

## HOW (MUCH) TO SAVE A LIFE?: EVALUATING THE IMPACT INSURANCE COMPANIES HAVE ON HEALTH CARE

JORDAN LEWANDOWSKI\*

*Currently, almost half of Medicaid patients diagnosed with chronic hepatitis C have been denied access to Sovaldi. Restricted access to Sovaldi, Gilead Sciences' "blockbuster" hepatitis C drug, is becoming an unfair reality for the majority of Medicaid recipients. Although almost every Medicaid program covers Sovaldi, the prior authorization restrictions placed on the availability of the drug make it practically impossible to obtain. This Note argues that insurance companies, specifically Medicaid, should not have unbridled control over the availability of specialty drugs to patients who cannot afford treatment on their own. Providing a tax benefit to the pharmaceutical companies that manufacture these specialty drugs, or to insurance companies that choose to cover a significant portion of the cost of specialty pharmaceuticals, will counteract the considerable research, development, and manufacturing costs of these drugs and will make them more affordable to those who are suffering.*

### TABLE OF CONTENTS

I.	INTRODUCTION .....	2046
II.	BACKGROUND .....	2049
	A. <i>Medicaid's Role in Health Care</i> .....	2049
	B. <i>Specialty Drug Pricing</i> .....	2051
	C. <i>Sovaldi's Impact on Hepatitis C</i> .....	2052
	D. <i>Medicaid's Enormous Impact on Sovaldi's Success</i> .....	2054
	E. <i>The New Issue Facing Sovaldi</i> .....	2056
III.	ANALYSIS .....	2057
	A. <i>The Pricing Scale of "Blockbuster" Drugs is Currently Skewed</i> .....	2058
	B. <i>Many Hepatitis C Patients Fall Victim to Health Care Rationing and Are Continually Denied Treatment Through Medicaid, Forcing Them to Cope with Their Symptoms on Their Own</i> .....	2064

---

\* J.D. 2017, University of Illinois College of Law.

	C.	<i>Insurance Companies, Specifically Medicaid, Should Not Be Allowed to Arbitrarily Decide Which Patients Receive Treatment and Which Do Not</i> .....	2066
IV.		RECOMMENDATION .....	2069
	A.	<i>Incentives Offered to Pharmaceutical Companies Can Provide Motivation for Companies to Produce the Drugs at a Lower Price Rather than Price Gouging Patients</i> .....	2069
	B.	<i>Providing Specialty Pharmaceuticals at Lower Prices to Individuals Suffering from Chronic Illnesses Saves the Government Money in the Long Run Because of the Money Saved on Future Treatment</i> .....	2070
	C.	<i>The Government Must Take a Stand and More Closely Regulate the Medicaid Program</i> .....	2073
V.		CONCLUSION .....	2075

## I. INTRODUCTION

Medicaid, “the nation’s main public health insurance program for people with low income and the single largest source of public health coverage in the U.S.,” currently provides health care coverage to almost 70 million Americans.<sup>1</sup> Medicaid confers over ten substantial, mandatory benefits including inpatient hospital services, laboratory and x-ray services, and home health services, yet one major category of health care seems to be missing.<sup>2</sup> This missing benefit, prescription drug coverage, falls under the category of “selected optional services” of Medicaid benefits.<sup>3</sup> Congress has attempted to regulate this prescription drug coverage issue through the passage of legislation, specifically the Affordable Care Act.<sup>4</sup> However, the new Medicare Part D prescription-drug program, enacted through the Affordable Care Act, only requires certain health plans to cover certain prescription drugs.<sup>5</sup> Optional services are provided through Medicaid on a state-by-state basis and have been regarded as optional because “under federal Medicaid rules, a state may receive fed-

1. Julia Paradise, *Medicaid Moving Forward*, HENRY J. KAISER FAM. FOUND. (Mar. 9, 2015), <http://kff.org/health-reform/issue-brief/medicaid-moving-forward/> (“Medicaid is a core source of financing for safety-net hospitals and health centers that serve low-income communities, including many of the uninsured.”).

2. *Id.* Although Medicaid requires states to provide certain benefits to their beneficiaries, they are no longer required “to provide the same benefits to all Medicaid beneficiaries statewide.” *Id.* As of 2006, states are granted some flexibility to “provide ‘benchmark’ benefits to some Medicaid beneficiaries based on one of three commercial insurance plans specified in the law or a benefit package determined appropriate by the HHS Secretary.” *Id.*

3. *Id.*

4. SUZANNE M. KIRCHHOFF, CONG. RESEARCH SERV., R44132, SPECIALTY DRUGS: BACKGROUND AND POLICY CONCERNS ii (2015).

5. *Id.*

eral matching funds for the costs of covering a specific population group or service.”<sup>6</sup>

One of these optionally covered prescription drugs is Sovaldi, Gilead Sciences’ “blockbuster” hepatitis C drug that essentially cures an individual infected with hepatitis C after only twelve weeks of treatment.<sup>7</sup> Although almost every Medicaid program across the country covers Sovaldi, the restrictions placed on the availability of the drug make it practically impossible to obtain, almost as if Medicaid did not cover it in the first place.<sup>8</sup> One of these restrictions, prior authorization, has been employed in Medicaid programs in over thirty-five states and often requires that patients undergo a liver biopsy to determine just how serious their hepatitis C infection is.<sup>9</sup> Over 3 million Americans are currently suffering from chronic hepatitis C.<sup>10</sup> Surprisingly enough, hepatitis C kills more people annually than HIV, a disease that receives significantly more publicity when it comes to treatment and awareness.<sup>11</sup> Chronic hepatitis C causes “inflammation of the liver that can lead to diminished liver function or liver failure.”<sup>12</sup> While not every person living with hepatitis C receives health care through Medicaid, an alarming number do.

Studies show that the largest group of individuals living with chronic hepatitis C are those born between 1945 and 1965, which is the same age group—those age sixty-five and older—covered almost entirely by Medicaid.<sup>13</sup> Approximately 75–85% of hepatitis C cases become a chronic illness for infected individuals, and the following breakdown shows the severity of hepatitis C.<sup>14</sup> Of the 3.2 million Americans currently infected

---

6. *Medicaid: An Overview of Spending on “Mandatory” vs. “Optional” Populations and Services*, HENRY J. KAISER FAM. FOUND. (2005), <https://kaiserfamilyfoundation.files.wordpress.com/2013/01/medicaid-an-overview-of-spending-on.pdf>.

7. See Soumitri Barua et al., *Restrictions for Medicaid Reimbursement of Sofosbuvir for the Treatment of Hepatitis C Virus Infection in the United States*, ANNALS INTERNAL MED. (Aug. 4, 2015), <http://annals.org/article.aspx?articleid=2362306&resultclick=1>.

8. Bruce Japsen, *As Pricy Hepatitis Pill Harvoni Joins Sovaldi, States Erect Medicaid Hurdles*, FORBES (Oct. 10, 2014, 8:38 AM), <http://www.forbes.com/sites/brucejapsen/2014/10/10/as-hepatitis-pill-harvoni-joins-sovaldi-states-erect-medicaid-hurdles/#3c1bf1475096> (“There is no doubt that Sovaldi is a great advance in the treatment of HCV, but it won’t do any good if no one can afford it.”) (quoting Jeff M. Myers, president and CEO of Medicaid Health Plans of America).

9. *Id.* (“The prior authorization efforts are the best clinical effort to make sure those that need it most get it first, and our plans are doing their best to help the states manage this tsunami of cost.”) (quoting Jeff M. Myers).

10. *Viral Hepatitis—Hepatitis C Information*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/hepatitis/hcv/hcvfaq.htm#section1> (last updated Aug. 3, 2017).

11. Nicholas Bakalar, *Awareness: Hepatitis C Death Rate Creeps Past AIDS*, N.Y. TIMES (Feb. 27, 2012), <http://www.nytimes.com/2012/02/28/health/research/hepatitis-c-deaths-creep-past-aids-study-finds.html>.

12. Mark Lowery, *Sovaldi Approved to Treat Chronic Hepatitis C*, MODERNMEDICINE NETWORK (Dec. 9, 2013), <http://formularyjournal.modernmedicine.com/formulary-journal/content/tags/gilead/sovaldi-approved-treat-chronic-hepatitis-c>.

13. *Viral Hepatitis—Hepatitis C Information*, *supra* note 10; see Paradise, *supra* note 1 (“[F]ederal law provide[s] federal funding for Medicaid only for specified categories of low-income individuals: children, pregnant women, parents of dependent children, individuals with disabilities, and people age 65 and older.”).

14. *Viral Hepatitis—Hepatitis C Information*, *supra* note 10.

with hepatitis C, 60–70% will develop chronic liver disease, between 5–20% will eventually develop cirrhosis, and almost 5% of all infected individuals will die from the disease without access to pharmaceutical treatment.<sup>15</sup> Sadly, this means that over 160,000 Americans who are currently infected will die from an infection related to hepatitis C if left untreated.<sup>16</sup> To put this in perspective, if we were to look at these 160,000 individuals as a city population, this “city” would be the third largest in Illinois, only third to Chicago and Aurora.<sup>17</sup>

All of this data inevitably leads one to wonder: should insurance companies, such as government-funded Medicaid, be allowed to seemingly arbitrarily pick and choose which individuals display “enough” life-threatening symptoms to deserve treatment from blockbuster specialty drugs that, if made readily available to the masses, would almost eradicate certain chronic illnesses across the country?

Currently, Medicaid requires most patients to be in the worst stage of hepatitis C, cirrhosis, and already exhibiting symptoms of severe liver damage before authorizing treatment, which often runs upwards of \$84,000 per patient.<sup>18</sup> Even worse, these Medicaid restrictions concerning hepatitis C are generally applicable to the poorest individuals who have the least access to sufficient medical treatment.<sup>19</sup> Because of these strict restrictions, almost half of Medicaid patients diagnosed with chronic hepatitis C have been denied access to Sovaldi—a cure to their chronic suffering.<sup>20</sup> What was once a research project at Emory School of Medicine in Atlanta is now a lifesaving pharmaceutical treatment capable of completely eradicating hepatitis C across the world.<sup>21</sup> Providing a tax benefit to the pharmaceutical companies that manufacture these specialty drugs, or to insurance companies that cover a significant portion of the cost of these specialty pharmaceuticals, will counteract the cost of the re-

---

15. Chris Kardish, *The Risky Business of Limiting Medicaid Access to Sovaldi*, GOVERNING (Aug. 19, 2014), <http://www.governing.com/topics/health-human-services/gov-hepatitis-coverage-sovaldi-lawsuits.html>; *Viral Hepatitis—Hepatitis C Information*, *supra* note 10.

16. See *Viral Hepatitis—Hepatitis C Information*, *supra* note 10 (reporting that 2.7–3.9 million people in the United States have chronic hepatitis C and that 1–5 people (out of every 100) will die from consequences of chronic infection).

17. See Pamela Gentry, *5 Biggest Cities in Illinois: How Well Do You Know the Prairie State?*, NEWSMAX (Apr. 5, 2015, 12:27 PM), <http://www.newsmax.com/FastFeatures/biggest-cities-illinois/2015/04/05/id/636521/>.

18. See Kardish, *supra* note 15.

19. *Study Shows Medicaid Restrictions for Sovaldi Create Barriers for Care*, HEALIO (July 1, 2015), <http://www.healio.com/hepatology/hepatitis-c/news/online/%7B2197f158-e515-4f6d-9554-33c7f9b75802%7D/study-shows-medicaid-restrictions-for-sovaldi-create-barriers-for-care>.

20. Dennis Thompson, *Pricey Hepatitis C Drugs Denied to Almost Half of Medicaid Patients: Study*, HEALTHDAY (Nov. 24, 2015), <http://consumer.healthday.com/infectious-disease-information-21/hepatitis-news-373/almost-half-of-medicaid-patients-who-need-pricey-hepatitis-c-drugs-are-denied-study-705552.html>. In four northeastern states, approximately 46% of Medicaid patients were denied access to new DAA drugs, including Sovaldi, which (when used) cure more than 90% of hepatitis C patients. *Id.*

21. Robert Weisman, *Demand for Expensive Hepatitis C Drug Strains Insurers*, BOS. GLOBE (June 1, 2014), <https://www.bostonglobe.com/business/2014/05/31/costly-new-hepatitis-treatments-curing-patients-but-straining-health-care-system-finances/SmBE9NoUESxjfgphfqvXKL/story.html>.

search, development, and manufacturing of these drugs and will thus allow the specialty drugs to be made readily available at a lower cost to those who are suffering.

This Note argues that insurance companies, specifically Medicaid, should not have unbridled control over the availability of specialty drugs to patients who cannot afford treatment on their own accord. Part II examines the significance of Medicaid to the foundation of our current health care system, the history of specialty drugs, the role that Medicaid plays in making specialty drugs affordable to the masses, and how the new hepatitis C drug, Sovaldi, fits into this seemingly one-sided discussion.

Part III examines the research and studies conducted thus far concerning the ever-ambiguous pricing scale for “blockbuster” drugs, exposes just how many individuals are being left untreated due to the current Medicaid program, and analyzes the serious issue of continuing to allow insurance companies to determine which individuals should receive particular treatments and which should instead be left to suffer until they display certain symptoms. Finally, Part IV recommends an approach that attempts to balance the main driver in the pricing of specialty pharmaceuticals, research and development costs, with the amount of coverage that insurance companies provide to patients suffering from chronic illnesses who require such pharmaceutical treatment.

## II. BACKGROUND

### A. Medicaid’s Role in Health Care

In 1965, under Title XIX of the Social Security Act, Congress enacted the beginning of what is now the current government-funded public insurance program known as Medicaid.<sup>22</sup> Medicaid funds safety-net hospitals and health centers that provide medical benefits to low-income individuals, who are often uninsured.<sup>23</sup> In total, Medicaid accounts for 16% of all personal health spending in the country.<sup>24</sup> In 2013 alone, Medicaid spending amounted to over \$400 billion, with two-thirds going towards acute care and one-quarter towards long-term care.<sup>25</sup> Medicaid provides coverage to a wide range of low-income individuals, including children, pregnant women, parents of dependent children, individuals with disabilities, and people over the age of sixty-five.<sup>26</sup> But the current structure of the Medicaid system is often under scrutiny as to its cost and

---

22. See Grants to States for Medical Assistance Programs Act, Pub. L. No. 89-97, 79 Stat. 343 (1965) (codified at 42 U.S.C. § 1396).

23. Paradise, *supra* note 1.

24. *Id.*

25. *Id.* Acute care is primarily composed of inpatient costs, outpatient/clinic costs, and payments to MCOs. *Id.* Long-term care categories include home health care, personal care, mental health, nursing facilities, and payments to Medicare. *Id.*

26. Paradise, *supra* note 1.

overall effectiveness. Multiple studies have shown that “patients on Medicaid do no better, and often do worse, than those with no insurance at all.”<sup>27</sup>

Considering the fact that taxpayers spent more than \$450 billion on Medicaid funding in 2013 alone, one would think that this well-funded program would provide much more comprehensive health care to those under its coverage.<sup>28</sup> Individuals enrolled in the Medicaid program present Medicaid providers with excessively complex health problems that often accompany lower-income Americans.<sup>29</sup> Although Medicaid may have earnest intentions to help lower-income Americans gain access to adequate health care, Medicaid beneficiaries sadly “often attain worse health outcomes than those enrolled in commercial health insurance . . . [or] those without any form of health insurance . . . .”<sup>30</sup>

The United States’ Medicare program has attempted to correct some of the issues left unaddressed by Medicaid through their Part D prescription-drug program. Under Medicare’s voluntary Part D program, price is the foremost factor analyzed when determining “whether an insurer may classify a drug as a specialty product and impose higher cost sharing.”<sup>31</sup> As long as the Part D provider utilizes a formulary tier when pricing pharmaceuticals, the provider may include an exception for specialty drugs in its pricing structure that explicitly excludes these unique drugs from the tiering exception.<sup>32</sup> This specialized tier often requires enrollees to pay coinsurance rather than copayments, allowing providers to place more of the burden of price inflation for these expensive drugs on the enrollees.<sup>33</sup> The drug must retail at over \$600 per month, however, in order to be classified as a specialty-tier medication excluded from the price-tiering exception.<sup>34</sup> While this price qualification seemingly restricts Medicare’s ability to pass most of the costs of these specialty drugs on to the beneficiaries, many of these specialty drugs are unique products, have no available substitutes, and meet this \$600 threshold.<sup>35</sup> This increase in cost sharing will ultimately have a negative impact on health care according to studies which indicate that patients stop taking their prescribed medications as price sharing increases.<sup>36</sup> While Medicare’s voluntary Part D program was intended to increase the public’s access to prescription pharmaceuticals, the specialized tier of pricing seems to

---

27. AVIK ROY, *HOW MEDICAID FAILS THE POOR* 4 (2013).

28. *Id.* at 5.

29. Ann Marie Marciarille, *The Medicaid Gamble*, 17 J. HEALTH CARE L. & POL’Y 55, 90–91 (2014).

30. *Id.* at 82–83.

31. KIRCHHOFF, *supra* note 4, at 8.

32. 42 C.F.R. § 423.578(a)(7) (2017).

33. KIRCHHOFF, *supra* note 4, at 16.

34. CTR. FOR MEDICARE & MEDICAID SERVS. *MEDICARE PART D SPECIALTY TIER 1* (2014), <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Downloads/SpecialtyTierMethodology.pdf>.

35. *See* KIRCHHOFF, *supra* note 4, at 23.

36. *Id.*

make this goal less attainable for the masses who cannot afford these co-insurance payments.

### B. Specialty Drug Pricing

Specialty-drug use is on the rise and is expected to continue along this explosive path in the coming years as more pharmaceuticals come to the market over the next decade or so.<sup>37</sup> Although pharmaceutical research, in any form, is crucial to our current health care system, pharmaceutical manufacturers, as well as the FDA, have begun focusing almost exclusively on specialty drugs.<sup>38</sup> An alarming 70% of all new drug approvals in 2013 were specialty medications.<sup>39</sup> Insurance providers did not anticipate such high prices for the newly released specialty drugs and must now decide between covering these new specialty pharmaceuticals or covering other basic treatments for their beneficiaries.<sup>40</sup>

Specialty drugs are not prescribed for the majority of commercial health care plan enrollees. In fact, usually only one in every one hundred insured individuals is prescribed treatment utilizing a specialty medication.<sup>41</sup> Monetarily speaking, specialty-drug prescriptions account for less than 1% of all prescriptions filled in the United States, yet these prescriptions account for almost one-third of all prescription-drug spending.<sup>42</sup> Specialty pharmacies are different than “regular” pharmacies in that they provide patients with a special level of care through specialty pharmaceuticals.<sup>43</sup> Specialty drugs may be subject to different pricing guidelines than other drugs, may be provided as part of a medical benefit, or may require a higher level of care.<sup>44</sup> They are also classified as “high-cost injectable, infused, oral or inhaled drugs that generally require close supervision and monitoring of the patient’s drug therapy.”<sup>45</sup> Specialty drugs are often difficult to concretely classify, but specialty drugs share a few defining characteristics. First, specialty drugs are incredibly expensive, often exceeding \$1,200 per patient, per month.<sup>46</sup> Next, specialty drugs are often accompanied by special handling requirements, such as refrigerated storage, and are typically administered by a registered clini-

---

37. Ha T. Tu & Divya R. Samuel, *Limited Options to Manage Specialty Drug Spending*, 22 CTR. FOR STUDYING HEALTH SYS. CHANGE 1, 1 (2012).

38. See *Twenty-First Century Cures: Examining the Role of Incentives in Advancing Treatments and Cures for Patients: Hearing Before the Subcomm. on Health of the Comm. on Energy and Commerce*, 113th Cong. 54 (2014) (statement of Steven Miller, Senior Vice President and Chief Medical Officer, Express Scripts Holding Company).

39. *Id.*

40. See *id.* at 55.

41. Tu & Samuel, *supra* note 37, at 1.

42. KIRCHHOFF, *supra* note 4, at 1–2.

43. U.S. Patent No. 8,160,898 B2 (filed Aug. 25, 2011).

44. *Id.*

45. CURASCRIPT, 2004 SPECIALTY PHARMACY MANAGEMENT GUIDE & TREND REPORT 15 (2005),

46. Tu & Samuel, *supra* note 37, at 2.

cian.<sup>47</sup> Lastly, specialty-drug use must be closely monitored to ensure effectiveness and successful management of various complex health conditions, including, but not limited to, hepatitis C, multiple sclerosis, and cancer.<sup>48</sup>

“The specialty pharmaceutical market is valued at more than \$77 billion” and is growing at 9% annually.<sup>49</sup> Specialty pharmaceuticals are priced significantly higher to cover the research and development costs.<sup>50</sup> In addition to the incredibly steep research and development capital expenditures, there are very few substitutes for specialty drugs currently on the market, allowing prices to further increase. “Even after discounts and rebates, specialty drug prices remain very high because, within most therapeutic categories, there tends to be at most a few drugs, which typically are imperfect substitutes for one another, and each drug is made by a single manufacturer.”<sup>51</sup> While the steady demand for these lifesaving pharmaceuticals provides manufacturers the opportunity to arbitrarily price their products, the skyrocketing price tags that accompany these drugs must be backed by outside support—the federal government. It is far easier for pharmaceutical manufacturers to retail their specialty drugs at a higher price when granted limited monopolies in which to sell their products once their pharmaceutical is patented.<sup>52</sup> Still, insurance companies generally face the majority of the backlash for the high price tags that accompany these specialty pharmaceutical drugs. While research companies are certainly not without blame, insurance companies often restrict access to specialty drugs by requiring some enrollees to obtain prior authorization for these specialty prescriptions, by charging higher out-of-pocket amounts to fill prescriptions, or even by simply withholding coverage for only the sickest patients.<sup>53</sup>

### C. *Sovaldi's Impact on Hepatitis C*

Sofosbuvir, more commonly known as the prescription drug Sovaldi, is the first FDA-approved drug to effectively treat certain types of chronic hepatitis C without the coadministration of interferons, a staple in the treatment of hepatitis C thus far.<sup>54</sup> Currently, treatment for the hepatitis C virus includes weekly injections of various drugs, often ac-

---

47. *Id.*

48. KIRCHHOFF, *supra* note 4, at 1; Tu & Samuel, *supra* note 37, at 2.

49. Kathryn S. Burnett, *White-Bagging vs. Buy-and-Bill: Practical Considerations for Physicians Administering Specialty Pharmaceuticals*, 8 J. HEALTH & LIFE SCI. L. 42, 45 (2015).

50. *Id.*

51. Tu & Samuel, *supra* note 37, at 6.

52. Naren P. Tallapragada, *Off-Patent Drugs at Brand-Name Prices: A Puzzle for Policymakers*, J.L. BIOSCIENCES 1, 2 (2016).

53. KIRCHHOFF, *supra* note 4, at 3.

54. Lowery, *supra* note 12 (“Sovaldi [has] demonstrated efficacy in participants who could not tolerate or take an interferon-based treatment regimen and in participants with liver cancer awaiting liver transplantation.”).

accompanied by incapacitating side effects.<sup>55</sup> Sovaldi completely eliminates the need for these painful, weekly injections by providing the same treatment through a simple, oral pill, without all of the unpleasant side effects.<sup>56</sup> Sovaldi is ground-breaking in the world of hepatitis C treatment in that it is “a direct acting antiviral agent and . . . [a] nucleotide analog inhibitor.”<sup>57</sup> Sovaldi works by inhibiting HCV NS5B RNA-dependent RNA polymerase, the particular protein needed for hepatitis C replication.<sup>58</sup>

In the United States and across the world, an enormous number of individuals infected with hepatitis C are classified as low-income, further intensifying the importance of this issue.<sup>59</sup> Still, Medicaid continues to restrict access to Sovaldi based on seemingly insensitive criteria, even though Sovaldi has the potential to eradicate the hepatitis C virus in the United States. Over 75% of states require proof of advanced fibrosis, or even cirrhosis, prior to authorizing Sovaldi treatment to Medicaid patients.<sup>60</sup> While this may not initially seem alarming, only 20–30% of people living with hepatitis C develop cirrhosis, leaving the other 70–80% of infected individuals without the option of taking Sovaldi.<sup>61</sup> Some of the abysmal symptoms of cirrhosis include: fatigue, nausea, jaundice, bacterial peritonitis, variceal hemorrhaging, and combined kidney and liver failure.<sup>62</sup> Although these painful symptoms could easily be avoided with Sovaldi’s twelve-week treatment, 75% of states require a patient to develop cirrhosis, and thus endure these excruciating symptoms, before Medicaid will even consider providing treatment for the patient’s hepatitis C.<sup>63</sup> This restriction, implemented by over thirty-seven states, is morally appalling and is also inconsistent with the FDA’s labeling of Sofosbuvir, yet another reason why these Medicaid restrictions must be re-evaluated if we ever hope to utilize Sovaldi at its highest potential and

---

55. *Id.*

56. *Id.*

57. Abimbola Farinde, *Drugs in Perspective: Sovaldi (sofosbuvir)*, MODERNMEDICINE NETWORK (May 15, 2014), <http://formularyjournal.modernmedicine.com/formulary-journal/content/tags/drugs-perspective/drug-overview-sovaldi-sofosbuvir?page=full>.

58. *Id.* (“It [then] undergoes a metabolism to form the active uridine analog triphosphate . . . that is combined into HCV RNA by NS5B polymerase.”).

59. Barua et al., *supra* note 7.

60. *Id.* (“[P]ersons with advanced fibrosis remain at risk for HCC even after achieving sustained virologic response (SVR) and must have long-term surveillance. In contrast, once HCV is cured in persons with mild to moderate liver disease, liver disease progression is rare.”).

61. Christine Case-Lo, *Cirrhosis and Hepatitis C: Their Connection, Prognosis, and More*, HEALTHLINE (Apr. 11, 2014), <http://www.healthline.com/health/cirrhosis-and-hepatitis-c#2>.

62. *Id.* (noting that a hepatitis C-infected individual “may not have any signs or symptoms of cirrhosis until it has done considerable damage to [the] liver”). Those individuals who are infected with another virus, such as HIV or hepatitis B, in addition to being infected with hepatitis C may be at an increased risk for cirrhosis. *Id.* Cirrhosis often accelerates in individuals with hepatitis C once they reach forty-five because fibrosis and scarring increase. Thus, it is imperative that younger individuals who are infected with hepatitis C are aggressively treated in order to prevent the development of cirrhosis. *Id.*

63. Barua et al., *supra* note 7.

eradicate hepatitis C in the United States.<sup>64</sup> If this is not enough to convince Medicaid to reconsider its restriction guidelines, the American Association for the Study of Liver Diseases (“AASLD”) recommends treatment for “all patients with chronic HCV (regardless of disease stage) because HCV therapy is curative; improves quality of life; slows liver disease progression; and reduces the risk for cirrhosis, end-stage liver disease, HCC, and all-cause mortality.”<sup>65</sup> Medicaid’s current practice of prior authorization is clearly in violation of these recommendations and is something that must be seriously addressed going forward.

*D. Medicaid’s Enormous Impact on Sovaldi’s Success*

The government is tasked with the moral issue of regulating the pricing of various specialty drugs on the market today.<sup>66</sup> “The challenge inherent in weighing extremely high costs for individual patients against specialty drugs’ ability . . . to extend lives and change the course of diseases rather than just treat symptoms is profound.”<sup>67</sup> Hepatitis C currently affects 3.2 million people in the United States, many of whom are poor, imprisoned, or elderly individuals who are unable to afford their health care treatment.<sup>68</sup> Restrictions placed on Sovaldi treatment are designed to disqualify almost all of the hepatitis C patients who would benefit most from the specialty pharmaceutical. A recent study found that the Medicaid program in most states will only allow Sovaldi treatment for patients who have advanced fibrosis or, even worse, liver scarring.<sup>69</sup> The liver is the only organ in the body able to regenerate once it has sustained damage, yet this process of regeneration is made impossible once scar tissue has formed.<sup>70</sup> If there ever was an appropriate time to say “too little, too late,” it would be now. By requiring patients to suffer from cirrhosis before providing them with access to Sovaldi, Medicaid is essentially throwing money away on patients who will still have liver damage even after they are cured of hepatitis C. If these inconceivable re-

---

64. *Id.*

65. *Id.* The recommendations do, however, state that “patients at highest priority for immediate treatment include those with advanced fibrosis (F3) or compensated cirrhosis (F4) because of the higher risk for severe complications.” *Id.*

66. Uwe Reinhardt, *Probing Our Moral Values in Health Care: The Pricing of Specialty Drugs*, J. AM. MED. ASS’N (Sept. 8, 2015), <http://jama.jamanetwork.com/article.aspx?articleid=2434671>. Manufacturers of specialty pharmaceuticals, aware of the reluctance of U.S. consumers to discuss such morally complex issues, take advantage of this unique situation to explore the maximum price that these reluctant U.S. consumers will pay. *Id.*

67. Tu & Samuel, *supra* note 37.

68. Kardish, *supra* note 15.

69. Olga Khazan, *The True Cost of an Expensive Medication*, ATLANTIC (Sept. 25, 2015), <http://www.theatlantic.com/health/archive/2015/09/an-expensive-medications-human-cost/407299/>.

Additionally, two-thirds of states require urine drug tests for drugs and alcohol prior to authorizing medication coverage. This urine test, along with the requirement of showing advanced fibrosis or liver scarring, is inconsistent with FDA recommendations and guidelines. *Id.*

70. *Liver Disease: Frequently Asked Questions*, U. IOWA HOSPS. & CLINICS, <https://www.uihealthcare.org/liver-disease-frequently-asked-questions/> (last visited Aug. 11, 2017).

strictions were not enough, Medicaid also often requires medical providers to perform risky liver biopsies on patients to prove that an individual is “sick enough” for Medicaid to cover Sovaldi treatment.<sup>71</sup> Thus, individuals who are infected with hepatitis C but who have yet to display any symptoms whatsoever are consistently denied access to Sovaldi even though the disease may silently be causing liver damage.<sup>72</sup>

Individuals suffering from hepatitis C who are insured through Medicaid should theoretically be able to undergo Sovaldi treatment, yet this is often not the case. “Because the federal guidelines [regarding Medicaid coverage] are broad, states have a great deal of flexibility in designing and administering their programs.”<sup>73</sup> It goes without saying that this “flexibility” lends itself to discrepancies regarding the scope of services that various states provide under the Medicaid program.<sup>74</sup> In 2014, total spending on hepatitis C drugs, including Sovaldi, amounted to \$11.3 billion, but Medicare Part D spending on hepatitis C medications only accounted for \$4.5 billion of that total.<sup>75</sup> Many infected individuals were still able to obtain \$6.8 billion dollars of treatment, but what happened to those individuals on Medicare who did not receive a single dollar of that \$4.5 billion spent on hepatitis C treatment?

In Illinois, in one month alone, forty-three out of fifty patients who requested treatment for hepatitis C were denied.<sup>76</sup> Thirty-six of these forty-three patients were denied treatment because their livers were deemed not to be in bad enough condition to necessitate treatment at that time.<sup>77</sup> This should come as no surprise considering the fact that Illinois requires “patients to meet more than two dozen criteria” before dispensing Sovaldi to them, and it “will only dispense the drug for two weeks at a time” over the course of twelve weeks.<sup>78</sup> This situation places doctors and other health care providers in a difficult situation. As Dr. Andrew Aronsohn, a liver specialist at the University of Chicago Medical Center, observed: “[i]t’s a very strange conversation to say . . . I have a drug that’s very safe to cure this disease and I think it’d be great if you

---

71. Khazan, *supra* note 69. If these biopsies do not indicate significant liver damage, hepatitis C patients are forced to essentially “get sicker before they can get better.” *Id.* While waiting for their livers to harden, these patients sadly “face a high[] risk of developing depression, nerve pain, and lymphoma.” *Id.*

72. See Weisman, *supra* note 21.

73. *Policy Basics: Introduction to Medicaid*, CTR. ON BUDGET & POL’Y PRIORITIES, <http://www.cbpp.org/research/health/policy-basics-introduction-to-medicaid> (last updated Aug. 16, 2017).

74. *Id.*

75. KIRCHHOFF, *supra* note 4, at 10.

76. Wes Venteicher, *Medicaid Patients Denied New Hepatitis C Cures*, CHI. TRIB. (Nov. 16, 2014, 2:39 PM), <http://www.chicagotribune.com/news/ct-medicaid-hepatitis-met-20141116-story.html>.

77. *Id.* Sadly, the livers of the six patients who were denied treatment were damaged enough to warrant treatment but failed to meet some other criteria. *Id.* “[P]atients’ livers are severely damaged by the time they qualify—some to the point of requiring an expensive transplant.” *Id.*

78. Japsen, *supra* note 8.

could get it, but I don't think you'll be able to get it because nobody wants to pay for it."<sup>79</sup>

Doctors are not the only ones struggling with the morality issues accompanying these outrageous Medicaid restrictions. Nurses, who generally spend more time with these hepatitis C patients, are often placed in difficult positions, having to watch infected individuals waste away until they are deemed "sick enough" to warrant Sovaldi treatment by Medicaid. One nurse practitioner in New Mexico, Laura Bush, described what happens when patients infected with hepatitis C do not receive proper treatment: "People with end-stage liver disease vomit blood, feel confused, and turn yellow and bloated. 'At the end you die not knowing who you are, your belly looks 12 months pregnant, you're malnourished, and you're bleeding to death.'"<sup>80</sup> If the results from the biopsy do not show serious enough liver damage or if the patient refuses to undergo the precarious surgery, the patients have no choice but to wait until they reach late-stage liver disease before Medicaid will consider them eligible for Sovaldi coverage.<sup>81</sup>

#### *E. The New Issue Facing Sovaldi*

Medicaid is required, by law, to pay for FDA-approved drugs from Gilead, the manufacturer of Sovaldi, but individual states are allowed to restrict distribution of the drug within state borders.<sup>82</sup> Medicaid provides two seemingly logical reasons for restricting access to Sovaldi, yet the underlying moral and medical issues still stand out. First, Medicaid feels justified in the decision to restrict access to costly treatment due to the fact that only 30% of individuals infected with hepatitis C will go on to develop advanced liver cirrhosis or liver cancer.<sup>83</sup> It can be inferred that Medicaid prioritizes expending resources on curing other health conditions, rather than on curing hepatitis C patients who have yet to exhibit symptoms of cirrhosis or liver cancer. Medicaid's second argument is that, while these individuals infected with hepatitis C are currently Medicaid beneficiaries, many individuals will be able to better their economic status over time and, at some point, might stop receiving Medicaid services.<sup>84</sup> The government allows these restrictions because federal officials are concerned that requiring Medicaid coverage of hepatitis C drugs may

---

79. Venteicher, *supra* note 76.

80. Khazan, *supra* note 69.

81. *Id.*

82. Venteicher, *supra* note 76 (noting that criteria that limit treatment to patients with cirrhosis are "overly restrictive").

83. Leonard Fleck, *The Ethical Challenges Raised by Hepatitis C Drugs*, MSU BIOETHICS (Oct. 23, 2014), <http://msubioethics.com/2014/10/23/hepatitis-c/comment-page-1/>.

84. *Id.* This rationale is also used when individuals infected with hepatitis C are in prison. The prison system feels that it should not be held responsible for covering the costs of treatment for a prisoner who will serve his or her time and then leave the system. *Id.*

set a precedent going forward as more and more new drugs are developed to treat other various conditions.<sup>85</sup>

Although Medicaid is hesitant to provide treatment to its beneficiaries for a wide gamut of reasons, it is undoubtedly certain that their prior authorization criteria would be much more lenient if Sovaldi were priced in a more cost-conscious manner. “Sovaldi is on track to become the world’s best-selling drug (in terms of total dollars spent on the drug by payers and patients), most likely exceeding \$10 billion in sales in its first year on the market.”<sup>86</sup> Most pharmaceutical manufacturers justify the high prices of pharmaceuticals because of the steep research and development costs that are necessary to develop drugs. Gilead itself, however, did not expend capital to research and develop Sovaldi, but, rather, Gilead purchased New Jersey pharmaceutical company Pharmasset for \$11 billion in late 2011.<sup>87</sup> Gilead purchased Pharmasset to spearhead the marketing of Sovaldi, and Gilead ultimately recovered every dollar of this \$11 billion investment in just the first year of sales.<sup>88</sup> Therefore, Gilead has no basis for justifying the high market price of Sovaldi because it has already recovered its initial investment in the drug and does not have any other research and development costs left to recover.

### III. ANALYSIS

Restricted access to lifesaving pharmaceuticals that have the potential to completely eradicate deadly diseases is an issue that the government can no longer afford to ignore. The implications of these Medicaid-enforced restrictions are exceptionally remarkable considering that only 25–50% of those infected with hepatitis C have been diagnosed, and, of those aware of their condition, only 40% undergo treatment “due to barriers endemic to the marginalized demographic HCV often impacts.”<sup>89</sup> Although there are arguments dismissing the importance of lowering the price of specific specialty pharmaceuticals (like Sovaldi), the current health care system cannot continue to overlook the inevitable breaking point on the horizon. While Gilead’s pricing decisions for Sovaldi may

---

85. Robert Pear, *White House is Pressed to Help Widen Access to Hepatitis C Drugs via Medicaid*, N.Y. TIMES (Aug. 25, 2015), [http://www.nytimes.com/2015/08/26/us/wider-reach-is-sought-for-new-hepatitis-c-treatments.html?\\_r=0](http://www.nytimes.com/2015/08/26/us/wider-reach-is-sought-for-new-hepatitis-c-treatments.html?_r=0).

86. Laura Fegraus & Murray Ross, *Sovaldi, Harvoni, and Why It’s Different This Time*, HEALTH AFF.: BLOG (Nov. 21, 2014), <http://healthaffairs.org/blog/2014/11/21/sovaldi-harvoni-and-why-its-different-this-time/>.

87. Weisman, *supra* note 21.

88. Jerry Avorn, *The \$2.6 Billion Pill—Methodologic and Policy Considerations*, NEW ENG. J. MED. (May 14, 2015), <http://www.nejm.org/doi/full/10.1056/NEJMp1500848>; Weisman, *supra* note 21 (“Pharmasset’s research outlays on Sovaldi totaled more than \$14 million, but Gilead spent tens of millions more to shepherd the drug through clinical trials.”).

89. Stacey B. Trooskin et al., *Access to Costly New Hepatitis C Drugs: Medicine, Money, and Advocacy*, 61 CLINICAL INFECTIOUS DISEASES: VIEWPOINTS 1825, 1826 (2015) (“[T]he proportion of serious complications such as cirrhosis, liver failure, and hepatocellular carcinoma is expected to increase by at least double by 2030 if improved treatments with curative direct-acting antiviral agents are not implemented.”).

not specifically have a substantial impact on Medicaid and national health care spending, Sovaldi is essentially a benchmark for every future specialty drug that is currently being developed to cure significant diseases such as HIV, cancer, diabetes, heart disease, and Alzheimer's. The efforts of pharmaceutical researchers everywhere will be frustrated if the pricing scale of these specialty pharmaceuticals continues to spiral out of control.

First, it is important to ascertain how arbitrarily pharmaceutical manufacturers price these highly-sought-after "blockbuster" drugs that have the ability to cure certain chronic illnesses. Next, the Note will add Medicaid, the largest insurance company in the United States,<sup>90</sup> into the equation and address how it is callously limiting beneficiaries' access to these lifesaving medications. Finally, this Note will attempt to fully illustrate and analyze the seriousness of allowing insurance providers, particularly Medicaid, to continue implementing outrageous restrictions on coverage that essentially allow them to determine which individuals receive treatment and which are left to fall victim to another case of health care rationing.

*A. The Pricing Scale of "Blockbuster" Drugs is Currently Skewed*

According to a 2015 poll conducted by the Henry J. Kaiser Family Foundation, "[t]he public's top health care priority overall (and across party lines) is making sure that high-cost drugs for chronic conditions, such as HIV, hepatitis, mental illness and cancer, are affordable to those who need them."<sup>91</sup> This data should send enormous signals to the legislators and policy-makers who continue to allow pharmaceutical manufacturers to increase the price tags on their specialty pharmaceuticals. "Not that long ago, a drug was characterized as a blockbuster if it could make 1 billion a year. Last year, three new medications for hepatitis C brought in \$4.5 billion combined . . . and that was just from Medicare."<sup>92</sup>

In a recent report from the Tufts Center for the Study of Drug Development, a pharmaceutical company must now spend \$2.6 billion to develop a single successful drug due to the costs of all the failed prototypes the company develops before finding an effective one.<sup>93</sup> A considerable number of researchers, however, have argued that the true cost of the initial development of a prescription drug is likely to be much lower.<sup>94</sup>

---

90. KAISER COMM'N ON MEDICAID & THE UNINSURED, HENRY J. KAISER FAM. FOUND., MEDICAID: A PRIMER (2013), <https://kaiserfamilyfoundation.files.wordpress.com/2010/06/7334-05.pdf>.

91. Press Release, Henry J. Kaiser Fam. Found., Americans' Views on the Affordable Care Act Hold Steady, with 43% Now Viewing It Favorably and 42% Unfavorably (Apr. 21, 2015), <http://www.kff.org/health-reform/press-release/americans-views-on-the-affordable-care-act-hold-steady-with-43-now-viewing-it-favorably-and-42-unfavorably/> (reporting that 76% of the public views the affordability of high-cost drugs for chronic conditions as a "top priority").

92. Heather Boerner, *The High Cost of Cure: Doctors Wade into the Drug-Pricing Battles*, PHYSICIAN LEADERSHIP J., Sept.–Oct. 2015, at 46, 46.

93. *Id.*

94. KIRCHHOFF, *supra* note 4, at 11.

Although the initial capital investment in developing pharmaceuticals is incredibly expensive, research shows that manufacturing companies often price their drugs at a much higher mark-up than necessary, even when taking into account massive research expenditures.<sup>95</sup> “But as risky as drug development is, the pharmaceutical and biotech industries remain among the most profitable sectors of the U.S. economy and actually spend only a small fraction of their revenues on truly innovative research.”<sup>96</sup> Gilead is not the only pharmaceutical manufacturer currently under scrutiny for its questionable pricing practices. “In late 2012, Sanofi was forced to issue discounts that halved the price for its colon cancer drug Zaltrap . . . after resistance from a leading cancer center.”<sup>97</sup>

The issues with specialty-drug pricing are not unique problems specific to new drugs or to old drugs; the problems affect both, amplifying the impact on patients. Price increases on older drugs often go overlooked when singling out issues with specialty pharmaceutical pricing, yet raising prices on “older drugs” is an essential profit driver for these pharmaceutical manufacturers.<sup>98</sup> Surprisingly, over 80% of the net profit growth of pharmaceutical manufacturing companies came from price increases on old specialty pharmaceuticals that were already on the market,<sup>99</sup> but skyrocketing prices of older pharmaceuticals is not the only issue at hand. Orphan drugs can cost in excess of \$300,000 per year, and certain gene-therapy treatments can cost upwards of \$1 million for one-time treatments.<sup>100</sup> Perhaps the biggest issue is that pharmaceutical companies continue to develop costly blockbuster drugs without considering who will pay for these drugs or how this current pricing model cannot continue indefinitely into the future.<sup>101</sup>

While it is completely understandable that pharmaceutical manufacturers need to make a profit when selling specialty drugs on the market, one must wonder just how high specialty drugs need to be priced for manufacturers to turn a profit. The pharmaceutical industry saw a 13% increase in drug prices in the United States—the biggest increase in the

---

95. Avorn, *supra* note 88 (“However, nearly half the total cost of developing a new drug (\$1.2 billion) was ascribed to this cost of capital, with only \$1.4 billion attributed to funds actually spent on research.”).

96. *Id.* (“[S]ome of the most important recent new medications were not developed by large drug manufacturers but were acquired through purchase of the biotech firms that discovered them.”).

97. Melanie Senior, *Sovaldi Makes Blockbuster History, Ignites Drug Pricing Unrest*, 32 NATURE BIOTECHNOLOGY 501, 502 (2014).

98. Max Nisen, *Pharma’s Bizarre Pricing Shrug*, BLOOMBERG: GADFLY (Nov. 16, 2015, 8:00 AM), <http://www.bloomberg.com/gadfly/articles/2015-11-16/drug-price-pressures-have-only-just-begun>.

99. *Id.* The ever-increasing prices of existing drugs contributed significantly to the rise of U.S. drug prices in 2014, but they were not the sole culprits. *Id.* “Last year, driven in large part by a new generation of Hepatitis C drugs, U.S. drug prices rose by 13 percent, the biggest increase in a decade and far, far ahead of inflation.” *Id.*

100. *Id.*

101. *Id.* Despite the consolidation of pharmacy-benefit-management companies, “firms have made little effort to figure out pricing based on a medicine’s value to patients, instead of what the market can bear.” *Id.*

last ten years, far ahead of expected inflation rates.<sup>102</sup> And the pharmaceutical industry, as a whole, makes approximately \$375 billion per year in prescription drugs sales in the United States.<sup>103</sup> This substantial number makes one question just how much of a profit pharmaceutical manufacturers need to make?

Massachusetts, along with a few other states, has begun to take a stand against skyrocketing pharmaceutical prices with Bill S. 1048—an “Act to promote transparency and cost control of pharmaceutical drug prices.”<sup>104</sup> The bill, should it pass through the Massachusetts Legislature’s Committee on Health Care Financing, would significantly alter the future of pharmaceutical manufacturing.<sup>105</sup> Between the months of January and March 2014 alone, Massachusetts’ Medicaid program paid over \$20 million in Sovaldi-related claims.<sup>106</sup> Although the pricey drug is taking a noticeable toll on the budgets of almost every medical insurance provider in the state, many involved in legislation, including Massachusetts’ Secretary of Health and Human Services, stand behind Sovaldi because of its ability to significantly improve the quality of life for those who undergo treatment.<sup>107</sup>

Bill S. 1048 requires the manufacturer of a critical pharmaceutical to pass various, complex hurdles, such as justifying the current market price.<sup>108</sup> Under the bill, the Massachusetts Health Policy Commission would develop a list “of critical prescription drugs for which there is a substantial public interest in understanding the development of its pricing.”<sup>109</sup> For each drug the commission chooses, the product manufacturers would have to report the: total cost of production; approximate cost per dose; research and development costs of the drug; marketing and advertising costs for the drug; prices charged to purchasers outside of the United States; prices charged to purchasers in Massachusetts; and, finally, the true net typical price charged to prescription-drug benefit manag-

---

102. *Id.*

103. Stephanie Armour, *Lawmakers, Candidates Target High Drug Prices*, WALL ST. J. (Nov. 15, 2015), <http://www.wsj.com/articles/lawmakers-candidates-target-high-drug-prices-1447635567>.

104. S.B. 1048, 189th Gen. Court, Reg. Sess. (Mass. 2015).

105. *Id.*

106. Weisman, *supra* note 21. These expenditures alone resulted in first-quarter losses for most Massachusetts Medicaid insurers. *Id.*

107. *Id.* (“But he hailed Sovaldi as ‘a drug that could take out hep C’ and potentially save millions of dollars that would otherwise be spent treating diseases caused by the virus, such as liver scarring and cancer.”).

108. S.B. 1048, 189th Gen. Court, Reg. Sess. (Mass. 2015).

109. Thomas Sullivan, *Massachusetts Introduces Drug Cost Transparency Bill that Would Cap Prices for Certain Products; North Carolina and Pennsylvania Also Introduce Bills Requiring Drug Cost Reports*, POL’Y & MED. (Apr. 23, 2015, 5:30 AM), <http://www.policymed.com/2015/04/massachusetts-introduces-drug-cost-transparency-bill-that-could-cap-prices-for-certain-products-nort.html>. When selecting which drugs to include in this listing, the commission would be asked to consider: the cost of the drug to public health care programs, the current price at which the drug retails in the state, how often the drug is being utilized in Massachusetts, as well as how significant of an impact the cost of the drug may have on “Massachusetts achievement of the statewide health care cost growth benchmark.” *Id.*

ers.<sup>110</sup> The commission would then use this information to prepare an annual report on prescription-drug prices, which would be posted on commission's website and may include "recommendations for actions to lower prescription-drug costs and spending across the commonwealth while maintaining access to and quality health care."<sup>111</sup>

In addition, the bill also empowers the Health Policy Commission to determine whether the price of a prescription drug is "significantly high."<sup>112</sup> If a prescription drug is found to have a significantly high price tag, the commission may set the "maximum allowable price" that can be charged by the manufacturer going forward.<sup>113</sup> Although this legislation is only currently being discussed at the state level, requiring transparency in drug pricing would be a significant step towards correcting our broken, blockbuster-drug pricing scale. If the federal government were to enact legislation requiring prescription-drug price transparency on a national basis, pharmaceutical manufacturers, such as Gilead, would ultimately have to implement some sort of plan to lower the cost of their critical pharmaceuticals.

As of early 2016, state lawmakers have either proposed or filed legislation on this issue in eleven states—Massachusetts, Colorado, Michigan, North Carolina, Oregon, Pennsylvania, Tennessee, Virginia, Washington, New York, and California.<sup>114</sup> Given that Massachusetts is not the only state taking steps towards enacting legislation concerning price transparency of prescription drugs, this national requirement of price transparency may be a reality in the near future. A national standard implemented by the federal government would make price transparency measures the norm going forward, ultimately reducing the cost and increasing the availability of these blockbuster pharmaceuticals. Although pharmaceutical manufacturers have received praise for their recent groundbreaking developments, the focus of the pharmaceutical world seems to be shifting to scrutinizing the cost of these groundbreaking products and considering how to control these costs.<sup>115</sup>

Pharmaceutical manufacturers are undoubtedly going to push back against proposed legislation concerning price transparency as these measures threaten their economic profitability. In fact, the opposition has already begun.<sup>116</sup> This is not surprising considering the impact the

---

110. *Id.*

111. S.B. 1048, 189th Gen. Court, Reg. Sess. (Mass. 2015).

112. Sullivan, *supra* note 109.

113. *Id.*

114. Michael Ollove, *High Drug Prices Prompt Demands for Transparency*, GOV'T TECH. (Mar. 7, 2016), <http://www.govtech.com/state/High-Drug-Prices-Prompt-Demands-for-Transparency.html>. None of the transparency bills filed in 2015 passed. *Id.*

115. Sullivan, *supra* note 109.

116. Ed Silverman, *Angry Over Drug Prices, More States Push Bills for Pharma to Disclose Costs*, WALL ST. J.: PHARMALOT (Apr. 24, 2015, 9:40 PM), <http://blogs.wsj.com/pharmalot/2015/04/24/angry-over-drug-prices-more-states-push-bills-for-pharma-to-disclose-costs/> (describing efforts from pharmaceutical manufacturers to defeat or postpone legislation concerning price transparency).

proposed legislation may have on the financial success of these manufacturers. The arguments these greedy manufacturers raise, however, cannot hold up when compared to the arguments legislators, who have the general public's best interest in mind, make. Manufacturers have long conveyed to the general public, as well as to the government, that the high price tags that accompany certain blockbuster drugs are necessary not only to recoup the development costs of the successful pharmaceutical, but also to recover the significant losses that the manufacturer sustained from other medications that failed in the past. One particular manufacturer in California fought proposed price-transparency legislation on the basis that restricting the ability of pharmaceutical manufacturers to price their own products would "stifle innovation" because the manufacturers would not be able to recover any losses sustained during the development of drugs that ultimately failed.<sup>117</sup> While it is understandable that pharmaceutical manufacturers need to recover some of their development costs in order to stay profitable, there is an underlying ethical dilemma in allowing these manufacturers to overprice their products whenever they do happen to develop and manufacture a successful drug. What good is a lifesaving medication if those who need treatment cannot afford it?

Sovaldi-manufacturer Gilead attempted to "shine" by providing Sovaldi to low-income countries at a low price, such as \$900 for a twelve-week treatment in Egypt.<sup>118</sup> But this "special treatment" for low-income countries undoubtedly leaves countries like the United States (\$84,000 per patient for a twelve-week treatment) and the United Kingdom (approximately \$53,000 per patient for a twelve-week treatment) wondering just how Gilead is able to supply Sovaldi to some countries at an almost 99% discount.<sup>119</sup> Gilead purchased the rights to Sovaldi for a mere \$11 billion before placing the drug on the market in the United States at the price of approximately \$1,000 per pill, a price that typically only accompanies drugs treating "orphan conditions," which are those that affect a much smaller population than the 3.2 million Americans affected by hepatitis C.<sup>120</sup> In the United States, the pharmaceutical companies are in the driver's seat in this pricing dilemma. "[P]harmaceutical companies set the price for the drugs they manufacture and let the doctors, patients, and payers grapple with the massive tradeoffs that result."<sup>121</sup> It is hard to not question this hierarchy when new pharmaceuticals, like Sovaldi, have the ability to have a significant impact in eradicating hepatitis C in the United States, as well as across the globe.

---

117. *See id.*

118. John P. Rice, *Hepatitis C Treatment: Back to the Warehouse*, 6 *CLINICAL LIVER DISEASE* 27, 27–29 (2015).

119. *Id.*

120. *See* Fegraus & Ross, *supra* note 86.

121. *Id.* ("The unsustainable price of these drugs has forced a scientific community, traditionally focused on the quality and safety of therapeutic interventions, into an untenable position while we await their recommendations on Harvoni.")

Gilead unquestionably deserves to make a return on its risky \$11 billion investment in Sovaldi. Although they themselves did not develop the drug, they now are tasked with providing the treatment worldwide, at a price they deem fair, before other pharmaceutical companies begin copying the hepatitis C treatment and producing it at a much lower price. Gilead's profit margin on this particular specialty pharmaceutical, however, is arguably drastic. If health care providers across the United States treated every single individual infected with hepatitis C with Sovaldi, they would have to shell out over \$300 billion.<sup>122</sup> That \$300 billion is approximately what the United States government spends annually on all other prescription drugs combined.<sup>123</sup> We must question why Gilead is able to price Sovaldi much higher in the United States than anywhere else globally when the vast majority of our hepatitis C patients are uninsured, insured through Medicaid, or incarcerated in federal prison.<sup>124</sup>

Sovaldi only costs around \$130 per pill to manufacture, yet Gilead retails that \$130 pill for \$1,000 to the poorest of Americans.<sup>125</sup> The price of hepatitis C treatments is forecasted only to rise going forward,<sup>126</sup> something the United States government must figure out how to address in a more effective way than through restricting access to the drugs and implementing strict prior authorization protocols. This could be a huge moment in pharmaceutical history if the government takes the initiative to regulate the soaring prices of these specialty pharmaceuticals. Sovaldi is not the first outrageously priced blockbuster drug, and it most certainly will not be the last. With many promising treatments in sight for diseases that affect the masses—such as cancer, Alzheimer's, diabetes, and heart disease—health care providers, along with our government leaders, must send a firm message that this blatant price-gouging is unacceptable.<sup>127</sup> If Gilead ultimately gets away with its exorbitant pricing of Sovaldi, all other pharmaceutical manufacturers of lifesaving treatments will sell their specialty pharmaceuticals at the same outrageous price, if not higher. The United States is on a fast path towards becoming the country with the most sophisticated, lifesaving pharmaceutical treatments worldwide that will go to waste. What is the point of researchers developing these miraculous cures for terminal diseases that affect so many people around the world if those who are suffering cannot afford the treatment?

---

122. Steve Miller, *The Sovaldi Tax: Gilead Can't Justify the Price It's Asking for Hepatitis C Therapy*, FORBES (June 17, 2014, 8:46 AM), <http://www.forbes.com/sites/theapothecary/2014/06/17/the-sovaldi-tax-gilead-cant-justify-the-price-its-asking-americans-to-pay/#72263d4865e1>.

123. *Id.*

124. *Id.*

125. *Id.*

126. *See id.*

127. *Id.* (explaining that, unless action is taken now, future therapies for deadly diseases will follow suit with Sovaldi and “be priced at what the market will bear, even though the market can't bear much more”).

*B. Many Hepatitis C Patients Fall Victim to Health Care Rationing and Are Continually Denied Treatment Through Medicaid, Forcing Them to Cope with Their Symptoms on Their Own*

By placing huge prior authorization restrictions on Medicaid coverage of Sovaldi treatments, hundreds of thousands, if not millions, of Americans are left to deal with the chronic symptoms of hepatitis C with few other options for comfort. Sadly, the demand for Sovaldi has grown so rapidly that insurance companies, primarily Medicaid, have placed massive restrictions on direct access to the drug.<sup>128</sup> In denying these individuals access to Sovaldi, Medicaid is essentially saying that they would rather let those who are denied treatment suffer, while their infections lead to liver cancer and possibly even liver failure, than pay for treatment.<sup>129</sup> This denial of access is a significant violation of a basic human right—equal access to health-care. This equal access to testing and treatment is central to core human-rights arguments and must not be violated by Medicaid restrictions on specialty pharmaceuticals.<sup>130</sup>

Hepatitis C, often referred to as a “silent epidemic,” is responsible for the deaths of nearly twenty-thousand people in the United States annually.<sup>131</sup> The number of annual AIDS-related deaths is almost half that number, yet eradicating AIDS receives a great deal more funding and attention.<sup>132</sup> The overwhelming majority of state-specific Medicaid programs restrict access to Sovaldi for people who inject drugs, who are receiving drug-dependency treatment, and who are alcoholics. A substantial portion of those currently infected with hepatitis C abuse alcohol, illicit drugs, or both. Medicaid’s prior authorization criteria for Sovaldi may deny patients access to treatment until they can prove up to twelve months of sobriety.<sup>133</sup> While this specific prior authorization crite-

---

128. Weisman, *supra* note 21.

129. See Pear, *supra* note 85 (“These criteria defy clinical guidelines and best practices. Rather than recommending the exclusion of people who inject drugs, we should encourage earlier treatment as a way to prevent transmission of the virus.”) (quoting Robert L. Greenwald, a health law and policy expert at Harvard Law School).

130. WORLD HEALTH ORG., GUIDELINES FOR THE SCREENING, CARE AND TREATMENT OF PERSONS WITH HEPATITIS C INFECTION 37 (2014), [http://apps.who.int/iris/bitstream/10665/111747/1/9789241548755\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/111747/1/9789241548755_eng.pdf) (“The protection of human rights for all persons infected with HCV is a central precept of these guidelines. People with HCV infection frequently come from vulnerable groups because of low socioeconomic status, poor access to appropriate healthcare, or because they belong to groups that are marginalized or stigmatized such as PWID or prisoners”).

131. Pear, *supra* note 85.

132. See Liz Highleyman, *Hepatitis C Kills More People Than Any Other Infectious Disease in US*, *CDC Says*, AIDS MAP (May 6, 2016), <http://www.aidsmap.com/Hepatitis-C-kills-more-people-than-any-other-infectious-disease-in-US-CDC-says/page/3054834/>; Pear, *supra* note 85.

133. Eric Pianin, *Should We Be Rationing Hepatitis Drugs? Obama Pressured to End Restrictions*, *FISCAL TIMES* (Aug. 26, 2015), <http://www.thefiscaltimes.com/2015/08/26/Should-We-Be-Rationing-Hepatitis-Drugs-Obama-Pressured-End-Restrictions> (quoting a report written by Lauren A. Canary, who works as an epidemiologist with the Centers for Disease Control and Prevention). State Medicaid prior approval criteria show “the pressure that approval of new, costly HCV treatments places on state Medicaid programs and the resultant warehousing policies that limit access to lifesaving treatment.” *Id.*

tion makes sense when trying to rehab specific individuals with substance abuse issues, this is not the time to try to correct destructive behaviors. Requiring individuals who are infected with hepatitis C who also have substance abuse issues to “sober up” for twelve months before treatment not only patronizes them for their struggle, but also causes these suffering individuals to endure twelve months of pain that could otherwise have been avoided if they were allowed to begin Sovaldi treatment from the start. Further, “[a]ccording to [a] study, published in the *Annals of Internal Medicine*, the restrictions may violate federal Medicaid law.”<sup>134</sup>

According to experts from the Public Health Service and the Advisory Council on HIV/AIDS, the current restrictions on the drug’s accessibility that are effective in almost every state are “inconsistent with sound medical practice, as reflected in treatment guidelines issued by health care professionals . . . .”<sup>135</sup> In the same way, the majority of Medicaid’s state-level programs do not follow the guidelines published by the Infectious Diseases Society of America and the American Association for the Study of Liver Diseases and, instead, attempt to ration this life-saving hepatitis C medication.<sup>136</sup> Medicaid stands firmly behind its statement that individual states are responsible for this situation because they are allowed to manage their Medicaid benefits in whatever way they choose.<sup>137</sup> While this statement is valid, if Medicaid oversees the individual state-specific Medicaid programs, what is stopping them from requiring state programs to cover Sovaldi treatment?

Medicaid programs attempt to justify their restrictions by pointing to the high volume of hepatitis C patients, an aggravating factor that is only going to get worse.<sup>138</sup> Some Medicaid-contracted insurance companies receive as many as three or four new requests for Sovaldi each day.<sup>139</sup> Medicaid’s restrictions with regard to Sovaldi treatment, however, appear rather harsh. “Patients are only allowed to get two weeks’ worth of medicine at a time, and if they fail to refill their prescriptions, the treatment is canceled.”<sup>140</sup> Medicaid not only places restrictions on the supply of Sovaldi, but also restricts the number of treatments a patient can re-

---

134. Nathaniel Weixel, *Medicaid Restrictions on Gilead’s Sovaldi Illegal, Should Be Lifted*, *Study Says*, BLOOMBERG BNA (July 1, 2015), <http://www.bna.com/medicaid-restrictions-gileads-n17179928974/>. The restriction of access for those who inject drugs, those who receive drug dependency treatment, and those with alcohol problems does not “seem to meet the criteria for permissible restrictions” imposed by the Food and Drug Administration. *Id.*

135. Pear, *supra* note 85.

136. *Id.*

137. *Id.* Although state Medicaid administrators stand behind their restrictions on hepatitis C treatments, these very same restrictions have been criticized as “unreasonable and discriminatory.” *Id.* (quoting an advisory council letter written to President Obama regarding the restrictions).

138. See Leora Schiff, *Finding Truth in a World Full of Spin: Myth-Busting in the Case of Sovaldi*, 37 *SCI. DIRECT* 1092, 1104 (2015).

139. Weisman, *supra* note 21.

140. Venteicher, *supra* note 76.

ceive.<sup>141</sup> “A ‘once in a lifetime’ provision in the criteria means that if treatment fails, the program will not pay for the patient to try again.”<sup>142</sup>

*C. Insurance Companies, Specifically Medicaid, Should Not Be Allowed to Arbitrarily Decide Which Patients Receive Treatment and Which Do Not*

Medicaid restrictions on Sovaldi inherently defeat the work of the pharmaceutical industry to help save the lives of chronically ill individuals. According to two recent studies, published in June 2015 by the *Annals of Internal Medicine*, the majority of states are in fact “picking and choosing which Medicaid patients will be granted access to Sovaldi.”<sup>143</sup> “[A]part from potentially being a human rights violation, they do not make (economic) sense in terms of clinical, public, and long-term health.”<sup>144</sup> Although states may be saving money initially by requiring prior authorization before covering Sovaldi for patients, over time, the individuals who are suffering from hepatitis C still require medical care, most often funded by Medicaid. This extensive, additional medical care is often long-term and costs just as much, if not more, than a twelve-week course of Sovaldi treatment.<sup>145</sup> This limitation on access to Sovaldi, however, is not going unnoticed. As recently as November of 2015, the Centers for Medicare and Medicaid Services (“CMS”) sent letters to the Medicaid directors of all fifty states, in addition to Sovaldi-manufacturer Gilead warning against limiting access to Sovaldi, as well as other drugs, purely due to the pharmaceutical’s price tag.<sup>146</sup> CMS was also quick to remind states that, if they were going to cover prescription drugs, like Sovaldi, at all under Medicaid, they would have an explicit obligation not to limit access to the drug unless furthered by a medical necessity.<sup>147</sup> In addition to their questions concerning prior-authorization and access restrictions, CMS also further inquired about Gilead Science’s method for pricing Sovaldi and whether they utilized any value-based purchasing arrangements in their dealings with Medicaid that would allow Medicaid to obtain the pharmaceuticals at a better price.<sup>148</sup> While this outside pres-

---

141. *See id.*

142. *Id.*

143. Pianin, *supra* note 133. Because Sovaldi is a “non-preferred” drug, health officials seek cheaper and often less-effective alternatives to prescribe instead. *Id.*

144. Weixel, *supra* note 134 (“[B]y restricting coverage for Sovaldi, states are saving upfront costs but are paying more in the long term, as the costs of hepatitis C continue to rise.”) (internal citation omitted).

145. *Id.*

146. Nathaniel Weixel, *CMS Enters Pricey Hepatitis C Drug Debate*, BLOOMBERG BNA: HEALTH CARE BLOG (Nov. 10, 2015), <http://www.bna.com/cms-enters-pricey-b57982063428/>. These unprecedented letters asked manufacturers to disclose how they price their drugs and which kinds of “value-based” purchasing arrangements they offer to private insurers, as well as Medicaid. *Id.*

147. *Id.* (“Specifically, the agency cited examples of states limiting the drug to people who have reached Stage 3 or Stage 4 liver fibrosis.”).

148. *Id.*

sure from CMS is certainly a step in the right direction, the battle to remove Medicaid's prior authorization process is far from over.

On paper, the \$84,000 price tag is more than enough to deter most insurance companies, let alone Medicaid, from providing treatment for insured hepatitis C patients. But insurance companies need to look past the near future when making the decision whether to cover Sovaldi treatment for patients who are infected with hepatitis C. Sovaldi, sometimes referred to as a "wonder drug" for hepatitis C patients, could eliminate the long-term medical treatment that all individuals with chronic hepatitis C, as well as their insurance companies, ultimately face.<sup>149</sup> "We could literally end the hepatitis C epidemic if we put these tools to use."<sup>150</sup> Instead, patients must currently suffer throughout life with hepatitis C or suffer until they develop cirrhosis. In a given six-month period, out of the 377 patients denied access to Sovaldi, 233 of those denials were Medicaid patients.<sup>151</sup> The most common reasons Medicaid cites for denial include "insufficient information to assess medical need," "lack of medical necessity," and a positive alcohol or drug screen.<sup>152</sup> While Sovaldi treatment costs a hefty \$84,000, a routine liver transplant, the solution to cirrhosis, costs close to \$300,000.<sup>153</sup>

Even so, many are left wondering if it is worth attempting to eradicate hepatitis C because only 20% of individuals infected will develop cirrhosis and because many patients are able to live infected with the hepatitis C virus without any significant harm or extended complications.<sup>154</sup> Private insurance companies are hesitant to provide proper treatment to insured individuals who are infected with hepatitis C. Medicaid coverage varies from state to state on certain topics, such as prescription drug coverage and prior authorization requirements, yet, as a whole, Medicaid's decision-making process with regard to prior authorization has been regarded as a process of "choosing approval criteria based on a mix of medical evidence, cost considerations, and perhaps-unmeasured preferences."<sup>155</sup> It is up to Medicaid to establish some sort of standard or system with regard to treatment restrictions "so that where a Medicaid patient lives does not dictate what treatment she or he receives."<sup>156</sup>

---

149. Joseph Walker, *Gilead's \$1,000 Pill Is Hard for States to Swallow*, WALL ST. J. (Apr. 8, 2015, 4:37 PM), <http://www.wsj.com/articles/gileads-1-000-hep-c-pill-is-hard-for-states-to-swallow-1428525426>.

150. *Id.*

151. Thompson, *supra* note 20. That leaves 104 denials for privately insured patients and forty denials for Medicare patients. *Id.*

152. *Id.*

153. See generally Peter J. Pitts, *Access to Medical Innovation: Obstacles & Opportunities*, 21 J. COM. BIOTECHNOLOGY 53, 55 (2015).

154. Rice, *supra* note 118.

155. Pianin, *supra* note 133.

156. Barua et al., *supra* note 7.

There is no doubt that a uniform standard addressing Medicaid coverage for hepatitis C treatment must be adopted if we expect to have any significant impact on the lives of those currently infected with hepatitis C. This standard should essentially focus on the federal requirements regarding the amount, duration, and scope of services that are already supposed to be governing Medicaid's coverage decisions. "The Medicaid agency may not arbitrarily deny or reduce the amount, duration, or scope of a required service under §§ 440.210 and 440.220 to an otherwise eligible recipient solely because of the diagnosis, type of illness, or condition."<sup>157</sup> Additionally, this standard should incorporate and consider: the protection of human rights for all individuals infected with hepatitis C, the basic human right of access to health care, providing quality care and treatment to those infected, and the integrated health care needs of those who require additional treatment.<sup>158</sup> We do not have to look any further than to the World Health Organization ("WHO") for an example of this type of standard. The central objective of WHO is "to achieve the highest possible level of health for all people."<sup>159</sup>

State-based Medicaid programs should not be able to enforce such complex restrictions on the disbursement of Sovaldi to their beneficiaries. As of now, the majority of states require a person to be diagnosed with advanced fibrosis or cirrhosis before they will cover Sovaldi treatment for any enrollee, something that is entirely inconsistent with recent American Association for the Study of Liver Disease ("AASLD") recommendations.<sup>160</sup> Treatment is recommended for all patients with chronic hepatitis C infections regardless of what stage of the disease they are in, not only because treatment is curative and slows the progression of liver disease but also because it improves the quality of life for the patient and reduces the risk for cirrhosis and, ultimately, death.<sup>161</sup> Behind individuals with advanced fibrosis and cirrhosis, hepatitis C patients with fibrosis are listed in the next priority group for treatment because of their high risk for complications.<sup>162</sup> Yet, most states do not include individuals with fibrosis in the criteria for their Medicaid reimbursement programs, leaving these individuals untreated.<sup>163</sup> In addition to Medicaid's disregard for treating all individuals infected with hepatitis C, some of Medicaid's other criteria, specifically requiring liver biopsies, are particularly dangerous for beneficiaries who are infected with hepatitis C. Undergoing a liver biopsy while infected with hepatitis C poses a high risk of death for

---

157. 42 C.F.R. § 440.230(c) (2017).

158. WORLD HEALTH ORG., *supra* note 130, at 37.

159. *Id.*

160. Barua et al., *supra* note 7 ("[T]hus a state 'may not arbitrarily deny or reduce the amount, duration, or scope of a required service . . . to an otherwise eligible beneficiary solely because of the diagnosis, type of illness, or condition.'").

161. *Id.*

162. *Id.*

163. *Id.*

the patient.<sup>164</sup> Not only are Medicaid programs placing their enrollees at a disadvantage by withholding proper treatment, they are also requiring patients to risk death by undergoing a biopsy to determine whether they are “sick enough” to justify treatment. There are countless long-term public-health and economic benefits in curing hepatitis C, something our legislators must take into consideration and weigh against the initial cost of treatment.<sup>165</sup>

#### IV. RECOMMENDATION

##### *A. Incentives Offered to Pharmaceutical Companies Can Provide Motivation for Companies to Produce the Drugs at a Lower Price Rather than Price Gouging Patients*

This is an issue that has to be addressed at some point in the near future. By 2018, it is estimated that spending on specialty pharmaceuticals will exceed half of all pharmaceutical spending in total, or approximately \$218 billion dollars.<sup>166</sup> Manufacturers of Sovaldi, which essentially provides a cure for hepatitis C, justify the price of this pharmaceutical by stating that, although it is an exceedingly expensive drug, it is “worth it” in the long run because of the large number of Americans currently suffering from the chronic disease.<sup>167</sup>

Congress attempted to curb the ever-rising prices of specialty drugs through the 1984 Hatch-Waxman Act, which encourages the development of lower-cost, generic drugs.<sup>168</sup> The Act sped up the approval process for generic drugs, allowing generic alternatives to enter the market more quickly once the patents for brand-name prescription drugs expire.<sup>169</sup> Providing pharmaceutical manufacturers with incentives to develop low-cost, generic drugs is a win-win solution for the current blockbuster-drug pricing dilemma. Pharmaceutical manufacturers can enter the market with generic drugs more quickly while also allowing patients

---

164. *Id.*

165. *Id.* (“Although the price of new therapies creates financial challenges for federal and state Medicaid budgets, decisions for prioritizing patients for more immediate therapy should be based on clinical criteria and medical evidence.”).

166. Jon Christianson, *Sovaldi and Specialty Drugs: The End of the Beginning?*, MEDICA RES. INST. (May 7, 2015), <http://www.medicaresearchinstitute.org/news-and-events/blog/2015/05/looking-ahead-medica-research-institute/>. “It seems inevitable that more attention will be focused on specialty drugs as a major contributor to growing health care costs.” *Id.* The exponential growth of pharmaceutical prices, solely set by manufacturers, will come under increased scrutiny, particularly from Congress.

167. *Id.* Because Sovaldi is justified as “worth it,” its prices are “set to reflect expected demand, not production costs.” *Id.* Unlike most specialty pharmaceuticals with small markets, “the potential U.S. market for Sovaldi is the 3 to 5 million Americans estimated to have hepatitis C.” *Id.*

168. KIRCHHOFF, *supra* note 4, at 6.

169. *Id.* However, it is important to note that, according to new research by the Centers for Medicare & Medicaid Services, the implementation of the Affordable Care Act is helping drive health care spending regardless of the generic substitutes available. The Affordable Care Act has allowed millions of Americans to either become insured or to acquire more comprehensive coverage that includes prescription drug benefits. *Id.*

the opportunity to obtain their prescriptions at a discount of up to 75–80%.<sup>170</sup> But analysts have predicted that the market for producing generic drugs will level off in the next few years after reaching maximum potential at 91–92% of all prescriptions filled.<sup>171</sup> Unfortunately, this leveling off has led manufacturers to increase prices for many existing generic drugs.<sup>172</sup>

In future attempts to pass new legislation to mandate prescription drug coverage across the board, Congress may want to consider sticking to its roots and focusing more on a historically effective and less controversial solution—providing tax credits to research companies. These nonrefundable tax credits encourage pharmaceutical research companies to focus on developing breakthrough drugs as well as low-cost substitutes to the specialty drugs that are currently on the market.<sup>173</sup> Congress enacted one of these research and development tax credits in 1981 and has renewed it over a dozen times over the past thirty years, hinting at the tax credit's historical effectiveness and success rate.<sup>174</sup> Moreover, the research and development tax credit has been such a success that the House of Representatives is currently working to make the credit a permanent part of the tax code.<sup>175</sup>

*B. Providing Specialty Pharmaceuticals at Lower Prices to Individuals Suffering from Chronic Illnesses Saves the Government Money in the Long Run Because of the Money Saved on Future Treatment*

Insurance companies and state budget officials raise understandable concerns regarding providing specialty pharmaceuticals to the mass public. Because of the decentralized nature of health care in the United States, many insurance companies are reluctant to provide these high-cost, specialty pharmaceuticals to their beneficiaries without some type of guarantee that the individual undergoing treatment will not switch to a different provider or drop health insurance coverage altogether once healthy.<sup>176</sup> The underlying logic backing these concerns, however, does not hold up against the long-term advantages of providing specialty drugs to every infected individual. “[B]etter medications are actually the best and swiftest way for this country to cut down our health care expenses.”<sup>177</sup> Private insurance companies and state budget officials say that “hepatitis C drugs are just the tip of the iceberg” when it comes to spe-

---

170. *Id.*

171. *Id.* at 7.

172. *Id.*

173. *Id.* at ii.

174. Glenn Hess, *R&D Tax Credit Stuck in Limbo*, CHEMICAL & ENGINEERING NEWS (July 14, 2014), <http://cen.acs.org/articles/92/i28/RD-Tax-Credit-Stuck-Limbo.html?>

175. *Id.*

176. KIRCHHOFF, *supra* note 4, at 2–3.

177. Pitts, *supra* note 153, at 56.

cialty-pharmaceutical treatment.<sup>178</sup> The hidden agendas of these companies and officials cannot stand up over time. “All that’s standing in the way are . . . drug company efforts to protect their bottom lines, and an anxious health-care industry looking to keep spending from spiraling out of control.”<sup>179</sup> There will undoubtedly be more specialty pharmaceuticals—with remarkably high price tags—developed to treat various diseases in the future, but this should not prevent individuals who are suffering daily from receiving treatment that is currently available and could essentially eradicate the hepatitis C epidemic. After all, “[b]y more effectively combating disease and improving patients’ lives, drugs reduce long-term medical costs and bolster the overall economy.”<sup>180</sup>

These restrictions do not make economic sense with regard to the public and the long-term health of our population and are arguably not weighed evenly against the up-front treatment costs.<sup>181</sup> Data from PwC Health Research Institute shows that the use of Sovaldi to treat patients with hepatitis C will drive down overall spending on hepatitis C treatment in the next ten years, a trade-off that is incredibly sensible with regard to the economy.<sup>182</sup> “[S]tudies have confirmed that treating the hepatitis C virus, or HCV, are cost-effective even at the current prices, but insurers are holding out for cheaper treatments . . . .”<sup>183</sup> Clearly, insurance providers are costing themselves a great deal of money in the long run as these restrictive policies deny patients who may ultimately “develop liver cancer or liver failure requiring costly treatments, hospitalizations, or transplantation.”<sup>184</sup>

In addition to improving the quality of life for thousands of individuals, early treatment of hepatitis C has, in fact, recently been found to be economically practical. In a 2015 study by the Journal of the American Medical Association (“JAMA”), researchers found that nearly \$3.3 billion in lifetime health care expenses could be saved if every patient currently infected with hepatitis C underwent Sovaldi treatment, regardless of what stage of the infection they happen to be in.<sup>185</sup> Dr. James Kahn suggested that, contrary to popular belief, it is cost effective to treat indi-

---

178. Jason Millman, *The Coming Revolution in Much Cheaper Life-Saving Drugs*, WASH. POST: WONKBLOG (Jan. 16, 2015), <http://www.washingtonpost.com/news/wonkblog/wp/2015/01/16/the-coming-revolution-in-much-cheaper-life-saving-drugs/>. On the other hand, drug companies say that these hepatitis C treatments are “worth the cost and will save the health-care system money in the long-run.” *Id.*

179. *Id.* Biosimilars have begun replacing traditional generic drugs while the health care industry and regulators grapple with establishing guidelines for their use. “The decisions they make will ultimately affect how broadly these drugs . . . will be available in the United States and just how much of the billions of dollars in expected savings will eventually materialize.” *Id.*

180. Pitts, *supra* note 153, at 55.

181. Barua et al., *supra* note 7.

182. Pitts, *supra* note 153, at 56.

183. Brian Krans, *One-Fourth of Hepatitis C Patients Initially Denied Life-Saving Treatment*, HEALTHLINE (Aug. 27, 2015), <http://www.healthline.com/health-news/one-fourth-of-hepatitis-c-patients-initially-denied-life-saving-treatment-082715>.

184. *Id.*

185. Thompson, *supra* note 20.

viduals infected with hepatitis C as soon as the disease is detected rather than waiting until the infection progresses to advanced liver disease as many current Medicaid restrictions require.<sup>186</sup> Hepatitis C is currently responsible for over one-third of all liver transplants in the United States, and data suggests that this number will only go up in the future as more and more hepatitis C patients go untreated.<sup>187</sup>

While \$84,000 for each individual infected with hepatitis C may be a tough pill for government-funded Medicaid programs to swallow, the costs incurred by leaving those individuals untreated is even greater when all is said and done. A recent article published by Dartmouth Medical School was quick to point out the massive health care costs associated with lifetime treatment of hepatitis C. With the cost of a single liver transplant averaging \$280,000 and approximately 1,000 patients with hepatitis C needing a transplant each year, the cost of liver transplants for patients with hepatitis C alone reaches almost \$300 million per year.<sup>188</sup> Advocates of current Medicaid standards may argue that only roughly 20–30% of individuals infected with hepatitis C will require such a costly liver transplant in their lifetime, but the average lifetime cost to treat hepatitis C, without undergoing a liver transplant, is just as costly.<sup>189</sup> The lifetime cost of treatment for hepatitis C, without a liver transplant, is roughly \$100,000 per individual patient.<sup>190</sup> While only 20–30% of all patients with hepatitis C will require a liver transplant, almost 80% will develop chronic liver disease.<sup>191</sup> Lifetime treatment for these individuals is estimated at an incredible \$360 billion, given a forty-year life expectancy once diagnosed.<sup>192</sup> Although government funding may take a substantial hit by covering Sovaldi treatment for all 3.2 million infected people, it is still economically beneficial in the long run. Providing Sovaldi to all patients would cost approximately \$269 billion, exceeding the \$263 billion spent in 2011 for all other conditions combined.<sup>193</sup> This \$269 billion, however, is still almost \$100 billion less than the total lifetime treatment for all individuals infected with hepatitis C in the United States.<sup>194</sup> While I am not suggesting that paying for Sovaldi treatment is a bargain, or that Gilead is justified in its price-gouging tactics, I am suggesting that providing treatment to every single person with hepatitis C in the United States is not as outrageous or economically impossible as portrayed by the government.

---

186. *Id.*

187. *Hepatitis C: An Epidemic for Anyone*, DARTMOUTH MED. SCH., <http://www.epidemic.org/thefacts/theepidemic/USHealthCareCosts/> (last visited Aug. 11, 2017).

188. *Id.*

189. *See id.*

190. *Id.*

191. *Id.*

192. *Id.*

193. Trooskin et al., *supra* note 89.

194. *Hepatitis C: An Epidemic for Anyone*, *supra* note 187.

As medical treatment progresses into the future, it will inevitably become increasingly ineffective and expensive to have fifty-one different Medicaid-managed care plans with potentially fifty-one different standards and requirements for hepatitis C treatment.<sup>195</sup> There are fifty-one different standards for standard, fee-for-service Medicaid programs; within these programs, there are programs with different requirements for specific populations and different models of care, payment, and delivery.<sup>196</sup>

We, as a society and a country as a whole, must seriously consider the impact that this unprecedented direct-acting antiviral (“DAA”) treatment may have on the future of health care. Medicaid may be setting a precedent with regard to DAA treatment going forward.<sup>197</sup> It is only a matter of time before more DAAs become available to the population to treat various illnesses that have a significant impact on the lives of millions of Americans.

*C. The Government Must Take a Stand and More Closely Regulate the Medicaid Program*

Increasing regulation would not be the first time the government has stepped in to reign in Medicaid standards. In 1996, President Clinton took a stand against federally mandated Medicaid coverage of pricey new AIDS drugs.<sup>198</sup> Once the AIDS pharmaceuticals began hitting shelves, the President’s administration began requiring state Medicaid directors to cover the new drugs, albeit subject to state-imposed limitations.<sup>199</sup> The government’s directions, however, explicitly rejected limits that “excessively or unreasonably restrict[ed] coverage of effective treatments.”<sup>200</sup> There is seemingly nothing stopping President Trump from taking these same steps to coerce Medicaid programs to cover Sovaldi for more of their beneficiaries. Although the goal of the Affordable Care Act was to mandate insurance coverage across the board, the same individuals who could not previously get insured due to hepatitis C are finding themselves unable to get treatment for the very same condition even though they are now insured.<sup>201</sup> With nearly 500,000 prisoners infected with hepatitis C and another 750,000 people with hepatitis C insured by Medicaid, it is inevitable that this epidemic is going to get worse before it gets any better.<sup>202</sup>

---

195. Barua et al., *supra* note 7.

196. *Id.*

197. *Id.* (“Transparent, easily accessible, consistent, and evidence-based Medicaid criteria will permit greater and more equitable access to DAAs.”).

198. Pear, *supra* note 85.

199. *Id.*

200. *Id.*

201. *Id.*

202. Fleck, *supra* note 83 (“If all who were eligible for Medicaid coverage and HCV infected were treated this year, the cost to the states would be \$55 billion. The same would be true in the prison system.”) (internal citation omitted).

If the government does not take a stand against the seemingly arbitrary restrictions enforced by Medicaid's individual state programs, there is no telling how many individuals will suffer from a disease that can be eradicated through twelve simple weeks of treatment. State government officials, as well as insurance providers, stick behind their belief that patients that have been prescribed Sovaldi by their doctors will eventually be granted access to the drug.<sup>203</sup> What state governments do not contemplate, or are seemingly able to avoid addressing, is the fact that many of these patients will fall victim to health care rationing, something that has plagued the United States health care system for decades.<sup>204</sup> If specialty pharmaceutical pricing is not controlled soon, our health care system is likely to spiral out of control. Although the pricing issue surrounding Sovaldi may not seem pressing to the majority of American households, the long-term implications of how this situation is handled are going to be extensive. "Setting coverage priorities for Sovaldi . . . could create a model for dealing with other high-priced drugs being developed."<sup>205</sup>

Still, the government is indisputably placed in a difficult situation with regard to this hepatitis C epidemic due to the demographics of those who are infected. Hepatitis C has been called "a disease of the marginalized" due to its prevalence among homeless people, severely mentally-ill individuals, intravenous drug users, and those who are incarcerated.<sup>206</sup> Unless the government steps in to more closely regulate the restrictions Medicaid places on access to Sovaldi, these poorer and less-advantaged individuals are going to continue to suffer unnecessarily. This is not an issue that the government, or health care providers, can take lightly. Although the traditional cause of new hepatitis C infections in the United States is illicit injection-drug use, hepatitis C can also be transmitted through blood transfusions made prior to 1992, birth from an infected mother, unintended exposure in a health care setting, and, possibly most importantly, unprotected sexual contact.<sup>207</sup> While many are quick to brush hepatitis C off as "a disease of the marginalized," every single one of us could become infected with the disease through almost no fault of our own.

In 2013 alone, the United States spent over \$17 billion on statins in hopes of preventing heart attacks and strokes.<sup>208</sup> Those showing warning signs of heart attacks or strokes were not asked to wait until they actually

---

203. Weisman, *supra* note 21 ("A lot of experts think everybody doesn't need to get this drug in the first instance.").

204. *Id.*

205. *Id.* Sovaldi is the first drug that has attracted attention because of its ability to cure a chronic and deadly disease, but it is merely the beginning of a potential catastrophe. *Id.* If precedent is not set with Sovaldi, new developments in cancer and HIV research will follow suit and be just as unaffordable, leaving thousands of sick individuals unable to undergo life-saving treatment.

206. Trooskin et al., *supra* note 89.

207. *Id.*

208. Fleck, *supra* note 83.

suffered a heart attack or stroke before they were offered treatment.<sup>209</sup> Protocols for treating individuals who are infected with hepatitis C should demand that same level of urgency. We cannot, as a population, sit back and allow those infected with hepatitis C to suffer alone just because they are of a poorer socioeconomic status.

## V. CONCLUSION

The present hepatitis C epidemic is something that our political leaders and health care providers can no longer afford to ignore. With over 3 million Americans currently infected with hepatitis C and new drugs on the market with proven cure rates of over 90%, there is absolutely no excuse not to take action.<sup>210</sup> Medicaid finds itself in a position where rationing Sovaldi and enforcing strict prior authorization restrictions are necessary steps due to the excessive cost of treatment and the significant size of the population needing this treatment.<sup>211</sup> It is time for a dramatic change in the way our country treats those infected with hepatitis C. Approximately 15,000 Americans will die annually from their hepatitis C infection, even though there are new drugs on the market that are incredibly effective and have hardly any side effects.<sup>212</sup>

Pharmaceutical manufacturers need to take a serious look at the implications of their pricing decisions. Although Sovaldi costs approximately \$130 per pill to manufacture, Gilead purchased Sovaldi from its developer for almost \$11 billion.<sup>213</sup> Gilead uses this hefty investment as justification for its outrageous pricing model. But if health care providers were to treat every infected individual in the United States, Gilead would receive a \$250 billion return on that \$11 billion investment, and that figure only accounts for treatments in the United States.<sup>214</sup> At what point does seeking a return on an investment turn into greed? There are an estimated 130 to 150 million people worldwide currently infected with hepatitis C.<sup>215</sup> Gilead could easily reduce the cost of Sovaldi from \$1,000 per pill to \$1,000 for the entire course of treatment and still make over \$170 billion, which is \$159 billion more than they paid for the right to manufacture the drug. This issue, however, is much larger than a pharmaceuti-

---

209. *Id.*

210. Trooskin et al., *supra* note 89 (“The lack of transparency surrounding pricing is one of several issues to be addressed, as financial barriers impeding access to the 2014 HCV drug market as a whole remain significant.”).

211. *Id.* (“At Sovaldi’s initial wholesale acquisition cost, the expense to treat 3 million people would have totaled >\$250 billion dollars. By contrast, total US prescription drug spending was \$263 billion for all conditions combined in 2011.”).

212. *Id.*

213. *Id.* Many are unsympathetic towards Gilead and its endeavor to recover its \$11 billion investment when profits from Sovaldi are expected to reach \$200 billion, which would give Gilead a return on investment of twenty to one. *Id.*

214. *Id.*

215. *Hepatitis C*, WORLD HEALTH ORG., <http://www.who.int/mediacentre/factsheets/fs164/en/> (last visited Aug. 11, 2017).

cal manufacturer recovering its investment in a product. There are 3.2 million Americans currently infected with hepatitis C, some of whom are already suffering from cirrhosis and others of whom are awaiting their fate as the chronic disease begins ravaging their livers. Legislators must remember that this is bigger than Medicaid and bigger than the bottom line of government spending on public health care. There are 3.2 million Americans currently suffering from hepatitis C, and this conversation is ultimately about them.