

The Pharmaceutical Access Act: An Administrative Eminent Domain Solution to High Drug Prices

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INTRODUCTION

Monopolies created by patents, regulations, and marketing have contributed to an unhealthy market in which brand-name pharmaceuticals are priced to maximize profits at the expense of public health. These monopolies allow pharmaceutical companies to price new medications far in excess of the amount required to pay for research and development (“R&D”) and provide for a reasonable profit. Additionally, these monopolies allow pharmaceutical companies to massively increase the price of old medications long after their patents have expired and their R&D costs have been recouped. Ultimately, pharmaceutical companies with monopolies profit at the expense of patients who are unable to afford medication.

High drug prices show no sign of leveling off or abating under the current laws, regulations, and economic atmosphere. Rather, pharmaceutical costs are outpacing inflation and other health care costs.¹ These growing costs indicate that there are insufficient regulatory price controls and that some new source of price moderation is needed.

1. OFFICE OF THE ASSISTANT SEC’Y FOR PLANNING & EVALUATION, DEP’T OF HEALTH & HUMAN SERVS., ASPE ISSUE BRIEF: OBSERVATIONS ON TRENDS IN PRESCRIPTION DRUG SPENDING 1 (2016), <https://aspe.hhs.gov/sites/default/files/pdf/187586/Drugspending.pdf> [<https://perma.cc/QSA4-FJBK>].

Commentators have occasionally suggested eminent domain as a potential solution to rising pharmaceutical costs.² These commentators suggest that the government should use its eminent domain power to either seize pharmaceutical patents or issue compulsory licenses for those patents. Similarly, some scholars³ and politicians⁴ have suggested that the federal government use 28 U.S.C. Section 1498 (“Section 1498”)⁵ to provide pharmaceuticals to some patients and decrease pharmaceutical costs for all patients. Section 1498 effectively allows the government to take a compulsory license to a patent by limiting a patent owner’s remedies for government patent infringement to money damages.⁶

Both eminent domain and Section 1498, however, suffer from several key problems in the pharmaceutical context. As tools of general applicability, they are blunt instruments unsuited to treat the specific illnesses of the pharmaceutical industry. The pharmaceutical market is complicated. Pharmaceutical companies

2. See, e.g., Andy Johnson, *Intellectual Property and Eminent Domain: A Plausible Combination?*, IP PROSPECTIVE (July 2, 2009), <http://www.ipprospective.com/copyright-caucus/intellectual-property-and-eminent-domain-a-plausible-combination> [https://perma.cc/TSC9-BTL7]; Susan Levine, *Eminent Domain Urged as Tool to Cut Drug Costs*, WASH. POST (Mar. 17, 2005), <http://www.washingtonpost.com/wp-dyn/articles/A41050-2005Mar16.html> [https://perma.cc/B2CG-32RW]; Mark Parsons, Opinion, *How About “Eminent Domain” for Patents on Products like EpiPen?*, DENVER POST (Aug. 29, 2016), <http://www.denverpost.com/2016/08/29/how-about-eminent-domain-for-patents-on-products-like-epipen> [https://perma.cc/QBZ2-6HCV]; Zain Rizvi, Amy Kapczynski & Aaron Kesselheim, Opinion, *A Simple Way for the Government to Curb Inflated Drug Prices*, WASH. POST (May 12, 2016), https://www.washingtonpost.com/opinions/a-simple-way-for-the-government-to-curb-inflated-drug-prices/2016/05/12/ed89c9b4-16fc-11e6-aa55-670cabef46e0_story.html?utm_term=.12b1fef4f1ea [https://perma.cc/5B9Y-4MZX].

3. Hannah Brennan, Amy Kapczynski, Christine H. Monahan & Zain Rizvi, *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275 (2016).

4. See, e.g., Sarah Jane Tribble, *Louisiana Proposes Tapping a Century-Old Patent Law To Cut Hepatitis C Drug Prices*, WASH. POST (May 2, 2017), https://www.washingtonpost.com/national/health-science/louisiana-proposes-tapping-a-century-old-patent-law-to-cut-hepatitis-c-drug-prices/2017/05/02/fc611990-2f76-11e7-9534-00e4656c22aa_story.html?utm_term=.d0b3bf9be6cd [https://perma.cc/S55R-DYW2]; Press Release, Charles E. Schumer, U.S. Senator for N.Y., *As Avian Flu Closes in on U.S., Schumer Calls for Immediate Action: Demands Suspension of Tamiflu Patent so Vaccine Can Be Mass-Produced, Dramatically Increasing Supply* (Aug. 8, 2006), <https://www.schumer.senate.gov/newsroom/press-releases/as-avian-flu-closes-in-on-us-schumer-calls-for-immediate-action-demands-suspension-of-tamiflu-patent-so-vaccine-can-be-mass-produced-dramatically-increasing-supply> [https://perma.cc/TF4R-JUEN]; Letter from Bernard Sanders, U.S. Senator for Vt., to Robert A. McDonald, Sec’y of the U.S. Dep’t of Veterans Affairs (May 12, 2005), <https://www.sanders.senate.gov/download/051215-letter/?inline=file> [https://perma.cc/KK3V-ETP3] [hereinafter Letter from Bernard Sanders to Robert A. McDonald].

5. 28 U.S.C. § 1498(a) (2012) (“Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same, the owner’s remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture.”).

6. *Id.*; see also *Motorola, Inc. v. United States*, 729 F.2d 765, 768 (Fed. Cir. 1984) (internal citations omitted) (“In this context, the United States is not in the position of an ordinary infringer, but rather a compulsory, nonexclusive licensee.”).

invest heavily in research and development.⁷ Further, the industry is already highly regulated.⁸ Any intervention in the pharmaceutical market must be carefully considered and applied to avoid negative impacts on future pharmaceutical product innovation.

To avoid the pitfalls of eminent domain and Section 1498, this Note recommends that Congress enact a statute, which I call the Pharmaceutical Access Act (“PAA”), to create an executive agency with the power to grant compulsory licenses to pharmaceutical patents. This administrative solution is inspired by the Atomic Energy Act of 1954,⁹ which, among other provisions, allowed a commission to issue compulsory licenses for atomic energy patents to “promote world peace, improve the general welfare, increase the standard of living, and strengthen free competition in private enterprise.”¹⁰ Similarly, the PAA would create an agency with the power to issue compulsory licenses to improve public health.

The proposed agency would be composed of experts in the pharmaceutical market who could adequately balance public health, the need for continued innovation, and other concerns implicated by intervention in the pharmaceutical market. The agency would first be tasked with creating standards to determine which pharmaceuticals merit government intervention and the appropriate measure of damages to compensate pharmaceutical patent owners for such intervention. The agency would then be tasked with monitoring the pharmaceutical market and issuing compulsory licenses for pharmaceutical products pursuant to its standards.

The PAA would be an improvement over Section 1498 and similarly unguided uses of the government’s eminent domain power because it would create an executive agency capable of judiciously balancing public access to existing pharmaceuticals against a pharmaceutical company’s incentives for future innovation. As opposed to Section 1498, which allows for *carte blanche* government infringement,¹¹ and eminent domain, which requires only that a taking be for the “public use,”¹² the PAA would provide an intelligible standard

7. See *Economic Impact*, PHRMA, <http://www.phrma.org/media/economic-impact> [<https://perma.cc/3CPQ-TSNH>].

8. See Patricia M. Danzon, *Economics of the Pharmaceutical Industry*, NBER (2006), <http://www.nber.org/reporter/fall06/danzon.html> [<https://perma.cc/6X8R-9Z53>].

9. 42 U.S.C. §§ 2011–2297 (2012).

10. 42 U.S.C. §§ 2011, 2183 (2012).

11. 28 U.S.C. § 1498(a) (emphasis added) (limiting the remedies available to a patent owner “[w]henever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner thereof or lawful right to use or manufacture the same”).

12. See U.S. CONST. amend V (“[N]or shall private property be taken for public use, without just compensation.”); *Brown v. Legal Found. of Wash.*, 538 U.S. 216, 231 (2003) (“While it confirms the State’s authority to confiscate private property, the text of the Fifth Amendment imposes two conditions on the exercise of such authority: the taking must be for a ‘public use’ and ‘just compensation’ must be paid.”).

that constrains the government's actions. The PAA would establish a standard of judicial review for any licensure, which would both encourage the agency to practice restraint and reassure patent holders that their research investments are safe, thus encouraging continued R&D.

Additionally, the PAA would allow the agency to create rules for compensating patent holders for their research investment. Section 1498 relies on a judicial determination of "reasonable and entire compensation" for government infringement. The PAA's specific remedies would be more closely tailored to the unique economics of the pharmaceutical industry and would provide greater economic certainty to pharmaceutical companies.

Most importantly, the PAA would provide constant regulatory pressure in a way that Section 1498 and general government eminent domain powers do not. Even if the agency never exercises the PAA's compulsory licensing power, the PAA would provide for constant oversight by a dedicated agency, which would encourage pharmaceutical companies to consider patient access to drugs in their pricing schemes. The threat of the PAA's licensing power would provide a limiting force on pharmaceutical prices as companies seek to avoid regulatory attention.

Part I of this Note describes the economics of drug pricing. It explores the three factors that contribute to excessive pharmaceutical prices: monopolistic market share, inflexible demand, and insufficient regulatory control.

Part II reviews the overall cost of pharmaceuticals in the United States and explores three recent high-profile cases of drugs priced so high that patient access to those drugs has been restricted. First, Gilead Sciences produces three innovative patented Hepatitis C medications priced between \$70,000 and \$94,500 per treatment regimen. Second, Mylan NV has increased the price of its epinephrine autoinjector EpiPen from just over \$100 to \$600 over the course of ten years. Third, Turing Pharmaceuticals raised the price of its toxoplasmosis drug Daraprim from \$13.50 per pill to \$750 per pill in 2015. All three companies exercise monopoly power created by patents, regulations, and marketing, or a combination of the three. These three examples are not exhaustive, but rather illustrative of a common theme of excessive pricing and price increases for pharmaceuticals in the United States.

Part III discusses the shortcomings of current regulatory pressure on drug pricing. It explains that regulatory pressure is the government's most direct method of control over pharmaceutical pricing, but existing regulations are insufficient to exercise such control.

Part IV proposes that Congress increase regulatory pressure on pharmaceutical pricing to lower drug prices and increase drug access through the PAA. Congress should enact legislation similar to the Atomic Energy Act of 1958 to create an agency to assert direct regulatory pressure on pharmaceutical companies. The agency would have the power to issue compulsory licenses for

pharmaceutical patents in cases where patented drugs have been priced far higher than necessary and where access to drugs is unduly restricted.

Part V discusses the PAA's interaction with international law and establishes that the PAA does not violate the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS").

Part VI compares the proposed PAA to Section 1498 and other sources of regulatory pressure. This Part explains how the PAA could improve on the broad compulsory licensing power granted in Section 1498 by consolidating decision-making power in a small group of experts. Additionally, this Part outlines the benefits of determining reasonable royalties before granting compulsory licenses. Predetermining license royalties will provide greater certainty in the pharmaceutical industry than that provided by the judicially determined reasonable royalties currently available under Section 1498.

Part VII of this Note acknowledges potential disadvantages to the PAA. It briefly addresses the likelihood of enactment considering the pharmaceutical industry's substantial lobbying group, the Pharmaceutical Research and Manufacturers of America ("PhRMA"). This Part also addresses the additional cost of creating a new administrative body. Finally, it discusses the negative consequences of allowing an administrative agency to exercise compulsory licensure power over pharmaceuticals: the potential for regulatory capture and the risk of giving broad power over the pharmaceutical economy to a politically insulated agency.

I.

THE ECONOMICS OF PHARMACEUTICAL PRICING IN THE UNITED STATES: A BROKEN MARKET

Per capita pharmaceutical spending in the United States is the highest in the world¹³ and continues to grow.¹⁴ In 2015, the United States' per capita pharmaceutical expenditures were \$1,162.¹⁵ In Switzerland, which had the next

13. Aaron S. Kesselheim, Jerry Avorn & Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 J. AM. MED. ASS'N 858 (2016); *The High Cost of High Prices for HIV/AIDS Drugs and the Prize Fund Alternative: Hearing before the Subcomm. on Primary Health and Aging of the S. Comm. on Health, Educ., Labor, and Pensions*, 112th Cong. 24 (2012) (statement of Joseph E. Stiglitz, Professor at Columbia University) ("America is the most innovative country in the world. It has the best universities, attracting the best minds from around the world. But America also has the least efficient healthcare system in the world, spending more money per capita, and a larger fraction of GDP, on the health care sector than any other country—and getting far poorer outcomes than countries that spend much less."); Nadia Kounang, *Why Pharmaceuticals Are Cheaper Abroad*, CNN (Sept. 28, 2015), <http://www.cnn.com/2015/09/28/health/us-pays-more-for-drugs> [<https://perma.cc/UW2Q-WL2P>].

14. OFFICE OF THE ASSISTANT SEC'Y FOR PLANNING & EVALUATION, *supra* note 1, at 1.

15. This figure includes spending on both prescription and over-the-counter drugs, but excludes spending on drugs consumed in hospitals or other health care settings. *OECD Data: Pharmaceutical Spending*, OECD, <https://data.oecd.org/healthres/pharmaceutical-spending.htm> [<https://perma.cc/F52V-HNE5>].

highest per capita pharmaceutical expenditures, they were \$1,056.¹⁶ Per capita expenditures for other countries were much lower. Canada and Germany, which had the next highest per capita expenditures, spent \$807 and \$766 per capita in 2015, respectively.¹⁷

These outsized expenditures are driven in large part by the high price of medication in the United States, which continues to grow. Between 2013 and 2015, spending on pharmaceuticals in the United States increased 20 percent.¹⁸ During the same period, spending on all health care, including pharmaceuticals, increased only 11 percent.¹⁹ Both rates are much higher than the inflation rate, which, according to the Bureau of Labor Statistics Consumer Price Index, was approximately 1.5 percent between 2013 and 2015.²⁰ Thus, pharmaceutical spending is increasing far faster than both overall health-care spending and inflation.²¹

Like most products, pharmaceutical prices are a function not of production costs, but of supply,²² demand, and regulatory pressure. However, there are several features which distinguish the pharmaceutical market from other markets.²³ First, demand for pharmaceuticals is extraordinarily inelastic.²⁴ Thus, patients are not as responsive to high prices for pharmaceuticals as they would be to high prices for products with more elastic demand. Both the monopolistic supply and the inelastic demand of the pharmaceutical market encourage high prices. Second, the supply of brand-name pharmaceuticals is nearly always determined by a monopolist who controls the entire market for a particular product.²⁵ Accordingly, a monopolist pharmaceutical maker can easily exploit

16. *Id.* Values were calculated using the United States' Purchasing Power Parity.

17. *Id.* Values were calculated using the United States' Purchasing Power Parity.

18. Kesselheim, *supra* note 13, at 859.

19. *Id.*

20. *CPI Inflation Calculator*, BUREAU LABOR STAT., https://www.bls.gov/data/inflation_calculator.htm [<https://perma.cc/9XSF-7JKQ>]; *see also Why Health Care Eats More of Your Paycheck Every Year*, NBC NEWS (Nov. 4, 2016), <https://www.nbcnews.com/health/health-news/why-health-care-eats-more-your-paycheck-every-year-n678051> [<https://perma.cc/G7DM-JV5A>].

21. OFFICE OF THE ASSISTANT SEC^Y FOR PLANNING & EVALUATION, *supra* note 1, at 5.

22. Because of the often-monopolistic nature of pharmaceutical markets, pharmaceutical supply is determined by a monopolist. Thus, it may be more accurate to say that pharmaceutical prices are a function of market share, demand, and regulatory pressure, rather than a function of supply, demand, and regulatory pressure.

23. F. M. Scherer, *The Pharmaceutical Industry*, in 1B HANDBOOK OF HEALTH ECONOMICS 1297, 1300 (Anthony J. Culyer & Joseph P. Newhouse eds., 2000) [hereinafter Scherer, *Pharmaceutical Industry*] (“The pharmaceuticals industry has a number of characteristics differentiating it from most industries serving demands outside the health sector.”).

24. MARIN GEMMILL, *THE PRICE ELASTICITY OF DEMAND FOR PRESCRIPTION DRUGS: AN EXPLORATION OF DEMAND IN DIFFERENT SETTINGS* 49 (2008) (“The range of elasticity values for brand-name drugs is even larger (-1.60 to -0.03). This result can be expected, though, given that the demand for brand-name drugs should be very inelastic when there are few therapeutic and no molecular substitutes and much higher when there are generic drugs available.”).

25. Gail B. Rattinger et al., *Principles of Economics Crucial to Pharmacy Students' Understanding of the Prescription Drug Market*, 72 AM. J. PHARMACEUTICAL EDUC. 1, 2 (2008)

the inelastic demand for its product by charging overly high prices. Consequently, regulatory pressure is needed to provide a dampening force on pharmaceutical prices. But current regulatory pressure has proven ineffective.²⁶

Demand for pharmaceuticals is notoriously inelastic for several reasons. First, patients are willing to pay much more for products that will spare them illness, pain, or death than they are willing to pay for other, less essential, products. Second, information asymmetries prevent patients from making educated choices about the costs and benefits of pharmaceutical products. These information asymmetries are caused by doctors and insurance companies that act as intermediaries between pharmaceutical consumers and pharmaceutical manufacturers.²⁷ Third, because doctors and insurance providers are intermediaries between pharmaceutical makers and patients, they are susceptible to agency problems and may consider factors other than their patients' physical and economic well-being when prescribing medications.²⁸ Fourth, insurance spreads the cost of expensive pharmaceuticals so that individual consumers do not bear the full cost. Consequently, consumers may not question the cost of pharmaceuticals when making purchasing decisions because they are not bearing the full price.²⁹ Fifth, some purchasers of pharmaceuticals are required by law to

("Unlike markets for other goods, in the pharmaceutical marketplace there are a limited number of manufacturers (often just one for a particular drug) . . .").

26. Scottie Lee Meyers, *Lack of Regulation Allows Pharmaceutical Companies to Raise Prices of Lifesaving Drugs, Experts Say*, WIS. PUB. RADIO (Sept. 6, 2016), <https://www.wpr.org/lack-regulation-allows-pharmaceutical-companies-raise-prices-lifesaving-drugs-expert-says> [<https://perma.cc/4VPU-ZVGR>].

27. PATRICIA M. DANZON, COMPETITION AND ANTITRUST ISSUES IN THE PHARMACEUTICAL INDUSTRY 8 (July 2014), <https://faculty.wharton.upenn.edu/wp-content/uploads/2017/06/Competition-and-Antitrust-Issues-in-the-Pharmaceutical-IndustryFinal7.2.14.pdf> [<https://perma.cc/WK5Z-6KWB>] ("Physician agency for patients in deciding whether/which drugs to prescribe tends to make demand more inelastic, because physicians are unaware of drug prices . . ."). The information asymmetry caused by doctors acting on their patients' behalf to prescribe pharmaceuticals is enshrined in the common law learned intermediary doctrine. See *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974) ("Pharmaceutical companies . . . in selling prescription drugs are required to warn only the prescribing physician, who acts as a 'learned intermediary' between manufacturer and consumer.").

28. Physician prescribing behavior has been shown to depend on factors other than the patient's well-being. See, e.g., Rena M. Conti & Peter B. Bach, *Cost Consequences of the 340B Drug Discount Program*, 309 J. AM. MED. ASS'N 1995, 1995 (2013) ("[T]he availability of profits from administering expensive cancer drugs is known to alter physician prescribing behavior."). Insurance providers also have incentives that depart from their customers' best interests. Insurers consider their own profits in addition to their customers' health. This conflict may lead to suboptimal outcomes for the insured. For example, recent investigations have shown that some insurers encouraged patients to take addictive opioids rather than more expensive, but safer, painkillers. Katie Thomas & Charles Ornstein, *Amid Opioid Crisis, Insurers Restrict Pricey, Less Addictive Painkillers*, N.Y. TIMES (Sept. 17, 2017), <https://www.nytimes.com/2017/09/17/health/opioid-painkillers-insurance-companies.html> [<https://perma.cc/6XU3-99CL>].

29. Rattinger, *supra* note 25, at 3 ("Insurance provides cost sharing and thereby reduces the price that the patient perceives when purchasing prescription drugs."); Amitabh Chandra, David Cutler & Zirui Song, *Who Ordered That? The Economics of Treatment Choices in Medical Care*, in 2 HANDBOOK OF HEALTH ECONOMICS 397, 398 (Mark V. Pauly, Thomas G. Mcguire & Pedro P. Barros eds., 2012) ("[G]iven the large variation in medical treatments, the roles of price and income in medicine

purchase pharmaceuticals irrespective of their price. For example, the government is required to provide medical care to prison inmates.³⁰ These purchasers have little negotiating power and enable pharmaceutical companies to charge exorbitant prices, often at taxpayer expense.³¹ Sixth, pharmaceutical companies invest heavily in advertising³² to increase the inelasticity of demand.³³ These factors are all market failures that increase the inelasticity of the demand for pharmaceuticals.

Many of these market failures deprive patients of complete information about the costs of their medications. For example, a patient's doctor may not consider a drug's price, or inform their patient of the price, before prescribing it.³⁴ That patient might not learn about the true out-of-pocket cost of their medication until they reach a pharmacy checkout, at which time it may feel like it is too late for them to discuss cheaper alternative treatments with their doctor. Further, cost-spreading mechanisms, such as health insurance and taxpayer-funded purchases, insulate patients from the shock of some high pharmaceutical costs. But patients, taxpayers, and those with health insurance still pay those high costs through their taxes and insurance premiums. These market failures prevent most consumers from making the same well-informed decisions regarding

are blunted. Substantial insurance coverage means that prices do not vary significantly across people and income has little role to play in clinical decisions.”).

30. The government has a constitutional obligation, under the Eighth Amendment, to provide medical care to prisoners. when failing to do so would constitute “deliberate indifference to serious medical needs” rising to the level of “unnecessary and wanton infliction of pain.” *Estelle v. Gamble*, 429 U.S. 97, 104 (1976).

31. Brennan, *supra* note 3, at 285 (“While these requirements are intended to help ensure individuals receive the care they need, payors that must cover a drug, whether overpriced or not, have little leverage to bring down prices.”).

32. Richard Anderson, *Pharmaceutical Industry Gets High on Fat Profits*, BBC NEWS (Nov. 6, 2014), <http://www.bbc.com/news/business-28212223> [<https://perma.cc/F59K-NRP9>] (“[D]rug companies spend far more on marketing drugs—in some cases twice as much—than on developing them.”); DANZON, *supra* note 27 (“Given the high margin of price over marginal cost for originator drugs, originator manufacturers invest heavily in promotion to physicians. This promotion focuses solely on brand and clinical benefits of the drug, not the price, and the same is true of direct-to-consumer advertising in the US.”).

33. *The High Cost of High Prices for HIV/AIDS Drugs and the Prize Fund Alternative: Hearing before the Subcomm. on Primary Health and Aging of the S. Comm. on Health, Educ., Labor, and Pensions*, 112th Cong. 23 (2012) (statement of Joseph E. Stiglitz, Professor at Columbia University) (“[M]uch of the difference between the cost of [pharmaceutical] production and what is charged does not go into research, but into advertising and marketing, and much of that is not spent to transmit information that would lead to better health, but to decrease the elasticity of demand across products, thereby increasing monopoly power and profits.”).

34. A 2007 review of studies of physician awareness of drug prices found that “[p]hysicians’ awareness of the cost of therapeutics is poor.” Thus, a doctor is unlikely to be able to provide accurate cost information to their patients. G. Michael Allan, Joel Lexchin & Natasha Wiebe, *Physician Awareness of Drug Cost: A Systematic Review*, 4 PLOS MED. 1486, 1486, 1491 (2007) (“Doctors’ ignorance of costs, combined with their tendency to underestimate the price of expensive drugs and overestimate the price of inexpensive ones, demonstrate a lack of appreciation of the large difference in cost between inexpensive and expensive drugs. This discrepancy in turn could have profound implications for overall drug expenditures.”).

pharmaceutical costs that they make regarding other products, thus contributing to the inelasticity of pharmaceutical demand.

Inelasticity of demand, such as that found in many pharmaceutical markets, is exploited where the only provider of a product is a monopolist. Pharmaceutical markets are often monopolistic.³⁵ Patents create monopolies for new pharmaceuticals, which are then preserved by regulations and marketing campaigns. Patent monopolies usually have an effective monopoly term of fourteen years or more under current laws.³⁶ Even where therapeutic equivalents that do not infringe on a patent exist, studies have shown that those therapeutic equivalents do not compete with patented brand-name pharmaceuticals.³⁷ Instead, only competing treatments with the same active ingredient as a brand-name product have been shown to provide any substantial competition.³⁸ Even where generics do threaten a pharmaceutical's market share, the brand-name product can retain its monopoly through savvy marketing and regulatory inertia. Thus, patents, regulations, and marketing create monopolies for most pharmaceuticals.

This monopoly over most pharmaceutical products means that the monopoly holder, not the free market, determines pharmaceutical prices.³⁹ No nuanced knowledge of microeconomics is needed to understand a monopolist's behavior in this situation—a monopolist will raise the price of the product until consumers stop buying it. A monopoly holder will never set the price of a product at an inelastic part of that product's demand curve, but will instead raise the price until demand for the product becomes elastic.⁴⁰ Combined with inelastic demand

35. See Rattinger, *supra* note 25 (“Unlike markets for other goods, in the pharmaceutical marketplace there are a limited number of manufacturers (often just one for a particular drug) . . .”).

36. See 35 U.S.C. § 156(c)(3) (2012); Dana Goldman & Darius Lakdawalla, *Intellectual Property, Information Technology, Biomedical Research, and Marketing of Patented Products*, in 2 HANDBOOK OF HEALTH ECONOMICS 825, 844 (Mark V. Pauly, Thomas G. McGuire & Pedro P. Barros eds., 2011) (“[B]etween 1990 and 1995, the average effective life of a pharmaceutical was 11.7 years with an average Hatch-Waxman extension of 2.33 years.”) (citing Henry G. Grabowski, *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries*, in SCIENCE AND CENTS: EXPLORING THE ECONOMICS OF BIOTECHNOLOGY: PROCEEDINGS OF THE 2002 CONFERENCE ON EXPLORING THE ECONOMICS OF BIOTECHNOLOGY 87 (John V. Duca & Mine K. Yücel eds., 2003)).

37. Nina Pavcnik, *Do Pharmaceutical Prices Respond to Potential Patient Out-of-Pocket Expenses?*, 33 RAND J. ECON. 469, 485 (2002) (“[T]he relevant competition in the pharmaceutical market occurs between generics and the brand-name version of the same active ingredient rather than across products that are therapeutics substitutes, i.e., products with different active ingredients but belonging to the same therapeutic group.”).

38. *Id.*

39. Rattinger, *supra* note 25 (“Since the monopolist is the only seller of a particular medicine, the monopolist determines the price of the medicine. This establishes the monopolist as a *price setter*, permitting prices above the perfectly competitive price by controlling the quantity of medication produced in the marketplace.”).

40. DOUGLAS CURTIS & IAN IRVINE, MICROECONOMICS: MARKETS, METHODS & MODELS 270 (2017) (“[I]t must be the case that the profit maximizing price for a monopolist always lies on the elastic segment of the demand curve.”) (emphasis removed).

of pharmaceutical markets, this monopolistic price setting forces patients to continue to purchase drugs that stretch, or even break, their erstwhile budgets.

To justify high pharmaceutical prices, pharmaceutical companies sometimes claim their prices are determined by R&D costs.⁴¹ Income from pharmaceutical products does, of course, pay for corporate costs, including R&D. However, claiming that drug prices are set primarily based on R&D costs is misleading.⁴² R&D costs and other corporate costs merely establish a floor for pharmaceutical prices.⁴³ As discussed above, those production costs alone do not dictate the actual price of a product: the actual price is instead determined by the inelastic demand for pharmaceuticals and the often-monopolistic nature of pharmaceutical supply.⁴⁴

Government intervention in the form of regulation is necessary to compensate for these numerous market failures.⁴⁵ Current regulations, however, have failed to address the problem of exorbitant pharmaceutical prices. Regulatory pressure currently comes from a variety of sources including antitrust laws, congressional investigations, Section 1498, and targeted rebate or discount programs. These sources of regulatory pressure and their shortcomings are discussed in more detail in Part III.

II.

MARKET FAILURE EXAMPLES: HEPATITIS C DRUGS, EPIPEN, AND DARAPRIM

As discussed in Part I, numerous market failures cause drug prices to be exorbitantly high. This Part presents three examples of pharmaceuticals whose prices have increased until some patients can no longer afford to purchase them.

41. See, e.g., Michael Hiltzik, *The \$2.5-Billion Mistake: A Gullible Trump Bought into Big Pharma's Inflated Claim About Drug R&D Costs*, L.A. TIMES (Jan. 31, 2017), <http://www.latimes.com/business/hiltzik/la-fi-hiltzik-trump-pharma-20170131-story.html> [<https://perma.cc/38SL-FVJV>].

42. See F. M. Scherer, *The F.T.C., Oligopoly, and Shared Monopoly* 4–7 (Harvard Kennedy Sch., Research Working Paper No. 13-031) (Scherer, who Pfizer hired as an economic consultant after the Federal Trade Commission (“FTC”) alleged that Pfizer had colluded to obtain a patent on the antibiotic tetracycline and had fixed prices on tetracycline and related antibiotics, reminisced: “[w]e advised Pfizer, ‘When [Senator] Kefauver says profits, you respond R&D.’ For decades thereafter my conscience was troubled over the realization that I might have contributed in a small way to misleading the Senate and hence the American public.”).

43. *Hepatitis C and Veterans: Hearing Before the S. Comm. on Veterans' Affairs*, 113th Cong. 42–43 (2014) (statement of Mr. Rother, President and Chief Executive Officer, National Coalition on Health Care, on behalf of the Campaign for Sustainable Prescription Pricing) (“I do think that the traditional justification for high prices in pharmaceuticals is obsolete, and Gilead, to their credit, has not tried to justify price on the basis of R&D, because they cannot. And, that is probably true for many of the new specialty drugs. The price is divorced from the cost of development.”).

44. See *id.*

45. See Jennifer J. Watts & Leonie Segal, *Market Failure, Policy Failure and Other Distortions in Chronic Disease Markets*, 9 BMC HEALTH SERVS. RES. 102, 103 (2009) (“Market failures, inefficiencies and distributional issues (equity) are the primary reasons for government intervention in the health care market.”).

Each of these products has monopolies created by patents, regulations, marketing, or a combination of the three.

A. Gilead Sets High Prices for Patented Hepatitis C Treatments

Since 2013, Gilead Sciences (“Gilead”) has brought three innovative Hepatitis C treatments to market: Sovaldi, Harvoni, and Epclusa. These drugs provide a massive improvement over previously available Hepatitis C treatments. Sovaldi, Harvoni, and Epclusa have a cure rate of 84 percent to 100 percent⁴⁶ and require between twelve and twenty-four weeks of treatment.⁴⁷ Before the introduction of these medications, chronic Hepatitis C was treated with forty-eight weekly injections of interferon and ribavirin, a treatment that only cured approximately half of recipients and caused frequent, dangerous side effects.⁴⁸

Gilead’s drugs offer greatly improved life expectancy and quality of life for many people—but only if those patients can afford the treatments. An estimated 2.7–3.9 million people have chronic Hepatitis C in the United States.⁴⁹ Globally, approximately 130–150 million people have the disease.⁵⁰ If those people can access treatment for their disease, they can avoid the dire long-term effects of chronic Hepatitis C, which include liver disease and other complications.⁵¹ These complications kill approximately 400,000 people each year⁵² and are the leading cause of liver failure requiring a transplant.⁵³

Unfortunately, Gilead has placed such a high price on Sovaldi, Harvoni, and Epclusa that many patients are forced to forego treatment or rely on older,

46. Clinical trials showed that treatment with Sovaldi and ribavirin cured 93 percent of patients with genotype 2 chronic Hepatitis C and 84 percent of patients with genotype 3 chronic Hepatitis C. SOVALDI, www.sovaldi.com [https://perma.cc/93FM-3XMG]. Clinical trials showed that Harvoni cured 96–99 percent of patients with genotype 1 Hepatitis C who had not been previously treated. HARVONI, www.harvoni.com [https://perma.cc/5MVD-ZZ3F]. Clinical trials showed that Epclusa cured over 95 percent of patients with any genotype of chronic Hepatitis C. EPCLUSA, www.epclusainfo.com [https://perma.cc/5LBC-E8MW].

47. *Highlights of Prescribing Information: Sovaldi*, GILEAD (Apr. 2017), http://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/sovaldi/sovaldi_pi.pdf [https://perma.cc/NYZ5-2XLL]; *Highlights of Prescribing Information: Harvoni*, GILEAD (Apr. 2017), https://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/harvoni/harvoni_pi.pdf [https://perma.cc/N99D-TCUY]; *Highlights of Prescribing Information: Epclusa*, GILEAD (Aug. 2017), https://www.gilead.com/~media/Files/pdfs/medicines/liver-disease/epclusa/epclusa_pi.pdf?la=en [https://perma.cc/2JQL-SCBR].

48. *Hepatitis C Fact Sheet*, WORLD HEALTH ORG. (Oct. 2017), <http://www.who.int/mediacentre/factsheets/fs164/en> [https://perma.cc/4WMM-VMQZ] [hereinafter *Hepatitis C Fact Sheet*].

49. *Hepatitis C FAQs for Health Professionals*, CTRS. FOR DISEASE CONTROL & PREVENTION (Jan. 27, 2017), <https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm> [https://perma.cc/54FD-BZFS] [hereinafter *Hepatitis C FAQs*].

50. *Hepatitis C Fact Sheet*, *supra* note 48.

51. *Hepatitis C FAQs*, *supra* note 49.

52. *Hepatitis C Fact Sheet*, *supra* note 48.

53. *Hepatitis C FAQs*, *supra* note 49.

much less effective treatments. Epclusa, the newest and cheapest of the three treatments, has a list price of \$74,760 for a twelve-week course of treatment, or approximately \$900 per tablet.⁵⁴ Sovaldi and Harvoni have list prices of \$84,000 and \$94,500 for twelve-week treatments, respectively.⁵⁵ These high prices prevent many patients from accessing these treatments. Patients without insurance may not be able to afford the high out-of-pocket price of this medication. Similarly, private and government insurance programs cannot afford to cover the treatment for all enrollees that would benefit from it. Therefore, these insurers use high co-pays or access controls to manage their own expenditures on Sovaldi, Harvoni, and Epclusa.⁵⁶ In 2014, before Harvoni or Epclusa were available, only 2.4 percent of Medicaid enrollees with chronic Hepatitis C were able to receive treatment with Sovaldi.⁵⁷ This left 97.6 percent of Medicaid enrollees with chronic Hepatitis C, approximately 683,000 people, without access to the most effective treatment for their serious illness.⁵⁸ Treating just this small percentage of chronic Hepatitis C patients costs Medicaid over \$1.3 billion dollars, before rebates.⁵⁹ Similarly, the Department of Veterans Affairs purchased the treatments at half price and spent over a billion dollars in 2015 before Epclusa was available.⁶⁰ However, only 15 percent of the 200,000 US veterans with chronic Hepatitis C had received treatment with Sovaldi or Harvoni as of 2016.⁶¹

Gilead's high prices are enabled by a monopoly created by a combination of eighteen patents set to expire between 2028 and 2032.⁶² The company and its

54. Caroline Chen, *Gilead's New Hepatitis C Drug Approved by FDA, Priced at \$74,760*, BLOOMBERG (June 28, 2016), <https://www.bloomberg.com/news/articles/2016-06-28/gilead-wins-fda-approval-of-hepatitis-c-drug-for-all-genotypes> [<https://perma.cc/KV99-VVVZ>].

55. *Id.*

56. See, e.g., Sony Salzman, *How Insurance Providers Deny Hepatitis C Patients Lifesaving Drugs*, ALJAZEERA AM. (Oct. 16, 2015), <http://america.aljazeera.com/articles/2015/10/16/insurance-providers-deny-hepatitis-drugs.html> [<https://perma.cc/Z3V4-JBXP>] (explaining that common policies restrict access by denying patients who are "not sick enough" or who use drugs or drink alcohol, or by requiring prescriptions written by liver specialists rather than general practitioners).

57. Press Release, U.S. Senate Comm. on Fin., Wyden-Grassley Sovaldi Investigation Finds Revenue-Driven Pricing Strategy Behind \$84,000 Hepatitis Drug (Dec. 1, 2015), http://www.finance.senate.gov/ranking-members-news/wyden-grassley-sovaldi-investigation-finds-revenue-driven-pricing-strategy-behind-84-000-hepatitis-drug?utm_source=msn [<https://perma.cc/H3YS-474S>] [hereinafter Press Release, U.S. Senate Comm. on Fin.].

58. *Id.*

59. *Id.*

60. *Lawmaker: Costly Hepatitis C Drug "A Slap in the Face to the Veterans,"* CBS NEWS (Feb. 3, 2016), <http://www.cbsnews.com/news/hepatitis-c-cure-veterans-affairs-congressional-hearing-cbs-news-investigation> [<https://perma.cc/M6KS-UTCZ>].

61. *Id.*

62. Sovaldi is covered by eight patents. *Orange Book: Sovaldi*, U.S. FOOD & DRUG ADMIN, http://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=204671&Appl_type=N [<https://perma.cc/9RPX-2D59>]. These patents are set to expire between 2028 and 2030. *Id.* Sovaldi's New Chemical Entity Exclusivity expires on December 6, 2018. *Id.* Harvoni is covered by fourteen patents, the eight that cover Sovaldi and six additional patents. *Orange Book: Harvoni*, U.S. FOOD & DRUG ADMIN,

defenders have pointed to a number of dubious justifications for its excessive prices. For instance, Gilead publicly justifies its prices by noting that the medications cost less than alternative treatments, such as a liver transplant.⁶³ Additionally, Gilead says that the price for its Hepatitis C medications “reflects the significant clinical, economic and public health value” of these drugs.⁶⁴ Although Gilead did not try to justify its high prices as necessary to recoup the cost of R&D during a Senate Committee hearing concerning its high prices,⁶⁵ it did trot out that justification during a later interview with the Wall Street Journal.⁶⁶

The Senate Committee on Finance investigated Gilead’s pricing strategies for both Sovaldi and Harvoni in 2014 and 2015.⁶⁷ The investigation determined that Gilead set prices on both Sovaldi and Harvoni to maximize revenue, not to create affordable access to the drugs.⁶⁸ The investigation found no concrete evidence that R&D costs determined Sovaldi and Harvoni’s prices.⁶⁹ Rather,

http://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=205834&Appl_type=N [<https://perma.cc/UTT4-RBY5>]. These patents are set to expire between 2028 and 2031. *Id.* Harvoni’s New Chemical Entity Exclusivity expires on October 10, 2019. *Id.* Epclusa is covered by twelve patents, the eight that cover Sovaldi and four additional patents. *Orange Book: Epclusa*, U.S. FOOD & DRUG ADMIN., http://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=208341&Appl_type=N [<https://perma.cc/BL8R-KVF5>]. These patents are currently set to expire between 2028 and 2032. *Id.* Epclusa’s New Chemical Entity Exclusivity is set to expire on June 28, 2021. *Id.*

63. Andrew Pollack, *Gilead Faces Fights over Hepatitis C and H.I.V. Drugs*, N.Y. TIMES (Jan. 27, 2016), <https://www.nytimes.com/2016/01/28/business/gilead-faces-fights-over-hepatitis-c-and-hiv-drugs.html> [<https://perma.cc/T5ZE-QWEW>]. The average cost of a liver transplant in the US in 2014 was approximately \$740,000. T. Scott Bentley, *2014 U.S. Organ and Tissue Transplant Cost Estimates and Discussion*, MILLIMAN (Dec. 2014), http://www.milliman.com/uploadedFiles/insight/Research/health-rr/1938HDP_20141230.pdf [<https://perma.cc/X59V-Q7UJ>]. However, not everyone who needs a liver and can afford a transplant will survive the wait. In 2014, 16,000 people were on the liver waiting list but fewer than 6,000 livers were transplanted. Dany Habka et al., *Future Economics of Liver Transplantation: A 20-Year Cost Modeling Forecast and the Prospect of Bioengineering Autologous Liver Grafts*, PLOS ONE 1, 2 (2015), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4503760/pdf/pone.0131764.pdf> [<https://perma.cc/2MZ8-EKUU>].

64. *Gilead Sciences Policy Position: Innovating and Expanding Access to Hepatitis C Treatments*, GILEAD (Oct. 2014), <https://www.gilead.com/~media/files/pdfs/policy-perspectives/expanding-access-to-hcv-treatments-102814.pdf?la=en> [<https://perma.cc/P8EX-G5E6>].

65. *Hepatitis C and Veterans: Hearing Before the S. Comm. on Veterans’ Affairs*, *supra* note 43.

66. Tunku Varadarajan, *The Business of Saving Lives: Gilead Science’s Executive Chairman Talks About the New Era of Biomedicine and Why Drugs Cost So Much, As Donald Trump Has Noticed*, WALL ST. J. (Oct. 20, 2017), <https://www.wsj.com/articles/the-business-of-saving-lives-1508538402> [<https://perma.cc/R6Y2-66B4>] (“Developing new drugs, Mr. Martin says, is ‘extraordinarily expensive. Most products fail. And when a patent runs out, you need to have something else.’ A patent, he says, is like a license to continue innovation, and the often high cost of drugs must include profits that ‘go back to the company to continue to innovate.’”).

67. Press Release, U.S. Senate Comm. on Fin., *supra* note 57.

68. *Id.*

69. *Id.*

Gilead set prices to the highest level that they believed the market would bear.⁷⁰ Additionally, the investigation found that Gilead set a high price for Sovaldi in part to justify a high price for later released treatments, like Harvoni.⁷¹

The Committee's investigation also found that the high price of Gilead's Hepatitis C medications inflicted a substantial financial burden on Medicare, Medicaid, and the Bureau of Prisons.⁷² Specifically, the investigation found that the high costs of Sovaldi and Harvoni caused Medicare, Medicaid, and the Bureau of Prisons to institute access restrictions, preventing many people from receiving the treatments.⁷³ Private insurance companies reacted similarly and initially restricted access to the new expensive treatments.⁷⁴ Although Gilead has negotiated discounts with some buyers of Sovaldi and Harvoni, the treatments are still prohibitively expensive.⁷⁵

B. Mylan Gradually Aggressively Marketed EpiPens Before Hiking Prices

Mylan NV ("Mylan") has increased the price of its epinephrine autoinjector, EpiPen, gradually over the course of ten years. In 2007, when Mylan acquired the EpiPen autoinjector, the list price for two EpiPen shots was about \$114.⁷⁶ As of 2016, the list price for two EpiPens was about \$608.⁷⁷ This massive price increase was delivered in 20 to 32 percent price jumps every year.⁷⁸ Mylan was able to increase EpiPen's price thanks to its patented autoinjector mechanism and a huge marketing campaign which increased demand for the EpiPen.

70. *Id.*

71. *Id.*

72. *Id.*

73. *Id.*

74. Salzman, *supra* note 56 ("[P]rivate insurance companies and state managed programs alike commonly employ similar coverage restrictions. In fact, a recent Yale University study found that one in four patients was denied Harvoni after the first request, regardless of insurance provider.").

75. See Ed Silverman, *What the "Shocking" Gilead Discounts on its Hepatitis C Drugs Will Mean*, WALL ST. J. (Feb. 4, 2015), <http://blogs.wsj.com/pharmalot/2015/02/04/what-the-shocking-gilead-discounts-on-its-hepatitis-c-drugs-will-mean> [<https://perma.cc/T7PT-GN39>] ("[D]iscounts for the treatments, which Gilead and its supporters argue are more cost-effective than the previous standard of care, will more than double this year—to 46%, on average. Gilead cited the need to offer lower prices to Medicaid and the U.S. Department of Veterans Affairs, in particular.").

76. Cynthia Koons & Robert Langreth, *How Marketing Turned the EpiPen into a Billion-Dollar Business*, BLOOMBERG (Sept. 23, 2015), <https://www.bloomberg.com/news/articles/2015-09-23/how-marketing-turned-the-epipen-into-a-billion-dollar-business> [<https://perma.cc/5T52-RCKU>].

77. Dan Mangan, *This Chart Shows Why Everyone's Angry About Soaring Price of Lifesaving EpiPen*, CNBC (Aug. 23, 2016), <http://www.cnbc.com/2016/08/23/this-chart-shows-you-why-a-lot-of-people-are-angry-about-the-price-of-epipen.html> [<https://perma.cc/UH3U-S87Y>].

78. *Id.*

Mylan's monopoly in the US comes not from the inexpensive medication contained in the EpiPen, but from its patented delivery system.⁷⁹ Epinephrine, the medication contained in each EpiPen, costs about a dollar per EpiPen dosage.⁸⁰ The patent disclosing epinephrine was granted in 1904 and expired nearly a century ago.⁸¹ However, the EpiPen injection mechanism is covered by four patents which will not expire until September 11, 2025.⁸²

Although the EpiPen autoinjector is patented, there are other epinephrine autoinjector options for patients, but these other options do not suffice to bring down prices. Adrenaclick, occasionally referred to as a generic of EpiPen, is available for \$110 for a two-pack at some retailers,⁸³ but it is not an FDA-authorized generic for EpiPen.⁸⁴ Authorized generics are biosimilar products which the FDA has certified as having the same active ingredients, dosage form, routes of administration, and strength as a brand-name drug.⁸⁵ All states have adopted automatic substitution legislation which allows pharmacists to automatically substitute an authorized generic for a brand-name drug.⁸⁶ However, Adrenaclick does not have the same patented injection mechanism as EpiPen and is not an authorized generic. Consequently, pharmacists may not substitute the cheaper Adrenaclick for the more expensive EpiPen if a patient's prescription calls for an EpiPen.⁸⁷ A prescription must specifically call for

79. Emily Willingham, *Why Did Mylan Hike EpiPen Prices 400%? Because They Could*, FORBES (Aug. 21, 2016), <http://www.forbes.com/sites/emilywillingham/2016/08/21/why-did-mylan-hike-epipen-prices-400-because-they-could/#241013bc477a> [<https://perma.cc/T2CD-SZDB>].

80. *Id.*

81. U.S. Patent No. 730,176 (filed Jan. 14, 1903).

82. *Orange Book: EpiPen*, U.S. FOOD & DRUG ADMIN., http://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&Appl_No=019430&Appl_type=N [<https://perma.cc/U3VE-E45H>].

83. Ginger Skinner, *How to Get the Cheaper EpiPen Alternative*, CONSUMER REPS. (Aug. 24, 2016), <http://www.consumerreports.org/drugs/how-to-get-cheaper-epipen-alternative> [<https://perma.cc/8JR3-Z97W>]. Adrenaclick is available at an undiscounted price of just \$110 at some retailers. Press Release, Pharmacy Times, CVS Offers 2-Pack Adrenaclick for Fraction of EpiPen Price, (Jan. 16, 2017), <http://www.pharmacytimes.com/sap-news/cvs-offers-2pack-adrenaclick-for-fraction-of-epipen-price> [<https://perma.cc/88A3-NAZB>].

84. *Drugs@FDA: FDA Approved Drug Products: EpiPen*, U.S. FOOD & DRUG ADMIN., <http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=019430> [<https://perma.cc/Y8V3-AXVF>] (listing only EpiPen brand products as therapeutic equivalents for EpiPen); see also *Why Aren't Doctors Prescribing the Cheaper EpiPen Alternative?*, CBS NEWS (Nov. 6, 2016), <https://www.cbsnews.com/news/why-arent-doctors-prescribing-the-cheaper-epipen-alternative> [<https://perma.cc/GV4U-F9MC>].

85. DANZON, *supra* note 27, at 10; see also *Orange Book Preface*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm> [<https://perma.cc/MV44-9D8A>].

86. DANZON, *supra* note 27, at 10 (“[P]harmacies may substitute any AB-rated generic for the originator brand, unless the physician explicitly requires the brand. Thus pharmacy substitution is the default from which a prescriber must opt out, rather than an option to which prescribers must opt in.”).

87. Skinner, *supra* note 83.

Adrenaclick, or for generic epinephrine before a pharmacy can dispense the less expensive alternative.⁸⁸

Even where doctors are aware of the cheaper alternative, doctors may be reticent to prescribe Adrenaclick or other injection mechanisms simply because they differ from the EpiPen mechanism. Doctors and pharmacists may be concerned that Adrenaclick's delivery mechanism may be less effective simply because people used to EpiPen will be confused by a different mechanism.⁸⁹ Mylan itself has argued that epinephrine injectors other than EpiPen are less safe for this reason.⁹⁰

This reliance on EpiPen's patented injection mechanism to deliver a common and inexpensive medication stems in part from Mylan's successful marketing strategy.⁹¹ Mylan wants to stock every public place with EpiPens and has been successful, particularly in schools.⁹² Mylan donated over 70,000 free EpiPens to schools between 2012 and 2016.⁹³ In 2014, Mylan contracted with Disney to stock EpiPens in Disney's cruise lines and theme parks.⁹⁴ Mylan has been active in lobbying the government for laws requiring schools, hotels, restaurants, and commercial airline flights to stock EpiPens.⁹⁵ This marketing

88. *Id.*; Dani Krass, *Generic EpiPen Will Likely Secure Profits for Mylan*, LAW360 (Sept. 22, 2016) <https://www.law360.com/articles/843170/generic-epipen-will-likely-secure-profits-for-mylan> [<https://perma.cc/V5RM-VHK9>].

89. Willingham, *supra* note 79 (“The big caveat with using the non-EpiPen version of the delivery system is that the two devices work differently, in ways that can lead to critical errors if users aren't properly trained. For example, the EpiPen requires removal of a single cap for use whereas the Adrenaclick reportedly requires removal of two caps.”).

90. Sydney Lupkin, *FDA Fees on Industry Haven't Fixed Delays in Generic Drug Approvals*, NPR (Sept. 1, 2016), <http://www.npr.org/sections/health-shots/2016/09/01/492235796/fda-fees-on-industry-havent-fixed-delays-in-generic-drug-approvals> [<https://perma.cc/HQ9D-AM7U>] (“Mylan submitted a citizen petition to the FDA arguing that people trained to use EpiPens wouldn't be able to use Teva's pending generic epinephrine auto-injector because of design differences.”).

91. Elisabeth Rosenthal, Opinion, *The Lesson of EpiPens: Why Drug Prices Spike, Again and Again*, N.Y. TIMES (Sept. 2, 2016), <http://www.nytimes.com/2016/09/04/opinion/sunday/the-lesson-of-epipens-why-drug-prices-spike-again-and-again.html> [<https://perma.cc/8YBC-JAK2>] (“Other companies tried to sell other injectors at a slightly lower price, but competing with Mylan was tough, since the EpiPen seemed synonymous with the drug.”).

92. Koons, *supra* note 76 (“The CEO [of Mylan] has made no secret of her strategy to increase demand for EpiPens by getting them stocked for emergency use in more schools and other public places.”).

93. Carolyn Y. Johnson & Catherine Ho, *How Mylan, the Maker of EpiPen Became a Virtual Monopoly*, WASH. POST (Aug. 25, 2016), https://www.washingtonpost.com/business/economy/2016/08/25/7f83728a-6aee-11e6-ba32-5a4bf5aad4fa_story.html?utm_term=.7616ce0d1db5 [<https://perma.cc/Z7GK-ME86>].

94. Koons, *supra* note 76.

95. Eric Lipton & Rachel Abrams, *EpiPen Maker Lobbies to Shift High Costs to Others*, N.Y. TIMES (Sept. 16, 2016) <http://www.nytimes.com/2016/09/16/business/epipen-maker-mylan-preventative-drug-campaign.html> [<https://perma.cc/UQ4S-S9TP>] (“Mylan was actively involved in pushing a 2013 federal law encouraging schools nationwide to stock EpiPens. And the company takes credit for legislation in at least 10 states that require the product in hotels, restaurants and other places, and additional school-related legislation in nearly every state. It is also helping push legislation pending in Congress that would require epinephrine auto-injectors on all commercial airline flights.”).

strategy has given Mylan a near monopoly on the epinephrine autoinjector market.⁹⁶

As Mylan heavily marketed the EpiPen to both the public and the government, it also increased the price of the device. When Mylan acquired EpiPen in 2007, the product created only \$200 million in annual revenue.⁹⁷ As of 2016, EpiPen annual revenues had quintupled to \$1 billion.⁹⁸ Profit margins on EpiPens rose from 9 percent in 2008 to 55 percent in 2014. After federal guidelines recommended that patients be prescribed two doses of epinephrine rather than one in 2010, Mylan stopped selling single doses, even though thirty-five percent of prescriptions at the time were for single EpiPens.⁹⁹ Now, Mylan only sells double packs of EpiPens,¹⁰⁰ further increasing profits on a medication that patients hope never to use.

In response to the high price for the EpiPen, some patients have resorted to making their own epinephrine injection devices.¹⁰¹ Instructions for making the EpiPencil, a \$35 stand in for the EpiPen, were available on YouTube.¹⁰² Those instructions were removed by YouTube for “violating YouTube’s policy on harmful or dangerous content.”¹⁰³ Although these homemade alternatives are not illegal,¹⁰⁴ they may not be as safe as FDA-approved delivery systems.¹⁰⁵ Self-assembled injection systems may not be properly sterilized and may not contain the correct dosages.¹⁰⁶ Additionally, these systems have the same risk as commercially available EpiPen competitors—users may not know how to use the home-assembled injector, especially in times of emergency.¹⁰⁷

96. At the time of this writing, this monopoly still exists despite EpiPen’s high price, although it shows signs of weakening. Dan Mangan, *EpiPen Prescriptions Increase Despite Spotlight on Price Hikes, but Market Share Drops*, CNBC (Oct. 25, 2016), <http://www.cnbc.com/2016/10/25/epipen-prescriptions-increase-despite-spotlight-on-price-hikes-but-market-share-drops.html> [<https://perma.cc/T4HK-GEV6>].

97. Koons, *supra* note 76.

98. *Id.*

99. *Id.*

100. *Id.*

101. Selena Larson, *Outrageous EpiPen Prices Lead Some People to Make Their Own*, CNN TECH (Sept. 24, 2016), <http://money.cnn.com/2016/09/24/technology/diy-epipen-affordable-alternatives> [<https://perma.cc/D756-QBBS>].

102. *Id.*; Michael Laufer, *EpiPencil*, YOUTUBE (Sept. 18, 2016), <https://www.youtube.com/watch?v=ldFFJRdhVs8>, available at https://archive.org/details/EpiPencil_201801 [<https://perma.cc/8DRE-T3NN>] (providing instructions for making an “EpiPencil,” a homemade alternative to the EpiPen).

103. Laufer, *supra* note 102.

104. Larson, *supra* note 101 (“The FDA can’t do anything about DIY devices like the EpiPencil as long as you have a prescription for epinephrine, since the components are legal.”).

105. *Id.*

106. *Id.*

107. *Cf.* Willingham, *supra* note 79 (“The big caveat with using the non-EpiPen version of the delivery system is that the two devices work differently, in ways that can lead to critical errors if users aren’t properly trained.”).

Some doctors attempt to mitigate the prohibitive cost of the EpiPen for their patients by simply prescribing syringes of epinephrine.¹⁰⁸ However, syringes have their own dangers. They may contain an incorrect dose of epinephrine.¹⁰⁹ Further, syringes increase the risk of accidental injection into a vein, rather than a muscle, which can be fatal.¹¹⁰

Although there has been widespread public disapproval of Mylan's monopolistic behavior,¹¹¹ as of the time of this publication, Mylan has announced no plans to decrease the cost of the EpiPen.¹¹² Instead, Mylan plans to create the first authorized generic EpiPen that will sell for half the price of its branded version.¹¹³ While this move is a step in the right direction for consumers, it may not be entirely selfless on Mylan's part. Some analysts say that by eliminating intermediaries in the sale of the authorized generic, Mylan may receive greater profits from the authorized generic than from the branded EpiPen.¹¹⁴ Additionally, Mylan's generic may discourage competitors from entering the market with their own generic, thus further preserving Mylan's monopoly.¹¹⁵

C. Turing Leveraged Regulatory Barriers to Increase Price of Daraprim

In 2015, Turing Pharmaceuticals ("Turing") increased the price of Daraprim, a treatment for toxoplasmosis, by over 5,000 percent—from \$13.50 per pill to \$750 per pill.¹¹⁶ A year-long course of treatment for patients weighing over 132 pounds costs over \$600,000 after the price hike.¹¹⁷ This price hike was especially harmful to immunocompromised toxoplasmosis patients, such as

108. Larson, *supra* note 101.

109. Willingham, *supra* note 79 ("A syringe doesn't offer the benefit and safety advantage of a well-calibrated dose . . .").

110. *Id.*

111. Even Martin Shkreli, the infamous poster boy of the exorbitant Daraprim price hike, said of Mylan, "these guys are really vultures." *Id.*

112. Lydia Ramsey, *Here's What the EpiPen Maker Says About Why It Won't Just Cut the Drug's Price*, BUS. INSIDER (Sept. 9, 2016), <http://www.businessinsider.com/why-mylan-wont-lower-the-price-of-the-epipen-2016-9> [<https://perma.cc/S8KZ-RL4P>].

113. Lydia Ramsey, *Why Mylan Could Stand to Make Even More Money off a Generic Version of the EpiPen*, BUS. INSIDER (Aug. 30, 2016), <http://www.businessinsider.com/authorized-generic-version-of-epipen-mylan-2016-8> [<https://perma.cc/2MQD-MNKT>].

114. *Id.*

115. Rosenthal, *supra* note 91 ("Mylan can hang onto the market for doctors and patients who demand the trusted brand name, while cornering an incipient generic market.").

116. Laura Lorenzetti, *Here's Why Turing Pharmaceuticals Says 5,000% Price Bump Is Necessary*, FORTUNE (Sept. 22, 2015), <http://fortune.com/2015/09/21/turing-pharmaceuticals-martin-shkreli-response> [<https://perma.cc/JPT4-GYXX>].

117. Anna Almendrala, *What the Daraprim Price Hike Actually Does to Health Care*, HUFFINGTON POST (Sept. 23, 2015), http://www.huffingtonpost.com/entry/daraprim-price-turing-shkreli_us_560063cee4b00310edf82060 [<https://perma.cc/Z9X6-NQV9>] ("A joint letter from the Infectious Diseases Society of America and the HIV Medicine Association wrote that hospitals and pharmacies are no longer able to stock the medication. They also calculate that year-long treatment for toxoplasmosis will now cost \$336,000 for those who weigh less than 132 pounds, and \$634,500 for those who weigh more than that.").

AIDS patients with toxoplasmosis, who may require lifelong Daraprim treatment.¹¹⁸

Daraprim, which was initially approved by the FDA in 1953,¹¹⁹ is not the subject of any unexpired US patents or FDA exclusivity restrictions.¹²⁰ A generic could be made in the United States. However, there is no generic currently available.¹²¹ Before the price hike, there was little incentive for generic manufacturers to compete with Daraprim because the market for Daraprim was relatively small,¹²² and the profit potential was low.¹²³ With no generic on the market or in the FDA's regulatory pipeline, Daraprim had an effective monopoly¹²⁴ in a small, but desperate, market.¹²⁵ Even if a generic manufacturer began the FDA approval process on the day that Turing announced the Daraprim price hike, Turing's effective monopoly would have lasted at least ten to fifteen months and likely would have lasted several years due to the time required to acquire FDA approval for a new generic.¹²⁶

Turing attempted to justify the price hike as an incentive for investors to fund research into new medication to eradicate toxoplasmosis.¹²⁷ However, there

118. *Parasites—Toxoplasmosis (Toxoplasma Infection)*, CTRS. FOR DISEASE CONTROL & PREVENTION (Jan 10, 2013), <https://www.cdc.gov/parasites/toxoplasmosis/treatment.html> [<https://perma.cc/9VA9-XEZP>].

119. *Drugs@FDA: FDA Approved Drug Products: Daraprim*, U.S. FOOD & DRUG ADMIN., <https://www.accessdata.fda.gov/scripts/cder/dafi/index.cfm?event=overview.process&AppNo=008578> [<https://perma.cc/KY75-UNRQ>] (accessed Oct. 26, 2018) [hereinafter *Drugs@FDA: Daraprim*].

120. *Orange Book: Daraprim*, U.S. FOOD & DRUG ADMIN., http://www.accessdata.fda.gov/scripts/cder/ob/patent_info.cfm?Product_No=001&AppNo=008578 &AppType=N [<https://perma.cc/9ZNY-VJG3>] (accessed Oct. 26, 2018).

121. *Drugs@FDA: Daraprim*, *supra* note 119.

122. Per year, only two thousand people in the US receive treatment with Daraprim. Tess Saperstein, *Medicated Monopolies*, HARV. POL. REV. (Dec. 10, 2015), <http://harvardpolitics.com/covers/medicated-monopolies> [<https://perma.cc/NG5K-54HH>].

123. James Surowiecki, *Taking on the Drug Profiteers*, NEW YORKER (Oct. 12, 2015) <http://www.newyorker.com/magazine/2015/10/12/taking-on-the-drug-profiteers> [<https://perma.cc/4QTP-TQ87>]. Several companies produce generic versions of Daraprim outside of the US. *Id.*

124. *Id.* (“Essentially, Shkreli is exploiting rules devised to protect consumer safety in order to create a virtual monopoly and then charge whatever he wants.”).

125. Saperstein, *supra* note 122.

126. *Developments in the Prescription Drug Market: Oversight: Hearing Before the H. Comm. on Oversight and Government Reform*, 114th Cong. 89 (2016) (statement of Rep. Blake Farenthold) (discussing ten-to-fifteen-month goal FDA approval time for Abbreviated New Drug Application (“ANDA”)) (“You are saying you are getting down to 10 and 15 months, but you have basically created a 10- and 15-month monopoly for anybody who is a single source of a generic drug.”). This ten-to-fifteen-month timeline is just for approval of a generic's ANDA. It does not account for the time that a generic manufacturer spends preparing its ANDA or preparing to manufacture and market the new drug. The Generic Pharmaceutical Association reports that the median FDA generic approval time is forty-seven months. Lupkin, *supra* note 90.

127. Lorenzetti, *supra* note 116 (quoting an email from Turing to Fortune) (“Toxoplasmosis is a very serious, sometimes deadly disease, yet there have been no significant advances or research into this disease area in decades . . . Turing hopes to change that by targeting investments that both improve on the current formulation and seek to develop new therapeutics with better clinical profiles that we hope will eradicate the disease.”).

is no pressing need for new toxoplasmosis medications because toxoplasmosis has not developed drug resistance to Daraprim.¹²⁸

After widespread public outrage, Turing reduced the price of Daraprim to \$375 for most patients.¹²⁹ Turing billed this reduction as a 50 percent reduction in price, compared to the \$750 per pill price tag introduced in 2015.¹³⁰ However, this new price was still over a 2,700 percent increase compared to the original \$13.50 per pill.

Although Daraprim is one of the most egregious and well-known cases of a price hike on an old brand-name medication, it is not the only case.¹³¹ Between 2006 and 2013, 140 brand-name medications had their prices increased by an average of 113 percent.¹³² One reason given for these price hikes is that the increased profits will fund R&D on new medications.¹³³ But that reasoning is dubious. For example, in 2015, Valeant¹³⁴ spent only 3 percent of its total sales on R&D, a mere fraction of the amount spent by other pharmaceutical companies.¹³⁵ In the same year, Valeant more than quadrupled the list prices of several of its drugs.¹³⁶ The pharmaceutical market as a whole spends much more money on marketing than it does on R&D.¹³⁷ It seems that the more likely reason for price hikes is to increase profits rather than increase R&D.

128. *Id.*

129. Heather Long, *Here's What Happened to AIDS Drug that Spiked 5,000%*, CNN MONEY (Aug. 25, 2016), <http://money.cnn.com/2016/08/25/news/economy/daraprim-aids-drug-high-price> [<https://perma.cc/3WY6-64UV>].

130. *Id.*

131. Lorenzetti, *supra* note 116 (describing recent price increases for old drugs including a 2,160 percent price hike for cycloserine in August 2015, a 525 percent price hike for Isuprel in 2015, a 212 percent price hike for Nitropress in 2015, and a 9,245 percent price hike for doxycycline in April 2014).

132. Saperstein, *supra* note 122.

133. *Id.*

134. Valeant rebranded itself as “Bausch Health” in 2018. Jonathan D. Rockoff, *Valeant Pharmaceuticals to Change Its Name to Bausch Health.*, WALL ST. J. (May 8, 2018), <https://www.wsj.com/articles/valeant-pharmaceuticals-to-change-its-name-to-bausch-health-1525752878> [<https://perma.cc/D9YB-FBEQ>].

135. Saperstein, *supra* note 122 (“Valeant—which has pursued an aggressive drug acquisition strategy—spends significantly less than its counterparts on research and development. Over the past year, the company spent just three percent of its total sales on research and development, while one of its competitors, Bristol-Myers Squibb, spent over 30 percent.”).

136. In 2015, Valeant increased the price of Cuprimine, a treatment for Wilson’s disease, from \$6,547 to \$26,189, a four-time increase in price. Valeant also increased the price of Zegerid, a treatment for acid reflux, from \$421 to \$3,034, a seven-time increase in price, and Glumetza, a treatment for diabetes, from \$572 to \$5,148, a nine-time increase in price. Gretchen Morgenson, *How Valeant Cashed in Twice on Higher Drug Prices*, N.Y. TIMES (July 29, 2016), https://www.nytimes.com/2016/07/31/business/how-valeant-cashed-in-twice-on-higher-drug-prices.html?_r=0 [<https://perma.cc/U9HM-7UCH>].

137. Anderson, *supra* note 32.

III.

CURRENT REGULATORY PRESSURE

As these cases illustrate, pharmaceutical market share is often monopolistic, and those monopolies can come from many sources. These cases also demonstrate the inflexibility of pharmaceutical demand. Rational consumers will go deep into debt, or resort to risky substitutes before they go without life-saving medications. Regulatory pressure is the only variable in the pharmaceutical price equation that is easy for the government to control. However, these cases also illustrate that regulatory pressure has been insufficient to prevent overpricing. This Part will outline the four main sources of regulatory pressure that could conceivably impact pharmaceutical pricing: congressional hearings, antitrust laws, piecemeal regulations which regulate prices or rebates for certain purchasers, and Section 1498. A survey of these forms of regulation reveals that none are sufficient to address the problem of overpriced drugs.

A. Congressional Hearings

In each of the cases described in Part II, pharmaceutical company representatives were called before Congress for congressional hearings.¹³⁸ However, the utility of congressional castigation as a method of influencing pharmaceutical pricing schemes is dubious. Congressional scolding does not pay shareholder dividends—profits do.¹³⁹ Of twenty-nine drugs that were specifically mentioned during congressional hearings or in letters from legislators from 2014 to 2016, only five had their prices decreased and two had their prices increased.¹⁴⁰ Regulations must threaten the corporate pocketbook, not just the corporate ego, to be an effective tool for controlling pharmaceutical prices.

B. Antitrust Laws

Another way for regulatory pressure to threaten corporate profits is through antitrust laws. However, antitrust laws generally do not limit pharmaceutical profits because simply setting a high price for a necessary good is not an antitrust

138. Press Release, U.S. Senate Comm. on Fin., *supra* note 57; Press Release, U.S. Senate Special Comm. on Aging, Sudden Price Spikes in Decades-Old Rx Drugs: Inside the Monopoly Business Model (Mar. 17, 2016), <https://www.aging.senate.gov/press-releases/sudden-price-spikes-in-decades-old-rx-drugs-inside-the-monopoly-business-model> [<https://perma.cc/5FGG-BZJK>]; U.S. House Comm. on Oversight & Government Reform, Reviewing the Rising Price of EpiPens (Sept. 21, 2016), <https://oversight.house.gov/hearing/reviewing-rising-price-epipens-2> [<https://perma.cc/T7PR-UXNB>].

139. See *Dodge v. Ford Motor Co.*, 170 N.W. 668, 684 (Mich. 1919) (“A business corporation is organized and carried on primarily for the profit of the stockholders.”).

140. Matthew Perrone, *Drug Prices Don't Budge Even After Pressure from Congress*, ASS. PRESS (Nov. 16, 2016), <https://www.apnews.com/8bb39908692f418e85ee15fd9516bd9c> [<https://perma.cc/3QED-3NS9>].

violation.¹⁴¹ Most patent monopolies are legally created through the patent system, rather than through violations of the antitrust laws. Consequently, antitrust laws and Federal Trade Commission (“FTC”) regulations are an imperfect solution to the problem of high drug prices. Notably, in cases where antitrust violations do exist, the government has used antitrust laws and regulations to diminish the violator’s market share through compulsory licensing of pharmaceutical patents.¹⁴²

Although antitrust law does not restrict a monopolist’s ability to set prices as high as the market will bear for lawfully obtained patents, it may apply where a patent owner attempts to extend their patent’s term beyond its normal lifespan. In the pharmaceutical industry, this behavior often takes two forms: evergreening or product switching.

First, evergreening is the practice of patenting trivial modifications of a product to extend its patent term.¹⁴³ In addition to increasing the overall monopoly term for a patented drug, these frivolous follow-on patents increase the costs of a generic seeking to enter the market before the expiration of the patents by increasing the number of patent claims that the generic must challenge as invalid.¹⁴⁴

Second, product switching is the practice of switching patients from one patented formulation of a drug, to another slightly different formulation right before the expiration of the patent on the original formulation.¹⁴⁵ Pharmacies may only automatically substitute a generic that has the same formulation and strength as a name brand drug listed on a prescription.¹⁴⁶ Thus, by ceasing to sell the original formulation and switching all patients over to a new formulation, the patent owner prevents automatic substitution of a generic developed with the original formulation in mind.¹⁴⁷ The FTC has specifically identified product switching as a problem, noting that the “potential for anticompetitive product

141. See, e.g., *Blue Cross & Blue Shield United of Wisconsin v. Marshfield Clinic*, 65 F.3d 1406, 1412–13 (7th Cir. 1995), *as amended on denial of reh’g* (Oct. 13, 1995) (“[T]he antitrust laws do not regulate the prices of natural monopolists.”); *Berkey Photo, Inc. v. Eastman Kodak Co.*, 603 F.2d 263, 297 (2d Cir. 1979) (“A pristine monopolist, we have held, may charge as high a rate as the market will bear.”).

142. Tens of thousands of US patents have been licensed either through antitrust litigation, or in settlements entered into under the shadow of antitrust litigation. F. M. Scherer, *The Political Economy of Patent Policy Reform in the United States*, 7 J. ON TELECOMM. & HIGH TECH. L. 167, 170–71 (2009).

143. Roger Collier, *Drug Patents: The Evergreening Problem*, 185 CANADIAN MED. ASS’N J. 385, 385 (2013).

144. DANZON, *supra* note 27, at 50 (“Antitrust authorities in both the US and the EU have challenged ‘patent evergreening,’ that is, the filing by originator firms of follow-on patents that may have little merit and are unlikely to withstand legal challenge. Such patents nevertheless raise costs for generics that must successfully challenge every filed patent before they can come to market. Frivolous patenting raises health care costs for consumers and reduces timely patent reviews by patent offices, which have limited resources.”).

145. *Id.*

146. *Id.*

147. *Id.*

redesign is particularly acute in the pharmaceutical industry” because patients’ selection of the new formulation does not reflect their preference for the new formulation, but rather medical or economic necessity.¹⁴⁸

Antitrust violations may also arise in “pay for delay” settlements, in which a brand-name drug maker pays a generic not to enter the market, thus extending the brand-name’s monopoly for a time.¹⁴⁹ Finally, antitrust violations in the pharmaceutical sector may arise in other situations, such as illegal tying, although these situations arise very rarely.¹⁵⁰

While antitrust laws can be used to restrain certain forms of patent abuse or anticompetitive behavior, they do not prohibit setting high prices for lawfully obtained patents. Thus, antitrust laws are unable to impact most high drug prices, which arise out of lawful patent, regulatory, and marketing-based monopolies.

C. Targeted Discount and Rebate Programs

In addition to congressional hearings and antitrust laws, the federal government has devised several regulatory schemes meant to control prices for government-purchased drugs. These schemes include the Medicaid Drug Rebate Program,¹⁵¹ the 340B Drug Pricing Program,¹⁵² and the Department of Veterans Affairs (VA) Federal Supply Schedule.¹⁵³ These programs suffer, however, from limited applicability because, by their very design, they can only affect the prices of drugs provided to beneficiaries of certain government programs.

Additionally, these programs may encourage manufacturers to set higher prices for private purchasers, either to increase the prices of drugs sold to the regulated programs or to make up for profits lost through selling to those programs.¹⁵⁴ For example, the Medicaid Drug Rebate Program requires pharmaceutical manufacturers to provide rebates to the government for any drugs covered by Medicaid.¹⁵⁵ Statutes and regulations set the rebates as a percent of the average market price, or the difference between the average market price and the lowest market price, whichever is greater.¹⁵⁶ This program saved

148. Federal Trade Commission’s Brief as Amicus Curiae, *Mylan Pharmaceuticals, Inc. v. Warner Chilcott Public Limited Co.*, No. 12-3824 (E.D. Pa. Dec. 3, 2012), 2015 WL 1736957, at *11–12.

149. DANZON, *supra* note 27, at 35–37.

150. *Id.* at 34.

151. *Medicaid Drug Rebate Program*, MEDICAID (Nov. 24, 2017), <https://www.medicare.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html> [<https://perma.cc/569C-5FG3>].

152. 42 U.S.C. § 256b (2012); *340B Drug Pricing Program*, HEALTH RESOURCES & SERVS. ADMIN. (Jan. 2018), <https://www.hrsa.gov/opa/index.html> [<https://perma.cc/B3US-QUSZ>].

153. *VA Federal Supply Schedule Service*, U.S. DEP’T OF VETERANS AFF. (Jan. 3, 2018), <https://www.fss.va.gov> [<https://perma.cc/7MWQ-T6D9>].

154. CONGRESSIONAL BUDGET OFFICE, *HOW THE MEDICAID REBATE ON PRESCRIPTION DRUGS AFFECTS PRICING IN THE PHARMACEUTICAL INDUSTRY* 27–28 (1996).

155. *Medicaid Drug Rebate Program*, *supra* note 151.

156. 42 U.S.C. § 1396r-8(c) (2012).

Medicaid money but may have had some negative effects.¹⁵⁷ For instance, the program discourages pharmaceutical manufacturers from providing discounts to private buyers because they would then have to provide that lower price to Medicaid.¹⁵⁸

D. 28 U.S.C. § 1498

Finally, the most flexible tool in the current regulatory toolkit for addressing high pharmaceutical prices is Section 1498, which provides a limited waiver of the United States' sovereign immunity with respect to patent infringement.¹⁵⁹ It allows patent owners to sue the United States for patent infringement.¹⁶⁰ However, the patent owner cannot enjoin the United States' infringement;¹⁶¹ the owner's only remedy under Section 1498 is monetary damages.¹⁶² This section effectively grants the United States the right to take a compulsory license for any United States patent.¹⁶³ Courts and commentators have analogized the Section 1498 waiver of sovereign immunity to the government's eminent domain power.¹⁶⁴

Although the government has used Section 1498 to access patented innovations in a broad range of areas, from hazardous waste cleanup to electronic passports,¹⁶⁵ it has not used Section 1498 to infringe pharmaceutical patents in several decades. The government used its Section 1498 power to acquire

157. CONGRESSIONAL BUDGET OFFICE, *supra* note 154, at ix (“[A]lthough the Medicaid rebate appears on the surface to be attractive, it may have had unintended consequences for private purchasers.”).

158. *Id.* (“[T]he best-price provision has increased the prices paid by some purchasers in the private sector. Since Medicaid constitutes between 10 percent and 15 percent of the market for outpatient prescription drugs, pharmaceutical manufacturers are much less willing to give large private purchasers steep discounts off the wholesale price when they also have to give Medicaid access to the same low price. As a result, the largest discounts that pharmaceutical manufacturers give off the wholesale price—the best-price discounts—have fallen from an average of more than 36 percent in 1991 to 19 percent in 1994.”).

159. 28 U.S.C. § 1498(a) (2012).

160. *Id.*

161. *Martin v. United States*, 99 Fed. Cl. 627, 632 (2011) (citing *Leesona Corp. v. United States*, 599 F.2d 958, 968 (Ct. Cl. 1979)) (“[I]njunctive relief under 35 U.S.C. § 283 is unavailable to a patent owner in a section 1498 action against the government.”); *Pitcairn v. United States*, 547 F.2d 1106, 1118 n.13 (Ct. Cl. 1976) (“[A] patentee cannot obtain an injunction against a government-supplier or government-contractor and is confined, for his exclusive remedy, to a suit for ‘reasonable and entire compensation’ (*i.e.*, monetary compensation) against the United States under 28 U.S.C. § 1498.”).

162. 28 U.S.C. § 1498(a).

163. *Honeywell Int’l Inc. v. United States*, 107 Fed. Cl. 659, 679 (2012) (“Therefore, as a matter of law, the Government may take a compulsory, compensable, and nonexclusive license in any United States patent.”).

164. *Motorola, Inc. v. United States*, 729 F.2d 765, 768 (Fed. Cir. 1984) (internal citations omitted) (“This is a 28 U.S.C. § 1498 action, and as such, the patent owner is seeking to recover just compensation for the Government’s unauthorized taking and use of his invention. The theoretical basis for his recovery is the doctrine of eminent domain. In this context, the United States is not in the position of an ordinary infringer, but rather a compulsory, nonexclusive licensee.”).

165. *Brennan*, *supra* note 3, at 302 (compiling instances of the government’s use of Section 1498).

inexpensive infringing medications several times throughout the 1950s and 1960s,¹⁶⁶ but it has not applied Section 1498 to pharmaceuticals in the nearly fifty years since.¹⁶⁷

This recent disuse is due in part to changes in the political zeitgeist, changes in the prevailing philosophies of intellectual property, and increases in pharmaceutical regulation.¹⁶⁸ For example, in 1965, the Senate Subcommittee on Patents, Trademarks, and Copyrights held a hearing in which representatives of the pharmaceutical industry led a variety of industries in airing grievances about the use of Section 1498 to infringe their patents.¹⁶⁹ A bill to amend Section 1498 to limit its application to uses necessary for national security was introduced but did not become law.¹⁷⁰ Although attempts to amend Section 1498 and limit its application to pharmaceutical patents failed, the proposed amendment is indicative of the changing political atmosphere. Application of Section 1498 to patented pharmaceuticals ceased even without amendment of the law.

Although Section 1498 has not been used to access patented pharmaceutical innovations in the past several decades, it has recently been used by two senators as a bargaining chip to encourage pharmaceutical companies to increase production or lower prices.

In 2001, Senator Chuck Schumer suggested that the government use Section 1498 to stockpile Cipro, a broad spectrum antibiotic used to treat Anthrax.¹⁷¹ In September 2001, letters containing anthrax spores were mailed to congressional and media offices.¹⁷² By the end of October 2001, dozens of people tested positive for anthrax exposure.¹⁷³ Fear of exposure led to increased demand for Cipro.¹⁷⁴ But there was not enough of the patented drug to meet the sudden demand.¹⁷⁵ In response to the shortage, New York Senator Charles Schumer suggested that the government allow generic manufacturers to infringe the Cipro patent to increase the government's stockpile of the drug.¹⁷⁶ Ultimately, however, actual government-mandated patent infringement was

166. *Id.* at 307.

167. *Id.*

168. *Id.*

169. Gerald J. Mossinghoff & Robert F. Allnut, *Patent Infringement in Government Procurement: A Remedy Without a Right*, 42 NOTRE DAME L. REV. 5, 13–14 (1967).

170. *Id.* at 16–19.

171. *Senator Seeks Generic Cipro*, CNN MONEY (Oct. 16, 2001), http://money.cnn.com/2001/10/16/news/generic_cipro [<https://perma.cc/W7F8-PWQY>].

172. *Timeline: How the Anthrax Terror Unfolded*, NPR (Feb. 15, 2011), <http://www.npr.org/2011/02/15/93170200/timeline-how-the-anthrax-terror-unfolded> [<https://perma.cc/BQM6-MGEB>].

173. David B. Resnik & Kenneth A. De Ville, *Bioterrorism and Patent Rights: "Compulsory Licensure" and the Case of Cipro*, 2 AM. J. BIOETHICS 29, 29 (2002).

174. *Id.*

175. *Id.*

176. *Senator Seeks Generic Cipro*, *supra* note 171 ("Schumer, in a press conference Tuesday, said he believes the Federal Government has the authority to order immediate production of generic ciproflaxin to expand the government's stockpile of the drug.").

unnecessary to accumulate the government's desired amount of Cipro.¹⁷⁷ By October 25, 2001, only eight days after Senator Schumer's suggestion, Bayer and the United States had agreed that Bayer would supply 100 million tablets of Cipro to the government at a discounted rate.¹⁷⁸

In 2006, Senator Schumer again called on the government to use Section 1498, this time to allow generic pharmaceutical makers to manufacture Tamiflu to treat the avian flu.¹⁷⁹ Roche, the patent holder for Tamiflu, was unable to produce the amount of Tamiflu desired by the United States as other countries stockpiled the drug in preparation for a potential avian flu outbreak.¹⁸⁰ Fortunately, the feared outbreak never occurred in the United States,¹⁸¹ and application of Section 1498 to the Tamiflu patent was unnecessary.

More recently in 2015, Vermont Senator Bernie Sanders sent a letter to the Secretary of the US Department of Veterans Affairs requesting that the Department use Section 1498 to procure Sovaldi—Gilead's patented Hepatitis C medication—at a lower cost.¹⁸² To date, there have been no actions on Senator Sanders' request.

Although the threat of Section 1498 may be an effective bargaining chip in securing adequate quantities of drugs, its actual use would create several problems. First, any government agency or department could potentially use Section 1498 to infringe pharmaceutical patents.¹⁸³ This widely dispersed decision-making power means that there is no dedicated governmental body monitoring drug prices and consistently applying Section 1498 to create regulatory pressure on pharmaceutical prices. Second, this diffuse power potentially allows agencies without the necessary expertise and information to indiscriminately infringe on pharmaceutical patents, thus potentially negatively affecting innovation incentives. Third, Section 1498's judicially determined damages may not provide sufficient certainty to preserve innovation incentives. Finally, Section 1498 can only be used to procure patented products for government use and may be of limited help for ensuring pharmaceutical access for patients who do not procure their medication through the government.

177. Resnik, *supra* note 173, at 30.

178. *Id.*

179. Press Release, Charles E. Schumer, *supra* note 4.

180. *Id.*

181. *Outbreaks of Avian Influenza in North America*, CTRS. FOR DISEASE CONTROL & PREVENTION (Feb. 2, 2017), <https://www.cdc.gov/flu/avianflu/outbreaks.htm> [<https://perma.cc/N39S-YJR6>] (reporting only one case of avian flu in a human in the United States after 2004).

182. Letter from Bernard Sanders to Robert A. McDonald, *supra* note 4.

183. See 18 U.S.C. § 1498(a) (2012) (not restricting application of Section 1498 to any particular subset of the United States' government, but rather stating that the Section applies “[w]henever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States”).

1. *Problems with Section 1498: Disperse Decision-Making Leads to a Bystander Effect*

Disperse decision-making power means that there is no single body responsible for monitoring drug prices and access to pharmaceuticals. This leads to a congressional bystander effect.¹⁸⁴ Legislators are not tasked with monitoring pharmaceutical prices¹⁸⁵ and have many other responsibilities which they may consider to be a higher priority. Because of this diffuse decision-making and lack of a dedicated price monitor, pharmaceutical companies have no consistent fear of regulatory action triggered by steep prices. As a result, Section 1498's regulatory pressure on pharmaceutical prices is only operative when a pharmaceutical's prices are so high that they attract congressional attention. Although individual agencies, such as the VA, could use Section 1498 to infringe pharmaceutical patents without Congressional approval, they have chosen not to do so since the 1960s. Thus, history shows that neither Congress nor agencies are using Section 1498 to access patented pharmaceuticals. And due to diffuse decision-making power and the congressional bystander effect inherent in Section 1498's broad grant of power to any government agency or department, neither seems likely to resurrect Section 1498 for this purpose.

2. *Problems with Section 1498: Potential Misapplication to Optimally Incented Products Discourages Investment in Innovation*

Because the potential decision makers under Section 1498 span both the executive and legislative branch, actors who are able to exercise Section 1498 power may lack the information necessary to make those decisions.

Responsible innovation policy requires that the Section 1498 power only be exercised in cases of high deadweight loss.¹⁸⁶ Patents provide an economic incentive for innovation by promising a monopoly period. But not every invention requires the same economic incentive to encourage research. For

184. The bystander effect refers to the tendency of bystanders to not offer emergency assistance when other bystanders are present. John M. Darley & Bibb Latané, *Bystander Intervention in Emergencies: Diffusion of Responsibility*, 8 J. PERSONALITY & SOC. PSYCHOL. 377 (1968). The likelihood that a bystander offers emergency assistance is inversely proportional to the size of the group of witnesses. *Id.* at 379–80. Additionally, bystanders who do help take longer to do so when they are in larger groups of witnesses. *Id.* at 380. The overall result of the bystander effect is that a victim whose emergency is witnessed by one bystander is more likely to receive prompt assistance than a victim whose emergency is witnessed by five bystanders. *Id.* Two explanations for the bystander effect exist in both emergency bystanders and in Congress. First, both experience diffuse responsibility because any other onlooker or congressperson could intervene. Second, both experience diffuse blame for inaction. *See id.* at 378.

185. Even if legislators are aware of high pharmaceutical prices, they have limited incentives to act absent public outrage. *See* Charles D. Ellison, *The Politics of Social Loafing*, HUFFINGTON POST (May 25, 2011), http://www.huffingtonpost.com/charles-d-ellison/the-politics-of-social-lo_b_626068.html [<https://perma.cc/D3N9-XPXM>] (“Paralysis by lack of reaction from the larger public is driving Congressional lethargy on key issues such as jobs. If the Senate isn’t seeing any public outrage, then what’s the hurry? And, really, what is the hurry?”).

186. Brennan, *supra* note 3, at 319.

example, a very simple invention which requires minimal research expenditure might be created even if the promised monopoly period is very short. But a complicated invention, or one whose success is very uncertain, would require a longer promised monopoly period to incent innovation. The American patent system is uniform; it provides a constant monopoly term for both simple and complex inventions. Thus, some inventions are overincented by patents, while others are optimally incented, and still others are under incented and will not be invented unless there is some other incentive to invent. Patents on overincented inventions create deadweight losses, an economic inefficiency where the price of a good is inefficiently high and the supply of the good is inefficiently low. Section 1498 should be used to issue compulsory licenses for overincented products, thus decreasing the deadweight losses created by an unnecessary monopoly. But if Section 1498 is used to take compulsory licenses of products that are optimally incented, the incentive to invest in innovations in those products will be lessened, and fewer pharmaceutical products will make it to market.

Determining which innovations are overincented or optimally incented is an information-heavy task. Even with complete information, it may not be possible to determine which innovations are overincented and thus accrue deadweight losses through patent protection. Thus, decision-makers may be forced to guess as to which products are overincented and should be disrupted by Section 1498, and which products are optimally incented and should be left to market forces. As a result, Section 1498 may be used to issue compulsory licenses for patented innovations that are already optimally incented by the current intellectual property regime, or decision-makers may fail to apply Section 1498 to innovations that are overincented by the current regime. Ultimately, where decision-makers do not have access to complete information, Section 1498 could be both overinclusive and underinclusive. Additionally, the uncertainty over which products might be subjected to Section 1498 will itself have a dampening effect on future innovation as pharmaceutical innovators are less willing to invest in products that might be unexpectedly licensed under Section 1498.¹⁸⁷

3. *Problems with Section 1498: Uncertainty of Damages*

Determination of “reasonable and entire compensation” under Section 1498 is uncertain for pharmaceutical patents because cases tend to settle, and there

187. Dirk Czamitzki & Andrew A. Toole, *Patent Protection, Market Uncertainty, and R&D Investment*, 93 REV. ECON. & STAT. 147, 147 (2011) (internal citations omitted) (“The real options framework predicts that greater uncertainty about market revenues may reduce current investment in irreversible capital by increasing the value of waiting to invest. R&D investment is highlighted in this literature as a particularly relevant example of irreversible capital because a large proportion of R&D supports the salaries of research personnel and cannot be recouped if projects fail. Firms can avoid large losses by waiting for new information about market conditions and forgoing investment when information is unfavorable. This would lower current R&D investment.”).

have been no final judicial determinations of damages in that context.¹⁸⁸ Even when Section 1498 was used for pharmaceuticals in the 1950s and 1960s, the cases always settled.¹⁸⁹ Thus, there is no judicial precedent for determining reasonable compensation for pharmaceutical patents under Section 1498.¹⁹⁰ Judicial precedent does exist for determining reasonable compensation in other markets.¹⁹¹ As this Note has explained, however, the pharmaceutical market is unique.¹⁹² Consequently, reasonable compensation in other markets may not be so reasonable when applied to the pharmaceutical market.

The uncertainty of calculating damages for pharmaceutical products purchased or produced by the government under Section 1498 discourages the government from using the statute because it is unclear whether the results of a patent infringement suit pursuant to the statute would actually result in lower prices.¹⁹³ Such uncertainty may, in turn, decrease the incentive to invest in R&D

188. Brennan, *supra* note 3, at 306; *Competitive Problems in the Drug Industry: Hearings on Present Status of Competition in the Pharmaceutical Industry Before the Subcomm. on Monopoly of the S. Select Comm. on Small Bus.*, 92nd Cong. 8016 (1971) (testimony of Paul Shnitzer, Assistant General Counsel to the Comptroller General of the United States) (“There is no decision of the Court of Claims with respect to the purchase of foreign drugs or the purchase of drugs in a foreign country.”). *But see id.* (testimony of Paul Shnitzer, Assistant General Counsel to the Comptroller General of the United States) (stating that a “large number” of Section 1498 cases have “gone to judgment” and suggesting that the complainant was typically paid 5 to 10 percent of the purchase price). I have been unable to locate any final judgments determining reasonable compensation for pharmaceutical products obtained under Section 1498. It may be that Mr. Shnitzer misspoke or that he had access to final adjudications that I have been unable to locate.

189. Brennan, *supra* note 3, at 306; *Competitive Problems in the Drug Industry: Hearings on Present Status of Competition in the Pharmaceutical Industry Before the Subcomm. on Monopoly of the S. Select Comm. on Small Bus.*, 92nd Cong. 8015 (1971) (testimony of Paul Shnitzer, Assistant General Counsel to the Comptroller General of the United States) (“There have been two suits, one which was settled, the other which is still pending.”).

190. *Supra* notes 189, 189.

191. *See, e.g.*, *Decca Ltd. v. United States*, 640 F.2d 1156 (Ct. Cl. 1980) (determining reasonable and entire compensation due to patentee for government infringement of a patent for a three-frequency radio navigational system); *Leesona Corp. v. United States*, 599 F.2d 958 (Ct. Cl. 1979) (mechanically rechargeable metal-air batteries); *Tektronix, Inc. v. United States*, 552 F.2d 343 (Ct. Cl. 1977), *opinion modified on denial of reh’g*, 557 F.2d 265 (Ct. Cl. 1977) (oscilloscopes); *Boeing Co. v. United States*, 86 Fed. Cl. 303, 306 (2009) (low temperature underaging of aluminum lithium alloys); *Hughes Aircraft Co. v. United States*, 86 F.3d 1566 (Fed. Cir. 1996), *cert. granted, judgment vacated*, 520 U.S. 1183 (1997) (spacecraft).

192. *See infra* Part I; *see also* STUART O. SCHWEITZER, PHARMACEUTICAL ECONOMICS POLICY 21 (2007) (“The pharmaceutical industry is unique in the American economy in that it is fundamentally based in research and development (R&D) but is also a manufacturing industry.”).

193. *Competitive Problems in the Drug Industry: Hearings on Present Status of Competition in the Pharmaceutical Industry Before the Subcomm. on Monopoly of the S. Select Comm. on Small Bus.*, 92nd Cong. 8014 (1971) (testimony of Dean Crowther, Assistant Director of the Civil Division of the Comptroller General of the United States) (“The problem with that, of course, is that we are not in much of a position to say that if a patent infringement suit were to follow, the results of the suit may actually reduce the price.”); Brennan, *supra* note 3, at 306–07. Interestingly, this problem also existed during the 1950s and 1960s, when the government used Section 1498 to obtain infringing pharmaceuticals. *Id.* at 303–07.

for innovations that are optimally incented by the current intellectual property regime without application of Section 1498.¹⁹⁴

A recent article by Hannah Brennan et al. developed a thoroughly researched and compelling measure of pharmaceutical patent damages under Section 1498.¹⁹⁵ The article distilled the judicial guidance on “reasonable and entire compensation” in other industries and then modified that measure of compensation to account for the factors that make the pharmaceutical market unique, such as the large sunk costs and risks associated with R&D.¹⁹⁶ The article convincingly argued that such formulation ensures that patent owners will receive enough compensation to preserve the innovation incentive while allowing the government to save money on medications necessary to preserve or improve public health.¹⁹⁷

Although the article presented a compelling measure of damages under Section 1498, the analysis and findings do not bind courts. Nor do prior settlement agreements. Thus, Section 1498 damages uncertainty remains. That uncertainty both discourages the government’s use of the statute and may discourage pharmaceutical companies from investing as heavily in R&D out of fear of uncertain recoveries under Section 1498.

4. *Problems with Section 1498: Only Available for Government Use*

The final problem with Section 1498 is that its applicability is limited. Section 1498 only limits liability for products manufactured for the United States government.¹⁹⁸ Thus, the government could only use Section 1498 to procure pharmaceuticals for patients that receive medication through federal government programs, such as the Department of Veterans Affairs, Indian Health Services, Federal Bureau of Prisons, Medicare, and Medicaid.¹⁹⁹ However, lack of access to steeply priced pharmaceuticals is not limited to patients in government health care programs. Half of Americans use private health insurance to purchase their

194. See Czarnitzki & Toole, *supra* note 187 (internal citations omitted) (“The real options framework predicts that greater uncertainty about market revenues may reduce current investment in irreversible capital by increasing the value of waiting to invest. . . . This would lower current R&D investment.”).

195. Brennan, *supra* note 3, at 307–18.

196. *Id.*

197. *Id.* at 353 (“Section 1498’s requirement of ‘reasonable’ compensation provides a unique opportunity to think critically about compensation for innovation, especially for drugs with high social value. In line with the goals of § 1498 and patent protection more broadly, our proposed compensation methodology tethers patent compensation to the risk-adjusted costs of innovation. Such compensation enables the government to reduce the inefficiencies associated with patent monopoly. Effectively, § 1498 can operate as a kind of ex post prize mechanism, with all of the attendant benefits emphasized by the prize literature. By allowing the government to set an ex post price that it is willing to pay for innovation, § 1498 can reduce deadweight loss and increase the efficiency of investment in research. Government use can improve the health of millions by increasing access to lifesaving treatments while preserving long-term innovation incentives.”).

198. 28 U.S.C. § 1498(a) (2012).

199. Brennan, *supra* note 3, at 346–50.

pharmaceuticals.²⁰⁰ Drugs may be too expensive for these Americans as well. Section 1498 is powerless to reach those patients unless the government enacts new legislation to provide pharmaceuticals to all Americans.²⁰¹

IV.

A POSSIBLE SOLUTION: THE PHARMACEUTICAL ACCESS ACT

The problems associated with Section 1498 can be mitigated by establishing an independent agency capable of issuing compulsory licenses for pharmaceutical patents and working with generic manufacturers to produce both patented and nonpatented pharmaceuticals. The agency would be established by the PAA.

Consolidated decision-making in a single agency would allow the agency to assert sustained regulatory pressure. The agency would be composed of experts who have knowledge of intellectual property policy and pharmaceutical market economics, allowing them to make well-thought-out, coherent decisions to issue compulsory licenses for pharmaceutical patents. The agency would have the power to collect information from pharmaceutical companies and other federal agencies, thus allowing it to holistically consider research costs, product prices, and access rates before deciding to issue a compulsory license. The agency's organic act would provide general guidance for calculating royalties owed to patent owners and would task the agency with developing a specific formula, thus providing increased predictability for remuneration to patent owners. Perhaps most importantly, the agency would be empowered to provide pharmaceutical access to all Americans, not just those that receive pharmaceuticals through existing government programs.

The details of this agency are elucidated in the following Parts. Part IV.A describes the agency's structure. Part IV.B considers standards for determining which drugs the new agency should choose to issue compulsory licenses for and potential procedures for judicial review of the agency's determinations. Part IV.C discusses calculations for the royalties paid to a patent owner and suggests procedures for negotiating with pharmaceutical owners and judicial review of the agency's royalty determinations.

A. PAA Agency Structure

There are various structural features that impact agency decision-making, including decision-maker term limits,²⁰² protections from removal,²⁰³ size of the

200. *Id.* at 350.

201. *Id.* at 352–53.

202. Jennifer L. Selin, *What Makes an Agency Independent?*, 59 AM. J. POL. SCI. 971, 973–74 (2015).

203. Marshall J. Breger & Gary J. Edles, *Established by Practice: The Theory and Operation of Independent Federal Agencies*, 52 ADMIN. L. REV. 1111, 1141–51 (2000).

agency membership,²⁰⁴ who appoints agency members,²⁰⁵ and requirements for agency decision-maker qualifications.²⁰⁶ A thorough examination of the optimal structure for the PAA agency is beyond the scope of this paper. It suffices to say that the agency should be led by health care and economics experts who can comprehend the complexities of the pharmaceutical market, anticipate the externalities of the regulations they enact, and rely on their own expertise when faced with the prodigious lobbying power of pharmaceutical manufacturers.

B. Standards for Taking under the PAA

The statutory language for determining which drugs the agency should license should be left intentionally vague to allow agency experts to determine the best standards. Instead, the PAA organic statute should task the agency with developing detailed rules for determining which patents should be subject to compulsory licenses.

While developing a more precise standard for which patents should be subject to compulsory licensure is beyond the scope of this paper, there is a wealth of scholarship and experience that the agency could rely on to develop its standard for a taking.²⁰⁷ The agency should, of course, consider the degree of public access to pharmaceuticals. It should also consider the difference between the cost to develop a drug and the price of the drug. Additionally, the agency should consider the societal value of the pharmaceutical, usually measured in Quality Adjusted Life Years.²⁰⁸ There are numerous other factors which will likely find a place in the agency's standards for issuing a license. The bottom line is the agency's experts would be in a better position than Congress or other agencies to consider these various factors and develop a standard that improves access without impinging on incentives to innovate.

Aside from determining substantive standards, the agency should be tasked with developing detailed procedures for a taking determination and for judicial review of that determination. The PAA statute need only provide the basic required procedures, such as affording the patent owner an opportunity to appear before the agency to argue against licensure. In the interest of efficiency, the agency should be able to determine details such as the timing of that hearing, which could occur at the same time as a required license negotiation.

204. *Id.* at 1198–99.

205. *Id.* at 1139–41.

206. Selin, *supra* note 202.

207. Brennan, *supra* note 3, at 319–21.

208. See, e.g., *How NICE Measures Value for Money in Relation to Public Health Interventions*, NICE (Sept. 1, 2013), <https://www.nice.org.uk/Media/Default/guidance/LGB10-Briefing-20150126.pdf> [<https://perma.cc/4F8Y-B9DS>].

C. *Compulsory License Negotiations*

After the agency determines that a patent should be licensed by the government or a third party, it should next attempt to negotiate a license with the patent owner. This negotiation serves three purposes. First, negotiating a voluntary license ensures compliance with the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”) Article 31, the international agreement governing patent infringement which requires that a government attempt to obtain a license to a patented product through voluntary negotiations before resorting to compulsory licensure.²⁰⁹ Second, voluntary negotiations avoid the administrative costs associated with compulsory licenses, including the costs of adjudicatively determining a reasonable royalty and any adjudicatory review of that determination. Third, negotiation puts the patent owner on notice that their patent is at risk of compulsory licensure, encouraging them to adjust their prices to avoid licensure altogether.²¹⁰

D. *Adequate Remuneration*

The standard for the adequate remuneration due to a patent owner whose patent is compulsorily licensed under the PAA, like the standard for a taking, should be left purposefully undeveloped in the statute. Instead, the statute should provide only the basic procedures for determining adequate remuneration and some guidance on the amount. It would be sufficient for the statute to simply state that the agency should determine adequate remuneration due to the patent owner. This requirement comes directly from TRIPS, which requires that “adequate remuneration” shall be paid to the right holder whose patent rights are the subject of a compulsory license.²¹¹ Notably, TRIPS does not define “adequate remuneration,” leaving that term for the interpretation of individual nations.²¹²

Similarly, the PAA should refrain from defining adequate remuneration in all but the broadest language and should instead instruct the agency to develop its own detailed rules for determining adequate remuneration. This will allow the agency to use its expertise to develop a measurement that both adequately compensates patent owners and provides for affordable patient access. Delegation to the agency will also allow a detailed remuneration calculation that

209. Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31, Apr. 15, 1994, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

210. Pavcnik, *supra* note 37, at 485.

211. TRIPS Agreement, *supra* note 209, at art. 31(h) (“Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder . . . the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization . . .”).

212. WORLD HEALTH ORG., REMUNERATION GUIDELINES FOR NON-VOLUNTARY USE OF A PATENT ON MEDICAL TECHNOLOGIES 5 (2005) [hereinafter REMUNERATION GUIDELINES] (“The terms ‘reasonable commercial terms’ and ‘adequate remuneration’ are not defined in the TRIPS Agreement. WTO Members are free to determine the appropriate method of implementing the TRIPS Agreement, within their own legal system and practice, and this extends to the standards they apply for ‘reasonable’ royalties, or ‘adequate’ remuneration.”).

can more quickly respond to changes in American and international laws than if the statute had to be amended to respond to those changes.

Again, similar to the determination of a takings standard, developing a precise adequate remuneration calculation is beyond the scope of this paper. Fortunately, in this context, there is perhaps even more scholarship and experience that the agency can look to. For instance, because TRIPS does not define “adequate remuneration,” other countries have taken it upon themselves to develop their own standards. Several nations have created compulsory pharmaceutical licensing schemes.²¹³ The United States can develop its measurement of adequate remuneration with the experiences of those countries in mind.²¹⁴

Additionally, in making its determination, the agency should review judicial opinions of “reasonable and entire compensation” under Section 1498.²¹⁵ Courts have interpreted “reasonable and entire compensation” to be a

213. For example, India has granted compulsory licenses to local manufacturers and intends to keep doing so. Maricel Estavillo, *India Grants First Compulsory License, for Bayer Cancer Drug*, INTELL. PROP. WATCH (Dec. 03, 2012), <https://www.ip-watch.org/2012/03/12/india-grants-first-compulsory-license-for-bayer-cancer-drug> [<https://perma.cc/5A9C-SYAC>]; *India Defends Rights to Issue Drug “Compulsory Licenses,”* REUTERS (Mar. 23, 2016), <http://www.reuters.com/article/us-india-patents-usa-idUSKCN0WP0T4> [<https://perma.cc/AWB2-SGUL>]. Several other nations have also developed systems for granting royalties for compulsory licenses. REMUNERATION GUIDELINES, *supra* note 212, at 5 (“A number of royalty systems have been adopted or proposed in recent years, and establish useful frameworks for consideration. Royalty guidelines proposed by the Japanese Patent Office (1998) and UNDP (2001) set royalties from 0 to 6% of the price charged by the generic competitor. The 2005 Canadian royalty guidelines for the export of medicines to countries that lack manufacturing capacity set royalties at 0 to 4% of the generic price, depending upon the level of development of the importing country.”).

214. The agency must exercise some care if it chooses to base its measure of adequate remuneration off of the adequate remuneration paid in other nations. Although it may be tempting to use the same measure of adequate remuneration as lower-income nations because those lower-income nations may pay little for a compulsory license, the agency must resist that urge. Pharmaceutical companies should instead be encouraged to use discriminatory pricing, which would allow lower-income nations to access their products at lower prices than those available to higher-income nations. F. M. Scherer & Jayashree Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing Nations*, 5 J. INT’L ECON. L. 913, 933 (2002) (“[T]here is much to be said for price discrimination in multinational drug markets. Setting prices lower in low-income nations than in high-income, low price elasticity markets achieves two desirable ends—it helps low-income nations’ consumers obtain vital drug supplies, and it enhances drug producers’ net revenues, which, if accurately foreseen, stimulates investment in research and the development of new drugs.”). If the United States were to engage in “external reference pricing” through the PAA, pharmaceutical companies would be discouraged from allowing low cost licenses in lower-income nations, to the ultimate detriment of patients in those nations. Thus, the United States should only consider the adequate remuneration paid in nations with a similar income, and not base its calculations on the remuneration paid in lower-income nations. *See id.* at 934 (“High-income nations should also agree not to base the prices they allow under their price control regimes on the prices observed in low-income nations, i.e. to limit the geographic scope of any external reference price-based controls.”).

215. 28 U.S.C. § 1498 (a) (2012).

“reasonable royalty” measuring less than the patentee’s lost profits.²¹⁶ The agency should also look at the proposals of Brennan et al., who suggested that Section 1498 damages for pharmaceutical patents should be modified to account for risk-adjusted R&D costs.²¹⁷ Alternately, the agency may look to the private sector for guidance and may consider the commonly used “hypothetical negotiation” by attempting to ascertain the royalty the parties would have agreed to had they successfully negotiated an agreement just before infringement began.²¹⁸ Royalty rates from voluntary licenses between private pharmaceutical companies can also provide a benchmark for the agency as it attempts to determine a calculation for adequate remuneration.²¹⁹ However, if the agency relies on royalties from a hypothetical negotiation or voluntary licensing agreements, it should be careful not to overcompensate; this could occur if the agency attempts to compensate the patent owner for the entire value of the patent monopoly rather than for just their investment in developing intellectual property.²²⁰ At the same time, the agency should also avoid limiting its adequate remuneration to just the development costs for the specific intellectual property at issue, both because it is difficult to calculate the development costs for any specific patent²²¹ and because the profits for a single product may subsidize the development costs for less profitable products.²²² The wealth of scholarship and

216. *Decca Ltd. v. United States*, 640 F.2d 1156, 1172 (Ct. Cl. 1980) (“The reasonable royalty method is the preferred method of ascertaining the value of patent rights taken by the Government.”); Brennan, *supra* note 3, at 311–14.

217. Brennan, *supra* note 3, at 282–83 (“Courts would begin by using the standard approach to reasonable compensation, establishing a baseline reasonable royalty calculated as a percentage of the generic drug price. If appropriate evidence is supplied by the patentee, courts would then adjust this compensation award upwards to account for the patentee’s risk-adjusted R&D costs and to ensure a reasonable profit.”).

218. *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1324 (Fed. Cir. 2009).

219. *WORLD HEALTH ORG.*, *supra* note 212, at 6 (“There is extensive experience of voluntary technology licensing in the private sector. The evidence of compensation for private, market-based license arrangements provides an important context for making determinations of royalty and remuneration arrangements in cases of compulsory licensing. There is some conflicting evidence on cross-industry licensing averages, but there seems to be agreements in reports from the pharmaceutical industry and others that licensing fees for the pharmaceutical industry congregate at 4–5%. The pharmaceutical industry has one of the higher licensing rates among all industries.”).

220. Scherer & Watal, *supra* note 214, at 939 (“From precedents established in industrialized nations, it seems clear that a ‘reasonable’ royalty is one that is higher than zero, but much less than the royalty that would compensate a patent holder fully for the loss of whatever monopoly position it might enjoy by virtue of the patent.”).

221. Patricia M. Danzon & Adrian Towse, *Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents*, 3 INT’L J. HEALTH CARE FIN. & ECON. 183, 199 (“[I]n the case of pharmaceuticals for which some recoupment of R&D is appropriate, the measurement and allocation of R&D costs pose additional problems. Product-specific accounting data would not reflect the cost of R&D failures, or the cumulative cost of R&D investments, plus the time cost of money, over the 10–15 year lag between drug discovery and product approval.”).

222. Scherer, *Pharmaceutical Industry*, *supra* note 23, at 1329–30 (“[C]urbing significantly the prices and profits of blockbuster drugs could make it difficult for companies to recover their research and development investments on less successful drugs. . . . Severe impairment of R&D incentives could result.”).

empirical evidence from various remuneration schemes used in the United States and the rest of the world will help the agency, staffed by pharmaceutical economics experts, develop its standard for adequate remuneration.

Similarly, the agency should develop detailed procedures for initially determining adequate remuneration and for judicial review of that initial determination. The PAA statute need only provide the basic outline of the required procedures by simply stating that the agency should determine adequate remuneration for compulsory licenses, that the agency should notify patent owners of the agency's determination, and that patent owners can challenge the agency's determination before a federal district court or agency adjudicatory body. The agency should be free to develop more specific procedures on its own to ensure efficient yet thorough determinations.

E. Power to Address Monopolies Created through Regulation and Marketing

Although much of the discussion up until this point has specifically addressed how the PAA can be used to mitigate negative externalities caused by patent monopolies, the same powers that allow the PAA agency to create generic versions of patented medications will allow the agency to create generic versions of any pharmaceutical whose price prohibits patient access. The agency will need to work closely with the FDA as it seeks regulatory approval for such generics. The resulting relationship with the FDA and knowledge of the regulatory process will allow the agency to efficiently produce generic versions of drugs with regulatory or marketing monopolies. The agency can either produce these generics itself or, more likely, assist other generic manufacturers through the regulatory hurdles which delay generic marketplace entry. Thus, the PAA will address shortages created by monopolists whether those monopolies are created by patents or regulations.

V.

INTERNATIONAL LAW: TRIPS AND THE PAA

As one of the initial members of the World Trade Organization (“WTO”),²²³ the United States is bound by the TRIPS agreement and the Doha Declaration on the TRIPS Agreement and Public Health (“Doha Declaration”).²²⁴ The Doha Declaration recognizes that patents, while encouraging pharmaceutical innovation and investment, also increase the cost of pharmaceuticals.²²⁵ To address concerns over high pharmaceutical prices, the

223. *Members and Observers*, WORLD TRADE ORG., https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm [<https://perma.cc/KV3S-374S>].

224. TRIPS Agreement, *supra* note 209, at art. 1 § 3.

225. World Trade Organization, Ministerial Declaration of 20 November 2001, WTO Doc. WT/MIN(01)/DEC/2 ¶ 3 (2001) [hereinafter Doha Declaration] (“We recognize that intellectual

Doha Declaration clarifies that the TRIPS agreement does not prevent nations from protecting their citizens' public health and that the agreement should be interpreted to promote universal access to medicines.²²⁶ In particular, the Doha Declaration specifies that WTO member nations have "the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."²²⁷ Thus, the PAA would comply with current international law.

VI.

PAA VERSUS SECTION 1498 AND OTHER EXISTING REGULATORY TOOLS

The PAA effectively addresses the limitations of current regulatory pharmaceutical price controls, including the downfalls of Section 1498. First, the PAA would provide constant consolidated oversight, unlike congressional oversight or Section 1498. Second, the PAA would provide a more certain predetermined royalty, unlike the post hoc royalty calculation of Section 1498. Third, the PAA would not be restricted to providing drugs for government use, as Section 1498 is. Finally, the PAA would be more flexible than some government rebate programs, such as the Medicaid Drug Rebate Program.

First, the PAA consolidates decision-making, thus providing a constant source of regulatory pressure which is less dependent on the whims of public and political attention than Section 1498 and congressional hearings. Pharmaceutical companies respond to political pressure by decreasing their prices to disperse political and public scrutiny.²²⁸ Any regulatory pressure that depends on such scrutiny, such as Section 1498, will necessarily have cyclical effectiveness as pharmaceutical companies actively work to both avoid and disperse such scrutiny. The PAA avoids this cycle by providing a dedicated agency to constantly review and pressure pharmaceutical pricing.

Second, the PAA avoids the unpredictability of post hoc judicial damages determinations by articulating a concrete standard for the royalty owed to pharmaceutical patent owners. The pharmaceutical economy is complicated.²²⁹ Allowing nonexperts to determine the reasonable royalty for a compulsory license increases the risk of creating policy externalities.²³⁰ Although judges can, and certainly would, hear from pharmaceutical economic experts in evaluating damages in Section 1498 cases, those cases are likely to turn into a "battle of the experts,"²³¹ leaving a nonexpert judge or jury to sort through a deluge of

property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.").

226. *Id.* ¶ 4.

227. *Id.* ¶ 5(b).

228. Pavcnik, *supra* note 37, at 485.

229. *See supra* Part I.

230. *See supra* Part III.D.2.

231. *See* STUART GRAHAM, PETER MENELL, CARL SHAPIRO & TIM SIMCO, FINAL REPORT OF THE BERKELEY CENTER FOR LAW & TECHNOLOGY PATENT DAMAGES WORKSHOP 20 (Aug. 15,

information without the background knowledge necessary to make sense of it all.²³² Even if judges applying Section 1498 were to use an optimal measure for the reasonable royalty in some cases, the uncertainty of consistent application could have a negative effect on future innovation.²³³ The PAA provides certainty through two mechanisms: pretaking negotiations and established standards for calculating royalties.

Third, the PAA allows the government to manufacture, or contract with third parties to manufacture, pharmaceuticals for general use. While Section 1498 may have limited applicability because it only allows for pharmaceuticals for government use, the PAA would have no such limitations. Instead, the PAA would allow a generic manufacturer to sell a patented medication to all purchasers. Accordingly, unlike the Medicaid Price Rebate Program, which encouraged pharmaceutical companies to provide preferential pricing to the government but compensate for decreased profits by raising prices for private consumers, the PAA would provide no incentive for such unjustified price discrimination.²³⁴

Finally, the flexibility of the PAA agency structure allows an agency of experts to change regulations to account for unforeseen consequences. For example, when Medicaid attempted to decrease the cost of pharmaceuticals purchased through Medicaid with its Medicaid Drug Rebate Program, it discouraged pharmaceutical manufacturers from providing discounts to private purchasers.²³⁵ Remediating this unforeseen consequence of the Medicaid Drug Rebate Program would require amending the law,²³⁶ along with the constitutionally imposed hurdles of bicameralism and presentment.²³⁷ In contrast, changing the details of the agency's calculation of reasonable royalty will only require compliance with the Administrative Procedure Act's standards for agency rulemaking. Thus, the PAA will avoid unforeseen long-term externalities, like that caused by the Medicaid "best price" provision, because its rules will be more easily modified than statutes.

VII.

DISADVANTAGES OF THE PAA

Some may criticize the PAA for going too far in granting consolidated decision-making authority to a small group of experts, while others may criticize

2016), <https://www.law.berkeley.edu/wp-content/uploads/2016/08/Berkeley-Patent-Damages-Final-Report-2016-08-15-2.pdf> [<https://perma.cc/JQA5-SHST>] (noting that "the determination of a reasonable royalty within the *Georgia-Pacific* framework produces an expensive, time-consuming, polarized battle of the experts").

232. *See id.*

233. *See supra* note 187.

234. *See supra* Part III.C.

235. *See id.*

236. 42 U.S.C. § 1396r-8(c) (2012).

237. U.S. CONST. art. 1, § 7.

the PAA for not going far enough in regulating patient access to drugs. However, this criticism illustrates the delicate balance that any pharmaceutical reform must consider and that an agency composed of experts is uniquely well equipped to perform. Instead, the key disadvantage of this proposal is that it requires passage of new legislation, which pharmaceutical companies would strongly lobby against. Thus, admittedly, the PAA is unlikely to pass in the near future. Other disadvantages stem from the administrative agency structure itself. In particular, there is a danger of regulatory capture by the very pharmaceutical companies which the PAA is intended to regulate. Finally, there is the added costs of creating a new administrative agency. Despite these disadvantages, the PAA remains a worthwhile proposal for all of the reasons presented previously in this Note.

A. Pharmaceutical Companies Will Strongly Oppose the PAA

Pharmaceutical companies will seek to protect their profit margins by avoiding any new regulatory pressure, including passage of the PAA. They will rely on campaign contributions and lobbying²³⁸ and may temporarily decrease their prices²³⁹ to prevent passage of the PAA or similar legislation.

Pharmaceutical companies have formidable lobbying powers. For example, the pharmaceutical industry was a key proponent of the TRIPS agreement, which increased worldwide intellectual property protections to the benefit of the pharmaceutical industry.²⁴⁰ With support from the pharmaceutical industry, TRIPS was enacted despite widespread opposition from leading economists, the Council of Economic Advisors, and the Office of Science and Technology.²⁴¹ In the context of the PAA, which would pose a direct threat to the pharmaceutical

238. Sara Fisher Ellison & Catherine Wolfram, *Coordinating on Lower Prices: Pharmaceutical Pricing Under Political Pressure*, 37 RAND J. ECON. 324, 325 (2006) (discussing pharmaceutical firms' substantial lobbying power); Steven H. Landers & Ashwini R. Sehgal, *Health Care Lobbying in the United States*, 116 AM. J. MED. 474, 474 (2004) ("Health care lobbying expenditures totaled \$237 million in 2000. These expenditures accounted for 15% of all federal lobbying and were larger than the lobbying expenditures of every other sector, including agriculture, communications, and defense. A total of 1192 organizations were involved in health care lobbying. Pharmaceutical and health product companies spent the most (\$96 million), followed by physicians and other health professionals (\$46 million)."); Ashley Balcerzak, *PhRMA Shows Biggest Spike in Lobbying Spending in First Quarter of President Trump*, OPEN SECRETS (Apr. 21, 2017), <https://www.opensecrets.org/news/2017/04/phrma-shows-biggest-spike-in-lobbying-spending-in-first-quarter-of-president-trump> [<https://perma.cc/TW27-UP9T>].

239. Pavcnik, *supra* note 37, at 485.

240. Joseph E. Stiglitz, *Economic Foundations of Intellectual Property Rights*, 57 DUKE L.J. 1693, 1694 (2008).

241. *Id.* ("When I was at the Council of Economic Advisors we opposed the Trade-Related Aspects of Intellectual Property Rights agreement (TRIPS), part of the Uruguay Round of trade negotiations. Interestingly, so did the Office of Science and Technology Policy. We were not alone in our opposition; indeed, it was a view held by many, if not most, of the people who understood the issues. These views stood in contrast to the views of most of the people who had some special interest on this issue, particularly from the pharmaceutical and entertainment industries, who argued that the stronger the intellectual property rights the better.").

profits, pharmaceutical companies are sure to use their formidable lobbying powers to stop such legislation

Additionally, pharmaceutical companies may also structure their pricing to avoid legislative and public attention, thus attempting to prevent “issues from coming to vote in the first place.”²⁴² EpiPen’s methodical annual price increases were a failed attempt to avoid the public notice that might eventually lead to increased regulation.²⁴³ This internal price modulation “can potentially be a much larger cost to firms than either campaign contributions or lobbying.”²⁴⁴ An empirical study of pharmaceutical prices during the early 1990s, when threats of increased pharmaceutical price regulation were prevalent, found that pricing patterns were “consistent with firms distorting prices to forestall regulation.”²⁴⁵ Thus, if pharmaceutical companies sense the threat of increased regulation through the PAA or other legislation, they may create short-term price decreases to reduce political attention.

However, if a pharmaceutical company chooses to self-regulate prices to avoid the threat of future regulation, that result is not entirely bad. After all, the goal is to provide consumer access to pharmaceuticals through affordable prices without decreasing the pharmaceutical companies’ incentives to innovate. If pharmaceutical companies are providing that result simply to avoid the creation of a new agency or the imposition of new legislative restrictions, that is a good result because it provides affordable medications without new administrative costs. But that result is unlikely to be long-lived. Public and congressional memory is short. Neither Congress nor the public is likely to continue to threaten pharmaceutical companies with impending regulation if the companies are pricing medications to avoid scrutiny. A better solution is to pass the PAA or similar legislation to create a price and access monitoring agency that can provide long-term regulatory pressure.

B. Potential for Agency Capture

Housing decision-making in a single agency gives the pharmaceutical industry a select group on which to focus their lobbying power. This would allow the pharmaceutical industry, which already has a formidable lobbying force,²⁴⁶ to more easily influence key decision-makers. Pharmaceutical companies may also try to position their insiders for positions within the agency to influence or control decision-making. Although it may be impossible to eliminate the risk of

242. Ellison & Wolfram, *supra* note 238, at 325.

243. Emma Court, *Big Pharma Won’t Stop Raising Prices in 2017—It’ll Just Do It Smarter*, MARKET WATCH (Jan. 3, 2017), <http://www.marketwatch.com/story/big-pharmas-new-playbook-for-a-scandal-free-2017-2016-12-19> [<https://perma.cc/NU37-JJC5a>].

244. Ellison & Wolfram, *supra* note 238, at 325.

245. *Id.* at 326.

246. *See supra* note 238.

agency capture, Congress may mitigate that risk by providing for careful selection of agency membership.

C. Increased Administrative Costs

Constant oversight, such as that instituted by the PAA, is not free. Any administrative agency requires funding. This added cost is a tangible disadvantage of the PAA. However, as previously explained, the PAA will create savings simply by providing constant oversight as pharmaceutical companies decrease their prices to avoid compulsory licenses. These savings may be difficult to quantify accurately. Nonetheless, the agency should endeavor to estimate the savings created. Congress, as part of its broad budgetary duties, should compare these savings to the administrative costs and use its judgment to determine if the agency should continue.

CONCLUSION

Many pharmaceuticals are subject to monopolies that cause needlessly high prices. These monopolies allow monopolists to set drug prices untethered from R&D costs and other fixed expenses. Without regulation, the price of monopoly goods is limited only to the price where demand becomes elastic. Demand for pharmaceutical products, however, is notoriously inelastic because of several economic failures of the pharmaceutical market. The confluence of inelastic demand and monopolist price-setting leaves only regulatory pressure to control pharmaceutical prices. However, the current regulatory pressure in the United States has been insufficient to control prices. Pharmaceutical prices in the United States are the highest in the world—much higher than prices in similarly situated nations. In fact, massive price hikes in the United States reveal the extent of the insufficiency of current regulatory pressure and how untethered pharmaceutical prices are from R&D expenditures.

The high prices caused by monopolies, inelastic demand, and insufficient regulatory pressure have kept private and public purchasers of pharmaceuticals from being able to afford the medications that they need. To address this price and access problem, this Note suggests creating a new administrative agency with the power to issue compulsory licenses for pharmaceutical patents through a piece of legislation known as the Pharmaceutical Access Act (“PAA”).

The PAA would allow a board of health economics experts to determine which drugs are priced so egregiously high that access is unnecessarily limited. The Act would then give the experts power to issue compulsory licenses for those pharmaceuticals, thereby providing increased patient access while ensuring that the patent holder is paid a royalty for the compulsory license that provides adequate incentives to innovate.

The PAA would decrease the price of steeply priced pharmaceuticals and, in turn, increase access to those pharmaceuticals by issuing compulsory licenses. In fact, the sustained regulatory pressure imposed by the PAA would likely affect

pharmaceutical prices, even without issuance of compulsory licenses. The specter of the agency's licensing power itself would encourage pharmaceutical firms to decrease prices and increase access to their products to avoid compulsory licensure. Thus, by establishing a formal procedure for compulsory licensing as well as creating a looming shadow of regulatory oversight by an agency of experts, the PAA would provide a comprehensive solution to the current lack of regulatory pressure in the pharmaceutical market.

