

12-13-2017

The EpiPen Problem: Analyzing Unethical Drug Price Increases and the Need for Greater Government Regulation

Talal Rashid

Follow this and additional works at: <https://repository.law.miami.edu/umblr>

 Part of the [Food and Drug Law Commons](#), and the [Health Law and Policy Commons](#)

Recommended Citation

Talal Rashid, *The EpiPen Problem: Analyzing Unethical Drug Price Increases and the Need for Greater Government Regulation*, 26 U. Miami Bus. L. Rev. 129 (2017)

Available at: <https://repository.law.miami.edu/umblr/vol26/iss1/7>

This Comment is brought to you for free and open access by University of Miami School of Law Institutional Repository. It has been accepted for inclusion in University of Miami Business Law Review by an authorized editor of University of Miami School of Law Institutional Repository. For more information, please contact library@law.miami.edu.

The EpiPen Problem: Analyzing Unethical Drug Price Increases and the Need for Greater Government Regulation

Talal Rashid*

In recent years, some pharmaceutical companies have started increasing the price of their existing drugs to exorbitant levels. Often, these drugs are medically necessary for patients, who are left to take on the high costs of the medicine. One recent example is Mylan, who raised the price of the EpiPen by four hundred percent, solely for the profit of its own company and to the detriment of consumers who rely on the EpiPen. Similar patterns of drug price increases have occurred in the past and will likely happen again in the future. This Comment will seek to identify the common elements of this pattern of increasing drug prices by looking at the behavior of corporations like Mylan and the way they operate, and it will assess current approaches to resolving this issue by looking at the roles of Congress, the Food and Drug Administration (FDA), and the Federal Trade Commission (FTC). The area of concern—apart from the way patients suffer from drug price increases—is that even after these companies are subjected to Congressional hearings to address their increasing drug prices, receive hefty fines from the FTC, experience bad press, and draw criticism about the issue of increasing drug prices, little change is made to resolve this problem.

At the same time, industrialized nations around the world do not face the issue of increasing drug prices to the extent seen in the

* Senior Notes and Comments Editor, Volume 26, University of Miami Business Law Review; Juris Doctor Candidate 2018, University of Miami School of Law; Bachelor of Arts in Political Science 2014, Florida International University. I would like to thank Professor Frances R. Hill for her invaluable insight and guidance while writing this Comment. I would also like to thank my family and friends for their endless support during my legal education.

United States. Three countries—Canada, Switzerland, and France—have protected their citizens by structuring their healthcare system in a way that gives pharmaceutical companies little room to raise drug prices to high levels. These countries utilize approaches such as implementing a price ceiling, negotiating with pharmaceutical companies by looking at a drug’s therapeutic value, and setting a reassessment standard to periodically check on pharmaceutical companies. To this end, this Comment will look at these approaches in more detail and will analyze how they can be applied to the United States’ own healthcare system in a way that would prevent pharmaceutical companies from raising the prices of their drugs to unethical levels and, ultimately, lower the cost of prescription drugs.

I.	INTRODUCTION	131
II.	THE BEHAVIOR OF THE CORPORATION	132
	A. <i>The Process of Raising Prices</i>	133
	B. <i>Moving Overseas</i>	135
	C. <i>Reaping the Benefits</i>	137
	D. <i>The Role of Advocacy Groups Who Speak for Patients</i>	138
III.	CURRENT APPROACHES TO REMEDYING DRUG PRICE INCREASES	139
	A. <i>The Role of Congress</i>	139
	B. <i>Solutions Offered by Pharmaceutical Companies</i>	141
	C. <i>The Role of the Food and Drug Administration</i>	143
	D. <i>The Role of the Federal Trade Commission</i>	144
IV.	A SOLUTION IN GOVERNMENT PRICE CONTROL	147
	A. <i>Models in Foreign Countries</i>	147
	1. Canada	147
	2. Switzerland	149
	3. France	150
	B. <i>Applying these Methods to the United States</i>	152
	1. <i>Setting a Price Ceiling for Off-Patent Medications</i>	152
	2. <i>Increasing the Negotiation Power of the Government</i>	153
V.	CONCLUSION	158

I. INTRODUCTION

Picture this: Harry, a retired carpenter, has been taking the same drug for more than fifty years to treat his nerve disorder. Suddenly, the price of that drug is quadrupled overnight. Luckily, he is covered by Medicare, which will cover a portion of the cost that he takes every month. However, he will now have to pay three times his original monthly out of pocket cost for the drug. Meanwhile, across the country, Susan, a retired nurse, is dependent on a multiple sclerosis drug that she has been taking since the nineties. The company behind that drug has slowly been increasing the price of that drug over the years and Susan has managed to keep up with her out of pocket cost for the drug. However, this month the company has increased the price of the drug once again. Unfortunately, this time, Susan is no longer able to pay her share of the drug's cost. She will have to go to her neurologist and seek a cheaper alternative, though it will not have as great of relief as the original drug.

These scenarios represent the plight for many Americans: high drug price increases. Increasing prescription drug prices have been at the center of much debate for years now. There is no better example of this than the recent controversy involving the EpiPen. Mylan, the manufacturer behind the lifesaving EpiPen, was criticized nationally for raising the price of the drug by four hundred percent.¹ Critics often argue that there is no need to increase the price of these drugs, while drug manufacturers go to great lengths to justify the price of their drugs. The discussion usually results in Congress confronting drug manufacturers about their high prices, drug manufacturers offering their own short-term solutions to avoid bad press, criticism of the policies of the Food and Drug Administration (FDA) and their part in handing over a monopoly to many of these companies, and the Federal Trade Commission fining some of these companies for anticompetitive behavior. However, all of this does very little to address the problem of drug price increases. In the end, the press forgets about the issue until the next public outcry.

This Comment argues that a greater solution is needed to address this pattern of pharmaceutical drug price increases that is posing real problems. There is research that shows that the United States pays more for drugs than many other developed countries.² Yet, critique of increasing prescription drug prices rarely focuses on what these other countries are

¹ Emily Willingham, *Why Did Mylan Hike EpiPen Prices 400%? Because They Could*, FORBES, <http://www.forbes.com/sites/emilywillingham/2016/08/21/why-did-mylan-hike-epipen-prices-400-because-they-could/> (last updated Aug. 22, 2016).

² See Robert Langreth, Blacki Migliozi, & Ketaki Gokhale, *The U.S. Pays a Lot More for Top Drugs Than Other Countries*, BLOOMBERG (Dec. 18, 2015), <https://www.bloomberg.com/graphics/2015-drug-prices/>.

doing and what sets them apart from the United States. For many of these countries, the government keeps drug prices in check by implementing a price ceiling, negotiating with drug manufacturers, and reassessing pharmaceutical companies after a certain time period to look at the cost-effectiveness of their drug. Opponents of the approaches followed in these countries argue that this government intervention discourages drug manufacturers from engaging in research and development, which results in fewer drugs being developed.³ Although this is true to some extent, there are ways to adopt aspects of these systems to the United States that would avoid this criticism, while lowering the cost of prescription drugs.

This Comment will focus on the issue of high pharmaceutical drug price increases by examining Mylan's EpiPen price controversy and the actions of other pharmaceutical companies that have also taken part in price increases and seeks to identify the common elements of the issue, as well as provide a workable solution to this problem. Part II analyzes the behavior of the pharmaceutical companies and their role in the United States' high drug costs. Part III looks at what is being done to address the issue by examining the role of Congress, the solutions that are being offered by pharmaceutical companies, the role of the FDA in handing over a monopoly to many of these companies, and the role of the FTC in curbing the harmful behavior of pharmaceutical companies that take part in anticompetitive behavior and increase the prices of their drugs. Finally, Part IV suggests a solution to high drug price increases by surveying government price control models of three developed nations—Canada, Switzerland, and France—and applies aspects of these models to the United States, while also addressing critics.

II. THE BEHAVIOR OF THE CORPORATION

Many pharmaceutical companies cite expensive research and developments costs as the reason behind high drug prices. These companies argue that because drug discovery can be so costly, they must raise drug prices to obtain increased profits and reimburse those costs.⁴ Indeed, the cost to develop a new prescription drug that gains marketing

³ See Kevin A. Hassett, *Pharmaceutical Price Controls in OECD Countries*, AM. ENTERPRISE INST. (Aug. 3, 2004), <https://www.aei.org/publication/pharmaceutical-price-controls-in-oecd-countries>.

⁴ Jeffrey Sachs, *The Drug That Is Bankrupting America*, THE HUFFINGTON POST, www.huffingtonpost.com/jeffrey-sachs/the-drug-that-is-bankrupt_b_6692340.html (last updated Apr. 18, 2015).

approval is around \$2.6 billion.⁵ The high cost of research and development largely stems from factors such as large clinical trial sizes and a focus on chronic and degenerative diseases.⁶

Yet, for some pharmaceutical companies, there is an increase in drug pricing, but no research and development cost to justify the price increase. In 2007, Mylan purchased a number of medicines from Merck KGaA, including the EpiPen auto injector.⁷ Today, the EpiPen, which has been around for decades and delivers \$1 worth of the hormone epinephrine, has allowed Mylan to generate a profit of \$1 billion per year.⁸ A detailed look at drug corporations, like Mylan, exposes the harmful behavior of these manufacturers, which ideally should give the federal government leverage in implementing meaningful changes.

A. *The Process of Raising Prices*

The path to increasing drug prices varies among pharmaceutical companies. For Mylan, that plan likely started in 2014, when it created a special, one-time stock grant that would allow its executives to be rewarded if Mylan's earnings and stock price met specific goals by the end of 2018.⁹ According to health data and analytics company, Truven Health Analytics, Mylan began increasing the price of the EpiPen soon after introducing the special grant.¹⁰ Price increases for the company went from twenty-two percent annually to thirty-two percent for 2014 and 2015.¹¹ These figures translate to a price increase from \$300 to \$600 over a period of two years for a two-pack of the EpiPen.¹²

For other companies, increasing drug prices is not a subtle process. In August 2015, Turing Pharmaceuticals acquired Daraprim, a drug used to treat potentially fatal parasitic infections, and increased the price from

⁵ Henry G. Grabowski & Ronald W. Hansen, *Cost to Develop and Win Marketing Approval For a New Drug Is \$2.6 Billion*, TUFTS CTR. FOR STUDY OF DRUG DEV. (Nov. 18, 2014), http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study.

⁶ *Id.*

⁷ Cynthia Koons & Robert Langreth, *How Marketing Turned the EpiPen Into a Billion-Dollar Business*, BLOOMBERG (Sept. 23, 2015, 10:00 AM), www.bloomberg.com/news/articles/2015-09-23/how-marketing-turned-the-epipen-into-a-billion-dollar-business.

⁸ *Id.*

⁹ Gretchen Morgenson, *EpiPen Price Rises Could Mean More Riches for Mylan Executives*, N.Y. TIMES (Sept. 1, 2016), <http://www.nytimes.com/2016/09/04/business/at-mylan-lets-pretend-is-more-than-a-game.html>.

¹⁰ *Id.*

¹¹ *Id.*

¹² Daniel Kozarich, *Mylan's EpiPen Pricing Crossed Ethical Boundaries*, FORTUNE (Sept. 27, 2016), <http://fortune.com/2016/09/27/mylan-epipen-heather-bresch/>.

\$13.50 a tablet to \$750.¹³ Similarly, Rodelis Therapeutics acquired Cycloserine, a drug that treats a highly resistant form of tuberculosis, and increased the price from \$500 for 30 pills to \$10,800.¹⁴ Valeant Pharmaceuticals was also criticized when it increased the price of Glumetza, a diabetes drug, from \$572 to \$3,432 and then increased it to \$5,148 six weeks later.¹⁵ For these companies, acquiring drugs is part of an investment strategy of buying older drugs and then turning them into higher-priced specialty drugs.¹⁶ Critics, like the Infectious Diseases Society of America and HIV Medicine Association, have argued that these sudden price increases are unjustifiable for medically vulnerable patients in desperate need of these medications.¹⁷

The pharmaceutical companies' response to criticism has generally been to divert attention away from these practices. In an interview with CNBC, Mylan's CEO Heather Bresch blamed the increasing price of the EpiPen on the health-care system and criticized it for requiring consumers to pay for both insurance premiums and out-of-pocket prescription medications that can sometimes reach full retail price.¹⁸ In her view, the system was never intended to make the consumers pay list price.¹⁹ Bresch also emphasized the costs Mylan faces, including the costs of manufacturing the product, distributing the product, and investing.²⁰ Other companies like Valeant and Turing have had similar responses, focusing on distracting critics from the price increases by emphasizing patient assistance programs and research and development costs.²¹

¹³ Andrew Pollack, *Drug Goes From \$13.50 a Tablet to \$750, Overnight*, N.Y. TIMES (Sept. 20, 2015), <http://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html>.

¹⁴ *Id.*

¹⁵ Gretchen Morgenson, *How Valeant Cashed In Twice on Higher Drug Prices*, N.Y. TIMES (July 29, 2016), <http://www.nytimes.com/2016/07/31/business/how-valeant-cashed-in-twice-on-higher-drug-prices.html>.

¹⁶ See Pollack, *supra* note 13.

¹⁷ *Id.*

¹⁸ Dan Mangan & Anita Balakrishnan, *Mylan CEO Bresch: 'No one's more frustrated than me' about EpiPen price furor*, CNBC (Aug. 25, 2016), <http://www.cnbc.com/2016/08/25/mylan-expands-epipen-cost-cutting-programs-after-charges-of-price-gouging.html> (last updated Aug. 25, 2016, 4:33 PM).

¹⁹ *Id.*

²⁰ *Id.*

²¹ See Linette Lopez, *A murky part of Valeant's business has suddenly caught everyone's attention — and the company can't be happy about it*, BUSINESS INSIDER (Apr. 29, 2016), <http://www.businessinsider.com/valeant-patient-assistance-programs-2016-4> (discussing Valeant's patient assistance programs and critics questioning why Valeant didn't just lower the prices of drugs that were too expensive for patients); see also Heather Long, *Here's what happened to AIDS drug that spiked 5,000%*, CNN MONEY (Aug. 25, 2016), <http://money.cnn.com/2016/08/25/news/economy/daraprim-aids-drug-high-price/index>.

As part of an investigation by Congress' Committee on Oversight and Government Reform, documents revealed company strategies to deal with critics opposing price increases.²² For Valeant, the public relations strategy was to launch a new patient assistance program called the "Valeant Coverage Plus Program," which was described as an "opportunity to expand patient access and utilization while maximizing value for niche brands."²³ The documents also detailed a public relations approach to increasing prices for orphan drugs—drugs treating rare conditions—and managing these price increases carefully to avoid negative press.²⁴ Turing responded to negative press by reaching out to outside consultants, who suggested that Turing respond to critics by saying it is investing over sixty percent of its revenues into research and development.²⁵ One consultant also suggested announcing a patient assistance program for patients who cannot access its drugs, which would force critics to shift their focus to the healthcare industry.²⁶

B. Moving Overseas

In 2014, Mylan bought Abbott Laboratories' generic drug manufacturing business for more than \$5 billion.²⁷ As a result of that deal, Mylan moved its headquarters to the Netherlands, which has a corporate tax of twenty percent, compared to the United States' thirty-five percent statutory rate.²⁸ Although this deal allowed Mylan to reduce its tax rate, nothing changed within the company—Mylan's operational headquarters are still located in Pennsylvania, along with its main workforce.²⁹ This

html ("Turing has said it needs the profits on the drug in order to fund research and development of new drugs.").

²² See COMM. ON OVERSIGHT AND GOV'T REFORM, 114TH CONG., Documents Obtained by Comm. from Valeant Pharmaceuticals (2016), available at <https://democrats-oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/Memo%20on%20Valeant%20Documents0.pdf>.

²³ *Id.*

²⁴ *Id.*

²⁵ COMM. ON OVERSIGHT AND GOV'T REFORM, 114TH CONG., Documents Obtained by Comm. from Turing Pharmaceuticals (2016), available at <https://democrats-oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/Memo%20on%20Turing%20Documents.pdf>.

²⁶ *Id.*

²⁷ Renae Merle, *EpiPen maker gave CEO more than \$5 million to cover personal U.S. tax bill*, WASH. POST. (Aug. 30, 2016), https://www.washingtonpost.com/news/wonk/wp/2016/08/30/epipen-maker-gave-ceo-more-than-5-million-to-cover-personal-u-s-tax-bill/?tid=a_inl.

²⁸ *Id.*

²⁹ Michael Hiltzik, *Another reason to hate Mylan, which jacked up the price of life-saving EpiPens: It's a tax dodger*, L.A. TIMES (Aug. 23, 2016, 10:45 AM), <http://www.latimes.com/business/hiltzik/la-fi-hiltzik-mylan-inversion-20160823-snap-story.html>.

strategy is known as tax inversion, a phenomenon that has been around since the 1980s.³⁰

Through tax inversion, an independent U.S. company can create or buy a foreign parent company and escape the U.S. tax on worldwide income.³¹ This also allows companies to take advantage of interest deductions for their own affiliates abroad.³² Although Congress tried to crackdown on tax inversion in 2004, a loophole allowed companies, like Mylan, to adopt the tax address of foreign acquisitions.³³ Tax inversion allows pharmaceutical companies to grow amid pressure from the government and insurance companies to control costs and compete with foreign rivals.³⁴ Bresch argued that before the inversion, Mylan found it impossible to maintain competitiveness under U.S. tax rules and criticized the unlevelled playing field in the country, which penalizes U.S.-based companies.³⁵

Tax inversion not only provided Mylan with a way to lower taxes, it was also a useful business strategy. When its shareholders approved the Abbott Laboratories acquisition, many overlooked an anti-takeover clause known as *stichting*.³⁶ A *stichting* is a Dutch legal entity that has no shareholders but may acquire and dispose of assets, grant security, and provide guarantees.³⁷ Through *stichting*, Dutch-listed corporations are allowed to have a separate class of voting shares that allow the holder to have a fixed dividend, with voting shares being given to a foundation established at the time the corporation goes public.³⁸

Mylan set up a *stichting* foundation comprised of a four-man board that would fight against threats to Mylan's interests by having voting

³⁰ Zachary Mider, *Tax Inversion*, BLOOMBERG, <https://www.bloomberg.com/quicktake/tax-inversion> (last updated Mar. 2, 2017, 9:35 PM UTC).

³¹ *Id.*

³² *Id.*

³³ Max Nisen, *Big Pharma Murdered Tax Inversions*, BLOOMBERG (Apr. 6, 2016 1:57 PM), <https://www.bloomberg.com/gadfly/articles/2016-04-06/big-pharma-ruined-tax-inversions-for-everybody>.

³⁴ Jonathan D. Rockoff, *Why Pharma Is Flocking to Inversions*, WALL ST. J. (July 14, 2014, 1:53 PM), <http://www.wsj.com/articles/why-pharma-is-flocking-to-inversions-1405360384>.

³⁵ See Hiltzik, *supra* note 29.

³⁶ Jen Wieczner, *Why Wall Street loves to hate Mylan's CEO*, FORTUNE (Sept. 11, 2015), <http://fortune.com/2015/09/11/mylan-ceo-heather-bresch/>.

³⁷ Robert A. Profusek et al., *Shedding Light on the Dutch "Stichting": The Originals and Purpose of an Obscure but Potentially Potent Dutch Entity*, JONES DAY (Feb. 2016), at 1, <http://www.jonesday.com/files/Publication/f4c70f5c-c1b1-4c3b-8141-b515d8eb472c/Presentation/PublicationAttachment/6f54fc41-e25d-404f-8420-5fdf6c80ad04/Shedding%20Light%20on%20the%20Dutch%20Stichting.pdf>.

³⁸ *Id.* at 2.

shares worth up to fifty percent of the company's voting rights.³⁹ This turned out to be useful when Mylan used the stichting to block Teva Pharmaceuticals' \$40 billion hostile takeover bid for the company, which would have been accepted by common shareholders.⁴⁰ Shareholders—who were in favor of the deal because it would give them a premium of as much as forty-eight percent over their shares' value—were told that Mylan was a stakeholder company, not a shareholder company, and it would consider the interests of employees, patients, and investors.⁴¹ Two shareholders responded by filing lawsuits that claimed references to the anti-takeover clause in the Abbott Laboratories' acquisition were vague and misleading.⁴²

Mylan was one of the last pharmaceutical companies to take advantage of tax inversion. These inversions caught the attention of the Obama administration, which proposed tougher regulations after Abbvie, a pharmaceutical company, tried to buy Ireland's Shire Pharmaceuticals in 2014.⁴³ Similarly, U.S.-based Pfizer Inc. and Ireland-based Allergan abandoned their \$160 billion merger, which would have allowed Pfizer to cut its tax bill by an estimated \$1 billion annually by moving its company to Ireland.⁴⁴ As a result of the U.S. Department of Treasury's new regulations, officials argue that tax inversions appear to be largely over.⁴⁵

C. Reaping the Benefits

Since acquiring the EpiPen and raising its price, Bresch has seen a compensation increase from more than \$2 million to nearly \$19 million.⁴⁶ Similarly, other Mylan executives, including its president and chief commercial officer, have seen their pay increased.⁴⁷ Mylan's stock price also tripled, increasing from \$13.29 in 2007 to a high of \$47.59 in 2016.⁴⁸

³⁹ See Wieczner, *supra* note 36.

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*

⁴³ See Nisen, *supra* note 33.

⁴⁴ Caroline Humer & Ankur Banerjee, *Pfizer, Allergan scrap \$160 billion deal after U.S. tax rule change*, REUTERS (Apr. 6, 2016, 6:54 AM), www.reuters.com/article/us-allergan-m-a-pfizer-idUSKCN0X3188.

⁴⁵ Kristen Hallam, Cynthia Koons and Zachary Tracer, *Pfizer, Allergan \$160 Billion Merger Killed by U.S. Tax Rules*, BLOOMBERG (Apr. 6, 2016), <http://www.bloomberg.com/news/articles/2016-04-06/pfizer-allergan-end-160-billion-merger-amid-new-tax-rules> (Membership to Bloomberg BNA is required to view archival articles).

⁴⁶ Ben Popken, *Mylan CEO's Pay Rose Over 600 Percent as EpiPen Price Rose 400 Percent*, NBC NEWS (Aug. 23, 2016), <http://www.nbcnews.com/business/consumer/mylan-execs-gave-themselves-raises-they-hiked-epipen-prices-n636591>.

⁴⁷ *Id.*

⁴⁸ *Id.*

Gilead Sciences is another company that profited immensely when it introduced expensive life-saving Hepatitis C medications, such as Sovaldi.⁴⁹ Sovaldi costs \$84,000 for a twelve-week treatment, while the manufacturing cost was between \$100 to \$1,400.⁵⁰ As a result of the increasing costs, Gilead's CEO, John C. Martin, saw his compensation grow from \$32.5 million in 2006 to \$192.8 million in 2014.⁵¹

Other pharmaceutical companies, like Valeant, make profit from price increases through price appreciation credits. Drug companies use these credits to raise the cost wholesalers have to pay for a product that they are contracted to distribute.⁵² Under these price appreciation credits, when Valeant raised the price of a drug, it would receive a credit from wholesalers that reflected the impact of those price increases on the wholesalers' inventory.⁵³ In its fourth quarter for 2015, these credits made up twenty-five percent, or \$138 million, of its \$562 million operating cash flow.⁵⁴ According to Adam J. Fein, President of Pembroke Consulting and author of the Drug Channels blog, these credits guaranteed Valeant that it would retain profit from price increases.⁵⁵

D. The Role of Advocacy Groups Who Speak for Patients

While pharmaceutical companies have continued to raise drug prices, patient advocacy groups have remained silent about the issue. Patient advocacy groups are organizations that provide patient and caregiver-related education, advocacy, and support services.⁵⁶ These groups play an important role in educating the public and lobbying the government to increase funding for research and treatment, as well as advocating for legislative changes for their target diseases.⁵⁷ By holding great influence

⁴⁹ William Rice and Frank Clemente, *Gilead Sciences: Price Gouger*, *Tax Dodger*, AMERICANS FOR TAX FAIRNESS (July 2016), <https://americansfortaxfairness.org/new-report-taxpayer-supported-gilead-sciences-is-price-gouging-the-public-then-dodging-taxes-on-the-huge-profits/> (follow "investigative report" in the first sentence of the news report for full document).

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² See Morgenson, *supra* note 9.

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ Susannah L. Rose, *Patient Advocacy Organizations: Institutional Conflicts of Interest, Trust, and Trustworthiness*, *J.L. MED. ETHICS* 680, 680 (2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4107906/> (follow hyperlink next to "doi" at the top of the HHS Public Access page to reach properly paginated PDF).

⁵⁷ Katie Thomas, *Furor Over Drug Prices Puts Patient Advocacy Groups in Bind*, *N.Y. TIMES* (Sept. 26, 2016), <http://www.nytimes.com/2016/09/28/business/furor-over-drug-prices-puts-patient-advocacy-groups-in-bind.html>.

in Washington DC and having multimillion-dollar budgets, these groups have all the necessary tools to make a positive impact on drug pricing.⁵⁸

Critics argue that because patient advocacy groups are funded by the same pharmaceutical companies that increase drug prices, there is a conflict of interest.⁵⁹ For example, the Leukemia and Lymphoma Society receives \$50 million a year from drug makers, which makes up sixteen percent of their funding.⁶⁰ Other groups receive up to twenty-percent of their revenue from drug funding.⁶¹ In exchange for these donations, the patient groups help drug companies by signing up participants for clinical trials, running financial assistance programs, and lobbying Congress to approve drugs or implement favorable legislation.⁶²

For these patient advocacy groups, their discussion with pharmaceutical companies has largely been limited to asking for better treatments or focusing price discussion on insurance companies.⁶³ When certain groups have proposed to review even modest plans to combat drug prices, they have been met with resistance from other patient groups, members of Congress, as well as pharmaceutical companies that donate to their group.⁶⁴ As a result, most remain silent on the issue. Critics have suggested that these patient advocacy groups must limit the relationship between fundraisers and policymakers and fully disclose financial relationships.⁶⁵ Otherwise, they risk losing their independence and, more importantly, the public's trust.⁶⁶

III. CURRENT APPROACHES TO REMEDYING DRUG PRICE INCREASES

A. *The Role of Congress*

Congress has responded to the public outcry about high drug prices by confronting pharmaceutical companies. In 2015, Democratic members of the House Committee on Oversight and Government Reform launched an Affordable Drug Pricing Task Force to address pharmaceutical companies

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ Jayne O'Donnell, *Patient groups funded by drugmakers are largely mum on high drug prices*, USA TODAY (Jan. 21, 2016), <http://www.usatoday.com/story/news/nation/2016/01/21/patient-groups-drug-makers-high-drug-prices/79001722/>.

⁶¹ *Id.*

⁶² *See* Thomas, *supra* note 57.

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *See* Rose, *supra* note 56.

⁶⁶ *Id.*

and their pricing strategies.⁶⁷ Spearheaded by Representative Elijah Cummings (D–MD), these Task Force members have sought to understand why companies increase their drug prices so quickly and with little transparency as to why these drugs have such a high cost.⁶⁸ Similarly, the Senate Special Committee on Aging has also held hearings regarding the sudden increasing prices of medicines that have been on the market for years.⁶⁹

The response from companies has varied. In early 2016, the House Committee on Oversight and Government Reform held a hearing with Valeant Pharmaceuticals, where Committee members accused the company of ruining the reputation of the pharmaceutical industry.⁷⁰ In turn, the company admitted that it bought off–patent medications that had no generic competition and raised the prices for maximum profit.⁷¹ Valeant’s interim CEO Howard Schiller assured the Committee that the company would be abandoning that method.⁷²

Later that year, the Committee held a hearing with Heather Bresch after news of Mylan’s aggressive EpiPen pricing strategy came into the public eye.⁷³ At the hearing, Committee members questioned Bresch about Mylan’s EpiPen price increases, as well as her pay and other company practices.⁷⁴ Bresch responded by defending her company and emphasized that it has expanded access to EpiPens by distributing them for free at schools. In her words, Mylan has found a balance between price and access to the EpiPen.⁷⁵ As a result of that hearing, Mylan made two promises: to extend EpiPen’s shelf life from 18 months to two years and to introduce a \$300 generic version of its product.⁷⁶

⁶⁷ Elizabeth Whitman, *Skyrocketing Prescription Drug Prices: House Democrats Launch Task Force To Tackle Costs, Transparency Issue*, INT’L BUS. TIMES (Nov. 4, 2015), <http://www.ibtimes.com/skyrocketing-prescription-drug-prices-house-democrats-launch-task-force-tackle-costs-2169265>.

⁶⁸ *Id.*

⁶⁹ Alison Kodjak, *Senate Questions ‘Egregious’ Price Hikes For Specialty Medicines*, NPR (Dec. 9, 2015), <http://www.npr.org/sections/health-shots/2015/12/09/458976680/senate-questions-egregious-price-hikes-for-specialty-medicines>.

⁷⁰ Laura Lorenzetti, *How Martin Shkreli Is ‘Trashing’ the Pharma Industry*, FORTUNE (Feb. 4, 2016), <http://fortune.com/2016/02/04/martin-shkreli-valeant-drug-price-hearing/>.

⁷¹ *Id.*

⁷² *Id.*

⁷³ Katie Thomas, *Mylan’s Chief Is Chastised by Lawmakers Questioning EpiPen Pricing*, N.Y. TIMES (Sept. 21, 2016), http://www.nytimes.com/2016/09/22/business/mylan-chief-to-insist-epipen-is-priced-fairly-at-house-hearing.html?_r=0.

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ Brett Norman & Sarah Karlin–Smith, *EpiPen hearing comes up empty*, POLITICO (Sept. 26, 2016), www.politico.com/tipsheets/prescription-pulse/2016/09/epipen-hearing-

Mylan's promises are, in fact, not very promising. An extension of the shelf life of the EpiPen still has no effect on the high cost of the drug. Furthermore, although a \$300 generic EpiPen two-pack sounds like a step in the right direction, this price is still three times the cost of the drug when Mylan acquired its rights in 2007.⁷⁷ As for Valeant, it has still been making headlines for raising its drug prices, although the company claims the price hikes are no longer as significant as they were in the past. Last October, the company raised the prices of several drugs from two to nine-percent of their original price, which Valeant argued was part of their commitment to keep drug prices affordable.⁷⁸ However, that same month, the company was also criticized for raising the price of a lead poisoning treatment from a price of \$950, at the time it was acquired by Valeant in 2013, to \$27,000.⁷⁹ Analysts have argued that these price increases lead them to believe that Valeant still relies on price increases to boost revenue streams.⁸⁰

The outcomes of these House Committee hearings highlight how little help they are in solving the problem of rising drug prices. In addition, these hearings have not resulted in any legislation that addresses the issue of drug price increases. Critics have argued that Committee members have little understanding of drug markets and fail to understand the bigger issue of overall drug costs.⁸¹ According to Ameet Sarpatwari, an instructor at Harvard Medical School, these hearings only serve as a way to release public frustration and fail to institute meaningful systemic reform.⁸²

B. Solutions Offered by Pharmaceutical Companies

In response to public scrutiny, pharmaceutical companies have taken it upon themselves to offer their own solutions. Following backlash over its price of the EpiPen, Mylan said it would offer instant savings cards worth \$300 to patients who pay full price for the drug out of pocket.⁸³ This

comes-up-emptyaddiction-drugs-under-congressional-state-scrutiny-us-hep-c-drug-prices-similar-to-other-countries-216521.

⁷⁷ Michael Hiltzik, *Don't be fooled: Mylan's 'bargain' price for its generic EpiPen conceals a massive price hike*, LA TIMES (Dec. 16, 2016), www.latimes.com/business/hiltzik/la-fi-hiltzik-mylan-generic-20161216-story.html.

⁷⁸ Sy Mukherjee, *How Valeant Is Justifying Its New Kinder, Gentler Drug Price Hikes*, FORTUNE (Oct. 17, 2016), <http://fortune.com/2016/10/17/valeant-new-drug-price-hikes/>.

⁷⁹ Ed Silverman, *Huge Valeant price hike on lead poisoning drug sparks anger*, STAT NEWS (Oct. 11, 2016), <https://www.statnews.com/pharmalot/2016/10/11/valeant-drug-prices-lead-poisoning/>.

⁸⁰ Mukherjee, *supra* note 78.

⁸¹ Norman & Karlin-Smith, *supra* note 76.

⁸² *Id.*

⁸³ Aaron Smith, *Mylan pledges to make EpiPen more affordable*, CNN MONEY (Aug. 25, 2016), <http://money.cnn.com/2016/08/25/news/companies/mylan-epipen/>.

would reduce the price by fifty percent for these patients who have no insurance or those who have a high deductible.⁸⁴ The company also said it would offer financial assistance to low-income families that would allow them to receive the EpiPen two-pack for free.⁸⁵

However, critics have argued that this is simply a public relations fix that fails to address the high price of the drug. According to them, the savings cards would only be used by a fraction of the people who use the EpiPen.⁸⁶ Furthermore, the high cost of the drug would still be paid by the insurer, which is subsequently reflected in higher premiums.⁸⁷ The savings cards also cannot be used by people without insurance or those enrolled in government-funded health programs, like Medicaid.⁸⁸ America's Health Insurance Plans, the leading health insurance lobbying group, said this tactic of implementing patient assistance programs and co-pay support has been used by pharmaceutical companies in the past in an attempt to cover price hikes.⁸⁹

This exact strategy was used in the past by Valeant Pharmaceuticals when it was in the public eye after its price increases. In 2015, Valeant struck a deal with Walgreens to distribute thirty of its products at generic prices, reducing their prices from five to ninety-five percent.⁹⁰ However, the next year, the company began charging those patients a co-pay of \$35 on certain drugs.⁹¹ Opponents of this strategy argued that Valeant was refusing to lower drug prices and was the same company in a new disguise.⁹² Similarly, Mylan's solution of creating a savings card and a financial assistance program does little to help the problem of an expensive EpiPen. Unfortunately, these approaches only put a temporary band-aid on the issue without seeking to fix the underlying issues.

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ Carolyn Y. Johnson, *Why Mylan's 'savings card' won't make EpiPen cheaper for all patients*, WASH. POST (Aug. 25, 2016), <https://www.washingtonpost.com/news/wonk/wp/2016/08/25/under-pressure-mylan-will-expand-patient-assistance-for-epipen/>.

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ See Mangan & Balakrishnan, *supra* note 18.

⁹⁰ Meg Tirrell, *Valeant strikes distribution deal with Walgreens*, CNBC (Dec. 15, 2015), <http://www.cnbc.com/2015/12/15/valeant-strikes-distribution-deal-with-walgreens.html>.

⁹¹ Jen Wiczner, *Valeant's Troubles Aren't Driving It To Lower Drug Prices*, FORTUNE (Aug. 9, 2016), <http://fortune.com/2016/08/09/valeant-earnings-drug-prices/>.

⁹² *Id.*

C. *The Role of the Food and Drug Administration*

In 1984, Congress passed the Hatch–Waxman Act, which governs today’s generic drug approval process.⁹³ The Hatch–Waxman Act was intended to accomplish two goals.⁹⁴ The first goal was to encourage the development of new drugs by allowing innovator drug manufacturers to have patent protection and market exclusivity for a certain time period, allowing them to regain their investment in the development of the drug.⁹⁵ Second, Congress wanted to make sure that, once that patent protection and market exclusivity period was over, consumers were able to access less expensive, generic versions of those innovator drugs.⁹⁶

The latter goal has become the subject of much debate, with critics arguing that the Food and Drug Administration (FDA) has not done its job in assuring that generic drugs are reaching the market in an efficient manner.⁹⁷ There is no better example of this than the EpiPen, which is an off–patent drug with no generic competitor.⁹⁸ According to a report by the Kaiser Family Foundation, as of July 1st 2016, the FDA had 4,036 generic drug applications awaiting approval, with the average approval time being forty–seven months.⁹⁹ However, the FDA’s approval process is not a new problem.¹⁰⁰ Beginning in 2012, the FDA’s generic backlog became such a big issue that the government began charging user fees to generic manufacturers to provide funds to speed up the process.¹⁰¹ As a result of these resources, the FDA moved the Office of Generic Drugs to the FDA’s main campus, hired an additional 1,000 employees, and replaced the office’s information technology system.¹⁰² The FDA argues that this will allow it to reduce the backlog of pending applications and the time required to review generic drug applications for safety.¹⁰³

⁹³ Daniel E. Troy, *Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch–Waxman Amendments)*, U.S. FOOD AND DRUG ADMINISTRATION (Aug. 1, 2003), <http://www.fda.gov/newsevents/testimony/ucm115033.htm>.

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ See Timothy Holbrook, *The real reason the EpiPen and other off–patents are so expensive*, ASSOCIATED PRESS (Aug. 25, 2016), <http://bigstory.ap.org/article/420451f777634194943e6bd3fe26e7b9/real-reason-epipen-and-other-patents-are-so-expensive>.

⁹⁸ *Id.*

⁹⁹ Sydney Lupkin, *EpiPen Controversy Fuels Concerns Over Generic Drug Approval Backlog*, KAISER HEALTH NEWS (Sept. 6, 2016), <http://khn.org/news/epipen-controversy-fuels-concerns-over-generic-drug-approval-backlog/>.

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ *Id.*

Nonetheless, critics are skeptical about whether these changes will truly result in a faster approval time for generics. Last year, U.S. Senator Tom Cotton (R–Ark) wrote a letter to the FDA to complain about there being a decrease in approvals, but an increase in the time it takes the agency to review applications.¹⁰⁴ Similarly, the Association for Accessible Medicines, which educates policymakers about the role of generics in the healthcare system,¹⁰⁵ has said it is cautious about whether there will be an improvement and will wait to see if the FDA’s actions translate to more generics being approved.¹⁰⁶

As for the EpiPen, there is some hope that it will face generic competition in the future, with Teva Pharmaceuticals due to release a generic version of the drug by late 2017 or early 2018.¹⁰⁷ Previously in 2016, Teva’s application for a generic version of the EpiPen was rejected by the FDA due to “certain major deficiencies.” The FDA’s delay in bringing Teva’s generic EpiPen to the market allowed Mylan to avoid a large decline in sales.¹⁰⁸ The effect that a generic EpiPen will have on the price of Mylan’s EpiPen remains to be seen. For now, one thing is for certain—the FDA has done a disservice to consumers by failing to introduce few, if any, generic competitors into the market for drugs like the EpiPen. Since many of these branded drugs have little generic competition,¹⁰⁹ the pharmaceutical companies behind these drugs don’t have much of an incentive to reduce the cost of these drugs. As a result, the FDA has essentially handed over a monopoly to these pharmaceutical companies, who control that specific drug’s market and are left to their free will to raise prices.

D. The Role of the Federal Trade Commission

The Federal Trade Commission (FTC) is another governmental agency that has a significant role in addressing increasing drug prices. The goal of the FTC is to protect customers against business practices that are

¹⁰⁴ Ed Silverman, *FDA still struggling with backlog of generic drug applications*, STAT NEWS (Mar. 2, 2016), <https://www.statnews.com/pharmalot/2016/03/02/fda-generic-drugs/>.

¹⁰⁵ See *generally Facts*, ASSOCIATION FOR ACCESSIBLE MEDICINES (AAM), <http://accessiblemeds.org/#facts> (last visited Mar. 13, 2017).

¹⁰⁶ *Id.*

¹⁰⁷ Ransdell Pierson, Deena Beasley, *Teva says aims to launch EpiPen–like device by 2018 in U.S.*, REUTERS (Sep. 9, 2016), <https://www.reuters.com/article/us-teva-pharm-ind-epipen/teva-says-aims-to-launch-epipen-like-device-by-2018-in-u-s-idUSKCN11F25K>.

¹⁰⁸ Carly Helfand, *FDA swats down Teva’s EpiPen copy, putting Mylan in cruise control*, FIERCEPHARMA (Mar. 1, 2016), <https://www.fiercepharma.com/sales-and-marketing/fda-swats-down-teva-s-epipen-copy-putting-mylan-cruise-control>.

¹⁰⁹ See *Id.* (“With its nemeses sidelined . . . EpiPen could capture about 95% of the blockbuster epinephrine injection market.”).

anticompetitive, to allow consumers to have knowledge about the competitive practices between corporations, and to allow consumers to have a choice between products.¹¹⁰ When it comes to drug price increases, the FTC does not have any power to force a manufacturer to regulate its drug prices.¹¹¹ However, the FTC can protect consumers when a price increase is the result of anticompetitive behavior.¹¹² For example, if there is an illegal anticompetitive agreement between drug manufacturers to increase prices or exclude a drug manufacturer from competing in the market, then the FTC can step in and penalize those who are taking part in the illegal activity.¹¹³

One recent example of the FTC's authority in the pharmaceutical sector is the case of Mallinckrodt, an Ireland-based drug manufacturer. In 2017, Mallinckrodt had to pay a \$100 million settlement with the FTC after the agency concluded that Questcor, a subsidiary of the drug maker, monopolized a drug and then raised its price.¹¹⁴ According to the FTC, Questcor was a major seller of a treatment for infantile spasms and multiple sclerosis and purchased the U.S. rights to a rival medicine from another pharmaceutical company.¹¹⁵ Consequently, Questcor no longer had competitors for its own medicine.¹¹⁶ As a result of its market control, Questcor began raising the price of its drug and this resulted in close to \$1 billion in annual sales.¹¹⁷ Mallinckrodt then acquired Questcor and continued to increase the price of the drug.¹¹⁸ Eventually, this caught the attention of the FTC, who fined Mallinckrodt \$100 million for maintaining the monopoly.¹¹⁹ Furthermore, the FTC required Mallinckrodt to sell off the U.S. rights to the competing drug that Questcor had bought.¹²⁰

Based on the FTC's handling of the Mallinckrodt case, the FTC seems to be an important figure in the discussion of increasing drug prices. The FTC's ability to monitor drug companies and penalize those who take part

¹¹⁰ *About the FTC*, FED. TRADE COMMISSION, <https://www.ftc.gov/about-ftc>.

¹¹¹ Alan Friedman, *From the antitrust mailbag: What can the FTC do about prescription drug price spikes?*, FED. TRADE COMMISSION (May 18, 2015), <https://www.ftc.gov/news-events/blogs/competition-matters/2015/05/antitrust-mailbag-what-can-ftc-do-about-prescription>.

¹¹² *Id.*

¹¹³ *Id.*; see *infra* note 124 for an example of the FTC's ability to penalize an illegal anticompetitive agreement.

¹¹⁴ Sy Mukherjee, *The \$100 Million Settlement That Shows Why Pharma Isn't Afraid to Behave Badly*, FORTUNE (Jan. 21, 2017), <http://fortune.com/2017/01/21/mallinckrodt-ftc-fine-monopoly/>.

¹¹⁵ *Id.*

¹¹⁶ *Id.*

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ *Id.*

¹²⁰ *Id.*

in anticompetitive behavior is a useful resource to have when manufacturers take part in this illegal activity. At the same time, the fact that the FTC's role is limited to overseeing anticompetitive behavior means that the agency alone is not enough to curb drug price increases. There has been discussion that although the FTC is able to obtain large settlements, these settlements pale in comparison to the profit made by the drug manufacturer.¹²¹ For example, Mallinckrodt was faced with a \$100 million fine for monopolizing a drug that brought in one third of its \$3.4 billion net sales in 2016.¹²² Since these fines are not a huge loss for the manufacturer, the company often repeats the illegal behavior and many of them have been repeat offenders of anticompetitive behavior.¹²³

A testament to these critics' concerns is Mylan itself. In 2000, the FTC found that Mylan had agreed to exclusive supply contracts with three suppliers of an ingredient used in manufacturing two anti-anxiety drugs.¹²⁴ The exclusive supply contracts prevented Mylan's competitors from obtaining the ingredients necessary to make the drugs.¹²⁵ Following this, Mylan obtained market exclusivity and began raising the price of its own anti-anxiety drugs.¹²⁶ As a result of this anticompetitive behavior, the FTC sued Mylan and the three suppliers, resulting in a \$100 million settlement.¹²⁷ In 2017, the FTC again opened a preliminary investigation into Mylan after suspecting that the company violated antitrust laws by making minor changes to the EpiPen, which prevented lower-priced competitors from entering the market.¹²⁸ The FTC is concerned about whether Mylan extended its patent by changing dosage levels and if the company entered into any agreements to delay market introduction of cheaper versions of the EpiPen.¹²⁹ The results of the FDA's preliminary investigation, however, remain to be seen.¹³⁰

¹²¹ *Id.*

¹²² *Id.*

¹²³ *Id.*

¹²⁴ Friedman, *supra* note 111.

¹²⁵ *Id.*

¹²⁶ *Id.*

¹²⁷ *Id.*

¹²⁸ David McLaughlin et al., *Mylan Faces U.S. Antitrust Investigation on EpiPen*, BLOOMBERG (Jan. 30, 2017), <https://www.bloomberg.com/news/articles/2017-01-30/mylan-faces-u-s-antitrust-investigation-on-epipen-practices>.

¹²⁹ *Id.*

¹³⁰ *Id.*

IV. A SOLUTION IN GOVERNMENT PRICE CONTROL

The increasing cost of drugs such as the EpiPen speaks to the bigger issue of whether consumers should be willing to accept any price these pharmaceutical companies present to them. According to a study performed by researchers from Harvard Medical School, in 2013, per capita spending on prescription drugs in the United States was higher than nineteen other industrialized nations.¹³¹ Statistics such as this emphasize how important it is to look at the healthcare systems of other countries and see what they are doing differently. An analysis of the approaches taken in three industrialized nations—Canada, Switzerland, and France—reveals that the governments of these countries have a greater role in regulating drug prices by negotiating prices with pharmaceutical companies, as well setting price ceilings to prevent companies from raising prices to egregious levels. More importantly, although these countries have healthcare systems that are different from the United States’—one example being universal healthcare—many aspects of the approaches taken by these countries can still be implemented in the U.S.

A. Models in Foreign Countries

1. Canada

In Canada, drug prices are monitored by the Patented Medicine Prices Review Board (PMPRB).¹³² Created in 1987, the PMPRB acts as an independent, quasi-judicial body that enforces sanctions and price reductions for patented pharmaceutical products.¹³³ The PMPRB limits its power to regulating the price of patented drugs during the duration of their patent time period.¹³⁴ The Board makes sure that drug prices are not excessive by comparing the price of the drug to the prices of existing drugs

¹³¹ Rachel Becker, *If you live in the US, you pay too much for prescription drugs*, THE VERGE (Aug. 23, 2016), <http://www.theverge.com/2016/8/23/12616730/prescription-drug-prices-american-healthcare-cost>. In his book *America's Bitter Pill*, journalist and lawyer, Steven Brill, explains that a report by McKinsey & Company found that overall prescription drug prices in the United States were fifty-percent higher for comparable products than other developed countries. STEVEN BRILL, *AMERICA'S BITTER PILL: MONEY, POLITICS, BACKROOM DEALS, AND THE FIGHT TO FIX OUR BROKEN HEALTHCARE SYSTEM*, 235 (2015). Furthermore, by 2012, the U.S. was spending more than \$280 billion every year on prescription drugs. *Id.* According to Brill, if the U.S. were to pay what other countries pay for the same drugs, it would save \$94 billion a year. *Id.*

¹³² Valerie Paris & Elizabeth Docteur, *Pharmaceutical Pricing and Reimbursement Policies in Canada*, OECD HEALTH WORKING PAPERS, No. 24, OECD PUB. (2006), at 12, http://www.oecd-ilibrary.org/social-issues-migration-health/pharmaceutical-pricing-and-reimbursement-policies-in-canada_346071162287.

¹³³ *Id.* at 12–13.

¹³⁴ *Id.* at 13.

in Canada or to prices in seven of the world's dominant markets, such as France, Switzerland, the United Kingdom, and the United States.¹³⁵ Under the Board's existing rules, the cost of a patented drug cannot exceed the highest price of the same drug in the seven countries.¹³⁶

As for new drugs, the Board assesses the price of these drugs by using a three-tiered scale that evaluates the degree of innovation.¹³⁷ Under the first category, drugs that are a new dosage or form of an existing medicine are considered to have an excessive price if the price does not have a reasonable relationship to the average price of that medicine in similar dosage forms.¹³⁸ Under the second category, drugs that are considered to be a breakthrough or a big improvement over similar existing medicines are excessive if the price is higher than that of comparable products in its therapeutic class and the international median price of that medicine.¹³⁹ Under the final category, drugs that provide little to moderate therapeutic advantage over similar medicines are considered to have an excessive price if the price is higher than similar products in the Canadian market or that drug's international median price.¹⁴⁰

By regulating prices through an agency like PMPRB, Canada has been able to lower its drug prices closer to median international prices.¹⁴¹ For example, in 1987, Canadian prices for patented medicines were higher than the international median price by more than twenty-percent.¹⁴² Following the creation of the PMPRB, the prices began to decrease in the early nineties and eventually stabilized to ten-percent below the median price in seven comparable countries.¹⁴³ Finally, in 2005, the prices of drugs were eight-percent lower than the median price of seven comparable countries.¹⁴⁴

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ *Id.*

¹⁴⁰ *Id.*

¹⁴¹ *Id.* at 15.

¹⁴² *Id.*

¹⁴³ *Id.*

¹⁴⁴ *Id.* Although the PMPRB has been able to regulate the maximum prices of patented drugs, accessibility to these drugs still remains an issue. In Canada, drugs administered by hospitals are covered through universal healthcare, while outpatient prescription drugs are not guaranteed coverage. *Id.* at 17. Canadians are either eligible for federal drug benefits, covered by the health plan provided by their province of residence or they choose private insurance. *Id.* As a result, accessibility of drugs depends on various factors, such as an individual's province or territory, whether they belong to a high-risk or low-income group, among other factors. *Id.* at 66-67. For these reasons, accessibility to prescription drugs varies and the extent to which the PMPRB can ensure that Canadians have access to affordable drugs is limited.

2. Switzerland

In Switzerland, the population is covered by a universal basic health insurance plan that includes drug coverage.¹⁴⁵ Drug coverage under the basic health insurance plan is limited to pharmaceuticals that have gone through an assessment process and are included in a Specialty List.¹⁴⁶ The Federal Office of Public Health (FOPH) regulates the inclusion of these drugs in the Switzerland's universal health insurance plan and oversees the price of covered drugs, whether on or off-patent.¹⁴⁷ A drug is covered if it's approved by Swissmedic (Switzerland's equivalent of the FDA), considered effective and appropriate, and has value-for-money.¹⁴⁸

When determining value-for-money, the FOPH compares at the manufacturer's proposed price to the manufacturer's set price abroad, the drug's therapeutic value compared to other similar medications, and the drug's daily cost or cost per cure compared to similar medications.¹⁴⁹ If the drug produces a therapeutic effect at the lowest possible cost, it is determined to be value-for-money.¹⁵⁰ Similar factors are looked at when the OFSP establishes a maximum price for newly listed drugs, including the price of the drug in foreign countries, such as Germany and the United Kingdom, the effectiveness of the new drug, and research and development costs.¹⁵¹ This same assessment is performed after the patent for the drug expires.¹⁵²

As a result of its price regulation, there is now a smaller gap between the price of drugs in Switzerland and other European countries.¹⁵³ At the same time, studies also show that the cost of Swiss drugs is still greater than other European countries because the prices of drugs are either set higher in Switzerland or the prices decrease in other countries after the drug launches in Switzerland.¹⁵⁴ Nonetheless, after the regulation of drug

¹⁴⁵ Valerie Paris & Elizabeth Docteur, *Pharmaceutical Pricing and Reimbursement Policies in Switzerland*, OECD HEALTH WORKING PAPERS, NO. 27, OECD PUB. (2007), at 12, <https://www.oecd.org/switzerland/38868953.pdf>.

¹⁴⁶ *Id.* at 14. The Specialty List, also known as a positive list, is a list of all the drugs that are covered by Switzerland's basic health insurance. The list includes around 2,500 drugs, which make up 30% of the drugs that are registered in Switzerland. *See Drug Unit*, SWISS NETWORK FOR HEALTH TECH. ASSESSMENT, www.snhta.ch/index.php?id=138&institution=15&type= (last visited Mar. 13, 2017).

¹⁴⁷ Paris & Docteur, *supra* note 145, at 11–12.

¹⁴⁸ *Id.* at 14.

¹⁴⁹ *Id.* at 15.

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

¹⁵² *Id.*

¹⁵³ *Id.* at 22.

¹⁵⁴ *Id.* at 23.

prices in the late nineties, Swiss drug prices are no longer significantly higher than other comparable countries.¹⁵⁵

3. France

In France, the general population is also covered by universal health insurance.¹⁵⁶ The country follows a step-by-step process for covering prescription medicines and setting their price.¹⁵⁷ Following approval to be sold in the market, the drug is then evaluated by the Transparency Committee, which assesses the therapeutic value of the drug and compares it with existing drugs.¹⁵⁸ When assessing the therapeutic value of the drug, the Transparency Committee categorizes the drug into five categories: major improvement, significant improvement, moderate improvement, minor improvement, and no improvement.¹⁵⁹ The Committee is also free to re-evaluate the drug every five years or earlier.¹⁶⁰ When determining a drug's category, the Committee looks at factors such as the drug's effectiveness and possible side effects, its medical benefit, seriousness of the condition it is treating, its preventative or symptomatic properties and its impact on the public's health.¹⁶¹

After the Committee evaluates the therapeutic value, the Health Product Pricing Committee then negotiates the price of the drug with the manufacturer and forms a contract that includes rebates and price re-evaluations.¹⁶² The system of categorizing drugs directly impacts the level of co-payment and the price negotiations, which depend on a drug's effectiveness.¹⁶³ For example, the reimbursement rates for drugs range from thirty-five percent to sixty-five percent.¹⁶⁴ As a result, a drug that falls into one of the first three categories is likely to have a higher reimbursement rate than a drug in the fourth or fifth category.¹⁶⁵ The

¹⁵⁵ *Id.*

¹⁵⁶ Victor G. Rodwin, *The Health Care System Under French National Health Insurance: Lessons for Health Reform in the United States*, 93 AM. J. PUB. HEALTH 31, 31 (2003), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1447687/>.

¹⁵⁷ Philippe Sauvage, *Pharmaceutical pricing in France: a critique*, 14 EUROHEALTH 6, at 6 (2008), <http://apps.who.int/medicinedocs/documents/s20974en/s20974en.pdf>.

¹⁵⁸ *Id.*

¹⁵⁹ *Id.* at 7.

¹⁶⁰ *Id.*

¹⁶¹ Andrea Chipman, *Value-based healthcare in France*, THE ECONOMIST INTELLIGENCE UNIT (2015), at 5, [https://www.eiuperspectives.economist.com/sites/default/files/Value basedhealthcareFrance.pdf](https://www.eiuperspectives.economist.com/sites/default/files/Value%20based%20healthcare%20France.pdf).

¹⁶² Sauvage, *supra* note 157, at 7.

¹⁶³ Chipman, *supra* note 161, at 6.

¹⁶⁴ *Id.*

¹⁶⁵ *Id.*

remaining cost is covered for most French citizens, who have complementary health insurance.¹⁶⁶

The Pricing Committee also sets a maximum price ceiling for medicines that are used for outpatient care and expensive hospital medicines, with innovative drugs being compared with prices in similar countries.¹⁶⁷ For these reasons, the final price of a drug is subject to various factors, including the category it is placed in and the price in similar countries.¹⁶⁸ Furthermore, the contract between the drug manufacturer and the Pricing Committee also includes a payback procedure.¹⁶⁹ The country's parliament approves a budget for the public health insurance system and defines a rate for its pharmaceutical expenditure.¹⁷⁰ When the pharmaceutical expenditure exceeds that rate, the drug manufacturer must offset that cost through a rebate.¹⁷¹ These rebates are based on, among other factors, how innovative each company's product is and its share of the increase in expenditure.¹⁷²

Finally, due to legislation that places importance on cost-effectiveness data, manufacturers are sometimes required to produce additional data after a certain time period.¹⁷³ This data is used to reassess the drug's therapeutic value by looking at the drug's added value related to effectiveness, which is based on the standard used by the Transparency Committee in categorizing drugs.¹⁷⁴ This reassessment can result in price changes, such as a reduction in the reimbursement rates for companies.¹⁷⁵ However, innovative drugs that fall within the first three categories and offer a significant improvement receive the benefit of having a stable price for five years.¹⁷⁶ Overall, as a result of its regulation of drug prices, France has been able to maintain drug prices at a lower level than comparable countries, like Germany, Spain, and the United Kingdom.¹⁷⁷

¹⁶⁶ *Id.*

¹⁶⁷ *Id.*

¹⁶⁸ *Id.*

¹⁶⁹ Sauvage, *supra* note 157, at 7.

¹⁷⁰ *Id.*

¹⁷¹ *Id.*

¹⁷² *Id.*

¹⁷³ Chipman, *supra* note 161, at 6.

¹⁷⁴ *Id.*

¹⁷⁵ *Id.* at 6.

¹⁷⁶ *Id.*

¹⁷⁷ Nathalie Grandfils, *Drug price setting and regulation in France*, INST. FOR RES. AND DOCUMENTATION IN HEALTH ECON., 2 (2008), <http://www.irdes.fr/EspaceAnglais/Publications/WorkingPapers/DT16DrugPriceSettingRegulationFrance.pdf>.

B. Applying these Methods to the United States

1. Setting a Price Ceiling for Off-Patent Medications

One of the main complaints in the discussion of pharmaceutical drug pricing is the increase in the price of drugs that have been on the market for years.¹⁷⁸ Often, the list price for many of these existing drugs rises ten percent or more year after year.¹⁷⁹ One solution to this problem would be for the United States to set up an independent board, as seen in Canada, which would monitor the prices of off-patent medications. In Canada, the PMPRB monitors the price of patent medications by comparing them to seven of the world's most industrialized nations.¹⁸⁰ Similarly, the United States should monitor the prices of off-patent drugs by comparing the prices of these drugs to those in seven countries that have dominant markets like the U.S. Under this system, the U.S. would prevent drug manufacturers from raising the price of an off-patent drug higher than the highest price of a comparable drug in any of the seven countries. Since the United States ranks as paying the highest cost for drugs in the world, with the difference being substantial, this system could lead to significant changes.¹⁸¹ By implementing such a board, drug manufacturers of medications would no longer be able to raise prices to high levels.

Critics of a price control structure argue that a system that regulates the price of patented drugs impedes innovation by discouraging research and development of new medications.¹⁸² A report by the U.S. Department of Commerce concluded that countries that set price controls on new drugs reduce company compensation to levels closer to direct production costs, leaving less revenue for research and development.¹⁸³ As a result, a reduction in research and development impedes health benefits for the citizens of those countries.¹⁸⁴ Furthermore, another study concluded that if countries with price controls on patented drugs were to remove those regulations, research and development expenditure would increase from

¹⁷⁸ Andrew Pollack, *Drug Prices Soar, Prompting Calls for Justification*, N.Y. TIMES (July 23, 2015), <http://www.nytimes.com/2015/07/23/business/drug-companies-pushed-from-far-and-wide-to-explain-high-prices.html>.

¹⁷⁹ *Id.*

¹⁸⁰ See Paris & Docteur, *supra* note 132 at 12–13.

¹⁸¹ Roxanne Nelson, *Why Are Drug Costs So High in the United States?*, MEDSCAPE (Nov. 19, 2014), <http://www.medscape.com/viewarticle/835182>.

¹⁸² See Hassett, *supra* note 3.

¹⁸³ *Pharmaceutical Price Controls in OECD Countries*, U.S. DEP'T OF COM., vii (2004), <http://www.trade.gov/td/health/drugpricingstudy.pdf>.

¹⁸⁴ *Id.*

\$17 billion to \$22 billion.¹⁸⁵ In turn, this would result in newer drugs being developed.¹⁸⁶

However, the price ceiling system that is being argued for in this Comment is different from those seen in other countries, like Canada. Under the United States' price ceiling, the independent board would not set a price ceiling for patented drugs. As stated earlier in this Comment, under the Hatch–Waxman Act, innovator drug manufacturers are given a patent exclusivity period to regain their research and development costs.¹⁸⁷ For these reasons, a price control system in the U.S would focus exclusively on off–patent medications. The idea behind this is that if a medication is off–patent, it is past its patent exclusivity period. As a result, the manufacturer of that drug has regained much its research and development cost during the exclusivity period. By only regulating the price of the drug once it is no longer patent–protected, this would satisfy critics who argue that these price controls discourage the development of newer drugs by reducing a manufacturer's overall revenue.

Many of the drugs that have been subjected to high price increases are those that have expired patents.¹⁸⁸ By implementing a price control through the creation of an independent board, like the PMPRB, the United States would reduce the price of off–patent drugs and prevent companies from marking up drugs that have been on the market for years. As seen in Canada, regulation of patented drugs has allowed prices to stabilize below the median price in comparable countries. If the U.S. were to follow the same system, but only for off–patent medications, like the EpiPen, there would likely be a similar result here.

2. Increasing the Negotiation Power of the Government

One of the other areas of conflict in the conversation about drug price increases is the need for an expansion in the U.S. government's ability to negotiate drug prices with manufacturers. Currently, Medicaid is able to negotiate drug prices with manufacturers directly through the Medicaid Drug Rebate Program.¹⁸⁹ Under this program, manufacturers enter into rebate agreements with the Secretary of the Department of Health and Human Services and pay a rebate when a drug is paid for under a state

¹⁸⁵ Hassett, *supra* note 3.

¹⁸⁶ *Id.*

¹⁸⁷ See Troy, *supra* note 93.

¹⁸⁸ See Justin Fox, *The Strange Case of Off–Patent Drug Price Gougers*, BLOOMBERG (Sept. 9, 2016, 1:37 PM), <https://www.bloomberg.com/view/articles/2016-09-09/the-strange-case-of-off-patent-drug-price-gougers>.

¹⁸⁹ See *Medicaid Drug Rebate Program*, MEDICAID, <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html> (last updated Feb. 15, 2017).

plan.¹⁹⁰ The amount of the rebate is determined by factors such as whether it is an innovator drug, non-innovator drug, or a drug that is a new formulation of a brand name drug, among others.¹⁹¹ For example, an innovator drug manufacturer has to provide a minimum rebate of 23.1% of the average price that the manufacturer receives for sale per unit.¹⁹² As for Medicare Part D, which covers prescription drug coverage, Congress has prohibited the government from negotiating drug prices for Medicare beneficiaries.¹⁹³ Instead, this negotiating power is given to private insurers that have a contract with Medicare, who also obtain rebates.¹⁹⁴

One way to address increasing drug prices would be for Congress to repeal part of the Medicare Modernization Act, which prohibits the government from negotiating drug prices for Medicare Part D beneficiaries.¹⁹⁵ The Congressional Budget Office (CBO) has argued that if the federal government were to negotiate lower prices for Medicare beneficiaries, it would have a harmful effect on federal spending.¹⁹⁶ The CBO based this conclusion on its understanding that the government would not be able to obtain greater discounts than those obtained by the private plans that have a contract with Medicare.¹⁹⁷ Furthermore, the CBO has argued that private plans compete for beneficiaries based on cost and coverage, which means they face the risk of paying for costs that exceed their projections.¹⁹⁸ Other opponents have a similar view, arguing that the government would not be able to obtain greater discounts than the private plans already do.¹⁹⁹

However, there has been great support for allowing the government to negotiate drug prices for Part D beneficiaries. Proponents of this plan argue that if the government was able to negotiate drug prices on behalf of Medicare Part D beneficiaries, it would obtain deeper discounts.²⁰⁰ These

¹⁹⁰ *Id.*

¹⁹¹ *Id.* An “innovator drug” means a multiple source drug that was marketed under an original new drug application (NDA) approved by the Food and Drug Administration. 42 C.F.R. § 447.502 (2017). A “non-innovator drug” is a drug that is not an innovator drug or a multiple source drug and is marketed under an existing NDA. *Id.*

¹⁹² MEDICAID, *supra* note 189.

¹⁹³ Robert Pear, *Medicaid Pays Less Than Medicare for Many Prescription Drugs*, U.S. Report Finds, N.Y. TIMES (Aug. 15, 2011), <http://www.nytimes.com/2011/08/16/us/16drug.html>.

¹⁹⁴ *Id.*

¹⁹⁵ See 42 U.S.C. § 1395w-111 (2017).

¹⁹⁶ Juliette Cubanski & Tricia Neuman, *Searching for Savings in Medicare Drug Price Negotiations*, KAISER FAM. FOUND., at 3 (Jan. 23, 2017), <http://files.kff.org/attachment/issue-brief-searching-for-savings-in-medicare-drug-price-negotiations>.

¹⁹⁷ *Id.*

¹⁹⁸ *Id.*

¹⁹⁹ *Id.* at 2.

²⁰⁰ *Id.*

proponents argue that discounts would be especially beneficial for high-priced drugs that have no competition, which includes many of the drugs that have seen high price increases.²⁰¹ These supporters are correct and the federal government should be allowed to negotiate drug prices for Medicare Part D and obtain the same rebates that are obtained through Medicaid. For example, the rebates obtained by Medicare reduce spending on drugs by nineteen percent, while the rebates obtained by Medicaid reduce spending by forty-five percent.²⁰² By negotiating on behalf of Medicare Part D beneficiaries, as does Medicaid, the government could likely be able to reduce spending on drugs.

Furthermore, under Medicaid, drug companies must pay a greater rebate if the price of their drug rises faster than the general inflation.²⁰³ Since many of these drug prices do end up rising faster than general inflation, these rebates account for more than half of the rebates paid to Medicaid.²⁰⁴ A similar negotiation under Medicare Part D would expand these discounts to an additional group consisting of 30 million older Americans and individuals with disabilities.²⁰⁵

Critics of high drug prices also complain about the lack of transparency when it comes to drug price increases.²⁰⁶ Many of these critics argue that the federal government should have access to the information that the manufacturer believes justifies the high cost.²⁰⁷ Transparency for newly introduced drugs includes payments manufacturers make to doctors for research, meals and entertainment, and consulting and giving promotional speeches.²⁰⁸ In addition, manufacturers have had to disclose the results of their clinical trials.²⁰⁹

²⁰¹ *Id.*

²⁰² Pear, *supra* note 193. Although both Medicaid and Medicare Part D obtain rebates from drug manufacturers, an increase in the price of a drug does have a harmful impact on federal spending for both of these programs. For example, from 2011 to 2015, Medicaid's spending on EpiPen prescriptions increased from \$24.5 million before rebates to \$139.7 million before rebates. See Katherine Young & Rachel Garfield, *Spending and Utilization of EpiPen within Medicaid*, KAISER FAM. FOUND., 2 (Oct. 7, 2016), <http://files.kff.org/attachment/Data-Note-Spending-and-Utilization-of-EpiPen-within-Medicaid>. Similarly, from 2007 to 2014, Medicare Part D's spending on the EpiPen increased from \$7 million before rebates to \$87.9 million before rebates. Juliette Cubanski & Tricia Neuman, *How Much Has Medicare Spent on the EpiPen Since 2007?*, KAISER FAM. FOUND., 1 (Sept. 20, 2016), <http://files.kff.org/attachment/Data-Note-How-Much-Has-Medicare-Spent-on-the-EpiPen-Since-2007>.

²⁰³ Pear, *supra* note 193.

²⁰⁴ *Id.*

²⁰⁵ *Id.*

²⁰⁶ See Pollack, *supra* note 178.

²⁰⁷ *Id.*

²⁰⁸ *Id.*

²⁰⁹ *Id.*

States have also taken it upon themselves to address drug price increases and the lack of transparency. In 2016, Vermont was the first state to require drug manufacturers to give an explanation for large price increases.²¹⁰ The state requires officials to identify drugs that saw price increases of at least fifteen-percent in the previous year and over fifty-percent over the last five years.²¹¹ Following this assessment, the state requires Vermont's attorney general to reach out to drug manufacturers and seek explanations for the increases.²¹² As of now, the law is limited to transparency and doesn't give Vermont the power to cap prices that are excessive, but the state is allowed to fine manufacturers who don't provide information about their price increases.²¹³ However, outside of this Vermont law, when it comes to price increases of existing drugs, there is little transparency about how drug manufacturers implement new prices.²¹⁴

To address the issue of transparency and expand the federal government's negotiation power for both Medicaid and Medicare Part D, an evaluation process should be instituted, like that in Sweden and France. Both of these countries evaluate a drug by analyzing its therapeutic value, comparing them to existing drugs, and/or looking at research and development costs. The government, negotiating for Medicaid and Medicare Part D, should also look at these factors by requiring participating drug manufacturers to disclose such information to them when seeking to be covered by these plans. For example, if a drug offers a high therapeutic value, an increase in the drug rebate should be obtained so that patients are able to have access to these medications at a lower price. At the same time, research and development would also be factored into the rebate paid by companies. By factoring in the cost of research and development of a new medicine, drug manufacturers who spend a large amount of money on research and development and create innovative medicines with a high therapeutic value would pay a lower rebate percentage. Factoring in the cost of research and development would also address the argument that negotiating drugs impedes the creation of new medicines by discouraging research and development.²¹⁵ By rewarding

²¹⁰ Peter Loftus, *Drug Pricing Report Shows Limits of Transparency Push*, WALL ST. J. (Dec. 31, 2016, 9:00 AM), <https://www.wsj.com/articles/drug-pricing-report-shows-limits-of-transparency-push-1483192856>.

²¹¹ *Id.*

²¹² *Id.*

²¹³ *Id.*

²¹⁴ *See id.*

²¹⁵ *See* Rachel Becker, *If you live in the US, you pay too much for prescription drugs*, THE VERGE (Aug. 23, 2016, 7:01 PM), <http://www.theverge.com/2016/8/23/12616730/prescription-drug-prices-american-healthcare-cost>.

drug manufacturers with a lower rebate amount, this increased negotiating power of the government would likely not get in the way of the creation of new, innovating drugs.

In addition, following the evaluation process, the government should use a reassessment standard, such as the kind seen in France. In France, following a certain time period after drug prices are set, manufacturers are sometimes required to produce additional cost-effectiveness data.²¹⁶ The Transparency Committee uses this data to reassess the drug, which can impact its price and the rebate the manufacturer obtains.²¹⁷ The United States should implement a similar reassessment standard for drugs after the government's original negotiations for Medicaid and Medicare Part D.

Currently, under Medicaid, a drug manufacturer has to pay a higher rebate if the price of their drug rises faster than general inflation.²¹⁸ Although this is a useful way to reprimand drug manufacturers for increasing the price of their drugs, a reassessment standard can be a better way to hold manufacturers more accountable for price increases. A reassessment would be limited to those drug manufacturers whose products have seen high price increases following the initial negotiations. Under this reassessment standard, the United States would require these drug manufacturers to justify why they raise the price of their medicines and explain how they come up with the new price. Based on the information received by drug manufacturers, the government would then determine how much of a higher rebate amount the manufacturer should pay for its price increase. At the same time, the information received by manufacturers would have a positive effect on the public's discussion of drug price increases.

As stated in this Comment, drug manufacturers have been guarded about why they increase the price of their drugs. By requiring these manufacturers to release that information once they have implemented a high price increase, the public would finally know their reasoning behind these increases. This can also lead to a more thoughtful dialogue between manufacturers and the public than the kind seen in the past, such as at congressional hearings. Furthermore, a reassessment might act as a deterrence by making drug manufacturers hesitant about raising prices, since manufacturers will know that they will be required to disclose reassessment data once their drugs have reached a high price.

²¹⁶ Chipman, *supra* note 161, at 9.

²¹⁷ *Id.* at 4–5.

²¹⁸ Pear, *supra* note 193.

V. CONCLUSION

When it comes to increasing prescription drug prices, there is a great need for reform in the pharmaceutical industry. However, there is no perfect fix. A solution requires carefully evaluating all of the players affecting the cost of drugs, while keeping in mind that the United States has a healthcare system that is different from those seen in other countries around the world. Furthermore, reform should strike a delicate balance of pleasing both the public and drug manufacturers. One such solution to high drug prices is a system that sets a price ceiling for off-patent medications, increases the negotiation power of the U.S. government by allowing the government to negotiate for Medicare Part D beneficiaries, and requires greater transparency when manufacturers seek to have their drugs covered under Medicaid and Medicare Part D. Although this will not completely alleviate the problem of drug price increases, it is a step in the right direction and will likely result in lower drug prices. By increasing the price of their drugs, pharmaceutical companies have directly impacted the ability of consumers to access drugs and have forced them to seek out alternatives. Ultimately, the United States government must recognize this widespread problem and prioritize the livelihood of Americans across the country.