DRUG PRICING & CHALLENGES TO HEPATITIS C TREATMENT ACCESS

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I. HEALTH CARE PROBLEM

Rising health care costs are a major problem in the United States. Over the last ten years, increases in health care costs have driven down real income gains for individuals and increased the federal deficit. If health care spending continues to increase at the same rate, in the year 2082 it will account for nearly fifty percent of the United States’ GDP.¹ The United States spends nearly ninety percent more on health care than many other industrialized nations.² This higher level of spending is not due to a higher prevalence of disease, or a higher rate of patient treatment, rather it is because costs themselves are higher.³ Differential use of new technology is a leading contributor to this difference in spending. The impact of technology on the United States’ growth in health care spending is estimated to be between twenty-five and seventy-five percent.⁴

⁴ Corinna Sorenson et al., Medical Technology as a Key Driver of Rising Health Expenditure: Disentangling the Relationship, 5 CLINICOECONOMICS & OUTCOMES RES. 223, 226 (2013) (analyzing statistics of health care costs and spending).
Drug spending in particular in the United States is higher than in other industrialized nations.\(^5\) Drug costs are higher in the United States in large part due to the higher use of new drugs.\(^6\) Within the drug industry, the use of biotechnology accounts for much of the differences in the cost of new drugs.\(^7\) While biotechnology has led to breakthroughs in patient care—through the development of biologics—it has also driven up health care spending on drugs.\(^8\) Additionally, as insurers attempt to limit spending on high cost drugs, patients often experience decreased access. The aim of this paper will be to utilize the recent case of Hepatitis C biotechnological drug innovations as a case study from which to explore the problem of how biologic drugs are leading to unsustainable increases in national drug expenditures and decreasing access to care.

II. CASE STUDY

Hepatitis C will be utilized as a case study to understand how biotechnology led to problems in high health care spending and limited access to care within the United States. Hepatitis C is among the leading causes of death in the United States.\(^9\) In the United States, 3.7 million people are infected with chronic Hepatitis C.\(^10\) Chronic Hepatitis C infections can be lifelong and lead to severe liver problems including cirrhosis.

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\(^6\) See id. at 859 n.11.

\(^7\) Patricia M. Danzon & Li-Wei Chao, *Cross-National Price Differences for Pharmaceuticals: How Large, and Why?*, 19 J. OF HEALTH Econ. 159, 163 (2000) (evaluating international cost disparities between prescription drugs).


and cancer. The mortality rate from Hepatitis C is increasing. In 2007 alone, 15,106 people died from Hepatitis C in the United States. Finally, not all Hepatitis C infections are identical. There are six different Hepatitis C genotypes, and some are more aggressive or resistant to treatment.

Historically, Hepatitis C treatment has been lengthy and included multiple severe side effects. However, new innovations in Hepatitis C treatment have revolutionized care. In December of 2013, Sovaldi (sofosbuvir) and Olysio (simeprevir) were approved by the United States Food and Drug Administration. The chemical composition of both Sovaldi and Olysio are different than traditional medications in that they are biologics. Biologics are derived from living organisms, and in the case of Sovaldi and Olysio, produced through biotechnology. Biotechnological production involves the use of a living system to manufacture a medication. Biologic drugs also fall under a different regulatory category than traditional medications.

Both Sovaldi and Olysio are prescribed in combination with other drugs to complete an antiretroviral treatment for Hepatitis C. These drugs were the first all oral, 

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14. See Lam, supra note 9 (evaluating the new Hepatitis C drug treatments, cost and effectiveness).
15. See id. at 670 (explaining the history of these newly approved drugs).
16. See Jim Kling, Fresh From the Biotech Pipeline—2013: Despite an Overall Dip in FDA Approvals of New Chemical and Biologic Entities, 2013 Wasn’t a Bad Year for Innovator Drugs, Jim Kling Reports, 32 Nature Biotech. 16 (2014) (analyzing impact of new FDA approved drugs on evolving care for patients).
18. See id. at 215 (describing the process for biologics).
19. See Lam, supra note 9, at 670.
interferon-free treatments with minimal side effects for Hepatitis C. This is groundbreaking because many patients were unable to tolerate the side effects or concurrently prescribed interferon of previous Hepatitis C treatments. While both Sovaldi and Olysio have transformed Hepatitis C treatment, Sovaldi has been shown to be superior. Sovaldi has been demonstrated to have a cure rate of over ninety percent in some populations. Additionally, Sovaldi’s effectiveness has been shown across infection genotypes.

Olysio is slightly less effective than Sovaldi, as it is not recommended to treat Hepatitis C genotype 1a. However, like Sovaldi, Olysio is more effective, better tolerated, safer, and requires a shorter treatment duration than other previous treatments.

The drawback to these revolutionary drugs is that they are extraordinarily costly to the United States’ health care system. Just one pill of Sovaldi costs approximately $1,000. This brings the total cost of the twelve-week treatment to $84,000. Olysio has an estimated cost of $23,600 per month of treatment. However, the treatment duration of Olysio is even longer than Sovaldi at twenty-four to forty-eight weeks. While this is

23 See Lam, supra note 9, at 671.
25 See Lam, supra note 9, at 676.
26 See Senior, supra note 21, at 501 (describing the prices of specific biological products).
27 Id. (detailing more specific information for the cost of sovadi medication).
28 See Alan M. Lotvin et al., Specialty Medications: Traditional and Novel Tools Can Address Rising Spending on These Costly Drugs, 33 HEALTH AFF. 1738 (2014) (explaining the rising costs of drugs for hepatitis C treatment).
29 See Lam, supra note 9 (detailing the duration of specific treatments for Hepatitis C).
very expensive, the primary problem with the pricing is not the price alone, rather it is the combination of the price and the large number of people prescribed the drug. Spending in 2014 on Sovaldi represented seventy-eight percent of all Hepatitis C antiviral drug expenditures.\(^{30}\)

The high costs associated with Sovaldi reflect a combination of the large size of the population treated, the high cost of the drug, and how it has dominated the market due to its superior effectiveness. The total health care expenditure on Sovaldi, in just one year was $6.5 billion, making it the drug with most overall expenditures in the United States in 2014.\(^{31}\) Of this figure, Medicare’s share of this spending was reportedly $4.5 billion dollars.\(^{32}\) The cost to treat the entire population of 3.7 million chronically infected Hepatitis C patients in the United States with Sovaldi, at the estimated rate of $84,000 per patient, would be $310 billion. For comparison, the total spending in the United States on all drugs for 2014 was $360.7 billion.\(^{33}\) At this cost, treating all chronically infected Hepatitis C patients in the United States with Sovaldi is not affordable.

These high costs of innovative Hepatitis C treatments have led to limits in access to treatment for patients with chronic Hepatitis C. There have been reports of some insurers either denying coverage of Sovaldi altogether, or only approving the drug after the patient has documented fibrotic changes in the liver.\(^{34}\) One study demonstrated that approximately twenty-five percent of all patients prescribed Sovaldi were initially denied

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\(^{31}\) See id. at 723. (detailing the total expenditures for 2014 of a specific drug).


\(^{33}\) See Schumock, *supra* note 30, at 717 (listing comparative totals of costs in a macro level).

\(^{34}\) See id. at 731 (highlighting an example of a specific instance of Medicare issue).
insurance coverage for the drug. However, most of these patients were later approved. The disparity between initial and later approval of Sovaldi suggests that some insurance companies have developed an excessively aggressive prior authorization system to limit spending on Sovaldi. However, this strategy appears to be more widely used in the private insurance sector, as patients with Medicare and Medicaid were more likely to be initially approved. However, even Medicare has become more restrictive in coverage determinations. Medicaid has also instituted strict restrictions to accessing Sovaldi. A recent review found that these limitations restricted patient access to Sovaldi beyond that which is recommended by professional organizations. Additional restrictions to Medicaid patients include the requirement of a specialist referral and abstinence from alcohol. These restrictions limit access to persons struggling with alcohol use disorder and persons living in rural areas who may not have access to a specialist that accepts Medicaid.

35 See Albert Do et al., Drug Authorization for Sofosbuvir/Ledipasvir (Harvoni) for Chronic HCV Infection in a Real-World Cohort: A New Barrier in the HCV Care Cascade, 10 PLOS ONE 2 (2015) (explaining specific instance of use of Solvadi in a study).
36 See id. (explaining the information surrounding certain studies and certain drugs).
37 See id. at 12 (detailing strategies around insurance approval and expenditure).
39 See Stacey B. Trooskin et al., Access to New Hepatitis C Drugs: Medicine, Money, and Advocacy, 61 CLINICAL INFECTIONOUS DISEASES 1825, 1827 (2015) (“Sovaldi is being rationed due to expense, and that current pricing is unsustainable for Medicare and Medicaid programs.”).
41 See Lauren A Canary et al., Limited Access to New Hepatitis C Virus Treatment Under State Medicaid Programs, 163 ANNALS OF INTERNAL MED. 226 (2015) (exploring high price and the resulting difficulty in accessing the drugs).
III. REASONS FOR PROBLEM

The high prices of Sovaldi and Olysio are part of a larger issue within health economics of the United States. The reasons for these higher drug prices are related to the high cost of innovation, a free market economy, and a lack of national drug price negotiations in the United States. The cost of bringing a drug to market in the United States has been estimated to be between $92.0-$883.6 million. However, these costs do not reflect the lost investment on drugs that are not effective or do not meet approval standards. These failed investments represent a substantial number of the drugs that are developed. One study found that ninety percent of drugs that entered phase one clinical development did not receive Food and Drug Administration approval. Development of these failed drugs may later be modified to contribute to successful medication. However, much of this investment is lost. In 2012, the total spending in the United States on biomedical/health research was $116.5 billion, spending by private industry represented eighty-six percent of this figure. Therefore, drug pricing reflects not only the high cost of bringing a particular drug to market, but also the even higher costs of other failures in development.

Another factor driving up drug prices in the United States is the nature of the market. The health care market in the United States is consumer driven due to the free market economy and the lack of a single payer government health care system. This consumer-driven health care market creates sensitivity for patient demand in determining what drugs are purchased. Consumers make decisions about which drugs are preferred.
based on access to information about drug innovation. Information is accessed both through widespread utilization of information technology and through direct-to-consumer advertising. The cost of maintaining advertising also contributes to higher drug prices.\textsuperscript{45} Additionally, insured consumers do not make decisions based on price, as their insurance company generally pays the bulk of the cost differential between newer and older drugs.\textsuperscript{46} Therefore, educated consumers often demand the latest or most effective drugs, despite their overall value to that particular patient. For example, a patient with a less complex Hepatitis C medication may demand Sovaldi, despite the fact that an older drug may be just as likely to cure their infection, and at a fraction of the cost. Consequently, the United States uses newer drugs more frequently than other countries.\textsuperscript{47} This trend is mirrored in the increase in Sovaldi use, which has been rapid in the United States as compared to other countries.\textsuperscript{48}

In the United Kingdom, Sovaldi was approved for use in September of 2014.\textsuperscript{49} However, the United Kingdom’s National Health Service did not approve its funding until August of 2015.\textsuperscript{50} By that time, patients in the United States already had access to

\textsuperscript{45}See id. at 178-82 (describing factors contributing to higher prices).


\textsuperscript{48}See Chow & Danzon, supra note 46 (providing usage statistics for Sovaldi).


Sovaldi for almost two years.\textsuperscript{51} The reason for the slow uptake in Sovaldi internationally is largely due to price negotiations. During the delay in funding Sovaldi, the United Kingdom successfully established a thirty-seven percent discount in the price.\textsuperscript{52} The impact of this discount is far reaching, as seventeen other countries set their drug prices based on the United Kingdom’s prices.\textsuperscript{53} Since the United States’ government does not negotiate drug prices for the entire country, once a drug’s safety has been approved it moves into the consumer market, where consumer demand impacts consumption.\textsuperscript{54}

IV. POTENTIAL SOLUTIONS

Initial strategies to contain exorbitant spending for innovative Hepatitis C drugs have been to utilize prior authorization.\textsuperscript{55} Prior authorization has attempted to limit drug access to only the most ill.\textsuperscript{56} While these strategies appear to have been conducted in an overzealous manner, a more sensitive strategy of prior authorization use may be merited, as these drugs do not provide equal value to all patients. Multiple studies have suggested that for some genotypes, new expensive treatments may not be as cost effective as standard of care.\textsuperscript{57} Therefore, limiting newer more expensive treatments to the


\textsuperscript{52} See John P. Rice, Hepatitis C Treatment: Back to the Warehouse, 6 CLINICAL LIVER DISEASE 27, 28 (2015) (providing table of comparative prices).


\textsuperscript{56} See id. at 8 (suggesting prior authorization focuses on need and severity).

\textsuperscript{57} See Sai Zhang et al., Cost-Effectiveness of Sofosbuvir-Based Treatments for Chronic Hepatitis C in the US, 15 BMC GASTROENTEROLOGY 1 (2015) (suggesting Sofosbuvir is not cost-effective due to high cost). See also S Johnson et al., Cost-Effectiveness of Treating Hepatitis C Virus (HCV) Genotype 1 (GT1) Patients with Abbvie 3D (Paritaprevir/Ritonavir/Ombitasvir and Dasabuvir)+/ribavirin Compared
populations for which they have the most value is a reasonable approach to managing the Hepatitis C burden with the limited resources available. However, in developing this approach, it is crucial that prior authorization be applied sensitively to ensure that it does not limit access to care that is truly needed.

Another solution to limiting spending on innovative Hepatitis C drugs is through national price negotiation to lower the price of the new drugs. Internationally, this has been an effective strategy. However, within the United States, employing national price negotiation strategies is more complicated due to the decentralized insurance market. However, the large percentage of Hepatitis C patients on Medicare and Medicaid could be leveraged to negotiate a lower price for this population. Historically, this has been difficult due to the free market structure of the health care system in the United States. As previously discussed, since its launch, Sovaldi’s effectiveness has led to extremely high consumer demand, thus giving the manufacturer little incentive to lower price. Additionally, lowering drug prices causes decreased revenue for pharmaceutical companies and has been linked to decreases in innovation. Subsequently, decreases in innovation leads to a cascade of other negative outcomes such as decreased development of lifesaving technologies. Also, competition is lower when there are fewer drugs in the

\[\text{to Harvoni (Sofosbuvir/Ledipasvir) in the United States}, \text{18 VALUE IN HEALTH A225 (2015)}\]
\(\text{(establishing Abbvie 3d is substantially more cost-effective).} \)
\(\text{See Rice, supra note 52 (suggesting decline of innovation regarding Hepatitis C treatment is inevitable).} \)
\(\text{See Kelvin Chan, Drug Pricing Part 2: The Pharma vs. Health Insurance Showdown, MEDIUM: UNRAVELING HEALTHCARE (Feb. 24, 2016) (discussing tug-of-war between insurers and pharmaceuticals).} \)
\(\text{See Chow & Danzon, supra note 46 and discussion (discussing uptick in Solvaldi demand).} \)
\(\text{See Carmelo Giaccotto et al., Drug Prices and Research and Development Investment Behavior in the Pharmaceutical Industry, 48 J. L. & ECON. 195, 195 (2005) (arguing decreases in revenue decreases R&D).} \)
\(\text{See Robert Adler, Entering a Dark Age of Innovation, NEW SCIENTIST (July 2, 2005),} \)
\(\text{https://www.newscientist.com/article/dn7616-entering-a-dark-age-of-innovation/ (discussing consequences of declines in innovation).} \)
market. Finally, lack of competition maintains upward pressure on prices. Therefore, national price negotiation is not recommended.

In the United States, drug price negotiations occur more frequently through the free market. As more innovative drugs for Hepatitis C are developed, Sovaldi and Olysio will lose their hold on the market due to increased competition, which in turn will drive down prices of all competing drugs. This is already starting to occur. Since the introduction of Viekira Pak and Harvoni in December of 2014, Medicare, Medicaid, and the Veteran’s Administration have been able to negotiate lower prices for Sovaldi. Viekira Pak and Harvoni were demonstrated to have most of the benefits of Sovaldi and to be more cost effective than Sovaldi for certain genotypes. Both Viekira Pak and Harvoni are still very expensive costing $95,000 and $83,319, to complete treatment, respectively. However, market competition remains active and will likely continue to put downward pressure on prices. Continuing to encourage price negotiation through insurers is a fruitful strategy to pursue.

Another approach to managing the both the market and spending would be to place additional limitations on direct-to-consumer advertising, and to increase enforcement of current restrictions. Decreasing direct-to-consumer advertising would have the effect of reducing high costs from advertising that are passed on to consumers.

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63 See Zhang et al., supra note 57. “Sofosbuvir-based treatments for genotype 1 in general are not cost-effective due to its substantial high costs.” Id. at 1. “For genotype 1, sofosbuvir-based treatments are not cost-effective compared to Viekira Pak and Harvoni, although a [thirty percent] reduction in Sofosbuvir price would change this result.” Id.


65 See Lee Ventola, Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic, 36 PHARMACY & THERAPEUTICS 669 (2011) (discussing the beneficial and detrimental effects of DTCPA to the public health) (“The FDA regulates DTCPA, but critics say that the rules are too relaxed and inadequately enforced.”).
In 2005, within the United States, $29.9 billion was spent on direct-to-consumer advertising.\textsuperscript{67} Despite these high costs, the amount of spending related to increased sales is even higher. The proportion of these sales that are related to overprescribing, or prescribing based on innovation rather than value is not known, but is estimated to be high.\textsuperscript{68} Therefore, reducing direct-to-consumer spending would also reduce the impact of consumer demand for newer drugs regardless of value, thereby reducing the market hold of newer drugs. Reducing the market share of newer drugs would also increase competition and drive down prices. Therefore, increased regulation and enforcement of existing regulations on direct-to-consumer advertising is recommended.

Tiered copays have been used as a method of cost containment for other expensive drugs.\textsuperscript{69} These systems generally encourage the substitution of lower cost generics, or, in the case of biologics, biosimilars, for preferred brands.\textsuperscript{70} However, this is a long term cost containment strategy as these relatively new drugs will all continue to be protected from replication via biosimilars through the expiration of their patents, which

\textsuperscript{66} See id. ("The U.S. and New Zealand are the only countries that allow DTCPA that includes product claims."). "Notably, in 2008, 22 of the 27 EU member states voted against proposed legislation that would have allowed even limited “information to patients” to be provided." \textit{Id.}

\textsuperscript{67} See Julie M Donohue, \textit{A Decade of Direct-to-Consumer Advertising of Prescription Drugs}, 357 NEW ENGLAND J. OF MED. 673 (2007) (explaining concerns of advertising that has led to an increased prescription of drugs carrying risk).


\textsuperscript{69} See id. ("A prescription drug plan will usually cover more of the costs of a tier 1 generic prescription. This means tier 1 prescriptions will usually have lower copays and coinsurance amounts.").

\textsuperscript{70} See Adam Cecil, \textit{Understanding Drug Tiers and Prescription Drug Coverage}, POLICYGENIUS (Oct. 14, 2016), https://www.policygenius.com/blog/how-prescription-drug-coverage-works/ (explaining that new drugs and brand name drugs will be placed in tier 3). "Non-preferred and expensive brand-name drugs are usually in this tier. These drugs will cost you a significant amount out-of-pocket." \textit{Id.}
last twelve years.\textsuperscript{71} At twelve years, the United States has the longest patent length for biologics.\textsuperscript{72} In contrast the patent length in the United Kingdom is ten years and in Canada it is eight years.\textsuperscript{73} Decreasing the length of the patents could speed up the process through which biosimilars could be produced. This would also increase competition, further driving down prices. Another limitation to the development of biosimilars is that they are more difficult to produce because they utilize biological systems to produce the drugs.\textsuperscript{74} This biotechnical production process makes biosimilars more expensive to produce and thus leads to reduced savings as compared to more traditional generics.\textsuperscript{75} However, this could be a useful strategy in combination with other efforts.

Clearing the Food and Drug Administration’s backlog of drugs waiting for approval would help this process along. In 2012, there was a backlog of 2,500 new abbreviated drug applications.\textsuperscript{76} Additionally, the average time to approval for a generic

\textsuperscript{71} See Andrew Pollack, \textit{Critics Say 12 Years Is Too Long to Protect Biotech Drugs From Generics}, N.Y. TIMES (Oct. 15, 2009), https://prescriptionsblogs.nytimes.com/2009/10/15/critics-say-12-years-is-too-long-to-protect-biotech-drugs-from-generics/ (explaining that it discourage competitors from developing biosimilars exactly the same as the brand-name drug).

\textsuperscript{72} See Michael Mezher, \textit{Trade Talks Stumble Over Biologics Data Exclusivity}, REGULATORY AFF. PROFS. SOCIETY (2015), http://www.raps.org/Regulatory-Focus/News/2015/02/11/21309/Trade-Talks-Stumble-over-Biologics-Data-Exclusivity/#sthash.vMa7F3dr.dpuf (noting the patent length in other countries compared to the United States).

\textsuperscript{73} See Ahmad Al-Sabbagh, \textit{Development of Biosimilars}, 45 SEMINARS IN ARTHRITIS & RHEUMATISM 512 (2016) (discussing the manufacturing process of biosimilars and the biological systems that need environments in living cells).


\textsuperscript{75} See Evens & Kaitin, supra note 74 (discussing biotechnology’s impact on health care through innovations in science, government activity, business development, and patient care).

\textsuperscript{76} See Brittany La Couture, \textit{Primer: Genetic Drug Approval Backlog}, AM. ACTION FORUM (Mar. 8, 2016), https://www.americanactionforum.org/research/primer-generic-drug-approval-backlog/. Factors contributing to this overload include the relative ease with which manufacturers can obtain generic drug approvals since the passage of the Hatch-Waxman Act, and the lack of an increase in FDA reviewers to process the increased number of applications. See id.
drug was thirty-one months. A process to address this issue is already in place. In 2012, the Food and Drug Administration Safety and Innovation Act was passed. This law included provisions for increased fees to pharmaceutical companies filing for approval. These fees fund efforts to clear the Food and Drug Administration backlog for generic and biosimilar drugs. Fees also fund efforts to accelerate approval times for these same drugs. Due to the limited time since the passage of this law, there is little research evaluating its downstream effects on pricing. Therefore, more research is recommended to monitor the impacts of this legislation and recommend possible changes.

Easing restrictions on the importation of drugs is another possible solution to reducing costs for innovative Hepatitis C drugs. Currently, it is illegal for an individual to import more than a personal ninety-day supply of medication, into the United States. As previously discussed, other countries have successfully negotiated lower prices and will obtain access to lower cost biosimilars faster. Therefore, many people believe that if

77 See id. The goal is to decrease the approval time to ten months or less. See id.
80 See id. User fees may be collected from industry to fund reviews of innovator drugs, medical devices, generic drugs and biosimilar biological products. See id.
81 See id.
82 See id (referencing the Act’s goal to accelerate approval times that had increased to thirty-one months to ten months or less).
83 See Monali J. Bhosle & Rajesh Balkrishnan, Drug Reimportation Practices in the United States, 3 THERAPEUTICS AND CLINICAL RISK MGMT. 41 (2007). A growing number of Americans are choosing to buy medications in other countries, such as Canada and Mexico, due to increasing costs on prescription medications in the United States. See id. Until the United States government reduces medication costs, it may be impossible to stop citizens from buying medications available at lower costs across the border. See id.
84 See supra notes 52-54 and accompanying text. After the United Kingdom established a discount in the price of a drug, seventeen other countries set their drug prices based on the
patients in the United States were to purchase drugs abroad via mail, huge savings could be achieved. However, this logic is flawed. Drugs sold abroad are often manufactured in the same plants as those sold in the United States. In fact, eighty-six percent of drugs sold in the United States are manufactured abroad. Therefore, the United States is already essentially purchasing drugs abroad and is still paying more for the same drugs. This is because drug pricing does not directly stem from the manufacturing costs. In order to avoid high markups related to costs for research/development and advertising, drugs could instead be purchased from international pharmacies, at their in-country negotiated rates. However, this approach is not recommended due difficulties in managing drug safety.

Purchasing drugs through international pharmacies is replete with problems. Over the internet pharmacies could misrepresent their location and where they obtained the medications. Additionally, many countries do not meet the same rigorous standards United Kingdom’s. See id. The United States government, however, does not negotiate drug prices for the entire country, so drugs move into the consumer market where consumer demand impacts consumption and therefore impacts price. See id.

See Bhosle & Balkrishnan, supra note 83 (discussing how many Americans perceive drug reimportation as a cost-cutting strategy).


See Jessica Wapner, How Prescription Drugs Get Their Prices, Explained, NEWSWEEK (Mar. 17, 2017), http://www.newsweek.com/prescription-drug-pricing-569444. In the United States, where the government does not negotiate drug prices for the entire country, estimating what a drug is worth depends largely on the size of the market. See id. A drug with a market of 10,000 or 20,000 patients will be priced very differently from a drug with a market of 1,000 patients, because smaller markets often mean fewer sales. See id.
of drug production and screening at the United States. Problems related to misrepresentation and lower international regulation have been seen in Panama, where the importation of medication from China is legal.

In 2007, 365 people there died from poisoned cough syrup that was manufactured in China. Additionally, purchasing drugs internationally at lower rates has negative downstream market effects, as purchasing drugs internationally would essentially be a backdoor approach to national drug price negotiations. For these reasons international importation of drugs is not recommended.

Shifting how Hepatitis C patients are insured is another potential solution. Some analysts have suggested that even with the high upfront costs, Sovaldi may provide financial value over the long run. This is due to the fact that Hepatitis C has been a historically chronic and expensive illness to treat. Sovaldi shifts the course of the disease, essentially curing it in a short time period. This provides an enormous savings in the form of unneeded expensive medical care later in the Hepatitis C patient’s life. This was demonstrated by Poonsapaya et. al, who found that over fourteen years, treatment with

89 See 21 C.F.R. § 207.1 (stating all drugs manufactured domestically or abroad must meet FDA standards). The regulation accounts for the differences in testing and screening procedures in other countries. See id.
90 See Walt Bogdanich & Jake Hooker, From China to Panama, a Trail of Poisoned Medicine, N.Y TIMES (May 6, 2007), https://www.nytimes.com/2007/05/06/world/americas/06poison.html (discussing Panamanian deaths resulting from imported Chinese poison marketed as glycerin). Panama purchased what was marketed as ninety-nine percent glycerin. See id. Panama had unknowingly mixed the poison into cold medicine, resulting in three-hundred sixty-five deaths. See id.
91 See id. and accompanying text.
93 See Toich, supra note 92 (discussing the high cost of Hepatitis C treatment causing significant strain on the health care system).
new oral Hepatitis C medications is less costly than standard of care. However, since the average person is only employed at the same job for four point six years and thus likely only insured with the same provider for less than four point six years, this does not allow the insurance provider to reap the benefits of the savings. By shifting Hepatitis C patients to a long-term pharmacy benefits provider system, like a modified Medicare Part D program, these savings could be kept in house.

V. RECOMMENDATIONS

The majority of these recommendations have included the involvement of insurance companies. However, a large percentage of people who have Hepatitis C are uninsured. One study estimated that the percentage of people infected with Hepatitis C who were uninsured was thirty percent, while another estimated that it was as high as sixty-five point seven percent. Both estimates used data from prior to the rollout of the Affordable Care Act, and figures since its initiation are not yet available. Additionally, of those people infected with Hepatitis C who were insured, they were less likely to have private insurance. Expansions to Medicaid stemming from the Affordable Care Act are likely to increase insurance coverage to people infected with Hepatitis C, as more than

94 See Poonsapaya et al., *New All Oral Therapy for Chronic Hepatitis C Virus (HCV): A Novel Long-Term Cost Comparison*, 13 COST EFFECTIVENESS & RESOURCE ALLOCATION 1 (2015) (arguing the financial burden of Hepatitis C treatment for a patient lasts fourteen years). By using Hepatitis C drugs such as Sovaldi, patients can save three-thousand dollars a year compared to the standard of care. See id.

95 See Economic News Release: Employee Tenure Summary, BUREAU OF LABOR AND STATISTICS (Sep. 22, 2016), https://www.bls.gov/news.release/tenure.nr0.htm (stating the median employee tenure is four point two years, down from four point six years).


97 See Stepanova, supra note 96. Coverage rates for Medicare/Medicaid are similar between the general population and Hepatitis C patients. See id.
thirty percent of people with Hepatitis C fall below 150% of the federal poverty line.98

Prior to the passage of the Affordable Care Act, Hepatitis C infection was also found to be a significant predictor of being uninsured.99 This may have been, at least partly, due to insurance denial for the preexisting condition of Hepatitis C.100 The changes to limitations for preexisting conditions, brought forth by the Affordable Care Act, will likely also result in an expansion of insurance coverage for people infected with Hepatitis C.

By insuring more people with Hepatitis C, the demand for innovative drugs will likely increase. This increased demand could intensify upward pressure on prices, thus worsening the budgetary impact of innovative Hepatitis C drugs. For these reasons, it is important to take action to curb spending and decrease prices of innovative Hepatitis C medications. A balanced approach is recommended. This approach would include the following: (1) sensitive employment of preauthorization to limit expensive treatments to those for whom it truly provides value, (2) encourage insurance provider price negotiations, (3) increase research on the Food and Drug Administration Safety and Innovation Act’s effect on reducing backlog, (4) increase restrictions on and enforcement of limitations to direct-to-consumer advertising, (5) reduce the length of the biologic patent, and (6) expand insurance coverage and create innovative insurance plans for

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99 See Stepanova, supra note 96 (noting the high correlation between the uninsured and Hepatitis C).
100 See Charitha Gowda, Nearly Half of Hepatitis C Patients on Medicaid Denied Coverage for Life-Saving Drugs, Penn Researchers Report, PENN MED. NEWS (Nov. 16, 2015), https://www.pennmedicine.org/news/news-releases/2015/november/nearly-half-of-hepatitis-c-pat (describing the Hepatitis C patients’ struggles to get coverage for treatments). Penn Medicine researchers found almost half of all Hepatitis C are denied coverage for drugs or therapies. See id. Penn argues payors claim the treatments are not medically necessary, or they claim the patient tested positive for drugs or alcohol. See id.
people infected with Hepatitis C. By adopting this balanced approach, limitations to each individual solution can be managed. Additionally, this approach aims to decrease spending while maintaining innovation and increasing access to these lifesaving treatments.