Getting High on Profits: An Analysis of Current State and Federal Proposals to Rein in Soaring Drug Prices

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I. INTRODUCTION

In mid-September of 2015, Turing Pharmaceuticals ("Turing"), a start-up pharmaceutical company run by former hedge fund manager Martin Shkreli ("Shkreli"), made international headlines after purchasing the rights to a little-known drug named Daraprim and increasing its price by 5,000 percent overnight. Daraprim, whose primary consumers are individuals suffering from cancer and AIDS, is the only medication capable of treating toxoplasmosis, a parasitic infection commonly acquired by those with compromised immune systems. Shortly after the news broke of Daraprim’s price increase, Turing, Daraprim, and Shkreli became household names. Shkreli faced near-

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3 See Kim LaCapria, Daraprim Price Hike Controversy, SNOPES.COM (Sept. 21, 2015), http://m.snopes.com/2015/09/21/daraprim/ (discussing the controversy of the sudden price increase for the drug Daraprim).
universal condemnation for the price increase.⁴ Rather than taking a conciliatory stance amongst public scrutiny, Shkreli defended the price hike as “altruistic,” and took to Twitter to insult his critics.⁵ After the deluge of criticism failed to subside, Shkreli finally announced that Turing would lower the price of Daraprim.⁶ Months after announcing that the drug’s price would be reduced, however, Daraprim’s cost remains unchanged.⁷

Shortly after the Daraprim story broke, drug and biotechnology industry trade groups began distancing themselves from both Turing and Shkreli.⁸ The Pharmaceutical Research and Manufacturers of America (“PhRMA”), a trade group that represents biopharmaceutical researchers and biotechnology companies, tweeted: “[Turing] does not

⁶ See Gillian Mohney, Daraprim Still Being Sold at High Price Weeks After CEO Vowed Price Cut, ABC NEWS (Oct. 9, 2015), http://abcnews.go.com/Health/daraprim-still-sold-high-price-weeks-ceo-vowed-price/story?id=34377054 (discussing the outcry to lower the price on Daraprim to a point that is more affordable).
⁷ See Lydia Ramsey, 2 Weeks After Controversial Pharma CEO Martin Shkreli Announced He Would Lower the Price of Daraprim, it’s the Exact Same Price, BUSINESS INSIDER (Oct. 7 2015), http://www.businessinsider.com/martin-shkreli-update-on-daraprim-price-2015-10. The current price for a thirty-day course of treatment at the time of writing is upwards of $27,000. Id. See also Emma Court, Here’s Why Daraprim Still Costs $750 a Pill, MARKETWATCH.COM (Feb. 4, 2016), http://www.marketwatch.com/story/heres-why-daraprim-still-costs-750-a-pill-2016-02-03 (discussing the need and benefit of lowering the price of Daraprim).
represent the values of PhRMA member companies. 9 The Biotechnology Industry Organization, the largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations, likewise rescinded Turing’s membership in its organization. 10

While Shkreli’s actions seemed shock industry insiders and outsiders alike, this was not an isolated incident, as pharmaceutical companies have been raising prices on existing drugs for a number of years. 11 Statistics show that both brand-name drugs and generics are becoming more expensive for consumers. 12 For example, six years ago, URL Pharma was granted exclusive marketing rights for a compound called Colchicine, and promptly raised the price from $0.09 per tablet to about $5 per tablet. 13 Colchicine was used in ancient Greece to treat gout, and has been on the market in pill form in the United States for the same purpose since the 19th century. 14 Likewise, in 2011, KV

9 See About BIO, BIO.ORG, https://www.bio.org/articles/about-bio (last visited Apr. 6, 2016) (discussing PhRMA’s views on Turing); About PhRMA, PHRMA.ORG, http://www.pharma.org/about (last visited Mar. 20, 2016) (discussing the origina of PhRMA); Cha, supra note 8 (discussing PhRMA’s response to Shkreli’s actions via Twitter). See also PhRMA, TWITTER (Sept. 22, 2015, 9:46 AM), https://twitter.com/PhRMA/status/646365063226519552?ref_src=twsrc%5Etfw (stating PhRMA’s distaste for Shkreli’s actions).

10 See Cha, supra note 8 (noting how Biotechnology Industry Organization rescinded Turing’s membership in its organization). See also About BIO, supra note 9 (describing the framework of the association).


13 See Tracy Staton, The Huge Price Hike as Sales Strategy, Taken to Extremes by Retrophin, FIERCEPHARMA.COM (Sept. 11, 2014), http://www.fiercepharma.com/story/huge-price-hike-sales-strategy-taken-extremes-retrophin/2014-09-11 (highlighting the strategic maneuvers of hiking the price of drugs used to treat rare diseases). See also Johnson, supra note 11 (discussing URL Pharma’s price hike on colchicine).

14 See Johnson, supra note 11 (noting that colchicine is not a new medicine that warrants such a high price tag).
Pharmaceuticals made headlines when it put an old standby hormone treatment for preterm labor through new tests and clinical trials, marketed it under the brand-name Makena, and increased the price from $20 per dose to $1,500 per dose.\textsuperscript{15} KV Pharmaceuticals defended its pricing by citing the high cost of clinical trials and developmental costs.\textsuperscript{16} In the same year, Rare Disease Therapeutics received U.S. approval to distribute Anascorp, a scorpion antivenom drug that is priced upwards of $3,500 per vial.\textsuperscript{17} Rare Disease Therapeutics neither developed nor manufactured Anascorp.\textsuperscript{18} Rare Disease Therapeutics simply marketed the drug under license from Instituto Bioclon, a company that manufactured the drug in Mexico and sold it for $100 per vial south of the U.S. border.\textsuperscript{19} In October of 2015, news spread that U.S. Attorneys’ offices in Massachusetts and New York issued subpoenas to Valeant Pharmaceutical International ("Valeant") seeking information on its drug pricing and distribution policies, which subsequently caused the company’s shares to fall by almost five percent.\textsuperscript{20}

Pharmaceutical drug pricing is complex and multifaceted, and has become a major topic of discussion among state legislatures and politicians as they seek to increase access and affordability of necessary medications.\textsuperscript{21} This note analyzes cost drivers


\textsuperscript{16} \textit{Id.}

\textsuperscript{17} \textit{Id.}

\textsuperscript{18} \textit{Id.}

\textsuperscript{19} \textit{Id.}


behind pharmaceutical prices for generic and brand-name drugs, some of the proposals put forward by state legislatures and politicians to control drug prices, as well as the legality and likely effectiveness of such proposals. Part I of this note introduces and describes some of the federal statutory schemes governing the pharmaceutical marketplace, prescription drug coverage under the federal Medicare and Medicaid programs, the intersection of pay-for-delay arrangements and antitrust law, and the constitutionality of price control laws as applied to pharmaceuticals. Part II describes the state of the current pharmaceutical marketplace, state-level measures being introduced to control drug prices, and proposals from some of the 2016 U.S. presidential candidates and other politicians to address the problem. Part III analyzes the efficacy of the measures being considered to reduce drug prices and offers suggestions for how the federal government and individual states should act to control pharmaceutical prices going forward. This note ultimately concludes that it would likely be more effective to control costs of pharmaceuticals by both allowing Medicare Part D to negotiate with drug manufacturers and leverage information obtained from state-level pharmaceutical transparency bills, and granting purchasers the power to source medications from trusted sources abroad, rather than implementing price regulations or expanding statutorily-mandated rebates and reimbursements that are similar to those under Medicaid.

II. HISTORY

A. Patent Law, the pre-1984 Pharmaceutical Marketplace, and the Advent of the Hatch-Waxman Act and the Affordable Care Act

In 2014, the total expenditure on medicine in the United States was approximately $374 billion.\(^2\) Strong intellectual property protections are of particular importance for

the pharmaceutical industry due to the high investment costs of profitable drugs that are developed and the ease with which products can be subsequently copied.\textsuperscript{23} Federal patent laws are the protections that provide the financial motivation to further innovation and make these discoveries profitable by conferring on innovative companies a monopoly on profits for the life of the patent period of exclusivity in the marketplace.\textsuperscript{24} The U.S. patent system has three purposes: (1) to foster and reward invention; (2) to stimulate further invention; and (3) to ensure free use of ideas in the public domain.\textsuperscript{25} In general, patents expire twenty years after the date of their filing.\textsuperscript{26} Patent protection is said to be the


\textsuperscript{26} See 35 U.S.C. § 154 (2012). On June 8, 1995, Congress changed the duration of a patent term from seventeen years effective on the date of issuance to twenty years from the effective filing date. See Elga A. Goodman et al., The Concept of a Patent—Patent term, in 50 N.J. Prac., Business Law Deskbook § 14:6 (2015-16). Congress allowed patents that were issued after June 8, 1995, but were filed prior to that date to expire seventeen years after the date of issuance or twenty years from the effective filing date, whichever is longer. Id. See also Gene Quinn, A Brave New Patent World—First to File Becomes Law, IPWatchdog.com (Mar. 16, 2013), http://www.ipwatchdog.com/2013/03/16/a-brave-new-patent-world-first-to-file-becomes-law/id=37601/ (discussing how America Invents Act changed U.S. patent system to “first inventor to file” system).
“lifeblood” of drug companies. The importance of strong patent laws was recognized by the United States’ Founding Fathers and, consequently, the nation’s first patent protections were codified in the United States Constitution.

Prior to 1984, federal patent laws, in conjunction with the Food and Drug Cosmetics Act, were the primary sources of law governing the pharmaceutical marketplace, but this led to significant consumer and industry issues, such as high economic barriers to entry of generic drugs into the marketplace by pharmaceutical

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28 U.S. CONST. art. I, § 8, cl. 8. “The Congress shall have the power . . . [t]o promote the [p]rogress of [s]cience and useful [a]rts, by securing for limited times to authors and inventors the exclusive [r]ight to their respective [w]ritings and [d]iscoveries.” Id.
companies and a paucity of lower-cost generic alternatives available to consumers. The pharmaceutical marketplace at the time was dominated by expensive brand-name drugs, despite their patent protections having lapsed, and drug manufacturers frequently complained about rising costs of innovative drug development. Generic manufacturers could not even begin experimental preclinical testing with drugs under patent until all relevant patents expired, thus causing a several-year lag before marketing could begin. In 1984, the Food and Drug Administration ("FDA") estimated that there were approximately 150 name brand drugs with no generic equivalent. Furthermore, the patent system at the time inspired drug manufacturers to employ defensive measures

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29 See Aaron S. Kesselheim & Jonathan J. Darrow, Hatch-Waxman Turns 30: Do We Need a Redesigned Approach for the Modern Era?, 15 YALE J. HEALTH POL’Y L. & ETHICS 293, 297 (2015), available at http://digitalcommons.law.yale.edu/cgi/viewcontent.cgi?article=1240&context=yjhple (discussing how Hatch-Waxman was borne out of dissatisfaction with the federal legislative scheme). Market economics reduced incentives for manufacturers to undertake producing generic alternatives. Id. at 299. Between 1976 and 1982, only two of the top thirteen drugs had a generic alternative within one year of patent expiration. Id. at 300. Furthermore, there were no provisions in the Kefauver-Harris Amendments to the Food, Drug and Cosmetic Act—the most significant federal legislation at the time that affected the pharmaceutical market—to expedite approval of drugs that were the same as products already approved by the FDA. Id. at 298. See also Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-397 (2000).

30 Kesselheim, supra note 29, at 295 (describing why the costs in the pharmaceutical market were rising).

31 Id. at 299-300 (discussing Roche’s enjoinder of generic manufacturer using its product for experimental testing before patent expiry). See also Roche Products Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858, 863 (Fed. Cir. 1984) (explaining Bolar’s patented drug use did not fall under experimental use exception, and constituted infringement); Step 3: Clinical Research, U.S. FOOD AND DRUG ADMIN. (Nov. 23, 2015), http://www.fda.gov/ForPatients/Approvals/Drugs/ucm405622.htm (discussing how before marketing can begin, there must be favorable clinical trial data).

32 See FED. TRADE COMM’N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 4 (2002) [hereinafter FED. TRADE COMM’N, GENERIC DRUG ENTRY], available at https://www.fcc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf (stating that some drugs on the market did not have a generic form). See also Kesselheim, supra note 29, at 300 (discussing how 150 brand-name drugs lacked generic versions despite being off-patent). Generics only accounted for nineteen percent of all prescriptions in the late 1970s. Id.
during the drug approval process. For example, brand-name manufacturers secured patents for their drugs prior to entering into what are frequently lengthy clinical trials in order to prevent a competitor or a generic company from patenting identical drugs while the brand-name manufacturers awaited official FDA approval. As a result, this reduced the length of the exclusivity period enjoyed for drugs under patent, and therefore shortened the time available for companies to recoup their research and development costs.

In order to address the shortage of generic drugs on the market as well as reduced exclusivity periods for brand-name manufacturers, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, which is known more commonly as the Hatch-Waxman Act (“Hatch-Waxman”). The Hatch-Waxman Act essentially created the modern generic drug industry. Since 1938, a brand-name drug company seeking to market a new product must first obtain FDA approval by filing a New Drug Application (“NDA”), which requires developing time-consuming and costly information.

34 Id. at 6-7.
35 Id. at 7.
37 See Kesselheim, supra note 29, at 293 (discussing how Hatch-Waxman catalyzed creation of the generic drug marketplace).
including clinical trial data. Under Hatch-Waxman, a generic manufacturer seeking to market a bioequivalent drug need only file an Abbreviated New Drug Application ("ANDA") instead of repeating the entire NDA process, which includes clinical trials. Additionally, Hatch-Waxman provides for its own period of exclusivity, known as "Hatch-Waxman exclusivity," which allows for protection from competition in the marketplace once a drug is approved. The exclusivity period for a new drug is five years and, as such, a generic version cannot enter the market before this period has expired.


39 See FED. TRADE COMM'N, GENERIC DRUG ENTRY, supra note 32, at 5. ANDA applicants must make one of four certification options when filing their application: (1) the required patent information hasn't been filed, (2) the patent has expired, (3) the patent has not expired but will expire on a particular date and approval is sought after patent expiration, or (4) the patent is invalid or will not be infringed by the generic drug for which the ANDA applicant seeks approval. Id. See also Gerald J. Mossinghoff, Overview of the Hatch-Waxman Act and Its Impact on the Drug Development Process, 54 FOOD & DRUG L.J. 187, 189 (1999). Although ANDAs do not contain clinical information, they are required to contain information establishing bioequivalence to the reference-listed drug they are basing themselves off of. See FED. TRADE COMM'N, supra note 32, at 5 (discussing ANDA requirements).


41 See Mossinghoff, supra note 39, at 189 (discussing Hatch-Waxman provisions). See also 21 C.F.R. § 314.108 (1994). ANDA applications cannot even be submitted during the period of exclusivity unless they contain a certification of noninfringement or that the NDA patent is invalid. See Frequently Asked Questions on Patents and Exclusivity, supra note 40 (discussing time periods for new drug product exclusivity). In a presentation obtained from Retrophin—another company formerly headed by Martin Shkreli—it is suggested that by moving a drug that is off-patent and has no exclusivity left to a closed distribution system with specialty distributors, the Hatch-Waxman ANDA system can be thwarted because generic manufacturers cannot access the drug for bioequivalence studies unless the company illegally penetrates the specialty distributor. See Derek Lowe, The Most Unconscionable Drug Price Hike I Have Yet Seen, SCIENCE MAG. (Sept. 11, 2014), http://blogs.sciencemag.org/pipeline/archives/2014/09/11/the_most_unconscionable_drug_price_hike_i_have_yet_seen.
If an ANDA challenges the validity of an NDA patent or claims it will not infringe on the NDA patent, the ANDA applicant may submit a paragraph IV certification to seek a 180-day exclusivity period for its generic product.\textsuperscript{42}

The Patient Protection and Affordable Care Act ("ACA") is a landmark comprehensive health reform law signed into effect by President Obama in March of 2010, and generally requires Americans to buy health insurance.\textsuperscript{43} The ACA also requires states to create "exchanges," or marketplaces, for health insurance that allows consumers to compare prices and purchase health insurance.\textsuperscript{44} All health plans offered in state marketplaces must offer prescription drug coverage.\textsuperscript{45} If a certain medication is not covered under the plan's formulary, a patient can request that the insurer cover the

\textsuperscript{42} See Small Business Assistance: 180-Day Generic Drug Exclusivity, FDA.GOV, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm069964.htm (last updated Feb. 11, 2016). The exclusivity period begins either from the date it begins commercial marketing of the drug, or from the date of a successful court decision invalidating the NDA patent. \textit{Id.}

\textsuperscript{43} See I.R.C. § 5000A (2013) (providing a requirement to maintain minimum essential coverage). See also Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S.Ct. 2566, 2584 (2012) (describing how the penalty for failing to purchase health insurance can be considered a tax). Prescription drug coverage is one of the ten essential health benefits the Affordable Care Act seeks to address. \textit{Id. See also Health Insurance Glossary-Affordable Care Act (ACA), HEALTHINSURANCE.ORG, https://www.healthinsurance.org/glossary/affordable-care-act/} (last visited Apr. 6, 2016) (characterizing the ACA as comprehensive health care reform).

\textsuperscript{44} See 42 U.S.C. §§ 18031, 18041 (2010). See also King v. Burwell, 135 S.Ct. 2480, 2482 (2015). If the state chooses not to set up its own exchange, the federal government will do it for the state. \textit{Id. See also State Health Insurance Exchange: State Run Exchanges, OBAMACAREFACTS.COM, http://obamacarefacts.com/state-health-insurance-exchange/} (last visited May 18, 2016) (discussing the purpose of state run exchanges implemented by the ACA).

Different health plans have different methods of charging patients as well. Under some health plans, the subscriber pays what is known as a coinsurance for the medicines that amounts to a fixed percentage of the drug's cost. With other plans, there is a prescription copay where the subscriber pays a fixed amount for each prescription drug she buys. Many health care plans have a tiered drug pricing structure ranging from generic drugs to specialty medicines, which are often costly brand-name drugs. Despite expanding prescription drug accessibility to millions of Americans, the ACA contains no provisions that relate to prescription drug pricing.

See Prescription Drug Costs and Health Reform: FAQ, supra note 45. There is also a method for appealing if the request is denied. See also Pharmacy: Aetna Preferred Drug List/Brand and Generic Drug FAQs, AETNA.COM, https://www.aetna.com/faqs-health-insurance/pharmacy-preferred-drug-plan-brand-generic-faqs.html (last visited Apr. 6, 2016) (discussing how to get a drug added to the formulary guide).

See Prescription Drug Costs and Health Reform: FAQ, supra note 45 (outlining methods health plans charge patients).


See How Do Drug Tiers Work?, BCBSM.COM, http://www.bcbsm.com/medicare/help/understanding-plans/pharmacy-prescription-drugs/tiers.html (last visited Apr 7, 2016). Tier 1 drugs are usually lower cost generic alternatives, while Tier 5 “specialty drugs” will typically be the most expensive drugs on the list.

B. Medicare and Medicaid: Major Providers of Prescription Drugs in the United States

Medicare and Medicaid are two of the primary federal programs that are integral in providing prescription drugs to Americans.\(^\text{52}\) While Medicare can be characterized as an insurance program, Medicaid can be characterized as an assistance program.\(^\text{53}\) Medicare is a federal program that primarily serves Americans over the age of sixty-five, regardless of their income.\(^\text{54}\) Enrollees pay monthly premiums for non-hospital coverage and pay part of the costs of hospital expenditures and other services through deductibles.\(^\text{55}\) Medicaid is a federal-state program run by state and local governments within federal guidelines and, as a result, the programs vary from state to state.\(^\text{56}\) Unlike Medicare, Medicaid serves low-income persons of every age, and patients do not usually pay costs associated with covered medical expenses.\(^\text{57}\)

The Medicare program consists of four parts: A, B, C, and D.\(^\text{58}\) Medicare Part D is offered by private companies, known as sponsors, and provides prescription drug


\(^{54}\) See What is the difference between Medicare and Medicaid?, supra note 53 (discussing the basic tenets of Medicare).

\(^{55}\) Id.

\(^{56}\) Id.

\(^{57}\) Id.

\(^{58}\) See What’s Medicare?, MEDICARE.GOV, https://www.medicare.gov/sign-up-change-plans/decide-how-to-get-medicare/whats-medicare/what-is-medicare.html (last visited Apr. 10, 2016). Medicare Part A covers hospital insurance including inpatient care, care in skilled nursing facilities, hospice, and home health care to an extent. \(^\text{Id.}\) Medicare Part B covers medical insurance including certain doctors’ services, outpatient care, medical supplies, and preventive services. \(^\text{Id.}\) Medicare Part C provides for Medicare Advantage Plans—a type of Medicare health plan offered by private companies that contract with Medicare to provide enrollees with Part A and Part B benefits. \(^\text{Id.}\) Medicare Part D provides for prescription drug coverage. \(^\text{Id.}\)
coverage. Two key features of Medicare Part D are drug reimbursements and rebates. Part D sponsors, which are private companies that contract with Health and Human Services to provide drug coverage to enrollees, independently negotiate pharmacy reimbursement and price concessions with manufacturers and pharmacies and pass the savings from price concessions onto Part D enrollees at the point of sale. Sponsors also negotiate prices with drug manufacturers in order to secure rebates that serve to reduce the cost of the Part D program and increase drug sales for manufacturers. Rebates


60 See DEP’T OF HEALTH & HUMAN SERVS., MEDICAID REBATES, supra note 59, at 2. Negotiated prices are the basis of pharmacy reimbursement under Medicare Part D. Id. Reimbursements are the amounts the Part D sponsor and pharmacy have negotiated as the amount the pharmacy will receive for a particular drug, and rebates are price concessions that lower the costs of the program to enrollees and the government. Id.


secured under Part D are passed on to beneficiaries in the form of lower premiums.  

Medicaid's central features also include rebates and reimbursements, as state Medicaid agencies reimburse pharmacies for drugs dispensed to Medicaid beneficiaries.  

In general, drug manufacturers are statutorily required to contract into rebate agreements with the Secretary of Health and Human Services and pay quarterly rebates to states in order for federal payment to be available for covered drugs under Medicaid.  

States then invoice manufacturers for reimbursed units, and manufacturers then pay the rebates back to the states. Medicaid rebate amounts are statutorily defined, and manufacturers are required to pay an additional rebate amount if the average manufacturer price ("AMP") for a brand-name drug has risen faster than the rate of inflation. Unlike Medicaid,


64 See DEP'T OF Health & HUMAN SERVS., MEDICAID REBATES, supra note 59, at 3 (discussing Medicaid’s rebates and reimbursement system).  

65 Id.  

66 Id.  

Congress added language that expressly forbade Medicare from negotiating lower prices with drug manufacturers, thus relegating the negotiations to private companies who are Medicare Part D sponsors. However, success in negotiating lower prices necessarily depends on the existence of alternatives to choose from, which is often not the case for single-source drugs or orphan drugs that treat rare diseases.

Medicaid drug expenditures in 2012 accounted for nearly half of the amount of Medicare Part D expenditures in 2012, yet overall Medicaid rebates exceeded Part D rebates by more than sixty percent in the same year. The Congressional Budget Office

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69 See Steven Simoens, Pricing and Reimbursement of Orphan Drugs: the Need for more Transparency, 6 SIMOENS ORPHANET J. RARE DISEASE 1, 2 (2011), available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3132155/pdf/1750-1172-6-42.pdf (discussing how the lack of alternative health technology has strengthened an orphan drug’s monopolistic power). Health care payers have limited negotiating power with orphan drugs because they do not have access to information about cost structure and are simultaneously pressured to accommodate the drugs by patient advocacy groups. Id. Orphan drugs’ monopolistic power results in higher prices. Id. See also DEP’T OF HEALTH & HUMAN SERVS, STRATEGIES TO REDUCE MEDICAID, supra note 62, at ii (discussing how success in price negotiations is contingent on restricting payments for high cost drugs).

70 See DEP’T OF HEALTH & HUMAN SERVS., MEDICAID REBATES, supra note 59, at 6 (discussing rebate disparities between Medicare Part D and Medicaid). In 2012, Medicaid and Medicare Part D expenditures were $35.7 billion and $66.5 billion respectively, but rebate amounts for Medicaid and Medicare Part D were $16.7 billion and $10.3 billion respectively. Id. Rebates accounted for
estimates that the basic rebate under Medicaid for a single-source, brand-name prescription drug is twenty-two percent of the AMP, and the additional inflation rebate is thirteen percent of the AMP.\textsuperscript{71} The AMP and retail price for brand-name drugs usually rises faster than the rate of inflation.\textsuperscript{72} As a result, the inflation rebate represents just over half of the total rebates for brand-name drugs in Medicaid.\textsuperscript{73}

C. Antitrust Law and Arrangements between Competing Companies

Generic competition generally leads to lower drug prices.\textsuperscript{74} Since entry of a generic competitor cuts into a drug manufacturer's market share and profits, there is ample incentive for pharmaceutical companies to keep competition out of the marketplace.\textsuperscript{75} Some brand-name drug manufacturers thus engage in patent settlements, more commonly known as "pay-for-delay" agreements, in which the brand-name drug

\textsuperscript{71} See CONG. BUDGET Office, PRICES FOR BRAND-NAME DRUGS, supra note 67, at 11. The Congressional Budget Office concluded that the net price manufacturers receive for Medicaid sales—the average manufacturer's price minus the Medicaid rebate—averages about fifty-one percent of the average wholesale price, which equates to twelve percent below the best price. \textit{Id.} at 9.

\textsuperscript{72} See CONG. BUDGET OFFICE, COMPETITION AND THE COST OF MEDICARE'S PRESCRIPTION DRUG PROGRAM, supra note 67, at 15-16 (discussing the inflation rebate with respect to brand-name drugs). Between 2007 and 2010, the average retail price of brand-name drugs rose 8.5 percent per year while inflation only rose 1.7 percent per year on average. \textit{Id.} at 29. \textit{See also} DEPT OF HEALTH & HUMAN SERVS., MEDICAID REBATES, supra note 59, at 9 (discussing how the inflation rebate accounts for the disparity between Medicare and Medicaid). More than half of Medicaid rebates owed by manufacturers were due to the inflation-based add-on rebate in 2012, meaning it occurs often enough to account for a large disparity between Medicare Part D rebates and Medicaid rebates. \textit{Id.}

\textsuperscript{73} See DEPT OF Health & HUMAN SERVS., MEDICAID REBATES, supra note 59, at ii.

\textsuperscript{74} See Generic Competition and Drug Prices, FDA.GOV, http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm (last updated May 13, 2015) (discussing how generic competition is associated with lower prices).

\textsuperscript{75} See Pay-for-Delay: When Drug Companies Agree Not To Compete, FED. TRADE COMM’N, https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay (last visited Apr. 10, 2016) (discussing how brand-name manufacturers use pay-for-delay to stifle competition from lower cost generic manufacturers).
patent holders pay generic manufacturers a sum of money to hold their competing products off the market for a period of time. These types of agreements have been roundly criticized as anticompetitive and poor for consumers. In 2002, about one-quarter of new Federal Trade Commission ("FTC") investigations involving competition claims stemmed from the pharmaceutical industry. In 2003, an appellate court determined that pay-for-delay agreements were per se illegal because they constituted a horizontal restraint of trade in violation of the Sherman Act.

More recently, in FTC v. Actavis, Inc., the Supreme Court addressed the antitrust implications of patent settlement agreements and held that "reverse payment settlements ... can sometimes violate antitrust laws." Broadly speaking, the Sherman Act, which is


77 See Fed. Trade Comm'n, Pay-for-Delay, supra note 76, at 1-2 (summarizing pay-for-delay agreements' effects).


79 In re Cardizem CD Antitrust Litigation, 332 F.3d 896, 908 (6th Cir. 2003). See also Fed. Trade Comm'n, Pay-for-Delay, supra note 76, at 1 (discussing how a 2003 case found pay-for-delay agreements per se illegal).

80 See FTC v. Actavis Inc. 133 S. Ct. 2223, 2227 (2013). The Actavis decision adopted the "rule of reason" test and overturned the previous "scope-of-patent" test adopted by some courts, which essentially immunized pay-for-delay settlements from antitrust scrutiny. Id. at 2236.
considered to be the pioneer of antitrust law, bans "contracts in restraint of trade." The ban on these contracts only applies to unreasonable restraints and those that impair competition. In the absence of any federal laws expressly prohibiting pay-for-delay settlements, the FTC is relegated to filing individual antitrust lawsuits against violators to stop these deals. Actavis therefore gave the green light to the FTC to pursue lawsuits against drug makers based on potential antitrust law violations.

D. Constraint on State Powers to Regulate Drug Prices: Preemption

One of the major legal constraints on a state’s power to regulate pharmaceutical prices is the concept of preemption, where the police powers of the state may be

Consumers From Anticompetitive Pay-for-Delay Drug Settlements, FED. TRADE COMM’N. (Jul. 23, 2013), https://www.ftc.gov/news-events/press-releases/2013/07/ftc-recent-supreme-court-decision-puts-agency-stronger-position (affirming FTC efforts to stop anticompetitive pay-for-delay deals). Actavis alleged that patent settlements were immune from antitrust scrutiny. Actavis, 133 S. Ct. at 2225. See also HOFER, supra note 76. In discussing how these types of agreements may give rise to unjustified anticompetitive harm including increased costs to consumers, Justice Breyer explained that these types of agreements are subject to antitrust scrutiny under the rule of reason, echoing the FTC Commissioner’s opinion roughly a decade before. See Actavis, 133 S. Ct. at 2236. See also HOFER, supra note 76.

83 See Fazzio, supra note 33, at 23 (discussing Sherman Act and relevant antitrust laws).

82 See Bd. of Trade of City of Chicago v. United States, 246 U.S. 231, 244 (1918) (imposing antitrust laws only to ban illegal restraints of trade which suppress or destroy competition). See also Sherman Antitrust Act, 15 U.S.C. §§ 1-7 (2012) (codifying antitrust laws that regulate anticompetitive behaviors of monopolies and trusts); State Oil Co. v. Khan, 522 U.S. 3, 10 (1997) (applying “rule of reason” analysis to antitrust claims). The “rule of reason” is the prevailing standard of analysis for these antitrust claims. Continental T.V., Inc. v. GTE Sylvania Inc., 433 U.S. 36, 49 (1977) (citing Standard Oil Co. v. United States, 221 U.S. 1 (1911)). Under the “rule of reason,” the fact finder weighs all of the circumstances of a case in deciding whether a restrictive practice is an unreasonable restraint on competition. Id.

superseded by a federal act. With roots in the United States Constitution, three types of preemption exist: (1) express preemption, (2) field preemption, and (3) conflict preemption. In order for a challenging party to proceed, it must first overcome the presumption that a state statute is valid. The presumption against preemption is even stronger when the law relates to matters traditionally relegated to states under the police power, such as health and safety. In order to find that a health or safety regulation is preempted by federal law, there must be a “showing of implicit preemption of the whole field, or of a conflict between a particular local provision and the federal scheme, that is strong enough to overcome the presumption [that both laws] can constitutionally coexist.” A lone demonstration that a federal law is comprehensive is insufficient to show that a state statute is preempted.

Of particular importance for legislatures interested in imposing pharmaceutical pricing regulations is conflict preemption with the Patent Act. Conflict preemption

85 See Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230-31 (1947) (discussing manners by which police powers may be superseded by federal acts).
86 See Gade v. Nat’l Solid Wastes Management Assoc., 505 U.S. 88, 109 (1992) (identifying three circumstances in which federal statute preempts state law); Serena Lipski, Excessive Pricing and Pharmaceuticals: Why the Federal Patent Act Does Not Preempt State Regulation of Pharmaceutical Prices, 39 U. TOL. L. REV. 913, 925 (2008) (discussing three types of preemption: express, conflict, and field preemption). Express preemption occurs when the federal law contains a clause that states that the law pre-empts any state laws on the same subject. Id. at 926. Field preemption occurs when federal regulation is so pervasive that there is a reasonable inference that Congress left no room for states to supplement the law, or the field is an interest for which the federal interest is so dominant that it precludes state laws on the same subject matter. Santa Fe Elevator Corp., 331 U.S. at 230. See U.S. CONST. art. VI, cl. 2 (outlining Supremacy Clause).
89 Id. at 716.
90 Id. at 718.
91 See Lipski, supra note 86, at 926 (discussing how courts have applied conflict preemption in cases involving the Patent Act). See also Biotechnology Indus. Org. v. D.C., 496 F.3d 1362, 1374 (Fed. Cir. 2007). Washington, D.C., passed a pharmaceutical pricing regulation that was eventually deemed to be conflict preempted by federal patent law. Id. The Patent Act in its entirety does not contain an express preemption clause, so the only relevant preemption types are field and conflict preemption. See Patent Act, 35 U.S.C. §§ 1-376 (2012).
occurs when compliance with both the state and federal law is deemed impossible, or when the state law frustrates the purpose of the federal law. In the latter preemption scenario, the state law is deemed to be an “obstacle to the accomplishment and execution of the full purposes and objectives of Congress,” and cannot stand. What constitutes a sufficient obstacle is a matter of judgment determined by the court in light of examining the federal statute’s purpose and intended effects.

E. Price Controls & State Powers to Regulate Prices

The Constitution created a federal government of limited powers, and one of the powers left to the states was the police power. State legislation concerning the sale of goods and incidentally affecting prices is valid under the police power. Even so, the state power to fix prices generally only exists when the business or industry is closely intertwined with the public interest. The Due Process Clause usually does not prevent the states from fixing the prices of products or commodities of an industry closely intertwined with the public interest unless the price control is unconstitutional by virtue of it being arbitrary, discriminatory, or demonstrably irrelevant to the policy the legislature

94 Id.
97 See Nebbia, 291 U.S. at 538 (holding that price fixing is justifiable when concerning public interest). See also Kelly-Sullivan, Inc. v. Moss, 22 N.Y.S.2d 491, 498 (N.Y. App. Div. 1940) (stating that the power to fix prices exists when there is a public interest).
is free to adopt. In general, however, indirect pricing regulations are more common than direct regulations on goods and commodities. Within member-countries of the Organization for Economic Co-Operation and Development ("OECD"), only the United States and Chile do not control or regulate drug prices.

Some states have taken affirmative legislative measures to try to curb rising drug prices. For example, Massachusetts adopted the Interchangeable Drug Products Act, which requires pharmacists to dispense a less expensive, reasonably available drug in place of a more expensive, brand-name drug, unless the physician writes "no substitution" on the script. To assist both the physician and pharmacist in choosing permissible

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98 Nebbia, 291 U.S. at 539. If the price control is deemed unconstitutional, then it becomes "an unnecessary and unwarranted interference with individual liberty." Id. See also 20 N.Y. JUR. 2D Constitutional Law § 254 (providing a summary on price regulation).


alternative drugs, the Act requires preparation of a "Drug Formulary of Interchangeable Drug Products" by a state formulary commission, and requires that it be regularly updated.  

Another example of a state-level attempt to control drug prices is the Maine Act to Establish Fairer Pricing for Prescription Drugs, which established the Maine Rx Program in 2000. The purpose of the program is to reduce prescription drug prices for state residents, which is to be accomplished through the state's attempts to negotiate rebates on purchases from drug manufacturers. Enrollees in the program purchase their prescription drugs at discounted prices from participating pharmacies, and the discount obtained is reimbursed to the pharmacies out of rebate payments collected from participating drug manufacturers. If a company does not enter into a rebate agreement, its Medicaid sales will be subjected to a "prior authorization" procedure that requires state agency approval to qualify a doctor's prescription for reimbursement.

103 Id. See also MASS. GEN. LAWS. ch. 17, § 13 (2015) (discussing formulary regulations and requirements); MASS. GEN. LAWS. ch. 17, § 13(b)(6) (2015) (noting the formularies do not include pharmaceuticals covered under patent); THOMAS B. MERRITT, 36 MASS. PRAC. CONSUMER LAW § 24:97 (Thomson West, 3d ed., 2015) (discussing Massachusetts' application of nomenclature and maintaining low affordable pharmaceutical cost).


105 See Walsh, 538 U.S. at 653-54 (discussing the Maine Rx Program). In 1990, Congress enacted a cost-saving measure in response to increasing Medicaid expenditures that requires drug companies to pay rebates to states on their Medicaid purchases. Id. at 644. See also 42 U.S.C. § 1396r-8 (2015). Rebates are calculated based on a statutory ratio measured by the average price of the drug on the market. Id.

106 See Walsh, 538 U.S. at 654 (describing how Rx Program functions).

107 Id. After PhRMA tried arguing that the law was pre-empted by the Medicaid Act, the Court upheld the law. Id. at 670. Maine's prescription drug rebate program did not impose a disparate burden on out-of-state manufacturers in violation of the Commerce Clause. Id. In discussing preemption, the Court noted that there is a presumption against federal preemption of a state statute designed to foster public health, and this presumption against preemption has special force when it appears the state government and federal government are pursuing common purposes. Id. at 646. The Court also noted that just because the prior authorization procedure
The Maine Rx Program exercises price controls by instituting maximum prices for drugs during times of emergency, and prohibits "profiteering" in prescription drugs, which acts as a functional equivalent of a pricing restriction. The program also allows for a commissioner to set maximum retail prices if a drug's cost is not reasonably comparable to the lowest price for the same drug or other drugs needed during times of crisis. The program goes further by prohibiting both "unconscionable prices"—prices that lead to "unjust or unreasonable profit"—and limiting drug distribution to the state in retaliation for enacting the laws. The program makes no distinction between drugs that are under patent, brand-name, or generic. In effect, the Maine Rx Program regulates the price of patented pharmaceuticals by providing point of sale price reductions at the expense of drug manufacturers, and uses Maine's Medicaid market power to control drug prices for program enrollees. At the time, Maine was the first state to attempt to control prescription drug prices, but a few years later, Washington, D.C., passed a drug-

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108 See ME. REV. STAT tit. 22, § 2693 (2015) (establishing maximum retail pricing for prescription drugs in Maine during emergency situations). See also Lockwood, supra note 104, at 157 (describing the Medicaid rebate system for patients); tit. 22, § 2697 (prohibiting profiteering off prescription drug sales in Maine).

109 Tit. 22, § 2693(1)(B).

110 ME. REV. STAT tit. 22, § 2697(2)(A), (D).

111 See tit. 22, §§ 2681-2968(B) (containing no express language that distinguishes between brand name and generic drugs).

112 Lockwood, supra note 104, at 158. See also Christopher R. Stambaugh, State Price Control Laws are the Wrong Prescription for the Problem of Unaffordable Drugs, 12 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 897, 923 (2002). Although the program in Maine is beneficial to the community, it does have several limitations, such as keeping some drugs out of the reach of citizens with financial and medical need. Id. at 925. See Lipski, supra note 86, at 919-20. Pharmaceutical manufacturers are not required to join the program and may choose not to do so. Id. at 919. Furthermore, there is also no tiered structure to entry into the financial and medical needs category, so residents who do not qualify may still struggle to obtain the drugs they need. Id. Finally, patients with insurance coverage may still see expensive bills for medications that insurance companies pass on to policyholders. Id.
pricing law that broadened the scope of power even beyond that of Maine’s law, but was ultimately struck down.113

On October 4, 2005, the District of Columbia City Council approved the Prescription Drug Excessive Pricing Act (“the Act”) in response to the District Council’s findings that high costs of prescription drugs were threatening the health and welfare of its citizens.114 The Act’s stated purpose was to “promote the health, safety, and welfare” of residents by taking action to “restrain the excessive prices of prescription drugs.”115 Unlike Maine’s Rx Program, the Act took aim directly at patented prescription drugs, and expressly outlawed “[patented] prescription drug[s] being sold in the District for an excessive price.”116 The law provided that a prima facie case of excessive pricing is made by showing that “wholesale prices for the drug in the District is over [thirty percent] higher than the comparable price in any high income country in which the product is protected by patents or other exclusive marketing rights.”117

113 See Shawna Lydon Woodward, Will Price Control Legislation Satisfactorily Address the Issue of High Prescription Drug Prices? Several States are Waiting in the Balance for PhRMA v. Concannon, 26 SEATTLE U. L. REV. 169, 170 (2002) (discussing how the law was the first in the country of its kind). See also Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1374 (Fed. Cir. 2007) (upholding the lower court’s decision to strike down the law).


115 See § 28-4551 (offering overview of the Council of the District of Columbia’s excessive pricing findings).

116 See § 28-4553 (defining “excessive pricing”).

117 See § 28-4554(a) (explaining where the burden of proof lies with excessive pricing). Pharmaceutical companies were free to rebut this presumption by showing the following:

[C]osts of invention, development and production of the prescription drug, global sales and profits to date, consideration of any government funded research that supported the development of the drug, and the impact of price on access to the prescription drug by residents and the government of the District of Columbia.

Id. at (b). Judicial remedies include possible treble damages, injunctions on sales, fines, attorney’s fees, costs of litigation, and any other relief the court deems proper. See § 28-4555.
Predictably, this raised the ire of the biotechnology and pharmaceutical industry trade organizations, which took swift legal action against the District of Columbia by filing suit on October 12, 2005, and seeking declaratory relief from enforcement of the Act. A few days later, the Biotechnology Industry Organization filed a similar suit against Washington, D.C., in which it sought the same declaratory relief as PhRMA. The District of Columbia district court consolidated the Biotechnology Industry Organization and PhRMA lawsuits, and held that D.C.’s attempt to rein in excessive pharmaceutical prices was preempted by federal patent law. The District of Columbia district court struck down the Act on the basis that it was preempted by federal patent law and violated the Commerce Clause. With regard to the preemption challenge, the court found that “using the litigation process to determine on a drug to drug basis the application of a given drug’s pricing [compared to wholesale pricing in a foreign country] interferes with, and second guesses, the balance set by Congress in the current system of patents and market exclusivity.”

The District of Columbia appealed the judgment, and the Federal Circuit heard the case only to determine the conflict preemption issue. The court held that the Act

119 See Biotechnology Indus. Org. v. D.C., 496 F.3d 1362, 1366 (Fed. Cir. 2007) (providing background on the timing of the filing of the respective suits).
120 See Pharm. Research, 406 F. Supp. 2d 56 at 67 (discussing why cases were consolidated).
121 See id. at 66-67. The court held that D.C.’s law punished the holders of pharmaceutical patents by setting their price to no more than thirty percent of the wholesale price in designated foreign countries, and that this action undermined the system of rewards calculated by Congress.
122 Id. at 67.
123 See Biotechnology Indus. Org., 496 F.3d at 1371-74. The court declined to address the Foreign Commerce Clause issue because it had decided the preemption challenge. Id. at 1374.
“stood as an obstacle to the federal patent law’s balance of objectives as established by Congress,” and determined that it was preempted by federal patent law. The court ceded, however, that there was no express provision in the patent statute prohibiting states from regulating the prices of patented goods, and that “federal patent laws did not create any affirmative right to make, use, or sell anything.” However, state pricing regulations are preempted “if [they stand] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.” The court further described economic rewards under a period of exclusivity as the carrot that drives investment in innovation under the Patent Act. The court seemingly gave carte blanche to pharmaceutical companies in pricing their drugs by going further and saying “[u]pon grant of the patent, the only limitation on the size of the carrot should be the dictates of the marketplace.”

The Federal Circuit also stated that the Patent Act’s goal in providing periods of exclusivity for “limited times,” is in conflict with the Patent Act’s ultimate goal of providing the public with the benefit of lower prices through unfettered competition. When a patent expires and exclusivity goes away, the idea is that others enter the market

124 See id.
125 See id. at 1372 (quoting Leatherman Tool Group, Inc. v. Cooper Indus., Inc., 131 F.3d 1011, 1015 (Fed. Cir. 1997)).
126 See id. (quoting Hines v. Davidowitz, 312 U.S. 52, 67 (1941)). The court listed the pecuniary rewards stemming from patents and encouragement of investment-based risk as purposes and objectives of Congress in instituting the current patent regime’s right to exclude. Id. at 1372-73. The court also quoted the U.S. Constitution in identifying the ultimate goal of the patent regime, stating it was enacted “[t]o promote the Progress of Science and Useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” See Biotechnology Indus. Org., 496 F.3d at 1372 (quoting U.S. CONST. art. I, § 8, cl. 8).
127 Id. at 1372.
128 Id. at 1383.
129 Id. at 1373. The court stated that “patent laws are not intended merely to shift wealth from the public to inventors.” Id. The court noted that the objectives of providing inventors with incentive-driven profits and keeping prices reasonable for consumers are in “dialectic tension.” See id. The court further stated that the Supreme Court has noted this constant tension to exploit the full potential of innovative resources and creating incentives to deploy the resources. Biotechnology Indus. Org., 496 F.3d at 1373.
with products based on the teachings of the patent, and this new competition drives down the price. The court concluded that the Patent Act, in its current iteration, represents the best balance between these two disparate goals that Congress has ultimately been charged with balancing.  

III. FACTS  

A. Today's Pharmaceutical Marketplace Environment  

Even though prescription drug prices are on the rise, American consumers still generally do not pay the full sticker price out-of-pocket for their prescription drugs. Health care provider-, state-, and government-sponsored prescription assistance programs often assist with costs of prescription drugs. Despite these safety nets, Americans still face the prospect of spending considerable sums of money for medicine they need to keep them alive. In fact, some patients face the prospects of either going

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130 Id.
131 Id.
134 See Hogan, supra note 133 (asserting that there are additional out-of-pocket expenses beyond governmental support).
bankrupt to obtain the medications they need or foregoing the medicine altogether.\textsuperscript{135} So-called “wonder drugs”—breakthrough medications for treating chronic conditions such as multiple sclerosis, cancer, HIV, and hepatitis C—can cost tens of thousands of dollars per year.\textsuperscript{136} Pharmaceutical companies justify their prices on breakthrough pharmaceuticals by citing the high cost of research and development in creating the drugs.\textsuperscript{137} Once a drug is developed, passes clinical trials, and receives approval from the FDA, production costs are relatively low going forward.\textsuperscript{138} However, by some estimates, the total cost of getting a drug to the market can be upwards of $5.5 billion to $5.9 billion, and the success rate of drugs that make it through clinical trials to FDA approval is one out of ten.\textsuperscript{139}

Following Turing’s high-profile acquisition of Daraprim, the most recent pharmaceutical company in the news is a publicly traded Canada-based drug company

\textsuperscript{135} See Lee Graczyk, Americans Can’t Afford U.S. Medication, Need a Safe Alternative, THE HILL (Nov. 12, 2014), http://thehill.com/blogs/congress-blog/healthcare/223650-americans-cant-afford-us-medication-need-a-safe-alternative (illustrating that many Americans cannot afford their medications); Llamas, supra note 133. Fifty million Americans between the ages of nineteen and sixty-four skipped filling a prescription due to cost in 2012. Id.

\textsuperscript{136} See Llamas, supra note 172 (reviewing expensive costs of various drugs); John Tozzi, Who Should Pay the Bill for Wonder Drugs? BLOOMBERG (Jul. 10, 2014), http://www.bloomberg.com/bw/articles/2014-07-10/insurers-big-pharma-fight-over-who-pays-for-pricey-drugs (discussing how cancer drugs can cost more than $100,000 per year).


\textsuperscript{138} Id. at 16.

called Valeant Pharmaceuticals ("Valeant").

Valeant made headlines in October of 2015 following a report from a short-selling research firm called Citron Research, which accused Valeant of using "specialty pharmacies," whose services Valeant controlled, to steer customers to expensive drugs sold by Valeant. Prior to those allegations, Valeant received a slew of bad publicity in February 2015 after acquiring the rights to two heart drugs, Isuprel and Nitropress, from Marathon Pharmaceuticals, and promptly raising both drugs' prices by 525 percent and 212 percent respectively.

By many accounts, Valeant's business model revolves around purchasing the rights to existing drugs and raising prices aggressively rather than researching and developing new drugs of its own. Valeant's CEO, Michael Pearson ("Pearson"), has stated that pharmaceutical companies are too fixated on how much they spend on

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research and development, and should focus instead on what they bring to the market.\footnote{144 See Rockoff & Whalen, supra note 141 (discussing the implications of practices that pharmaceutical companies have engaged in).}

Pearson has further stated that his aim is to bring ten to twenty products to the market per year, but he does not believe Valeant has to innovate all of them itself.\footnote{145 Id.} In fact, Valeant spent just three percent of its revenue on research and development in 2013, compared to an industry-wide median of fifteen percent.\footnote{146 Id. Some estimates put the fifteen percent figure higher at around eighteen percent. See How Much of a Drug Company’s Spending is Allocated to Research and Development on Average?, INVESTOPEDIA.COM, http://www.investopedia.com/ask/answers/060115/how-much-drug-companys-spending-allocated-research-and-development-average.asp (last visited Apr. 7, 2016).}

investigations of drug maker price-gouging of four pharmaceutical companies deemed the “worst offenders”: (1) Valeant Pharmaceuticals, (2) Turing Pharmaceuticals, (3) Retrophin Inc., and (4) Rodelis Therapeutics.\textsuperscript{149}

The special committee will investigate substantial price increases on recently acquired off-patent pharmaceuticals, mergers and acquisitions within the pharmaceutical industry that occasionally lead to price increases in off-patent drugs, and the FDA’s role in the drug-approval process for generics.\textsuperscript{150} Democrats in the House of Representatives have separately launched an Affordable Drug Pricing Task Force to address high prices of pharmaceuticals.\textsuperscript{151} Turing has since hired lobbyists who have experience working with the FDA, the U.S. Department of Health and Human Services, and the U.S. Centers for Medicare and Medicaid Services.\textsuperscript{152}


B. State Level Measures to Control Pharmaceutical Prices

States have also begun taking the initiative to rein in drug prices by passing a number of bills aimed at making pharmaceutical prices transparent relative to the amount of investment that goes into developing the drugs.\(^{153}\) If the state proposals impose direct price regulations on patented pharmaceuticals, however, a court may strike down the laws as preempted by the Patent Act.\(^{154}\) After Biotechnology Industry Organization v. District of Columbia, courts may be unlikely to uphold direct pricing regulations on pharmaceuticals under patent.\(^{155}\)

In February of 2015, the Pharmaceutical Cost Transparency Act of 2015 was introduced in the California legislature.\(^{156}\) This bill would require pharmaceutical manufacturers to file a report on the cost drivers of the drug if their drugs are sold in the state with a wholesale acquisition cost of $10,000 or more annually (or per course of


\(^{154}\) See D.C. CODE §§ 28-4553, 4554 (providing legislation aimed at controlling excessive prescription drug pricing). D.C.’s Prescription Drug Excessive Pricing Act was challenged and deemed unconstitutional because it was conflict preempted by the federal Patent Act. See also Biotechnology Indus. Org., 496 F.3d at 1374 (holding federal patent laws preempt the act, which aims to restrain excessive drug prices).

\(^{155}\) See § 28-4554. The law that was eventually overturned specifically cited “patented prescription drug[s].” Id. See also Biotechnology Indus. Org., 496 F.3d at 1374. The Act was an attempt to rein in prescription drug prices, but did so at the expense of patentees, thus diminishing the reward for their work and standing as an obstacle to the goals set out by Congress when it enacted the Patent Act. Id. The court stated that the current balance struck by Congress between patentees’ exclusionary power, length of patent terms, and conditions for patent eligibility represent the best balance between free use and exclusion. Id.

treatment). Manufacturers would also have to disclose a history of the average wholesale price as well as wholesale acquisition cost increases for the drug. Profits that are attributable to the drug, expressed in total dollars and as a percentage of total company profits derived from sale of the drug, are also subject to disclosure under the law. Finally, the amount of financial assistance the manufacturer has provided through patient prescription assistance programs, if available, would also need to be disclosed. The information submitted for disclosure would need to be audited by an independent third-party for verification. A nearly identical bill with the same provisions was also put forward in Oregon in 2015 as House Bill 3486.

In April of 2015, House Bill 839 was introduced in the North Carolina legislature with the goal of increasing information transparency regarding pharmaceutical costs and utilization. The bill accomplishes this by requiring manufacturers of brand medication

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157 See id. § 1. The report should include total production costs of the drug including research and development costs paid by the manufacturer and any predecessors in the drug’s development, manufacturer’s and predecessors’ clinical trial costs and costs of materials, and the costs of manufacture and administration. Id. The manufacturer would also have to disclose costs paid by entities other than the manufacturer or predecessors for research and development including federal, state, or other governmental subsidies, grants, or other forms of support. Id. Acquisition costs, including costs for purchase of patents, licensing, or acquisition of any corporate entity owning any rights to the drug while in development, would also need to be disclosed. Id. Marketing and advertising costs would also need to be disclosed under the bill. Id. § 1(E) (2). On January 4, 2016, the bill was amended to include “[t]he total costs of drugs or research projects that failed to succeed through the process to market approval.” AB 463 § 1(E)(6).

158 See id.

159 See id.

160 See id.

161 See id.

162 See H.B. 3486, 78th Leg. Assemb., 2015 Reg. Sess. (Or. 2015), available at https://olis.leg.state.or.us/liz/2015R1/Downloads/MeasureDocument/HB3486/Introduced. Although this bill is similar to California’s proposed legislation, this bill does not contain any provisions about taking into account costs of failed drugs. Id.

drugs sold in North Carolina to report the total costs of production of the drug.\textsuperscript{164} Subsection (c) of the bill delineates which drugs would be subject to the regulations regardless of costs.\textsuperscript{165}

One of the boldest new laws introduced as a response to rising drug costs is Massachusetts Senate Bill 1048, which was introduced in 2015.\textsuperscript{166} Notably, this bill was filed in Massachusetts—one of the world’s leading biotechnology and life sciences hubs.\textsuperscript{167} The goal of the bill is not only to promote transparency, but to control costs of pharmaceutical drug prices as well.\textsuperscript{168} First, a state commission compiles a list of prescription drugs for which there is “substantial public interest” in understanding its pricing.\textsuperscript{169} Once the list is in place, manufacturers would be required to report various

\textsuperscript{164} Id. The bill requires manufacturers to report average wholesale cost of the drug, as well as a five-year history of average wholesale price expressed as a percentage, and the month each increase took effect. Id. Total research and development costs paid by the manufacturer must also be disclosed, as well as administrative, marketing, and advertising costs. Id. Total profit represented in dollars and a percentage of total company profit derived from sale of the drug must also be disclosed, as well as financial assistance the manufacturer provides through patient prescription assistance programs, if available. Id.

\textsuperscript{165} H.B. 839. Medications subjected to the regulations include anticancer, painkillers, antidepressants, asthma and allergy medications, and injection medications including insulin. Id.


\textsuperscript{168} See S. 1048, 189th Gen. Court (Mass. 2015).

\textsuperscript{169} See id. at § 1 (discussing the mechanics of the bill). Considerations for compiling the list include the cost of the drug to public health care programs, the current drug cost in Massachusetts, the extent of utilization of the drug in Massachusetts, and the potential impact of the drug’s cost on Massachusetts’ achievement of the statewide health care cost growth benchmark established in another section of the bill. Id.
cost factors that go into the drug’s pricing.\footnote{See id. These factors include total cost of production including cost per dose and research and development costs including those paid with public funds, after-tax costs paid by the manufacturer, and costs paid by third parties. Id. Marketing and advertising costs must also be disclosed. Id. The bill also mandates manufacturers to report the prices of the drugs charged to purchasers outside the United States by country. See S. 1048 § 1.} Manufacturers must also disclose prices charged to typical direct purchasers, such as pharmacies, and true net typical prices after factoring in rebates and reimbursements.\footnote{See id. See also Pollack, supra note 153 (discussing Massachusetts state commission setting maximum price for drug deemed to be too high).} Senate Bill 1048 goes a step further than the proposals in California, Oregon, and North Carolina by allowing the Massachusetts state government to set a maximum allowable price for which a manufacturer may charge for a prescription drug sold in Massachusetts if it is determined that the price is “significantly high.”\footnote{See id. See also Pollack, supra note 153 (discussing Massachusetts state commission setting maximum price for drug deemed to be too high).}

C. Federal-Level Proposals to Rein in Drug Prices and Proposals from Presidential Candidates

Twitter from Hillary Clinton ("Clinton") in September, 2015, assailing "price gouging" in the specialty pharmaceutical market sent the NASDAQ Biotechnology Index tumbling 4.7 percent in one day.\textsuperscript{174} Citing the prices of more than 1,200 generic medications that increased an average of 448 percent between July 2013 through July 2014, Vermont Senator Bernie Sanders ("Sanders") and Maryland Representative Elijah Cummings proposed the Medicaid Generic Drug Price Fairness Act in May of 2015, which aimed to tamp down rising generic drug prices and Medicaid spending.\textsuperscript{175} Later, in September of 2015, Sanders introduced the Prescription Drug Affordability Act in an effort to lower drug prices and increase access to necessary medication.\textsuperscript{176} In some cases, the prices of

\textsuperscript{174} See Robert Langreth & Drew Armstrong, Clinton's Tweet on High Drug Prices Sends Biotech Stocks Down, BLOOMBERG (Sept. 21, 2015), http://www.bloomberg.com/news/articles/2015-09-21/clinton-s-tweet-on-high-drug-prices-sends-biotech-stocks-down. See also Matt Egan, Hillary Clinton Tweet Crushes Biotech Stocks, CNN (Sept. 22, 2015), http://money.cnn.com/2015/09/21/investing/hillary-clinton-biotech-price-gouging/. Hillary's tweet stated, "[P]rice gouging like this in the specialty drug market is outrageous... [t]omorrow I'll lay out a plan to take it on. -H." Hillary Clinton, TWITTER.COM (Sept. 21 2015), https://twitter.com/hillarycinton/status/64597477275408862.\textsuperscript{75} See Medicaid Drug Price Fairness Act of 2015, S. 1364, 114th Cong. (2015). See also Sanders Takes Aim at Generic Drug Prices in Medicaid, COMMITTEE FOR A RESPONSIBLE FEDERAL BUDGET (May 21, 2015), http://crfb.org/blogs/sanders-takes-aim-generic-drug-prices-medicaid (discussing how proposed bill would extend inflation rebate to generic drugs as well as brand name). See also Gillian Mohney, Generic Drug Price Sticker Shock Prompts Probe by Congress, ABC NEWS (Nov. 21, 2014), http://abcnews.go.com/Health/generic-drug-prices-skyrocketing-lawmakers-warn/story?id=27060992. Sanders and Representative Elijah Cummings announced they were investigating why some generic drug prices have risen hundreds or thousands of percent. \textit{Id.} In particular, Sanders and Cummings cited price increases in the asthma medication albuterol sulfate, which saw a more than forty fold increase ($11 for two tablets to $434) between October 2013 and April 2014, and the antibiotic doxycycline hyclate, which saw a more than ninety fold increase ($20 per bottle to $1,849) between October 2013 and April 2014. \textit{Id.} See also Sanders Fights Rising Drug Prices, SANDERS.SENATE.GOV (May 18, 2015), http://www.sanders.senate.gov/newsroom/recent-business/sanders-fights-rising-drug-prices.\textsuperscript{176} See Prescription Drug Affordability Act of 2015, S. 2023, 114th Cong. (2015); The Prescription Drug Affordability Act of 2015, SANDERS.SENATE.GOV, http://www.sanders.senate.gov/download/summary-of-prescription-drug-affordability-act.pdf. The proposed bill would allow for the Secretary of Health and Human Services to negotiate prices with drug manufacturers under Medicare Part D, import drugs from Canada, prohibit pay-for-delay arrangements, and require drug cost transparency among some of its provisions. \textit{The Prescription Drug Affordability Act, supra.} None of the Republican presidential candidates' proposals to rein in drug prices to date have been as substantive or detailed as those offered on the democratic side, as they have chosen instead to blame over-regulation and a few bad apples in the industry. See Paul Demko & Sarah Karlin, GOP Candidates Stuck on Drug Prices,
generic drugs are only slightly less expensive than the brand-name drugs they emulate.177

Under current law, brand-name drug manufacturers must pay a rebate to Medicaid when prices increase at a rate steeper than inflation ("inflation rebate").178 The premise behind the Medicaid Generic Drug Price Fairness Act revolves around extending the aforementioned inflation rebate that currently applies only to brand-name drugs to generic pharmaceuticals, thereby ensuring lower drug prices through higher rebates for consumers.179

The Prescription Drug Affordability Act ("PDAA") calls for allowing the Secretary of Health and Human Services to negotiate drug prices under Medicare Part

177 See Ellen Jean Hirst, Generic Drug Prices Skyrocket in Past Year, CHICAGO TRIBUNE, Nov. 21, 2014, http://www.chicagotribune.com/business/ct-rising-generic-drug-prices-1102-biz-20141121-story.html. To cope with the rising prices, insurance companies have introduced co-payment tiers to their plans to offset rising generic prices. See id. (quoting pharmacy benefit manager Catamaran’s Chief Medical Officer Dr. Sumit Dutta).

178 See Sanders Fights Rising Drug Prices, supra note 175 (discussing the “inflation rebate” under current law).

179 Id. See also S. 1364, 114th Cong. (2015).
D. PDAA also calls for drug re-importation from Canada, where pharmaceuticals are typically less expensive than those in the U.S. Incorporating the proposals from the Medicaid Generic Drug Price Fairness Act, this bill also calls for requiring generic drug manufacturers to pay an additional rebate to Medicaid if the prices of their drugs rise faster than inflation. PDAA also calls for prohibiting so-called “pay-for-delay” arrangements. Finally, PDAA calls for mandating pharmaceutical companies to publicly report information that affects drug pricing, including total costs incurred for research and development and clinical trials, and the portion of drug development expenses offset by tax credits or federal grants. This drug pricing and cost transparency provision further calls for drug manufacturers to report domestic drug prices, as well as submit prices, profits, and sale information in other countries in which those products are sold.

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181 Id. § 201(a)-(b). Individuals, pharmacists, and wholesalers would be able to import prescription drugs from licensed Canadian pharmacies. Id. The bill also directs the United States Trade Representative to reject provisions in any trade agreement that would raise drug prices in the U.S., extend periods of patent exclusivity, or remove flexibilities in U.S. law regarding drug pricing. Id. § 202. See also JOEL LEXCHIN, PHARMACEUTICAL PRICES IN THE 21ST CENTURY 30 (Zaheer-Ud-Din Babar ed., 2015) (discussing how Canadian prices for patented drugs are calculated using the Maximum Average Potential Price); Sean Davidson, Drug Price Regulations Need Overhaul to Protect Consumers, Experts Say, CBC.CA (Sept. 23, 2015), http://www.cbc.ca/news/health/prescription-drug-prices-1.3239317 (discussing that drug prices for patented drugs are calculated using a median average of prices from other countries); Fighting to Lower Prescription Drug Prices, BERNIESANDERS.COM, https://berniesanders.com/issues/fighting-to-lower-prescription-drug-prices/ (last visited Apr. 7, 2016) (discussing how drug prices are less expensive in Canada than the United States).
183 Id. § 401(a)-(b). The Act also calls for terminating market exclusivity on any product found in violation of criminal or civil law through a federal fraud conviction or settlement, including violating anti-monopoly practices. Id. § 569D(a)-(c).
184 See id. § 601(a)-(b).
185 Id.
Clinton’s plan for lowering prescription drug costs centers on the idea that seniors are the largest market for pharmaceuticals.186 One feature of Clinton’s plan would require pharmaceutical companies that receive federal support to invest a “sufficient” amount of their revenue into research and development.187 The plan further proposes providing funding for the FDA to clear the “multi-year generic drug approval backlog,” and lowering the exclusivity period for new biologics from its current twelve years to seven years.188 Another proposal is to “offer prioritized, expedited review to biosimilar applications that only have one or two competitors in the marketplace.”189 Banning pay-for-delay arrangements and allowing foreign pharmaceutical imports are among some of the other tenets.190 Another feature is to offer rebates to low-income Medicare enrollees that are equivalent in value to rebates offered under Medicaid.191 Finally, the plan

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186 See Hillary Clinton’s Plan for Lowering Prescription Drug Costs, HILLARYCLINTON.COM, https://www.hillaryclinton.com/p/briefing/factsheets/2015/09/21/hillary-clinton-plan-for-lowering-prescription-drug-costs/ (last visited Mar. 18, 2016). The website states that every month, ninety percent of seniors and half of all Americans take a prescription drug. Id. Her stated goals are to stop excessive profiteering and marketing. Id.

187 Id. If a company does not meet its targets, the plan proposes boosting their investment or paying rebates to support their basic research. Id. The plan states that the principle behind this idea is “based on a provision of the Affordable Care Act that required insurance companies to pay rebates to consumers if their profits and administrative costs were an excessive share of benefits actually paid out to consumers.” Id. The average expenditure pharmaceutical companies put into research and development hovers around fifteen to eighteen percent while Valeant invests just three percent. See supra note 146 and accompanying text (discussing the amount each pharmaceutical company spends on research and development).

188 See Hillary Clinton’s Plan for Lowering Prescription Drug Costs, supra note 186 (providing details on Clinton’s plan to expedite the drug approval process). The plan also proposes “encouraging” generic versions of specialty drugs, without discussing specifically how. Id.

189 Id.


191 See Hillary Clinton’s Plan for Lowering Prescription Drug Costs, supra note 186. Under current law, the Medicaid rebates offered are more generous than those under Medicare. Id. See also supra
proposes allowing Medicare to negotiate drug and biologic prices directly with manufacturers.\footnote{70 and accompanying text (describing the disparity in rebates between Medicare and Medicaid).}

Echoing both Sanders’ and Clinton’s key provisions, United States Senators Amy Klobuchar and Chuck Grassley reintroduced a bill in September of 2015, called the Preserve Access to Affordable Generics Act.\footnote{See Hillary Clinton’s Plan for Lowering Prescription Drug Costs, supra note 186. Other proposals include eliminating direct-to-consumer drug company advertising subsidies, using funds acquired from eliminating subsidies to go towards making permanent and simplifying research and development tax credits, requiring insurance companies to place a $250 monthly limit on covered out-of-pocket prescription drug costs for Americans with chronic or serious health conditions. \textit{Id.} The plan claims that direct-to-consumer advertising leads to increased prescription drug costs, and eliminating these subsidies would save the government “billions over the next decade.” \textit{Id.} The plan also proposes requiring insurance companies to place a $250 monthly limit on covered out-of-pocket prescription drug costs for Americans with chronic or serious health conditions. \textit{Id.} The cap would apply to FDA-approved prescriptions covered by insurance. \textit{Id.} See S. 214, 113th Cong. (2013). The bill, “Preserve Access to Affordable Generics Act,” was first introduced in February of 2013. \textit{Id. See also} Zachary Brennan, Senators Reintroduce Bill to Make Pay-for-Delay Deals Illegal, \textit{REGULATORY AFFAIRS PROFESSIONALS SOCIETY} (Sept. 10, 2015), http://www.raps.org/Regulatory-Focus/News/2015/09/10/23181/Senators-Reintroduce-Bill-to-Make-Pay-For-Delay-Deals-Ilegal/ (discussing the Preserve Access to Affordable Generics Act); Kurt R. Karst, Lather, Rinse, Repeat: Senators take Another Stab at Passing the Preserve Access to Affordable Generics Act, \textit{FDALAWBLOG.NET} (Sept. 14, 2015), http://www.fdalawblog.net/fda_law_blog_byman Phelps/2015/09/lather-rinse-repeat-senators-take-another-stab-at-passing-the-preserve-access-to-affordable-generics.html (discussing the passing of the Preserve Access Act). The two main purposes of the Preserve Access to Generics Act are to foster pharmaceutical competition by stopping “anticompetitive [pay-for-delay] agreements” and to “support the purpose and intent of antitrust law” by prohibiting these agreements. \textit{See S. 214, § 2(b).} } The goal of this bill is to prevent branded and generic drug companies from making deals that delay the launch of generic drugs.\footnote{See S. 214.} An agreement will be presumed to be anticompetitive if an ANDA filer receives compensation and agrees to forego “research, development, manufacturing, marketing, or sales of the ANDA product for any period of time.”\footnote{See id. § 28(a)(2)(A).} This presumption is rebuttable by demonstrating with “clear and convincing evidence” that the procompetitive benefits
outweigh the anticompetitive benefits. Penalties for violations include treble damages, cease-and-desist orders, and civil penalties.

IV. ANALYSIS

A. Statutory Rebates, Reimbursements, and the Efficacy of Granting Medicare Part D the Power to Negotiate

The basic rebate for Medicaid increased in 2010 from 15.1 percent to 23.1 percent due to implementation of the Affordable Care Act. The Congressional Budget Office expects manufacturers to raise before-rebate prices for new drugs in response to the statutory rebate increase in order to recoup and offset lost revenues that occur as a result of the increase. On November 2, 2015, President Obama signed into law H.R. 1314, the Bipartisan Budget Act of 2015 ("BBA"), which substantively incorporated the Medicaid Generic Drug Price Fairness Act. Expected to yield significant long-term savings, section 602 of the BBA applies the Medicaid inflation rebate to generic drugs, which had previously applied only to brand-name drugs.

Pharmacy reimbursements are typically similar under Medicare and Medicaid, but after factoring in rebates, Medicaid's net costs for brand-name drugs are significantly lower.
lower than Medicare Part D net costs. The Congressional Budget Office has determined that the primary reason rebates are significantly higher for Medicaid than Medicare Part D is because Medicaid’s rebates, which are prescribed by law, are higher than the rebates Part D sponsors are able to independently negotiate with drug manufacturers. If Congress were to adopt rebates under Medicare Part D similar to Medicaid’s mandatory rebates, costs for Medicare would be reduced substantially in the short term. However, manufacturers would likely respond by charging higher pre-rebate prices for drugs, which would thereby offset any savings over the long-term, and may also curtail future research and development. Perhaps recognizing these limitations, instead of mandating a “basic rebate” amount, Sanders’ and Clinton’s proposals to lower prescription drug costs include allowing Medicare Part D to negotiate rebates directly with manufacturers as opposed to the present system that utilizes sponsors.

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202 See DEP’T OF HEALTH & HUMAN SERVS., MEDICAID REBATES, supra note 59, at 6 (comparing the amount of pharmacy reimbursements under Medicare Part D and Medicaid).
203 See CONG. BUDGET OFFICE, PRICES FOR BRAND-NAME DRUGS, supra note 67, at 3 (discussing the CBO’s analysis of Medicaid rebates). The prices Medicaid paid for drugs was twenty-seven to thirty-eight percent lower than prices Medicare Part D paid in 2010. Id.
204 See CONG. BUDGET OFFICE, PRICES FOR BRAND-NAME DRUGS, supra note 67, at 34. By one estimate, federal spending for Medicare would be reduced by $123 billion from 2014 to 2023 if Medicaid-style rebates were implemented on Medicare Part D. Id.
205 See CONG. BUDGET OFFICE, PRICES FOR BRAND-NAME DRUGS, supra note 67, at 3 (discussing implementing Medicaid-style rebates to Part D incentivizing manufacturers to alter pricing strategies). Initially prices would fall to levels comparable to Medicaid but the CBO predicts manufacturers would launch new brand-name drugs at higher prices as a result. Id. at 35. This in turn would have the effect of reducing profits from the development of new drugs and decrease incentives to develop new drugs. Id. See also GAGNON & WOLFE, supra note 59, at 9 (discussing how mandatory rebates encourage manufacturers to charge higher prices). Statutorily mandated rebates like those under Medicaid ("basic rebates") on official prices can achieve savings, but eventually they create an adverse effect by encouraging manufacturers to artificially raise prices to recoup losses. Id.
206 See Prescription Drug Affordability Act, S. 2023, 114th Cong. (2015) § 101. See also Hillary Clinton’s Plan for Lowering Prescription Drug Costs, supra note 186. Hillary Clinton’s plan also calls for offering “equivalent rebates” to low-income Medicare enrollees as those offered under Medicaid which may actually be a statutorily mandated “basic rebate” system. Id.
Allowing Medicare Part D to negotiate lower prices would likely result in significant savings for both the government and consumers.\(^\text{207}\) Part D was designed around a model of "managed competition" among private insurers called sponsors.\(^\text{208}\) Countries that utilize universal health care models, such as Switzerland and the Netherlands, use the same "managed competition" model through regulated private insurers.\(^\text{209}\) Competition among private insurers in those countries has not suffered adverse effects from government negotiation of lower brand-name drug prices, and beneficiaries pay significantly lower premiums.\(^\text{210}\) The governments in these countries are allowed to negotiate with manufacturers when buying drugs in large volumes, and they consistently obtain lower per-unit costs.\(^\text{211}\) These bulk purchases generate cost savings that can then be passed along to consumers.\(^\text{212}\) In fact, average brand-name drug prices in Switzerland, excluding rebates, are thirty-four percent less than after-rebate prices under Medicare Part D, and average brand-name drug prices in the Netherlands, excluding rebates, are fifty-seven percent less than prices under Medicare Part D.\(^\text{213}\)

\(^{207}\) See GAGNON & WOLFE, supra note 63, at 14 (discussing allowing Medicare Part D negotiations not undermining sponsors’ competitive system leading to higher costs). Medicare Part D is designed based on a model of "managed competition," and in other countries that also utilize "managed competition" models beneficiaries pay significantly lower premiums. \textit{Id.} See also Silverman, supra note 68 (discussing annual savings of $15 billion to $16 billion Part D could negotiate the same prices as Medicaid). Assuming that allowing Medicare Part D to negotiate directly with manufacturers would yield the same rebates as those seen under Medicaid, the government could save between $15.2 billion and $16 billion annually. \textit{Id.}

\(^{208}\) See GAGNON & WOLFE, supra note 63, at 14 (describing structural system of Part D).

\(^{209}\) See supra note 208 and accompanying text (comparing different countries and their managed care systems).

\(^{210}\) See supra note 208 and accompanying text (describing effect of managed care for different countries).

\(^{211}\) See Bacchus, supra note 68, at 35 (discussing ways government can negotiate lower pharmaceuticals prices if permitted to negotiate directly with manufacturers).

\(^{212}\) See supra note 211 and accompanying text (discussing the limitations of governmental provisions of universal pharmaceutical insurance).

\(^{213}\) See GAGNON & WOLFE, supra note 63, at 14 (comparing brand-name drug prices in Switzerland and the Netherlands to after-rebate prices under Medicare Part D).
Medicare to negotiate with manufacturers would likely achieve lower prices for many
drugs, but it would not necessarily be a cure-all because single-source drugs often enjoy a
monopoly in the marketplace, and the efficacy of negotiation is largely contingent upon
the existence of alternatives to choose from.  

B. Pay-for-Delay: The Bogeyman Circumventing Hatch-Waxman

Pay-for-delay deals frustrate the purpose of Hatch-Waxman by delaying generic
entry into the marketplace and by blocking consumer access to lower-cost prescription
drugs. These types of agreements are estimated to cost consumers around $35 billion
over a ten year span from 2010-2020. In 2005, the FTC found only three instances of
patent settlement agreements involving delayed entry of generics and compensation, but
that number jumped to nineteen in 2009. The FTC found that agreements involving
compensation from the brand-name manufacturer to the generic manufacturer delays
generic entry seventeen months longer than agreements that do not involve payments.
Prohibiting pay-for-delay settlements would thus yield enormous benefits to consumers
by providing access to lower cost generics drugs, even if only marginally less expensive,

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and free up FTC investigative resources. The only winners in pay-for-delay arrangements are the drug manufacturers—both brand-name and generic—and their success comes at the expense of consumers and a circumvented Hatch-Waxman Act. Because competition is a direct driver of lower prices in the pharmaceutical marketplace, eliminating pay-for-delay arrangements would foster earlier entry of generics into the marketplace, lower pharmaceutical prices, and increase access to prescription drugs to consumers. Following the Actavis decision in 2013, 2014 saw only twenty-one agreements the FTC identified as possible pay-for-delay agreements, compared to twenty-nine in the year before, indicating that the ruling may have had a chilling effect on pharmaceutical companies engaging in these types of agreements.

219 See Muris, supra note 78, at 3 (discussing how pharmaceutical cases are the bulk of what the Commission’s antitrust resources go towards). In 1996 less than five percent of new competition investigations involved the pharmaceutical industry, but in 2001, that number rose to twenty-five percent. Id. at 3 n.13. The Chairman of the FTC describes pay-for-delay settlements as “naked price fixing . . . condemned under antitrust laws, because it has no pro-competitive justifications.” Id. at 17. The Commissioner has further stated that the FTC’s first generation of pharmaceutical litigation focused on investigating these pay-for-delay arrangements. Id. at 14. Generic drug prices compared to brand name can be up to ninety percent less expensive. See S. 214 § 2(a)(4). See also FED. TRADE COMM’N, PAY-FOR-DELAY, supra note 76, at 1 (discussing how generics can be up to percent less expensive than brand-name drugs). The FTC has admitted that it lacks sufficient resources to investigate and litigate all pay-for-delay agreements. Id. at 7.

220 FED. TRADE COMM’N, PAY-FOR-DELAY, supra note 76, at 3 (describing how these agreements result in consumers losing the benefits that Hatch-Waxman intended to create).

221 See Biotechnology Indus. Org., 496 F.3d at 1373. “If the market functions properly, this new participation will bring down the formerly elevated price of the patented product to competitive levels.” Id. See also FED. TRADE COMM’N, PAY-FOR-DELAY, supra note 76, at 1-2. Outlawing pay-for-delay would eliminate the seventeen month delay that patent settlements create prior to a generic’s entry into the marketplace. Id. Since generics can be significantly less expensive than brand-name drugs, this further increases pharmaceutical access for consumers aside from simply bringing the drugs to market. Id.

222 See Shuchman supra note 84 (discussing a possible lasting effect of the Actavis decision on pay-for-delay arrangements).
C. Direct Price Controls on Pharmaceutical Prices

Aside from emergency scenarios, such as war or a public health crisis, direct price controls are distinctly foreign to the American free market economy. \(^{223}\) Per its constitutional police power, the Commonwealth of Massachusetts is vested with the power to institute price controls on medicines, like the one proposed under Senate Bill 1048, which considers the benefits of the medicine, its cost, and its price in other countries. \(^{224}\) The pharmaceutical industry is inextricably intertwined with the public interest so as to subject it to price control regulations if need be. \(^{225}\) Other countries institute price control schemes for pharmaceuticals that purport to assess the value of new medicines, which is similar to Massachusetts’ proposed law. \(^{226}\) For example, price controls have succeeded to an extent in reducing drug prices in Canada. \(^{227}\)

Canadian price controls have had the greatest success in controlling prices of patented drugs, but have had less success in controlling prices of generic drugs. \(^{228}\) Prices


\(^{224}\) See generally Nebbia, 291 U.S. at 539 (upholding New York state law meant to protect public). Price controls can be instituted by states on industries where there is a strong public interest. \(Id.\) \(See also S. 1048, 189th Gen. Court (Mass. 2015).\) The proposed law would allow the state to set a maximum allowable price for pharmaceuticals sold in the state. \(Id.\)

\(^{225}\) See Lipski, supra note 86, at 915 (discussing the interest of states in controlling the high cost of drugs). Certain medications decrease mortality rates and improve quality of life. \(Id.\) \(See also D.C. CODE § 28-4551 (2005).\) The Council of the District of Columbia cited excessive prices of prescription drugs that threatened the health and welfare of residents as the impetus for instituting price control regulations on pharmaceuticals. \(Id.\)

\(^{226}\) See Osborn, supra note 99 (discussing how Canada, Germany, and the United Kingdom have pharmaceutical price control regulations in place).

\(^{227}\) See Menon, supra note 99, at 99. In a 1996 study, the United States had ninety-six percent higher drug prices than Canada. \(Id.\) Populist reform proposals call for importing pharmaceuticals from Canada because of the fact that they are generally cheaper across the border. \(See also Fighting to Lower Prescription Drug Prices, BERNIESANDERS.COM, https://berniesanders.com/issues/fighting-to-lower-prescription-drug-prices/\) (last visited Apr. 8, 2016) (discussing nation’s problem with rising drug prices in comparison to Canada); supra note 181 and accompanying text (discussing differences between drug prices in U.S. and Canada).

\(^{228}\) See LEXCHIN, supra note 181 at 28-32 (discussing Canadian regulation of generic and brand-name drugs).
for patented drugs are set at the federal level through the Patented Medicine Prices Review Board.229 It sets a maximum introductory price for new medicines using a median average price, compared to prices of the drugs in other countries, and limits the rate of increase in those prices to the rate of inflation.230 The Patented Medicine Prices Review Board found that on average, prices for patented drugs in the United States were 1.69 times higher than the price of those same drugs in Canada.231 However, the prices for generic drugs in the United States are, on average, less than half the price of those same drugs in Canada.232 One reason for the price disparity between generics and patented medicines in Canada is that the level of competition between generic manufacturers is lower in Canada due to a smaller population size when compared to the United States.233 A glaring problem with the approach Canada is taking to pricing patented medicines is that it bases its price on the sticker price of the drugs listed in other countries rather than the final price countries pay after securing undisclosed rebates from the drug manufacturers.234 This leads to Canada paying a higher price for patented medicines due to its use of a pre-rebate price rather than the actual final price after rebates are paid.235

229 Id. at 25. The countries whose prices they use to determine the introductory price for patented drugs are France, Germany, Italy, Switzerland, United Kingdom, and the United States. Id. at 31-32. See also Davidson, supra note 181 (describing the problems of Canada’s drug pricing regulations).

230 See Davidson, supra note 181. The countries whose prices they use to determine the introductory price for patented drugs are France, Germany, Italy, Switzerland, United Kingdom, and the United States. Id.

231 See Lexchin, supra note 181, at 32 (comparing the average foreign-to-Canadian price ratio for patented drugs).

232 Id. at 35 (comparing the average foreign-to-Canadian price ratio of generic drugs).

233 Id. at 35 (discussing the influence of population on pharmaceutical competition).

234 See Davidson, supra note 181 (comparing Canada’s sticker price regulations to other countries and assessing the impact of these disparities).

235 See Davidson, supra note 181 (discussing drawbacks of the Canadian drug pricing system).
Canada's (and other countries') price control schemes of pharmaceuticals are accompanied by a variety of issues. It has been reported that certain drugs have not been launched in Canada despite having undergone regulatory review because of some board rulings regarding pricing, thus potentially denying Canadian citizens access to critical medicines. For instance, Rx&D, the patented drug manufacturers’ association in Canada, has expressed concerns that pricing restrictions may lead to Canadian citizens’ reduced access to new medications. Furthermore, critics have assailed government agencies that attempt to control drug prices, stating they are “vehicle[s] for rationing drugs and health care services to meet pre-established fiscal spending targets.” The fact that price controls artificially distort supply and demand profiles in a free market economy is not a new revelation and provides a further drawback of price control schemes. Aside from adversely affecting access to needed medicines, pharmaceutical price controls may even stifle investments in drug innovation and cause a slight decrease in life expectancies. A study by the RAND Corporation, regarded as a centrist policy think tank, found that price controls implementation would provide a modest benefit in the short-term, but would ultimately lead to decreased life expectancies as a direct result from

236 See Menon, supra note 99, at 99-102 (discussing various issues that accompany Canada’s price control measures). See also Osborn supra note 99, at 2 (discussing how price control schemes fail to consider patients’ health and wellness). See also Goldman et al., supra note 99, at 2-3 (discussing how price controls reduce life expectancy over time).
237 See Menon, supra note 99, at 100 (discussing how some drugs have now been launched in Canada due to regulatory rulings).
238 Id.
239 See Osborn, supra note 99, at 2 (discussing how health care agencies in countries with price control regimes ration drugs).
240 See Rockoff, supra note 99. Price controls prevent the price system from rationing the available supply. Id. Price floors generally create surpluses, while price ceilings, such as those proposed in pharmaceutical price control regimes, generally cause shortages. Id.
241 See Brachmann, supra note 99 (discussing how price controls reduce life expectancy and reduce innovation).
decreased drug innovation.\textsuperscript{242} The downsides of price controls far outweigh the benefits, especially considering they would be of marginal value to U.S. consumers because they can only be applied to off-patent pharmaceuticals.\textsuperscript{243}

Aside from the social and economic costs of pharmaceutical price controls, Massachusetts’s proposed price control provision in Senate Bill 1048 may be facially unconstitutional because it is likely preempted by the federal Patent Act.\textsuperscript{244} While the proposed Massachusetts law does not expressly target patented prescription drugs (like the District of Columbia’s Prescription Drug Excessive Pricing Act), Senate Bill 1048 does not exclude prescription drugs from regulation either, and thus encompasses them within the scope of the bill.\textsuperscript{245} The Bill may, in fact, be targeting patented prescription drugs because the criteria that the legislation lists in determining whether or not to include a drug on its list of critical drugs with substantial public interest includes research and development costs paid with public funds, the manufacturer, and third parties.\textsuperscript{246} Generic manufacturers may file an ANDA in order to bring their products to market, which does not require repeating clinical trial data and saves substantial costs on research and development.\textsuperscript{247} While it is true that what may stand as a sufficient obstacle to the accomplishment and execution of the full purposes and objectives of Congress is a matter

\textsuperscript{242} Id. See also Goldman et al., supra note 99, at 2-3 (discussing consequences of price control systems).

\textsuperscript{243} See Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1374 (Fed. Cir. 2007) (rejecting imposition of price controls on patented pharmaceuticals). See also Goldman et al., supra note 99, at 2-3 (discussing the negative consequences of price controls).

\textsuperscript{244} Compare S. 1048, 189th Gen. Ct. (Mass. 2015) (explaining the requirement for drug prices being listed), with D.C. CODE § 28-4553-4554 (2005) (describing how excessive drug pricing is not allowed). The court in the Biotechnology case made it clear that an act, which diminishes the economic rewards to patent holders, is contrary to the goals established by Congress in the Patent Act. See Biotechnology Indus. Org., 496 F.3d at 1374.

\textsuperscript{245} See Mass. S. 1048.

\textsuperscript{246} Id.

\textsuperscript{247} See FED. TRADE COMM’N, GENERIC DRUG ENTRY, supra note 32, at 5 (outlining the federal requirements for generic manufacturers to bring their products to market).
of judgment, *Biotechnology Industry Organization v. District of Columbia* has made it clear that if a legislative act diminishes the economic reward to patent holders by setting a maximum allowable price, it will be deemed preempted by the Patent Act.\(^{248}\) Since Senate Bill 1048 makes no distinction between generic or patented pharmaceuticals, the provision capping prices may be deemed unconstitutional because it may act to diminish the economic reward to patent holders.\(^{249}\)

The wave of pharmaceutical-cost transparency bills being introduced in states across the country are largely borne from distrust of an industry whose member companies seemingly charge what they want for drugs in an arbitrary manner.\(^{250}\) Even with transparency bills, there is no guarantee that knowing the costs that go into developing a drug will lower prices.\(^{251}\) Some criticism of transparency bills comes from the fact that the information may only tell part of the story behind pricing because the bills only focus on costs to develop a particular drug that gets approved.\(^{252}\) The transparency bills that have been introduced largely ignore money spent on drugs that fail during development, which could lead to a gross underestimation of the actual costs in bringing a particular drug to market.\(^{253}\) Some estimates put the total cost of getting a drug

\(^{248}\) See *Biotechnology Indus. Org.*, 496 F.3d at 1372-74 (ruling that federal patent law preempts legislation in regards to economic awards to patent holders).

\(^{249}\) Compare Mass. S.1048 (explaining the requirement for transparency in drug pricing process and controlling pricing) with *Biotechnology Indus. Org.*, 496 F.3d at 1374 (stating patent holders should fully exercise their rights in pricing granted by Patent Act).

\(^{250}\) See Pollack, *Drug Prices Soar*, supra note 153 (discussing drug companies’ ability to charge drug rates however way they please).

\(^{251}\) Id.

\(^{252}\) Id.

to market at almost $6 billion, while the number of drugs that actually make it through clinical trials to FDA approval is approximately ten percent.\textsuperscript{254} Perhaps taking this criticism into consideration, California updated its transparency bill in January of 2016 to include reporting the costs of drugs or other research projects that failed to succeed through the process to market approval.\textsuperscript{255}

V. CONCLUSION

With prices of brand name, generic, and "wonder drugs" on the rise, pharmaceutical importation from other trusted countries would be the most viable long-term solution because drug prices are far less expensive in virtually every other country than in the United States. Another solution that would provide savings is to allow Medicare Part D the ability to negotiate with manufacturers, but the extent of the discounts would largely depend on whether or not there are alternative bioequivalent drugs available. However, transparency bills may provide the government with leverage in these negotiations. Whether or not drug cost transparency bills would have any effect on drug prices also remains to be seen. California’s proposed transparency bill is the model for the time being because it factors in the cost of failed drugs that do not make it to market in addition to the costs of research and development that need to be recouped for drugs that do ultimately succeed.

Hatch-Waxman continues to remain invaluable in providing consumers access to lower-cost generics, but drug manufacturers also remain free to price their drugs at whatever cost they choose. Furthermore, it remains to be seen whether the Actavis

\textsuperscript{254} See Herper, supra note 139 (outlining the discrepancies of cost to produce drugs versus drugs that reach the market); Seaton, supra note 139 (noting the number of drugs reaching the market is significantly low).

\textsuperscript{255} See AB 463, 2015-2016 Reg. Sess. (Cal. 2015).
decision will have a long-term stifling effect on pay-for-delay deals, but legislation banning these agreements would emphatically dissuade manufacturers from entering into them. Statutory rebates can also provide short-term relief, but pharmaceutical manufacturers would likely respond by raising pre-rebate prices to offset any potential losses. Direct price controls would be of marginal value to lowering drug costs since their only legal application would be on generic drugs following the *Biotechnology Industry Organization v. District of Columbia* decision. For this reason, Massachusetts’ provision in its transparency bill allowing for price controls on pharmaceuticals may eventually be struck down because it does not exclude drugs on-patent. Price controls are also unpalatable because they tend to distort the free market supply-and-demand profile, and may have the effect of stifling drug innovation, thus decreasing life expectancy in the long-term.