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A Prescription to Cure the High Cost of Pharmaceuticals in America

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**A PRESCRIPTION TO CURE THE HIGH
COST OF PHARMACEUTICALS IN
AMERICA**

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I. INTRODUCTION

Pharmaceutical drugs are an extremely important part of medical care and integral to maintaining a person's health and wellbeing. Given that most American citizens will have to purchase a pharmaceutical during their lifetime, affordability is an important issue that affects everyone. Pharmaceuticals are supposed to help afflicted Americans, not harm them financially. A dilemma exists when pharmaceuticals are prescribed as necessary to a person's medical care and treatment, but the person cannot afford to purchase them. Pharmaceuticals in the United States should not be cost prohibitive. How can we balance the interests of people who need pharmaceuticals with the interests of pharmaceutical companies? The answer is negotiation. However, this seemingly simple answer does not come without complications. Medicare, the largest buyer of brand-name prescription drugs in the United States, is not allowed to negotiate with pharmaceutical companies. Therefore, this comment will focus on Medicare's inability to negotiate with pharmaceutical companies.

This comment addresses the high price of brand-name pharmaceuticals in the United States and suggests how the price of pharmaceuticals can be lowered. This comment will compare the United States' system, that lacks price controls, to the systems implemented in Canada and the United Kingdom. Both Canada and the United Kingdom allow their governments to negotiate directly with pharmaceutical companies. As a result, the price of brand-name pharmaceuticals in Canada and the United Kingdom are drastically lower than the price of brand-name pharmaceuticals in the United States. In addition to negotiation, Canada and the United Kingdom both regulate pharmaceutical prices. Canada regulates the maximum price of the pharmaceuticals and the United Kingdom regulates the amount of profit pharmaceuticals generate. This comment will argue that the United States government should allow Medicare to negotiate directly with brand-name pharmaceutical companies, referencing both Canada and the United Kingdom as models for regulating the prices of brand-name pharmaceuticals.

This comment proceeds in seven parts. Part I of this comment discusses the pricing of brand-name pharmaceuticals in the United States. This discussion will include the history of Medicare, the prohibition of Medicare directly negotiating with brand-name pharmaceutical companies, Medicare's purchasing process, and a recent example of a brand-name pharmaceutical company increasing the price of their pharmaceutical. Part II of this comment discusses the impact high priced brand-name pharmaceuticals have on consumers. Part III of this comment explains Canada's approach to setting prices for brand-name pharmaceuticals and Part IV explains the approach taken by the United Kingdom when setting prices of brand-name pharmaceuticals. Part V of this comment analyzes and explains how allowing Medicare to negotiate directly with brand-name pharmaceutical companies would decrease the price of brand-name pharmaceuticals. This part of the comment also discusses what processes the United States should implement and addresses arguments against allowing Medicare to negotiate directly with brand-name pharmaceutical companies. Part VI of this comment lists other possible ways to lower pharmaceutical prices in the United States, but explains why allowing Medicare to negotiate directly with brand-name pharmaceutical companies would best achieve that goal. Part VII summarizes and concludes the comment.

II. PHARMACEUTICAL SALES AND PRICING IN THE UNITED STATES

The price of brand-name pharmaceuticals in the United States is higher than any other developed country in the world.¹ In order to grasp the severity of this problem, one must look to some statistics. The International Federation of Health Plans found that people in the United States pay two to six times more than the rest of the world for brand-name pharmaceuticals.² A Reuters analysis showed that the United States pays as much as seven times more

¹ Nadia Kounang, *Why pharmaceuticals are cheaper abroad*, CNN (Sept. 28, 2015, 8:46AM), www.cnn.com/2015/09/28/health/us-pays-more-for-drugs.

² *Id.* (comparing the price of brand-name pharmaceuticals in the United States to the price of brand-name pharmaceuticals in other countries).

than the United Kingdom for some top-selling drugs.³ Prices for top pharmaceuticals increased by 127 percent from 2008 to 2014.⁴ Pharmaceuticals are far outpacing inflation.⁵ Moreover, drug prices have risen approximately 10 percent over a one-year period ending in May 2016.⁶ The inflation rate at that time was only 1 percent.⁷ One reason for the high prices is that Medicare cannot directly negotiate prices with brand-name pharmaceutical companies. Medicare has tremendous bargaining power to negotiate lower prices being that it is the largest buyer of pharmaceuticals in the United States. Because Medicare cannot negotiate, however, pharmaceutical companies place outrageous price tags on their products. The Director of Memorial Sloan Kettering's Center for Health Policy and Outcomes said pharmaceutical companies place high prices on pharmaceuticals simply "because they can."⁸

A. History of Medicare and Its Inability to Negotiate in the United States

In 1965 the Social Security Act established a health insurance program called Medicare.⁹ Medicare consists of four parts, Parts A, B, C, and D.¹⁰ Medicare Part D was created by the Medicare

³ Carolyn Y. Johnson, *Why America pays so much more for drugs*, THE WASHINGTON POST (Feb. 25, 2016), <https://www.washingtonpost.com/news/wonk/wp/2016/02/25/why-america-pays-so-much-more-for-drugs/>.

⁴ Ben Hirschler, *Americans Pay More For Drugs Than Anyone In The World*, THE HUFFINGTON POST (Oct. 12, 2015, 12:21 PM), https://www.huffingtonpost.com/entry/americans-pay-more-for-drugs-than-anyone-in-the-world_us_561bd a8fe4b0e66ad4c89449.

⁵ See Johnson, *supra* note 3.

⁶ Brad Tuttle, *Prescription Drug Prices in America Are Rising Like No Other Industry*, TIME (July 14, 2016), <http://time.com/money/4406167/prescription-drug-prices-increase-why/>.

⁷ *Id.*

⁸ See Kounang, *supra* note 1 (explaining that brand-name pharmaceutical companies place excessive prices on their products because "[w]e have no rational system in the U.S. for managing prices of drugs").

⁹ Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (1935) (amended 1965).

¹⁰ Part A covers medically necessary hospital, skilled nursing facility, home health, and hospice care; Part B covers medically necessary doctor's services such as preventive care, outpatient services, x-rays, and laboratory tests; Part C is not a

Prescription Drug, Improvement, and Modernization Act.¹¹ It amended Title XVIII of the Social Security Act to provide a voluntary prescription drug benefit under Medicare.¹² This federal law was signed by President George W. Bush on December 8, 2003.¹³ The Medicare Prescription Drug, Improvement, and Modernization Act prohibits Medicare from negotiating directly with pharmaceutical companies.¹⁴

B. The Procedure Medicare Utilizes to Purchase Pharmaceuticals
Due to the Prohibition on Negotiating Directly with
Pharmaceutical Companies

The United States bars Medicare from negotiating for lower prices with pharmaceutical companies.¹⁵ Part B and Part D of Medicare deal with the prescription drug market.¹⁶ Part B determines the price of drugs by the average sales price in the previous quarter.¹⁷ Prices under Part D are fixed through private prescription drug plans negotiating with pharmaceutical companies.¹⁸ The prescription drug plans then submit their bids to the Center for Medicare and Medicaid Services (CMS), which determines the purchase price of the drug and

separate benefit, but rather it allows private health insurance companies to give Medicare benefits; Part D provides outpatient prescription drug coverage and is only provided through private insurance companies that have government contracts. See *What does Medicare cover (Parts A, B, C, and D)?*, MEDICARE INTERACTIVE, <https://www.medicareinteractive.org/get-answers/introduction-to-medicare/explaining-medicare/what-does-medicare-cover-parts-a-b-c-and-d> (last visited Nov. 13, 2017).

¹¹ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003).

¹² *Id.*

¹³ *Id.*

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *What does Medicare cover (Parts A, B, C, and D)?*, *supra* note 10.

¹⁷ John B. Kirkwood, Article, *Buyer Power and Healthcare Prices*, 91 WASH. L. REV. 253, 262 (2016) (explaining that “Medicare is a price taker” due to a lack of negotiating with pharmaceutical companies by stating “[i]n essence, what drug companies charged the prior quarter determines what they can charge this quarter”).

¹⁸ *Id.* (explaining how the price Medicare pays for brand-name pharmaceuticals is set).

the price beneficiaries must pay.¹⁹ A Medicare beneficiary then joins and pays premiums to a prescription drug plan to obtain prescription drugs.²⁰ Pharmaceutical companies also negotiate privately with insurance companies and employers. Although the private prescription drug plans can discount the price of the prescription drugs, the discounts would be greater if the largest buyer, Medicare, could negotiate with drug manufacturers.²¹ If Medicare was allowed to negotiate directly with pharmaceutical companies, the prices would decrease as a result of leverage gained from the threat of lost business.

C. Recent Example of a High Priced Brand-name Pharmaceutical in the United States

1. The EpiPen Price Increase

Recently, United States citizens have been outraged by the increase in the price of EpiPen. The drug in EpiPen is epinephrine.²² EpiPens are injected into people who experience anaphylaxis, an allergic reaction that causes airways to close.²³ Over sixty million EpiPens have been dispensed from 1987 to May 2016, indicating that there is a large demand for this drug in the United States.²⁴ Mylan Pharmaceuticals, the manufacturer of EpiPen, has increased the price

¹⁹ Joshua C. Snow, Note, *Reducing Pharmaceutical Fraud: In Search of The Cocktail Prescription*, 41 PUB. CONT. L.J. 1027, 1030 (2012).

²⁰ *Id.* at 1031 (citing Susan Adler Channick, *The Medicare Prescription Drug Improvement and Modernization Act of 2003: Will It Be Good Medicine for U.S. Health Policy?*, 14 ELDER L.J. 237, 246-48 (2006)).

²¹ See Kirkwood, *supra* note 17, at 269.

²² EpiPen is used to treat anaphylaxis which is a potentially life threatening allergic reaction that can occur within a couple of minutes. Anaphylaxis can be caused by allergens such as foods, insect bites, and medications. Anaphylaxis causes skin irritation, swelling of the lips, tongue, and airways. See *Frequently Asked Questions*, EPIPEN, <https://www.epipen.com/about-epipen/faq> (last visited Nov. 13, 2017).

²³ Jana Kasperkevic, *New York investigates EpiPen maker Mylan after price hike of medication*, THE GUARDIAN (Sept. 2, 2016), <https://www.theguardian.com/business/2016/sep/06/epipen-price-hike-mylan-new-york-investigation>.

²⁴ *Frequently Asked Questions*, *supra* note 22, (“EpiPen Auto-Injector has been available for more than 25 years.”).

of this allergy medication by 471 percent since 2007.²⁵ The cost of EpiPen recently rose from \$100 to more than \$600.²⁶ Citizens are worried about this drastic price increase because families often have to purchase multiple EpiPens to keep in different locations such as at school and home.²⁷ Additionally, like other drugs EpiPens have an expiration date and must be refilled before they expire.²⁸ Therefore, if the EpiPen is not used before it expires, the money paid for it is essentially lost.

2. Americans Turn to Canada

A number of Americans have turned to Canada for lower priced EpiPens.²⁹ According to the general manager of the Canadian International Pharmaceutical Association, the price of a single EpiPen in Canada ranges from \$100 to \$145.³⁰ This difference in price is substantial. The price of EpiPen in Canada is approximately \$500 cheaper than the price of EpiPen in the United States. Therefore, a number of Americans have purchased EpiPen from Canadian online pharmacies to avoid high prices in the United States.³¹

3. Mylan Pharmaceuticals' Solution to the Price Increase

Mylan Pharmaceuticals, the manufacturer of EpiPen, responded to the outrage by saying they would offer discounts to customers.³² Mylan Pharmaceuticals' short-term solution to satisfy customers is to offer coupons for up to \$300 to patients who face

²⁵ In 2007 Mylan acquired EpiPen. *Id.*

²⁶ Gillian Mohny, *EpiPen Price Hike Prompts Some US Families to Buy the Drug in Canada*, ABC NEWS (Aug. 31, 2016, 12:30 PM), <http://abcnews.go.com/Health/epipen-price-hike-prompts-us-families-buy-drug/story?id=41769704>.

²⁷ *Id.* (stating that one woman used to keep three or even four EpiPen packs in different areas when her son was a child).

²⁸ *Frequently Asked Questions*, *supra* note 22.

²⁹ *See* Mohny, *supra* note 26.

³⁰ *Id.*

³¹ *Id.*

³² Nathan Bomey, *EpiPen Maker to offer discounts after price hike firestorm*, USA TODAY (Aug. 26, 2016, 7:43 AM), <http://www.usatoday.com/story/money/2016/08/25/epipen-maker-offer-discounts-after-firestorm/89329122/>.

high out-of-pocket costs.³³ Additionally, Mylan Pharmaceuticals stated that they planned to make a generic version of EpiPen so people would not have to pay for the expensive brand-name EpiPen.³⁴ However, there is currently no generic or brand name drug that is similar to EpiPen.³⁵

The Chairman of the House Oversight and Government Reform Committee wrote a letter to the CEO of Mylan Pharmaceuticals. He stated that Mylan has a monopoly over the EpiPen market and their command of the market has given Mylan the ability to charge any price they want for EpiPen.³⁶ The unfortunate result is that consumers must pay the high prices for pharmaceuticals or go without their medication.

³³ *Id.* (“Mylan also said it would double the income level at which families are eligible for assistance in purchasing the medication to 400% of the federal poverty level, which stands at \$24,300 for a family of four.”).

³⁴ The price of the generic EpiPen will cost approximately \$300 for a two pack. A mother who purchases EpiPen for her child was interviewed by ABC News and said the generic price could still be prohibitive to many families. *See* Mohney, *supra* note 26.

³⁵ There is no generic substitute to EpiPen which means that people in need of that medication have no other option for proper treatment. They must purchase the brand-name EpiPen in order to receive the treatment they need. *See* Bomey, *supra* note 32.

³⁶ Letter from Jason Chaffetz, House Oversight and Government Reform Committee Chairman to Heather Bresch, Chief Executive Officer of Mylan, Inc. (Aug. 29, 2016), <http://democrats.oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/2016-08-29%20JC%20and%20EEC%20to%20Bresch-Mylan%20EpiPen%20Pricing.pdf>, (“Mylan has a virtual monopoly over the epinephrine auto-injector market. A national dependence on accessibility to EpiPens has been well established since Mylan’s acquisition of the device in 2007. This command of the market has given Mylan the unbridled ability to increase the price of the two-pack EpiPen.”); *see also* Brad Tuttle, *Prescription Drug Prices in America Are Rising Like No Other Industry*, TIME (July 14, 2016), <http://time.com/money/4406167/prescription-drug-prices-increase-why/> (stating medication is essential so people have little choice but to buy them no matter how much they cost).

III. THE CONSEQUENCES OF HIGH PHARMACEUTICAL PRICES

The EpiPen example is largely demonstrative of the current pharmaceutical market in the United States. The price of pharmaceuticals in the United States is often a large barrier for people in need of treatment. Consumers of pharmaceuticals in the United States often have to decide whether to fill their prescriptions or buy other daily necessities such as food. Some individuals have to decide whether to go bankrupt and obtain their medication or forego their medicine altogether.³⁷ Pharmaceuticals can be cost prohibitive. It is a regular occurrence for people to not fill their prescriptions once they find out the price, and thus sacrifice the treatment they need. Experts estimate that approximately 20 percent of prescribed medications are never filled.³⁸ While there are other reasons that patients do not take or fill their prescriptions, such as side effects and lack of symptoms, the biggest reason is the cost of prescriptions.³⁹ Pharmaceuticals are essential to a patient's health and in extreme situations a patient could die from not taking their prescriptions.⁴⁰ Therefore, the people of the United States must pay a high price for

³⁷ Brendan Murphy, Note, *Getting High on Profits: An Analysis of Current State and Federal Proposals to Rein in Soaring Drug Prices*, 12 J. HEALTH & BIOMED. L. 37, 64-5 (2016) (citing Lee Graczyk, *Americans can't afford U.S. medication, need a safe alternative* (Nov. 12, 2014), <http://thehill.com/blogs/congress-blog/healthcare/223650-americans-cant-afford-us-medication-need-a-safe-alternative>).

³⁸ Christina Sumners, *Why People Aren't Taking Their Prescription Medications*, VITAL RECORD (Mar. 31, 2016), [https://vitalrecord.tamhsc.edu/medication-non-adherence-people-arent-taking-prescription-medications/\(explaining that non-adherence means patients willfully refusing to do what they should\)](https://vitalrecord.tamhsc.edu/medication-non-adherence-people-arent-taking-prescription-medications/(explaining%20that%20non-adherence%20means%20patients%20willfully%20refusing%20to%20do%20what%20they%20should);); *Id.* ("One of the aspects of non-adherence is when the patient doesn't take prescribed drugs according to the provider's instructions. This non-adherence leads to hospitalizations when chronic conditions flare up, and these hospitalizations cost the health care system between \$100 billion and \$289 billion each year.").

³⁹ *Id.* (explaining that even though there are a number of other reasons why a person will not get the pharmaceuticals they need price is the largest deterrent); see also Pauline W. Chen, *When Patients Don't Fill Their Prescriptions*, THE NEW YORK TIMES (May 20, 2010), <http://www.nytimes.com/2010/05/20/health/20chen.html> (explaining patient nonadherence and stating among other reasons affordability is an important factor contributing to nonadherence).

⁴⁰ *Id.* ("Failure to follow prescriptions causes some 125,000 deaths a year and up to 10 percent of all hospitalizations.").

brand-name pharmaceuticals or take a high risk of making their situations worse.

IV. PHARMACEUTICAL PRICING IN CANADA

Canada has significantly lower pharmaceutical drug prices than the United States. In 1987, Canada put the Patented Medicines Review Board in place through amendments to the Patent Act in response to the North American Free Trade Agreement.⁴¹ The Canadian federal government set up the Patented Medicine Prices Review Board (PMPRB).⁴² The PMPRB has a dual regulatory and reporting mandate.⁴³ The Patented Medicine Prices Review Board regulates the price of patented drugs to ensure that the prices are not excessive.⁴⁴ The PMPRB is made up of Board “Staff” and Board “Members.”⁴⁵ The Staff carries out the daily work and is responsible for reviewing prices charged for all patented drugs sold in Canada.⁴⁶ If a price is found to be excessive, the Staff will try to resolve the issue with the patented drug company, but if the price issue is not resolved, the Board Members may hold a hearing.⁴⁷ The Members are

⁴¹ *Mandate and Jurisdiction*, CANADA PATENTED MEDICAL PRICES REVIEW BOARD, <http://pmprb-cepmb.gc.ca/about-us/mandate-and-jurisdiction> (last visited Nov. 13, 2017).

⁴² *Id.*

⁴³ *Strategic Plan 2015-2018: The Role of the PMPRB*, CANADA PATENTED MEDICAL PRICES REVIEW BOARD, <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1197#a11> (last visited Nov. 13, 2017), (explaining that the reporting mandate requires the PMPRB to report to Parliament annually on its price reviews activities, the prices of patented medicines and price trends, and on Research and Development expenditures).

⁴⁴ *Id.* (explaining that the PMPRB “operates independently of Health Canada, which approves drugs for safety and efficacy; other health Portfolio members, such as the Public Health Agency of Canada, and the Canadian Institute for Health Research; and provincial drug plans, which approve the listing of drugs on their respective formularies for reimbursement purposes”).

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ *Strategic Plan 2015-2018: The Hearing Process*, CANADA PATENTED MEDICAL PRICES REVIEW BOARD, <http://www.pmprb-cepmb.gc.ca/en/hearings/the-hearing-process> (last visited Nov. 13, 2017) (explaining that at a hearing the Board acts as a neutral arbiter between parties before the Board, principally the Board Staff and the patentee).

appointed by the Governor-in-Council and are responsible for conducting hearings when a price is allegedly excessive.⁴⁸ The Board Members have the power to reduce the price of the patented drug or order the patented drug company to offset excess revenues, if they find that the price is excessive.⁴⁹

Canada's system is different from that of other countries because they do not have a national purchasing authority to buy patented drugs for the entire population.⁵⁰ Instead, the PMPRB sets price ceilings for all patented drugs.⁵¹ The Patented Medicine Prices Review Board takes several factors into account when setting these ceilings, including the level of therapeutic improvement, domestic prices, prices in seven countries, and changes in the Consumer Price Index.⁵²

Nevertheless, Canada's system of pharmaceutical price controls is not without flaws.⁵³ The largest flaw of Canada's pricing system is that it looks at the sticker prices of the same brand-name pharmaceuticals in other countries.⁵⁴ Canada, looking at the sticker

⁴⁸ *Id.*

⁴⁹ *Patented Medicine Prices Review Board*, GOVERNMENT OF CANADA, <https://www.canada.ca/en/patented-medicine-prices-review.html> (last visited Nov. 13, 2017).

⁵⁰ *Strategic Plan 2015-2018: The Pharmaceutical Environment in Canada*, CANADA PATENTED MEDICAL PRICES REVIEW BOARD, <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1197#a11>, (last visited Nov. 13, 2017).

⁵¹ *Id.*

⁵² The countries Canada compares their pharmaceutical prices with are France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States. *Id.*

⁵³ See generally Karen L. Tang, William A. Ghali, & Braden J. Manns, *Addressing cost-related barriers to prescription drug use in Canada*, 186(4) CMAJ: CANADIAN MEDICAL ASSOCIATION JOURNAL. 276, 276-280 (2014) (explaining that the Patented Medicine Review Board currently compares prices to countries with some of the highest drug prices worldwide and they should instead compare to countries with lower prices in order to lower brand-name pharmaceutical prices in Canada).

⁵⁴ Brendan Murphy, *Note: Getting High on Profits: An Analysis of Current State and Federal Proposals to Rein in Soaring Drug Prices*, 12 J. HEALTH & BIOMED. L. 37, 84 (2016) (citing Sean Davidson, *Drug Price Regulations Need Overhaul to Protect Consumers, Experts Say*, CBC.CA (Sept. 23, 2015), <http://www.cbc.ca/news/health/>

prices of brand-name pharmaceuticals in other countries for comparison, does not take into account the final price the country pays for the pharmaceutical.⁵⁵ In other words, Canada does not take into account the rebates other countries receive from brand-name pharmaceutical companies.⁵⁶ Therefore, the price Canada refers to is not the final price that other countries pay for the brand-name pharmaceutical. Considering other countries' pre-rebate prices, leads to Canadians paying higher prices than the other countries do for the same brand-name pharmaceuticals.⁵⁷

V. PHARMACEUTICAL PRICING IN THE UNITED KINGDOM

In the United Kingdom, the Pharmaceutical Price Regulation Scheme (PPRS) has been in existence since 1957.⁵⁸ In the United Kingdom, the prices of brand-name pharmaceuticals supplied to the National Health Service (NHS) are regulated by either a voluntary agreement or by the Health Service Branded Medicines Regulations.⁵⁹ The voluntary agreement, the Pharmaceutical Price Regulation Scheme (PPRS), is between the Department of Health and the Association of the British Pharmaceutical Industry (ABPI), which deals with the supply of branded drugs to the National Health Service.⁶⁰ The agreement is normally negotiated for a period of five

prescription-drug-prices-1.3239317 (discussing that drug prices for patented drugs are calculated using a median average of prices from other countries, comparing Canada's pharmaceutical price regulations to other countries and assessing the impact of the disparities between them).

⁵⁵ *Id.*

⁵⁶ A rebate is a "return of a portion of a purchase price by a seller to a buyer, usually on purchase of a specified quantity, or value, of goods within a specified period. Unlike discount (which is deducted in advance of payment), rebate is given after the payment of full invoice amount." *Rebate*, DICTIONARY.COM, <http://www.dictionary.com/browse/rebate> (last visited Nov. 13, 2017).

⁵⁷ See Murphy, *supra* note 54.

⁵⁸ *Understanding the 2014 Pharmaceutical Price Regulation Scheme*, THE ASSOCIATION OF THE BRITISH PHARMACEUTICAL INDUSTRY, http://www.abpi.org.uk/our-work/policyparliamentary/Documents/understanding_pprs2014.pdf (last visited Nov. 13, 2017).

⁵⁹ *Id.*

⁶⁰ *Id.*

years and then renegotiated thereafter.⁶¹ The current scheme is the 2014 Pharmaceutical Price Regulation Scheme, which became effective on January 1, 2014.⁶² The agreement regulates the profit that brand-name drug companies can generate, instead of regulating the price of the drugs directly, like some other countries do.⁶³ Any brand-name pharmaceutical company that supplies the NHS with pharmaceuticals can participate in this scheme.⁶⁴

Simply stated, the Pharmaceutical Price Regulatory Scheme regulates the cost of the brand-name pharmaceuticals by limiting the amount of profit pharmaceutical companies may generate.⁶⁵ Pharmaceuticals are then allocated domestically in the United Kingdom through the National Health Service. If pharmaceutical companies are not satisfied with the price negotiated by the Pharmaceutical Price Regulatory Scheme, they can sell their pharmaceuticals privately. Pharmaceutical companies who chose to sell their pharmaceuticals privately automatically fall under the Statutory Scheme which imposes a list price cut of 15 percent on all products.⁶⁶ Even though membership to the Pharmaceutical Price Regulatory Scheme is voluntary, most pharmaceutical companies

⁶¹ *Id.* (explaining that the PPRS is usually negotiated for a period of five years, but has often lasted longer than five years and has only once been terminated before the agreement was to expire).

⁶² The 2014 Pharmaceutical Price Regulation Scheme will terminate on December 31, 2018. *Id.*

⁶³ Murphy, *supra* note 54 (“It regulates the profit that companies can achieve on sales to the NHS, rather than regulating prices directly. However, it does not guarantee profit. Instead, it is based on a range of maximum allowances covering R&D, manufacturing costs, information, sales and marketing, and general administrative costs. These are then subject to a maximum percentage profit. The underlying assessment of profit remains the core basis of the 2014 PPRS.”).

⁶⁴ Pharmaceutical companies who choose not to participate in the PPRS are regulated by a different set of statutes. *Id.* at 4.

⁶⁵ *Id.*

⁶⁶ Aurelie Mahalatchimy, *Reimbursement of cell-based regenerative therapy in the UK and France*, 24(2) *MED. LAW REV.* 234, 234 (2016) (citing The Health Service Medicines (Control of Prices and Supply of Information) (Amendment) Regulations 2013, Statutory Instrument No. 2881) (explaining the scheme pharmaceutical companies follow when they do not participate in voluntary negotiations).

choose to join.⁶⁷ The purpose of the Scheme is to ensure that safe and effective pharmaceuticals are available on reasonable terms with the NHS and to maintain a strong, efficient, and profitable pharmaceutical industry.⁶⁸

VI. ALLOWING MEDICARE TO NEGOTIATE DIRECTLY WITH PHARMACEUTICAL COMPANIES

A. Explanation of How Negotiation Would Lower Pharmaceutical Prices

Allowing Medicare to negotiate directly with pharmaceutical companies is the most effective way to lower the price of pharmaceuticals. Medicare would be able to lower pharmaceutical prices through negotiation because all developed countries that allow negotiation with pharmaceutical companies pay lower prices for pharmaceuticals than the United States. As previously stated, Medicare is the largest purchaser of prescription drugs in the United States.⁶⁹ This gives Medicare significant bargaining power to negotiate price with pharmaceutical companies. Bargaining power in negotiations is the ability of one party to dominate the other due to its influence, power, size, status, or through a combination of other different persuasion tactics.⁷⁰

Moreover, pharmaceutical companies would lower their prices if Medicare negotiated with them because the pharmaceutical companies have an incentive to keep Medicare as a customer. Pharmaceutical companies would lower the price of their pharmaceuticals because there would be a threat of lost business if Medicare did not buy their pharmaceuticals due to the price. If Medicare walked away from a deal because the price of the pharmaceutical was too high, pharmaceutical companies would not

⁶⁷ *Id.*

⁶⁸ *Understanding the 2014 Pharmaceutical Price Regulation Scheme*, *supra* note 58.

⁶⁹ Jeanne Whalen, *Why the U.S. Pays More Than Other Countries for Drugs*, THE WALL STREET JOURNAL (DEC. 1, 2015, 9:27 PM), <https://www.wsj.com/articles/why-the-u-s-pays-more-than-other-countries-for-drugs-1448939481>.

⁷⁰ *Bargaining Power*, BUSINESS DICTIONARY, <http://www.businessdictionary.com/definition/bargaining-power.html> (last visited Nov. 13, 2017).

make any profit. Additionally, pharmaceutical companies would have to find more buyers for their product in an attempt to make up for the lost business of the largest purchaser in the industry. This would prove to be time consuming and use more of the companies' resources. Therefore, it follows that pharmaceutical companies would likely lower the price of pharmaceuticals because a decrease in profit is better than making no profit at all. These pharmaceutical companies could lower their prices to a point where they could still make a profit while making the price attractive to Medicare. The additional business the pharmaceutical companies would receive from Medicare in the future, would justify the reduction in price.

In addition, pharmaceutical companies can still retain their bargaining power. The Centers for Medicare and Medicaid Services (CMS) force prescription drug plans (PDPs) to cover almost all drugs in certain categories.⁷¹ This requirement has a number of effects on the negotiation process.⁷² This gives pharmaceutical companies bargaining power because Medicare would not be able to walk away from a deal if they are required to cover the drug. Additionally, this requirement protects consumers. Consumers would not have to fear that a brand-name pharmaceutical they need will not be covered because of Medicare's ability to negotiate with pharmaceutical companies. If Medicare is required to cover a drug, it has no choice but to purchase the drug.

However, this will only be the case if only one or two drugs are offered on the market. If there are multiple drugs on the market, Medicare can choose to obtain a lower price on a substitute from a pharmaceutical competitor. This will encourage competition among pharmaceutical companies competing for Medicare's business. This competition between pharmaceutical companies would cause the

⁷¹ *Report to Congress: Medicare Payment Policy*, MEDICARE PAYMENT ADVISORY COMMISSION at 401, (March 23, 2016), http://medpac.gov/docs/default-source/reports/mar17_entirereport.pdf (explaining “[f]or six drug classes, CMS requires Part D plans to cover ‘all or substantially all’ drugs in the class (protected class)”).

⁷² *Id.* (“This policy is intended to allow competition in classes with multiple products while protecting beneficiaries who need a drug that is the only one available to treat a certain condition.”).

pharmaceutical companies to lower their prices so Medicare will buy their product and not their competitor's product.

B. Canada and the United Kingdom as a Model for Pharmaceutical Pricing

The United States should implement a pharmaceutical pricing system, that models parts of the systems currently in place in Canada and in the United Kingdom, to negotiate and set brand-name pharmaceutical prices. The United States should allow brand-name pharmaceutical companies to choose whether or not they want to negotiate with Medicare, just as the United Kingdom allows pharmaceutical companies to choose whether or not they want to participate in the Pharmaceutical Price Regulation Scheme (PPRS).⁷³ Further, if certain brand-name pharmaceutical companies choose not to negotiate with Medicare, they would be subject to pricing regulations. This mirrors the United Kingdom's system wherein pharmaceutical companies that do not participate in the Pharmaceutical Price Regulation Scheme are subject to separate regulations.⁷⁴

The United Kingdom regulates the amount of profit brand-name pharmaceutical companies can generate rather than setting a cap on the price of the pharmaceutical.⁷⁵ The United States should implement a regulation regime similar to the United Kingdom's. This method ensures that brand-name pharmaceutical companies are generating a profit and not just covering their costs.⁷⁶ It is important that brand-name pharmaceutical companies continue to realize a profit or they would stop manufacturing the pharmaceuticals to avoid

⁷³ See Murphy, *supra* note 54. (prices of brand-name pharmaceuticals supplied to the National Health Service (NHS) are regulated by either a voluntary agreement, or the Health Service Branded Medicines Regulations).

⁷⁴ *Understanding the 2014 Pharmaceutical Price Regulation Scheme*, *supra* note 58.

⁷⁵ *Id.*

⁷⁶ *Id.* (explaining that the United Kingdom's Pharmaceutical Price Regulation Scheme allows companies to make a reasonable profit to enable them to continue investing in the development of new pharmaceuticals and setting a limit on profit helps secure value for money for the NHS).

losses.⁷⁷ Moreover, regulating the profit rather than the final price of a pharmaceutical would aid in safeguarding the profitability of the pharmaceutical companies.

Regulating the profit a pharmaceutical company could generate, would reduce the price of pharmaceuticals. For example, if a brand-name pharmaceutical company was only permitted to generate \$1 of profit on each pharmaceutical sold and the cost of production was \$1, the price of the pharmaceutical could not exceed \$2. The United Kingdom's Scheme recognizes the importance of balancing the interests of the pharmaceutical industry and the interests of patients.⁷⁸ The United States should regulate profit like the United Kingdom does because it strikes the needed balance between the interests of brand-name pharmaceutical companies, that are in business to make profit, and the interests of the citizens, who need the pharmaceuticals to remain in good health.

The United States should also put a board in place to be responsible for setting a cap, or limit, on the amount of profit brand-name pharmaceutical companies could generate if they chose not to negotiate with Medicare. The Canadian federal government set up the Patented Medicine Prices Review Board, which is responsible for overseeing the prices of brand-name pharmaceuticals and ensuring that the prices are not excessive.⁷⁹ The United States should create a board similar to Canada's Board. This board could consider a range of factors when setting the cap on the amount of profit brand-name pharmaceutical companies could generate from their pharmaceuticals. The United States board could consider factors that are similar to the factors Canada's Patented Medicine Prices Review Board considers

⁷⁷ Although discovering new drugs is important to pharmaceutical companies there must be a potential to make profit. "People invest in areas where they can get a return on their investment. An area . . . which offers no possible return on investment would be summarily dismissed." John LaMattina, *Do Drug Companies Make Drugs, Or Money?*, FORBES (July 29, 2014, 9:03AM), <http://www.forbes.com/sites/johnlamattina/2014/07/29/do-drug-companies-make-drugs-or-money/#237b8db47fcf>.

⁷⁸ *Understanding the 2014 Pharmaceutical Price Regulation Scheme*, *supra* note 58 (stating "The PPRS recognizes the importance of striking a balance to promote the common interests of patients, the NHS, the industry and the taxpayer").

⁷⁹ *Strategic Plan 2015-2018: The Role of the PMPRB*, *supra* note 43.

when determining the price ceiling for pharmaceuticals. The Patented Medicine Prices Review Board takes several factors into account when setting the price ceiling, including the level of therapeutic improvement, domestic prices, prices in seven other countries, and changes in the Consumer Price Index.⁸⁰

As a cautionary note, the United States should learn from the flaws in Canada's system and consider the price of pharmaceuticals in other countries after rebates. The United States should not merely look at the sticker price of the pharmaceuticals in other countries as Canada does because that sticker price decreases after rebates.

C. Arguments Against Medicare Negotiating with Brand-name Pharmaceutical Companies

It is argued that Medicare should not be allowed to directly negotiate with pharmaceutical companies. One of the main arguments is that it will adversely impact research and development (R&D).⁸¹ It is argued that if Medicare was allowed to negotiate with pharmaceutical companies, the price of the company's product would fall and as a result they would have less money to advance research and development. As a consequence of less research and development, fewer drugs would be brought to market. Pharmaceutical Research and Manufacturers of America (PhRMA) argues that high pharmaceutical prices are due to the cost of research and development to bring a new drug to market.⁸² Many drugs do not even make it to the market.⁸³ PhRMA claims that it takes

⁸⁰ *Strategic Plan 2015-2018: The Pharmaceutical Environment in Canada*, *supra* note 50.

⁸¹ See Joseph Gulfo, *Medicare negotiating with pharma is not the answer*, THE HILL (Dec. 4, 2015, 7:00 AM), <http://thehill.com/blogs/pundits-blog/healthcare/262077-medicare-negotiating-with-pharma-is-not-the-answer>.

⁸² See Kounang, *supra* note 1.

⁸³ California Biomedical Research Association, *Fact Sheet: New Drug Development Process*, CALIFORNIA BIOMEDICAL RESEARCH ASSOCIATION, <http://www.ca-biomed.org/pdf/media-kit/fact-sheets/FS-DrugDevelop.pdf> (last visited Nov. 13, 2017) (explaining that it takes approximately 12 years for a drug to make it to the patient, and only 1 in 5,000 drugs are approved for patient usage); see also *Drug Approvals- From Invention to Market . . . A 12- Year Trip*, MEDICALNET.COM,

approximately ten years and around two and a half billion dollars to bring a new drug to the market.⁸⁴

However, lower pharmaceutical prices will not necessarily decrease research and development in pharmaceuticals. Past research and development costs are not very relevant to the present price of the pharmaceutical because the price is determined by the demand for the pharmaceutical.⁸⁵ Further, the prices charged for pharmaceuticals are the prices the market will bear.⁸⁶ Although some costs of research and development are passed to the buyer, pharmaceutical companies also share the expense and consider it a sunk cost.⁸⁷ Healthcare America Now explained that research and development would not suffer as a result of lower pharmaceutical prices because, from 1998 to 2007, half of the innovative drugs approved resulted from research done by universities and biotech firms, not pharmaceutical companies.⁸⁸

In addition, pharmaceutical companies spend nineteen times more on marketing their products than on research and

<http://www.medicinenet.com/script/main/art.asp?articlekey=9877> (last visited Nov. 13, 2017).

⁸⁴ See Kounang, *supra* note 1.

⁸⁵ Tomas Philipson, *Why the Drug Industry and Its Critics Are Both Wrong About How R&D Spending Affects Pricing*, FORBES (Oct. 6, 2016), <http://www.forbes.com/sites/tomasphilipson/2016/10/06/why-the-drug-industry-and-its-critics-are-both-wrong-about-how-rd-spending-affects-pricing/#cb5980df9818> (explaining that past research and development costs should not be given great weight when setting the price of a brand-name pharmaceutical, instead the prices of the brand-name pharmaceuticals drive Research and Development spending).

⁸⁶ *Id.*

⁸⁷ See *Sunk cost*, BUSINESS DICTIONARY, <http://www.businessdictionary.com/definition/sunk-cost.html> (last visited Nov. 13, 2017) (“Money already spent and permanently lost. Sunk costs are past opportunity costs that are partially (as salvage, if any) or totally irretrievable and, therefore, should be considered irrelevant to future decision making . . . Also called embedded cost, prior year cost, standard cost, or sunk capital.”).

⁸⁸ *Legislative Brief Why Can't Medicare Negotiate Drug Prices with Pharmaceutical Companies?*, OHIO COUNCIL OF CHURCHES (October 18, 2016), <http://diosohio.org/publicpolicy/why-cant-medicare-negotiate-drug-prices-with-pharmaceutical-companies/>.

development.⁸⁹ This high marketing cost shows that pharmaceutical companies have the ability to maintain the same level of research and development and cut costs in other areas. Additionally, the profit generated by pharmaceutical companies is not likely to fall when the pharmaceuticals do not have a substitute. Furthermore, if there are no other competitors on the market, Medicare would be forced to purchase the new pharmaceutical and the pharmaceutical companies would generate a large return on their research and development. This creates an incentive for pharmaceutical companies to invest in research and development and be the first company to bring a pharmaceutical to the market. As the first to bring a pharmaceutical to the market, profits will be high as a result of market dominance.

Others argue that Medicare negotiating directly with brand-name pharmaceutical companies would be impractical.⁹⁰ The argument is that it would not be practical for the Centers for Medicare and Medicaid Services to negotiate the prices of pharmaceuticals because the process would be extremely time consuming and expensive.⁹¹ However, this argument is not persuasive because the benefit of lower prices of pharmaceuticals greatly outweighs the time and expense of the negotiations. Further, the Food and Drug Administration (FDA) must examine all pharmaceuticals before they reach the market.⁹² Even though it takes the FDA some time to examine all of the pharmaceuticals, it is seen as worthwhile. The same logic follows for allowing Medicare to negotiate with pharmaceutical companies. Although it could be a lengthy process, it would be worthwhile.

Finally, critics argue that allowing Medicare to negotiate directly with pharmaceutical companies will simply not lower the

⁸⁹ *Id.* (explaining that although pharmaceutical companies strongly argue attempts to lower prices would kill their research and development, pharmaceutical companies spend a lot more money in other areas such as marketing).

⁹⁰ David Nather, *Washington has big hopes, but little power, to negotiate drug prices*, STAT NEWS (Jan. 6, 2016), <https://www.statnews.com/2016/01/06/medicare-negotiate-drug-prices>.

⁹¹ *Id.*

⁹² *Development & Approval Process (Drugs)*, U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/> (last visited Nov. 13, 2017).

price of pharmaceuticals.⁹³ It is argued that Medicare will not be able to reduce the price of pharmaceuticals because they do not have the ability to reject a pharmaceutical.⁹⁴ They argue that because Congress put rules in place to strengthen pharmaceutical companies' negotiations, the need for Medicare to negotiate is unnecessary to lower prices.⁹⁵ Essentially the price of pharmaceuticals will not decrease, even if Medicare was allowed to negotiate with pharmaceutical companies, because Medicare does not have the ability to refuse to buy the drug.

However, this argument only applies in situations when there are only one or two drugs on the market. When there are multiple competitors in the market, Medicare would have the leverage stemming from the option to buy a competitor's pharmaceutical. The threat of Medicare saying no and buying a competitor's product would motivate a company to lower the price of their pharmaceutical so they do not lose a major buyer.

Additionally, this argument does not favor prohibiting Medicare from negotiating directly with pharmaceutical companies. This argument merely identifies a step that is required in order for Medicare to effectively negotiate with pharmaceutical companies. Medicare must be allowed to say no to a pharmaceutical company otherwise the use of their bargaining power would be to no avail. The threat of not buying a pharmaceutical must be real in order to negotiate lower prices.

The United States currently has a government program in place that is allowed to negotiate with pharmaceutical companies and refuse to buy the pharmaceutical, the Department of Veterans

⁹³ Margot Sanger-Katz, *The Real Reason Medicare Is a Lousy Drug Negotiator: It Can't Say No*, THE NEW YORK TIMES (Feb. 2, 2016), http://www.nytimes.com/2016/02/02/upshot/the-real-reason-medicare-is-a-lousy-drug-negotiator-it-cant-say-no.html?_r=0.

⁹⁴ *Id.*

⁹⁵ *Id.* (explaining that Medicare must cover most pharmaceuticals and would need to be bound by fewer rules and have the ability to say no to pharmaceutical companies which would result in less drugs being covered by Medicare).

Affairs.⁹⁶ The Veterans Administration offers a drug benefit with lower costs than Medicare beneficiaries receive. The Veteran's Administration imposes price ceilings on some drugs and also negotiates with pharmaceutical companies for discounts.⁹⁷ This demonstrates that it is possible to allow Medicare to refuse to buy a drug from pharmaceutical companies. Therefore, the argument is unfounded.

VII. OTHER SUGGESTED REFORMS TO LOWER THE COST OF PHARMACEUTICALS

There are multiple other reform proposals suggested to lower the prices of pharmaceuticals in the United States, including increasing the number of generic pharmaceuticals and importing pharmaceuticals from foreign countries.⁹⁸ However, these proposals would not be as effective in lowering pharmaceutical prices as allowing Medicare to negotiate directly with pharmaceutical companies.

It is argued that increasing the number of generic pharmaceuticals on the market will cause pharmaceutical prices to drop. A generic drug is a drug that is comparable to a brand-name drug in dosage, strength, administration, quality, and performance.⁹⁹ In the United States nearly 8 to 10 prescriptions filled are for generic drugs.¹⁰⁰ Additionally, research shows that generics work as well as

⁹⁶ *Id.*

⁹⁷ John E. Dicken, *Prescription Drugs: An Overview of Approaches to Negotiate Drug Prices Used by Other Countries and U.S. Private Payors and Federal Programs*, Testimony before the United States Senate, GAO-07-358T (Jan. 11, 2007).

⁹⁸ See generally Paula Tironi, *Article: Pharmaceutical Pricing: A Review of Proposals to Improve Access and Affordability of Prescription Drugs*, 19 ANN. HEALTH L. 311 (2010).

⁹⁹ *Abbreviated New Drug Application (ANDA)*, U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/default.htm> (last visited Nov. 13, 2017).

¹⁰⁰ *Generic Drugs Facts*, U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm> (last visited Nov. 13, 2017).

brand-name pharmaceuticals.¹⁰¹ However, innovators of new pharmaceuticals obtain patents to protect their product from being duplicated.¹⁰² The owner of a patent can exclude anyone from making, using, offering for sale, or selling their invention for twenty years from the filing of the patent application.¹⁰³ This means that generic pharmaceuticals cannot be released into the market until the innovator's patent expires. Therefore, increasing the number of generic pharmaceuticals cannot happen until the patent expires, which defeats this proposal.

Additionally, when the patents of brand-name pharmaceutical companies' expire, they often pay generic pharmaceutical manufacturers to wait to release their generic version.¹⁰⁴ This is referred to as "pay for delay."¹⁰⁵ These pay for delay deals are made so brand-name pharmaceutical companies can continue to generate profits with no competition on the market.¹⁰⁶ These transactions are attractive to generic pharmaceutical companies because the money they receive from the brand-name pharmaceutical companies replaces the profit they would have made from the sales of their product. The FDA also needs to approve the generic pharmaceutical before it goes to market, which is a very lengthy process.¹⁰⁷ The slow pace of the

¹⁰¹ *Id.* ("A study evaluated the results of 38 clinical trials that compared cardiovascular generic drugs to their brand-name counterparts. There was no evidence that brand-name heart drugs worked any better than generic heart drugs.").

¹⁰² Bruce Lehman, *The Pharmaceutical Industry and the Patent System*, INTERNATIONAL INTELLECTUAL PROPERTY INSTITUTE (2003), http://users.wfu.edu/mcfallta/DIR0/pharma_patents.pdf.

¹⁰³ *Id.*

¹⁰⁴ Roxanne Nelson, *Pay-for-Delay Drug Deals: Do They Hurt or Help Patients?*, MEDSCAPE (Apr. 15, 2015), <http://www.medscape.com/viewarticle/843231>.

¹⁰⁵ *Id.*

¹⁰⁶ Diane Bartz, *Controversial 'pay-for-delay' deals drop after FTC's win in top court*, REUTERS (Jan. 13, 2016, 1:40PM), <http://www.reuters.com/article/us-pharmaceuticals-patent-ftc-idUSKCN0UR2JA20160113> ("In a typical pay-for-delay deal, a branded drug company will give a generic firm money or some other consideration in exchange for the generic firm's agreement to delay bringing out a cheaper version of the medicine.").

¹⁰⁷ Michael Hiltzik, *The FDA can single-handedly reduce the drug price-gouging. Why is it waiting?*, LOS ANGELES TIMES (Jan. 5, 2016, 12:31PM), <http://www.latimes.com/business/hiltzik/la-fi-mh-the-fda-can-single-handedly-stop-2016010>

FDA approval process for generic pharmaceuticals reduces the competition in the market and therefore, prices of brand-name pharmaceuticals are not reduced. For these reasons, increasing the number of generic pharmaceuticals on the market will not be an effective way to reduce the price of pharmaceuticals.

Other reform proposals suggest allowing consumers to import drugs from other countries.¹⁰⁸ Given that the United States pays more for prescription drugs than any other developed country, this proposal seems attractive. However, the United States Federal Food, Drug, and Cosmetic Act prohibits the interstate shipment, including importation, of unapproved new drugs.¹⁰⁹ In other words, the importation of drugs that are not approved by the Food and Drug Administration (FDA) violates the Food, Drug, and Cosmetic Act except under certain circumstances.¹¹⁰ Unapproved drugs are drugs, including foreign-made versions, that have not been manufactured in accordance to FDA approval.¹¹¹ However, as previously mentioned in the EpiPen example, people in the United

5-column.html (“The FDA’s years-long backlog of approvals now runs to thousands of drugs. Because of the backlog from previous years, of the nearly 1,600 applications for new generic drug approvals submitted in fiscal 2014, not a single one was approved by the end of the fiscal year.”).

¹⁰⁸ See Tironi, *supra* note 89.

¹⁰⁹ 21 U.S.C.S. § 331 (2016).

¹¹⁰ The FDA does not object to personal imports of drugs that the FDA has not approved under certain circumstances such as, “[t]he drug is for a serious condition for which effective treatment is not available in the United States; [t]here is not commercialization or promotion of the drug to U.S. residents; [t]he drug is considered not to represent an unreasonable risk; [t]he individual importing the drug verifies in writing that it is for his or her own use, and provides contact information for the doctor providing treatment or shows the product is for the continuation of treatment begun in a foreign country; and [g]enerally, not more than a 3-month supply of the drug is imported.” *Is it legal for me to personally import drugs?*, U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194904.htm> (last visited Nov. 13, 2017).

¹¹¹ Under the Act the FDA may refuse admission of any drug that “appears” to be unapproved. The burden is then on the person attempting to import the drug to show that the drug is FDA approved. Marvin A. Blumberg, *Importation of Drugs*, U.S. FOOD AND DRUG ADMINISTRATION, <http://www.fda.gov/forindustry/importprogram/ucm173751.htm> (last visited Nov. 13, 2017).

States often buy pharmaceuticals from foreign countries.¹¹² A major concern with drug importation is safety.¹¹³ People may think they are buying an approved drug, when in reality they are buying a counterfeit.¹¹⁴ Some additional safety concerns include incorrect doses, contaminated pharmaceuticals, toxic ingredients, and ineffectiveness. Further, federal regulators cannot guarantee where or how drugs sold abroad were made.¹¹⁵ The FDA also has a limited ability to take action against these foreign sellers.¹¹⁶ People buying foreign pharmaceuticals must rely on the foreign governments to inspect the pharmaceuticals. These foreign governments may not inspect the pharmaceuticals as thoroughly as the United States government. Legalizing the importation of pharmaceuticals from foreign countries would create more problems than benefits.

VIII. CONCLUSION

In conclusion, Medicare should be allowed to negotiate directly with brand-name pharmaceutical companies in order to reduce the price of pharmaceuticals. Medicare should be allowed to use their bargaining power to reduce the price of brand-name pharmaceuticals. This comment described how Canada and the United Kingdom have achieved lower prices for brand-name pharmaceuticals and suggests that the United States should adopt certain aspects of both Canada's system and the United Kingdom's system to create an efficient, effective, and safe system for its citizens. Pharmaceutical pricing is an extremely important issue that will affect

¹¹² See *Mohney*, *supra* note 26.

¹¹⁴ Sally C. Pipes, *Letting patients buy Canadian drugs will only import trouble*, THE HILL (Feb. 2, 2015, 1:00 PM), <http://thehill.com/blogs/congress-blog/healthcare/231320-letting-patients-buy-canadian-drugs-will-only-import-trouble>.

¹¹⁵ *Id.* (explaining that purchasing brand-name pharmaceuticals from foreign countries is not safe due to a lack of knowledge about the safety measures in the foreign countries and a lack of knowledge about the chemical composition of the foreign country's pharmaceutical).

¹¹⁶ John M. Taylor, III, *Importation of Prescription Drugs*, Testimony before the Permanent Subcommittee of Investigations Senate Committee on Governmental Affairs, (July, 22, 2004).

most people throughout their lifetime. No person should be restricted from receiving proper treatment because they cannot afford to buy the pharmaceuticals they need. Allowing Medicare to negotiate directly with brand-name pharmaceutical companies is the most effective way to cure the high costs of pharmaceuticals in America.