A Case for Care and the Costs of Capitalism: The Ethics of Prescription Drug Pricing

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Introduction

In many ways, the United States is the Pharmaceutical Capital of the World. Four out of the top 10 grossing pharmaceutical companies are based in the United States and the US develops more drugs than any other nation\(^1\). Americans also consume more drugs than almost any other developed nation, at an average of 2.2 prescriptions taken regularly per capita\(^2\). However, the US also spends more on prescription drugs than any other nation\(^3\). The US spends twice the average amount paid by industrialized nations for pharmaceuticals per capita calculated by the Organization for Economic Co-operation and Development\(^4\). While we have no centralized, single-payer system, our public expenditure on healthcare overall is comparable with that of most European governments with single-payer systems (see Appendix 3)\(^5\). What distinguishes us from these other industrialized countries is our massive private expenditure (a combination of premiums, deductibles, co-pays, and out of pocket costs) on healthcare and prescription drugs, which exceeds our public expenditure and is more than double the next largest private contribution\(^6\)\(^7\). Furthermore, our drug spending has been steeply and steadily rising in


\(^4\) Ibid, 31.


\(^6\) Ibid

the last 10 years and is projected to continue rising at higher and higher rates (Appendix 2)\textsuperscript{8}.

America’s high pharmaceutical spending is part of a trend in high healthcare costs in the United States. The US spends 16.9\% of its GDP on health costs, while the OECD average is 9.3\% of GDP.\textsuperscript{9} Our public expenditure amounts to half of our overall healthcare costs while the average OECD nation has a 72\% public expenditure\textsuperscript{10}. Similarly, roughly two thirds of our pharmaceutical spending comes from private insurance and out of pocket spending.\textsuperscript{11} While the US Government (and thus the American tax-payer) is paying roughly the same amount per capita as other OECD nations, American consumers are being asked to pay again through private insurance and out-of-pocket costs and thus are effectively double charged\textsuperscript{12,13}. What is remarkable about American healthcare is that, while we pay twice the average of comparable countries our health outcomes are average at best and by some measures significantly worse. In 2012, the United States had an average life-expectancy at birth of 78.7 years compared to the OECD average of 80.2 years, this earned us a ranking of 27\textsuperscript{th} out 34 OECD nations\textsuperscript{14}. Our mortality rate for cardio-vascular disease was 261.2 deaths per 100,000 compared to the average 296.4 deaths per 100,000 landing us a rank of 17/34\textsuperscript{15}. Mortality from cancer in the US was 198.7 out of 100,000 compared to 213.1, which

\textsuperscript{9} Kane, Jason. "Health Costs: How the U.S. Compares With Other Countries." (2017)
\textsuperscript{10} Ibid.
\textsuperscript{12} Ibid.
\textsuperscript{13} Kane, Jason. "Health Costs: How the U.S. Compares With Other Countries." (2017)
\textsuperscript{15} Ibid.
placed us at 25/34\footnote{Ibid.}. These statistics place us squarely in the middle of the pack, which might be respectable if we were not paying more than any other comparable country for our care. And those are our good stats, our obesity rates land us a number one ranking, meaning we are the most obese of all industrialized nations\footnote{Ibid.}. These statistics show that while we pay more than any other nation, we are not healthier than other nations. So what are paying for if not health outcomes?

While prescription drugs are not the only expensive aspect of our health system, it is an aspect that touches the lives of most Americans, it accounts for a large percentage of our health expenditure, and the costs are prohibitive for many people. 54\% of Americans take at least one prescription drug regularly and many take several drugs regularly\footnote{Brodie, Mollyann, Jamie Firth, and Bianca DiJulio. "Kaiser Health Tracking Poll: August 2015." The Henry J. Kaiser Family Foundation. August 20, 2015. Accessed January 10, 2017. http://kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-august-2015/}. Around a quarter of all Americans taking prescription drugs (14\% of all Americans) admit to difficulty affording their medication\footnote{Ibid.}. Among uninsured Americans, 17\% stated that at some point they had forgone, delayed or decreased a prescription dose because of the cost of their medication\footnote{"How does cost affect access to care?" Peterson-Kaiser Health System Tracker. November 29, 2016. Accessed January 25, 2017. http://www.healthsystemtracker.org/chart-collection/how-does-cost-affect-access-to-care/}. Even among the insured, 5\% report engaging in the same tactics because of the high prices, this amounts to 1/10 Americans being unable to afford their prescribed drugs\footnote{Ibid.}. Most Americans (72\%)—whether or not they are taking drugs themselves—believe that the costs of pharmaceuticals are too high\footnote{Brodie, et.al. "Kaiser Health Tracking Poll: August 2015."}. 

\begin{footnotes}
\item[16] Ibid.
\item[17] Ibid.
\item[19] Ibid.
\item[21] Ibid.
\item[22] Brodie, et.al. "Kaiser Health Tracking Poll: August 2015."
It is clear that both compared to other countries and compared to what our own citizens can afford, the US is facing high costs for pharmaceuticals. The purpose of this exploration is to determine (1) whether these high costs are ethically justifiable and (2) who is responsible for making drugs more affordable. In considering these questions, we will need to start with a framework for how we consider our pharmaceutical system. In order to limit the scope of this study and to make any policy recommendations plausible, we will start with a non-ideal model. There will be no attempt in this paper to fundamentally restructure the US healthcare or pharmaceutical systems, and all policy recommendations will maintain the multi-payer healthcare system and the private/corporate drug industry. Rather, I will look at the industry as it is, consider how the many facets of our healthcare industry and regulations influence prices and consumers, and make recommendations to increase or decrease regulations as necessary to make drugs more affordable. These policy options also will exist within the real world, and will consist of public and private efforts that could be made at any moment that the political will should arise.

Since we will be working within the system that already exists, in order to determine whether prices are justified we must consider what the goals of our system are. These goals can be summarized by the values of fairness, equity and quality; and in order for the high prices paid to be ethically justified, the costs must contribute to the achievement of these goals. The goal of any healthcare system is to maximize population health by providing accessible, affordable and good quality care that maintains individual liberty and autonomy in health decisions\textsuperscript{23}. A further goal that should guide all health

systems is to limit social injustice and maximize social good, while correcting for poverty and systematic disadvantage\textsuperscript{24}. In America our private pharmaceutical systems mean that profits are necessarily a goal. While this is not directly an ethical goal, prices cannot be justified if they would make pharmaceutical companies unprofitable, because it would make the achievement of our ethical goals impossible. Problems in setting ethical prices arise when there is conflict between our ethical goals or between the ethical goals and the necessity of profit.

In order to meet the goal of maximizing health, quality prescription drugs must be fairly and equitably accessible. Quality in this circumstance means a few different things; at its most basic, it means that the drugs on the market must be safe and effective, but in broader terms it could mean a duty to create innovative or the most effective drugs possible. If taken in the broader sense, there is a responsibility for innovation built into the requirements for an ethical pharmaceutical system. This seems to be the interpretation favored by drug companies, and is often used to explain high prices. If companies are obligated to innovate, then they are justified in charging the prices that are necessary to fund that innovation. The second duty involved in maximizing health is the responsibility to make drugs equitably accessible. This duty to equity encompasses the goals of accessibility, affordability, and correcting for systematic disadvantage. To accomplish these goals, vital drugs need to be affordable to everyone with no barriers to access such as limited suppliers or insufficient quantity. Equity can also have a relationship with price discrimination, which is the practice of charging different buyers different prices based on their willingness or ability to pay. In order to make drugs fairly and equitably accessible while maintaining profits a certain amount of price

\textsuperscript{24} Ibid.
discrimination may be necessary; but price discrimination should be used in order to lower what the poorest and most vulnerable pay, not to take advantage of those who lack bargaining power. Here we reach our first problem in justifying pharmaceutical prices. If the pharmaceutical industry is producing good quality, life saving, innovative drugs, but charging prices that are unaffordable, how can they be justified? What is the highest priority? It seems fair to say that if one is able to achieve the simultaneous goals of quality and access then one should be required to do so. Thus, if companies do not need to charge high prices in order to create quality drugs, than they would not be justified in pricing people out of their treatments. However, if high prices are necessary in order to create quality treatments, than the pharmaceutical industry would be justified in charging a lot, even if it meant that some or even most could not afford it. If this is the case, we might hope or expect that some other payer, like private insurance, government insurance or charities might step in to help those with lower incomes afford necessary treatment; but it would not fall to the company to sacrifice quality for accessibility. However, this rests on the supposition that the quality of medication requires high prices.

After considerations of quality and equitable access comes the goal of fairness. Fairness can mean many things, but in this investigation will be used to describe access to the conditions and information necessary for patients and buyers of pharmaceuticals to make informed decisions. Liberty and autonomy are wrapped up in this definition of fairness, because fairness is necessary for people to make free and autonomous choices concerning their healthcare. In order for a pharmaceutical system to ensure liberty and autonomy for consumers there must be adequate information about drugs being sold. Patients, doctors, hospitals, insurers, and the government are all buyers of
pharmaceuticals, and are all entitled to sufficient information about the quality and cost of the products they wish to buy. This information might be about the efficacy of a drug, the treatment alternatives, the list price and the cost breakdown. A just pharmaceutical system must make this information available to consumers. Finally, in order to achieve the ethical goals outlined above, profit is a necessary pragmatic goal in the US pharmaceutical system. Without sustained profits for companies, they could not continue to produce drugs and no one would have access to the drugs they make. However, while it is true that it is in everyone’s interest to ensure that pharmaceutical companies are making enough profit to stay in business, that does not mean there is an obligation to pay high prices beyond what it takes to create good quality and widely available drugs.

Some of these goals are not so different from most other consumer industries; in most purchases, whether it is cars, phones, groceries or clothes, there is a similar balance to strike. There is an expectation of safety, effectiveness, affordability and profit in all industries. However, what makes pharmaceuticals and other health industry purchases different is that the stakes are so much higher for consumers; it is not like buying a new phone (no matter what certain representatives in Congress might think) because going without a phone because of its cost is inconvenient but not fatal. When 10% of Americans have faced the decision to delay or forgo taking their prescriptions because of

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In March of 2017, amidst the debate over repealing and replacing the Affordable Care Act, Republican Congressman Jason Chaffetz, a proponent of the new bill, made some insensitive comments about American healthcare tradeoffs. In recognizing that the bill would raise healthcare costs for many Americans (it would take away insurance from many and eliminate many of the federal subsidies for low income Americans buying insurance), he commented that poor Americans would have to decide between buying a new iPhone and buying health insurance.
cost, that is a much greater problem than if 10% are going without the latest iPhone\textsuperscript{26}.

There already exists an intuition in our own country (though it is less developed than in single payer countries) that no one should be turned away from accessing care; hospitals cannot turn patients away if they lack money or insurance, and we have many different systems for providing healthcare for those who cannot afford it. So it does not seem that there is a strong belief that the poor or the uninsured or the very sick should be deprived of health services; rather, there are different strategies for improving access. What further distinguishes the pharmaceutical and broader health industries from other consumer products is the fact that the buyers of the products are often not the consumers.

With our complicated network of stakeholders, which ranges from the government to private insurance to private pharmacies to individual patients, the person making the purchasing decision is rarely the patient alone and so conflicts of interest are bound to arise.

After we consider how well the pharmaceutical industry is meeting its goals we need to answer the question of who is responsible for costs. Responsibility can refer to blame for the state of high prices, but also the duty to remedy the problem. In this ethical investigation I will touch on the aspect of blame, but will to focus on the duty to act.

After determining whether the prices for drugs are justified, I will set out to find who is responsible for bringing down costs and making drugs more equitably and fairly accessible. We cannot assume that drug companies are solely responsible for bringing down prices, because profit is an intrinsic goal of any company and because they were not alone in creating the problem of inequitable access. While it is drug companies that

\textsuperscript{26} How does cost affect access to care?” Peterson-Kaiser Health System Tracker. November 29, 2016.
set prices, they did not create the income inequality that causes differing abilities to pay, so they might argue that it is not their responsibility to make drugs available to the poor and uninsured. However, if the prices they have set are unjustifiable and they could create quality drugs that are affordable while still making a profit, then they are not justified in raising prices to make their products inaccessible. Furthermore, it is not very realistic for a company providing such a vital service to ignore the economic disadvantages that do exist. If water companies raised prices and cut off the water of low income Americans, we would not settle for the explanation that it is income inequality and not high prices that are causing the water to be shut off. While income inequality is certainly a problem that should be addressed, it is hard to see how high prices on essential services do anything to alleviate that problem or the hardships people with low incomes face. It seems that pharmaceutical companies cannot avoid all responsibility for the inaccessibility caused by high prices, but their responsibility for ensuring greater accessibility might be shared. Again, eliminating income inequality is not the most expedient means of increasing access to pharmaceutical treatments, but income inequality is clearly exacerbating inequitable access to drugs. So who is responsible for increasing equity? The government certainly has its share of responsibility, and has acknowledged that responsibility through programs like Medicaid and Medicare. Individuals by contributing to government and charitable programs have similarly accepted a responsibility to improve access. So there are many stakeholders with responsibilities to improving access, and these responsibilities are rooted in both individual and collective interests. Individually it is in the interest of most of these stakeholders to make drugs more widely available. The government and taxpayers would benefit from lower prices
since it would lower their health expenditure while improving health. Individual private expenditure (co-pays, deductibles, and premiums) would be lessened if prices were lowered, and more people had access to affordable medications. The interest of the pharmaceutical industry in making drugs more affordable is the least obvious, but it is still present. Pharmaceutical companies have one of the lowest approval ratings of any industry, even lower than oil companies, with only 12% of Americans holding a favorable view of pharmaceutical companies. Most Americans do not see drug companies as making significantly greater contributions to quality of life than any other industry, but they do see them as making too much money and being too focused on profits. Taking greater action to make drugs more affordable would not only be a more sustainable model, but would improve the image of companies tremendously.

In addition to these individual or self-interests in improving pharmaceutical access, there are also collective reasons why improving access to drugs is a worthy goal. While lowering costs would be financially beneficial for everyone, it would also improve the health and lives of those currently struggling to afford their medications. While the goals of health industries are articulated through quality and access, the overall goal is to improve health. We have a responsibility to each other and to our collective health. We saw from the statistics on life expectancy, mortality and morbidity, that we are not doing a great job of improving the health of our fellow Americans compared to other nations. Whether we look at these aggregate statistics of health or at the rates of people who cannot afford medications or at the stories of individuals who struggle to afford healthcare, it is clear that any collective duty to protect the health of others is being

27 Brodie, Mollyann, Jamie Firth, and Bianca DiJulio. "Kaiser Health Tracking Poll: August 2015."
28 Ibid.
shirked. But again a problem arises in pinpointing where the responsibility lies in making drugs affordable when there are so many stakeholders.

In order to investigate pharmaceutical pricing and access and to determine whether the prices charged are justifiable, we must evaluate how the industry and our pharmacy benefit system measures up against the goals and responsibilities outlined above. This will require both empirical and ethical evaluations of the actions of drug manufacturers, government entities and private insurers. Empirical evaluations are necessary to consider claims made by pharmaceutical companies that living up to their quality responsibilities requires high prices, which limit access. Empirical evaluations are also necessary to understand whether the pharmaceutical industry is truly living up to its obligations to quality and fairness. To accomplish these empirical and ethical evaluations I will use a case study method to understand the nuances of pharmaceutical pricing, the problems created by high costs and the justifications that may exist. The case studies I will employ are all drugs that have received media attention in the last year concerning their high cost. While the drugs are all very different, they are all examples of drugs that have become cost prohibitive. Some of the causes for their high prices overlap and so do some of the solutions, but they also present unique challenges and policy ideas. The first case, EpiPen, is a unique pharmaceutical device that can save patients experiencing anaphylactic shock; yet in the last 10 years the price has gone up 500%, not because of investments in the device, but because of investments in marketing and lobbying. The second case, Hepatitis C anti-virals, are a very promising new class of drug with the ability to cure most patients with Hepatitis C; yet the high price tag has the potential not only to bankrupt individual patients, but Medicare and Medicaid as well.
Finally, Multiple Sclerosis therapies are unique in that increase in competition among MS medications has led to an increase rather than a decrease in the cost of treatment. With their various challenges, each case has shown the possibility for different policy solutions. In reviewing possible policy interventions, I found very little evidence that any government or private regulation of drug prices would have a negative effect on quality of care or the price of pharmaceuticals. While it is difficult if not impossible to predict what the exact outcome of any given policy would be, the risks of further regulating the pharmaceutical industry are not high. On the other hand, the costs to the health of patients and the bank accounts of stakeholders are already great, and will only increase if no intervention is taken. Unfortunately, many of the steps that I will suggest require a significant amount of political will that would be difficult to muster even in the most effective of political climates, but certainly will be even more difficult under the current anti-regulatory administration. However, while many of the government solutions will not be possible until a shift in political priorities takes place, there are private and individual steps that can be taken to limit the negative effects of rising prices. Public pressure and outrage have led to companies lowering prices or introducing generics, and the informed decisions of healthcare providers like doctors and hospitals to choose more cost effective options have also made an impact on drug expenditure. While there are many challenges to achieving equitable access to drugs, there are a myriad of solutions. This variety can be daunting, and it is hard to say what the most effective solutions will be, but not knowing which path to choose should not stop us from moving forward to address the unaffordable cost of pharmaceuticals in the United States.
Chapter 1: Case Study on EpiPen Prices

In 2015, 3.6 million Americans were prescribed EpiPen to assist in medical emergencies caused by contact with an allergen. Unfortunately, due to high costs, many Americans have to make difficult decisions about whether they can afford the life saving drug. EpiPen is an auto-injector, which safely delivers a measured dose of epinephrine into the muscle tissue of an individual experiencing symptoms of anaphylactic shock. While epinephrine (also known as adrenaline) has been used to treat anaphylaxis long before EpiPen, auto-injectors have become the safest and quickest way to deliver epinephrine, and are easy enough to use that patients and bystanders can inject the drug themselves. This was an important development in the treatment of severe allergies because, in cases of anaphylaxis, speedy delivery of epinephrine can save lives, and in many cases there is not enough time to wait for a health care professional. While neither the drug itself nor the injection technologies are new, auto-injectors are so essential to those living with severe allergies, that EpiPen (which has a near monopoly on the auto-injector industry) has been able to steadily raise prices over the last 10 years without raising much concern.

Since 2007 when Mylan, a company that mostly produces generic drugs, purchased EpiPen, the cost has been rising steadily by about 20% per year. In 2015, the

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31 Ibid.
price spiked to $600 for a set of two\textsuperscript{32}. While the price paid by individuals varies based on their health plan, the burden to the healthcare system as a whole is considerable. Between 2007 and 2014 average out of pocket spending for patients on EpiPen has increased from $34 to $75 with 18\% of patients paying over $100 and 5\% paying over $200 out of pocket\textsuperscript{33}. This is a significant burden for patients to bear, and one which is magnified when you consider than many patients may elect to buy multiple EpiPens to keep in the home, car, work/school, and bag, and magnified again because the drug expires after 12 months, requiring that the drug be replaced annually. Even if an allergy patient has a great health plan with minimal co-pays, the $600 price tag is significant for insurers and can contribute to the existing problem of insurance premium increases. Furthermore, many of the buyers of EpiPens are government insurers like Medicare & Medicaid, or other tax funded institutions like schools and emergency services. Overall, whether you have an allergy or not, everyone is helping to pay for the rising costs of EpiPens.

This latest price increase has led many to question what the reason could be for a 500\% price increase over 10 years, when few improvements have been made to the auto-injectors, and when the demand seems to be ever-expanding. While Mylan has been very secretive about their contracts with their manufacturers and distributors, and unwilling to give a complete breakdown of their expenses, they have suggested that improvements like a retractable needle and better grip have resulted in a significant capital investment in


the injector. Critics wonder if these costs were truly high enough to require such extreme price hikes, and furthermore, if the changes were a significant enough improvement to make the increased cost worth it for patients. Some critics believe that the only real capital investments Mylan has made in EpiPen are their advertising and lobbying efforts\textsuperscript{34}. Without any internal documents or data from Mylan outlining why the price increases are necessary, it is hard to believe that what seem like minimal changes could cause a 500% price increase over 9 years.

Mylan CEO, Heather Bresch, was called by Congress to testify to the EpiPen price hikes, but in her testimony, Bresch was not very forthcoming about the cost of EpiPen. She has stated that she cannot disclose the details of Mylan’s contracts with manufacturers and distributors due to confidentiality agreements. While confidentiality agreements are common among business partners, when there is such a public risk associated with rising healthcare costs it seems that more transparency might be necessary. Bresch continues to play her cards close to her vest, but has made claims that it costs about $69 to make 2 EpiPens. Independent estimates have produced slightly different findings; one study concluded that one EpiPen likely only cost $30 to make, or $60 for the pack of 2\textsuperscript{35}. While this difference is not huge, the difference between both estimates and the $600 price tag certainly is.

Besides the mystery around the true cost of EpiPen, there is also some controversy over how much Mylan makes off each injector. Bresch has stated that the


$300 rebates they give to insurance companies cut into their profits significantly and that after rebates and fees Mylan only make $274 per pack\textsuperscript{36}. She further states that other unnamed fees bring the profits down to about $100 per pack ($160 pre-tax)\textsuperscript{37}. Without a rigorous account of Mylan’s expenses and costs, it is hard to know whether we can trust this account. Ronny Gal, a pharmaceutical industry analyst at the investment firm Sanford Bernstein, says Mylan may make a 40 percent profit margin on the EpiPen, and that is a conservative estimate\textsuperscript{38}. Critics might claim that demanding a 40% profit margin off a ubiquitous but life saving drug is highway robbery, especially when one considers that the 40% profit is likely what is made after the maximum number of rebates and discounts are offered, and there are likely many EpiPens sold where the profit is far more than 40%.

EpiPen is not the only drug that has steadily or suddenly increased its prices in the last few years, but many factors make it an interesting case study in the ethics of drug pricing. In order to evaluate the ethics of EpiPen’s price, we must compare it to the framework we have established. In order for a $600 price to be justified, EpiPen must be a quality drug that is both equitably and fairly accessible. Ethical problems involved in the EpiPen controversy include questions about the justness of patent law, the use of marketing and lobbying by “big pharma”, the secrecy with which it operates, the relationship between drug companies and insurers, and their proposed release of a generic version of their own product. EpiPen is a safe and effective drug, but is hardly a recent innovation; yet it remains under patent protection and consumes a 93% market share in

\textsuperscript{37} Ibid.
\textsuperscript{38} Ibid.
auto-injectors\textsuperscript{39}. Innovation is rewarded and protected by patents, which offer market exclusivity for a limited period, so investigating the quality, and accessibility of a drug requires an evaluation of patent protection. First, the market exclusivity offered by patents allows companies to charge whatever they please with little ability for patients, insurers or the government to contribute to the determination of a good price. Second, patents allow companies to sue competitors who attempt to introduce competing drugs on the basis of patent infringement, and even if the competitor would or could win the challenge the expense and delay allows the first company to maintain their exclusivity\textsuperscript{40}. Third, in the case of EpiPen, which is a medical device, not a drug, there are concerns that it is not really worthy of continued patent protection. Fourth and finally, the argument for patents is that they encourage innovation and allow companies to recoup the losses they sustain during drug development, but there is an argument to be made that this system is not working out as intended and that the current patent system is actually hindering innovation.

Critics have accused Mylan of taking advantage of the limited competition in the market for epinephrine auto-injectors by raising prices before their patent expires and generics begin to compete. EpiPen will be under patent protection until 2025, meaning no other company can replicate its design until then\textsuperscript{41}. Furthermore, any company that attempts to patent a new design could face litigation from Mylan if they believe the new product too closely resembles theirs. This has led to EpiPen taking up a 93\% market share.


share. This near monopoly is made possible by the patent protections that the US government offers Mylan and other drug companies. The idea behind these temporary monopolies is to allow drug companies to make up for capital losses incurred in the research and development of new drugs, and to protect intellectual property and encourage innovation. Most companies, including Mylan, argue that while their prices are often high, they provide great value, and customers are willing to pay a lot for that value. In an August 2016 interview, Martin Shkreli (also known as Pharma Bro) actually argued that the $600 price tag on EpiPen is a great value for both patients and insurers because of the life-saving and potential cost saving affects of the drug. While it is true that EpiPen can save lives and limit some of the most serious symptoms of anaphylactic shock, most cases where an EpiPen is used also require a hospital visit and even an ambulance ride, which possibly limits the effectiveness of down-the-line cost savings as an argument for the high price tag. However, even if we were to acknowledge that it is a drug with life-saving and cost-saving capability, it must also be acknowledged that many people cannot afford to pay $600 a year for EpiPens, so whether the responsibility lies with Mylan to lower costs or with insurers to improve benefits, the problem remains that individuals cannot afford the drug.

Besides the value of their products, companies often argue that while patents are what allow them to have temporary monopolies at all, the process for obtaining market access and exclusivity are also to blame for the high prices. Drug companies might argue that the reason they must charge so much and increase their prices so often is that

the window of exclusivity they have is too short, and they can’t make a significant enough profit in that time to satisfy their shareholders if they charge a price that consumers would consider fair. Currently, patents last twenty years and take effect as soon as the drug is invented\textsuperscript{44}. This seems like a long time, but the FDA approval process is also very long, often eight and sometimes 12 years, and during that time the exclusivity clock winds down while the company sees no profits. This would be understandably frustrating as an executive of a pharmaceutical company and may have trickle down effects that limit investor confidence in drug research and thus limit innovation. But does it justify the price spikes that patients endure? While EpiPen is a quality drug in its safety and effectiveness, it is unaffordable for many Americans, and this is unjustifiable if the high price is not a necessary cost of ensuring quality. EpiPen has had patent protection for a long time and will continue to have it till 2025; it has long since paid for itself and any losses incurred during its development, and yet prices remain high and Mylan’s profits continue to grow. While there may be an argument that high prices are necessary to recoup losses, they cannot be justified indefinitely, nor can price increases be justified once profits exceed the initial loss. Therefore, it seems that the price of EpiPen is unjustifiable and patent protection is playing a part in allowing the unjustified prices to continue.

However sympathetic one might be to the “plight” drug companies face in waiting for approval from the FDA, one could counter that not all products deserve the exclusivity they are granted, and furthermore that drug companies use very shady practices to maintain their exclusivity. In the case of EpiPen, the product that is licensed

\textsuperscript{44}Amin and Kesselheim. "Secondary Patenting Of Branded Pharmaceuticals: A Case Study Of How Patents On Two HIV Drugs Could Be Extended For Decades." (2012)
is not epinephrine but the auto-injector. There are several factors that can call into question whether EpiPen deserves the protection it has. To start, the patent for EpiPen is for the design of the auto-injector and for the stabilized epinephrine solution. The injector design, while technically unique, is not completely novel; it was based on a 1970s design for an auto-injector that is used by the military to deliver anti-nerve gas serums to soldiers affected by chemical weapons45. The company that still manufacturers those injectors is contracted by Mylan to manufacture the EpiPen. So at the time of its creation the EpiPen was no more innovative than some of the competing injectors that have been prevented from reaching the market today. The fact that the EpiPen is primarily a medical device, not a drug, is significant because it is actually more difficult to improve upon or redesign without appearing to be stealing designs. If it were just a drug, than one could prove its uniqueness by the chemical formula, but devices are much harder to prove to be novel. This makes introducing competition to the auto-injector market more difficult and actually stifles innovation.

There may be some problems in determining what novelty in a medical device or drug means, but there are really no restrictions on the ability of drug companies to sue companies that attempt to patent or gain market access for competing products. While drug companies claim that they deserve market exclusivity because of their innovation and the value of their products, and while they accuse the process of getting FDA approval to be too long and costly, they spend their money and the taxpayer’s money on long legal battles to prevent innovation and competition from other companies. While companies need to be able to defend their intellectual property, there must be more intervention on the part of the government to prevent trivial lawsuits. If companies could

45 Keshavan “5 reasons why no one has built a better EpiPen.” (2016)
just copy old drugs and products and sell them, that would set a dangerous precedent and could easily harm the pharmaceutical industry and its ability to draw investors in innovation. However, trivial suits set the same dangerous precedent; they make it impossible for viable competitors to enter the market because any new drug, even if it is truly novel, could face a legal challenge if it treats the same condition as another drug.

Currently, even if a suit fails and the new drug is determined to be novel, there is no legal or financial consequence to the company that challenges the new drug, except the sunken costs of the suit, which may be worth it to the company if it has delayed the new drug entering the market. Mylan has prevented other auto-injectors from entering the market through such lawsuits, and while it is difficult to say whether they were right about their claims of copyright infringement, the effect has been that there is no competition for EpiPen and they can set their own prices.

I have described many problems with the patent system, both in the eyes of drug companies and on behalf of consumers. Essentially, drug companies argue that they need longer lasting patents in order to make enough off their drugs to recoup losses from development and satisfy shareholders. These points are unconvincing for a lot of reasons. First, the global pharmaceutical market is worth $300 billion, so companies make enormous profits and clearly are creating returns for shareholders. Second, it is hard to see a direct connection between increasing profits and increasing innovation, the most profitable drug on the market is Lipitor, which is one of many cholesterol-lowering drugs.

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47 Keshavan "5 reasons why no one has built a better EpiPen." (2016)
and has not been proven more effective than any of the others\textsuperscript{49}. Yet, while the connection between profits and innovation is dubious, we allow drug companies to set their own prices unchecked for the duration of their patent life. Furthermore, profits and private investors are not the only ones sponsoring pharmaceutical research, the Federal Government provides $32 billion annually to fund medical research\textsuperscript{50}. It seems counter-intuitive that the people should fund innovation, then be asked to pay high prices in order to pay back investors. We all have an interest in seeing innovative drugs developed, and it is great that there is both private and public investment in those innovations. But it seems that if the government is such a large investor, they should be seeing returns on those investments, either in the form of lower prices or dividends on profits.

An upshot of market exclusivity is price setting, which leads to price discrimination, meaning that while they have one list price, they can provide different discounts or rebates to different customers. By practicing price discrimination companies are able to charge high prices to those who can afford it, or those who are unable to bargain (Medicare) without loosing access to markets where customers cannot afford or won’t pay such high prices. This occurs on an international level with drug companies, including Mylan, charging different prices in different countries, and this practice has led to the United States paying more for drugs than any other country in the world. But this price discrimination also occurs within the United States, because companies like Mylan negotiate with each buyer separately and can provide different sized rebates to each insurer. Furthermore, while the rebates they provide may not be enough to allow every


\textsuperscript{50} Angel, \textit{The truth about the drug companies: how they deceive us and what to do about it}. (2006)
patient to access the drug, they can still provide individual discounts to patients based on income. While providing discounts to poor patients should be a sign of positive price discrimination that improves access, in general, the process of price discrimination means that companies can extract every available penny from the healthcare industry.

In order for price discrimination to be justifiable in the pharmaceutical industry, it must enhance rather than hinder equity of access. Thus, price discrimination should not just allow private groups to bargain for lower prices, but should actively seek to ensure that the most vulnerable pay the least for drugs. What is notable about price discrimination in the United States is that while those without insurance may receive discounts from manufacturers, Medicare and Medicaid, which insure the elderly and the poor respectively, often end up receiving the worst deals in price negotiation. In the case of Medicare, this is because they are unable to bargain for lower prices at all, and in Medicaid because it is managed differently in each state and lacks strong support from the federal government. Despite the difficulties in negotiating lower prices for Medicare and Medicaid, it would seem that there is a positive duty on behalf of manufacturers to ensure that these programs have access to a low price for drugs, at least as low (if not lower) than the prices negotiated by private insurers. But what happens all too often is that these government programs, which represent the most vulnerable segments of our population, pay the highest prices for drugs. Prices are not justifiable if their price discrimination disadvantages the vulnerable, and when this is the case the positive responsibility to take action lies with the drug company to use negotiation tactics that are more equitable.
While the price discrimination practiced by drug companies is unjustifiable, companies would naturally resist the idea of price regulation, perhaps arguing that the forces effecting drug prices are varied, complex and dynamic, and setting a price cap would not allow the industry to be responsive to changes. It seems fair to say that there are factors that lead to price fluctuation, but there is no evidence that the dramatic price increases we have seen across the medical industry due to “changing market forces.” Rather it seems that the dramatic increases are due to the industry being allowed to regulate itself. In the case of EpiPen the only fluctuation that seems to appear in their costs is the dramatic increase in advertising, lobbying and information campaigns. Furthermore, it may be that Mylan purposefully chose the beginning of the school year as the time to raise prices as both students and schools were stocking up for the year. This is especially problematic when we consider the extensive effort Mylan made to lobby the federal government to encourage schools to stock EpiPens.

Mylan has recently succeeded in getting a federal law passed to provide funding for schools to stock EpiPens, as well several state laws that mandate EpiPens be carried in schools. In theory this would be a noble goal that expands access to a life-saving drug, but in practice it is a means Mylan secured a legal mandate for more customers to purchase their product before jacking their prices up further. In a way, Mylan has pulled the wool over the eyes of legislators, lobbying them to mandate that the product then raising the prices once the schools, which are already underfunded in most districts, cannot opt out. Furthermore, Congress passed the law with a certain budget in mind, and that budget will not stretch as far now that the prices have increased. What adds insult to

injury is that Mylan cites their lobbying efforts as justification for their price increases. Mylan executives do not deny that their lobbying efforts were a major expense and may be a part of the price increase, but they do not seem to see the worry that crops up when a private corporation convinces the government to encourage or even require the purchase of their product and then increases the price. Mylan might argue that they provided a public service in expanding access, and relieved some of the burden on families to have multiple pens for their child, because at least the school would always have one. But by raising their prices they limit the good this program could have done, by increasing the burden for already strained school budgets and increasing the burden for families, who still need to buy a pen for their child for when they aren’t at school. To compensate for that, Mylan gave out thousands of free EpiPens to schools after the new law was passed, in response to the high prices. But providing some EpiPens for free does not make up for the damage done by the extreme costs to the school and health systems caused by their price increases.

Perhaps the public should be expected to take on all the costs of bringing EpiPens into schools because it is a public good that the government should have seen to without Mylan’s lobbying. After all, Mylan wasn't the only group advocating for more awareness of anaphylaxis and greater availability of EpiPen. The Food Allergy Research and Education group (FARE) also supports greater availability of EpiPen, but Mylan is a significant donor to FARE, so can the public trust their recommendations? Overall, giving out EpiPens to schools and providing savings cards to low and middle/low income Americans do not necessarily improve access, because they may exclude as many people

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52 Coy. "The EpiPen Drama Shows What's Wrong With How Drugs Are Priced." (2016)
as they include, and the measures only help if they offer them year after year, and if they
don’t continue to raise their prices. Mylan might say that the $600 price is “worth it” to
consumers, insurers and taxpayers, but just because a drug is “worth” a certain price,
doesn’t mean that that price is fair, especially when those prices are coming out of patient
pockets. Many people may say that EpiPen is “worth” the $600, but if they don’t have
$600 its worth doesn’t matter because they simply can’t afford it. Mylan’s spending on
advertising, lobbying and even their “charitable” gifts to non-profits, call into question
whether consumers are being given the opportunity to make informed decisions about
their health. If government decisions are being influenced by lobbying, and public
opinion is being swayed by advertising and EpiPen subsidized education campaigns, then
it is difficult to say whether consumers are able to make informed choices. Add to that
the opacity of Mylan’s communications about their costs, and the public has virtually no
trustworthy information about EpiPen.

In addition to their suspicious practices in lobbying the government, Mylan and
other drug companies have participated in creative but questionable bargaining practices
with insurance companies. Mylan offers $300 rebates to many insurance companies who
include EpiPen in their formularies, which raises questions about whether the insurers
have any interest in lowering prices, and about why the prices would be so high if the
private insurers all pay less\textsuperscript{54}. The answer may be that because Medicare cannot bargain
for lower prices, taxpayers and the elderly may be paying the $600 sticker price when no
one else is. These rebates are suspicious because they suggest that there really is no
reason for the $600 price tag, except for the fact that Mylan has nothing stopping it from

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\textsuperscript{54} Bedford. "Medical Ethicist Art Caplan: $600 EpiPen Controversy Is Just Part Of A (Much
Larger) Problem." (2016)
charging as much as they want, since there is a costumer (Medicare) who will have to pay whatever price they are offered. What is further disturbing and implicates insurers in rising costs, is that despite the rebates given to the insurers, many patients still have high out of pocket costs, suggesting that insurers are not passing their savings on to customers. These deals between insurers and drug companies are also problematic in the exclusivity of the deals that are made. If these bargains were not struck, one could argue that EpiPen’s competitors may have had an easier time gaining market share. As it stands, if an insurer wishes to pay less than $600 they most likely have to agree not to cover non EpiPen auto-injectors. It seems that there should be a shared sense of responsibility for setting fair prices, and insurance companies should allow their customers to retain their choice of drugs and treatments, especially where cost differences exist.

Many problems associated with drug pricing and drug company practices, including Mylan, are difficult to really parse out because of the secrecy under which the industry operates. Even when called in to testify for Congress, Heather Bresch refused to give the full picture of the costs of manufacturing and selling EpiPen, or the deals made with insurers. This cloud of secrecy makes it very difficult to fully understand the true reasons for rising drug costs and thus makes it difficult to determine for certain whether prices are ethically justifiable. This opacity must be cleared if we are to get an accurate picture of drug pricing ethics. Furthermore, while the opacity makes it difficult to understand the drug pricing landscape, it also suggests fishy practices on the part of pharmaceutical companies. The lack of information is a problem because it hinders our ability to answer some of our ethical questions about the fairness of prices being set, but it is also an ethical problem in itself. We do not only want to know about the workings of

Mylan in order to know whether they are up to no good, we also just have a right to know what we are paying for, and to make informed decisions about all our purchases. This right to make informed decisions is even more important in health industries, because of the high stakes for patients and high costs to consumers.

All of these ethical questions have been raised since the last price increase of EpiPen, and in response to the public outcry about the unreasonable cost Mylan has decided to release a generic version of the EpiPen. While it is certainly a positive step that the company felt the need to take steps in response to the public outcry, their decision to release a generic to compete with their own product is an interesting one, and may have further effects on price discrimination. Once they release the generic, which will be completely identical to EpiPen except for the label, Mylan plans to list it at $300 for a pack of two. But the question is why not just lower the price of the brand name to $300, especially since that is already the price most insurers pay after rebates? There has been some speculation that releasing a generic will actually have very little impact on the cost of EpiPens, because insurance companies will continue to cover the brand name with the old rebates, or will purchase the generic for the same price. The offer of a generic may have an effect on Medicare because their lack of bargaining power may mean that they have paid the most for brand name EpiPens, but again because of the secrecy of the industry we do not know who pays what.

Throughout this case study, several key questions arose that will relate to future case studies, and to the overall goal of determining whether the prices we pay for pharmaceuticals are justified. Mylan is certainly not the only company to take advantage

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of market exclusivity, and it may not be right to place blame on them for trying to make a profit when that is their goal as a private company. However, the way in which Mylan and other companies use market exclusivity is wrong, and we should not allow them to set their own prices without the regulation of government or competition. This seems at least in part to be because of a lack of reciprocity between the pharmaceutical companies and the public, the public provides patent protection so the pharmaceutical companies should be paying them back by not charging exorbitant rates, or at least not by wasting public resources with long legal battles to extend exclusivity. Another issue of reciprocity seems to be in the issue of research and development, prevailing studies seem to indicate that drug companies spend much more on money on advertising then research (this is certainly the case with EpiPen), while the NIH takes on the risk of investing billions in innovation. Without diving into the complex slew of ethical issues associated with drug marketing, it is clear in the case of EpiPen, the public is being charged repeatedly for the same product: first through the taxpayer dollars funding innovation, Medicare and Medicaid, second through health insurance premiums and third at the pharmacy counter. In order for the price of EpiPen to be justified, it must match the criteria established; it much be a quality product available to all at prices they can afford that allows for both consumer choice and corporate profit. EpiPen is a quality product that saves lives, but its price makes it unaffordable to many Americans and places as high burden on individuals and insurers (particularly the most vulnerable). Furthermore, the high prices are not necessary for recouping any losses sustained in improving the quality of EpiPen, because the prices have been going up even when no changes had been made. Additionally, the secrecy under which Mylan operates and their marketing and lobbying
efforts have limited consumer choice and obstructed the right of patients and consumers to know what they are paying for. While the prices charged by Mylan are not justifiable, there is a shared responsibility for bringing down costs. Mylan certainly takes the blame for taking advantage of market exclusivity to set high prices, practice unfair price discrimination and hiding information from the public, but private insurers, the government, and individuals also must accept responsibility for bringing down costs. After reviewing all of the case studies, I will show what policies can be implemented by all of these groups to lower costs.
Chapter 2: Case Study on Hepatitis C Treatment Costs

Hepatitis is a tricky disease to nail down, some estimate that between three and five million Americans are infected, but only half know it. This is because Hepatitis can lay dormant in the body for decades, or present itself with flu-like symptoms early on. Around a quarter of those affected by the disease have it for only a short time because their bodies fight it off on their own. Most people infected with Hepatitis, about 2.7 million Americans, develop chronic Hepatitis (Hepatitis C or Hep C). Hepatitis C has a spectrum of severity within itself as well as a six distinct virus strains. Chronic Hepatitis can also start with flu symptoms, but down the line can lead to chronic liver disease, cirrhosis of the liver, and liver cancer. Hepatitis is a blood borne illness and most patients develop it through injected drug use, or from blood transfusions received prior to 1992 (at which time a screening test was developed to detect Hepatitis)\(^{57}\). The connection between Hepatitis C and injected drug use creates many problems for treatment, because patients may be disconnected from health care, they may face stigma in trying to access care, and if they are uninsured they may not be able to afford it. Furthermore, there are some concerns that even when Hepatitis patients who use drugs receive treatment they do not follow through.

Treating Hepatitis C has always been costly, even before anti-viral treatments were available, the cost of treating the long-term liver damage can be millions of dollars for just one patient. Early anti-viral drugs attempted to curb these costs and the harm done by the disease by attacking the virus before it can cause too much damage. These early anti-viral medications were administered intravenously in hospitals, so it was very

difficult for patients to keep up with the treatment. Furthermore, they were not very effective, safe nor cheap. Since 1991, when the FDA approved the first Hepatitis C treatment, advances have slowly been made to improve the quality of life and health outcomes for Hep C patients. At the start, even with treatment there was very little chance of clearing the infection. Most treatments were administered intravenously in hospitals and were prescribed only to those who had already developed liver disease. The necessity of getting to a hospital and possibly remaining there for long stretches of time was a significant burden for patients, especially those who suffered from drug addiction or were uninsured. Treatments before 2013 were not recommended for patients suffering from HIV co-infection or liver cancer nor were they effective across the spectrum of Hepatitis C genotypes.\textsuperscript{58}

Since 2013, treatments have become safer, more effective and more widely usable—across multiple Hepatitis genotypes, in patients with co-infections like HIV and during many stages of disease progression. In 2013 the first oral medications for Hep C - Sovaldi and Olysio - were approved, making treatment easier for patients to obtain and keep up with; however these treatments were still recommended in conjunction with intravenous, hospital-administered medication. While these medications made dramatic steps in efficacy and in the spectrum of patients that could be treated, fully outpatient care was still out of reach for another year. In 2014, Harvoni and Viekira Pak were approved by the FDA as fully oral regimes; however they are only shown effective in patients with Hepatitis C genotype 1 and not for patients with co-infections. In the next year other oral treatments were introduced to treat Hepatitis C genotypes 3 and 4, but in 2016 the first drugs designed to treat the full spectrum of Hepatitis genotypes are approved. These

\textsuperscript{58} Ibid.
drugs - Zepatier and Epclusa - are all oral, single tablet regimens, which after 12 weeks see 94-100 percent of patients’ virus free. For patients fighting Hepatitis, these drugs could be life-saving and come with both more guarantee of success and less commitment from the patient59. However, while these new drugs truly solve some of the pressing issues of Hepatitis C treatment, and reduce some of the costs associated with hospital administered treatment, the cost of these drugs is still very high and is causing major problems for both individuals and providers.

With the greater efficacy, broader use and ease of new treatments comes higher demand. More and more people with Hepatitis C are looking for a cure, but due to the high cost of the treatment providers are worried about the increased costs. Since 2014, new Hepatitis C medications have led to a 13.1% increase in prescription drug spending nationally and the Center for Medicare and Medicaid services estimates that the demand for and cost of Hep C drugs will lead to an additional $65 billion in spending over the next 5 years in comparison with previous treatments60. These costs are staggering, but are not surprising given the $54,000-$94,000 price tags. It is certainly shocking when Zepatier can advertise itself as a bargain at $54,000 for a 12-week course because their biggest competitor Epclusa costs $74,000. To be fair, compared to the costs the last generation of Hepatitis C medications (Harvoni costs an average of $94,000 per course), the newer generation does save money61. This is further true when we factor in the cost saving associated with reduced rates of liver disease (a liver transplant can cost $700,000

59 Ibid.
for the surgery alone\textsuperscript{62}, but in the short term costs are going way up because of the increased demand for the improved drugs.

The increase in demand is significant and has many causes; the newer drugs are more effective, have fewer immediate side effects and are less cumbersome as they generally consist of a once daily pill. Furthermore, previous generations of treatments have been unavailable and unusable for broad spectrums of the Hepatitis C infected populations. Previous generations of drugs were only effective on individuals at specific stages of liver disease caused by Hepatitis C, and not available to those with HIV co-infection. Because the newer drugs are usable by broader spectrums of the Hep C positive population, the demand, and thus cost, is going up. This has caused rationing on the part of insurers in order to limit the amount of patients eligible for the new drugs. Many insurers have decided that in order to receive these drugs a patient must have liver disease diagnosed by biopsy\textsuperscript{63}. This means that many patients who are Hep C positive are not eligible for treatment until they are experiencing liver disease which may have painful symptoms and which must be diagnosed through a somewhat dangerous procedure. Some exceptions to these rationing rules can be made in cases where co-infection can increase the risks associated with liver disease or biopsy, such as kidney disease or HIV, but overall it seems that there are some serious problems caused by the costs of Hep C medications.

The prohibitive costs of Hepatitis C drugs are problematic for one major reason; it forces a decision for healthcare providers in which they must choose between the prime

\textsuperscript{62} Ibid.
objective of doctors to improve health and prevent illness, and the necessity of having a sustainable healthcare system that can continue to treat and support patients for years to come. The position that the prices of Hepatitis C drugs put us in is one where we must decide to prevent and fight liver disease by attacking its cause—Hepatitis C—but in doing so bankrupt our healthcare system. This is an impossible situation because whatever the choice, the outcome means that patients will not receive treatment, whether now or in the future.

While insurance companies and doctors state the need to lower the costs to treat a wider range of patients, drug companies state that the prices they have set for their products are fair. Many of their reasons are similar to those we have heard from Mylan and other drug companies, which is that the innovation of their company comes at a price. This argument is more compelling in this case than in Mylan’s, because we can see from the progression of Hepatitis C treatments that these newer drugs are better than what has come before, and the research needed to develop them may well have been expensive. On their last drug to treat Hepatitis C – Harvoni—which costs over $1000 per pill, Gilead industries made $18 billion in 2015 alone, and on their new drug, Epclusa, which costs around $900 per pill they could stand to make even more because of increased demand. Whatever the losses sustained in research or from lower sales of Harvoni and other older drugs, Gilead still stands to increase revenue by $1.8 billion this year. There is no doubt that they will make money from Epclusa nor that Epclusa is a better treatment and will help more people than previous generations. But how much

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profit is necessary to stimulate innovation? A company would never invest in drugs that they couldn't profit from or would lose money on, and we want to invest in innovation and encourage companies to develop new drugs. But the cost of treating Hepatitis C could bankrupt our public healthcare systems. Part of the reason why costs to our overall health system are going up even though Epclusa and its competitors cost less than the last generation of drugs is that they are effective in more patients, so demand has gone up.

But because the drugs are priced so high, insurers are limiting who can access them, so one might wonder whether it is in Gilead’s or the public’s interest to maintain the high prices. Setting a lower price could mean that all 2.7 million people effected by Hep C in the US have access to treatment, and Gilead could still make a huge profit. Even if they couldn’t make more money, or even the same amount of money by making it available to more people, they would certainly still be making a great deal of money. While Gilead is certainly benefiting form the price they set, many Americans are losing out, and many more are becoming affected, as those with the disease pass it on to others. The incredible possibility created by being able to cure Hep C, is that we cannot only help those already effected, but can help stop the spread of the disease. Currently a major hurdle to fighting Hep C, is that patients continue to practice high-risk behaviors like drug use, and pass on the disease to others. But being able to cure Hep C is almost as good as a vaccine in that it stops patients from being able to infect others. The truly troubling question this raises is whether it is in Gilead’s interest to cure everyone of Hep C, because it would mean they are not guaranteed a large customer base in the future. This further raises the question of whether Gilead may be intentionally making their drug unaffordable to ensure that many people remain in need of care.
The problem with Hepatitis C is that its primary patient base is drug users, which means that before there were curative treatments that are relatively easy to follow through with, the amount of patients seeking treatment for their Hep C was small. Many drug users were unwilling or unable to be in the hospital for long-term treatment and were unlikely to be aware that they carried the virus till late in the stages of cirrhosis. With expansion of health insurance and healthcare, and with more ease of treatment there is a far greater demand for treatment, but unfortunately the prejudice against injecting drug users does not make them sympathetic victims of healthcare rationing. When a child is at risk of death from anaphylactic shock, there is very understandable public outcry, but when a drug user or former drug user develops cirrhosis, they are seen to have brought their troubles on themselves. Thus there is some concern that drug companies and insurers may not see the harm in rationing Hep C drugs, or waiting until patients get sick before they provide cures, because the most needy patients in Hep C cases are those who are seen as untrustworthy and likely to relapse. So even if companies like Gilead are intentionally ensuring that many people remain sick, public outrage is not as likely if the victims are unsympathetic.

This problem is further complicated by the fact that most of these high-risk patients will get their insurance through Medicaid and Medicare, which are in the most precarious financial position and have the least ability to bargain with drug companies over cost. Hepatitis C is likely to cost Medicaid and Medicare 10’s of billions of dollars in the next five years, and the only possible means to avoiding financial disaster seems to be denying care, which is unconscionable, and negotiating lower prices, which is currently illegal. While it is certainly true that curing more people of Hep C will reduce
the amount of liver transplants and hospital stays that are associated with cirrhosis caused by Hep C, those savings won’t be seen for years. For now, the insurance industry is dealing with the costs of those who developed cirrhosis before a cure was available, those who are experiencing symptoms of cirrhosis while they wait for their disease to develop to the point that they qualify for the cure, and the cost of the cure. So in reality, costs are getting much higher and will remain high so long as more people develop Hep C than there is money to cure them.

New Hepatitis treatments align with the goal of improving health, they are certainly innovative, and while not without their share of serious side effects, they improve health outcomes for patients and can generally be regarded as both safe and effective. Furthermore, there were certainly high costs incurred to achieve this breakthrough and so there may be a justification for high prices. One may be sympathetic with the argument that while prices are high they reflect future savings. Still, one would hope that the aim of the health industry in making technological advances is to improve the quality of life for patients and reduce the toll of illness on our patients and our wallets. So perhaps cost savings are not as relevant as the life saving benefits of the drug, and justification for high costs should come from the value of the drug and the cost of research, not the cost savings. In my view, citing down-the-line savings for health insurers is a type of veiled reference to down-the-line losses for drug companies. We should not factor in future losses to current prices, only past losses. The projections for Gilead’s revenue show an increase of over a billion dollars in profit within the first year of Epclusa reaching patients. This shows that even accounting for investment in its research and losses on increasingly obsolete treatments, Gilead is making plenty of
money off their new product. But in making these billions, Gilead is denying access to
millions of Americans and putting our entire healthcare system in jeopardy. By making
their product inaccessible, Gilead is forcing patients to suffer through liver disease when
it is no longer necessary for them to do so. This high human cost can only be justified if
it is necessary to pay for the development of the drug, or necessary to keep them in
business. This is not the case for Gilead; their high profits in the first year of selling their
product even as huge portions of customers are excluded, show that there is room in their
bottom line to negotiate lower prices. With 2.7 million possible customers in the US
alone, there is a huge margin for profit, and it is not necessary to set such high prices.
Chapter 3: Case Study On the Cost of Treatment of Multiple Sclerosis

Multiple Sclerosis, or MS, is a relatively rare and potentially debilitating disease of the central nervous system. MS is generally developed by patients between the ages of 20 and 50 with about 200,000 patients developing the disease per year in the US. While the exact cause is unknown, it is likely caused by a combination of genetic and environmental risk factors. In cases of Multiple Sclerosis, the patients’ immune system begins to attack the protective coating around nerve fibers, preventing the patient’s brain and spinal cord from engaging in proper communication with the rest of the body. Multiple Sclerosis is a progressive disease, and the deterioration of nerve coating can spread over time and can also become permanent. The symptoms of MS are wide ranging from numbness or weakness in one or more limbs to vision problems to tingling and pain in any part of the body to tremors and loss of motor control.66

Cases of MS fall into a couple different categories, from relapsing-remitting to primary and secondary-progressive MS. Most people with Multiple Sclerosis have relapsing-remitting disease courses in which they experience a-symptomatic periods broken up by relapses that may last days or weeks but which lift partially or completely; periods of remission may last months or even years. However, 60-70% of people with relapsing-remitting MS experience a steady progression of their symptoms into secondary-progressive MS. In these cases patients have an increase in the severity or frequency of their symptoms, and may or may not experience as many or as lengthy periods of remission. The final and most rare category of MS is primary-progressive; in these cases patients experience a steady progression of symptoms from the onset of their

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illness, while this progression may be very slow these patients experience no relapses or periods of remission\textsuperscript{67}.

While there is still no cure for Multiple Sclerosis, there are two main avenues of treatment. One means of treatment is to assist in the recovery of patients after MS relapses or acute symptoms. To treat acute attacks of MS, patients might use steroids to reduce nerve inflammation or might receive blood plasma exchanges if they have not responded to steroids. Patients may attempt to relieve and manage symptoms by using muscle relaxants to alleviate muscle pain and spasms, or may use physical therapy and/or mobility aids to learn to manage their symptoms and continue on with their lives and jobs while fighting MS. The other avenue, is to attempt to slow the progression of the disease and prevent relapses; this form of treatment is expensive and ongoing and will be the focus of this chapter. There are many treatments available to modify disease progression, but many of them come with serious side effects and may lose their efficacy requiring regular evaluation and treatment changes. Disease Modifying Treatments or DMTs were first introduced in 1993 and at first there were very few options, but now there are about ten main DMTs prescribed to MS patients\textsuperscript{68}. It should be noted that there is some debate in the scientific community concerning the efficacy of DMTs for MS\textsuperscript{69}. I will address the need for more studies on the comparative efficacy of the different treatments, but I will be giving both companies and patients the benefit of the doubt and will work with the assumption that these drugs provide value to patients.

The first class of these drugs are beta interferons, which are the most widely prescribed and are very effective in reducing relapses, but they carry side effects of flu

\textsuperscript{67} Ibid.
\textsuperscript{68} Ibid.
\textsuperscript{69} Ibid.
symptoms, require injections which may cause negative reactions, can do irreversible liver damage, and can lose their efficacy after prolonged periods of use. Other first line medications include: 1) Copaxone, which may stop the patient’s immune system from attacking the nerve coating but causes injection site reactions, 2) Tecfidera, which is taken orally but has digestive and immune side effects, and 3) Gilenva, another oral medication which reduces relapses but also slows the heart rate and causes headaches, high blood pressure and blurred vision. Aubagio is another oral medication that reduces relapse rate, but also causes liver damage, hair loss, and can be harmful to a developing fetus. Tysabri stops immune cells from reaching the spinal cord and brain, but is generally used as a second line defense after other medications have failed or as a first line in very severe cases, because blocking immune cells from the spinal cord and brain can put patients at a high risk of infection. Lemtrada is another aggressive but risky drug, it can limit potential nerve damage caused by immune cells, but it can also inhibit the body’s ability to fight infection, and requires several days of hospitalization while the drug is administered. Finally, Mitoxantrone is another immunosuppressant that is used in a very limited capacity to treat the most severe and advanced cases of MS, this drug can damage a patients heart and may contribute to the development of some blood cancers.\textsuperscript{70}

In the last 20 years there has been vast improvement in the number of disease-modifying therapies available for MS, from one beta-interferon treatment in 1993 to 10 different treatments today. While this has provided more choice to doctors and patients, and has given them the ability to find the treatment that works best for each patient, there is still no cure for MS nor is there a drug that consistently or completely stops relapses. Furthermore the side effects of these drugs run the gamut from irritating to risky to

\textsuperscript{70} Ibid.
potentially fatal. While the symptoms of MS and the side effects of its treatments are distressing enough, another layer of anxiety is added by the extreme cost of MS disease-modifying treatments. There is currently no DMT with a sticker price of less than $50,000 per year, and this is not a one-time cost, patients wishing to limit their relapses or manage their disease progression need to remain on DMTs for their whole life\textsuperscript{71}. Very few individuals or insurers pay the full price for these medications, but Medicare does, and even after negotiations and rebates, the price remains very high for insurers, patients, and our health care system as a whole. And what is further distressing about the price of these drugs is that despite the increase in competition, prices have gone up not down, defying our classical economic expectations and the common fears expressed by the pharmaceutical industry regarding competition.

In the last three years there have been two major reviews of the cost of Multiple Sclerosis treatment. In 2013, the \textit{Journal of Medical Economics} found that the costs of treating MS had risen from an average of $8,500 per year in 1999 to more than $50,000 per year in 2008. According to this study, the rising costs of DMTs accounted for most of this increase\textsuperscript{72}. These rising costs pose major problems for patients, doctors and insurers; rising costs have contributed to increases in premiums for all insured Americans and these rising costs and premiums have also led to more high deductible plans and high co-pays. High co-pays and deductibles are particularly problematic for MS patients since many are unable to work because of their disease. According to Dr. LaRocca, vice president of healthcare delivery and policy research at the National Multiple Sclerosis


\textsuperscript{72} Ibid.
Society (NMSS), “Over the last few years, the prices of MS disease-modifying drugs have escalated faster than inflation. Most people with MS are able to cover their healthcare expenses, but it is challenging and has led many of them to make compromises, such as skipping doses or taking drug holidays.” Skipping doses or taking smaller doses than prescribed can be very dangerous, especially in MS medications that have both serious side effects, and serious symptoms when drugs are ineffective; drug holidays, where patients temporarily stop filling their prescriptions are also very dangerous and put patients at risk for experiencing disease progression or relapse. These cost saving measures are not things that any patient should ever have to consider.

Another study, published by the American Academy of Neurology in 2015, evaluated the effect that new drugs entering the market had on the price of existing drugs and on the average cost of DMTs. It is a generally accepted theory of classical economics that as the number of products meeting a certain demand increases, then the competition for buyers will drive the prices of these products down. This should be especially true if newer drugs are more effective or more convenient, because older drugs would need to price themselves lower to compete with the better drugs, or at least this is what classical economists teach us. However, the results of this study showed something very different. The first drugs to treat MS came on to the market priced between $8,000 and $12,000 per year, and after 1996 new drugs entering the market had a list price about 25-60% higher than the old medications. This price difference is to be expected, the newer medications would be offering some new value, for which they would demand a higher price. What is surprising, however, is large increases in the costs of first-generation drugs, but after the approval of the third beta-interferon drug (Rebif) in 2002

73 Ibid.
and Natalizumab in 2006, the prices of both old and new drugs began to increase dramatically. The costs of MS drugs have been increasing far faster than inflation, the average cost of prescription drugs in general, and even faster than other medication within the same class (Biologics). If the cost of the first-generation beta-interferons had been increasing at the rate of inflation, they would have cost between $12,000 and $19,000 per year in 2013, but instead they cost $62,000 per year. In 2015 DMTs cost two to three times more in the US compared to similar countries, and there are now no DMTs costing less than $50,000 per year (before rebates).

It is not just shocking that the cost of first-generations have increased despite competition, but that the first-generations have raised prices at a higher annual rate than their competitors, and some of the early drugs actually cost more than newer ones. The average increase in prescription drug prices in America between 1996 and 2010 was about 3%-5% annually. During the same period, the average annual price increase of first generation DMTs is 21%-36%, while the newer oral medications, have increased prices 8%-17% annually. Currently, the very first MS drug ever introduced, Betaseron (released 1993), costs $61,000 per year while Extavia (released 2009) costs $51,000 per year, both of these drugs are beta-interferons with similar modes of delivery and side effects. The dramatic increase in first-generation prices seems closely tied with the introduction of newer drugs, but not because of some increase in manufacturing costs, otherwise international prices would have risen too. This suggests that companies

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increased their prices in response to the prices of their competitors. This trend defies the rules given to us by classical economists. John Tozzi has an interesting analogy for the problem with these MS drug-pricing schemes. He compares these drugs to iPhones and asks us to imagine if Apple sold its oldest iPhone alongside each generation of new iPhone and each time it released a new phone it raised the price of the older generation to match the price of the new phone\textsuperscript{76}. Obviously that would make no sense, no one would buy the older phone and they would be forced to abandon the practice. So why is this working for the manufacturers of MS drugs?

In the 2015 Neurology study, a few different reasons for this extreme increase are posited. The simplest explanation, in their view, is that the drug companies are just taking advantage of our flawed system, which puts no limits on the prices of pharmaceuticals and thus allows companies to steadily increase prices in order to maximize profits\textsuperscript{77}. Old companies realize that there is a willingness to pay more for their drugs, and because there is no ability to boycott drugs there is no public or private sector means of limiting the price increases. Unfortunately the payers most affected by these increases are Medicare patients, and taxpayers funding Medicare. Medicare is one of the largest health insurance providers in the United States, but is likely the only one paying the full sticker price for the horrendously expensive drugs in this country. The Neurology study admits that the landscape of drug pricing is very complicated and there are more reasons than just greed leading to high prices; complications caused by patent monopolies, third party pharmacy benefit managers, and lack of comparative clinical


\textsuperscript{77} Hartung et.al. The cost of multiple sclerosis drugs in the US and the pharmaceutical industry: Too big to fail?" (2015).
studies all led to our current dysfunctional system. However, there is also very little transparency in these price setting decisions and that can lead some to some very cynical speculations, like that these price hikes suggest collusion between drug companies. While price data may not be enough to prove collusion, the general market trends in the pharmaceutical industry suggest that companies are not competing on price.

Pharmaceutical industry representatives dispute claims that drug inflation has been greater than medical inflation overall. However in the case of MS this seems to be false, as the costs have risen by over 20% annually for first generation drugs compared to the 3%-5% increase for pharmaceuticals overall. Another claim is that most of the price increases on innovative drugs are offset by price reductions in other areas as generics hit the market, but one could argue that drug companies have been working hard to prevent generics from accomplishing this balance by preventing them from reaching the market. They also argue that looking at the list price is not a fair measure, because so many of the insurers receive rebates or negotiate lower prices, and patients often receive help from drug companies in managing co-pays when they are prohibitive. However, while this is true for private insurers, Medicaid and the VA, it is not true for Medicare and so both Medicare beneficiaries and taxpayers are paying the full list price for MS drugs. Furthermore, waiting for and depending upon financial assistance from drug companies is a vary precarious position to be in as a patient and it seems like it would be much simpler if the drug companies would only charge a fair price for their products.

Dr Kenneth Kaitin, Professor of Medicine at Tufts University has an interesting take on pharmaceutical pricing that is both skeptical of and sympathetic to drug

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78 Ibid.
companies. He has a healthy amount of suspicion about the pricing decisions made by drug companies, because he has never seen any description of their pricing process and there is currently no requirement or incentive for them to be forthcoming about those decisions. This lack of transparency allows the companies to drive the narrative about drug pricing, they can claim that the high costs of research, development and bringing drugs to market all drive up prices. Dr. Kaitin suspects that something else is at work though, and that is value.

The real factor is value. If you develop a very expensive drug that few people are interested in, then you’re not going to price it high because then even fewer people will be interested in it. In that regard, pharmaceuticals are just like any other commodity, any other product…If you develop a product that doesn’t cost too much to manufacture, however if it’s of tremendously high value, it’s going to be priced very high.

Dr. Kaitin is explaining here that in some ways they are limited by the laws of supply and demand; they cannot charge the extreme prices they do for MS drugs for products with very little value. However, because unlike other products, consumers cannot choose to forgo purchasing a drug, and in some ways may not even be able to go to a competitor for a drug if that is not covered or if it will not be effective in their case. Dr. Kaitin emphasized the need for drug companies to have balanced portfolios of drugs, some that are high earners, like DMTs, so that they can support less profitable drugs and fund research efforts. While major drug companies may not be doing very innovative research to find cures in house, they invest heavily in smaller labs, which often go under.\textsuperscript{80}

Despite these defenses of drug companies price setting choices, there seems to be something particularly disturbing about the trend in Multiple Sclerosis medication.

pricing. Part of the reason for this concern is the consequences it is already having for patients and payers, and the fact that there is nothing really stopping the prices from increasing indefinitely. These price increases are already leading to serious consequences for patients and insurers. The high prices have caused insurance companies to make decisions on their formularies based on preferential price negotiations rather than by the value of the drugs to patients. Furthermore, insurance companies have a tendency to deny first requests by patients for expensive drugs, causing delays for patients in accessing care as doctors and patients comply with the multiple approval steps. All together the high costs of drugs and the responses to them by insurance companies has added undue burdens to patients already struggling with the stress and complications of serious diseases. It seems that there are four main ethical problems with the price of Multiple Sclerosis drugs; 1) the backwards practice of drug companies raising prices to match competitors, 2) the lack of any cap or end to this inflation, 3) the rebates used to lower prices for patients and insurance companies rather than actually lowering prices and 4) the problems with the bargaining power of Medicare and patients.

The pricing of MS medications defies all the rules we are supposed to accept concerning competition and prices. This poses a very serious objection to the way our pharmaceutical system works and is concerning for the future of the industry. DMT prices have shown that there is no invisible hand guiding drug prices and keeping them affordable, even in cases where there is competition. Each increase in price or introduction of a new drug has just proven that the willingness to pay for MS drugs is high, and each increase in price for one drug has encouraged competitors to raise prices. This is a very problematic system, because while it is true that there is a high willingness
to pay for these drugs, this willingness is coming from a point of near duress for patients and providers. Patients and providers are not willing to pay the high prices, they are forced to pay whatever price the companies decide on because the alternative is MS attacks, relapses and a steady progression of symptoms.

These price increases seem to show that companies are not setting prices based on increasing manufacturing costs or other variables. Even if companies are using their blockbuster or strong revenue producing drugs to pay for research ventures, it does not follow that these prices are reasonable. It is in the interest of our medical system and of MS patients themselves for more research to go into finding better therapies and hopefully cures for MS and other diseases, but ever increasing costs of drugs puts a tremendous burden on patients and on our healthcare system. If premiums continue to increase, then there won’t be enough people able to afford health insurance and support the system. While MS drugs are not the only culprits in skyrocketing healthcare costs, their strange anti-competitive pricing is indicative of the problems associated with unregulated pricing, and what is even more troubling about the lack of regulation is that there is no end in sight to these price increases.

There is nothing legally stopping drug manufacturers from continually increasing their prices, and it is very difficult for patients, doctors and insurers to have any impact on prices without sacrificing patient outcomes. Due to the lack of regulation on the drug industry’s price setting, unless there is some evidence of collusion among the manufacturers, there is really no way to stop them from continually raising prices, and so far there is no evidence of collusion except the strange price trends. Without this there is currently no real regulatory authority to restrict these price increases. Furthermore, as
mentioned before, patients and for the most part insurers have no collective means of
demanding lower prices. While insurers (besides Medicare) can bargain for lower prices
or demand rebates for drugs, it is very difficult to negotiate lower prices without
sacrificing patient outcomes. An insurer is unlikely to be able to negotiate lower prices
on all the MS drugs on the market because most likely negotiations involve some sort of
price preferential, where the insurer agrees to give preference to one brand over another
on their formulary. This is a sacrifice of patient outcomes because patients all respond
differently to different drugs and the insurer preference drugs may not be the most
effective for every patient.

A further problem with the way prices are set is the use of rebates, which must be
negotiated by insurers and thus excludes Medicare. Medicare, and thus the taxpayer,
pays a higher rate for drugs than any other payer. By setting high prices but allowing
negotiation the drug companies are essentially discriminating against Medicare. While it
is true that it is Congress that made this rule for Medicare, and pharmaceutical companies
are just exploiting it, the fact is that the pharmaceutical companies lobbied Congress
heavily to ensure that Medicare was denied bargaining power. Thus the industry has
made a loop-hole for itself that allows them a large customer base (the largest of all the
public and private insurers) that is forced to pay whatever price they set. This creates a
gigantic burden for our public health care systems which are on the verge of bankruptcy
and are shifting more and more burden on patients to pay for care.

Which brings us to the last problem: the unheard voice of the patient in price
setting. There has been much public outcry about the cost of drugs in this country, and
while this public image crisis has led to changes in some products, most drugs remain
high priced and companies continue to point to rebates, or payment plans, or coupons that reduce co-pays, and the systemic problem remains. The sad fact is that while patients and doctors can point to unfair prices and attempt to raise public awareness, they have no bargaining power themselves. Doctors and patients can educate themselves on prices and search for low cost alternatives, but in cases like MS where no alternative exists patients are forced to pay up. The healthcare system is unique because there is no option to walk away from the negotiating table and no boycott option. Manufacturers and regulators must come to some consensus on what a fair price is, and how much a company can over charge in the name of investment and research.
Chapter 4: Policies to reduce drug prices

The previous chapters have reviewed case studies in an attempt to understand whether the prices we pay for drugs are justified. In general it seems that prices are unjustifiably high, but there is some opacity in the pharmaceutical industry that makes it difficult to fully understand whether prices are justified. This opacity comes with its own ethical problems; by withholding information pharmaceutical companies are violating their responsibility to create fair access. Patients and buyers have the right to information about the products they are buying, including information about how prices are set. Thus, even if we cannot determine whether all high prices are unjustified, it is clear that the pharmaceutical industry is not living up to its ethical obligations. Furthermore, whether or not prices are unjustifiably expensive the fact remains that pharmaceuticals are unaffordable for many Americans; thus the American health system is not living up to its obligation to provide equitable access to drugs. There is plenty of blame to be shared for inequitable access; many pharmaceutical companies are taking advantage of loopholes and other problems with our health policies, but the blame for allowing companies to do so is shared among the entire American population and government. Without the unregulated system that exists in America pharmaceutical companies would not be able to set high prices. Pharmaceutical companies are in the business of making profit, and it is the job of the government to protect patients and consumers from unethical practices.

Thus the responsibility for bringing down costs rests with the government. There are several policy actions that could change the landscape of prescription drug pricing. These actions fall roughly into three categories: 1) enforcement of current regulations, 2)
creation of new legislation, or 3) amending old legislation. These proposals include policy recommendations as well as descriptions of some initiatives that have already been taken or attempted. While they vary in their feasibility and difficulty, none of the recommendations listed would require an extreme overhaul of our system, but rather would be changes in the government regulation of pharmaceuticals and changes in the practices of non-government stakeholders. I will begin with an overview of the steps that could be taken and conclude with some progress that has already been made.

**Possible actions:**

There are several different policy avenues open to the federal government from stricter enforcement of current policy to the repeal of ineffective legislation to the passage of new legislation. While it should be noted that the latter two would require a lot of political will, especially considering the recent track record of Congress in passing new legislation, the current debate over the future of American Healthcare could provide a forum for re-opening discussion of pharmaceutical regulation. A current hurdle for many of these proposals will be President Trump’s Executive Order mandating that federal agencies repeal two regulations for every regulation they add\(^1\). While this mandate does not stand in the way of more strictly enforcing the regulations currently in place it impedes the ability of agencies to add new regulation without going through Congress. Furthermore, the Trump Administration has made many statements regarding the high cost of drugs and the need to address the rising prices but those statements have generally argued for reducing costs by deregulating the industry. While some of the

policies recommended include the repeal of certain laws or parts of laws, these proposals are to remove restrictions on government interference, not to remove regulations on the pharmaceutical industry.

1. The **existing laws and regulations** that could be enforced include returning to the original interpretation of patent law, use of antitrust law to regulate prices, and tightening of FDA control over pharmaceutical advertising. In recent years the FDA and many courts have weakened the restrictions on what can be patented and how patent challenges can be litigated\(^\text{82}\).

   a. **Patent law** was written to ensure that only novel, useful and non-obvious drugs could receive patents and market exclusivity. But the patent office has allowed for several means by which these requirements can be dodged. Patents are issued to drug companies for features of drugs rather than the specific formula of the drug. This means that when one patent expires, the company can apply for a patent for a different feature of the same drug, thus obtaining a patent and 20 years of market exclusivity for absolutely no innovation. This creates a problem for competition because when a feature rather than formula is patented then it is harder to discern whether competitors entering the market are truly novel, because there is no direct formula comparison to determine patent infringement. Furthermore, allowing companies to get new patents for new uses of an old drug rather than a truly new treatment is that it both limits the entry of generics for both the new and old uses of the drug and limits the incentives for companies to invest in research for truly new drugs. In order for a drug to receive patent protection and market

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exclusivity the drug should be new, and it should accomplish something new; it should not just be better than a placebo but better than the existing treatments. To require true novelty and improved utility in order to receive FDA approval would require new regulation or law, but to require it for patent protection would simply require a changed interpretation of existing regulations and would have a profound effect. Finally, the Patent office should remove the incentives that pay patent officers bonuses based on the number of cases they review. This practice leads to more patent approvals and a more rushed process, because approving a patent actually takes less time than denying one.\(^{83}\)

b. Antitrust law is another route of existing law that could serve to curtail the rising costs of drugs. The practices of both generic and brand companies are in many ways very anti-competitive, and the point of antitrust law is to ensure that unlawful monopolies do not crop up. This could be pointed towards Big Pharma by limiting the amount of mergers and buy-outs in the pharmaceutical industry and ruling against other anti-competitive practices, like evergreening (constantly applying for new patents on old drugs) and pay-for-delay (essentially bribing generic companies to delay the entry of competition).

c. Finally, the FDA already has the ability to regulate pharmaceutical advertising, but they currently use this power very sparingly. The FDA currently regulates advertising only to make sure that companies describe the risks and side effects of medications and do not make overtly false claims about the benefits. They could however, take more serious steps to curtail the advertising efforts of pharmaceutical companies. Limiting the advertising could mean requiring that pharmaceutical companies state the comparative benefit that their drugs provide, or the price, or other

\(^{83}\) Ibid. pp. 427, 439
pertinent information. Or the regulation could be limiting the kinds of claims that the pharmaceutical company can make, today many companies make statements in ads about the possible unintended positive effects of the drug such as weight loss or “increased energy” which have limited basis in research. By using the regulating power already given to the FDA, we could limit the amount of misleading claims that drug companies make, and could possibly curb the demand for high priced drugs. If the ads stop falsely driving up demand, companies might abandon them, which could pull down costs.\textsuperscript{84}

2. In addition to enforcing the laws and regulations already in effect, \textbf{new policies} could be enacted to limit the rise of drug prices. Changes could include the repeal or amendment of some existing laws and the creation of new laws and regulations.

\textbf{a. Laws that should be repealed or amended} are the Medicare Prescription Drug Benefit Reform of 2003 (Medicare Part D) and the Hatch-Waxman Act. Both of these laws create loopholes for the pharmaceutical industry: limiting the power of the government and private actors to resist price increases. Medicare Part D prohibits the director of Medicare and Medicaid Services from bargaining to lower prices for Medicare beneficiaries\textsuperscript{85}. This is a giant loophole that accomplishes nothing except increasing pharmaceutical profits at the expense of taxpayers and Medicare beneficiaries. Medicare Part D also includes a provision that bans the re-importation of drugs from Canada unless the Director of Health and Human Services gives explicit permission. This provision was included with the explanation that safety standards could not be ensured if drugs were re-imported through Canada. While there is virtually no evidence that drugs imported from

\begin{footnotes}\footnotetext{84}{Ibid. pp. 448}\footnotetext{85}{Ibid. pp. 453}\end{footnotes}
Canada are more dangerous than drugs manufactured and directly sold in the US (and in fact there is some evidence that Canadian imports are safer), no Director of HHS has used their power to allow the importation of drugs from Canada. It should be noted here that importing drugs is not a long term solution to rising drug costs, but it is an important tool at our disposal to be used when prices on certain drugs becomes too high.

The Hatch-Waxman Act should also be repealed or amended to remove the loopholes that exist for companies in the patent application and litigation processes. This is the law that allows old drugs to be re-patented for uses outside of the original patent, which contributes to the practice of “evergreening,” increases costs and limits innovation by making old drugs more profitable than new ones. This act has a further problem in its regulation of patent litigation; under this law, whenever a patent challenge is raised in court, an automatic 30-month window of market exclusivity is given to the patented product, this serves only to limit the entry of generics and competitors which might drive down prices, and increase the amount of frivolous law suits brought to lengthen market exclusivity. Repealing or amending Hatch-Waxman would bring down drugs costs by allowing for more entry of generic drugs.

b. In addition to the amendment of old legislation, new laws and regulations could be created to bring down drug prices, there are possible steps to be taken at virtually every stage of the pharmaceutical industry: from research to clinical trials to patenting to regulating pricing and requiring transparency. To start, there are important changes that can be made to the way clinical trials of drugs are conducted. Currently, clinical trials only have to show that a drug has more benefit than a placebo and has minimal harmful side effects, but new policy should be made requiring that drugs not

86 Ibid. pp. 441
only be tested against placebos, but against drugs already on the market for the same purpose. Along with this new policy would be several others to support it, including making all study results public so that companies cannot bury negative results, and a reorganization of the exclusivity period granted after patent and FDA approval. A reorganization of the market exclusivity would mean a reduction in the amount of years that a company was granted exclusivity (currently the period is 20 years), but the exclusivity would begin after the drug finished clinical trials and received FDA approval. This policy change would have several positive effects, it would lesson the amount of time of market exclusivity, allowing for competition to begin sooner and prices to go down, it would reduce the rush that is placed on clinical trials since they would no longer eat into the exclusivity period and our knowledge of the drugs on market and our consumer power would be increased since we would have more information about the relative effectiveness of new drugs.

In order to accomplish these changes there would need to be some changes made to the operations of the FDA. This is one of the more difficult policies to enact as it would require more government investment in the FDA and would remove a lot of the influence of drug companies on FDA practices. In order to make sure that the FDA is serving the public by regulating drug companies and ensuring the development and distribution of safe and useful drugs, we need to get the FDA out of the pockets of Big Pharma. Currently the FDA is essentially paid by the pharmaceutical industry to review their drugs as they are required to pay “user fees” to the FDA when they submit a drug for approval. While this policy was enacted to ease some of the financial burden from the federal government, its result has been that the FDA is now incentivized to review and

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87 Ibid. pp. 427
approve new drugs\textsuperscript{88}. Along with the reform of clinical trials, this would hopefully reduce the amount of frivolous trials and refocus the industry on putting forward truly innovative drugs, and with more funding from the government, the FDA could serve its purposes of protecting people from harmful drugs and making sure that new drugs are useful and worth the price we pay. In order to accomplish any of these FDA reforms we would first need to remove those with ties to the pharmaceutical industry from the FDA advisory boards, as these boards are currently populated with people who have conflicts of interests and incentives to keep the FDA working for companies rather than people.

Once there is more adequate research into the comparative effectiveness of various drugs and once Medicare can join the rest of the healthcare payers in advocating lower prices, an “indication specific” model for pricing can be used. An indication specific pricing model uses the comparative effectiveness of drugs to establish their value\textsuperscript{89}. Currently, any new drug on the market is likely to cost twice as much as an older version whether it provides more patient benefit or not. While some hospitals, doctors and insurers have taken the initiative to refuse to purchase and prescribe marked up drugs with no added benefit, there is currently no national system for comparing the cost effectiveness of drugs within the same class. This needs to be changed if all the various payers and stakeholders are going to make informed decisions about which drugs to buy and how much to pay.

The final step in creating new policy is \textbf{accountability}. Drug companies need to be held accountable for their practices and the effects of their drugs. This starts with an

\textsuperscript{88} Ibid. pp. 431  
opening of the books, drug companies need to be required to break down their expenses more thoroughly and be more honest about their practices. If some of the Research and Development budget goes into market research rather than drug research, we have the right to know and if “outreach and administration” includes lobbying and marketing drugs to doctors and medical students, than we should have the right not to pay for those expenses. Furthermore, companies should have outcome accountability, if a drug doesn't work for a patient then that patient should not have to pay for the treatment they received. This is a policy that has been successfully implemented in countries like Denmark, and has reduced expenses and drug dependency in the healthcare industry, since companies no longer push drugs on those who are unlikely to be helped by them.

Policy already initiated:

I have enumerated many ways by which we might bring pharmaceutical prices down, or at least stop them from rising quite so rapidly. Currently, two bills await hearings in the Senate Finance Committee, both aimed at lowering the costs Americans face in purchasing prescription drugs. These two bills address some of the policy proposals I outlined above, but they are both rather modest in their scope.

The first of these bills was introduced by Bernie Sanders, the Independent Senator from Vermont and 2016 Democratic Presidential Candidate, and co-sponsored by Representative Elijah Cummings, a Democrat from Maryland. This bill, “The Prescription Drug Affordability Act of 2015” outlines several different strategies for tackling the problem of rising drug prices including Medicare Part D negotiations, re-

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90 Angell The truth about the drug companies: how they deceive us and what to do about it. pp. 444, 449
importation of prescriptions from Canada, Medicare and Medicaid rebates, prohibiting “pay for delay,” harsher penalties for fraud committed by pharmaceutical companies and requirements for more transparency in pharmaceutical costs and prices. Many of these policy proposals have already come up in this investigation of drug prices, particularly Medicare negotiation and prohibiting “pay for delay.91”

The other piece of legislation, also stalled in committee, is a bi-partisan proposal from Senator Wyden and Senator Grassley called “Reducing Existing Costs Associated With Pharmaceuticals For Seniors Act of 2016.” While this bill is mostly targeting the costs of drugs for seniors, it’s policies, particularly the call for transparency, could have ripple effects in the broader landscape of drug prices. This bill would also increase the rebates given to Medicare by drug companies, and the rebates given to seniors by Medicare. Requiring greater rebates for Medicare (similar to those given to Medicaid) would limit the costs to the federal government in providing prescription drug benefits, and allow more money to give to seniors who still struggle to pay the co-pays for their prescription drugs. This bill would also give the Director of HHS the ability to negotiate directly with drug companies to bring down costs. This would be accomplished by leveraging the power the Federal Government has as this single largest contributor to pharmaceutical research92.

While these policies are not sweeping and do not comprehensively solve the issues of the pharmaceutical industry, they all would make a difference in bring down

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costs or keeping them from going up. The bottom line is that something needs to be done, because the current cost landscape is unsustainable. Many of these policies would be very difficult to enact because the pharmaceutical industry has so much power in Washington DC and there is very little consensus among representatives about what causes high prices and what the solutions should be, thus the two bills mentioned have each been waiting for a vote in the Senate Finance Committee for over a year.
Chapter 5: Policy Recommendations By Case Study

I have reviewed some strategies for combating high drug prices, but now I will put them into context by applying these policy changes to the EpiPen, Hepatitis C and Multiple Sclerosis case studies. While none of the strategies I outlined would likely raise prices, they would likely have different effects on different classes of drugs. While there were certainly similarities between each of the cases, there were also slight differences in the causes of the high prices. **EpiPen**, more than the other cases, owed much of its price hikes to the costs of marketing and lobbying and to the secrecy surrounding the spending of drug companies. Therefore the policies most effective in addressing the costs of EpiPen, would be those curtailing the spending of companies on marketing and lobbying and those requiring that spending breakdowns be made public. However, with **Hepatitis C** Treatments, the biggest problems are the inability of all insurers to negotiate. Finally, the largest problems with **Multiple Sclerosis** treatments are the lack of comparative effectiveness information, and the resulting ability of companies to increase their prices to match the cost of new drugs, even if there are no improvements to the drugs. While I have highlighted the current problems of each drug and the corresponding policy solutions, this is not to suggest that other policies would not work in the present or future to bring down the costs of those drugs. For example, all of these drugs would or could benefit from amendments to patent and FDA policies as well as more negotiating power.

As mentioned, **EpiPen** would benefit from policies that focus on marketing spending and transparency. It is very difficult to know exactly how much it costs Mylan to produce EpiPen, how much they spent on minor changes to the device and how much was spent on marketing and “education”. However, while we do not know the exact
breakdown of Mylan’s EpiPen costs, we do know that there have been increases in advertising and lobbying efforts of Mylan. This information, or lack there of, presents some key problems and policy solutions. Until recently brand name EpiPen was practically the only option for epinephrine auto-injectors, and so the public was forced to pay whatever price Mylan set. Mylan has insisted that the $600 price was a fair one, but has not backed up this claim by revealing any information about their costs. Without this information, we cannot hold drug companies accountable for setting fair prices. Furthermore, there is still the suspicion that most of the expenses leading to high prices are advertising and lobbying costs, which creates several problems of its own. Companies should not expect that the government, which buys its products, pay for the efforts to lobby them and the American people. I see the process for addressing this as falling into 3 steps, first, drug companies like Mylan need to open up their books to the public so that we can make informed decisions about our purchases and better understand what they are paying for. Then, once this information is public, either the government should take action to set caps on the amount of money that can be spent on lobbying and ads or use the FDA to limit the amount of advertising done without setting price caps. If the government chose not to take action after information was made public, then private individuals or organizations could take action to use their purchasing power to demand that drug companies prioritize innovation over marketing and bring down costs. In the case of Mylan, after the public outcry over high prices, both Mylan and CVS released generic auto-injectors. While this was not initiated by any government policy change, it does show how public interest into prices can effect the actions of companies. Thus
releasing the information about the spending of drug companies has the potential to create public pressure for drug companies to change.

Unlike with EpiPen, the biggest challenge facing the price of the Hepatitis C is the lack of bargaining power given to the state insurers. There is such a demand for the newer curative treatments for Hepatitis C, that these medications could cost Medicare and Medicaid $65 billion over the next 5 years, and have the potential to bankrupt many state Medicaid programs. This has led to rationing of these treatments, with patients being forced to wait until they have sustained irreversible liver damage until they can receive their curative treatments. If Medicare and Medicaid were both able to use their bargaining power at a national level, than they could bring down those costs, saving money and providing more treatments to more people. The two Senate bills I already mentioned would both accomplish this goal by allowing the director of the Health and Human Services Department to negotiate for lower prices.

Finally, in the case of Multiple Sclerosis, the largest contributor to high prices is the lack of comparative effectiveness studies for new medications. If each new multiple sclerosis drug had to prove that it was better than the existing ones in order to get a patent, then we may not have seen each new drug set its price above the existing ones, or the existing drugs raise their prices to match the new drugs. If we knew the comparative effectiveness of drugs than we could have value based pricing, where drugs that provide more benefit can cost proportionally more, but drugs with equal or lesser value must reflect that value in the price. In order to make value based pricing universal, the FDA and patent office would need to make comparative effectiveness studies a part of the process for getting approval. This would require some significant changes to law and
regulation as well as more capital investment in the FDA. Without government oversight of comparative effectiveness studies there is no way to make them universal, we instead must rely on private studies, which are subject to bias since they are often funded by drug companies. There must be some sort of government intervention in creating these studies or we will continue to see prices rise without knowing for sure if the costs are tied to real patient benefits.
A1: Organization of Economic Co-operation and Development review of drug expenditure per capita in 29 developed nations. The US is on shown on the far left, spending $1,026 per capita, compared to OECD average (shown in red) of $515 per capita.
A2: The rise of prescription drug spending in the US from 2005 to 2014, with projections to spending in 2024.
A3: The OECD calculated expenditure on overall health services, public and private.

A4: Cost increase of 9 MS DMTs compared with average consumer product inflation and the inflation of prescription drug costs specifically.
A5: An overview of the increases in price for nine MS disease modifying drugs. The initial cost is adjusted for inflation to the comparable cost if the drug was released in 2013, and compared to the actual cost in 2013.

<table>
<thead>
<tr>
<th>DRUG</th>
<th>DATE APPROVED</th>
<th>INITIAL COST (IN 2013 DOLLARS)</th>
<th>2013 COST</th>
<th>INCREASE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interferon-β-1b (Betaseron)</td>
<td>7/23/1993</td>
<td>$18,591</td>
<td>$61,529</td>
<td>231.0%</td>
</tr>
<tr>
<td>Interferon-β-1a IM (Avonex)</td>
<td>5/17/1996</td>
<td>$12,951</td>
<td>$62,394</td>
<td>381.8%</td>
</tr>
<tr>
<td>Glatiramer acetate (Copaxone)</td>
<td>12/20/1996</td>
<td>$12,312</td>
<td>$59,158</td>
<td>380.5%</td>
</tr>
<tr>
<td>Interferon-β-1a SC (Rebif)</td>
<td>3/7/2002</td>
<td>$19,763</td>
<td>$66,394</td>
<td>236.0%</td>
</tr>
<tr>
<td>Natalizumab (Tysabri)</td>
<td>11/23/2004</td>
<td>$31,879</td>
<td>$64,233</td>
<td>101.5%</td>
</tr>
<tr>
<td>Interferon-β-1b (Extavia)</td>
<td>8/14/2009</td>
<td>$35,644</td>
<td>$51,427</td>
<td>44.3%</td>
</tr>
<tr>
<td>Fingolimod (Gilenya)</td>
<td>9/21/2010</td>
<td>$54,245</td>
<td>$63,806</td>
<td>17.6%</td>
</tr>
<tr>
<td>Teriflunomide (Aubagio)</td>
<td>9/12/2012</td>
<td>$48,349</td>
<td>$57,553</td>
<td>19.0%</td>
</tr>
<tr>
<td>Dimethyl fumarate (Tecfidera)</td>
<td>3/27/2013</td>
<td>$57,816</td>
<td>$63,315</td>
<td>9.5%</td>
</tr>
</tbody>
</table>

**Notes**

All costs are annual.
2013 costs were sampled in December of that year.
Interferon-β-1b is marketed as Betaseron by Bayer and Extavia by Novartis.

*Credit: NPR*
References


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