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Keeping Consumers Out of the Crossfire: Final-Offer Arbitration in the Pharmaceutical Market

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ABSTRACT

Big pharma greed is not the sole cause of skyrocketing drug prices. A consumer's out-of-pocket drug cost is decided each year at a negotiating table, where insurance companies leverage price concessions from drug companies by threatening to limit coverage for a certain drug. As a result, the health insurance industry is also booming, but it is an expensive way to save money.

Social value in the drug industry comes from ensuring that consumers get the drugs they need. But it also comes from encouraging new drug development. Thus, any solution that lowers the consumer cost of drugs, must preserve as much as possible the incentive for drug companies to innovate. In the United States, where new drug development is largely in the hands of drug manufacturers, these objectives directly conflict: Less drug company revenue amounts to less invested toward the next breakthrough drug. To achieve a suitable balance, this Comment suggests making two changes to the market, both to ensure that insurance companies deliver reasonable coverage and that drug companies agree to reasonable prices.

First, a system of dispute resolution known as final-offer arbitration, used in collective bargaining disputes, should be implemented to change drug company pricing behavior at the negotiating table. In this system, the arbitrator selects the more reasonable of the negotiating parties' final offers, rather than determining a reasonable price on her own. The threat of losing one's negotiating position has been shown to encourage reasonable pricing and can offset the practically unlimited pricing power drug companies exert on patent-protected drugs.

With this in place, various cost-containment strategies that insurance companies use to externalize the cost of drugs onto third parties should be restricted.

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INTRODUCTION

Pharmaceuticals in the United States cost too much,[1] and consumers pay too much of the cost. Twenty percent of drug purchasers now spend more on drugs than on their mortgage or rent payments.[2] One study found that one in three chronically ill patients was forced to stop taking prescriptions or else stop buying food.[3] Meanwhile, the pharmaceutical industry posts stellar profits each year.[4] The industry's profitability, together with the sensationally bad behavior of some of its corporate managers,[5] has caused many to blame the drug pricing problem on big pharma greed.[6]

1. *See, e.g.*, Joe Nocera, *The $300,000 Drug*, N.Y. TIMES (July 18, 2014), https://www.nytimes.com/2014/07/19/opinion/joe-nocera-cystic-fibrosis-drug-price.html?_r=0; Joseph Walker, *Patients Struggle With High Drug Prices*, WALL STREET J. (Dec. 31, 2015, 10:38 AM), http://www.wsj.com/articles/patients-struggle-with-high-drug-prices-1451557981 (discussing a leukemia sufferer who resorted to chemotherapy because she was unable to afford a safer drug that cost her $8000 per year).
2. Richard Evans, Sector & Sovereign Research, Address at the Alliance for Health Reform: Prescription Drug Costs: Trends and Tradeoffs in the Pipeline From Lab to Market 4 (Sept. 18, 2015), http://www.allhealthpolicy.org/wp-content/uploads/2016/12/91815TRANSCRIPT_KO.pdf [https://perma.cc/P4ZB-A38R].
3. Seth A. Berkowitz et al., *Treat or Eat: Food Insecurity, Cost-Related Medication Underuse, and Unmet Needs*, 127 AM. J. MED. 303, 303 (2014).
4. The healthcare technology industry, which contains major and generic pharmaceutical industries, was "by far the most profitable industry" of 2015, with a 21 percent average net profit margin. Keith Speights, *12 Big Pharma Stats That Will Blow You Away*, MOTLEY FOOL (July 31, 2016, 2:04 PM), http://www.fool.com/investing/2016/07/31/12-big-pharma-stats-that-will-blow-you-away.aspx [https://perma.cc/784T-YNJM].
5. For example, Martin Shkreli, CEO of Turing Pharmaceuticals and *enfant terrible* of the industry, acquired the rights to Daraprim and increased its price by 5000 percent overnight. *See* Zoe Thomas & Tim Swift, *Who Is Martin Shkreli—'The Most Hated Man in America'?*, BBC NEWS (Aug. 4, 2017), http://www.bbc.com/news/world-us-canada-34331761 [https://perma.cc/35XM-JYLK]. Another recent example is Heather Bresch, CEO of Mylan Manufacturing, who made the controversial decision to raise the price of the EpiPen by 500 percent. Gigi Douban, *Mylan Says Raising EpiPen Price 500% Isn't the Problem*, MARKETPLACE (Aug. 25, 2016, 1:42 PM), https://www.marketplace.org/2016/08/25/health-care/mylan-says-raising-epipen-price-500-isnt-problem [https://perma.cc/753X-SHDT].
6. *See, e.g.*, Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275 (2016) (arguing for the government's use of compulsory licensing of patented drugs to competitors); Walter Einenkel, *Bernie Tweets About Big Pharma Company's Greed—They Lose $400 Million That Afternoon*, DAILY KOS (Oct. 17, 2016, 7:50 AM), http://www.dailykos.com/story/2016/10/17/1583527/-Bernie-tweets-about-Big-Pharma-company-s-greed-they-lose-400-million-that-afternoon [https://perma.cc/U6KG-GT8Y].

But drug companies play only an indirect role in setting the out-of-pocket cost of a drug. The price that a consumer pays at the pharmacy is only a portion of the drug's list price, and the size of that portion is set by insurance companies through pharmaceutical benefit managers (PBMs).[7] PBMs, little discussed outside the industry, are separate entities that manage insurance formularies[8] and negotiate drug prices on behalf of insurance companies.[9] Essentially, PBMs argue for discounts on a drug's price to them, in exchange for agreeing to lower the consumer copay, which generates more sales.[10] Conversely, PBMs and insurance companies leverage drug companies to lower list prices by threatening to raise copays, restricting access to consumers, which results in fewer sales. This tactic has helped make the health insurance industry very profitable.[11] But pharmaceuticals are not pure commodities, and people who are sick often must choose between very expensive drugs and less effective or even more dangerous alternatives—if alternatives are even available. So while PBMs and drug companies wage war for higher profits, rampantly increasing consumer prices are collateral damage: Any solution that aims to lower consumer prices must therefore consider both sides of the negotiating table.

Lowering consumer prices means squeezing the margins of one industry or the other, and the importance of protecting pharmaceutical research and development (R&D) suggests disturbing drug company profits as little as possible. In the United States, drug development is largely privatized and conducted by drug companies themselves. New drugs provide enormous social value, both economically to the healthcare system and to people's

7. A consumer's out-of-pocket cost is his copay. An insured consumer who is covered by a given plan is called a beneficiary of that plan.

8. A formulary is a list of drugs covered by a given insurance plan. For an example of a five-tier formulary, see COVENTRYONE, 2016 COVENTRYONE PRESCRIPTION DRUG LIST 1 (2016), https://fm.formularynavigator.com/MemberPages/pdf/2016CoventryOnePrescriptionDrugList_7146_Full_0.pdf [https://perma.cc/5P4B-FY57].

9. For a discussion of the role of pharmaceutical benefit managers (PBMs), see Elizabeth L. Mitchell, *The Potential for Self-Interested Behavior by Pharmaceutical Manufacturers Through Vertical Integration With Pharmacy Benefit Managers: The Need for a New Regulatory Approach*, 54 FOOD & DRUG L.J. 151, 154–56 (1999).

10. *Id.*

11. Rising insurance premiums have also played a role. *See* Katie Thomas, *The Complex Math Behind Spiraling Prescription Drug Prices*, N.Y. TIMES (Aug. 24, 2016), https://www.nytimes.com/2016/08/25/business/high-drug-prices-explained-epipen-heart-medications.html; Angelo Young, *Making a Killing Under Obamacare: The ACA Gets Blamed for Rising Premiums, While Insurance Companies Are Reaping Massive Profits*, SALON (Oct. 28, 2016, 2:00 AM), http://www.salon.com/2016/10/28/making-a-killing-under-obamacare-the-aca-gets-the-blame-for-rising-premiums-while-insurance-companies-are-reaping-massive-profits [https://perma.cc/5R9S-9XCD].

quality of life, and the United States is a perennial world leader in new drug development.[12]

To balance these tradeoffs in a way that achieves the most social value, this Comment forwards a multipart proposal that aims to relieve consumer price pressure by spreading the cost of drugs more equitably between the pharmaceutical and insurance industries. First, drug companies and PBMs should negotiate prices subject to final-offer arbitration.[13] Under this system, these parties have a period of time to negotiate a price. If they cannot agree, they submit to binding arbitration. Each side puts forth its best offer, and the arbitrator picks the more reasonable of the two without splitting the difference (as is the case in conventional arbitration).[14] This model has been demonstrated to encourage parties to negotiate reasonably from the outset.[15] Applied to the pharmaceutical industry, final-offer arbitration can check drug companies' monopolistic pricing power when that power is exercised unreasonably, and drug prices to insurers will drop.

With this in place, PBMs and insurance companies must then be limited in their use of cost externalization strategies if savings are to ever reach consumers.[16] This Comment also suggests limiting formulary design by disallowing midyear, nonmedical switching, where an insurance company removes a drug from a formulary during the plan year for reasons other than patient safety. This tactic effectively requires beneficiaries to switch insurance companies or else pay for the cost of the drug by themselves.[17] Other cost-containment strategies, such as coinsurance, prior authorization, and step therapy, can be restricted or eliminated in order to strike a satisfactory balance in allocating the cost of drugs between drug companies (through lower prices), insurers, and consumers.[18]

12. By number of newly patented drugs, U.S. drug companies are the most innovative in the world. *See* ROSS C. DEVOL ET AL., MILKEN INST., THE GLOBAL BIOMEDICAL INDUSTRY: PRESERVING U.S. LEADERSHIP 5 tbl.2 (2011) (noting that U.S. drug companies developed 57 percent of all new chemical entities between 2001 and 2010).
13. Final-offer arbitration was originally proposed for use in the healthcare industry in the narrower context of Medicare Part D. *See* Richard G. Frank & Joseph P. Newhouse, *Should Drug Prices Be Negotiated Under Part D of Medicare? And If So, How?*, 27 HEALTH AFF. 33, 40–42 (2008).
14. How an arbitrator will determine what is reasonable is discussed *infra* Subpart IV.B.
15. *See* Elissa M. Meth, *Final Offer Arbitration: A Model for Dispute Resolution in Domestic and International Disputes*, 10 AM. REV. INT'L ARB. 383, 407–08 (1999). *See generally infra* Part III.
16. *See infra* Subpart I.C.
17. *Non-Medical Switching*, PRESCRIPTION PROCESS, http://prescriptionprocess.com/barriers-to-access/non-medical-switching [https://perma.cc/9X57-HVFT].
18. *See infra* Subpart I.C; *see also Copayment/Coinsurance in Drug Plans*, MEDICARE, https://www.medicare.gov/part-d/costs/copayment-coinsurance/drug-plan-copayments.html

Part I examines the current pharmaceutical market. Generally, high prices are the result of the exercise of monopoly power by the drug companies. Part I.A explains the legal and political framework that permits these monopolies in the pharmaceutical market, where buyers have little choice not to buy the monopolists' products. Part I.B introduces an analytical framework for discussing types of drug company monopolies. Part I.C examines the role insurance companies and PBMs play in the rising price of drugs.

Part II considers various proposals that focus on curbing the market power of drug companies. Part III explains the final-offer model and why it is more effective than other proposals. Part IV considers industry-specific implementation decisions to be made, including when and how to adopt value-based and R&D-based pricing models for determining a reasonable price. It examines the various tradeoffs and adjustments that could be made to strike a balance to best serve the public, including the extent to which formulary design should be restricted, as well as methods for determining whose offer is more reasonable. Part V addresses the counterarguments.

I. WHY ARE DRUGS SO EXPENSIVE?

A. Monopolies in the Pharmaceutical Market: The Legal and Political Framework

A seller with an incentive to maximize profits will raise the price of his goods until contending market forces make it unprofitable to raise it any more.[19] One price-restraining force is competition from other sellers who are willing to sell similar products for a lower price. Most drugs, however, are not interchangeable. Many are produced by only one manufacturer, and alternative medications for a given illness often differ, sometimes drastically, both in effectiveness and potential side effects.[20] The lack of horizontal price

[https://perma.cc/QB2M-84FP]. Because drug prices change during a plan year, a beneficiary paying coinsurance has no way of knowing how much money she must pay until a pharmacy refills her prescription.

19. For more on these fundamental economic concepts, see ROGER LEROY MILLER & ROGER E. MEINERS, INTERMEDIATE MICROECONOMICS (3d ed. 1986).

20. That is, drug companies often have monopolies on their products. *See infra* Subpart I.B. Richard Evans, an industry expert, analogizes market power to a rising balloon. *See* Alliance for Health Policy, *Prescription Drug Costs: Trends and Tradeoffs in the Pipeline From Lab to Market*, YOUTUBE 5:51 (Sept. 18, 2015), https://youtu.be/5SkgoJXr9OA. A buyer's ability to choose not to buy a product may be likened to a counterweight tied to the balloon; the density of the entire object is increased, making it less buoyant. But in a market where a monopolist is selling a necessary good, there is no counterweight; the

restraints make monopolistic power commonplace in the pharmaceutical market.[21]

Monopolistic power can be constrained by law in a number of ways, but U.S. lawmakers have historically been reluctant to do so.[22] Neither Section 2 of the Sherman Antitrust Act,[23] nor any other antitrust law, prohibits monopolies per se.[24] Rather, U.S. antimonopoly law's singular focus is the prevention of restraints on trade.[25] Generally, this refers to conduct that keeps competitors from entering the market, and monopolies are permitted so long as they are legally obtained.[26] Therefore, a monopolist who charges excessively low prices breaks the law by making it impossible to compete with her,[27] but a monopolist who charges excessively high prices does not.[28]

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balloon rises until it no longer can. Price controls by the government could be likened to putting the balloon in a room—the balloon will only rise to the level of the ceiling. *See id.*

21. The various ways a monopoly may form in this industry are described in Subpart I.B.
22. In fact, some laws actually reward innovators with monopolistic pricing power. One relevant example is the Patent Act. *See* 35 U.S.C. § 271 (2012).
23. 15 U.S.C. § 2 (2012). This statute is the basis of U.S. antimonopoly law.
24. *See* Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 407 (2004).
25. The Sherman Antitrust Act, the cornerstone of American antitrust law, "was designed to be a comprehensive charter of economic liberty aimed at preserving *free and unfettered competition* as the rule of trade." N. Pac. Ry. Co. v. United States, 356 U.S. 1, 4 (1958) (emphasis added). *See* Louis Altman & Malla Pollack, *The Character of the Antitrust Laws—Freedom of Competition*, *in* CALLMANN ON UNFAIR COMPETITION, TRADEMARKS AND MONOPOLIES 4-3 (4th ed. 2016).
26. Altman & Pollack, *supra* note 25, at 4–6 n.3. The U.S. Supreme Court stated:

> It is settled law that this offense requires, in addition to the possession of monopoly power in the relevant market, "the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." The mere possession of monopoly power, and the concomitant charging of monopoly prices, is not only not unlawful; it is an important element of the free-market system.

Trinko, 540 U.S. at 407 (quoting United States v. Grinnell Corp., 384 U.S. 563, 570–71 (1966)).

27. *See, e.g.*, Nat'l Dairy Prods. Corp. v. FTC, 412 F.2d 605 (7th Cir. 1969) (affirming a judgment that a dairy company's practice of pricing its products so as to undercut its competitors was a violation of U.S. antitrust laws).
28. *Trinko*, 540 U.S. at 407. Courts have rejected the argument that excessively high prices violate antimonopoly laws. According to the Second Circuit, even though the aim of antitrust law is to prevent excessive prices, "a pristine monopolist, we have held, may charge as high a rate as the market may bear." Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 297 (2d Cir. 1979); *see also* Frederick M. Abbott, *Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health*, 6 U.C. IRVINE L. REV. 281, 319 (2016) (arguing that the United States should "incorporate excessive pricing doctrine in its antitrust arsenal"). Because of this federal policy, even state law consumer protection claims for excessive pricing have failed. *See, e.g.*, Se. Pa. Transp. Auth. v. Gilead Scis., Inc., 102 F. Supp. 3d 688 (E.D. Pa. 2015) (holding that a drug company did not violate various state laws by charging excessive prices).

Theoretically, high prices incentivize competitors to sell their products more cheaply. A company that can sell milk at $5 per gallon will find it very profitable to enter a market where the only producer of milk charges $20 per gallon. But the pharmaceutical industry is not a normal market. Pressure from competing manufacturers is limited and sometimes eliminated: Patents eliminate competition for a period, and even when drugs lose patent protection, stringent Food and Drug Administration (FDA) requirements impose high costs on market entry and can dissuade generic competitors from ever entering.[29]

The other price-restraining force, aside from competition, is a buyer's ability to decline to purchase a monopolist's product. But the nature of the healthcare market also severely limits buyers' ability to pursue other options. The choice of which drug to purchase is not primarily an economic one, nor should it be[30]: While a milk-drinker might settle for water, a pancreatic cancer patient needs Abraxane.[31] Insurance companies are also required by formulary laws to cover a certain number of drugs in each class, and sometimes even nonformulary drugs, so their ability to refuse to purchase drugs is limited.[32] And ironically, the existence of health insurance has increased the total money available to buy drugs, driving prices higher still.[33]

Markets that involve monopolies selling essential products are often subject to price controls.[34] While some drug legislation (like generic

29. A generic drug is one which is equivalent in "dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use" to a brand-name drug. *Generic Drugs: Questions & Answers*, FDA, https://www.fda.gov/Drugs/ ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm [https://perma.cc/H49Y-FAS9]. For a discussion of barriers to a competitor's entry into the pharmaceutical market, see *infra* Subpart I.B.

30. Justice Ginsburg similarly recognized that the healthcare industry is not a typical market, since it is one in which "all individuals inevitably participate." For her, this was an important reason why the Affordable Care Act's individual mandate was necessary. *See* Nat'l Fed'n of Indep. Bus. v. Sebelius, 567 U.S. 519, 589 (2012) (Ginsburg, J., concurring).

31. Alliance for Health Policy, *supra* note 20, at 1:22:53.

32. *See, e.g.*, 45 C.F.R. § 156.122(a) (2018) (requiring health plans to cover one drug in every pharmaceutical class); CAL. HEALTH & SAFETY CODE § 1367.24 (West 2016) (mandating a procedure by which plan beneficiaries may gain coverage for nonformulary drugs).

33. *See* Frank & Newhouse, *supra* note 13, at 39 ("The combination of patent protection, lack of competitor drugs, and insurance coverage for a high percentage of the patient's cost effectively puts the patent system on steroids.").

34. For example, California regulates the price of electricity. Thomas Sowell, *The Cause of the California Electricity Shortages: "Price Controls"*, CAPITALISM MAG. (Jan. 11, 2001), http://capitalismmagazine.com/2001/01/the-cause-of-the-california-electricity-shortages-price-controls [https://perma.cc/GJ4Y-EAQ5].

substitution laws[35]) has price-control-like qualities, the United States has not seriously considered implementing price controls on pharmaceuticals. The reason for this is partly political. Even a bill to allow the government to negotiate with drug companies on behalf of Medicare Part D beneficiaries was voted down for being too similar to governmental price intervention.[36]

So despite the public outrage, a drug company that legally obtains a monopoly may charge whatever price "the market will bear."[37]

B. The Types of Drug Company Monopolies

There are three different ways in which a drug company can obtain a monopoly: (1) through patent protection as a drug developer, sometimes known as an originator; (2) by purchasing the rights to a patent-protected drug or the originator itself; or (3) by obtaining a natural monopoly on a drug without patent protection. Any proposal to deal with excessive drug pricing must address each of these unique scenarios.

1. Originator Monopolies and the R&D Conundrum

In 2001, researchers at Pfizer succeeded in creating Ibrance (palbociclib), a breakthrough pill used to treat breast cancer.[38] The research took six years, but it paid off: Clinical trials showed that the drug slows tumor growth by nearly half.[39] In 2003 Pfizer received three patents protecting the

35. Most states have generic substitution laws, which either allow or require a pharmacy to substitute cheaper alternative to a brand-name drug if it is sufficiently bioequivalent. For a discussion of the effects of these laws on drug prices, see ALISON MASSON & ROBERT L. STEINER, FTC, GENERIC SUBSTITUTION AND PRESCRIPTION DRUG PRICES: ECONOMIC EFFECTS OF STATE DRUG PRODUCT SELECTION LAWS (1985).

36. *See* Robert Pear, *Bill to Let Medicare Negotiate Drug Prices Is Blocked*, N.Y. TIMES (Apr. 18, 2007), http://www.nytimes.com/2007/04/18/washington/18cnd-medicare.html. Many other countries have some type of governmental control on the price of drugs. *See* Amy Nordrum, *Should Government Control the Price of Prescription Drugs?*, INT'L BUS. TIMES (Sept. 24, 2015, 2:46 PM), http://www.ibtimes.com/should-government-control-price-prescription-drugs-2112771 [https://perma.cc/L9KR-8S3L]. A few of these systems are explored *infra* Subpart II.A.1. This Comment argues, however, that the current pharmaceutical market is unamenable to direct governmental price control. *See infra* Subpart II.A.

37. Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 297 (1979).

38. Jack McCain, *First-In-Class CDK4/6 Inhibitor Palbociclib Could Usher in a New Wave of Combination Therapies for HR+, HER2– Breast Cancer*, 40 PHARMACY & THERAPEUTICS 511 (2015) [available at https://www.ncbi.nlm.nih.gov/pmc/articles/ PMC4517534].

39. Deena Beasley, *Pfizer Drug Doubles Time to Breast Cancer Tumor Growth in Trial*, YAHOO! (Apr. 6, 2014), https://www.yahoo.com/news/pfizer-drug-doubles-time-breast-cancer-tumor-growth-143050725—finance.html [https://perma.cc/B3UW-MN8L].

production process for Ibrance.[40] The clinical trial process began in 2004 and was halted by a number of mergers and restructurings[41] for 11 years, when the FDA finally approved Ibrance.[42] With exclusive rights to the drug until at least 2023,[43] Pfizer set the price at an astounding $9850 per month, or $118,200 per year.[44]

Pfizer executives conducted market research for three years to set that price.[45] They started within the ballpark of $9000 to $12,000, which they based on the prices of their closest competitors.[46] Then they met with insurance company managers to determine a price that was just below what would automatically trigger prior doctor authorization, resulting in fewer sales.[47]

Originator companies such as Pfizer usually justify their high prices by pointing to the high cost of R&D.[48] But determining whether the price for a drug is required to offset its R&D cost is difficult since there is currently no requirement that drug companies disclose the cost of developing drugs on

40. *Palbociclib*, DRUGBANK, https://www.drugbank.ca/drugs/DB09073 https://perma.cc/P4A3-REWB].
41. Derek Lowe, *Drug Industry Spending: R&D vs. Marketing*, SEEKING ALPHA (July 9, 2009, 9:15 AM), http://seekingalpha.com/article/147881-drug-industry-spending-r-and-d-vs-marketing [https://perma.cc/AB9M-H8VN].
42. Press Release, Pfizer, *Pfizer Receives U.S. FDA Accelerated Approval of Ibrance (Palbociclib)* (Feb. 3, 2015, 6:00 PM), http://www.pfizer.com/news/press-release/press-release-detail/pfizer_receives_u_s_fda_accelerated_approval_of_ibrance_palbociclib [https://perma.cc/9YN7-XMV6].
43. Patents provide a right to exclude others from manufacturing or selling the drug for twenty years from the date on which the application was filed. 35 U.S.C. § 154(a)(2) (2012). Drug companies sometimes use controversial techniques, such as altering drugs by a few molecules, to extend the life of patent protection. This is known as evergreening. For an extended discussion on this issue, see Roger Collier, *Drug Patents: The Evergreening Problem*, 185 CAN. MED. ASS'N J. E385 (2013).
44. Jonathan D. Rockoff, *How Pfizer Set the Cost of Its New Drug at $9,850 a Month*, WALL STREET J. (Dec. 9, 2015, 12:01 AM), http://www.wsj.com/articles/the-art-of-setting-a-drug-price-1449628081.
45. *Id.*
46. *Id.*
47. Prior authorization is a cost-containment strategy used by insurance companies. Insurers require doctors to vouch for the necessity of the prescriptions through written appeals. Prior authorization does encourage careful spending; on the other hand, it imposes enormous transactional costs on doctors' offices, which currently spend twenty hours a week on average writing authorizations. *See* Jeffrey Bendix, *The Prior Authorization Predicament*, MED. ECON. (July 8, 2014), http://medicaleconomics.modernmedicine.com/medical-economics/content/tags/insurance-companies/prior-authorization-predicament [https://perma.cc/Y8CV-8ZGF]. Prior Authorization is discussed further in Subpart I.C.
48. *See, e.g.*, CONG. BUDGET OFFICE, PUB. NO. 2589, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 1–2 (2006); Alliance for Health Policy, *supra* note 20, at 53:52.

a per drug basis.[49] Annual R&D expenses are disclosed, but allocating these expenses to specific drugs is difficult because they also include numerous failed projects.[50] One study found that 80 percent of drugs being developed are scrapped.[51] There is no question that the cost of developing a drug is high: One estimate put the total cost of developing a new drug from scratch at $2.558 billion, including false starts, foregone investments, and non-R&D expenses such as marketing.[52]

But that figure is controversial, because not all drugs are developed from scratch.[53] Roughly two-thirds of drugs given FDA approval are developed by making only minor changes to existing drugs, many of which are preexisting entities.[54] On average, the cost of bringing one of these drugs to market is a quarter the cost of a new drug.[55]

Whatever the figure, the pharmaceutical industry is undoubtedly fraught with risk.[56] But there is a simpler metric for gauging the morality of setting prices as high as they are: annual profit margin. In 2014, partly thanks to Ibrance, Pfizer posted a 42 percent net profit margin—a margin

49. Drug companies use Generally Accepted Accounting Principles (GAAP) in reporting their financial statements. Under GAAP standards, R&D is expensed in the period incurred, rather than capitalized as an asset. PRICEWATERHOUSECOOPERS, US GAAP: ISSUES AND SOLUTIONS FOR THE PHARMACEUTICALS AND LIFE SCIENCES INDUSTRIES 5 (2007), https://www.pwc.com/gx/en/pharma-life-sciences/pdf/1654_us-gaap-cd2.pdf [https://perma.cc/6X79-YFPJ].
50. CONG. BUDGET OFFICE, *supra* note 48, at 24.
51. John Graham, *Crisis in Pharma R&D: It Costs $2.6 Billion to Develop a New Medicine*; *2.5 Times More Than in 2003*, FORBES: APOTHECARY (Nov. 26, 2014, 5:44 PM), http://www.forbes.com/sites/theapothecary/2014/11/26/crisis-in-pharma-rd-it-costs-2-6-billion-to-develop-a-new-medicine-2-5-times-more-than-in-2003 [https://perma.cc/NK2A-NPXA].
52. *Id.*
53. It might also be wrong. *Compare id.*, *with* Timothy Noah, *The Make-Believe Billion*, SLATE (Mar. 3, 2011, 9:19 PM), http://www.slate.com/articles/business/the_customer/2011/03/the_makebelieve_billion.html [https://perma.cc/TB29-DRHF] (estimating R&D expenditures at $55 million per drug, far below the $1 billion estimate commonly cited in 2011).
54. *See* CONG. BUDGET OFFICE, *supra* note 48, at 21.
55. *Id.*
56. One study found that less than half of drug companies that get one drug approved ever get another. Alexander Gaffney, *How Many Drug Companies Manage to Get Two New Drugs Approved by FDA? Not Many*, REG. AFF. PROF'LS SOC'Y (Nov. 12, 2014), http://www.raps.org/Regulatory-Focus/News/2014/11/12/20726/How-Many-Drug-Companies-Manage-to-Get-Two-New-Drugs-Approved-by-FDA-Not-Many [https://perma.cc/L59S-U385].

that even an industry manager said he "wouldn't be able to justify."[57] To compare, the average profit margin of all industries was 7.9 percent in 2016.[58]

That kind of profit margin is difficult to justify when the price of these drugs keeps them away from the dying. But these companies also provide social value. In the United States, drug development is largely privatized, so drug company profits are what give us these drugs in the first place. In terms of innovation, these huge profit margins have paid off: Between 2001 and 2010, U.S. drug companies developed 57 percent of all new drugs.[59] The rest of the world also benefits from U.S. big pharma research, since U.S. companies sell their drugs worldwide. But in many countries, governments either impose rigid price controls on drugs or negotiate directly with drug companies.[60] Because the United States has rigidly adhered to free market principles both in monopoly law and in keeping the government out of price negotiations, Americans are now subsidizing the cost of new drug development for the rest of the world.[61]

Lowering drug prices, no matter how, will cause drug companies to restrict spending to some degree.[62] The danger is that R&D will be the first to go. Big pharma already spends significantly more on marketing and advertising than it does on R&D—almost twice as much in the case of Pfizer.[63]

57. Richard Anderson, *Pharmaceutical Industry Gets High on Fat Profits*, BBC NEWS (Nov. 6, 2014), http://www.bbc.com/news/business-28212223 [https://perma.cc/R5LL-TS2U].
58. MARGINS BY SECTOR, NYU STERN, Pages.Stern.nyu.edu/~adamodar/New_Home_Page/datafile/margin.html [https://perma.cc/HJD8-WSMY].
59. *See* DEVOL ET AL., *supra* note 12, at 5 tbl.2.
60. Alliance for Health Policy, *supra* note 20, at 1:01:30.
61. *See id.* Returning to the balloon analogy, other countries are squeezing the balloon, which causes the balloon to stretch wherever there is no compression—here in the United States. Some countries pay only a third of the price for U.S. drugs that Americans pay. Ashley Lutz, *See How Much More Americans Pay for Prescription Drugs*, BUS. INSIDER (Aug. 29, 2012, 4:55 PM), http://www.businessinsider.com/see-how-much-more-americans-pay-for-prescription-drugs-2012-8 [https://perma.cc/S2FZ-N4UH].
62. *See* CONG. BUDGET OFFICE, *supra* note 48, at 2 ("If companies expected to earn less from future drug sales, they would alter their research strategies to lower their average R&D spending per drug."). The impracticability of direct governmental action to force price concessions is explored *infra* Subpart II.A.
63. Tracy Staton, *Does Pharma Spend More on Marketing Than R&D? A Numbers Check*, FIERCEPHARMA (May 21, 2013, 11:46 AM), http://www.fiercepharma.com/regulatory/does-pharma-spend-more-on-marketing-than-r-d-a-numbers-check [https://perma.cc/ZGG9-M4ZK]. There is some debate as to the significance of this fact. *See, e.g.*, Christopher VanLang, *Is the High Cost of Drugs to Offset R&D Expenses Justified?*, FORBES (Mar. 23, 2016, 2:51 PM), http://www.forbes.com/sites/quora/2016/03/23/is-the-high-cost-of-drugs-to-offset-rd-expenditures-justified/ [https://perma.cc/6TRK-BYH2] (arguing that the amount of R&D expenditure in proportion to total revenue is comparable to that in other industries like software).

This is in part because marketing is a cheaper, more assured way of making money than new drug development.[64] Drug company managers, faced with a decision of whether to cut stable, cost-effective marketing programs, or incredibly risky research, would be jeopardizing their own jobs by cutting the former. Thus, the real conundrum is not that drug companies need all of these profits to afford R&D itself, but that the industry puts a risk premium on the cost of drug research, which makes it less cost effective and thus less attractive an investment than marketing. Any solution, therefore, that aims to generate the most social gains should also aim to preserve the amount that drug companies devote to drug R&D.[65]

2. Nonoriginator Monopolies: A New Type of Drug Company

In 1998, Pharmasset was a small startup with a mission to develop a cure for Hepatitis C.[66] By 2012, it had nearly succeeded in developing Sofosbuvir, a drug with a cure rate of over 90 percent.[67] Pharmasset had spent only $62.4 million (much less than the $2.558 billion quoted above) on developing the drug and planned to sell a twelve-week course of it for $36,000.[68] While Sofosbuvir was in the last stage of regulatory trials, Pharmasset was acquired for $11 billion by Gilead Pharmaceuticals, a major pharmaceutical corporation concerned with unpromising drugs in its development pipeline.[69] Gilead branded the drug Sovaldi, paid for the very last steps to bring the drug to market, and set the price at $84,000.[70] The price was made by a team of investment bankers with a plan to "max out revenue[;] . . . accessibility and

64. *See* Lowe, *supra* note 41 (showing the difference in expected market returns between R&D and marketing).

65. Final-offer arbitration could create a way to do so by requiring drug companies to justify their negotiated price point solely based on a market-multiple of R&D expenses, allowing higher drug prices for higher R&D (but not marketing) expenditures. *See infra* Subpart IV.B.1.

66. *See* Lewis Krauskopf & Anand Basu, *Gilead Bets $11 Billion on Hepatitis in Pharmasset Deal*, REUTERS (Nov. 21, 2011, 5:00 AM), http://www.reuters.com/article/us-gilead-pharmasset-idUSTRE7AK0XU20111121 [https://perma.cc/9ATP-M92T].

67. *Sovaldi Combination Therapy Cure Rates in Clinical Studies*, SOVALDI, https://web.archive.org/web/20160722215318/http://www.sovaldi.com/about-sovaldi/study-results [https://perma.cc/KF9R-GSHC].

68. STAFF OF S. COMM. ON FIN., 114TH CONG., THE PRICE OF SOVALDI AND ITS IMPACT ON THE U.S. HEALTH CARE SYSTEM 13, 17 (Comm. Print 2015).

69. Nicole Fisher & Scott Liebman, *Are M&A Replacing R&D in Pharma?*, FORBES (Apr. 22, 2015, 6:14 AM), http://www.forbes.com/sites/nicolefisher/2015/04/22/are-ma-replacing-rd-in-pharma/ [https://perma.cc/5QXK-DF8S].

70. STAFF OF S. COMM. ON FIN., *supra* note 68, at 17.

affordability were pretty much an afterthought."[71] The team thought the price would be just below what would hinder patient access at "uncomfortable levels," that is, limit sales.[72] Incidentally, they were wrong. Public and private insurers severely limited access to the drug. State Medicaid programs responded by limiting treatment: Oregon capped coverage at only five hundred patients a year after finding that treating the 10,000 patients who needed the drug would quadruple the entire budget spent on all drugs in the previous year.[73]

Gilead was the predecessor of a new breed of pharmaceutical company, which aims to "[g]row through serial deal-making, including tax 'inversion' purchases of foreign companies . . . . [and] stop spending so much money on risky research."[74] Essentially, these companies seek to cash in on others' R&D through corporate takeovers. They are a collective thorn in the side of those who argue that high-risk R&D justifies giving pharmaceutical companies free rein to set prices however they wish. It is true that exorbitantly priced takeovers like Gilead's could arguably incentivize other small companies to take on risky R&D. But the cost of Gilead's takeover was externalized onto public and private health plans, and through them, to Hepatitis C sufferers: The premium over Pharmasset's originally planned price for Sovaldi amounts to a fee for Gilead's accounting goodwill. The $48,000-per-treatment premium subsidized Gilead's investment choice, not drug research.

3. Off-Brand Drugs and Natural Monopolies

"Everyone hates Martin Shkreli."[75] Originally a hedge fund manager, he set his venture capitalist attitude upon the pharmaceutical industry when he

71. Carolyn Y. Johnson & Brady Dennis, *How an $84,000 Drug Got Its Price: 'Let's Hold Our Position . . . Whatever the Headlines'*, WASH. POST: WONKBLOG (Dec. 1, 2015), https://www.washingtonpost.com/news/wonk/wp/2015/12/01/how-an-84000-drug-got-its-price-lets-hold-our-position-whatever-the-headlines/ [https://perma.cc/NYW2-5LEB]. The congressional inquiry also revealed that Gilead made a point to set the price for Sovaldi at just below what it thought would trigger a congressional inquiry. STAFF OF S. COMM. ON FIN., *supra* note 68, at 29.
72. STAFF OF S. COMM. ON FIN., *supra* note 68, at 29.
73. Johnson & Dennis, *supra* note 71.
74. Bethany McLean, *The Valeant Meltdown and Wall Street's Major Drug Problem*, VANITY FAIR (June 5, 2016, 4:00 PM), http://www.vanityfair.com/news/2016/06/the-valeant-meltdown-and-wall-streets-major-drug-problem [https://perma.cc/L6QM-LXT3].
75. Kelefa Sanneh, *Everyone Hates Martin Shkreli. Everyone Is Missing the Point*, NEW YORKER (Feb. 5, 2016), https://www.newyorker.com/culture/cultural-comment/everyone-hates-martin-shkreli-everyone-is-missing-the-point [https://perma.cc/JL3P-3UKX]. A list of

formed Turing Pharmaceuticals and acquired the permits to produce Daraprim.[76] Daraprim treats toxoplasmosis, a rare disease that affects only those with weakened or compromised immune systems.[77] Invented in 1952, it has been off-patent for over forty years.[78] It costs $1 per tablet to manufacture, and the previous producer sold it for $13.50 per tablet.[79] Shkreli raised the price almost 5600 percent, to $750 per tablet, and solidified his position as the unapologetic poster child of drug industry greed.[80] The social value of a company like Turing Pharmaceuticals is obviously very low.

Whereas companies centered on mergers and acquisitions (M&A) take advantage of patent exclusivity itself, Shkreli, and others, exploit a secondary effect of patents in the pharmaceutical market. Patents encourage innovation by allowing inventors a period of exclusivity to recoup the cost of development.[81] Setting a time limitation on patent exclusivity is the legislature's attempt to balance the interests of an inventor against the detrimental economic effect of monopoly pricing on the market as a whole.[82] When a drug loses patent protection, other companies may produce a generic version of the drug. When a company does introduce a generic competitor, prices on the original drug

the controversies surrounding this man is beyond the scope of this Comment. *See, e.g.*, Allie Conti, *Wine, Wu-Tang, and Pharmaceuticals: Inside Martin Shkreli's World*, VICE (Jan. 26, 2016, 9:00 PM), https://www.vice.com/en_us/article/mvxw83/why-is-martin-shkreli-still-talking [https://perma.cc/52DJ-MAAQ]; Thomas & Swift, *supra* note 5.

76. Thomas & Swift, *supra* note 5.

77. David Kroll, *Imprimis' Fight Against Martin Shkreli Is Part of a Larger Battle*, FORBES (Oct. 23, 2015, 1:33 PM), http://www.forbes.com/sites/davidkroll/2015/10/23/imiprimis-ceo-on-compounding-a-low-cost-alternative-to-turings-daraprim-for-toxoplasmosis/#84949e4af6df [https://perma.cc/U9MU-C76M].

78. Mike Riggs, *Congress Has Failed (Yet Again) To Close the Martin Shkreli Loophole*, REASON (Feb. 15, 2018, 3:20 PM), https://reason.com/blog/2018/02/15/congress-has-failed-yet-again-to-close-t [https://perma.cc/CTN3-QZCZ].

79. Michelle Roberts, *What's a Fair Price for a Drug?*, BBC NEWS (Sept. 22, 2015), http://www.bbc.com/news/health-34322720 [https://perma.cc/6ULU-LKW5].

80. Tim Worstall, *Markets Work: Martin Shkreli, Daraprim and Turing Pharma Edition*, FORBES (Oct. 23, 2015, 2:35 AM), http://www.forbes.com/sites/timworstall/2015/10/23/markets-they-work-martin-shkreli-daraprim-and-turing-pharma-edition [https://perma.cc/KH5W-DUHR].

81. *See* Brennan et al., *supra* note 6, at 316. *See generally* JOHN GLADSTONE MILLS III ET AL., *What a Patent Is*, *in* 1 PATENT LAW FUNDAMENTALS § 1:24 (2d ed. 2004) (explaining the economic policy behind allowing innovators to recoup their R&D costs).

82. The detrimental effect of a patent may be understood as the amount paid for the product above the price of that product if it were produced in a competitive market; this effect is detrimental since it creates excessive profits for a company that may not reinvest it as effectively as another company. This excess price is known as patent deadweight loss. *See infra* note 221.

fall sharply: 51 percent on average within a year of patent expiration, and 77 percent within six years.[83]

But FDA regulations hinder generic entry, for better or worse. The Food, Drug and Cosmetic Act requires generic manufacturers to receive the same FDA approval as for brand name drugs.[84] Generic manufacturers must meet stringent safety requirements and must demonstrate that the drug is bioequivalent to the brand-name drug.[85] The process, known as a New Drug Application (NDA), can cost up to $620 million and take up to ten years.[86] The expenditures associated with generic entry are risky because the selling price of the drug can drop significantly by the time a company gets the permit to manufacture it.

It is these FDA barriers, which serve decidedly important purposes,[87] that Shkreli exploits. Drugs like Daraprim that treat only one rare disease have comparatively few sales and thus little or even no generic market potential, given the costs of generic market entry.[88] Because of this, the manufacturer of Daraprim faced no competition when the patent expired.[89] Although Shkreli significantly increased the price of Daraprim, which should have enticed competition, the fact that any potential competitor would have to complete a lengthy approval process before selling a generic version means Shkreli has a natural monopoly for the indefinite future.

83. IMS INST. FOR HEALTHCARE INFORMATICS, PRICE DECLINES AFTER BRANDED MEDICINES LOSE EXCLUSIVITY IN THE U.S. 3 tbl.1 (2016). Improved technology has also reduced the cost of manufacturing drugs, which makes the generics industry extremely profitable. *See, e.g.*, Elyse Tanouye, *Price Markups on Generics Can Top Brand-Name Drugs*, WALL STREET J. (Dec. 31, 1998, 12:01 AM), http://www.wsj.com/articles/SB915062993167849000 (showing that generic Haldol has a 2800 percent profit margin).

84. *See* Eric Lindenfeld & Jasper L. Tran, *Beyond Preemption of Generic Drug Claims*, 45 SW. L. REV. 241, 244 (2015).

85. *Id.* at 245. Bioequivalence means that the drug is essentially the same in all material aspects.

86. *See* Veronica S. Jae, Comment, *Simplifying FDASIA: The "Fast Track" to Expedited Drug Approval Efficiency*, 66 ADMIN. L. REV. 173, 177 (2014). The FDA has responded with an Abbreviated New Drug Application (ANDA). The efficacy of that process is hotly debated. *See generally* Stephanie Greene, *A Prescription for Change: How the Medicare Act Revises Hatch-Waxman to Speed Market Entry of Generic Drugs*, 30 J. CORP. L. 309 (2005) (discussing the effectiveness of the ANDA process).

87. *See infra* Subpart II.B.

88. Worstall, *supra* note 80.

89. Off-patent drugs that treat rare diseases and have only one manufacturer are known as orphan drugs. Their limited market usually prevents them from going generic. Roberts, *supra* note 79.

C. The Buyers: Insurance Companies, PBMs, and Managed Care Plans

Before condemning the pharmaceutical industry as cash rich yet morally bankrupt, it is important to understand the role health insurers and PBMs play in determining consumer costs.

Health insurance originally followed an indemnity insurance model, similar to automobile insurance.[90] In an indemnity plan, the beneficiary takes a doctor's prescription to a pharmacy, and the insurer pays a portion of the cost.[91] Meanwhile, the insurer invests the pooled value of its beneficiaries' premiums (monthly payments made to an insurer) and, if all goes well, comes out ahead. Assuming good faith on the part of the insurer, the level of premiums should correlate to the cost of the claims, so when drug prices go up, premiums increase accordingly. Under this indemnity model, health insurers had little negotiating power to lower the price of drugs, because the choice of whether or not they would purchase the drugs would ultimately be made by the doctor and the consumer. So when drug prices started to rise in the 1980s, some group plans saw double-digit growth in their premiums.[92]

During this time, PBMs developed an artificial way to exert pricing pressure on drug companies. PBMs are companies which originally performed managerial services for different entities in the pharmaceutical market. They contracted with insurance companies to help with processing prescriptions and managing computer systems, and they bought and sold drugs wholesale to pharmacies.[93] They now are ubiquitous entities in the market: Over 253 million individual Americans had a prescription processed by a PBM in 2015—most of the American population.[94] The market is also

90. Janet Hunt, *Traditional Indemnity Health Insurance Plans*, BALANCE (Aug. 22, 2016), https://www.thebalance.com/traditional-indemnity-health-insurance-plans-1969975.

91. Under any model, pharmacies purchase drugs (traditionally from drug companies, but now more often from PBMs acting as wholesalers), and make a profit on the spread between the purchase price and final sale price of a drug. *See* HENRY C. EICKELBERG, AM. HEALTH POL'Y INST., THE PRESCRIPTION DRUG SUPPLY CHAIN "BLACK BOX": HOW IT WORKS AND WHY YOU SHOULD CARE 7 (2015).

92. Rick Lindquist, *Part 2: The 1980s and 1990s—Employer-Based Health Insurance Begins to Unravel*, PEOPLEKEEP (June 6, 2014), https://www.zanebenefits.com/blog/part-2-the-1980s-and-1990s-employer-based-health-insurance-begins-to-unravel [https://perma.cc/8SGK-545T].

93. Allison Dabbs Garrett & Robert Garis, *Leveling the Playing Field in the Pharmacy Benefit Management Industry*, 42 VAL. U. L. REV. 33, 34 (2007).

94. *Hearing: The State of Competition in the Pharmacy Benefit Manager and Pharmacy Marketplaces*, CMTY. ONCOLOGY PHARMACY ASS'N (Nov. 17, 2015), http://www.coapharmacy.com/hearing-the-state-of-competition-in-the-pharmacy-benefit-manager-and-pharmacy-marketplaces [https://perma.cc/3GBG-J9LK]. By 2005, roughly 95 percent of insured Americans' plans were managed by PBMs. *See* Letter from Fed. Trade Comm'n Staff to

extremely consolidated: The top three PBMs process drugs for 180 million people.[95] Because PBMs serve many different insurers, they can exert more leverage in negotiating against drug companies than any single insurer. So PBMs began to act as intermediaries between drug companies, insurance companies, and pharmacies. Their importance in the healthcare market cannot be underestimated, but their role in the market is complex, and thus they are often overlooked, and largely unregulated.[96]

However, negotiating for more insurers does not by itself create more bargaining power, since under the old indemnity plans the choice to purchase a drug was still made entirely by the consumer and her doctor. So PBMs and insurance companies developed the managed care plan.[97] Broadly speaking, this insurance model creates disincentives for purchasing certain drugs by making them more expensive to plan beneficiaries. PBMs leverage drug companies for lower prices on the threat of implementing those disincentives. The first innovation was to separate insurance formularies, or lists of covered drugs, into tiers.[98] Drugs on a low tier have low copays, and copays increase progressively for drugs on higher tiers.[99] On modern formularies, the most expensive drugs are placed on the highest tiers, where consumers pay coinsurance, or a percentage of the drug's price.[100] When alternatives are available for a condition, PBMs give preferred status (also known as "value drugs") to one drug, placing it on a lower tier than others.[101] The idea is that plan beneficiaries will choose a preferred drug over a nonpreferred one because of the lower cost to them, and drug companies will be incentivized to lower their prices in exchange for the greater sales that result from preferred drug status.

When drugs are truly interchangeable, the consumer might as well choose the drug on the lowest tier. But usually, drugs that treat the same condition have significantly different efficacy rates and side effects.[102] Drugs

Richard L. Brown, Senator, N.D. Senate 4 (Mar. 8, 2005), http://www.ftc.gov/os/2005/03/050311northdakotacomnts.pdf [https://perma.cc/CF2J-3FDN].

95. CMTY. ONCOLOGY PHARMACY ASS'N, *supra* note 94.
96. Garrett & Garis, *supra* note 93, at 34.
97. In this arrangement, PBMs manage insurance companies' plan benefits, deciding what drugs to cover and how much of the cost the insurance company will cover. *Id.*
98. For an example of a five-tier formulary, see COVENTRYONE, *supra* note 8.
99. *Id.* at 2.
100. *See* ELIZABETH ABBOTT ET AL., PROMOTING ACCESS TO AFFORDABLE PRESCRIPTION DRUGS: POLICY ANALYSIS AND CONSUMER RECOMMENDATIONS FOR STATE POLICYMAKERS, CONSUMER ADVOCATES, AND HEALTH CARE STAKEHOLDERS 32 (2016).
101. *See* COVENTRYONE, *supra* note 8, at 2.
102. *See, e.g.*, Walker, *supra* note 1.

that are safest or most effective, especially when they treat the most serious conditions, are often the most expensive.[103] Unsurprisingly, these drugs are placed on the most expensive tier, now known as the specialty drug tier.[104] Thus, our country's most medically vulnerable (and often economically vulnerable) pay more out of pocket for the best drugs, and some are even forced to discontinue the drugs that keep them alive.[105]

PBMs also use another tactic, known as step therapy, to combat the price of recent breakthrough drugs. Step therapy requires patients to exhaust cheaper alternatives before using a nonpreferred or high-tier drug.[106] But delaying a patient's access to an effective breakthrough drug externalizes costs onto other parts of the healthcare system. For example, recent hepatitis C drugs might be expensive, but they are still far cheaper than a liver transplant.[107] Or consider one lung cancer patient: When her doctors instructed her to resume chemotherapy after a break, her insurance company required her to retry all the drugs that already failed for her before they agreed to continue paying for chemotherapy—meanwhile, her condition deteriorated, necessitating more expensive and complex treatments than if she would have simply received the top-tier drugs when she originally requested them.[108] Step therapy may also expose patients to dangerous side effects of older, cheaper drugs: One lupus sufferer had her vision affected.[109] It may prove successful for insurers, but step therapy goes a step beyond the purely economic incentives of formulary tiering: It overrules a doctor on her choice of prescription.

Another tactic which interferes with a doctor's choice of treatment is to require prior authorization before an insurer agrees to cover expensive

103. For example, the average out-of-pocket copay of Ibrance, a specialty drug, is $3152 to $12,608 per treatment, as of November 2017. *Ibrance*, GOODRX, https://www.goodrx.com /ibrance/medicare-coverage [https://perma.cc/PLF3-JBGD].

104. Some laws prohibit the practice of placing all drugs for a given condition on a high tier, on the grounds that it is discriminatory against sufferers of that illness. *See, e.g.*, 42 U.S.C. § 18116 (2012) (for Affordable Care Act plans). But these laws exist only in certain types of plans, and do not take into account that some drugs that treat a given disease may be much less effective than others.

105. *See* Walker, *supra* note 1.

106. *See id.*

107. *See* John LaMattina, *What Price Innovation? The Sovaldi Saga*, FORBES (May 29, 2014, 8:25 AM), https://www.forbes.com/sites/johnlamattina/2014/05/29/what-price-innovation-the-sovaldi-saga/#5eac95337f67 [https://perma.cc/Q4RW-37NZ].

108. *See* Bob Tedeschi, *Are Insurance Policies Saving Patients Money, or Keeping Them From the Treatment They Need?*, STAT (Aug. 22, 2016), https://www.statnews.com/2016/08/22/step-therapy-patients-insurance-treatments [https://perma.cc/Y962-LYM9].

109. *See id.*

drugs.[110] This process involves a time- and resource-consuming internal review in which the prescribing doctor must submit patient information to a panel employed by the insurance company, which decides whether the treatment is warranted.[111] The process can take up to thirty days.[112] It is very effective at achieving its goal: Estimates show that over 70 percent of prescriptions requiring prior authorization are not filled.[113] But the externalized costs are enormous. Physicians' offices now spend an average of twenty hours per week on prior authorization and lose an estimated $69 billion per year.[114]

Most drastically, PBMs can try not to cover a drug at all. Express Scripts, the largest PBM in the country, recently decided to remove drugs from its formulary when drug manufacturers refused to lower the prices.[115] This nuclear option took place in the middle of the plan year.[116] Chronic disease sufferers reliant on certain drugs received a letter stating they would have to switch medications or else pay the entire cost of the drug out of pocket.[117]

110. This tactic was implemented in the case of Sovaldi. *See infra* Subpart I.B.2.

111. *See* Douglas Moeller, *Manage Medical Advances With Automated Prior Authorization*, MANAGED HEALTHCARE EXECUTIVE (Aug. 1, 2009), http://managedhealthcareexecutive.modernmedicine.com/managed-healthcare-executive/content/manage-medical-advances-automated-prior-authorization [https://perma.cc/H28A-SBK2].

112. *See, e.g.*, Valerie Bauman, *Proposal Seeks to Streamline Health-Insurance Paperwork Logjam*, PUGET SOUND BUS. J. (Feb. 8, 2013, 2:39 PM), http://www.bizjournals.com/seattle/news/2013/02/08/docs-say-getting-buried-in-paperwork.html?page=all [https://perma.cc/6DK6-359S].

113. *See* FROST & SULLIVAN, THE IMPACT OF THE PRIOR AUTHORIZATION PROCESS ON BRANDED MEDICATIONS: PHYSICIAN PREFERENCE, PHARMACIST EFFICIENCY AND BRAND MARKET SHARE 9 (2013).

114. *See* Bendix, *supra* note 47.

115. *See* Alison Kodjak, *Fight to Lower Drug Prices Forces Some to Switch Medication*, NPR (Jan. 25, 2016, 5:10 AM), http://www.npr.org/sections/health-shots/2016/01/25/463809474/fight-to-lower-drug-prices-forces-some-to-switch-medication [https://perma.cc/6C5M-E6UJ].

116. *See* Elizabeth Davis, *50+ Brand-Name Drugs Dropped by Insurance in 2014*, GOODRX BLOG (Oct. 29, 2013, 1:03 PM), https://www.goodrx.com/blog/50-brand-name-drugs-dropped-by-insurance-in-2014 [https://perma.cc/WY4L-GP85] (showing a list of drugs dropped by Express Scripts and CVS Caremark between the middle of 2013 and the beginning of 2014).

117. *See e.g.*, Kodjak, *supra* note 115. One study demonstrated that nonmedical switching (removing drugs or altering copays midyear) causes high rates of discontinuation, which exacerbates illness and drives up costs in other areas of the healthcare system. *See* Yifei Liu et al., *Impact of Nonmedical Switching on Healthcare Costs: A Claims Database Analysis*, 18 VALUE HEALTH J. A252, A252 (2015).

The federal government quickly banned or restricted many of these practices for its Medicare plans.[118] Nonmedical switching on public plans was banned unless all beneficiaries were exempt until the end of the plan year.[119] State governments also responded with a variety of formulary laws. For example, New Mexico, whose laws tend to be more patient protective, now requires a grace period of 120 days before placing a drug on a higher tier, making it nonpreferred, removing it from the formulary, or establishing a prior authorization, among other things.[120] But formulary design in private commercial plans remains largely unregulated, and in most jurisdictions, drugs can be dropped at any time.

Whether managed care plans are successful at lowering drug prices is a contentious question, partly because drug pricing negotiations are confidential, and the deals struck between insurance companies and PBMs are not publicly available.[121] PBMs do not negotiate for lower drug prices per se, but for undisclosed rebates from the manufacturer when the PBM sells the drug to a pharmacy.[122] In theory, PBMs pass a portion of the rebate on to insurance companies, which can then lower premiums and copays for consumers. But because the rebate is not reflected in the price to the pharmacy, there is no way to know what the amount of the rebate is, aside from voluntary disclosure by a PBM.[123] PBMs have no requirement to disclose the amount of rebate they negotiate, nor how much they pass to insurance companies, and thus the

118. *See* ABBOTT ET AL., *supra* note 100, at 70. Under the Affordable Care Act, PBMs also manage public health plans. *See* 42 U.S.C. § 1320b-23 (2012) (discussing various disclosure requirements for PBMs in managing public plans under the ACA).

119. *See* ABBOTT ET AL., *supra* note 100, at 70.

120. *See* N.M. STAT. ANN. § 59A-22-49.4A (2017); *see also* CAL. INS. CODE § 10123.192 (West 2016); TEX. DEP'T INS., PHARMACY BENEFIT MANAGERS: A STUDY OF PRESCRIPTION DRUG MANAGEMENT PRACTICES & POLICIES 1–2 (2010).

121. *See, e.g.*, Thomas, *supra* note 11.

122. *See* Rockoff, *supra* note 44.

123. One PBM voluntarily disclosed that it receives a 20 percent rebate on each sale of Pfizer's Ibrance. *See id.* In negotiating with drug companies, PBMs act as fiduciaries of the insurer and are bound to act on their behalf. Nevertheless, PBMs may have an adverse incentive to keep the cost of drugs high. Since their profits consist of the spread between the price to them and to the pharmacy (and thus the consumer), the higher the price to the consumer, the more profit a PBM receives on the transaction. *See id.*; Alliance for Health Policy, *supra* note 20, at 50:51. These potential conflicts of interest in the PBM industry have been the subject of congressional investigation. *See* Mark Meador, *Squeezing the Middleman: Ending Underhanded Dealing in the Pharmacy Benefit Management Industry Through Regulation*, 20 ANNALS HEALTH L. 77, 78 (2011).

effect on consumer prices of their presence in the industry is largely unknown.[124]

There is evidence that the managed care plan and its cost-shifting strategies lower drug prices. In 2015, list prices for drugs rose roughly 12 percent, but insurers paid only about 2.8 percent more.[125] In fact, PBMs and health insurance companies have prospered despite escalating drug prices.[126] On the other hand, the managed care plan has made pharmaceuticals the least insured element of basic healthcare.[127] So the question remains as to whose prices are being lowered. But if drug prices are going up, and the price to insurers is not going up accordingly, then it is reasonable only to conclude that the managed care plan saves money for insurers by foisting a greater portion of the cost of healthcare on to consumers and doctors.

II. LEADING CURRENT PROPOSALS

Any solution to excessive drug pricing must achieve two fundamental goals: (1) lowering the cost of drugs to the consumer, and not just to formulary managers;[128] and (2) preserving as many resources for U.S. drug R&D as possible.[129] This Part discusses the efficacy of recent policy proposals in achieving these goals.

124. Some say that requiring PBMs to disclose their rebates would ensure that consumers see savings; others say the disclosures would be self-defeating, imposing needless transactional costs. *See* Joanna Shepherd, *Is More Information Always Better? Mandatory Disclosure Regulations in the Prescription Drug Market*, 99 CORNELL L. REV. ONLINE 1, 4 (2013). PBM oversight is beyond the scope of this Comment. But, undisclosed rebates allow drug companies to sell drugs at different prices to different PBMs, and avoid price discrimination laws; this flexibility is important to the implementation of final-offer arbitration, because PBMs will need to strike deals with drug companies on a per-drug basis in order to design cost-effective formularies. This is explained more thoroughly in Subpart IV.B. For purposes of this Comment, however, the reader need not dwell on the distinction between PBM rebates and lower prices—it is sufficient to think of PBMs as fiduciaries to insurers (as they are by law), negotiating for lower prices directly.

125. *See* Thomas, *supra* note 11.

126. *See, e.g.*, Linette Lopez, *It Looks as Though There's Only One Thing Big Drug Companies Are Afraid of*, BUS. INSIDER (Oct. 18, 2016, 4:24 PM), http://www.businessinsider.com/pharmacy-benefit-managers-taking-more-profits-from-drug-companies-2016-10 [https://perma.cc/Y2GV-D63U] (Express Scripts grew 12 percent in 2016); Wendell Potter, *No. Obamacare Isn't Killing the Insurance Industry*, HEALTHINSURANCE.ORG (Mar. 1, 2016), https://www.healthinsurance.org/blog/2016/03/01/no-obamacare-isnt-killing-the-insurance-industry [https://perma.cc/Y4UZ-TBA3] (discussing high health insurance profits).

127. *See* John A. Vernon, *Drug Research and Price Controls*, 25 REG. 22, 25 (2002–03).

128. *See supra* Subpart I.C.

129. *See supra* Subpart I.B.1.

Broadly, the most common proposals may be divided into two groups: (1) policies that restrict the market power of drug companies through direct governmental action, and (2) policies that aim to increase competition by increasing the number of drug manufacturers.

A. Direct Governmental Intervention

1. Price Controls and Single-Payer Insurance

Governments regulate the price of drugs in every major market in the world besides that of the United States.[130] This has led some policymakers to propose that the United States adopt the methods used by other countries.[131]

One method of price regulation, known as single-payer health insurance, involves the government essentially taking over the role of health insurers and negotiating directly with drug companies on behalf of all purchasers. If a drug company refuses to sell a drug at a price the government demands, the government refuses to indemnify consumers of the drug, and consumers have to purchase the drug out of pocket. Drug companies essentially risk being excluded from the country's market.

Under many single-payer systems, drug prices are negotiated with reference to the government's annual healthcare budget.[132] This approach is used in France and Italy,[133] and a variation of this approach was advocated by Senator Bernie Sanders during his 2016 presidential campaign.[134] Recently,

130. *See* David R. Francis, *The Effect of Price Controls on Pharmaceutical Research*, NAT'L BUREAU OF ECON. RES. (May 5, 2010), http://www.nber.org/digest/may05/w11114.html [https://perma.cc./3WPB-YN3H]. Even in the United States, certain governmental purchasers like the Veteran's Administration negotiate directly against drug companies, which is essentially a price-control mechanism. *See* David Blumenthal & David Squires, *Drug Price Control: How Some Government Programs Do It*, COMMONWEALTH FUND (May 10, 2016), http://www.commonwealthfund.org/publications/blog/2016/may/drug-price-control-how-some-government-programs-do-it [https://perma.cc/A7KK-ESFH] (describing a mandatory rebate for policy for state Medicaid programs, and a similar proposed policy for Medicare part B purchasers).

131. *See, e.g.*, Hilary Daniel, *Stemming the Escalating Cost of Prescription Drugs: A Position Paper of the American College of Physicians*, ANNALS OF INTERNAL MED. (July 5, 2016), http://annals.org/aim/article/2506848/stemming-escalating-cost-prescription-drugs-position-paper-american-college-physicians [https://perma.cc/8AXX-LPP7].

132. For example, France's system follows this model. Jerry Stanton, Comment, *Lesson for the United States From Foreign Price Controls on Pharmaceuticals*, 16 CONN. J. INT'L L. 149, 162 (2000).

133. Nathalie Grandfils, *Drug Price Setting and Regulation in France*, 16 INST. RES. & DOCUMENTATION HEALTH ECON. 1, 3–5 (2008).

134. *See* American Health Security Act, S. 1782, 113th Cong. (2013). Senator Bernie Sanders continued to endorse this position during his campaign.

the California Senate passed a bill for a single-payer plan on a statewide basis.[135] But one downside to setting the price of drugs subject to national expenditure caps is that a country may be forced to deny coverage for one life-saving drug in order to pay for another.[136]

The United Kingdom sets drug prices according to the Pharmaceutical Price Regulation Scheme (PPRS),[137] which historically regulated drug companies' profits rather than prices. Under the scheme, a drug company's total rate of return on capital (ROC) is limited to a given percentage of its entire portfolio of drugs sold in the country.[138] One shortcoming of ROC regulation is that it creates economic inefficiency by encouraging companies to artificially inflate their expenditures and accumulate capital in order to increase the real dollar amount of their profits.[139] To ameliorate this, the PPRS now uses other reference factors for determining a fair price, including estimates of a drug's social welfare value, measured by quality-adjusted life years (QALYs).[140]

Canada's Patented Medicines Price Review Board (PMPRB) limits drug companies to a reasonable return on investment, defined with reference to the drug's price in other countries, to similar products already in the market, and to inflation.[141] Previously, the PMPRB had no control over prices themselves; instead, it could invalidate the drug's patent if the company did not voluntarily lower its prices, exposing the manufacturer to generic competition.[142] This power has since been replaced with the ability to enact financial penalties.[143] Switzerland has even more direct control over prices,

135. George Skelton, *California Senators Passed a Single-Payer Healthcare Bill, but It's Going Nowhere Fast*, L.A. TIMES (June 5, 2017, 12:05 AM), http://beta.latimes.com/politics/la-pol-sac-skelton-single-payer-bill-20170605-story.html [https://perma.cc/UZZ4-KCSQ].
136. *See* Stanton, *supra* note 132, at 162–64.
137. *See* FINANCE & NHS/MEDICINES, U.K. DEP'T OF HEALTH, THE PHARMACEUTICAL PRICE REGULATION SCHEME 2014 (2013).
138. Stanton, *supra* note 132, at 163.
139. *See* Harvey Averch & Leland L. Johnson, *Behavior of the Firm Under Regulatory Constraint*, 52 AM. ECON. REV. 1052, 1068 (1962). Suppose a drug company can only make a 20 percent ROC in a given year, and that it has $20 in accumulated capital. If it expends $10 in research, it can only make $2. But if the drug company instead stashes its $20 in the bank, it can then raise the price of its drugs to make $4. This is inefficient since it actually encourages the artificial inflation of expenditures, rather than encouraging R&D specifically.
140. Brennan et al., *supra* note 6, at 323.
141. Stanton, *supra* note 132, at 161.
142. *Id.*
143. *Id.*

utilizing a rigid framework to set reasonable prices pursuant to criteria similar to Canada's.[144]

The massive bargaining power of a governmental payer system undoubtedly pushes drug prices down.[145] But most single-payer countries have largely socialized medicine, with private insurers offering only supplementary premium healthcare.[146] In the United States, private health insurance is deeply rooted in the public healthcare system. Implementing a federal single-payer plan would require regulating insurance profits and premiums to conform with the single-payer system, and at that point, private insurance's very existence would be economic deadweight.[147]

For better or worse, implementing direct price controls in the United States may be a political pipe dream, considering the United States's traditional antipathy toward anything that smells like price controls, let alone fully socialized healthcare.[148] A bill allowing the government to negotiate only on behalf of Medicare Part D beneficiaries died in the legislature, since even that was too far a "step down the road to a single-payer, government-run healthcare system."[149]

Politics aside, price controls almost surely would reduce innovation. While any method to make drugs cheaper will reduce R&D to some degree, price controls would have the most drastic effect, forcing price concessions from drug companies without taking advantage of the possibility that drugs

144. *See* U.S. DEP'T OF COMMERCE, PHARMACEUTICAL PRICE CONTROLS IN OECD COUNTRIES 104 (2004), https://2016.trade.gov/td/health/DrugPricingStudy.pdf [https://perma.cc/GC3W-JRKY].

145. For example, the average price of the same drug is 67 percent more in the United States than in Canada. Sona Ashchian, Comment, *Importing/Reimporting Prescription Drugs From Canada to the United States: Temporary Relief for High Drug Prices?*, 11 S.W. J.L. & TRADE AM. 323, 324 (2005).

146. *See, e.g.*, CAN. LIFE & HEALTH INS. ASS'N, A GUIDE TO SUPPLEMENTARY HEALTH INSURANCE, https://www.clhia.ca/domino/html/clhia/CLHIA_LP4W_LND_Webstation.nsf/resources/Consumer+Brochures/$file/Brochure_Guide_To_Health_ENG.pdf [https://perma.cc/4ZTP-DZ82].

147. The deadweight in this scenario would be insurance company profits, which require premiums plus investment returns to always exceed the cost of claims. Assuming a government can fulfill the role of health insurer, premiums in the form of taxes can equal the cost of claims, with minimal overhead and no surplus required.

148. *See* Pear, *supra* note 36.

149. *Id.* Subpart I.A discusses the free-competition approach to American Antitrust Law. As of publication of this Comment, the California Single-Payer bill is projected to die in the Assembly or be vetoed. Skelton, *supra* note 135. Even if it does not, there is a huge difference in the politics of passing single-payer healthcare in one state and doing so nationally. Putting aside the fact that California is traditionally liberal, single payer in a state does not require the essential takeover of the entire healthcare industry—something of which the insurance lobby would not be in favor.

could be subsidized by other actors in the system.[150] Revenue caps would make the problem even worse. Limiting the total amount of money that a drug company could make would mean that a drug company made less money on each drug that it sold after the first.[151] This would essentially penalize R&D reinvestment. Even now, R&D is risky enough that drug companies are turning to mergers and marketing.[152] Revenue caps would seriously exacerbate that problem.

The single-payer system could also be self-defeating in the long term. Less R&D would inhibit the efficiency that new drugs bring to other parts of the healthcare system.[153] Breakthrough drugs may be exorbitantly expensive, yet often are still cheaper than the procedures they replace, like surgery.[154] Furthermore, the political unpopularity of price controls would affect market perception of the riskiness of investing in drug companies. This would increase drug companies' cost of raising capital, which further constrains company profit margins, which in turn hurts investors, magnifying the effect on R&D. One study tentatively found that implementing price controls in the United States would reduce R&D spending by up to 47.5 percent.[155]

Lastly, and somewhat ironically, drug companies' vast profitability has even drawn government investors, such as CalPERS, that provide benefits to the very people that feel the burden of high drug prices in the first place.[156] It is possible, then, that decreasing the profitability of drug companies with a single-payer plan could cause drastic disruptions in the cost to the government (and thus to taxpayers) in administering a health plan.[157]

150. One of the benefits of final-offer arbitration is that it can lower the price of a drug to a consumer more than it lowers the overall price of the drug by forcing insurance companies to share a greater portion of the cost. *See infra* Part III.
151. *See supra* Subpart I.B.1 (discussing the relationship between profits and R&D).
152. *See supra* Subpart I.B.2.
153. *See* Stanton, *supra* note 132, at 152.
154. *See, e.g.*, David S. Geldmacher, *Cost-Effectiveness of Drug Therapies for Alzheimer's Disease: A Brief Review*, 4 NEUROPSYCHIATRIC DISEASE & TREATMENT 549 (2008).
155. Vernon, *supra* note 127, at 24.
156. *See, e.g.*, Stockerblog, *The Ten Largest Holdings of CalPERS, the Biggest U.S. Investor*, SEEKING ALPHA (Dec. 10, 2007, 5:58 AM), https://seekingalpha.com/article/56765-the-ten-largest-holding-of-calpers-the-biggest-u-s-investor [https://perma.cc/3G43-3YE9] (showing Pfizer as one of CalPERS's 10 largest shareholdings).
157. The proposed statewide single-payer system in California would most likely become a national system, with the same benefits and problems, but the onset of these effects would be delayed. Assuming California is the only state at first to enact the plan, prices to Californians would certainly drop, and in the short term, drug companies might be able to make up those profits by increasing prices in the private market in other states. But this would create incentives for more people to buy drugs from California, and political pressure on other states to run a like system. If enough states switch to single-

2. Public and Private Actions for Excessive Pricing

Another proposal is to create a cause of action for excessive pricing.[158] Courts have rejected the application of federal antitrust statutes to excessive pricing, for reasons described in Subpart I.A.[159] In order to avoid preemption by federal antitrust statutes, state consumer protection laws must similarly require that a litigant make a showing of fraud or other "unconscionable conduct" to sue for excessive pricing.[160] While today's drug prices may seem unconscionable, it seems highly unlikely that a court would find pricing behavior to be legally unconscionable when it has been expressly condoned by the U.S. Supreme Court.[161] But even assuming a cause of action could exist, the proposal has serious flaws.

The most pertinent law under which to create an excessive pricing claim is Section 5 of the Federal Trade Commission (FTC) Act.[162] Claims under this law may only be brought by the FTC and do not create a private cause of action.[163] But if the FTC acts as the primary enforcer, the effect is akin to direct government price controls, but with the additional administrative burden, expense, and uncertainty of employing the legal system. For example, the reasonable price of a drug would be decided by a judge who is unfamiliar with the market, necessitating costly expert testimony. Furthermore, actual enforcement would be minimal and unlikely to create systemic changes: The FTC has been understaffed and underfunded for

payer, prices would become intolerable in private market states. In the end, the country would have to decide whether to go with a federal-payer system, in which the problems discussed in this Part would apply, or to bar it altogether. State-by-state single-payer is a possibility, but could create unfair price differences between states simply based on population.

158. *See, e.g.*, Abbott, *supra* note 28; Eric M. Weiss, *Council Approves Bill on Suing Drug Companies Over Costs*, WASH. POST (Sept. 21, 2005), http://www.washingtonpost.com/wp-dyn/content/article/2005/09/20/AR2005092000886.html [https://perma.cc/SY7L-VBUE] (reporting on a bill in Washington, D.C. to create a state right of action for excessive pricing).

159. *See* Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 407 (2004); Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 297 (2d. Cir. 1979) ("A pristine monopolist, we have held, may charge as high a rate as the market will bear.").

160. *See, e.g.*, Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1374 (Fed. Cir. 2007) (finding that Washington D.C.'s excessive pricing statute was preempted by federal law).

161. *Trinko*, 540 U.S. at 407.

162. 15 U.S.C. § 45 (2012).

163. Holloway v. Bristol-Myers Corp., 485 F.2d 986, 988–89 (D.C. Cir. 1973).

nearly its entire history and is only able to pursue a tiny fraction of the over two million complaints it receives in one year.[164]

If instead PBMs or insurers were given a private right to file excessive pricing lawsuits, the transactional costs of filing a lawsuit would likely be passed on to plan beneficiaries. And allowing consumer actions would create a flood of costly litigation for drug companies. Thus, even assuming private claims for excessive pricing could exist, they may not actually result in lower consumer prices. And if PBMs or insurers could sue, they might also come to rely on these causes of action as a means of achieving their desired price points rather than negotiating with drug companies in a way that could best serve all parties.

Arguably, the risk of being sued could cause drug companies to self-correct and lower the price of drugs. But as I discuss below, final-offer arbitration can create the same deterrence industry-wide, with a fraction of the transactional costs of filing multiple lawsuits.[165]

B. Increasing Competition

The other broad group of proposals aims to increase the number of drug manufacturers, thereby increasing the number of competitive drugs. This can be done either by incentivizing or subsidizing additional companies to enter the market or by removing barriers for competitors to enter.[166]

1. Drug Importation and Reimportation

Because drugs are significantly cheaper in other countries,[167] some have suggested expanding consumers' rights to reimport drugs from other

164. FTC, CONSUMER SENTINEL NETWORK DATA BOOK FOR JANUARY-DECEMBER 2013 3 (2014), https://www.ftc.gov/system/files/documents/reports/consumer-sentinel-network-data-book-january-december-2013/sentinel-cy2013.pdf [https://perma.cc/W3T7-XHB7].

165. *See infra* Part III.

166. One unique proposal is the use of 28 U.S.C. § 1498, which allows the government to infringe on privately held patents by licensing other companies to manufacture brand-name drugs. *See generally* Brennan et al., *supra* note 6. This proposal has some of the qualities of both the government-price-control and the increasing-competition types of proposals. The main downsides are: (1) that the amount of royalty compensation to the patent holder would be decided by judges who are relatively unsophisticated in their understanding of this market, which creates an unpredictable and expensive price-control mechanism; and (2) the American distaste for social takeovers in the current climate.

167. For example, the average price of a drug in the United States is 67 percent more than the same drug in Canada. Ashchian, *supra* note 145, at 324.

countries.[168] Many individuals already purchase drugs from Canada over the internet, despite the illegality of it,[169] and the FDA has relaxed the enforcement of rules about bringing prescription drugs across the border for personal use if the prescription is filled in another country.[170] There are two main counterarguments to this proposal. First, the FDA itself has argued that it would be largely unable to regulate the safety of reimported drugs.[171] But reimportation would mostly affect only the most expensive drugs, inevitably those manufactured by U.S. companies and thus already subject to FDA requirements.[172] And the FDA already tests the quality of drugs manufactured overseas[173] and could easily create a list of approved online pharmacies to regulate the market.

The economic counterargument to reimportation is more significant. Drugs are cheaper in Canada because manufacturers are subject to rigid price controls when selling there.[174] Allowing reimportation of American-made drugs sold in the Canadian market effectively subjects U.S. drugs to the Canadian price-control framework. And since the Canadian market is significantly smaller than the U.S. market,[175] U.S. drug companies could find it more profitable to withdraw their drugs from Canada in order to sell at a

168. *See, e.g.*, Elliott A. Foote, *Prescription Drug Importation: An Expanded FDA Personal Use Exemption and Qualified Regulators for Foreign-Produced Pharmaceuticals*, 27 LOY. CONSUMER L. REV. 369 (2015). *Compare* Alliance for Health Policy, *supra* note 20, *with* Sally C. Pipes, *Letting Patients Buy Canadian Drugs Will Only Import Trouble*, HILL (Feb. 2, 2015, 1:00 PM), http://thehill.com/blogs/congress-blog/healthcare/231320-letting-patients-buy-canadian-drugs-will-only-import-trouble [https://perma.cc/9WLG-94S5].

169. Rob Low, *America's Favorite Illegal Canadian Import? Prescription Drugs*, FOX 31 DENVER (Mar. 25, 2015, 10:00 PM), http://kdvr.com/2015/03/25/americas-favorite-illegal-canadian-import-prescription-drugs [https://perma.cc/S3NH-SPRH].

170. Ashchian, *supra* note 145, at 327.

171. AARP, PRESCRIPTION DRUG RE-IMPORTATION QUESTION AND ANSWER SHEET, http://assets.aarp.org/www.aarp.org_/articles/international/ReimportationQA.pdf [https://perma.cc/CFJ9-QBB4].

172. Niteesh K. Choudhry & Allan S. Detsky, *A Perspective on US Drug Reimportation*, 293 JAMA 358, 359 (2005). Canada imports $3.8 billion worth of American pharmaceuticals per year, roughly a third of all of its pharmaceutical imports. U.S. DEP'T OF COM., 2016 TOP MARKETS REPORT PHARMACEUTICALS COUNTRY CASE STUDY: CANADA 1 (2016), https://www.trade.gov/topmarkets/pdf/Pharmaceuticals_Canada.pdf.

173. *How Does FDA Oversee Domestic and Foreign Drug Manufacturing?*, FDA (Nov. 9, 2017), https://www.fda.gov/AboutFDA/Transparency/Basics/ucm194989.htm [http://perma.cc/3NFS-APJM].

174. *See* Stanton, *supra* note 132, at 160–62.

175. U.S. pharmaceutical sales were $333 billion in 2016 whereas Canada's sales were $18 billion in 2015. U.S. DEP'T OF COMMERCE, *supra* note 172, at 7, 15.

higher price in the United States. Canada would then have to allow prices on U.S. drugs to rise in order to keep such drugs in their country.[176]

As for direct importation of Canadian-made drugs, the Canadian manufacturers would be unable to sustain the U.S. market at current prices. Canadian companies sell only 2 percent of the world's pharmaceuticals, whereas nearly 50 percent come from the United States.[177] Demand for Canadian drugs, and their prices, would skyrocket. Lastly, different countries have different patent systems, so a patented drug in the United States may have a generic equivalent in Canada. Thus, even assuming the doubtful scenario in which U.S. pharmaceutical companies lose no sales from reimportation, R&D would likely be chilled because the U.S. patent system would be compromised.

2. Deregulating the FDA

Yet another set of proposals looks to make the process for drug approval cheaper and quicker.[178] Proponents reason that the FDA's stringent manufacturing and clinical testing requirements impose extraordinary costs on drug companies,[179] dissuading them from manufacturing drugs that compete with those already on the market. These startup costs affect the generic market especially.[180] Furthermore, these costs provide a serious capitalization hurdle to startup pharmaceutical companies: The approval process can take up to eleven years,[181] and even the Abbreviated New Drug Approval (ANDA) process for generic drugs can cost up to $15 million.[182] These costs eliminate practically all incentives to produce a generic version of

176. U.S. companies developed the majority of newly patented drugs between 2001 and 2010; the most recent years for which I could find collected data. *See* DEVOL ET AL., *supra* note 12, at 5 tbl.2.

177. Choudry & Detsky, *supra* note 172, at 360.

178. This was recently considered by President Trump. Katie Thomas, *Trump's F.D.A. Pick Could Undo Decades of Drug Safeguards*, N.Y. TIMES (Feb. 5, 2017), https://www.nytimes.com/2017/02/05/health/with-fda-vacancy-trump-sees-chance-to-speed-drugs-to-the-market.html?_r=0. *See generally* Scott Gottlieb, *How Obama's FDA Keeps Generic Drugs Off the Market*, WALL STREET J. (Aug. 19, 2016, 6:25 PM), http://www.wsj.com/articles/how-obamas-fda-keeps-generic-drugs-off-the-market-1471645550; Mike Rappaport, *The Causes of the EpiPen Problem*, L. & LIBERTY (Sept. 1, 2016), http://www.libertylawsite.org/2016/09/01/the-causes-of-the-epipen-problem [https://perma.cc/7PEK-L45T].

179. *See, e.g.*, *The Drug Development and Approval Process*, INDEP. INST., http://www.fdareview.org/03_drug_development.php [https://perma.cc/RYS3-EMGA].

180. *See* Gottlieb, *supra* note 178.

181. *See The Drug Development and Approval Process*, *supra* note 179.

182. *See* Gottlieb, *supra* note 178. The ANDA process allows drugs to be introduced more quickly only if they are shown to be bioequivalent to an existing FDA-approved brand name drug. FTC, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 5 (2002).

drugs that target a specific disease, which is why off-patent drugs such as Daraprim are susceptible to pricing abuses by company managers who treat life-saving AIDS drugs like mortgage-backed securities.[183] Even outside of generics, one can argue that lower startup costs might persuade drug companies to invest in socially valuable but less profitable drugs.

But the tradeoffs are significant. Clinical trials weed out unsafe and ineffective drugs so that sick consumers do not have to waste time or money experimenting with foreign and untested compounds that may be ineffective or have dangerous side effects.[184] Lest history repeat itself, we should keep in mind that the NDA process was developed in direct response to medicinal compounds that turned out to be poisonous.[185] Recent reports of drug companies manipulating clinical trial results should make anyone think twice about relaxing FDA oversight.[186]

Aside from the cost to public health, unsafe drugs create externalized costs as well. In fact, a recent proposal by President Trump to relax FDA regulations was even opposed by drug companies. They feared that insurance companies would deny coverage of untested drugs because of the risk of undiscovered side effects.[187]

And while speeding up the approval process could affect the generic market, it would do little to lower the price of breakthrough drugs. Even assuming deregulation would result in more drugs being brought to market, patent exclusivity would still apply to them, and it is highly unlikely that a company would be able to invent and test a drug effective enough to compete with a breakthrough drug before that drug's patent expired.[188] Even if a competitive drug could be developed from scratch within the roughly thirteen years left of the original drug's patent exclusivity, a company would

183. *See supra* Subpart I.C.

184. For example, at least 21 percent of new drugs are eliminated between the first stage of clinical trials and the last. *The Drug Development and Approval Process*, *supra* note 179.

185. *See* Carlen S. Magad, Comment, *Generic Drugs: Breaking the Definitional Barriers to FDA Regulations*, 76 NW. U. L. REV. 613, 615 (1981).

186. *See, e.g.*, Jim Edwards, *FDA Finds Falsification of Drug Trial Results Affecting Dozens of Companies*, CBS NEWS: MONEY WATCH (July 27, 2011, 4:58 PM), http://www.cbsnews.com/news/fda-finds-falsification-of-drug-trial-results-affecting-dozens-of-companies [https://perma.cc/6WEY-T7Q4] (reporting a nationwide scandal of fabrication and manipulation of clinical trial results).

187. *See* Deena Beasley, *Pharma Industry Shuns Trump Push for Radical Shift at FDA*, REUTERS (Feb. 14, 2017, 10:09 PM), http://www.reuters.com/article/us-usa-trump-healthcare-regulation-analy-idUSKBN15U0GP?feedType=RSS&feedName=topNews [https://perma.cc/72WA-5A5R].

188. *See* Henry Grabowski et al., *Recent Trends in Brand-Name and Generic Drug Competition*, 17 J. MED. ECON. 207, 209–10 (2014).

still need to have the resources and research ready to develop a drug that is as good as, but chemically different from, a blockbuster drug that by definition is unique.

III. THE PROPOSED SOLUTION: FINAL-OFFER ARBITRATION[189]

Final-offer arbitration is a method of alternative dispute resolution originally developed for labor disputes in industries where a strike would jeopardize public interests.[190] First, parties to a negotiation are given a period of time to reach a deal point on their own.[191] If the time lapses and the parties have failed to reach a deal point, both parties are required to submit their best and final offers to an arbitrator (or sometimes a panel of arbitrators). But unlike conventional arbitration, where the arbitrator fashions a remedy from whole cloth, the final-offer arbitrator must select the more reasonable of the parties' final offers. The chosen price is legally binding and typically nonappealable.[192]

Today, final-offer negotiation is applied in disputes ranging from salary negotiations for major-league baseball players,[193] to royalty disputes,[194] to Apple's tax liability.[195] The common thread in these scenarios is situational factors which strip one of the two parties of all or nearly all of its bargaining power.[196] As discussed in Part I, this same dynamic exists in the

189. I am not the first to suggest using final-offer arbitration in the healthcare industry: Its application was originally posited in the limited context of Medicare Part D by Richard Frank and Joseph Newhouse. *See* Frank & Newhouse, *supra* note 13, at 40–42. This Comment expands on their proposal by suggesting its application to all drug-price negotiations and proposing specific procedural rules to ensure that the method will fulfill the desired policy goals.

190. Vincent P. Crawford, *Arbitration and Conflict Resolution in Labor-Management Bargaining*, 71 AM. ECON. REV. 205, 206 (1981); *see, e.g.*, CAL. CIV. PRO. § 1299.6 (2014) (authorizing final-offer-style negotiation in firefighter and law enforcement disputes); *see also* 24 PA. CONS. STAT. § 11-1125-A (2017) (providing for mandatory final-offer arbitration for school employees).

191. Frank & Newhouse, *supra* note 13, at 40–42.

192. JERRY M. CUSTIS, LITIGATION MANAGEMENT HANDBOOK § 9:18 (2011).

193. Josh Chetwynd, *Play Ball? An Analysis of Final-Offer Arbitration, Its Use in Major League Baseball and Its Potential Applicability to European Football Wage and Transfer Disputes*, 20 MARQ. SPORTS L. REV. 109, 109 (2009).

194. *See, e.g.*, Kagan v. Master Home Prods., Ltd., 193 S.W.3d 401 (Mo. Ct. App. 2006).

195. Richard Sansing, *Voluntary Binding Arbitration as an Alternative to Tax Court Litigation*, 50 NAT'L TAX J. 279, 279–80 (1997).

196. For example, public employee unions typically have limited ability to strike, the fundamental bargaining tool in such disputes. *See, e.g.*, OHIO REV. CODE ANN. § 4117.15 (West 2017) (granting cities injunctive rights to stop public employee strikes even in the case of unfair labor practices). A patent-infringer has limited bargaining power against a patent holder, since they are legally accountable to the holder for the fair-market value of their infringement. The MLB has limited negotiation power against a star player

pharmaceutical industry, and the managed care plan was the solution developed as a countermeasure to drug companies' monopolistic bargaining power.

Applying final-offer arbitration to the pharmaceutical market can effect a fundamental rebalancing of the market in a way that both increases accessibility to consumers and preserves as much profit as possible for drug companies. First, final-offer arbitration offers a "strikelike" mechanism to PBMs by imposing a requirement that drug companies set prices reasonably.[197] If a PBM believes that the price of a drug is artificially high, it can wait to submit to arbitration. This reasonableness mechanism should result in lower drug prices. Just how much lower depends on a number of factors, not the least of which is the very definition of a reasonable price.[198]

Because final-offer arbitration can be used to lower drug prices to PBMs and insurers, it can then supplement or even replace certain aspects of the managed care plan. Importantly, unlike other proposals, the flexibility of this solution allows the parameters of a reasonable price to be adjusted to balance the restrictions it places on managed care plans. This allows for fine-tuning of the allocation of costs between manufacturers, insurers, and consumers in a way that best serves all parties.

To understand why, first consider the effect of final-offer arbitration on a seller. Imagine a market in which insurance companies must purchase drugs whenever their beneficiaries submit a prescription.[199] Here, insurance companies are like a police officers' union that is legally barred from striking. The union can complain all it wants, but without the ability to strike, the city is in little danger of disruptions in police services, and thus has little incentive to increase wages. But with final-offer arbitration, an arbitrator could find that the city unfairly exploited its bargaining advantage against the police union, deem the city's wages unreasonable, and legally bind the city to pay the amount requested by the police union. The union now has the ability to leverage the city if it believes the city's wages are unreasonable, and the public is spared the danger of a police strike.[200] Final-offer arbitration could be used to exert similar pressure on drug companies without the social

because such players often generate significant revenue singlehandedly. In the case of Apple, it had already been found deficient and thus had no ability to simply walk away from paying taxes. *See* Apple Comput., Inc. v. Comm'r, 98 T.C. 232, 232 (1992).

197. *See* W. Des Moines Educ. Ass'n v. Pub. Emp. Rel. Bd., 266 N.W.2d 118, 119 (Iowa 1978).

198. *See infra* Part IV.

199. Whether insurance companies need to be restricted this much is debatable. *See infra* Subpart IV.A.

200. *See, e.g.*, *W. Des Moines Educ. Ass'n*, 266 N.W. 2d at 119.

inequity of the "strike-like mechanism" insurers developed themselves—the managed care plan.

Arbitration generally is more suitable for resolving these large-scale union disputes than the court system because it can end the dispute more quickly, with fewer transactional costs, with more flexibility in what evidence to consider, and with greater privacy.[201] Minimizing transactional costs in the drug market is important because arbitration will need to be invoked multiple times at the beginning of every plan year. A cost-saving mechanism that is costly is self-defeating. Furthermore, arbitrators may be selected from people who are familiar with the market, rather than by a judge whose general legal knowledge may be insufficient to fashion remedies that function well in the unfamiliar subtleties of this market.[202]

But conventional arbitration in this market would be ineffective and possibly counterproductive for a different reason. Conventional arbitrators who are free to decide on any deal point tend to compromise down the middle.[203] Where traditional arbitration is compulsory, both parties are incentivized to take more extreme bargaining positions in an effort to drag the midpoint toward their target deal point.[204] Where parties have vastly unequal bargaining power, this effect is magnified. If a buyer's only hope to get its desired price is to compel arbitration, and it knows that an arbitrator will tend toward the middle, it will benefit from being unreasonable. Suppose a buyer wants to buy a drug for $20, but the seller wants to sell it for $25. Both suspect that the arbitrator will settle at the midpoint. The buyer will need to argue for a price that sets $20 at the midpoint, so she thinks initially to ask for $15. But, she then anticipates that the seller will actually argue for $30 in an attempt to try to pull the arbitrator towards its own price. The buyer then realizes she needs to ask not for $15, but for $10, to offset the buyer's $30, and so forth. The seller would plan similarly. This is hardly an efficient use of resources and does nothing to encourage socially beneficial prices.

201. *See id.* at 126; AT&T Mobility LLC v. Concepcion, 563 U.S. 333, 344–45 (2011) (applying this reasoning somewhat more controversially to individual consumer disputes).
202. *See Concepcion*, 563 U.S. at 344–45 ("It can be specified, for example, that the decisionmaker be a specialist in the relevant field, or that proceedings be kept confidential to protect trade secrets. And the informality of arbitral proceedings is itself desirable, reducing the cost and increasing the speed of dispute resolution.").
203. One study found that arbitrators chose a middle point in 82.6 percent of all compulsory firefighter wage arbitration. Hoyt N. Wheeler, *Is Compromise the Rule in Fire Fighter Arbitration?* 29 ARB. J. 176, 179 (1974).
204. *See* Meth, *supra* note 15, at 387.

Final-offer arbitration solves this problem by exposing both parties to the risk of loss even before arbitration begins. Because the arbitrator must choose between the parties' last offers, each party stands to forfeit its entire bargaining position if the arbitrator decides that its offer was less reasonable than the other party's.[205] The optimal way to bargain in this scenario, at least in terms of game theory, is to estimate the arbitrator's reasonable price point and to end the negotiation with a price high enough to capture the bargaining surplus, but closer to the reasonable price than the other party's offer.[206] Thus, in the above hypothetical, suppose the buyer submits an offer of $10. If the seller believes there is a chance that the arbitrator could find $10 reasonable, rather than argue for $25, she would be better off arguing for an amount that reflects her desired amount, adjusted for the expected chance that the arbitrator would not find that amount reasonable.[207] Thus the seller here is incentivized to negotiate reasonably even before arbitration begins. Because it changes negotiating behavior itself, final-offer arbitration can even encourage parties to forgo arbitration entirely. If the parties' reasonable price point estimates are close to one another, their final offers will be close, and they will find it more economically sensible to settle, because the transactional costs of arbitrating will outweigh the risk-adjusted value of winning.[208] And if the parties' estimates are far off the reasonable price point, they will need to carefully rethink their positions in order to avoid the possibility that an arbitrator chooses the other party's offer, thus increasing the negotiating rapport and encouraging settlement.[209]

Alternatively, the system could be implemented in a way that encourages integrative bargaining, which aims to increase the value of an agreement to both parties, rather than one or the other. For example, a PBM may choose to forgo arbitration and simply agree on the price of a certain

205. *See W. Des Moines Educ. Ass'n*, 266 N.W. 2d at 119 ("Thus, there is an element of coercion which encourages mutual agreement . . . .' [F]inal offer arbitration . . . will function as a "strikelike" mechanism by posing potentially severe costs of disagreement in a manner that conventional arbitration does not.'").

206. *See* Meth, *supra* note 15, at 390. In negotiation jargon, the bargaining surplus is the range of all deal points to which both parties would possible agree, be it grudgingly or gleefully. Each party wants to capture more bargaining surplus, which means that the buyer wants to settle on the low range of all possible settlement prices, and the seller wants to settle on the high range.

207. For a thorough analysis of negotiating behavior under final-offer arbitration, see Sansing, *supra* note 195.

208. *See* Meth, *supra* note 15, at 390.

209. *See id.*

drug in exchange for concessions on other drugs that figure more prominently into that specific plan.

The final-offer system is not simply a proxy for price controls, because neither party knows the arbitrator's reasonable price point beforehand. This will have a different effect on the industry than price controls in a few important ways. First, the drug company would feel internal pressure to lower prices and thus would be able to adjust its financial strategies discretely and over time. This would avoid the drastic effects that the immediate implementation of price controls would have on the market, as well as the political backlash of a "socialist revolution" in the drug market. Each drug company, for each drug, would be able to argue why a certain price is reasonable and, presumably, to convince an arbitrator that certain drugs are priced reasonably even as they are now.

Second, requiring drug companies to justify their prices with regard to R&D expenditures could encourage more R&D, offsetting the effects that lower drug company profits have on innovation.[210] Drug companies might allocate more money to R&D to create drugs with genuine pharmaceutical value, as opposed to the many drugs released each year that only differ from preexisting ones by a few molecules, and whose main value is prolonging patent protection.[211] High prices on these drugs strain any standard of reasonableness, and tying the reasonable price of a drug to R&D can distinguish high-value from low-value drugs. Similarly, if a reasonable price is determined in whole or in part by the amount of R&D invested in the drug, the system could make M&A-based drug companies less profitable[212] while allowing drug companies with substantial R&D to continue to be extremely profitable.

As discussed below, final-offer arbitration must be implemented along with restrictions on the ways that insurance companies externalize costs to consumers. This is the key difference between this system and the aforementioned others—its flexibility allows a balance between decreasing drug prices and increasing the portion of the price that insurance companies pay.

210. *See* Stanton, *supra* note 132, at 168; *see also* CONG. BUDGET OFFICE, *supra* note 48, at 2 ("If companies expected to earn less from future drug sales, they would alter their research strategies to lower their average R&D spending per drug.").
211. *See generally* Collier, *supra* note 43.
212. *See supra* Subpart I.B.

IV. HOW FINAL-OFFER ARBITRATION CAN BE IMPLEMENTED

Final-offer arbitration has been adapted to a number of different industries, with procedural variations in each to optimize its effect. Because the goal of implementing final-offer arbitration in the pharmaceutical industry is to allow drug and insurance companies to balance their economic interests in a way that creates optimal social value, implementing it will require a very careful evaluation of the economic and behavioral effects of each procedural variation on each party.[213] Certain combinations of procedural choices could have significant unintended side effects. Predicting the economic effects will be difficult, and these effects will be found only through trial and error. This Part highlights some of the most important choices that will need to be made and suggests possible answers.

A. Restricting Formulary Design

One purpose of giving pharmaceutical buyers the right to final-offer arbitration is to restrict the ability of these companies to externalize costs on to consumers and others through formulary design.[214] But this requires deciding which formulary strategies to restrict. Generally, this decision should consider: (1) the extent to which formulary techniques restrict consumer access or impose costs on other parties in the healthcare system; (2) the extent to which drug prices drop in response to the reasonable pricing requirement; and (3) the effect of other procedural variations on drug price and insurance costs.

Each of the cost-containment strategies has its own unique effect. The most patently unfair (and likely most effective, from the insurer's prospective) of these strategies requires prior authorization of expensive drugs,[215] which results in 70 percent of prescriptions for those drugs not being filled,[216] opportunity costs for doctors of $69 billion annually,[217] and an

213. It should be noted that since final-offer arbitration would have to be mandatory for it to be effective, it would need to be created by statute. Many of these implementation decisions can be incorporated into the statute. For some of the more nuanced decisions, a congressional committee or possibly a new administrative agency might be necessary. But the majority of decisions could simply be made by arbitrators, the parties, and the precedent of previous arbitral decisions.

214. For a discussion of the various ways PBMs externalize costs, see *supra* Subpart I.C.

215. See, for example, the discussion on Sovaldi, *supra* Subpart I.B.1, and the discussion on prior authorization generally, *supra* Subpart I.C.

216. FROST & SULLIVAN, *supra* note 113, at 9.

217. Bendix, *supra* note 47.

indefinite amount of expenditure elsewhere in the healthcare system that results from denying access to consumers as their conditions deteriorate. This Comment recommends eliminating prior authorization and making up the difference in lost profits by lowering drug prices accordingly.[218]

Because price negotiations take place at the beginning of every plan year, the only restriction necessary for the final-offer system to work is to bar the use of midyear nonmedical switching. All drug prices and all formulary decisions regarding coverage and consumer copays will need to be decided together. It would be illogical to bind drug companies to a given price yet allow PBMs to drop that drug if they do not like the arbitrator's price. PBMs would have no incentive to negotiate; they could simply offer unreasonably low prices, wait to see if the arbitrator bites, and then back out if she does not.

Step therapy should be limited such that all cheaper step drugs that an insurer requires before paying for specialty drugs have similar effectiveness and no higher risk of side effects. Giving any more freedom for insurers to make decisions regarding treatment options than pharmacies have under generic drug substitution laws has no social value besides saving insurance companies money.[219] Allowing insurance companies rather than doctors to decide which drugs a patient receives serves patients only indirectly through hypothetically lower premiums. Meanwhile, patients are forced to try possibly less-effective, outdated drugs as their condition deteriorates, and they are put at a greater risk of side effects by trying multiple drugs.[220] Giving insurance companies an economic carrot and stick to deal with drug pricing is more equitable and could save a substantial amount of money.

The question of whether to restrict cost-tier systems or cap patient copays should likely be reserved until after the effects of the arbitration system are better known. For example, if insurance company costs rise significantly after implementation, heavy restrictions on formulary design might cause premiums to rise intolerably. But the tier system and related strategies, like granting preferred drug status, might be necessary in the final-offer system to increase bargaining options and to allow PBMs to bargain for cheap prices on certain drugs in exchange for high prices on others. Keeping

218. Alternatively, insurance companies could be required to compensate doctors for the time they spend fighting prior authorizations. But even this is not perfect because it results in unnecessary patient delays.

219. Generic drug substitution laws permit pharmacies to offer to switch brand name drugs with equivalent generics. *See supra* note 34.

220. *See* Walker, *supra* note 1.

tiered formularies would also allow insurance companies to control the effects of adverse selection without increasing the costs on everyone.[221]

B. What Is the Reasonable Price of a Drug?

Whereas restricting formulary design limits the bargaining power of PBMs, determining what constitutes a reasonable price is the limitation placed on drug companies. From a different perspective, while restricting formulary design would increase drug company sales, a reasonable price requirement means they will have to sell the drugs at a lower price. Thus, the most important factor in fashioning these rules is to balance the economic effects of each.

One factor to consider is the degree of predictability of what an arbitrator would find a reasonable price to be. On one hand, making the criteria for reasonable prices vague encourages reasonable pricing behavior at the negotiating table: The greater the possibility that the arbitrator will choose to side with the PBMs, the more drug companies will be incentivized to avoid arbitration entirely and be reasonable in negotiating. Thus the arbitrator should be free to a certain extent to consider various, even subjective factors, as opposed to applying a rigid rate schedule. On the other hand, too little predictability could make the drug industry so risky that drug companies would have difficulty making financial forecasts, which would increase their cost of capital and chill the industry. An arbitrator's decision must therefore be based on some objective measure in order to ensure at least some price predictability.

This Comment suggests using a mixed approach. The two most common ways of valuing a drug are based on a reasonable rate of return on R&D,[222] or based on its pharmaceutical value.[223] An arbitrator should

221. For example, if all drugs on plan X cost $10, but premiums were very high, the plan would attract only those who need expensive drugs. On the other hand, a drug plan with each drug costing $300, but low premiums, would attract only the healthy. But both are suboptimal for a person in average health. The tier system allows insurance companies to tailor plans according to their typical expenditures based on location, average age, or other factors.

222. This is used in Canada and formerly in the United Kingdom. Stanton, *supra* note 132, at 161, 163; *see also* Brennan et al., *supra* note 6, at 275 (arguing for the use of this metric to determine patent royalties resulting from government patent infringement via 28 U.S.C. § 1498 (2012)).

223. *See* HOUSES OF PARLIAMENT: PARLIAMENTARY OFF. SCI. & TECH., DRUG PRICING 3 (2010), https://www.parliament.uk/documents/post/postpn_364_drug_pricing.pdf [https://perma.cc/3FMY-NKEF]; *see also* Brennan et al., *supra* note 6, at 323.

consider both in determining which party's offer is more reasonable.[224] Additionally, to ensure that restrictions on formulary design do not drown health insurance companies in expenses, arbitrators should also consider the total cost to an insurance company when insuring a given plan.

It should be noted that the dynamics of final-offer arbitration make it unnecessary to actually determine whether a given price is reasonable for a given drug. Even if the arbitrator had predetermined an exact reasonable price beforehand, as long as the parties are unaware of that point, their final offers, and thus the arbitrator's choice, should be unaffected. Thus, the following methods should be applied based on their underlying policy rather than mechanically.

1. Pricing Based on a Risk-Adjusted Rate of Return of R&D Expenses

An arbitrator could determine which offer is more reasonable by comparing a proposed price for a drug to (1) the expenses associated with it, plus (2) a reasonable rate of return based on those expenses. In this metric, the rate of return is typically based off of industry-average profit margins. Of course, in the case of patent-protected goods, monopolistic power creates artificially wide profit margins that do not adequately reflect the market demand for the good.[225] Courts have dealt with this issue in the context of compulsory governmental licensing of patented goods under 28 U.S.C. § 1498.[226] There, courts generally estimate the profit margin as being equal to the cash price that a willing buyer would pay to a willing seller.[227]

First, however, one must determine which expenses to base the rate of return figure on. Although a rate-of-return metric typically uses the fully allocated expenses of research, market, production, and overhead costs of a given drug,[228] pharmaceutical companies might be incentivized to reinvest more into new drug development if the rate of return is calculated using R&D expenses alone, without regard to other expenses. This would obviously necessitate using a greater rate of return, such that if the drug company's total

224. The different types of pharmaceutical monopolies are described *supra* Subpart I.B.
225. This is known as patent deadweight. Brennan et al., *supra* note 6, at 293–94. Deadweight loss refers to the extent to which deadweight leaves consumers unable to buy the patent-protected drug.
226. *See, e.g.*, Tektronix, Inc. v. United States, 552 F.2d 343, 351 (Ct. Cl. 1977) ("[O]nly a reasonable, not an excessive, royalty should be allowed where the United States is the user—even though the patentee, as a monopolist, might be able to exact excessive gains from private users.").
227. *Id.* at 347.
228. *See, e.g.*, *id.* at 350 (assessing a reasonable patent royalty based on total costs).

expenses were deemed reasonable, the drug price would be the same either way.[229] This way, a drug company with more R&D expenditures would be able justify higher prices. But, as discussed in the next Part, if a drug company can prove that the drug provides significant social value, the arbitrator could consider that too.[230] Where a drug company acquires a patent by merger, however, the price could be set with regard to the R&D expenditures of the company that developed the drug. Thus, in the case of Gilead's $11.2 billion acquisition of Pharmasset and its subsequent price hike of Sovaldi from $35,000 to $84,000,[231] Gilead would not be able to include the $11.2 billion merger in the reasonable price baseline, and would instead have to argue for a reasonable price measured only by Pharmasset's original R&D expenses, unless Gilead could show it improved the drug's social value through its own continued research.

Next, the rate of return can be increased to reflect the riskiness of R&D expenditures, since drug research is nonlinear and involves numerous false starts.[232] Arbitrators should acknowledge the extremely high risk associated with R&D and seek to compensate drug companies for taking that risk.[233] A risk-adjusted rate can be arrived at in a few ways, one of which is by allowing the cost of a company's previous failed attempts at creating similar drugs to be included in the R&D expenditure base. Provided the company can demonstrate that the cost of these projects was reasonable, the arbitrator can consider them in determining which of the parties' final offers is fairer.

Deciding a reasonable price point based on a risk-adjusted rate of return on R&D has the benefit of directly tying drug company profits to the expenses

229. Say a company calculates all expenses for a drug to be $1 million, of which $100,000 are R&D expenses. It expects to sell 100,000 units. The company's breakeven price would be $10, and at that point, its rate of return on R&D would be 1000 percent. The arbitrator then determines the average return on R&D of comparable companies was 1200 percent. Applied to this company, then, the arbitrator would begin with a price of $12.

230. *See infra* Subpart IV.B.2.

231. *See supra* Subpart I.B.2.

232. *See* Alliance for Health Policy, *supra* note 20, at 28:30 (describing the drug industry as "a story of failure" in which roughly 90 percent of drugs never get FDA approval).

233. One problem associated with patents is that "they do not reward researchers for the externalities they create for other researchers." Michael Kremer, *Patent Buyouts: A Mechanism for Encouraging Innovation*, 113 Q.J. ECON. 1137, 1141 (1998). If a drug company is awarded a patent for a new drug that treats cancer, the sale price will reflect the extent to which society needs its drug. What it will not reflect, however, is the value of research that its competitors did *not* have to spend researching the same thing; the competitor can now simply learn from the patent. The risk-adjusted rate of return could help compensate for that.

that provide the most social value. If prices were tied, albeit loosely, to this reasonableness standard, drug company managers might find it more profitable to invest more in R&D as opposed to marketing or corporate takeovers, which are less socially valuable, but currently more profitable. This metric also rewards the development of drugs from scratch, which provide far more social benefit than the "substantial fraction of research funds . . . spent on wasteful duplication of existing products."[234] Furthermore, it disadvantages companies that seek to simply buy themselves into the market, rather than innovate themselves.

But this metric has drawbacks. A rate-of-return model encourages inefficient uses of cash and accounting gimmicks to inflate R&D. And it would also be difficult to price a fifty-year-old orphan drug that has significant social value relative to the cost of developing it.[235] In those cases, the price of the drug would be limited, but arbitrarily so.

2. Value-Based Pricing

There are two related approaches to pricing a drug based on the value that it provides to the healthcare system. The first begins by calculating the value of one year in perfect health, which is known as the quality-adjusted life year (QALY).[236] Every disease, from depression to cancer, is then given a value according to its expected length and the extent to which it affects the utility of the life year.[237] A drug's QALY value equals its effect on the length of time which a person suffers from a disease, as well as the extent to which it improves quality of life. A drug's total value would be the extent to which it increases this amount beyond the QALY value of any other drug.[238] This information is already freely available from FDA-required clinical trials.[239]

Alternatively, drug value can be calculated as the total savings gained by the healthcare system by using the drug to avoid hospital expenses and other procedures. Thus, a drug company might try to justify a price on a drug that

234. *Id.* at 1142.
235. See, for example, the discussion on Daraprim, *supra* Subpart I.B.3.
236. *See* Milton C. Weinstein et al., *QALYs: The Basics*, 12 VALUE HEALTH S5, S5 (2009).
237. *Id.*
238. *Id.*
239. F. HOFFMANN-LA ROCHE LTD., UNDERSTANDING CLINICAL TRIALS 5 (2013).

equals a reasonable savings from the cost of alternative treatments that this drug would allow a patient to forgo.[240]

In the case of generics, or where a drug's price as calculated based on R&D seems unreasonably low (for example, a hypothetical drug that cures pancreatic cancer but was found accidentally and very quickly), the value-based pricing model can be used by drug companies to argue that their offered price is more reasonable.

Value-based pricing often leads to high prices—in some cases, even higher than the price point that the drug company would set itself.[241] While this has led some to suggest not using this pricing metric,[242] there is no reason why a drug company in the context of a final-offer arbitration should not be able to introduce such evidence. But because the value of one QALY is controversial and somewhat arbitrary,[243] value-based pricing is only a rough indicator of true value and thus should not be relied on solely either. An arbitrator should also consider that the cost of a drug is incurred by the healthcare system now, yet offsetting savings from forgoing other treatments would not be reaped until years later, if at all.

Despite their inherent uncertainties, value-based metrics for reasonableness are compelling reasons for high drug prices, and they should be considered in conjunction with the others described here.

3. Accounting for Insurance Company Costs

Because formulary designers will be barred from using many of the cost-externalizing formulary strategies that they currently use, an arbitrator reasonably should also consider the total costs to an insurance company for running a proposed plan. For example, an insurer in a state which requires it

240. *See, e.g.*, *Pricey Successor Overtakes $1,000-Per-Pill Sovaldi*, MODERN HEALTHCARE (July 13, 2015), http://www.modernhealthcare.com/article/20150713/NEWS/307139980 [https://perma.cc/J3RM-ZKKQ] (reasoning that Harvoni, currently $98,000 per course, is reasonably priced because it avoids the cost of liver transplants which average $577,000).

241. *See, e.g.*, Michael Hiltzik, *Is That $100,000 Hepatitis Treatment Worth the Price? Yes, but Can Society Afford It?*, L.A. TIMES (Jan. 15, 2016, 2:35 PM), http://www.latimes.com/business/hiltzik/la-fi-mh-that-hepatitis-treatment-20160111-column.html [https://perma.cc/T5XM-AKH6] (stating that Sovaldi, which would have cost Medicare $106 billion to treat those who needed it, was actually cost effective according to a rule of thumb since it cost less than $150,000 per QALY).

242. *See, e.g.*, Brennan et al., *supra* note 6, at 324.

243. In the United States, one QALY equals $50,000, but some think that this number comes more from tradition than from actual value. *See* Peter J. Neumann et al., *Updating Cost-Effectiveness—The Curious Resilience of the $50,000-per-QALY Threshold*, 371 NEW ENG. J. MED. 796, 796 (2014). Some have calculated the QALY upwards of $300,000. *Id.* at 796–97.

to cover at least one drug in each pharmaceutical class might simply be unable to afford the price of a breakthrough drug based on the above metrics. Drug companies have always employed price discrimination in the form of different amounts of undisclosed rebates to different PBMs.[244] In the context of monopoly pricing, this actually results in a net benefit.[245] If a drug company were required to set its prices to all buyers at the lowest amount that any single insurer could pay, the patent system would essentially be circumvented, and R&D would tank. Price discrimination, provided it is used fairly, can help alleviate many of the issues associated with patent deadweight by adjusting the price to the highest point that each buyer is willing to pay, theoretically allowing all buyers to afford the drug in question.[246]

In the event that an insurance company should have to cover a given drug, whether due to federal or state formulary requirements, or otherwise, an arbitrator should consider whether the drug company's drug price would cause premiums to rise intolerably on a given plan (provided an insurance company can demonstrate the need to raise premiums). This can help offset the principle counterargument to closing formulary design: the increase in premiums.[247]

Once more, final-offer arbitration eliminates the need to determine an exact price to deem reasonable, and an arbitrator should remain flexible in deciding whose final offer is closer to the ballpark. Different tests should be employed in determining reasonable price points. The goal should be to balance price points against insurance company costs in a way that provides access to the most people, while rewarding and encouraging new drug development.

C. Other Implementation Issues

Drug companies and PBMs meet each year to negotiate drug prices and drug coverage for all plans in a given plan year. Although PBMs should not be able to remove drugs off a formulary during the plan year,[248] one issue is

244. *See* Richard G. Frank, *Prescription Drug Prices: Why Do Some Pay More Than Others Do?*, 20 HEALTH AFF. 115, 115–16 (2001). Price discrimination allows a seller to sell the same product at different prices to different buyers.
245. *See id.* at 126.
246. *See* Brennan et al., *supra* note 6, at 295 (explaining how price discrimination reduces patent deadweight loss).
247. *See infra* Part V.
248. *See supra* Subpart IV.A.

whether an insurance company can choose not to cover a specific drug at all, as opposed to creating a no-coverage tier with a higher copay.[249] The difference is not particularly important, as a no-coverage tier could leave consumers with the vast majority of the cost, as opposed to all of it. But such a tier would at least give consumers some stability in knowing how much such a drug will cost, rather than gambling on the current market price at the pharmacy. But PBMs could lose significant bargaining power if the insurers with whom they contract had to cover every drug, and the tediousness of deciding on price points for every drug would likely outweigh its social benefit.

That being said, the practice of allowing insurance companies to choose not to cover a drug needs to be squared with the compulsory arbitration process and binding price points. If an insurance company could simply decline to purchase a drug at any point during the negotiations, the purpose of final-offer arbitration would be defeated.[250] As a solution, arbitrators could enforce a mandatory cutoff date early in the negotiations, after which insurance companies could no longer choose to pull out of negotiations for a given drug. Arbitrators could also require insurance companies to create formularies and register them before the negotiations begin.[251]

One procedural variable is whether the arbitrator should adjudicate the price of all drugs on a given formulary or all drugs on the formulary by a given manufacturer (known as package final-offer arbitration), or should instead decide on the price of drugs individually (issue-by-issue).[252] The pharmaceutical industry almost surely requires issue-by-issue. The tedium, risk, and complication of arbitrating every drug on every individual plan would likely make the task impossible. But in issue-by-issue arbitration, only the drugs that companies cannot agree upon will need to be submitted to an

249. Public plans under the Affordable Care Act and Medicare Part D may decide not to cover the drug, but they must include an exception for non-formulary drugs when a prescriber can show that "[a]ll of the covered Part D drugs on any tier . . . would not be as effective . . . [or] would have adverse effects." 42 C.F.R. § 423.578(b)(5)(i) (2018); *see also Exceptions*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Exceptions.html [https://perma.cc/KR7X-34QG].

250. For example, insurance companies could be obstinate in negotiations in order to wait and see what the arbitrator does and then remove the drug from the formulary if they do not get the price they want.

251. The first solution allows insurance companies a bit more flexibility and more opportunity for integrative bargaining. For example, they could enter negotiations and learn that the drug company is trying to promote a certain drug and would want to choose that. On the other hand, requiring formularies to be registered before negotiations begin would simulate the inability to strike which could curb adverse negotiation behavior. *See infra* Part V.

252. Meth, *supra* note 15, at 394–95.

arbitrator. An arbitrator would still be free to consider the total cost of a given plan.

Lastly, who the arbitrator is—and how she is paid—should be carefully considered. One of the principal benefits of arbitration over the court system is that the decisionmaker can be an expert in the field.[253] But an arbitrator also needs to be insulated from political and economic influence. A government-appointed arbitrator is the most likely candidate, but care should be taken to choose an arbitrator who is familiar with the dynamics of the markets and who understands the deeper policy considerations at stake.[254]

V. ASSESSING THE COUNTERARGUMENTS

A significant concern with implementing this proposal is that it would result in higher consumer healthcare costs overall, even if the price of a certain drug is lower, since insurance companies could simply raise premiums to compensate for restrictions imposed on their ability to externalize the cost of drugs.[255]

Undoubtedly it is true that barring PBMs from employing cost-containment strategies, while keeping drugs at current prices, would cause insurance companies to raise their premiums. There are only three parties that could possibly absorb drug costs. Drug companies could pay costs in the form of lower prices; otherwise insurers and consumers divide the cost between themselves. The extent to which insurance premiums go up should be a direct result of the extent to which insurance companies' costs rise.

Assuming for the moment that premiums rise for just cause, a consumer would still be presented with a choice of plan that is significantly more transparent than it is now. Without midyear tier-switching, doctor authorization, and the like, choosing insurance plans would become a simple cost-benefit analysis of which plan fits the needs of a given consumer. If premiums go up, other insurance companies could be encouraged to choose benefits creatively and develop competitive plans with lower premiums.

But there is no guarantee that premiums will rise. This arbitration system can function to some extent as a form of government oversight and ensure that insurance companies do not take advantage of the healthcare

253. CUSTIS, *supra* note 192, at § 9:18(1)(h).
254. The fact that this process will be repeated multiple times per year does, however, limit the potential impact that any one arbitrator might have.
255. *See supra* Subpart I.C.

market and increase premiums for no reason.[256] Despite largely dodging political blame for high drug prices, insurance companies have raised premiums 131 percent between 1999 and 2011[257] and have managed to beat earnings estimates by a 45.7 percent average.[258] Unless insurance companies are somehow hiding razor-thin margins, final-offer arbitration may actually lower premiums. By considering insurance company costs in determining prices, arbitrators can ferret out unfair pricing behavior on the part of the insurance companies. An important predicate to this proposal is that increasing the cost for two of these three parties (consumers and drug companies) creates unacceptable social harm. If one agrees with this premise, insurance companies should subsidize more of the cost of drugs than they do currently.

Another principal benefit of final-offer arbitration is its flexibility. The balance between insurance costs and drug prices can be readjusted as the economic effects of the system play out.[259] For example, if insurers can show a genuine need to raise premiums to intolerably high levels, certain cost-containment strategies can be reintroduced.

Some would argue that implementing final-offer arbitration is as politically infeasible as the other proposals described above. While final-offer arbitration would have to be enacted as a statutory mandate in order to effect industry-wide change, this proposal's circuitous way of regulating prices may be its saving grace in the current political climate, where regulation is a rather dirty word. First, final-offer arbitration legislation would be more likely to pass than other proposals since it is only in the loosest sense a regulation. Unlike a price control system, or the use of compulsory licensing, this system does not directly involve a government entity in bargaining; neither an executive agency nor a legislative body will have anything to do with the bargaining process. Not even the courts need

256. The question of whether arbitrators should also be required to decide on premiums for plans raises a complex policy issue. It seems too draconian to require this. Furthermore, even without direct arbitrator supervision, drug companies would be incentivized to act as whistleblowers if premiums get too high, since fewer consumers on a plan means fewer drug sales.

257. *Fighting Unreasonable Health Insurance Premium Increases*, CTRS. MEDICARE & MEDICAID SERVS. (Nov. 16, 2011), https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/rate review 05192011a.html [https://perma.cc/BYS9-RKPB]. Premiums have risen an average of 25 percent for 2017. Robert Pear, *Some Health Plan Costs to Increase by an Average of 25%, U.S. Says*, N.Y. TIMES (Oct. 24, 2016), https://www.nytimes.com/2016/10/25/us/some-health-plan-costs-to-increase-by-an-average-of-25-percent-us-says.html?_r=0.

258. *Fighting Unreasonable Health Insurance Premium Increases*, *supra* note 257.

259. *See supra* Subparts IV.A–IV.B.

be involved; arbitrators can be selected from outside the government. Second, neither the insurance lobby nor the drug lobby should have significant qualms with the legislation, since an act implementing a final-offer system would not in itself affect drug prices. It is not the framework that will effect change—it is the specific rules regarding reasonable price and formulary design, and the way that they are balanced against one another, that will redistribute resources. Both insurance and drug companies will play a direct role in the design of these specifics, if for the very fact that they will be the ones making arguments as to what constitutes a reasonable price.[260] But the implementation of final-offer arbitration itself is politically neutral; it is merely a fresh board on which to restart the currently chaotic and inscrutable game of pharmaceutical pricing.

Many criticize final-offer arbitration as being too risky for the parties involved.[261] Some may argue that, no matter how the rules are designed, the system imposes too much risk on both pharmaceutical manufacturers, who are forced to undersell their drugs, and on insurance companies, who may have trouble predicting the cost of claims in a given year. But the nature of the pharmaceutical market, where drug companies have practically guaranteed profits through patent protection, makes arbitration less risky to them, and procedural designs can be introduced to alleviate some of the risk to insurers.[262] Furthermore, the cyclical process of renegotiating drug prices each plan year for all plans ensures that an unreasonable arbitration award will not affect any company too drastically, at any one time.

Another counterargument that has been raised against final-offer arbitration since its inception is that the system is gimmicky, academic, or ineffectual.[263] But its widespread use and adoption by state and federal legislatures for use in difficult markets are a testament to its effectiveness. Furthermore, final-offer arbitration has been statistically shown to encourage reasonable negotiation behavior. For example, Michigan switched its labor disputes from conventional arbitration to final-offer arbitration, and the number of settlements increased from 39 percent to 64 percent.[264] This should also demonstrate that final-offer arbitration avoids the oft-criticized

260. This would necessarily include considerations about the way that insurers and PBMs are managing formularies. *See supra* Subpart IV.B.3.
261. *See, e.g.*, Chetwynd, *supra* note 193, at 112–13.
262. *See, e.g.*, *supra* Subpart IV.B.3.
263. Chetwynd, *supra* note 193, at 112.
264. *Id.* at 113.

"narcotic effect" on parties who overuse conventional arbitration simply because it works well for them.[265]

CONCLUSION

Lowering the price of drugs is a bipartisan issue. On the campaign trail, then-candidate Donald Trump suggested deregulating the FDA.[266] The single-payer system was a hallmark of Senator Bernie Sanders's campaign,[267] and senators on both sides of the aisle have considered importing drugs from Canada.[268] The entire issue has been characterized as a "fight against" "Big Pharma greed."[269]

Greedy or not, privatized drug R&D means that we need big pharma. Whether one believes these companies are pure evil or just misunderstood is beside the point. Economically and rationally, the drug price conundrum amounts to a tradeoff between two social goods: If drug prices go up, we get more drugs, but fewer people can buy them, and vice versa.

What is needed is not lower drug prices per se. What is needed is a way to ensure that this market, which is so compromised by monopoly powers, by unscrupulous business practices, and political lobbying, runs efficiently. Direct governmental intervention may be a bad investment in the long term as drug innovation stagnates. Other proposals, such as reimportation or FDA deregulation, are likely to be ineffective for breakthrough drugs with no competitors or to create unacceptable safety hazards.

Implementing final-offer arbitration will allow contending market forces to be balanced, slowly but surely. PBMs can be limited in their use of cost-containment strategies, so that we can be sure that consumers have access to drugs. Then, drug by drug, arbitrators can evaluate the important tradeoffs to be made and balance the cost of healthcare in a way that efficiently allocates capital to the public good. Implemented correctly, this plan can put drugs in the hands of

265. Meth, *supra* note 15, at 407.
266. *See* Beasley, *supra* note 187.
267. Bernie Sanders, *A Single-Payer System Makes Economic Sense*, BERNIE SANDERS (Sept. 11, 2013), http://www.sanders.senate.gov/newsroom/must-read/a-single-payer-system-makes-economic-sense#content [https://perma.cc/YJ4B-9ZNJ].
268. Brad Reed, *Even Ted Cruz Voted to Import Cheaper Drugs From Canada - but These 13 Dems Voted Against It*, RAWSTORY (Jan. 12, 2017, 2:09 PM), http://www.rawstory.com/2017/01/even-ted-cruz-voted-to-import-cheaper-drugs-from-canada-but-these-13-dems-voted-against-it [https://perma.cc/4Y25-FPTH].
269. Bernie Sanders, *Bernie Sanders: Stand Up to Big Pharma Greed. Vote Yes on Proposition 61*, L.A. TIMES (Oct. 21, 2016, 4:00 AM), http://www.latimes.com/opinion/op-ed/la-oe-bernie-sanders-yes-on-proposition-61-20161021-snap-story.html [https://perma.cc/Z2Y2-BYUH].

those who desperately need them, but it can also help our country invest in a future of increasingly good health.