷ 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,” *Epidemiology of viral hepatitis*. *Hepatology*, 2013. 58: 216A–219A.

⁸ Lisa 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.

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

¹⁰ Centers 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 Hepatitis C,” available at: http://hcvadvocate.org/hepatitis/factsheets_pdf/Brief_History_HCV.pdf; and U.S. Department

Within the last year, however, a new and apparently 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

of Veterans Affairs, "Interferon and Ribavirin Side Effects," available at:
<http://www.hepatitis.va.gov/provider/reviews/treatment-side-effects.asp>.

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

¹² Food 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>.

¹³ 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.

¹⁴ Gretchen 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>.

¹⁵ National 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>.

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 million patients x \$84,000/patient = \$268.8 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 x \$50,000/patient). Assuming 1 million veterans with HCV (a low 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

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

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

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

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:

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

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

<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-hepatitisc-insight-graphi-idUSL1N0OD1F820140528>. 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 for Pricy 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.

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.

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.

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>.

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

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_Balasubramaniam_Maryland_Medicaid_AR_V_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

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 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

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>.

³³ Troyen 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.”)

³⁴ Gilead, “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

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 USC 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

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

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.”

³⁶ In 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 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>.)

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.

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

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 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

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](http://www.essentialaction.org/access/uploads/IJIPM1101Weissman-5.pdf), 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. 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.

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.

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.

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.

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.

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

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>.

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 access 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.

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.