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Sovaldi: The High Price for a Cure

By Theresa C. Mahfood, J.D.

The Hepatitis C virus (HCV) is among the deadliest viruses in the world, killing more Americans each day than the human immunodeficiency virus (HIV), as well as sixty other infectious diseases, combined.¹ Between 2.7 and 3.9 million people in the United States,² and seventy-one million people worldwide,³ live with chronic HCV, the most severe manifestation of the disease.⁴ The United States Department of Health and Human Services reported that approximately 17,000 new cases of HCV infection occur in the United States every year.⁵

Not all ethnic populations benefit from traditional HCV therapies;⁶ however, advancements in pharmacogenetic research and curative,⁷ personalized therapies such as Sovaldi,⁸ Harvoni,⁹ and Epclusa deliver fewer

1. *Hepatitis C Kills More Americans Than Any Other Infectious Disease*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/media/releases/2016/p0504-hepc-mortality.html> (last visited Dec. 5, 2017).

2. *Hepatitis C FAQs for Health Professionals*, CTRS. FOR DISEASE CONTROL & PREVENTION, (Jan. 27, 2017), <https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm>.

3. *Hepatitis C Fact Sheet*, WORLD HEALTH ORG., <http://www.who.int/mediacentre/factsheets/fs164/en/> (last updated July 2017).

4. Ann Pietrangelo, *Hepatitis C by the Numbers: Facts, Stats, & You*, HEALTHLINE, <https://www.healthline.com/health/hepatitis-c/facts-statistics-infographic#1> (last visited Dec. 5, 2017).

5. Office of Population Affairs, *Hepatitis C*, U.S. DEP'T HEALTH & HUM. SERVS, <https://www.hhs.gov/opa/reproductive-health/sexually-transmitted-infections/hepatitis-c/index.html> (last visited Dec. 5, 2017).

6. Brian L Pearlman, *Hepatitis C Virus Infection in African Americans*, 42 CLINICAL INFECTIOUS DISEASES 82, 84 (2006), <https://academic.oup.com/cid/article/42/1/82/397992/Hepatitis-C-Virus-Infection-in-African-Americans>.

7. The term “curative” in this context is used only to indicate “non-detectable viral load.” In other words, the virus becomes non-detectable in the human body. My use of the term, “cure”, throughout this article refers to treatments that have clinically been shown to be curative in at least 90% of patients.

8. Sovaldi is the brand name for generic drug, Sofosbuvir. *Hepatitis C Treatment Factsheet Sofosbuvir (Sovaldi)*, INFOHEP, <http://www.infohep.org/Hepatitis-C-treatment-factsheet-Sofosbuvir-iSovaldi/page/2845322/> (last visited Dec. 5, 2017).

9. Harvoni is the brand name for a Hepatitis C drug that combines sofosbuvir with ledipasvir. It is primarily used to treat patients with Genotypes 1 and 4, whereas Sovaldi is used to treat patients with Genotype 2. *See infra* Part 0 and accompanying notes; *Harvoni vs Sovaldi—Or is Epclusa The New Harvoni?*, HEPATITIS C SOCIETY,

side effects,¹⁰ greater barriers of resistance to HCV, and lower pill burdens than their predecessors.¹¹ Nevertheless, the high cost of HCV therapies, particularly of Sovaldi, presents a purchasing barrier to the HCV patients who stand to benefit the most.¹² As such, health insurance companies are left to pick up the slack.¹³ These high costs invite an ethical dilemma, questioning the fairness of Sovaldi's price and how Sovaldi may be justly allocated.¹⁴ Compounding this dilemma, many HCV patients experience economic instability and are underinsured.¹⁵

Drawing upon public outrage over the high price of Sovaldi, the Southeastern Pennsylvania Transit Authority (SEPTA) filed a class action lawsuit in 2015, claiming that Sovaldi's manufacturer, Gilead Sciences (Gilead), engaged in unlawfully exorbitant pricing schemes that make it difficult for racial minority consumers and the federal government to afford Sovaldi.¹⁶ SEPTA also claimed that Gilead violated the Patient Protection and Affordable Care Act (ACA) by engaging in price discrimination against disabled people.¹⁷ The District Court for Eastern Pennsylvania granted Gilead's motion to dismiss, holding that an individual's mere diagnosis of Hepatitis C does not constitute a disability.¹⁸ Furthermore, the District Court found that evidence of Gilead's high prices for Hepatitis C drugs, in light of certain ethnic populations' higher frequency of Hepatitis C diagnoses, was

<http://esofosbuvir.com/harvoni-medicine-even-better-sovaldi/harvoni-vs-sovaldi/> (last visited Dec. 5, 2017) [hereinafter, *Harvoni vs Sovaldi*].

10. Eplclusa, which is mainly used to treat patients with Genotype 3, combines sofosbuvir and velpatasvir. See *Harvoni vs Sovaldi*, *supra* note 9; *How come generic Eplclusa can cost less than \$1,000*, HEPATITIS C SOCIETY, <http://esofosbuvir.com/generic-eplclusa-sofosvel-indias-generics/> (last visited Nov. 14, 2017).

11. Sovaldi, Harvoni, and Eplclusa work according to the same biochemical mechanisms. Since Sofosbuvir (Sovaldi) is a component of both Harvoni and Eplclusa, to simplify, I will only reference Sovaldi for the remainder of this paper.

12. See Bruce Japsen, *At \$1,000 A Pill, Hepatitis C Drug Sovaldi Rattles Medicaid Programs*, FORBES (Apr. 28, 2014 8:00 AM), <https://www.forbes.com/sites/brucejapsen/2014/04/28/pricely-hepatitis-pill-sovaldi-rattles-medicaid-programs/#4c3ca4446efe>.

13. *Id.*

14. *Id.*

15. *Id.*

16. Pa. Transp. Auth. v. Gilead Sci., Inc., 102 F. Supp. 3d 688, 693–94 (E.D. Pa. 2015).

17. *Id.*; Allissa Wickham, *PA Transit Agency Slaps Gilead with Price Gouging Suit*, LAW 360 (Dec. 11, 2014, 5:38 PM) <https://www.law360.com/articles/603544/pa-transit-agency-slaps-gilead-with-price-gouging-suit> (explaining that SEPTA's claim that Gilead engaged in price discrimination against disabled people was based on SETPA's argument that Gilead caused the plaintiffs to be "excluded from a health activity that receives federal funds" based on their hepatitis C disability).

18. Pa. Transp. Auth., 102 F. Supp. at 700 (distinguishing between allegations of a mere diagnosis of Hepatitis C and an actual "disability" which is a "physical or mental impairment that substantially limits one or more major life activities."); 29 U.S.C. § 705(20)(B); 42 U.S.C. § 12102 (1)(A).

altogether insufficient to support a claim that Gilead discriminated on the basis of race.¹⁹ Ultimately, the court dismissed all ACA-related discrimination claims against Gilead.²⁰ Additionally, the court rejected the plaintiffs' attempt to invoke state law to challenge Gilead's pricing scheme for its patent-protected drugs.²¹

Although the court's final disposition did not favor SEPTA,²² the lawsuit reflects the attitudes of millions of Americans towards pharmaceutical manufacturers who develop and set high prices for new drugs.²³ While the legal issues outlined by SEPTA's class action lawsuit surpass the scope of this paper, this paper uses Sovaldi as a foundation for important ethical analyses pertaining to drug prices, the motivations of pharmaceutical companies, and public allocation of expensive drugs.

19. Pa. Transp. Auth., 102 F. Supp. at 701.

20. The plaintiffs in *SEPTA v. Gilead* argued that Gilead's pricing violated the Rehabilitation Act and the Civil Rights Act by discriminating against disabled persons and disparately impacting minorities, although they admitted the pricing may not have been intentionally discriminatory. *See Id.* at 697–99, 702 (rejecting plaintiffs' arguments that Gilead's pricing violated the Rehabilitation Act and the Civil Rights Act by discriminating against disabled persons and disparately impacting minorities); *see also* Nondiscrimination provisions of the ACA at 42 U.S.C. § 18116 (2010) (prohibiting any health program or activity receiving federal funding from excluding from participation, denying benefits to, or otherwise discriminating against any individual on the grounds of race, color, national origin sex, age, and disability).

21. Pa. Transp. Auth., 102 F. Supp. at 702–08 (finding that: “. . .to the extent that plaintiffs seek to use state law to challenge Gilead's exercise of its exclusive patent rights to make pricing decisions, plaintiffs' claims are preempted. Federal patent law contemplates the tradeoffs between exclusivity and access, and plaintiffs cannot use state law to adjust that balance by forcing Gilead to lower its prices or disgorge profits from the sale of its patented drugs . . . plaintiffs plead no facts to suggest or raise the inference that Gilead has used pricing discretion within its contracts to provide Sovaldi and Harvoni, or that SEPTA or another member of the putative class has been on the receiving end of unfair or bad faith dealing by Gilead pursuant to any discretion Gilead may have in a contract with it or another party . . . plaintiffs simply cannot invoke state law to challenge Gilead's overall pricing scheme for its patented drugs.”).

22. *Id.* at 708; *See e.g.*, Ed Silverman, *Lawsuit Alleges Price Gouging by Maker of Hepatitis Drug*, WALL ST. J. (Dec. 18, 2014, 10:50 PM), <https://www.wsj.com/articles/lawsuit-alleges-price-gouging-by-maker-of-hepatitis-drug-1418961024> [hereinafter, *Lawsuit Alleges Price Gouging*] (citing experts, including Professor C. Scott Hemphill, a Columbia Law School professor, who viewed SEPTA's antitrust claim as meritless because “having a monopoly and setting high prices do not violate antitrust law.”).

23. *See, e.g.*, Poll: Majorities of Democrats, Republicans and Independents Support Actions to Lower Drug Costs, Including Allowing Americans to Buy Drugs from Canada, THE HENRY J. KAISER FAM. FOUND. (May 1, 2017), http://www.kff.org/health-costs/press-release/poll-majorities-of-democrats-republicans-and-independents-support-actions-to-lower-drug-costs-including-allowing-americans-to-buy-drugs-from-canada/?utm_campaign=KFF-2017-May-Poll-Lower-Drug-Costs; Poll: Americans want government to bring down prescription drug prices, CBS (Aug. 20, 2015), <https://www.cbsnews.com/news/poll-americans-want-government-to-bring-down-prescription-drug-prices/>.

This paper concludes that there is insubstantial evidence proving that Gilead behaved unethically by setting the price of Sovaldi at \$1,000 per pill. The price may be deemed reasonable due to:

- (1) Sovaldi's superior quality and curative nature;
- (2) the high costs incurred by drug developers and manufacturers and the need to recoup those costs to continue developing new drugs;
- (3) the complicated healthcare system and its patent laws which do not restrict the prices drug manufacturers can set;
- (4) trends in rising drug prices over the last two decades; and
- (5) evidence that Gilead is supporting several altruistic patient support programs to distribute Sovaldi to millions of people free of charge.²⁴

Gilead seeks to recoup high enough profit margins to greatly expand its research and development (R&D) to develop many new cures for diseases, optimize benefits for future patients once the patent expires, and use a portion of its revenue to provide drugs free of charge or at lower prices for patients who cannot afford to pay the high price.²⁵ Therefore, despite opposing arguments, there is evidence that Gilead's ethical interests are, in fact, just and beneficent.

Part I of this paper provides an overview of Hepatitis C and why the development of Sovaldi was revolutionary. Part II describes the history of HCV treatment. Part III explains the development of Sovaldi and how Gilead acquired rights to manufacture and distribute the drug. Part IV tackles the ethical debate surrounding the Sovaldi controversy, and is divided into two sections: A and B. Section A discusses whether American HCV patients have a fundamental right to receive Sovaldi treatment. Section B describes some of the barriers preventing many Americans from obtaining Sovaldi.²⁶ Part V, across three sections, analyzes the ethics inherent in Gilead's justification of Sovaldi's price. Specifically, section A determines whether the quality of Sovaldi compared to competing HCV drugs is an ethical justification for the drug's price. Section B discusses common trends in the U.S. healthcare system that have contributed to the high prices of pharmaceuticals. Section C, provides evidence that, contrary to popular belief, Gilead's pricing decisions were not selfishly motivated.

24. See, e.g., *Sovaldi: Who's to Blame for the \$1,000 a Day Cure?*, KNOWLEDGE @ WHARTON (Apr. 16, 2014), <http://knowledge.wharton.upenn.edu/article/sovaldi-whos-blame-1000-day-cure> [hereinafter, *Sovaldi: Who's to Blame*].

25. See *id.*

26. Probable solutions as to the issue of what action(s) could be taken, either by Gilead or legislators to lower Sovaldi's price, are beyond the scope of this article.

I. THE HEPATITIS C INFECTION

HCV is a blood-borne, single stranded ribonucleic acid (RNA) virus that almost exclusively infects and abundantly replicates within hepatocytes.²⁷ Chronic Hepatitis C infection is a severe disease that leads to liver cirrhosis or liver cancer in a significant number of cases.²⁸ Most people living with chronic Hepatitis C infection are asymptomatic.²⁹

HCV is most commonly transmitted through unsafe needle injection practices, inadequate sterilization of medical equipment, and the use of unscreened blood and blood products.³⁰ High-risk populations include: drug users and people who share needles; children born from mothers infected by HCV; anyone who received an organ transplant or blood transfusion before 1992; patients who have spent many years on kidney dialysis; people with HCV-infected sex partners; and people with HIV infection.³¹ In the United States, African Americans have a substantially higher rate of chronic Hepatitis C infection than any other ethnic group.³² Today, there is no vaccine to prevent Hepatitis C.³³

Six distinct HCV genotypes with multiple subtypes have been identified worldwide.³⁴ In the U.S., genotype 1 is the most common, accounting for close to seventy-five percent of all HCV patients, as well as the most resistant to traditional standard therapies.³⁵ However, the prevalence of genotype 1 among African Americans is ninety-one percent, compared to sixty-seven percent among Caucasians.³⁶ There is no scientific consensus that explains the disparity among African Americans, and furthermore, African American genotypes have exhibited resistance to traditional HCV therapies more than

27. David R. McGivern & Stanley M. Lemon, *Virus-Specific Mechanisms of Carcinogenesis in Hepatitis C Virus Associated Liver Cancer*, 30 ONCOGENE 1969, 1971–72 (2011).

28. *Id.* at 1969.

29. *Hepatitis C FAQs for the Public*, CTRS. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/hepatitis/hcv/cfaq.htm> (last updated Oct. 17, 2016).

30. *Hepatitis C Fact Sheet*, *supra* note 3.

31. *Id.*

32. *Hepatitis C Disproportionately Affects the African American Community*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/hepatitis/blackhistmnth-hepc.htm> (last updated Feb. 1, 2017).

33. *Hepatitis C Fact Sheet*, *supra* note 3.

34. *Are There Different Types of Hepatitis C (Genotypes)?*, HEPATITIS CENT., <http://www.hepatitiscentral.com/hepatitis-cl/> (last visited Dec. 5, 2017) (“A genotype is a classification of a virus based on the genetic material in the Ribonucleic acid (RNA) strands of the virus.”).

35. Alan Franciscus, *African Americans and Hepatitis C*, HCV ADVOCATE (Aug. 2016) http://hcvadvocate.org/hepatitis/factsheets_pdf/African_Americans.pdf [hereinafter, *African Americans and Hepatitis C*].

36. *Id.*

Caucasian genotypes.³⁷

II. THE HISTORY OF HCV TREATMENT

Combination therapy prescribed by physicians, including pegylated interferon- α (pegIFN) and ribavirin (RBV), has traditionally constituted the standard of care for treating chronic Hepatitis C infection.³⁸ Physicians most commonly prescribed twelve to thirty-two weeks of an oral protease inhibitor, twenty-four to forty-eight weeks of pegIFN, and RBV to patients with HCV genotype 1, and twenty-four weeks of pegIFN to patients with HCV genotypes 2 and 3.³⁹ The duration of the therapy depended on each individual patient's stage of liver fibrosis and overall response rates to the treatment.⁴⁰ However, pegIFN and RBV could not cure the Hepatitis C infection, but merely *prevent* the infection from spreading, protecting the remaining healthy cells; even so, these therapies were not necessarily effective in treating patients with advanced liver disease.⁴¹ One 2010 study reported that, together, pegIFN and RBV were about fifty-four to sixty-three percent effective in treating HCV.⁴² Additionally, pegIFN and RBV were ineffective in treating patients with HCV genotype 1, which affects seventy to seventy-five percent of all HCV patients living in the United States.⁴³ HCV patients of each genotype reported harsh side effects while using pegIFN and RBV such as anemia, negative changes in thyroid function, low white blood cell and platelet count, hyperglycemia, hair loss, psychiatric illness, etcetera.⁴⁴ These disappointing outcomes were further exacerbated by the potential for human error, as HCV patients must maintain a complicated pill

37. Pearlman, *supra* note 6, at 88.

38. Colleen M. Story, *Hepatitis C Medications: Costs, Side Effects, and More*, HEALTHLINE (July 14, 2016) <http://www.healthline.com/health/hepatitis-c-medications-costs-side-effects-and-more#Traditionaldrugs2>.

39. *Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations*, THE DEP'T OF VETERANS AFFAIRS NAT'L HEPATITIS C RESOURCE CTR. PROGRAM & THE NAT'L VIRAL HEPATITIS PROGRAM IN THE OFFICE OF PATIENT CARE SERVS., [hereinafter, *Chronic Hepatitis C Virus (HCV) Infection*] <https://www.hepatitis.va.gov/pdf/treatment-considerations-2016-03-28.pdf> (last updated Mar. 28, 2016).

40. *Id.* at 31.

41. McGivern & Lemon, *supra* note 27, at 1969.

42. Fernando L Goncales Jr. et al., *Retreatment of Hepatitis C Patients with Pegylated Interferon Combined with Ribavirin in Non-Responders to Interferon plus Ribavirin: Is it different in Real life?*, 10 BMC INFECTIOUS DISEASES 1, 2 (2010).

43. *Id.* at 1; cf. *African Americans and Hepatitis C*, *supra* note 35. (Again, this burden is predominantly felt by African Americans, with 91% of infected African Americans possessing genotype 1, compared with 67% of infected Caucasians).

44. *HCV Medications, Ribavirin (Copegus, Rebetol, Ribasphere)*, HEPATITIS C ONLINE, <https://www.hepatitisc.uw.edu/page/treatment/drugs/ribavirin-drug/prescribing-information> (last visited Dec. 5, 2017) (Other harsh side effects of Ribavirin include flu-like symptoms, nausea, rash, vision problems, weight gain or loss, and insomnia.).

regimen to comply with traditional combination therapies.⁴⁵ Naturally, these negatives marshalled scientific investigators' motivation to develop a less burdensome and more efficacious HCV drug, with fewer side effects.⁴⁶ Increasing advancements in the field of pharmacogenomics, particularly in the wake of the Human Genome Project, inspired hope that a breakthrough HCV therapy was within reach.⁴⁷

III. THE DEVELOPMENT OF SOVALDI

Since the Acquired Immune Deficiency Syndrome (AIDS) became a widespread epidemic in the 1980s, the National Institutes of Health (NIH) has invested aggressively in university-based scientific investigators.⁴⁸ Specifically, the NIH provided large grants to build virology to foster the discovery of AIDS therapies through clinical trials.⁴⁹ In the 1990s, HCV became a similarly-pursued "hot topic" among investigators and pharmaceutical companies; as HCV and HIV share a similar structure, the NIH also financed the genetic investigation of Hepatitis C.⁵⁰ One investigator was Raymond Schinazi, Co-Director of the Virology and Drug Discover Core at the Emory School of Medicine in Atlanta.⁵¹ For over twenty years, Schinazi received approximately \$7.7 million from the National Institute of Allergy and Infectious Diseases to conduct clinical research.⁵² Schinazi, aspiring to develop an antiviral drug for treating various strains of hepatitis, formed the small pharmaceutical company, Pharmasset, in the late 1990s.⁵³ Pharmasset contained a library of inventive therapeutics to combat Hepatitis C, which investigators hoped could unlock the mystery of how to cure the disease.⁵⁴ One of those molecules, PSI-7977 (Sofosbuvir),⁵⁵ had first

45. *Id.*

46. Sarah Kliff, *This Drug Costs \$84,000, And There's Nothing the US Health-Care System Can Do to Stop It*, VOX (Dec. 2, 2014), <https://www.vox.com/2014/12/2/7282833/sovaldi-cost>.

47. Chun-Hsiang Wang et al., *Pharmacogenomics of Chronic Hepatitis C Therapy with Genome-wide Association Studies*, 2 J. OF EXPERIMENTAL PHARMACOLOGY 73, 77 (2010).

48. Merrill Goozner, *Why Sovaldi Shouldn't Cost \$84,000*, MODERN HEALTHCARE (May 3, 2014), <http://www.modernhealthcare.com/article/20140503/MAGAZINE/305039983>.

49. THE AIDS RES. PROGRAM OF THE NAT'L INSTS. OF HEALTH, 53-94 (1991).

50. *HIV and Opportunistic Infections, Coinfections, and Conditions: HIV and Hepatitis C*, DEP'T. OF HEALTH & HUMAN SERV., <https://aidsinfo.nih.gov/understanding-hiv-aids/fact-sheets/26/88/hiv-and-hepatitis-c> (last updated July 25, 2017).

51. Raymond Schinazi, PhD, EMORY YERKES NAT'L PRIMATE RES. CTR., http://www.yerkes.emory.edu/research/divisions/emory_vaccine_center/schinazi_raymond.html (last visited Dec. 5, 2017).

52. Goozner, *supra* note 48.

53. Sam Knight, *Hepatitis C: The Cure?*, FIN. TIMES (Mar. 15, 2013), <https://www.ft.com/content/542ad524-8b77-11e2-b1a4-00144feabdc0>.

54. Kliff, *supra* note 46.

55. Knight, *supra* note 53. (PSI-7977 and sofosbuvir are synonyms for the same chemical

been developed in the mid-2000s.⁵⁶ In what Schinazi described as “a collision of science and serendipity,” Pharmasett investigators realized that Sofosbuvir would surpass expectations.⁵⁷ Unlike compounds previously tested, Sofosbuvir represented a breakthrough discovery that the medical community would later deem a “cure” for Hepatitis C.⁵⁸

Other pharmaceutical companies learned of the revolutionary Sofosbuvir, thus catalyzing a bidding war over which company would get the rights to the drug.⁵⁹ In 2011, one of the world’s largest American-based biopharmaceutical companies, Gilead, emerged triumphant, purchasing Pharmasett and its holdings, including Sofosbuvir, for the steep price of \$11.4 billion.⁶⁰ Gilead went on to spend tens of millions of dollars to complete Sofosbuvir’s clinical trials.⁶¹ Sofosbuvir would eventually become commonly known as its popular brand name, Sovaldi.⁶²

Sovaldi works differently than previous Hepatitis C drugs.⁶³ Previously, existing HCV therapies did not work for all patients, and a treatment’s duration and success depended greatly on the individual patient’s genotype.⁶⁴ In contrast, Sovaldi combats HCV *directly*, targeting the virus’ genetic information (RNA), thus blocking the virus’ ability to multiply in liver cells.⁶⁵ Phase III clinical trials demonstrated that combination therapy with Sovaldi is effective for treating people with HCV genotype 1.⁶⁶

compound. The most famous brand name this compound is sold under is Sovaldi).

56. Kliff, *supra* note 46.

57. *Id.*

58. Knight, *supra* note 53.

59. Kliff, *supra* note 46.

60. *Id.*

61. Goozner, *supra* note 48; *see also*, *Safety Study of Regimens of Sofosbuvir, GS-0938, and Ribavirin in Patients With Chronic Hepatitis C Infection (QUANTUM)*, U.S. NAT’L LIBRARY OF MED., <https://clinicaltrials.gov/ct2/show/NCT01435044> (last updated Feb 6, 2014).

62. Kliff, *supra* note 46.

63. *Id.*

64. Kenneth Hirsch, *Hepatitis C Genotype: Your Questions Answered*, HEALTHLINE (June 15, 2017), <https://www.healthline.com/health/hepatitis-c-genotype-expert#2>; *see also* *Sofosbuvir (Sovaldi)*, HEPATITIS C ONLINE, <http://www.hepatitisc.uw.edu/page/treatment/drugs/sofosbuvir-drug> (last visited Dec. 5, 2017) (discussing HCV treatment based on genotype).

65. *Sovaldi (Sofosbuvir)*, *supra* note 64.

66. Alan Franciscus, *HCSP Fact Sheet*, HCV ADVOCATE (2015), http://hcvadvocate.org/hepatitis/factsheets_pdf/Sovaldi_GT2-3.pdf [hereinafter, *HCSP Fact Sheet*]; *see Combination Antiviral Therapy for Hepatitis C*, WEBMD (June 4, 2014), <http://www.webmd.com/hepatitis/combination-antiviral-therapy-for-hepatitis-c> (combination therapy is a form of treatment in which a patient is given two or more drugs for a single disease); *see also Course Modules, Treatment of HCV Genotype 1*, HEPATITIS C ONLINE, <https://www.hepatitisc.uw.edu/go/treatment-infection/treatment-genotype-1/core-concept/all> (last visited Dec. 5, 2017).

IV. THE ETHICAL DEBATE SURROUNDING SOVALDI

The controversy over Sovaldi's price is rooted in ethical questions of beneficence and social justice.⁶⁷ It bears understanding these theories at issue. The theory of beneficence obligates researchers to prioritize the welfare of research participants in any clinical trial or research study.⁶⁸ Two general rules direct this principle: (1) "do not harm;" and (2) "maximize possible benefits and minimize possible harms."⁶⁹ Similarly, under John Stuart Mill's theory of utilitarianism, the best action *maximizes* the well-being of sentient beings.⁷⁰ Clearly, beneficence and utilitarianism share the tenets of maximizing benefits, as well as, by extension, minimizing harms.⁷¹ By contrast, Mill's interpretation of *justice* concerns with the moral duties owed to people who have correlative rights.⁷² Thus, followers of Mill's ideas on utilitarianism would argue that justice is served most optimally when its principles lead to positive consequences.⁷³ Drawing from principles of both beneficence and utilitarianism, true social justice relies on the harmony between economic and social welfare for true justice to exist.⁷⁴

Considering society's finite wealth and resources, the question becomes how to most reasonably and optimally allocate benefits to members of society. Both economic and social justice are necessary to properly address this quandary. According to the Center for Economic and Social Justice, "social justice" encompasses "economic justice."⁷⁵ Economic justice involves "input, out-take, and feedback for restoring harmony or balance

67. For the purposes of this paper, the terms "social justice" and "fairness" will be used interchangeably.

68. *The Belmont Report*, DEP'T OF HEALTH, EDUC., & WELFARE, U.S. DEP'T OF HEALTH & HUMAN SERVS (Mar. 16, 2016), <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>.

69. *Id.*; see also *The Principle of Beneficence in Applied Ethics*, STANFORD ENCYCLOPEDIA OF PHIL. (Oct. 3, 2013), <http://plato.stanford.edu/entries/principle-beneficence/#utithe>.

70. *The Principle of Beneficence in Applied Ethics*, *supra* note 69; see also *John Stuart Mills: Ethics*, INTERNET ENCYCLOPEDIA OF PHIL., <http://www.iep.utm.edu/mill-eth/#H9>, (last visited Dec. 5, 2017) (defining "utility," or "the only things desirable as ends" as the "promotion of happiness" and the "freedom of pain.").

71. *The Principle of Beneficence in Applied Ethics*, *supra* note 69; *The Belmont Report*, *supra* note 68.

72. *John Stuart Mills: Ethics*, *supra* note 70; *Risk*, STANFORD ENCYCLOPEDIA OF PHILOSOPHY (Aug. 11, 2011), <https://plato.stanford.edu/entries/risk/> ("duty not to harm other people can be extended to a duty not to perform actions that increase their risk of being harmed.").

73. *John Stuart Mills: Ethics*, *supra* note 70.

74. See *The Belmont Report*, *supra* note 68.

75. *Defining Economic Justice and Social Justice*, CTR. FOR ECON. & SOC. JUSTICE, <http://www.cesj.org/learn/definitions/defining-economic-justice-and-social-justice/> (last visited Dec. 5, 2017).

between input and output.”⁷⁶ Notable political economists Louis Kelso and Mortimer Adler offer two additional essential and independent principles required to attain economic justice: the principle of participation (participative justice) and the principle of distribution (distributive justice).⁷⁷

Participative justice requires equal opportunity to both gain access to private property in productive assets and engage in productive work.⁷⁸ Participative justice describes how a person makes “input” or contributes to the economic process to make a living.⁷⁹ Monopolies, special privileges, and other exclusionary social barriers to economic self-reliance thus stand in direct opposition to participative justice.⁸⁰ However, participative justice does not guarantee equal results.⁸¹ As long as society’s institutions are structured in ways that allow each person to contribute to the economy by working and owning property, there is participative justice within that society.⁸² The laws governing the U.S. economy and financial institutions generally give each citizen the opportunity to participate in the economic market through working and ownership.⁸³ Inasmuch as the price of Sovaldi is high, the principle of participative justice is satisfied in the U.S.⁸⁴

The concept of distributive justice suitably addresses the question of how to most reasonably allocate benefits to members of society.⁸⁵ More specifically, distributive justice concerns the fair allocation of resources among diverse members of a community and takes into account the procedure, pattern, and goods portions of the distribution.⁸⁶ Under this concept, a person’s rights to an economic system’s “output” match his or her labor and capital inputs.⁸⁷ In a capitalistic society, distributive justice is “automatically linked to participative justice, and incomes are linked to productive contributions.”⁸⁸ Furthermore, contracts and property hold

76. *Id.*

77. LOUIS O. KELSO & MORTIMER J. ADLER, *THE CAPITALIST MANIFESTO* 80–81 (Literary Licensing, LLC 2011).

78. *Defining Economic Justice and Social Justice*, *supra* note 75.

79. *Id.*

80. *Id.*

81. *Id.*

82. *Id.*

83. *See id.*; *see also* U.S. CONST. amend. V (defining the right to property); *see also* *Truax v. Raich*, 239 U.S. 33, 41 (1915) (stating “[t]he right to work for a living in the common occupations of the community is of the essence of that personal freedom and opportunity which it was the purpose of the [Fourteenth] Amendment to secure”).

84. *See* U.S. CONST. amend. V; *see* *Truax*, 239 U.S. at 33; *see* *Defining Economic Justice and Social Justice*, *supra* note 75.

85. *Defining Economic Justice and Social Justice*, *supra* note 75.

86. *Id.*

87. *Id.*

88. *Id.*

important roles in society, which the principle of distributive justice aims to protect by utilizing the free and open marketplace, rather than the government, as the most democratic means of deciding just prices, wages, and profits.⁸⁹

The last principle of economic justice is social justice. The Oxford English Dictionary defines social justice as: “[j]ustice in terms of the distribution of wealth, opportunities, and privileges within a society.”⁹⁰ The Center for Economic and Social Justice takes this concept one step further, defining social justice as “the ‘feedback and corrective’ principle that detects distortions of the input and/or out-take principles, and guides the corrections needed to restore a just and balanced economic order for all.”⁹¹ Unjust barriers to participation, such as monopolies, threaten this principle.⁹²

In summary, Kelso and Adler emphasize that the principles of participative, distributive, and social justice must maintain an authoritative function in society, otherwise economic justice will collapse.⁹³ Therefore, a drug like Sovaldi must be fairly allocated and unjust barriers to participation in a competitive market must be eliminated in order for pure economic justice to be served.⁹⁴ The remainder of this paper will assess whether these conditions hold true with respect to the distribution of Sovaldi.

A. *Do American HCV Patients Have a Fundamental Right to Receive Sovaldi Treatment?*

In light of Sovaldi’s ability to “cure” chronic Hepatitis C when administered in combination with other HCV therapies,⁹⁵ barriers to patients’ access to Sovaldi may be perceived as unfair.⁹⁶ Embedded in the American justice paradigm is the notion that there are certain rights inherent to all

89. *Id.*

90. *Social Justice*, ENGLISH OXFORD LIVING DICTIONARIES (last visited Dec. 5, 2017) https://en.oxforddictionaries.com/definition/social_justice.

91. *Defining Economic Justice and Social Justice*, *supra* note 75.

92. *Id.*

93. *Id.*

94. *Id.*

95. *See African Americans and Hepatitis C*, *supra* note 35 (Sovaldi, in combination with other HCV drugs, is said to have a high cure rate for patients.); *see* Brian L. Pearlman & Nomi Traub, *Sustained Virologic Response to Antiviral Therapy for Chronic Hepatitis C Virus Infection: A Cure and So Much More*, 52 CID 889 (2011), <https://academic.oup.com/cid/article/52/7/889/300592/Sustained-Virologic-Response-to-Antiviral-Therapy> (“Cure rates” are based on Sustained Virologic Response (SVR). The medical community defines SVR as being free from detectable viruses in the blood plasma for 24 weeks after completion of antiviral therapy.).

96. Susan Scutti, *Will New Hepatitis C Guidelines From WHO Help Make Sovaldi And Other New Drugs More Affordable?*, MED. DAILY (Apr. 9, 2014, 1:56 PM), <http://www.medicaily.com/will-new-hepatitis-c-guidelines-who-help-make-sovaldi-and-other-new-drugs-more-affordable-275594>.

human beings regardless of social status, race, ethnicity, gender, or national origin.⁹⁷ Indeed, as the Declaration of Independence enshrined, “We hold these truths to be self-evident, that all men are created equal, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty, and the pursuit of Happiness.”⁹⁸ Strikingly similar is the Fourteenth Amendment, providing that no State shall deprive any person of “life, liberty, or property” without due process of law.⁹⁹ Clearly, the United States has historically recognized life as an inalienable right, and a fundamental right under the Fourteenth Amendment, to be protected both universally and through jurisprudence.¹⁰⁰ Less clear is what the protection of life actually entails.¹⁰¹

Ethical, economic, and legal authorities grapple with the notion of an inalienable right to life.¹⁰² Generally, a “right” is an entitlement to have or obtain something or to be treated a certain way.¹⁰³ *Inalienable* rights are based on natural law, codes of morality, and ethical principles.¹⁰⁴ Even more, inalienable rights are inherent of all individuals, and arguably fundamental in nature.¹⁰⁵ Accordingly, inalienable rights receive a high degree of protection against governmental encroachment, whereas the protections of strictly legal rights may shift to reflect changing laws.¹⁰⁶

While the “right to life” is fundamental, the “right to health care” does not meet this threshold in the United States. Whether health care constitutes an “inalienable right” or a privilege has been the crux of an ongoing, divisive debate within the United States.¹⁰⁷ In 2008, President Barack Obama opined

97. See, e.g., THE DECLARATION OF INDEPENDENCE para. 2 (U.S. 1776).

98. *Id.*

99. U.S. CONST. amend. XIV, § 1.

100. See generally Geoffrey R. Stone & William P. Marshall, *The Framers' Constitution Toward a Theory of Principled Constitutionalism*, AM. CONST. SOC'Y FOR LAW AND POL'Y (Sept. 2011), <https://www.acslaw.org/The%20Framers'%20Constitution%20-%20Stone%20and%20Marshall.pdf> (that the judicial system plays a big role in constitutional interpretation).

101. *Id.* (discussing the struggle of modern day conservatives and liberals to define the broad principles the farmers set forth in the constitution; recognizing).

102. See e.g., Charles I. Lugosi, *Conforming to the Rule of Law: When Person and Human Being Finally Mean the Same Thing in Fourteenth Amendment Jurisprudence*, 4 GEORGETOWN J. OF L. & POL'Y 361, 363–68 (2007) (discussing the right to life issue from a legal perspective); James Rogers, *Why it Matters That Some Rights Are “Inalienable”*, FOUND. FOR ECON. EDUC. (Apr. 17, 2017), <https://fee.org/articles/why-it-matters-that-some-rights-are-inalienable/> (explaining the economic significance of inalienable rights).

103. Leif Wenar, *Rights*, THE STANFORD ENCYCLOPEDIA OF PHIL. (Edward N. Zalta ed., Sept. 9, 2015), <http://plato.stanford.edu/entries/rights/>.

104. See Craig A. Stern & Gregory M. Jones, *The Coherence of Natural Inalienable Rights*, 76 UMKC L. REV. 939, 971–72 (2008).

105. *Id.* at 958.

106. *Id.* at 953–54.

107. *Is Healthcare a Right?*, Student Voices, PBS NEWS HOUR EXTRA (Sept. 30, 2013)

that health care “should be a ‘right’ for every American.”¹⁰⁸ President Donald Trump seems less sure, and has vacillated between two divergent opinions. During an interview in September 2015, Trump said, “Everybody’s got to be covered,” remarking, “This is a very un-Republican thing for me to say.”¹⁰⁹ Later in Trump’s presidential campaign, he framed health care as a privilege, rather than a right, stating: “You have some guy with no college degree working a minimum wage job; no ambition, no goals, nothing to show for it. Yet for some reason, the current administration believes he – and millions of people like him, should have access to health insurance. It’s outrageous.”¹¹⁰ Nonetheless, in March 2017, President Trump lauded Australia’s universal health care system.¹¹¹ More recently, however, President Trump seems against the notion that health care is a right that should be available to all U.S. citizens.¹¹²

The World Health Organization (WHO) Constitution preserves the highest possible standard of health as a fundamental right of every human being.¹¹³ However, the WHO’s Constitution is not controlling law, and its guidance is not dispositive. In *National Federation of Independent Business v. Sebelius*, the United States Supreme Court came close to categorizing health care as a “right” when it upheld an Individual Mandate under the Patient Protection and Affordable Care Act (ACA).¹¹⁴ However, the United States Supreme Court has yet to conclusively label health care as a fundamental right.

The argument becomes more convoluted when determining what constitutes “health care.” It is untenable to equate an inalienable right to health care with an inalienable right to receive a medical drug, even if that

<http://www.pbs.org/newshour/extra/student-voices/debating-health-care-right-america/>; Mahiben Maruthappu et al., *Is Health Care a Right? Health Reforms in the USA and their Impact Upon the Concept of Care*, 2(1) ANNALS OF MED. & SURGERY 15, 15 (2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4326121/pdf/main.pdf>; R. Hobbis, *Donald Trump: Healthcare is a Privilege, Not a Right*, REAL NEWS RIGHT NOW (Jan. 14, 2016), <http://realnewsrightnow.com/2016/01/donald-trump-healthcare-is-a-privilege-not-a-right/>.

108. *Health care is a right: something’s fundamentally wrong now*, ON THE ISSUES EVERY POL. LEADER ON EVERY ISSUE (2008), http://www.ontheissues.org/social/barack_obama_health_care.htm.

109. Aaron Blake, *Trump’s Forbidden Love: Single-payer Health Care*, WASH. POST (May 5, 2017), https://www.washingtonpost.com/news/the-fix/wp/2017/05/05/trumps-forbidden-love-singe-payer-health-care/?utm_term=.a5a7a4477668.

110. *Donald Trump: Healthcare is a Privilege, Not a Right*, *supra* note 107.

111. Ben Westcott, *Trump praises Australia’s universal health care after Obamacare repeal*, CNN POLITICS (May 5, 2017 3:53 AM), <http://www.cnn.com/2017/05/04/politics/trump-us-australia-health-care/index.html>.

112. *Trump calls Sanders’ single-payer plan ‘a curse on the U.S.’*, POLITICO (Sept. 14, 2017 03:51 PM), <http://www.politico.com/story/2017/09/14/trump-bernie-sanders-single-payer-health-plan-242728>.

113. *Health and Human Rights*, WORLD HEALTH ORG. (Dec. 2015), <http://www.who.int/mediacentre/factsheets/fs323/en/>.

114. *Nat’l Fed’n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 539 (2012).

drug is a cure. An argument for a patient's inalienable right to receive a cure is specious because, in the modern health care model, the *physician*, rather than the government, is responsible for determining options for treatment and exercising prescribing power.¹¹⁵ Therefore, a patient's "right to receive a particular medical drug only extends as far as the government's facilitation of a patient's access to that drug if, and only if, the patient's physician determines the drug is appropriate for treating the patient. Restated, the current physician-prescriber model preempts any inherent patient right to a prescription drug.

It is worth noting the potential for patient collaboration; the physician and patient may cooperate such that the physician can make the best decisions about a patient's care and which medical drug to prescribe.¹¹⁶ Nonetheless, prescription of treatment for each patient is the sole responsibility of the physician because the physician is the licensed expert.¹¹⁷ Only the physician is liable if the prescribed treatment harms the patient whereas it is the patient's responsibility to comply with the prescribed treatment.¹¹⁸

Physicians have a moral and ethical obligation to provide competent care to patients.¹¹⁹ For chronic Hepatitis C patients, Sovaldi is now considered the standard of care, whether in combination with RBV, RBV and pegINF, or Ledipasvir.¹²⁰ Nevertheless, a standard of care does not constitute a legal obligation.

Whether a physician's denial of a curative drug, like Sovaldi, is *ethical* is another question. Physicians are ethically obligated to do no harm.¹²¹ Most physicians prescribe Sovaldi for their patients.¹²² Generally, evidence indicates that most physicians act with the patient's best interest in mind.¹²³ A physician may consider Sovaldi inappropriate for an HCV patient for many reasons; for example, a physician may opt not to prescribe Sovaldi based on

115. Clayton Browne, *Roles of Doctors & Nurses*, CHRON, <http://work.chron.com/roles-doctors-nurses-10336.html> (last visited Dec. 5, 2017).

116. *Id.*

117. *Id.*

118. *Id.*

119. AM. MED. ASS'N, AM. MED. ASSOC. CODE OF MED. ETHICS: AM. MED. ASSOC. PRINCIPLES OF MEDICAL ETHICS (2001) [hereinafter, AM. MED. ASSOC. CODE OF MED. ETHICS].

120. *Hepatitis C Fact Sheet*, WORLD HEALTH ORG. (last updated Oct. 2017), <http://www.who.int/mediacentre/factsheets/fs164/en/>; *Advances in Medications to Treat Hepatitis C*, AM. LIVER FOUND. (Oct. 2016), <http://hepc.liverfoundation.org/treatment/the-basics-about-hepatitis-c-treatment/advances-in-medications/>.

121. *See generally* AM. MED. ASSOC. CODE OF MED. ETHICS, *supra* note 119.

122. William Looney, *Pharm Exec's 2015 Brand of the Year: Sovaldi and Harvoni for Hepatitis C*, PHARMEXEC.COM (May 12, 2015), <http://www.pharmexec.com/pharm-execs-2015-brand-year-sovaldi-and-harvoni-hepatitis-c?pageID=1>.

123. David B. Resnik, *The Patient's Duty to Adhere to Prescribed Treatment: An Ethical Analysis*, J. OF MED. & PHIL. 167, 176 (Aug. 16, 2006), <http://www.tandfonline.com/doi/full/10.1080/03605310590926849>.

potential contraindications.¹²⁴ In such cases, prescribing Sovaldi would potentially be detrimental to the patient's treatment regimen.¹²⁵

The argument that the denial of Sovaldi by physician determination is tantamount to a "denial of access" to the drug is spurious. *All* patients have access to Sovaldi.¹²⁶ The issue is not whether Sovaldi is accessible to all HCV patients, but whether the barriers to certain patients' access are ethical under principles of social justice.

Critically analyzing the Sovaldi controversy across the principles of beneficence and social justice highlights certain aspects of the American healthcare system, including: (1) increasing U.S. healthcare expenditure trends and the price of other "curative" and "non-curative" drugs on the market; (2) the role of health insurance companies in providing Sovaldi; and (3) U.S. patent laws. Understanding nuances within the U.S. healthcare system will make it easier to determine whether Gilead's economic and social interests in developing new drugs are sufficiently balanced against the economic and social interests of the HCV patients and insurance companies that demand Sovaldi.

B. Barriers to Receiving Sovaldi

Some patients experience prescriptive barriers to Sovaldi; however, for patients to whom Sovaldi was prescribed, economic barriers abound. One such economic barrier to Sovaldi treatment manifests in restrictions created by health insurance companies.¹²⁷ The United States' health insurance industry functions as a competitive market.¹²⁸ Since the late 1930s, with the establishment of Blue Cross Blue Shield, private and public health insurance

124. *Sovaldi*, RxLIST, http://www.rxlist.com/sovaldi-drug.htm#overdosage_contraindications (last visited Nov. 14, 2017) [hereinafter, RxLIST]; U.S. FOOD & DRUG ADMIN., FDA DRUG SAFETY COMMUNICATION: FDA WARNS OF SERIOUS SLOWING OF THE HEART RATE WHEN ANTIARRHYTHMIC DRUG AMIODARONE IS USED WITH HEPATITIS C TREATMENTS CONTAINING SOFOSBUVIR (HARVONI) OR SOVALDI IN COMBINATION WITH ANOTHER DIRECT ACTING ANTIVIRAL DRUG (2015), <https://www.fda.gov/downloads/Drugs/DrugSafety/UCM439492.pdf>.

125. RxLIST, *supra* note 124.

126. Carolyn Y. Johnson & Brady Dennis, *How an \$84,000 drug got its price: 'Let's hold our position...whatever the headlines,'* THE WASH. POST (Dec. 1, 2015, 5:41 PM), <http://www.chicagotribune.com/business/ct-gilead-sciences-hepatitis-c-sovaldi-drug-20151201-story.html> (reporting that although the price for the drug was high, Gilead executives say that it was "in line with previous standards of care").

127. Virgil Dickson, *As insurers limit access to hep C drugs, patients and doctors bristle*, MOD. HEALTHCARE (May 20, 2015), <http://www.modernhealthcare.com/article/20150520/NEWS/150519897> (discussing the prior-authorization barriers put in place by an increasing number of insurers).

128. Kevin Dayaratha, *Competitive Markets in Health Care: The Next Revolution*, THE HERITAGE FOUND. (Aug. 19, 2013), <http://www.heritage.org/health-care-reform/report/competitive-markets-health-care-the-next-revolution>.

companies have been legally permitted to provide services to patients.¹²⁹ Prior to the ACA, the individual health insurance market was highly concentrated with only modest competition in most states.¹³⁰ The ACA aimed to increase competition among private insurance companies across the country.¹³¹ However, there appears to be no nationwide consensus regarding the ACA's true impact on the private insurance market.¹³²

The Social Security Administration recognizes Hepatitis C as a disability, allowing HCV patients to qualify for Medicare.¹³³ However, the 2003 Medicare Modernization Act prohibits Medicare from negotiating discounts with pharmaceutical companies,¹³⁴ and prevents the government from establishing a formulary.¹³⁵ However, these restrictions do not apply to Medicaid, the Department of Veterans Affairs, and private health insurance companies.¹³⁶

Generally, when health insurance companies decide not to distribute Sovaldi to every patient with a prescription, the reasons can be ethical, economic, or contractual in nature.¹³⁷ Many insurance companies cannot afford to purchase large quantities of Sovaldi, and hence, only pay for a

129. Michael A. Morrissey, *History of Health Insurance in the United States*, AM. COLL. OF HEALTHCARE EXECS. 3, 6–8 (2013), https://www.ache.org/pubs/Morrissey2253_Chapter_1.pdf.

130. Julie Brill, *Competition in Health Care Markets*, HEALTH AFF. BLOG (Nov. 9, 2016), <http://healthaffairs.org/blog/2015/01/26/competition-in-health-care-markets>.

131. *Affordable Care Act Facts*, OBAMACARE FACTS, <https://obamacarefacts.com/affordable-care-act-facts/> (last visited Dec. 5, 2017).

132. See Reed Abelson & Haeyoun Park, *Obamacare Didn't Destroy Insurance Markets, but It Also Didn't Fix Them*, N.Y. TIMES (June 6, 2017), <https://www.nytimes.com/interactive/2017/06/06/health/insurance-market-before-and-after-aca.html?mcubz=1&module=ArrowsNav&contentCollection=Health&action=keypress®ion=FixedLeft&pptype=Multimedia> (discussing the variance in impact of Obamacare on states).

133. Ram Meyyappan, *Hepatitis C and Applying for Social Security Disability Benefits*, DISABILITY BENEFITS CENTER (Nov. 9, 2016), <http://www.hepcassoc.org/pdf/social-security-disability.pdf>.

134. Theodore T. Lee et al., *The Politics of Medicare and Drug-Price Negotiation (Updated)*, HEALTH AFF. BLOG (Sept. 19, 2016), <https://www.healthaffairs.org/action/showDoPubSecure?doi=10.1377%2Fhblog20160919.056632&format=full&see+generally+What's+Medicare>, MEDICARE.GOV, <https://www.medicare.gov/sign-up-change-plans/decide-how-to-get-medicare/whats-medicare/what-is-medicare.html> (explaining the different categories of Medicare coverage).

135. Ice Miller LLP, *Survey of Recent Developments in Health Law*, 39 IND. L. REV. 1051, 1058 (2006), <https://mckinneylaw.iu.edu/ilr/pdf/vol40p931.pdf>.

136. Lee et al., *supra* note 134.

137. See Sony Salzman, *How insurance providers deny hepatitis C patients lifesaving drugs*, ALJAZEERA AMERICA (Oct. 16, 2015, 5:00 AM), <http://america.aljazeera.com/articles/2015/10/16/insurance-providers-deny-hepatitis-drugs.html>.

limited number of HCV patients to receive treatment.¹³⁸ When insurance companies must ration Sovaldi due to the drug's high price, the rationale is, first and foremost, economic.¹³⁹ However, in some cases, insurance companies actively discriminate against certain types of patients regardless of a drug's price.¹⁴⁰ Deliberate discrimination may involve an ethical decision to only pay for patients most likely to be compliant or who meet certain criteria, or, it may involve a contractual obligation.¹⁴¹ For example, private health insurance companies will often restrict which HCV patients can receive Sovaldi when out of formulary.¹⁴² Most private insurance companies also require prior authorization.¹⁴³ Private insurance companies use some of the following criteria to determine whether to pay for beneficiaries to undergo a treatment regimen with Sovaldi: (1) the patient's genotype (most health insurance companies will only pay for patients with genotype 1); (2) the severity of the patient's illness; (3) the absence of significant or unstable cardiac disease; (4) the absence of severe renal impairment requiring

138. See, *id.* (explaining that the very high cost of Sovaldi, originally priced at roughly \$1,000 a pill, caused economic tension).

139. *Id.*

140. Olga Khazan, *How Insurance Companies Still Discriminate Against the Sick*, THE ATLANTIC (Jan. 28, 2015), <https://www.theatlantic.com/health/archive/2015/01/how-insurance-companies-still-discriminate-against-the-sick/384908/> ("No insurer wants to be saddled with all the most-expensive customers, so they may all rejigger their drug co-pays to be similarly harsh.").

141. In medicine, patient compliance is a synonym for patient adherence and describes the degree to which a patient correctly follows medical advice. Generally, a patient is noncompliant if he/she does not take a prescribed medication or drug as ordered or recommended by his/her physician, or, if the patient does not take care of himself/herself as recommended by the physician or comply with other types of therapy sessions. Examples of noncompliance include an HCV patient who skips days taking his/her medication or an HCV patient who engages in risky activities, while undergoing his/her treatment regimen, that may negatively impact the treatment outcome. *Adherence to Long Term Therapies: Evidence for Action*, WORLD HEALTH ORG. (2003), http://www.who.int/chp/knowledge/publications/adherence_full_report.pdf (defining patient adherence as "the extent to which the patient's history of therapeutic drug-taking coincides with the prescribed treatment").

142. See Shannon Firth, *HCV Patients Face Obstacles to Treatment*, MEDPAGE TODAY (Aug. 2, 2016), <http://www.medpagetoday.com/infectiousdisease/hepatitis/59485> (discussing the use of formularies to restrict access to HCV medication); see also *What is a Drug Formulary*, ARISE HEALTH PLAN, http://www.wecareforwisconsin.com/members/formulary/what_is_a_drug_formulary (last visited Dec. 5, 2017) ("A formulary for a health plan provides a list of medications that a team of healthcare specialists have approved. A physician writes a prescription based on a patient's medical needs, but the formulary provides him with recommendations from the pharmacist and physician team. A formulary that is based on safety and cost considerations is useful for limiting the drugs recommended by a patient's health insurance plan's healthcare professionals.").

143. See Dickinson, *supra* note 127 (Prior authorizations required by most insurance companies before deciding whether they will pay for a patient's medicine limit use of expensive treatments.).

hemodialysis; (5) whether the patient is pregnant; (6) psychiatric illness; (7) whether the patient has recently engaged in high risk behaviors such as drug use, alcohol abuse, or prostitution; and (8) whether the patient has had a liver transplant.¹⁴⁴ The many health insurance restrictions highlighted above, therefore, limit patient access.

The question then arises whether it is ethical for health insurance companies to set such restrictions. Usually, private insurance companies prefer to pay for patients with genotype 1 to receive Sovaldi.¹⁴⁵ Due to cost constraints, patients with more severe liver dysfunction or cirrhosis resulting from chronic Hepatitis C infection are more likely to be approved than patients with milder symptoms, especially if the patient is potentially in need of a liver transplant.¹⁴⁶ At first glance, it might seem unethical for insurance companies to pick and choose which HCV patients they pay for; however, an insurance company's decision to allocate Sovaldi to certain patients derives from rational and economic considerations.¹⁴⁷ It is less costly for an insurance company to pay for a twelve to twenty-four-week course of Sovaldi treatment than to pay for a liver transplant; thus, it is more cost-effective to treat patients with more advanced liver disease.¹⁴⁸ Hence, while the principle of utilitarianism ("maximizing the possible benefits") would ideally guide insurance companies to maximize the number of HCV patients able to afford Sovaldi through coverage, the high costs of the drug make such universal drug coverage impossible.¹⁴⁹ Therefore, insurance companies are not ethically unjust for allocating coverage to patients with the most urgent treatment needs.¹⁵⁰

The greatest limitation to widespread distribution of Sovaldi is the drug's cost.¹⁵¹ The price of Sovaldi is too high for many insurance companies to

144. *Prior Authorization/Notification Sovaldi*, UNITED HEALTHCARE (2014), https://www.uhcprovider.com/content/dam/provider/docs/public/prior-auth/drugspharmacy/Notification_Sovaldi.pdf.

145. Michelle Andrews, *Hepatitis C patients may not qualify for pricey drugs unless illness is advanced*, THE WASH. POST (Nov. 4, 2014), https://www.washingtonpost.com/national/health-science/hepatitis-c-patients-may-not-qualify-for-pricey-drugs-unless-illness-is-advanced/2014/11/03/6d0646bc-5f71-11e4-9f3a-7e28799e0549_story.html?utm_term=.4882b89caad7; Felice J. Freyer, *Hepatitis C patients often have to get sicker before insurance will pay for drugs*, BOS. GLOBE (Apr. 19, 2016), <https://www.bostonglobe.com/metro/2016/04/18/insurers-balk-paying-for-hepatitis-drugs/M9Iv0SZcMhHuw1ek3zclLL/story.html>.

146. Andrews, *supra* note 145; Freyer, *supra* note 145.

147. Andrews, *supra* note 145.

148. Michael Smith, *Treating HCV – Is the Price Right?*, MEDPAGE TODAY (Feb. 18, 2014), <https://www.medpagetoday.com/gastroenterology/hepatitis/44357>.

149. *Sovaldi: Who's to Blame*, *supra* note 24.

150. *Id.*

151. See Bertha Coombs, *Sovaldi—\$55 Billion Headache for States*, CNBC (July 17, 2014, 10:18 AM), <http://www.cnbc.com/id/101842469> (showing a state-by-state comparison

handle without going bankrupt.¹⁵² For example, if all HCV patients eligible for Medicaid coverage were treated in 2015, the cost to the states would be \$55 billion.¹⁵³ Similar costs would engulf the prison system.¹⁵⁴ For example, although less than one percent of over 106,200 state prisoners with HCV were recently treated with Sovaldi combination therapies, due to the drug's high cost, at least \$39.8 million was spent annually on HCV therapies.¹⁵⁵ If the remaining ninety-nine percent of HCV infected inmates received Sovaldi treatment, the financial burden on tax payers would be enormously high.¹⁵⁶ As a result, most states place several restrictions on access.¹⁵⁷ Ethically, this dilemma is challenging for insurance companies and policy makers because Sovaldi was proven to work best in patients who do not have advanced liver disease, and to some, it may seem unjust to wait until someone is extremely sick before paying for treatment.¹⁵⁸ However, because of limited resources and high drug costs, insurance companies are not ethically unjust for allocating coverage to patients with the most urgent treatment needs. After all, if it is only possible for an insurance company to provide Sovaldi to a limited number of HCV patients, it is reasonable that the HCV patients chosen to receive Sovaldi are those who are at highest risk of mortality and severe complications costly to the healthcare system.

Furthermore, prior authorizations - insurance companies' primary means of restricting drug coverage - are ethically justifiable.¹⁵⁹ Prior authorizations

of state spending on hepatitis C medications).

152. John Rother, *Sovaldi: Charting and Unsustainable Path*, MORNING CONSULT (July 23, 2014), <https://morningconsult.com/opinions/sovaldi-charting-unsustainable-path/>.

153. Coombs, *supra* note 151.

154. Ed Silverman, *Less than 1 percent of state prisoners with hepatitis C get treated due to drug costs*, STAT (Oct. 5, 2016), [hereinafter, *Less than 1 percent of state prisoners with hepatitis C*] <https://www.statnews.com/pharmalot/2016/10/05/prisons-hepatitis-drug-prices-gilead/>.

155. *Id.*

156. *Id.*; see *Study: Modern Hepatitis C Drugs are Very Costly and Unavailable to Many State Prisoners*, YALE L. SCH. (Oct. 4, 2016), <https://law.yale.edu/yls-today/news/study-modern-hepatitis-c-drugs-are-very-costly-and-unavailable-many-state-prisoners>.

157. See Soumitri Barua et al., *Restrictions for Medicaid Reimbursement of Sofosbuvir for the*

Treatment of Hepatitis C Virus Infection in the United States, ANNALS OF INTERNAL MED. 215, 215 (2015), <http://annals.org/aim/article/2362306/restrictions-medicare-reimbursement-sofosbuvir-treatment-hepatitis-c-virus-infection-united> ("Two thirds of states have restrictions based on prescriber type, and 88% include drug or alcohol use in their sofosbuvir eligibility criteria, with 50% requiring a period of abstinence and 64% requiring urine drug screening.").

158. *Hepatitis C Treatment Factsheet: Sofosbuvir (Sovaldi)*, INFOHEP (Oct. 2016), http://www.infohep.org/v636132534599770000/file/1187172/sofosbuvir_hep_c_factsheet.pdf ("Sofosbuvir can be used by people with all stages of liver disease including compensated and decompensated cirrhosis. However, it works better for people with less advanced liver damage.").

159. See *Sovaldi: Who's to Blame*, *supra* note 24 (explaining the ethical discussion

can be deemed reasonable, fair, and economically just because they take into consideration a patient's well-being and allocate the drug to patients who are more likely to be compliant, experience a better treatment outcome, and optimally utilize the drug.¹⁶⁰ Certain patient populations are more vulnerable to negative effects from Sovaldi.¹⁶¹ For instance, Sovaldi may worsen the health of patients with cardiac disease or psychiatric illness.¹⁶² Patients on hemodialysis and patients who engage in drug use are at high risk for continual exposure to varying strains of HCV.¹⁶³ Patients who abuse alcohol are more likely to worsen their liver conditions and respond poorly to treatment.¹⁶⁴ Prior authorizations allow insurance companies to screen such vulnerable patients from Sovaldi coverage, thereby protecting the individual's well-being, and also allowing insurance companies to minimize future costs so that they afford to purchase Sovaldi and provide it to other patients.¹⁶⁵

To conclude, universal access to Sovaldi is conditioned on physicians' prescribing power and, in light of the drug's astronomical cost, payers' need to allocate coverage.¹⁶⁶ Certainly, the more dominant the private insurer, the better that insurer is at negotiating drug prices with pharmaceutical companies like Gilead.¹⁶⁷ Deciding how a curative medical drug should be rationed to three million patients with an infectious disease is no small task

should not be focused on insurance companies, rather "the patent system as a whole"); see also Ed Silverman, *Interview with Illinois Medicaid Medical Director Re: their new restrictions on Sovaldi Access*, NATAP (Aug. 3, 2014, 9:15 PM), [hereinafter, *Interview with Illinois Medicaid Medical Director*] http://www.natap.org/2014/HCV/080814_07.htm (discussing why insurance companies rationing methods in favor of more advanced stage hepatitis C is not unjustifiable, the reality of high cost must be considered).

160. See generally, *Interview with Illinois Medicaid Medical Director*, *supra* note 159.

161. *Id.*

162. Gilead Sciences, Inc., *Sovaldi*, FDA Professional Drug Information, DRUGS.COM (last updated Apr. 2017), <https://www.drugs.com/pro/sovaldi.html>.

163. WA Alashek & M Altagdi, *Risk Factors and Genotypes of Hepatitis C Virus Infection in Libyan Patients*, 3(4) LIBYAN J. MED. 162, 162 (2008), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3074306/pdf/LJM-3-162.pdf>.

164. Eugene R. Schiff & Nuri Ozden, *Hepatitis C and Alcohol*, NAT'L INSTS. OF HEALTH: NAT'L INST. ON ALCOHOL ABUSE & ALCOHOLISM (Sept. 29, 2004), <https://pubs.niaaa.nih.gov/publications/arh27-3/232-239.htm>.

165. See generally, *Less than 1 percent of state prisoners with hepatitis C*, *supra* note 154.

166. Barua et al., *supra* note 157, at 220–21.

167. Michael Hiltzik, *Allowing Medicare to negotiate drug prices is a popular solution to healthcare costs. But it may not work*, L.A. TIMES (Jan. 11, 2017, 3:40 PM), <http://www.latimes.com/business/hiltzik/la-fi-hiltzik-medicare-negotiate-20170111-story.html>; Paul Barrett & Robert Langreth, *The Crazy Math Behind Drug Prices*, BLOOMBERG BUSINESSWEEK (June 29, 2017, 11:00 AM), <https://www.bloomberg.com/news/articles/2017-06-29/the-crazy-math-behind-drug-prices>.

for a health insurance company.¹⁶⁸ In order for insurance companies to increase their supply of Sovaldi, and consequently distribute Sovaldi to more patients, the price must drop.¹⁶⁹ The issue then becomes whether Gilead acted unethically in setting Sovaldi's price so high that policy makers and insurance companies must determine how best to ration the drug.

V. THE ETHICAL DEBATE INVOLVING GILEAD

Many Americans have accused Gilead of price gouging.¹⁷⁰ Price gouging occurs when a company charges a price that is higher than what is considered normal or fair.¹⁷¹ The practice is best framed as “increases in price due to temporary increase in demand, rather than increases in suppliers’ costs.”¹⁷² In other words, when there is a sharp increase in the demand of a good relative to its supply, there will be a shortage of the good unless the manufacturer raises the price in order to decrease demand, giving the manufacturer time to increase supply.¹⁷³ On its face, price gouging is unethical because it undermines the principle of social justice by creating an economic scheme close to a monopoly, and a monopoly leads to a disparity of allocated resources because only people who are most willing and able to purchase the good do so.¹⁷⁴ However, there is no conclusive evidence that Gilead was guilty of unethical price gouging.¹⁷⁵ Certainly, that a drug

168. See generally, *Lawsuit Alleges Price Gouging*, *supra* note 22.

169. *Id.*

170. *Id.* (citing experts, including Professor C. Scott Hemphill, a Columbia Law School professor, who viewed SEPTA’s antitrust claim as meritless because “having a monopoly and setting high prices do not violate antitrust law.”); *Breakthrough Hepatitis C Drug Causes Controversy*, ADVANCED RES. INST. (last visited Dec. 5, 2017), <http://www.advresearch.org/breakthrough-hepatitis-c-drug-causes-controversy/> (citing legislators and insurance companies, among others, of accusing Gilead of unethical practices due to their pricing scheme).

171. Jodi Beggs, *What is Price Gouging?*, THOUGHTCO. (Apr. 1, 2017), <http://economics.about.com/od/changes-in-equilibrium/ss/The-Economics-Of-Price-Gouging.htm>.

172. *Id.*

173. *Id.*

174. *Price Gouging*, LEGAL DICTIONARY, <https://legaldictionary.net/price-gouging/>. (last visited Dec. 5, 2017) (defining “price gouging”).

175. Brady Huggett, *America’s Drug Problem*, 34 NATURE BIOTECHNOLOGY 1231, 1233 (2016), <http://www.nature.com/nbt/journal/v34/n12/full/nbt.3734.html>; Andrew Pollack, *Gilead Faces Fights Over Hepatitis C and H.I.V. Drugs*, N. Y. TIMES (Jan. 27, 2016), <https://www.nytimes.com/2016/01/28/business/gilead-faces-fights-over-hepatitis-c-and-hiv-drugs.html> (“Gilead has argued that the prices are justified by the value provided by the drugs, curing a disease that gradually destroys the liver.”); *Lawsuit Alleges Price Gouging*, *supra* note 22 (“Gilead’s pricing is unlikely to be considered illegal, experts say. The transit agency is ‘complaining about high prices. But having a monopoly and setting high prices do not violate antitrust law,’ says C. Scott Hemphill, a Columbia Law School professor who specializes in antitrust issues and intellectual property. ‘Judging from the complaint, the

becomes less expensive after coming off-patent does not definitively indicate any existence of price gouging on-patent.¹⁷⁶ Sans evidence that Gilead would refuse to drop Sovaldi's price to adjust to the changing market value if other drug manufacturers dropped the prices of competing Hepatitis C drugs, there is insufficient evidence to prove that Gilead behaved unethically or, for that matter, acted unlawfully.¹⁷⁷ Furthermore, there is no evidence that Gilead's decision to adjust its price was *not* a response to a shifting market; the fact that Gilead already recouped so much money suggests that American consumers and health insurance companies are actually willing and able to purchase the product at \$1,000 per pill.¹⁷⁸ The following sections shed light on some of the reasons Gilead's actions appear to be ethically reasonable.

A. *Sovaldi's Superior Quality Justifies its Price*

Probably the most obvious justification for Sovaldi's high price is the superior quality compared to other Hepatitis C drugs currently on the market.¹⁷⁹ Gilead issued a public statement,

"We believe the price of Sovaldi reflects the value of the medicine. Sovaldi represents a significant therapeutic advance over other available therapies, as it has shortened the duration of treatment to as little as 12 weeks and has reduced or completely eliminated the need for interferon injections, depending on the patient's genotype."¹⁸⁰

Gilead further contended that the price of Sovaldi (in conjunction with interferon and ribavirin) was consistent with that of competing protease

antitrust claim is meritless.").

176. See, *Lawsuit Alleges Price Gouging*, *supra* note 22 (quoting Ankur Kapoor, "Monopolists, themselves, are not unlawful. They are allowed to charge any price they want. It's only if they take any anticompetitive conduct that a problem may exist").

177. Huggett, *supra* note 175, at 1233–35 (suggesting that the price of Sovaldi has adjusted for changing market value); *Sovaldi: Who's to Blame*, *supra* note 24 (citing Professor Patricia Danzon, Wharton professor of health care management, "Generally we do not adjust prices in a market-based system based on the number of consumers. Price is more related to value.").

178. Huggett, *supra* note 175, at 1233–35; *Sovaldi: Who's to Blame*, *supra*, *supra* note 24 (stating that Sovaldi was predicted to hit \$1-2 billion in its first quarter of sales and surpass Lipitor as the top-selling drug of all time); Max Nisen, *The staggering success of Gilead's hepatitis drugs, in one chart*, QUARTZ (July 28, 2015), <https://qz.com/466269/the-staggering-success-of-gileads-hepatitis-drugs-in-one-chart/>.

179. Pollack, *supra* note 175 ("Gilead has argued that the prices are justified by the value provided by the drugs, curing a disease that gradually destroys the liver."); Anne Harding, *Pros and Cons of New Hepatitis C Drugs*, EVERYDAY HEALTH, <https://www.everydayhealth.com/news/pros-cons-new-hepatitis-treatments-patients/> (last updated Apr. 7, 2015) (describing the Sovaldi and Harvoni, a combination of Sovaldi and ledipasvir, as having superior treatment outcomes than other Hepatitis C drugs).

180. *Sovaldi: Who's to Blame*, *supra* note 24.

inhibitors for treating Hepatitis C on the market.¹⁸¹ Moreover, Gilead shared that Sovaldi was projected to save money for the healthcare system over time by significantly reducing long-term complications of the disease, such as the need for liver transplants and liver failure, whereas competing HCV drugs will not.¹⁸² These projected savings appear plausible. The average cost of a liver transplant, including necessary pre-operative and post-operative expenses, is \$577,100.¹⁸³ The cost of being admitted to the hospital for liver failure is estimated to be \$110,576 and that number does not include hospital stay.¹⁸⁴ After adding those costs, more than \$687,676 will be spent on each patient admitted to the hospital with end stage liver disease (ESLD) who receives a liver transplant. This cost for an individual is equivalent to the cost necessary to treat more than eight HCV patients with Sovaldi for a 12-week cycle.¹⁸⁵ Considering that the healthcare system¹⁸⁶ paying for the brunt of liver transplants and ESLD-related hospital visits is the same healthcare system spending \$84,000 to cure one patient who will likely never need a costly treatment again after completing a twelve to twenty-four-week treatment regimen on Sovaldi, Gilead seems to make a valid point.¹⁸⁷

Sovaldi's superiority to other competing HCV drugs further buttresses its higher price.¹⁸⁸ First, Sovaldi carries a lower frequency of the harsh side

181. *Id.*

182. *Id.*

183. *Financial Matters: Liver Transplant Costs*, SUTTER HEALTH <http://www.cpmc.org/advanced/liver/patients/topics/finance.html#Transplantation%20Costs> (last visited Dec. 5, 2017).

184. Linda L. Wong et al., *The Cost of Dying of End-stage Liver Disease*, 157 ARCHIVES OF INTERNAL MED. 1429, 1432 (1997).

185. *Sofosbuvir (Sovaldi)*, HEPATITIS C ONLINE, <https://www.hepatitisc.uw.edu/page/treatment/drugs/sofosbuvir-drug> (last visited Dec. 5, 2017).

186. STRENGTHENING HEALTH SYSTEMS TO IMPROVE HEALTH OUTCOMES, WORLD HEALTH ORG. 1, 2 (2007), http://www.who.int/healthsystems/strategy/everybodys_business.pdf (According to the World Health Organization, a healthcare system consists of "all organizations, people and actions whose primary intent is to promote, restore or maintain health. This includes efforts to influence determinants of health as well as more direct health-improving activities. A health system is therefore more than the pyramid of publicly owned facilities that deliver personal health services. It includes, for example, a mother caring for a sick child at home; private providers; behavior change programs; vector-control campaigns; health insurance organizations; occupational health and safety legislation. It includes inter-sectoral action by health staff, for example, encouraging the ministry of education to promote female education, a well-known determinant of better health.").

187. Carolyn Johnson, *How an \$84,000 Drug Got Its Price: 'Let's Hold Our Position... Whatever the Headlines.'* THE WASH. POST (Dec. 1, 2015), https://www.washingtonpost.com/news/wonk/wp/2015/12/01/how-an-84000-drug-got-its-price-lets-hold-our-position-whatever-the-headlines/?utm_term=.7280e996bbfe.

188. Michael Hiltzik, *Is That \$100,000 Hepatitis Treatment Worth the Price? Yes, but Can Society Afford It?*, L.A. TIMES (Jan. 15, 2016), <http://www.latimes.com/business/hiltzik/la-fi-mh-that-hepatitis-treatment-20160111->

effects of the previously standard therapies, RBV and pegIFR.¹⁸⁹ The combination therapy of RBV and pegIFR carried the potential to cause severe hemolytic anemia and other harsh side effects.¹⁹⁰ Second, Sovaldi's cost, \$1,000 per pill,¹⁹¹ is comparable to the cost of other HCV drugs on the market and renders future health economic outcomes that are more favorable than other treatment regimens.¹⁹² Finally, Sovaldi surpasses the former therapies in effectiveness; the drug was over ninety percent curative in patients enrolled in Gilead's Phase III clinical trials after 12-weeks of treatment, while the combination of RBV and pegIFR only sustained a virological response (SVR) rate of thirty-five to sixty-six percent.¹⁹³

Some of Sovaldi's competitors include Telaprevir, Boceprevir, and Simeprevir; however, these drugs are far less efficacious and far more burdensome to patients living with chronic Hepatitis C, and out of these four HCV drugs, only¹⁹⁴ Sovaldi is regarded clinically as a "cure".¹⁹⁵ Telaprevir, manufactured by Vertex Pharmaceuticals, costs \$49,200 for a 12-week course of therapy, but has a high pill burden, which provides an opportunity

column.html.

189. *Harvoni and Depression: What's the Connection?*, HEALTHLINE, <https://www.healthline.com/health/hepatitis-c/harvoni-depression#overview1> (last visited Dec. 5, 2017) (When not combined with RBV or pegIFR, drugs containing Sovaldi, such as Harvoni, carry a low frequency of side effects.); *see also Harvoni vs. Sovaldi: A Side-by-Side Comparison*, HEALTHLINE, <https://www.healthline.com/health/hepatitis-c/harvoni-vs-sovaldi#side-effects4> (last visited Dec. 5, 2017).

190. *HCV Medications: Ribavirin*, *supra* note 44 (listing influenza-like symptoms, nausea, myalgia, neutropenia, thrombocytopenia, insomnia, and depression as additional side effects to the ones already mentioned).

191. Sam Aminov, *Epclusa Approved for Chronic Hepatitis C*, MYMATRIX (July 8, 2016), <https://www.mymatrixx.com/new-drug-alert-epclusa-approved-for-chronic-hepatitis-c/>.

192. S. Saab et al., *Cost-Effectiveness Analysis of Sofosbuvir plus peginterferon/ribavirin in the Treatment of Chronic Hepatitis C Virus Genotype 1 Infection*, 40 ALIMENT. PHARMACOL. THER. 657, 669 (2014).

193. Graham R. Foster, *Pegylated Interferons for the Treatment of Chronic Hepatitis C: Pharmacological and Clinical Differences Between Peginterferon-alpha-2a and Peginterferon-alpha-2b*, 70 DRUGS 147, 147 (2010).

194. *Zepatier vs Harvoni vs Epclusa: Which One is the Best for You?*, HEPATITIS C SOCIETY (last updated, June 28, 2016), <http://104.236.45.254/hepc-drugs-comparison-harvoni-vs-sovaldi-vs-viekirapak-vs-zepatier/> (Since Sovaldi, and other combination therapies that include Sovaldi (such as Harvoni and Epclusa), hit the market, a couple more HCV "cures" have been FDA approved for treating genotype 1, including Viekira Pak, Daklinza, and Zepatier. Deciding which of these HCV drugs is the most optimal treatment is patient dependent. Viekira Pak and Daklinza are priced about the same as Sovaldi. Zepatier, the newest addition to the market (added in 2016) is priced at a lesser price of \$54,600 per treatment regimen. However, Zepatier has more adverse side effects than Sovaldi.).

195. *See supra* note 7; *Fair Pricing Coalition Expresses Disappointment at the Price of Vertex's Newly Approved Hepatitis C Drug*, FAIR PRICING COALITION (May 24, 2011), <https://fairpricingcoalition.org/2011/05/24/the-fair-pricing-coalition-expresses-disappointment-at-the-price-of-vertexs-newly-approved-hepatitis-c-drug>.

for a patient to be noncompliant.¹⁹⁶ Furthermore, Telaprevir can potentially cause adverse events such as anorectal complaints, rash, anemia, and even serious conditions such as Steven's Johnson Syndrome.¹⁹⁷ Additionally, for every adverse side effect, patients will need additional costly medical care.¹⁹⁸ Adding to the limitations of Telaprevir is the fact that the drug has a rapid resistance to HCV in genotype 1 patients, significantly reducing its efficacy and potential to keep patients in remission.¹⁹⁹

Similarly, Boceprevir can cost close to \$50,000 for one course of treatment in patients with cirrhosis, but it is known for serious side effects and extremely high HCV resistance.²⁰⁰ Its high resistance to HCV causes greater than fifty percent of patients to never achieve an acceptable SVR rate.²⁰¹ Boceprevir has an even higher pill burden than Telaprevir, with patients taking up to 12 pills per day, plus a weekly injection of PEG-IFN.²⁰²

Simeprevir costs \$66,360 for a 12-week supply, has an extremely high resistance to HCV, and causes side effects such as rash, nausea, and serious photosensitivity reaction.²⁰³ Furthermore, Telaprevir, Boceprevir, and Simeprevir are typically only effective in one of the six genotypes and are no longer the standard of care for treating patients with genotype 1.²⁰⁴

Sovaldi, by contrast, can successfully treat patients with HCV genotypes 1-4 and has a high barrier to resistance that makes it practically curative, while also being able to achieve a high SVR rate in over ninety percent of patients.²⁰⁵ Drugs that contain Sovaldi, such as Epclusa and Harvoni, have a

196. *Id.*

197. A. Sidney Barritt, IV & Michael W. Fried, *Maximizing Opportunities & Avoiding Mistakes in Triple Therapy for Hepatitis C Virus*, 142 GASTROENTEROLOGY 1314, 1320 (2012).

198. *Id.*

199. *Id.* at 1316.

200. Jagpreet Chhatwal et al., *Cost-effectiveness of Boceprevir in Patients Previously Treated for Chronic Hepatitis C Genotype 1 Infection in the U.S.*, 16 VALUE HEALTH 1, 7 (2013).

201. *Boceprevir (Victrelis)*, HEPATITIS C ONLINE, <https://www.hepatitisc.uw.edu/page/treatment/drugs/boceprevir-drug/drug-summary> (last visited Dec. 5, 2017).

202. Barritt & Fried, *supra* note 197, at 1316 (“...boceprevir is prepared as 200-mg capsules and dosed as 4 capsules (800 mg), 3 times a day, 7–9 hours apart, with food.”).

203. *Simeprevir (Olysio)*, HEPATITIS C ONLINE, (Stating that patients on Simeprevir are urged to stay out of the sun) <http://www.hepatitisc.uw.edu/page/treatment/drugs/simeprevir-drug> (last visited Dec. 5, 2017).

204. David H. Spach & H. Nina Kim, *Treatment of HCV Genotype 1*, HEPATITIS C ONLINE (last visited Dec. 5, 2017) <https://www.hepatitisc.uw.edu/go/treatment-infection/treatment-genotype-1/core-concept/all>.

205. Paul Kwo, *The Future of Hepatitis C Virus Therapeutics*, 10 GASTROENTEROLOGY HEPATOLOGY 433, 435 (2014); *see also Sovaldi Highlights of Prescribing Information*, FOOD & DRUG ADMIN. (2015), https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/204671s0041bl.pdf (last visited

far superior efficacy to all of the other HCV drugs on the market.²⁰⁶ These drugs can also be used without PEG-IFN,²⁰⁷ and are even effective in treating patients with liver disease.²⁰⁸ Additionally, patients taking Sovaldi only have to take one tablet per day and the only known side effects are fatigue and mild headaches – two mild conditions that rarely require additional medical expense.²⁰⁹ Not only do harsh side effects harm patients in violation of the “do no harm” principle, harsh side effects often cause patients to stop complying with treatment altogether, and many patients on competing protease inhibitors with low HCV resistance will end up requiring treatment again in the future.²¹⁰ Therefore, even though Sovaldi costs more upfront than competing protease inhibitors, its efficacy makes it, comparatively, more cost-effective.²¹¹ Additionally, it cannot be minimized that Sovaldi dramatically improves the patient’s quality of life in curing HCV.²¹²

Most developed countries, including the United Kingdom,²¹³ have a mechanism for setting limits on what drugs should cost.²¹⁴ This mechanism is based on a party’s willingness to pay a certain amount for a “quality

Dec. 5, 2017).

206. Gilead’s All-Genotype Hep C Drug Boasts Excellent Cure Rates, HEPMAG (Sept. 23, 2015), <https://www.hepmag.com/article/Gilead-8217-s-All-Genotype-Hep-C-Drug-Boasts-Excellent-Cure-Rates-27833-1885851337>; see also *Epclusa: The Newest Hepatitis C Treatment*, HEPMAG (June 28, 2016), <https://www.hepmag.com/blog/epclusa-newest-hepatitis-c-treatment>.

207. *Epclusa: The Newest Hepatitis C Treatment*, *supra* note 206 (There are many patients who are ineligible to receive peg-IFN. Sovaldi gives them an alternative treatment option.); see also *Chronic Hepatitis C Virus (HCV) Infection*, *supra* note 39; see also Alan Hoi Lun Yau & Eric M. Yoshida, *Hepatitis C Drugs: The End of the Pegylated Interferon Era and the Emergence of an All-Oral, Interferon-Free Antiviral Regimens: A Concise Review*, 28 CAN. J. GASTROENTEROL. HEPATOL. 445, 447 (2014).

208. Joel V. Chua & Shyam Kottlilil, *Sofosbuvir and Velapatasvir: A Stellar Option For Patients with Decompensated Hepatitis C Virus (HCV) Cirrhosis*, 4 ANN. TRANSL. MED. 1, 4 (2016).

209. *Chronic Hepatitis C Virus (HCV) Infection*, *supra* note 39, at 19.

210. Sobia Kanwal & Tariq Mahmood, *Hepatitis C Virus Resistance to Interferon Therapy: An Alarming Situation*, 9 CENT. EUR. J. BIOL. 1155, 1167 (2014).

211. *Sovaldi Cost-Effectiveness/Disease Outcome Analysis*, NAT’L AIDS TREATMENT ADVICE CTR., http://www.natap.org/2014/HCV/101014_02.htm (last visited Dec. 5, 2017); Perica Davitkov et al., *Treatment Selection Choices Should Not Be Based on Benefits or Costs Alone: A Head-to Head Randomized Control Trial of Antiviral Drugs for Hepatitis C*, 11 PLOS ONE 1, 11 (2016); see also *Boceprevir: Overview*, LIVERTOX, <https://livertox.nih.gov/Boceprevir.htm> (last visited Dec. 5, 2017).

212. Denise Grady, *Are New Drugs for Hepatitis C Safe? A Report Raises Concerns*, N.Y. TIMES (Jan. 24, 2017).

213. Peter J. Neumann et al., *Updating Cost-Effectiveness: The Curious Resilience of the \$50,000-per-QALY Threshold*, NEW ENGLAND J. OF MED. (Aug. 28, 2014), <http://www.nejm.org/doi/full/10.1056/NEJMp1405158?af=R&rss=currentIssue#t=article> (While many U.S. policy makers utilize QALY measurements when making policy decisions, the U.S. has legislated against the explicit use of cost-per-QALY thresholds.).

214. *Sovaldi: Who’s to Blame*, *supra* note 24, at 3.

adjusted life year” (QALY) saved.²¹⁵ A QALY measures disease burden, including the quality and quantity of life lived, and is often used in assessing what monetary value should be placed on a medical intervention.²¹⁶ Research suggests that on average, the more expensive HCV drug combinations, such as Sovaldi, Olysio, and RBV (without PEG-IFN), yield a higher QALY value than less expensive drug combinations and save significantly more money in the long run.²¹⁷ Hence, based on these QALY measurements, Gilead reasonably believes that Sovaldi is a far superior product to competing HCV drugs on the market.²¹⁸ The question then becomes whether it is ethical for pharmaceutical companies to use the high quality of a drug as justification for setting high prices, which causes many patients to experience greater financial barriers. There is no simple answer. However, one may reasonably argue that this practice is ethical because it will likely benefit far more patients in the long run by increasing incentives and resources for continued R&D, leading to the discovery of newer, better medications. Currently, Gilead’s patent stands to expire in about ten years, at which point the price of Sovaldi will drop significantly in the U.S.²¹⁹ The next section of this paper expounds upon these concepts in more detail.

B. Sovaldi’s Price Reflects Legal Constructs Influencing the U.S. Healthcare System

Many opponents of Gilead are quick to call the company unethical for Sovaldi’s high price.²²⁰ However, several factors, partly out of Gilead’s control, contribute to Sovaldi’s high price.²²¹ Many scholars agree that the healthcare reimbursement and patent systems, in addition to the frequently-vilified pharmaceutical companies, should bear responsibility for high drug

215. *Id.*

216. *Measuring Effectiveness and Cost Effectiveness: The QALY*, NAT’L INST. FOR HEALTH & CLIN. EXCELLENCE, <https://web.archive.org/web/20090809124835/http://www.nice.org.uk/newsroom/features/measuringeffectivenessandcosteffectiveness/qaly.jsp> (last visited Dec. 5, 2017).

217. *Sovaldi-Olysio-Ribavirin Cost-Effective Over Sovaldi-Ribavirin*, HEPMAG, http://www.hepmag.com/articles/Sovaldi_cost_2501_25467.shtml (last visited Dec. 5, 2017).

218. Yevgeniy Feyman, *UK Says Sovaldi Is Worth It. We Should Listen.*, FORBES (Oct. 18, 2014), <https://www.forbes.com/sites/theapothecary/2014/08/18/uk-says-sovaldi-is-worth-it-we-should-listen/#4229e72d7569>.

219. *Id.*

220. *Breakthrough Hepatitis C Drug Causes Controversy*, ADVANCED RES. INST. <http://www.advresearch.org/breakthrough-hepatitis-c-drug-causes-controversy/> (last visited Dec. 5, 2017) (citing legislators and insurance companies, among others, of accusing Gilead of unethical practices due to their pricing scheme).

221. Hagop M. Kantarjian, et al., *Cancer Drugs in the United States: Justum Pretium—The Just Price*, 31 J. OF CLIN. ONCOLOGY 3600, 3602 (2013).

prices.²²² While politicians now bemoan Gilead's prices, asking the company to release years of data regarding its expenditures, it bears remembering that politicians have, to date, established no limits to the amounts pharmaceutical companies can charge.²²³ Ultimately, the U.S. patent system, when combined with increased healthcare expenditures, drives novel drug prices so high.²²⁴ In fact, prices of new drugs have doubled in the past decade,²²⁵ and Sovaldi is far from being the most expensive drug on the market.²²⁶ In 2012 alone, the FDA approved twelve different cancer drugs, eleven of which cost more than \$100,000 per year.²²⁷ In 1989, a powerful, newly discovered HIV drug, AZT, was priced at just \$8,000 per year.²²⁸ Today, even inefficacious antivirals are priced at more than \$30,000 per year.²²⁹ This trend of rising drug prices is more closely tied to healthcare costs and reimbursement than the ethics of drug manufacturers.²³⁰

Generally, most pharmaceutical companies, including Gilead, function with two very important, although conflicting, goals in mind: (1) to encourage a competitive market that typically includes generic competitors; and (2) to benefit as many patients as possible.²³¹ The first goal safeguards that affordable drugs are widely available to as many patients as possible, ensuring economic justice.²³² In order to meet this goal, pharmaceutical prices must reflect the marginal costs of production, which unfortunately means relatively high drug prices.²³³ Restated, pharmaceutical companies

222. *Id.*; *Who's to Blame for the \$1,000 a Day Cure?* KNOWLEDGE @ WHARTON (Apr. 16, 2014) <http://knowledge.wharton.upenn.edu/article/sovaldi-whos-blame-1000-day-cure/> (quoting Professor Patricia Danzon at the Wharton School of University of Pennsylvania as saying, "Companies obviously have an obligation to their shareholders to maximize profits . . . that generally means doing the best that you can within the reimbursement environment that exists in any particular country. In the U.S., we have established a system of reimbursement for pharmaceuticals that unfortunately puts absolutely no limits on the prices that companies can charge.").

223. John R. Graham, *Politicizing Gilead's Research and Development Costs for Sovaldi Is a Reckless and Dangerous Misadventure*, FORBES (July 25, 2014), <https://www.forbes.com/sites/theapothecary/2014/07/25/politicizing-gileads-research-and-development-costs-for-sovaldi-is-a-reckless-and-dangerous-misadventure/#3f62b0418650>.

224. *See* Wong et al., *supra* note 184.

225. *See* Kantarjian, et al., *supra* note 221, at 3600.

226. *Id.*

227. *Id.*

228. *AZT's Inhuman Cost*, N.Y. TIMES (Aug. 28, 1989), <http://www.nytimes.com/1989/08/28/opinion/azt-s-inhuman-cost.html>.

229. Kantarjian, et al., *supra* note 221, at 3600.

230. *See generally*, *id.*

231. Wayne Winegarden, *The Economics of Pharmaceutical Pricing*, PAC. RES. INST. 1, 5 (2014).

232. *Id.*

233. *Id.*; Sean Ross, *How Does Marginal Cost of Production Relate to Economies of Scale?*, INVESTOPEDIA (Jan. 30, 2015),

must adequately recoup capital costs in order to continue providing additional future drugs to patients.²³⁴ The second goal fulfills a pharmaceutical company's ethical obligation, under the principle of beneficence, to place high value on the welfare of each human subject so that generalized knowledge can have future long run benefits for all patients living with the disease in question.²³⁵

The current U.S. patent system provides a way for innovative pharmaceutical companies to prevent short-run competition against generics so that they can have a greater opportunity to recoup their costs.²³⁶ Any pharmaceutical company, including Gilead, is permitted to set prices of newly developed drugs at high rates, so long as the company does not violate pricing discrimination laws.²³⁷ Federal law creates a period of market exclusivity that provides an innovative pharmaceutical manufacturer with an opportunity to recover capital costs associated with research and development (R&D).²³⁸ Market exclusivity is a statutory provision granting an applicant of a New Drug Application (NDA) exclusive marketing rights by the United States Food and Drug Administration (FDA) upon approval of a drug.²³⁹ These laws promote a balance between new drug innovation and generic drug competition, and between pharmaceutical companies' dual goals.²⁴⁰

Since capital costs for manufacturing drugs tend to be extremely high, many pharmaceutical companies use the high costs as justification for setting

<http://www.investopedia.com/ask/answers/013015/how-does-marginal-cost-production-relate-economies-scale.asp> (stating that marginal cost is the cost of producing one more additional unit of a good).

234. See Winegarden, *supra* note 231 at 5, 18–23 (stating that R&D expenses are very high and also have a high failure rate).

235. Lawrence Perkins, *Pharmaceutical Companies Must Make Decisions Based on Profit*, 175 W. J. MED. 422, 423 (2001); David Shaywitz, *What's Holding Back Cures? Our Collective Ignorance (And No, Not a Pharma Conspiracy)*, FORBES (May 10, 2013), <https://www.forbes.com/sites/davidshaywitz/2013/05/10/whats-holding-back-cures-our-collective-ignorance-and-no-not-a-pharma-conspiracy/#7a44ff84236f>.

236. Annetine C. Gelijns & Ethan A. Halm, *The Changing Economics of Medical Technology*, THE INST. OF MED. 41 (1991), https://www.ncbi.nlm.nih.gov/books/NBK234308/pdf/Bookshelf_NBK234308.pdf.

237. Melody Peterson, *Here's Why Drug Prices Rise Even When There's Plenty of Competition*, L.A. TIMES (Sept. 1, 2016) <http://www.latimes.com/business/la-fi-mylan-price-hikes-20160830-snap-story.html>.

238. See generally, Winegarden, *supra* note 231.

239. 21 C.F.R. § 314.108 (2014).

240. *Frequently Asked Questions on Patents & Exclusivity*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/developmentapprovalprocess/ucm079031.htm> (last updated Dec. 5, 2016); see Winegarden, *supra* note 231, at 5.

high prices.²⁴¹ After all, pharmaceutical innovation is expensive.²⁴² The New York University Stern School of Business calculated a weighted average cost of capital (WACC) for the pharmaceutical industry, finding that for innovative pharmaceutical companies, the WACC is significantly higher than the average WACC for other types of businesses.²⁴³ This data indicates the greater risks involved in developing innovative pharmaceuticals compared to risks incurred by other types of manufacturing companies.²⁴⁴ Further, economists estimate that the total capital costs incurred by innovative pharmaceutical companies with a \$5.5 billion R&D budget over a fifteen-year period are around \$17.2 billion, the total capital costs incurred by a \$2.0 billion R&D budget is \$6.2 billion, and the total capital costs of a \$500 million R&D budget is \$1.6 billion.²⁴⁵ These staggering numbers account for the time and risk involved in developing a new drug.²⁴⁶

Each patented pharmaceutical's annual cost of capital is approximately \$1.5 billion per year.²⁴⁷ As such, a successful drug must earn \$1.5 billion in revenue each year to recover the capital costs for the company's R&D expenditures.²⁴⁸ Furthermore, most drug innovations often fail, causing companies focused on pharmaceutical development to lose a significant amount of money.²⁴⁹ It is far less costly to produce a drug that has already been invented and FDA approved, than to produce a drug during its clinical trial phase before the efficacy and safety of the drug is clearly understood.²⁵⁰ Further complicating this economic quandary, only two of ten medicines proven to be efficacious and safe is actually profitable enough to return an income stream greater than the cost of their R&D.²⁵¹ A pharmaceutical company's opportunity to recoup capital costs expires upon the expiration of its patent, at which point, generic competitors hit the market with lower prices.²⁵² Without the current structure of the U.S. patent system, many innovative pharmaceutical companies would potentially lose the opportunity to fully recoup capital costs.²⁵³ Pharmaceutical innovation is inextricably

241. Sydney Lupkin, *5 Reasons Prescription Drug Prices Are So High in the U.S.*, MONEY <http://time.com/money/4462919/prescription-drug-prices-too-high/> (last visited Dec. 5, 2017).

242. See Winegarden, *supra* note 231, at 18.

243. *Id.* at 20.

244. *Id.*

245. *Id.*

246. *Id.*

247. *Id.* at 7.

248. *Id.*

249. *Id.* at 6.

250. *Id.* at 22–23.

251. *Id.* at 5.

252. *Id.* at 7.

253. *Id.* at 5.

linked to an innovative pharmaceutical company's ability to recoup its costs of capital; if each innovator must immediately compete with generics manufactured by companies that avoided large capital costs, such innovation is impossible.²⁵⁴

Evidence concludes that the long-term value of Sovaldi outweighs the value of its competitors,²⁵⁵ and the price of Sovaldi lends to further R&D and innovation to benefit more patients over time.²⁵⁶ Stifling future R&D by immediately providing a lower priced curative, would cause more harm to HCV patients than good.²⁵⁷ Hence, the need for R&D is essential to improving the health of tomorrow's patients.

On the other hand, policy makers opposing Gilead,²⁵⁸ such as Democratic Senator Ron Wyden and Republican Senator Chuck Grassley, argue that the company cannot use high capital costs to justify the price of Sovaldi,²⁵⁹ because rather than creating the drug, Gilead bought out Pharmasset for \$11.2 billion,²⁶⁰ and in its first quarter on the market, Gilead astonishingly recouped more than \$2 billion.²⁶¹ This contingent further contends that by the time Gilead's patent expires, it will likely have one of the highest profit margins for any pharmaceutical company in U.S. history.²⁶² However, that argument fails to consider other costs associated with bringing a drug to market. For example, although Gilead did not develop Sovaldi, it entered Sovaldi into costly Phase III clinical trials to obtain FDA approval.²⁶³ This

254. *Id.* at 6–7.

255. *Gilead's All-Genotype Hep C Drug Boasts Excellent Cure Rates*, *supra* note 206; *Eplclusa: The Newest Hepatitis C Treatment*, *supra* note 206.

256. *See* Winegarden, *supra* note 231 at 5, 18–23; Perkins, *supra* note 235, at 423; Shaywitz, *supra* note 235.

257. *See* Winegarden, *supra* note 231, at 5.

258. UNITED STATES SENATE COMMITTEE ON FINANCE, LETTER TO JOHN C. MARTIN, CEO, GILEAD SCIENCES, INC. (2014).

259. Alex Keown, *New Report Accuses Gilead (GILD) of Putting Profit Ahead of Patients*, BIOSPACE (Dec. 2, 2015, 5:54 PM) <http://www.biospace.com/News/new-report-accuses-gilead-of-putting-profit-ahead/401541> (citing Senator Ron Wyden and Senator Chuck Grassley as opponents of Gilead, who believe Gilead cannot justify the high prices of its drugs by using research and development or the multi-billion-dollar acquisition of Pharmasset, Inc.).

260. Paris, et al., *New Health Technologies: Managing Access, Value and Sustainability*, ORG. FOR ECON. CO-OPERATION & DEV. 93 (2017), <http://g8fip1kplyr33r3krz5b97d1.wpengine.netdna-cdn.com/wp-content/uploads/2017/01/OECD-on-new-drugs-and-pricing.pdf>.

261. *The Top 10 Emerging Blockbusters: Billion Dollar Molecules*, C&EN SUPPLEMENT 10 (2014), <https://cen.acs.org/content/dam/cen/supplements/CEN-supplement092014.pdf>.

262. Mark Terry, *A Look at the 5 Most Profitable Biopharma Companies*, BIOSPACE (Jun. 20, 2017), <http://www.biospace.com/News/a-look-at-the-5-most-profitable-biopharma/460555> (showing that Gilead already has one of the highest profit margins of any company).

263. Alexander Gaffney, *Report: Phase III Clinical Trials Behind Increase in the Cost of Pharmaceuticals*, REG. AFFS. PROFS. SOC'Y (Apr. 25, 2012), <http://www.raps.org/focus->

highly regulated process likely cost Gilead hundreds of millions of dollars.²⁶⁴

Other costs likely abound. Although Gilead's manufacturing and other expenditures associated with Sovaldi are generally unknown,²⁶⁵ one may project the basic economic costs that apply to all pharmaceutical companies onto Gilead.²⁶⁶ It is estimated that only one in every 10,000 new compounds will be FDA approved, and out of those, five of them will make enough profit to justify the investment.²⁶⁷ If development of new medicine costs approximately \$5 billion, this amount begins to multiply when also considering the cost of the drugs which fail mid-development, or the cost of developing multiple drugs.²⁶⁸ Gilead did not develop Sovaldi, but Gilead represents an innovative company trying to create new antiviral medications.²⁶⁹ While, it takes close to fifteen years to develop a new drug,²⁷⁰ a pharmaceutical company's revenue may only derive from any drug it already invented over that time period.²⁷¹ As development costs grow more expensive every year, pharmaceutical companies like Gilead will continue to rely on high revenues to conduct R&D.²⁷²

C. Gilead's Willingness to Lower Drug Prices Overseas, and Active Participation in Sovaldi-Distributing Charities, Provide Evidence that

online/news/news-article-view/article/1359/.

264. *Id.*

265. Stephen Barlas, *The Clinical Trial Model is Up for Review*, NAT'L CTR. FOR BIOTECHNOLOGY INFO., (Oct. 29, 2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4189694/>.

266. *Economics for Pharmaceutical Management*, MGMT. SCI. FOR HEALTH 1, 14 (2012), <https://www.msh.org/sites/msh.org/files/mds3-ch10-pharmoeconomics-mar2012.pdf> (showing general economic costs that apply to pharmaceutical companies).

267. Timothy O'Shea, *The Unusual Discovery of 10 Commonly Prescribed Medications: Part 1*, PHARMACY TIMES (Sept. 11, 2017), <http://www.pharmacytimes.com/contributor/timothy-o-shea/2017/06/the-unusual-discovery-of-10-commonly-prescribed-medications-part-1>.

268. Matthew Herper, *The Cost of Creating a New Drug Now \$5 Billion, Pushing Big Pharma to Change*, FORBES (Aug. 11, 2013), <https://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine/#78910eee13c3>.

269. Avik Roy, *The Sovaldi Tax: Gilead Can't Justify the Price It's Asking for Hepatitis C Therapy*, FORBES (Jun. 17, 2014), <https://www.forbes.com/sites/theapothecary/2014/06/17/the-sovaldi-tax-gilead-cant-justify-the-price-its-asking-americans-to-pay/#549777555670>.

270. Roxane Nelson, *Why Are Drug Costs So High In The United States?*, MEDSCAPE (Sept. 11, 2017), http://www.medscape.com/viewarticle/835182#vp_8.

271. Ransdell Pierson, *Big Pharma is Innovating by Selling Old Drugs – and Making a lot of Money in the Process*, BUS. INSIDER (May 4, 2014), <http://www.businessinsider.com/r-big-pharma-stands-to-profit-by-cleaning-out-its-medicine-chests-2014-04>.

272. Herper, *supra* note 268.

Gilead's Behavior was not selfishly motivated.

Gilead demonstrated an interest in helping as many HCV patients as possible through its philanthropic endeavors.²⁷³ Opponents of Gilead argue that low prices of Sovaldi in foreign countries demonstrates that Gilead set the price of Sovaldi unconscionably high in the U.S.²⁷⁴ However, those arguments ignore the circumstances under which pharmaceuticals can be priced so low in countries such as Egypt and India.²⁷⁵ Gilead's marketing decisions reflect the differing laws among nations,²⁷⁶ and the lower prices offered in third world countries may, in part, be attributed to Gilead's generosity.²⁷⁷

Turning to two instances of price differentiation, a twelve-week treatment regimen of Sovaldi costs \$57,000 in the United Kingdom and \$55,000 in Canada.²⁷⁸ This discrepancy in pricing may be explained by the significantly different laws between the United States and these two countries.²⁷⁹ In the U.S., for example, Medicare is not legally permitted to negotiate with drug manufacturers.²⁸⁰ This is highlighted in Part IV B of this paper. The U.K. and Canada both operate single-payer health care, under which the government *can* negotiate drug prices directly with foreign manufacturers to attain discounted prices that it provides to its citizens at a uniform cost.²⁸¹ Furthermore, the United Kingdom's National Institute for Health and Care Excellence (NICE) evaluates every new drug and decides whether the U.K.'s healthcare system should pay for it. In 2013, NICE defended Gilead,

273. Maggie Fick & Ben Hirschler, *Gilead Offers Egypt New Hepatitis C Drug at 99 Percent Discount*, REUTERS (Mar. 21, 2014), <http://www.reuters.com/article/us-hepatitis-egypt-gilead-sciences/gilead-offers-egypt-new-hepatitis-c-drug-at-99-percent-discount-idUSBREA2K1VF20140321>(discussing Gilead's offer to supply Egypt at 99% discount to the US price).

274. Roy, *supra* note 269.

275. Fick & Hirschler, *supra* note 273; John LaMatinna, *When it Comes To Abusive Drug Pricing, Don't Confuse Shkreli for Hep C Drugs*, FORBES (July 19, 2017), <https://www.forbes.com/sites/johnlamattina/2017/07/19/when-it-comes-to-abusive-drug-pricing-dont-confuse-shkreli-with-hep-c-drugs/#3def1a34af68>.

276. Frederick M. Abbott, *Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health*, 6 U.C. IRVINE L. REV. 281, 283–85 (2016).

277. LaMatinna, *supra* note 275 (discussing Gilead should be congratulated for lowering prices in areas with a high rate of Hep C infections like India and Egypt).

278. LaMatinna, *supra* note 275; *Sovaldi: Who's to Blame*, *supra* note 24.

279. Aaron E. Carroll & Austin Frakt, *The Best Health Care System in the World: Which One Would You Pick?*, N.Y. TIMES (Sept. 18, 2017), <https://www.nytimes.com/interactive/2017/09/18/upshot/best-health-care-system-country-bracket.html>.

280. Michael Hiltzik, *Allowing Medicare to Negotiate Drug Prices is a Popular Solution to Healthcare Costs. But it May Not Work*, L.A. TIMES (Jan. 11, 2017), <http://www.latimes.com/business/hiltzik/la-fi-hiltzik-medicare-negotiate-20170111-story.html>.

281. *Sovaldi: Who's to Blame*, *supra* 24; Fick & Hirschler, *supra* note 273.

“Charging less for Sovaldi in the U.K. was reasonable because it is consistent with differential pricing and with the rules established by NICE.”²⁸²

Meanwhile, the U.S. spends more money on healthcare, *and* plays host to significantly more R&D for novel drugs, than anywhere else in the world.²⁸³ As a result, foreign countries with universal healthcare systems largely escape the capital costs, manufacturing costs, malpractice litigation, or any of the extremely high costs associated with developing a new drug in the U.S.²⁸⁴

Finally, Gilead’s domestic and international efforts to ensure access to Sovaldi challenge opponents’ characterization of Gilead as an unethical entity. Gilead has historically made its products available in impoverished countries.²⁸⁵ In 2011, Gilead became the first pharmaceutical company to form a deal with the United Nations-backed organization, Medicines Patent Pool (MPP), founded with the purpose of increasing access to HIV treatment.²⁸⁶ In order for inexpensive versions of Gilead’s HIV therapies to be manufactured and distributed in poor countries, Gilead donated four of its HIV-therapy patents to MPP.²⁸⁷ Moreover, in 2016, it was revealed that Gilead provides the country of Georgia with Sovaldi at little to no cost after Georgia’s Health Minister asked Gilead for help in eradicating HCV in Georgia altogether.²⁸⁸ In September 2014, Gilead announced that it granted a license to several Indian companies to produce a less expensive, generic version of Sovaldi and Harvoni to distribute in 112 developing countries.²⁸⁹

Gilead also proved its devotion to ensuring access to Sovaldi in resource-limited settings in the United States.²⁹⁰ The company developed a Hepatitis

282. *Sovaldi: Who’s to Blame*, *supra* note 24.

283. Susan Brink, *What Country Spends the Most (and Least) On Health Care Per Person?*, NPR (Sept. 11, 2017), <http://www.npr.org/sections/goatsandsoda/2017/04/20/524774195/what-country-spends-the-most-and-least-on-health-care-per-person>; *Biopharmaceutical Spotlight*, INT’L TRADE ADMIN., <https://www.selectusa.gov/pharmaceutical-and-biotech-industries-united-states> (last visited Dec. 5, 2017).

284. *Biopharmaceutical Spotlight*, *supra* note 283.

285. *Sovaldi: Who’s to Blame*, *supra* note 24; *Gilead Announces New Agreement with Medicines Patent Pool for Access to Medicines in Developing World Countries*, GILEAD SCI, INC. (July 24, 2014), <http://www.gilead.com/news/press-releases/2014/7/gilead-announces-new-agreement-with-medicines-patent-pool-for-access-to-medicines-in-developing-world-countries>.

286. *Sovaldi: Who’s to Blame*, *supra* note 24; *Gilead Announces New Agreement*, *supra* note 285.

287. *Sovaldi: Who’s to Blame*, *supra* note 24.

288. *Bloomberg: Gilead Provides Georgia with Sovaldi for Free, Claiming Virus Could be Eliminated in 10 Years or Less*, BUS. POL. INSIGHTS (Mar. 7, 2016), <http://bpi.ge/index.php/bloomberg-gilead-provides-georgia-with-sovaldi-for-free-claiming-virus-could-be-eliminated-in-10-years-or-less/?lang=en>.

289. *Gilead Announces New Agreement*, *supra* note 285.

290. *U.S. Food and Drug Administration Approves Gilead’s Sovaldi (Sofosbuvir) for the*

C treatment access program, that focuses on providing Sovaldi in countries with the greatest HCV burden.²⁹¹ Gilead even created the Support Path Patient Assistance Program in the U.S., which provides Sovaldi and Harvoni at no charge for eligible patients with no other insurance options.²⁹² Additionally, the Sovaldi and Harvoni Co-Pay Coupon Program is expected to provide co-pay assistance to eligible patients with private insurance who need help paying for out-of-pocket treatment costs.²⁹³ Through this program, HCV patients will pay no more than a \$5 co-pay.²⁹⁴ Such patient assistance programs evidence that Gilead has the best interest of HCV patients in mind, wants to use a portion of the recoupment costs to assist impoverished patients across the world, and has not violated the ethical principles of beneficence and justice.²⁹⁵

CONCLUSION

The discovery of Sovaldi is a medical breakthrough and is considered a clinical cure for treating HCV genotype 1 without peg-IFR.²⁹⁶ However, Sovaldi's high price at \$1,000 per pill makes it subject to ethical controversy. Americans do not have a fundamental or inalienable right to Sovaldi treatment. Therefore, although all HCV patients technically have access to the drug, prescriptive barriers, and barriers caused by health insurance companies, make accessing Sovaldi difficult for a large number of HCV patients. Sufficient evidence suggests that Gilead's pricing motivation was ethically sound because the drug's superior quality justifies its price and U.S. law prohibits drug pricing negotiations between the federal government and pharmaceutical companies. Moreover, there is evidence that Gilead's price setting behavior was merely a reflection of the U.S. patent system, which allows innovative pharmaceutical companies to prevent short-run competition on newly developed drugs against generics as a way to later

Treatment of Chronic Hepatitis, GILEAD (Dec. 6, 2013), <http://www.gilead.com/news/press-releases/2013/12/us-food-and-drug-administration-approves-gileads-sovaldi-sofosbuvir-for-the-treatment-of-chronic-hepatitis-c>.

291. *Hepatitis C and Drug Pricing: The Need for a Better Balance*, AMFAR (Sept. 11, 2017), http://www.amfar.org/uploadedFiles/_amfarorg/Articles/On_The_Hill/2015/amfAR%20HC%20Issue%20Brief%20Feb%202015.pdf.

292. *Support Path for Sovaldi and Harvoni*, GILEAD SCI. INC. (Sept. 11, 2017), <http://www.gilead.com/responsibility/us-patient-access/support%20path%20for%20sovaldi%20and%20harvoni%20and%20epclusa>.

293. *Id.*

294. *Id.*

295. *Id.*

296. John Carroll, *Sovaldi: Gilead hits pay dirt with a breakthrough hep. C drug*, FIERCEBIOTECH, <http://www.fiercebiotech.com/special-report/sovaldi-gilead-hits-pay-dirt-a-breakthrough-hep-c-drug> (last visited Dec. 5, 2017).

recoup the millions of dollars they spend during the drug development process. Lastly, Gilead's efforts to lower the price of Sovaldi in developing countries, and participation in charities distributing Sovaldi to low income Americans, provide further evidence that Gilead's pricing decisions were not unethically motivated.