Loyola of Los Angeles Law Review

Volume 56 | Number 1 Article 12

Spring 2-24-2023

Beyond Regulation: Competition in the Pharmaceutical Industry and the Public Manufacturing of Drugs

Jane Kaufman

BEYOND REGULATION: COMPETITION IN THE PHARMACEUTICAL INDUSTRY AND THE PUBLIC MANUFACTURING OF DRUGS

Jane Kaufman[*]

High generic drug prices affect patient access to health care. This is not only detrimental to individual members of the public but is also a problem for the entire healthcare system. Market conditions in the pharmaceutical industry as well as anticompetitive behavior by pharmaceutical companies can directly produce high drug prices. This Note argues that the government should go beyond the regulation of the pharmaceutical industry to lower drug costs and instead become a market player, adding competition to the generic drug market. The public manufacturing of drugs is likely an effective policy solution for the federal government or state governments to implement in addressing the multifaceted problem of rising generic drug costs. Public manufacturing avoids the most common legal challenges to state regulation and is the most direct way to improve patient access to necessary prescriptions.

* J.D. Candidate, May 2023, LMU Loyola Law School; B.A. in History, Duke University, December 2016. A huge thank you to Professor Brietta Clark who provided crucial feedback and helped me immensely. My interest in drug policy was sparked by the journalist Katherine Eban, and I am grateful for the work of all the researchers and journalists cited in this Note. I would also like to thank all the staff and editors of the *Loyola of Los Angeles Law Review* for their hard work, great edits, and most importantly, their time.

TABLE OF CONTENTS

INTRODUCTION

In 2016, a mother in Virginia filled her son's prescription for EpiPen, a drug used to reverse fatal allergic reactions, and found that she would be charged $1,212 for two 2-packs, even with her insurance.[1] As an alternative to the user-friendly EpiPen, a nurse suggested that she get a prescription for epinephrine (the active ingredient in EpiPen) and have a doctor put it into syringes.[2] The syringes would expire in about three months compared to EpiPen's one year shelf life, but the syringes would only cost twenty dollars.[3] While she planned to get the syringes soon, she had her older fifteen-year-old son carry expired EpiPens in the meantime.[4]

High drug costs, like the cost of EpiPen, affect patient access to health care. This is not only detrimental to individual members of the public but is also a problem for the entire healthcare system. High drug costs threaten the efficiency of the entire healthcare market by contributing to overall higher healthcare costs, which are borne by patients, hospitals, insurers, and the government. When people cannot receive necessary drug treatment, more expensive and consequential health issues may arise as a result.

Many Americans know that brand-name prescription drugs can be sold at extremely high prices in the United States.[5] Pharmaceutical companies often justify these high prices by contending that they are necessary to fund further research and development of new drugs; however, data suggests that most of this revenue goes straight to profit.[6] In 2018, brand-name drugs were, on average, 344 percent higher in the United States than in thirty-two comparison countries.[7] Generic drugs, which were created as a way to provide an affordable

1. Ike Swetlitz, *High Price of EpiPens Spurs Consumers, EMTs to Resort to Syringes for Allergic Reactions*, STAT (July 6, 2016), https://www.statnews.com/2016/07/06/epipen-prices-allergies [https://perma.cc/7GST-XMG9].

2. *Id.*

3. *Id.*

4. *Id.*

5. For an extreme example, the Novartis Gene Therapy drug Zolgensma has a $2.125 million annual cost. Hannah McQueen, *The 10 Most Expensive Drugs in the US, Period*, GOODRX HEALTH (June 2, 2022), https://www.goodrx.com/blog/most-expensive-drugs-period/ [https://perma.cc/8CLM-NJPE].

6. *See* Ezekiel J. Emanuel, *Big Pharma's Go-To Defense of Soaring Drug Prices Doesn't Add Up*, THE ATLANTIC (Mar. 23, 2019), https://www.theatlantic.com/health/archive/2019/03/drug-prices-high-cost-research-and-development/585253/ [https://perma.cc/RB8A-E6WD].

7. ANDREW W. MULCAHY ET AL., INTERNATIONAL PRESCRIPTION DRUG PRICE COMPARISONS: CURRENT EMPIRICAL ESTIMATES AND COMPARISONS WITH PREVIOUS STUDIES 36 (2021).

option to consumers, can also be sold at high prices, leaving consumers with no affordable options for obtaining their medication. Around fifty-seven million prescriptions a year cost more than $125 for a one-month supply.[8]

To understand the reasons why this problem is occurring, consider the following example. For decades, Morgantown, West Virginia was home to a pharmaceutical manufacturing plant.[9] The plant's operator, formerly Mylan Pharmaceuticals but then renamed Viartis after a merger with Pfizer, was one of the largest companies in the region and was among the dwindling number of generic drug manufacturers in the United States.[10] The Mylan-Pfizer merger completed in November 2020.[11] Just one month later, the company announced that it was closing the plant and moving most of its drug manufacturing to India and Australia.[12] On July 31, 2021, the plant closed, resulting in the loss of around 1,400 jobs.[13]

The closure was decades in the making. In the early 2000s, as Mylan started to lose market share to Indian companies that could operate at lower costs, Mylan's new corporate leadership started to make a series of decisions to raise profits.[14] In 2007, Mylan acquired EpiPen, which is used by millions of Americans.[15] By 2015, EpiPen represented 40 percent of Mylan's operating profits.[16] In 2016, Heather Bresch, Mylan's then CEO (and daughter of Senator Joe Manchin), was called to Congress to testify about why the price of EpiPen had

8. IQVIA INST., THE USE OF MEDICINES IN THE U.S.: SPENDING AND USAGE TRENDS AND OUTLOOK TO 2025, at 3 (2021).

9. Mike Nolting, *End of an Era: Mylan Workers Leave Morgantown Plant with Fond Memories*, METRONEWS (July 31, 2021, 11:17 AM), https://wvmetronews.com/2021/07/31/end-of-an-era-mylan-workers-leave-morgantown-plant-with-fond-memories [https://perma.cc/FLG4-V6AP].

10. *Id.*; *see* Peter Kolchinksy, *It's Time to Bring Generic Drug Manufacturing Back to the U.S.*, STAT (June 2, 2020), https://www.statnews.com/2020/06/02/bring-manufacturing-generic-drugs-back-to-u-s/ [https://perma.cc/E6WW-V3EY].

11. Nolting, *supra* note 9.

12. Katherine Eban, *"We Can't Reach Him": Joe Manchin Is Ghosting the West Virginia Union Workers Whose Jobs His Daughter Helped Outsource*, VANITY FAIR (July 23, 2021), https://www.vanityfair.com/news/2021/07/joe-manchin-is-ghosting-the-west-virginia-union-workers [https://perma.cc/MC48-52WV].

13. Nolting, *supra* note 9.

14. Eban, *supra* note 12.

15. *Id.*; Emily Willingham, *Why Did Mylan Hike EpiPen Prices 400%? Because They Could*, FORBES (Aug. 21, 2016, 9:00 AM), https://www.forbes.com/sites/emilywillingham/2016/08/21/why-did-mylan-hike-epipen-prices-400-because-they-could/?sh=4c4a599a280c [https://perma.cc/BQ8Y-TYBJ].

16. Willingham, *supra* note 15.

increased 400 percent since Mylan purchased it.[17] She flew by private jet to Washington where she blamed the price hike on a broken healthcare system.[18] The company settled a resulting antitrust class action suit for $264 million in 2022.[19] Earlier, in 2017, Mylan settled a different lawsuit with the U.S. government for $465 million after the Department of Justice accused it of fraud relating to EpiPen rebates.[20] Also around that time, Mylan was named along with other generic drug manufacturing companies in a civil complaint filed by over forty state attorneys general that alleged the companies colluded to keep drug prices artificially high.[21]

Before closing its doors, the Morgantown plant manufactured around seventeen billion doses of various medications each year for American consumers.[22] With operations moving abroad, the absence of domestically manufactured drugs leaves the United States' drug supply vulnerable to global drug shortages, supply chain issues, and regulatory blocks.[23] The story of Mylan provides an illustration of different and intersecting reasons for the high prices and low supply of drugs that jeopardize access, many of which will be explained in this Note.

This Note argues that the government should go beyond the regulation of the pharmaceutical industry to lower drug costs and instead add competition to the generic drug market by becoming a market player. The public manufacturing of drugs is likely an effective policy solution for the federal or state governments to implement in addressing the multifaceted problem of rising generic drug costs. Public manufacturing avoids the most common legal challenges to state regulation and is the most direct way to improve patient access to necessary prescriptions.

Public manufacturing is when a state or the federal government either manufactures its own drugs to sell directly to individuals,

17. Eban, *supra* note 12.

18. *Id*.

19. Jesus Jiménez, *Viatris Agrees to Settle EpiPen Antitrust Litigation for $264 Million*, N.Y. TIMES (Feb. 28, 2022), https://www.nytimes.com/2022/02/28/business/viatris-epipen-settlement.html [https://perma.cc/6TZA-ABGP].

20. Press Release, U.S. Dep't Just., Mylan Agrees to Pay $465 Million to Resolve False Claims Act Liability for Underpaying EpiPen Rebates (Aug. 17, 2017), https://www.justice.gov/opa/pr/mylan-agrees-pay-465-million-resolve-false-claims-act-liability-underpaying-epipen-rebates [http://perma.cc/9WRJ-AZXD].

21. *See* discussion *infra* Section II.B.2.

22. Eban, *supra* note 12.

23. *See* discussion *infra* Section II.B.1.

hospitals, and other government services, or contracts with a private company to do so. California passed the nation's first public manufacturing legislation in 2020, although similar legislation has been proposed federally.[24]

Part I of this Note provides the background for understanding the state of generic drugs today. After explaining the birth of the modern generic drug industry, this Note then discusses the main sources of high drug costs including the market conditions and anticompetitive behavior that produce high prices and, in some cases, result in low or inadequate supply. Part II considers the current legal landscape that allows this problem to persist, including examples of regulatory underenforcement by federal officials on the one hand, and legal impediments to more aggressive regulatory fixes by states on the other. Part II also highlights where regulatory approaches, even if aggressive, may not be well-suited to address certain aspects of this problem, especially low supply due to lack of competitor interest. Part III considers a very different approach to this problem—public manufacturing—as illustrated by California's first-in-the-nation public manufacturing law. Part IV outlines why public manufacturing, in going beyond the state's role as a regulator, could be more effective in lowering certain drug prices and increasing patient access to medication.

I. THE RISE OF COSTLY GENERIC DRUGS

A. The Birth of the Modern Generic Drug Industry

The pharmaceutical industry was completely changed by the Drug Price Competition and Patent Restoration Act of 1984 (the "Hatch-Waxman Act").[25] There were very few generic drugs in the United States prior to the passage of the Hatch-Waxman Act due to a costly and lengthy approval process.[26] The intention of the Hatch-Waxman Act was both to encourage drug innovation by pharmaceutical companies and competition between brand-name and generic

24. *See* discussion *infra* Part III.

25. *See* Drug Price Competition and Patent Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 35 & 42 U.S.C.).

26. *See* Garth Boehm et al., *Development of the Generic Drug Industry in the US After the Hatch-Waxman Act of 1984*, 3 ACTA PHARMACEUTICA SINICA B 297, 299 (2013).

drugs in the market to reduce drug prices, thus forming a compromise between the interests of brand-name and generic manufacturers.[27]

The general process for bringing new drugs to market is as follows. To get to market, drug sponsors must fill out a New Drug Application (NDA) formally proposing that the Food and Drug Administration (FDA) approve a new brand-name pharmaceutical after extensive clinical trials.[28] On average, this process takes at least ten years to complete from initial drug discovery to marketplace, including roughly six to seven years of clinical trials.[29] From there, the brand-name drug has a period of market exclusivity in which no similar generic drug may enter the market.[30]

New drugs approved by the FDA usually receive twelve to sixteen years of market protection, which includes patent protections and/or exclusivity periods.[31] As is true in any industry, monopoly power allows companies to set high prices for their products. Once the exclusivity period or patent term expires, generic manufacturers rush to bring their product to market, and the new competition brings down drug prices for consumers. The market entry of generic drugs is critical to lower drug costs.[32] The price of a generic drug can end up reduced by more than 95 percent of the brand-name drug,[33] which is why this

27. Brandon Ferlas & Chris Ploenzke, *Breakthrough Therapy and the Hatch-Waxman Act*, U.S. PHARMACIST (June 19, 2014), https://www.uspharmacist.com/article/breakthrough-therapy-and-the-hatchwaxman-act [https://perma.cc/GZM2-W3WE].

28. *New Drug Application (NDA*), U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/types-applications/new-drug-application-nda [https://perma.cc/KP69-RTXQ].

29. PHRMA, BIOPHARMACEUTICAL RESEARCH & DEVELOPMENT: THE PROCESS BEHIND NEW MEDICINES 1 (2015). The main trade association of the pharmaceutical industry, PhRMA, estimates each successful drug costs $2.6 billion dollars in research and development, and has a 12 percent clinical trial success rate. *Id.*

30. For a brief discussion on the difference between patent terms, which are usually around twenty years, and exclusivity periods, see *Frequently Asked Questions on Patents and Exclusivity*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity#What_is_the_difference_between_patents_a [https://perma.cc/Z9RR-CUMJ].

31. Aaron. S. Kesselheim et al., *Determinants of Market Exclusivity for Prescription Drugs in the United States*, 177 JAMA INTERNAL MED. 1658, 1661 (2017).

32. Frazer A. Tessema et al., *Generic but Expensive: Why Prices Can Remain High for Off-Patent Drugs*, 71 HASTINGS L.J. 1019, 1021 (2020) ("The market entry of these generic drugs—with market uptake augmented by automatic substitution of brand-name prescriptions at the pharmacy—remains the only market intervention that lowers prescription drug prices consistently and substantially.").

33. RYAN CONRAD & RANDALL LUTTER, U.S. FOOD & DRUG ADMIN., GENERIC COMPETITION AND DRUG PRICES: NEW EVIDENCE LINKING GREATER GENERIC COMPETITION AND LOWER GENERIC DRUG PRICES 3 (2019).

process is so important to the consumer and U.S. healthcare system as a whole.

A generic drug is a medication that uses the same active ingredients as a brand-name medicine and must be bioequivalent, i.e., provide the same clinical benefit as the brand-name drug and function the same in areas like dosage, route of administration, strength, and intended use.[34] To be approved by the FDA, the drug company submits an "abbreviated new drug application" (ANDA) that shows the new drug performs the same way in the body as the branded product.[35] The first ANDA for a specific drug submitted to the FDA may get market exclusivity for 180 days.[36] Prices for generic drugs are much lower than the brand-name drug because the FDA does not require repeat clinical trials of the bioequivalent drug, so the generic manufacturer incurs lower research and development costs to bring their drug to market. Generics obtain ample market share because of state drug product selection laws, which allow pharmacists to dispense a generic prescription when a patient fills a brand-name prescription.[37]

The Hatch-Waxman Act has been successful in enabling a robust generic drug business, which benefits both the consumer and the government. Generics constitute around 90 percent of filled prescriptions in the United States but account for only 20 percent of the total spending.[38] In 2019, generic and biosimilar drugs saved the U.S. healthcare system $313 billion.[39] Close to $2.2 trillion has been saved over the

34. *Generic Drugs: Questions & Answers*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/questions-answers/generic-drugs-questions-answers#q1 [https://perma.cc/MR6T-NFDM]. "The FDA Generic Drugs Program conducts a rigorous review to ensure generic medicines meet these standards, in addition to conducting inspections of manufacturing plants and monitoring drug safety after the generic medicine has been approved and brought to market." *Id.*

35. *See id.* (providing a more robust list of general ANDA requirements).

36. *See* U.S. DEP'T OF HEALTH & HUM. SERVS. ET AL., GUIDANCE FOR INDUSTRY 180-DAY EXCLUSIVITY WHEN MULTIPLE ANDAS ARE SUBMITTED ON THE SAME DAY 2–3 (2003); KATHERINE EBAN, BOTTLE OF LIES 35 (2019) ("Inside generic drug companies, the first-to-file incentive ignited a frenzy. 'Nothing was more important' . . . At issue was not just what day the application arrived at the FDA's Rockville, Maryland, campus, the agency's headquarters for generic drugs, but in what order. 'Minutes mattered' . . . ."); Boehm et al., *supra* note 26, at 299–300 (discussing the "Generic Drug Scandal" during the 1980s in which there was ample fraud surrounding the new ANDA process).

37. Tessema et al., *supra* note 32.

38. ASS'N FOR ACCESSIBLE MEDS., 2020 GENERIC DRUG & BIOSIMILARS ACCESS & SAVINGS IN THE U.S. REPORT 16 (2020). Compare this with generics consisting of just 35 percent of drug volume in comparison countries. MULCAHY ET AL., *supra* note 7, at vii.

39. ASS'N FOR ACCESSIBLE MEDS., *supra* note 38, at 16.

last decade.[40] In 2019, California had the largest savings of any state at $28.3 billion.[41]

While brand-name drugs in the United States are much more expensive than in other comparison countries, the generic drugs on average are cheaper by 16 percent than those abroad.[42] Market competition is what fuels lower costs for generic drugs, and generic prices are significantly lower than brand-name prices for purchasers both at market value and after insurance coverage is included.[43]

Because they are generally higher, brand-name drug prices in the United States can receive much attention and garner societal outrage. However, generic drugs see price increases as well, sometimes making headlines.[44] In fact, between July 2018 and July 2019, 50 percent of all Medicare Part D-covered drugs had list price increases that exceeded the rate of inflation (1.8 percent); 14 percent of all Part D-covered drugs increased by 10 percent or more.[45] Over time, these price increases can be quite large; between 2010 and 2015, prices of 315 of 1441 generic drugs (22 percent) sold in the United States increased by 100 percent or more.[46] These price increases can be felt by pharmaceutical purchasers nationwide and reveal serious gaps in the Hatch-Waxman Act's premise that market competition will keep prices low.

---

40. *Id.* at 4.

41. *Id.* at 22. This is to be expected given California's size.

42. MULCAHY ET AL., *supra* note 7, at vii.

43. *See* Chintan V. Dave et al., *Prices of Generic Drugs Associated with Numbers of Manufacturers*, 377 NEW ENG. J. MED. 2597, 2598 (2017) (presenting data that drugs with just three interchangeable generic competitors attain a 40 percent median reduction from brand-name price, and those with six competitive manufacturers attain a 62 percent median reduction); ASS'N FOR ACCESSIBLE MEDS., *supra* note 38, at 17 ("In 2019, the average generic primary copay was $6.97 versus an average primary copay for brand-name drugs of $56.32.").

44. For example, insulin, of which many people buy a generic version, is talked about for its continuously high prices. *See, e.g.*, Natasha Dado, *Rep. Katie Porter Calls Out 'Skyrocketing Cost' of Insulin with Vial Earrings on World Diabetes Day*, PEOPLE (Nov. 15, 2021, 11:27 AM), https://people.com/politics/rep-katie-porter-california-calls-out-cost-insulin-world-diabetes-day/ [https://perma.cc/7WVF-98TG] (profiling how Representative Katie Porter has been calling attention to unreasonable insulin prices, indicating that this is an important political topic).

45. Juliette Cubanski & Tricia Neuman, *Prices Increased Faster than Inflation for Half of All Drugs Covered by Medicare in 2020*, KAISER FAM. FOUND. (Feb. 25, 2022), https://www.kff.org/medicare/issue-brief/price-increases-continue-to-outpace-inflation-for-many-medicare-part-d-drugs [https://perma.cc/4DNH-F58M]. Medicare Part D is a federal government program that helps Medicare beneficiaries pay for self-administered prescription drugs and only covers certain drugs (called a formulary). *See What Medicare Part D Drug Plans Cover*, MEDICARE.GOV, https://www.medicare.gov/drug-coverage-part-d/what-medicare-part-d-drug-plans-cover [https://perma.cc/3FVU-HDG7].

46. U.S. GOV'T ACCOUNTABILITY OFF., GAO-16-706, GENERIC DRUGS UNDER MEDICARE: PART D GENERIC DRUG PRICES DECLINED OVERALL, BUT SOME HAD EXTRAORDINARY PRICE INCREASES 12 (2016).

Some of these issues can be regulated; however, some may be beyond the control of the government.

In 2020, prescription drug spending in the United States reached $348.4 billion,[47] and that amount is only increasing as net spending could reach $400 billion by 2025.[48] The pharmaceutical industry is colossal, and there are many market forces, interests, and regulatory mechanisms that factor into pricing a drug. For example, because the manufacturer does not sell its product directly to the consumer, price markups are taken by third-party intermediaries, including Pharmacy Benefit Managers (PBMs).[49] Drug manufacturers and PBMs consistently exchange blame for high drug prices:

> [Manufacturers] allege that PBMs are extracting ever-steeper rebates on products and that these savings are not being passed on to patients. PBMs counter that drug manufacturers are merely deflecting attention from rising net prices, that rebates are largely passed on to payers, and that insurers or employers are free to structure their contracts as they see fit.[50]

For those who have health insurance, there are certain insurance industry trends that may also affect what a consumer pays for a drug:

Coinsurance. Instead of a flat copay for a prescription, insurance companies may require the policyholder to pay a percentage of the full cost of the drug, typically 20 to 30 percent.[51] In 2004, only 3 percent of people were enrolled in plans that used a coinsurance percentage, whereas today about a third to half of people in commercial plans are enrolled in such plans.[52] This of course means that for those subject to

47. *See NHE Fact Sheet*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet [https://perma.cc/UHQ9-SXTZ] (archived Aug. 23, 2022).

48. IQVIA INST., *supra* note 8, at 3.

49. *See, e.g.*, *Pharmacy Benefit Managers and Their Role in Drug Spending*, COMMONWEALTH FUND (Apr. 22, 2019), https://www.commonwealthfund.org/publications/explainer/2019/apr/pharmacy-benefit-managers-and-their-role-drug-spending [https://perma.cc/LV5J-T5BC] (explaining the role of Pharmacy Benefit Managers and how drug manufacturers are blaming them for rising drug prices).

50. Erin C. Fuse Brown & Ameet Sarpatwari, *Removing ERISA's Impediment to State Health Reform*, 378 NEW ENG. J. MED. 5, 6 (2018).

51. *See* Lisa L. Gill, *The Shocking Rise of Prescription Drug Prices*, CONSUMER REPS. (Nov. 26, 2019), https://www.consumerreports.org/drug-prices/the-shocking-rise-of-prescription-drug-prices/ [https://perma.cc/4F68-A26S]. Gill suggests this payment scheme is gaining popularity specifically because it is a way for insurance companies to pay less for rising prescription drug costs. *Id.*

52. *Id.*

a coinsurance percentage, the rise in a drug's price is proportionally passed on.

Tiered Prescription Drug List. Usually, insurers will put their list of covered prescription drugs, called a formulary, in tiers to determine how much the policyholder must pay out of pocket. Tier 1 drugs are the least expensive and are often the generic version, while the higher tier drugs are more expensive and are often brand-name or specialty. Drugs put in higher tiers may be cost prohibitive for policyholders, and plans can change their formularies at any time.[53]

Steeper Deductibles. As they try to reduce their monthly premiums, many Americans have chosen insurance plans with a higher deductible—the amount the insured must pay out of pocket before their coverage kicks in.[54] Insurers often cover drug costs without requiring the policyholder to meet a deductible first. However, a growing number of plans (44 percent in 2019) now require a person to meet a deductible before the coverage begins, often requiring the insured to pay the full cost of the drug until they do.[55]

Although there are many factors at play that can cause high generic drug prices, this Note identifies market conditions and anticompetitive behavior of pharmaceutical companies alongside failures of the federal government and state regulation as the main contributors.

B. Main Sources of High Drug Costs

Market conditions in the pharmaceutical industry as well as anticompetitive behavior by pharmaceutical companies can directly produce high drug prices. In some cases, both situations may also result in low or inadequate supply of critical drugs or ingredients, which in turn can also produce price spikes.

1. Market Conditions

General supply and demand principles affect which drugs are profitable for companies to produce. For example, when too many generic competitors enter the market for a drug, prices drop. As a result, companies may no longer find it profitable to make the drug, and when they subsequently exit the market, prices can rise astronomically as

53. *See What Medicare Part D Drug Plans Cover*, *supra* note 45.

54. Aimee Picchi, *Higher Health Insurance Deductibles a Sickening Trend for Americans*, CBS NEWS (June 13, 2019, 3:34 PM), https://www.cbsnews.com/news/high-health-insurance-deductibles-a-sickening-trend-thats-causing-financial-hardship/ [https://perma.cc/3EXA-4JRY].

55. Gill, *supra* note 51.

"remaining competitors seek to leverage increased market share."[56] Having too few competitors can also negatively affect the price of a drug. Certain brand-name drugs may not attract generic competitors in the first place if fewer patients use the prescription, signaling that there are not good profits to be made.[57]

Sole-source or single-source drugs are drugs made by a single manufacturer, including a brand-named drug with no generic competition or an off-patent drug with only one manufacturer in the market.[58] In 2017, almost a third of generic drugs were single-source generic drugs.[59] Between 2014 and 2017, 26.5 percent of price spikes were among drugs with a single manufacturer.[60] In the context of prescription medication, one might consider raising prices to what the market can bear unethical, but some might just consider it a natural part of maximizing profits.

Single-source and sole-source drugs are not the only reason for price spikes. Generic price spikes are common among drugs with three or fewer generic manufacturers. Between 2014 and 2017, 64 percent of spikes were among drugs with three or fewer manufacturers.[61] On the other hand, "a surprising number of price spikes occurred among drugs with eight or more manufacturers, suggesting that increased competition alone may be insufficient to control price. This could be a result of market factors (for example, increased ingredient cost) but also suggests the possibility of price collusion."[62]

The general lack of competition in the pharmaceutical industry concerns not only politicians and legislators but also the FDA. In the early 2000s, the FDA realized that its review of generic drug applications was not keeping pace with submissions, leading to higher drug

56. Tessema et al., *supra* note 32, at 1023.

57. *Id.* at 1022.

58. The FDA keeps a list of drugs that have no generic manufacturers and for which the new drug applications (NDAs) are no longer protected by patents or exclusivity. *See List of Off-Patent, Off-Exclusivity Drugs Without an Approved Generic*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/list-patent-exclusivity-drugs-without-approved-generic [https://perma.cc/5EVV-BEXH]. "The FDA updates this list every six months (in June and December) to improve transparency and encourage the development and submission of ANDAs in markets with little competition." *Id.* The June 2021 list has nine pages of drugs in Part 1, which "identifies those drug products for which [the] FDA could immediately accept an ANDA without prior discussion." *Id.*

59. Aayan N. Patel et al., *Frequency of Generic Drug Price Spikes and Impact on Medicaid Spending*, 40 HEALTH AFFS. 779, 784 (2021).

60. *Id.* at 782.

61. *Id.*

62. *Id.* at 784. Price collusion is addressed *infra*, Section I.B.2.

prices.[63] The Generic Drug User Fee Amendments of 2012 gave more resources to the FDA to approve the ANDAs by "develop[ing] a user fee program to address the growing backlog, improv[ing] application review times, and increas[ing] inspections of foreign manufacturing facilities."[64] This legislation was effective: in 2013, there were 535 generic approvals or tentative approvals, and by 2017 there were 937 approvals or tentative approvals.[65]

Another set of factors that can contribute to high generic drug prices is pharmaceutical market consolidation, such as pharmaceutical manufacturers' mergers with or acquisitions of pharmaceutical product lines.[66] A 2018 study found that the median price for a cohort of thirty-seven off-patent, brand-name drugs (with either monopoly or duopoly levels of competition) more than doubled after an acquisition.[67] Market consolidation can lead to big profits and an increase in shareholder value for pharmaceutical giants.[68] However, when there are fewer manufacturers producing the same generics because they have been acquired by a manufacturing behemoth, those that hold the monopoly or duopoly power now control the price of the drug.

Drug shortages can also cause drug prices to increase. Drug shortages occur when there is less supply of a drug than is needed to meet its demand, or its projected demand. Shortages of generic drugs, whatever the cause may be, are associated with drug price increases during the lack of supply.[69] One 2018 study found that "[p]rescription drug shortages may drive up prices twice as much as they would rise with medicines in abundant supply, adding $230 million a year to U.S. drug

63. *See FDA Approves More Generic Drugs, but Competition Still Lags*, PEW TRUSTS (Feb. 25, 2019), https://www.pewtrusts.org/en/research-and-analysis/issue-briefs/2019/02/fda-approves-more-generic-drugs-but-competition-still-lags [https://perma.cc/EFS8-BJC6].

64. *Id*. Congress also passed Generic Drug User Fee Amendments II in 2017 which gave applications for drugs with three or fewer manufactures priority review and priority review and pre-application support to sole source drugs. *Id.*

65. Sally Choe, *Keynote: Generic Drug Program Update*, U.S. FOOD & DRUG ADMIN. (May 2020), https://www.fda.gov/media/130789/download [https://perma.cc/6M66-B3GW].

66. *See* Ravi Gupta et al., *The Impact of Off-Patent Drug Acquisitions on Prices*, 33 J. GEN. INTERNAL MED. 1007, 1007 (2018).

67. Tessema et al., *supra* note 32, at 1027.

68. *See* Roerich Bansal et al., *What's Behind the Pharmaceutical Sector's M&A Push*, MCKINSEY & CO. (Oct. 10, 2018), https://www.mckinsey.com/business-functions/strategy-and-corporate-finance/our-insights/whats-behind-the-pharmaceutical-sectors-m-and-a-push.

69. *See* Tessema et al., *supra* note 32, at 1030 (explaining that prices have jumped as high as 28.6% after the shortage began); *see also* Patel et al., *supra* note 59, at 782 (detailing that, where data was available, 9.1% of generic drugs experienced a shortage at some point between 2016–17, and among these drugs, 32.3% experienced a price strike compared to 8.9% of drugs that experienced a price spike without a shortage).

costs."[70] Additionally, it is common for price increases to continue after the shortage is resolved as the manufacturer may decide to keep prices elevated.[71] Aside from drug price increases, there are other reasons to be wary of drug shortages: "Shortages can delay or deny needed care for patients, creating a potential lapse in medical care. Shortages can also lead prescribers to use second-line alternatives, which may be less effective or pose additional risks compared to the drug in shortage."[72]

The most common cause of a drug shortage is a production disruption of some kind.[73] Examples include an interruption in manufacturing due to quality concerns, the unavailability of a raw material, or a manufacturer's discontinuation of a drug.[74] Supplies of sterile injectables—drugs that are passed by syringes into the bloodstream like insulin—are especially vulnerable to shortages given the drugs' highly specialized manufacturing processes.[75]

High profile manufacturing closures have also led to drug shortages. In 2011, FDA inspectors found a host of quality issues at an Ohio-based drug manufacturer, but instead of fixing those maintenance issues, the manufacturer shut its factory down.[76] The factory was the United States' sole supplier of Doxil, an injectable chemotherapy drug.[77] As the supply dwindled, prices increased. Similarly, in 2020 the FDA stated that it "continues to see residual effects from the closing of two manufacturing facilities in 2017 and 2018 by major drug manufacturers for remediation purposes, which resulted in the loss of the manufacturing capacity needed for the supplies of

70. Lisa Rapaport, *Drug Shortages May Add $230 Million to Annual U.S. Drug Costs*, REUTERS HEALTH (Sept. 21, 2018, 12:40 PM), https://www.reuters.com/article/us-health-drug-shortages-pricing/drug-shortages-may-add-230-million-to-annual-u-s-drug-costs-idUSKCN1M12LC [https://perma.cc/VG6B-RWC7].

71. Tessema et al., *supra* note 32, at 1029.

72. U.S. FOOD & DRUG ADMIN., DRUG SHORTAGES FOR CALENDAR YEAR 2020 2 (2020) [hereinafter DRUG SHORTAGES 2020].

73. *See* U.S. FOOD & DRUG ADMIN., STRATEGIC PLAN FOR PREVENTING AND MITIGATING DRUG SHORTAGES 11, 12 (2013) [hereinafter DRUG SHORTAGES STRATEGIC PLAN].

74. *Id.* at 12. In 2013, the FDA determined the top reasons for drug shortages were: manufacturing issues (37%), raw material unavailability (27%), and delay and capacity issues (27%). Valerie Jensen, *Preventing and Mitigating Drug Shortages—FDA's and Manufacturers' Roles*, U.S. FOOD & DRUG ADMIN. (Mar. 21, 2016), https://www.fda.gov/downloads/drugs/newsevents/ucm493617.pdf [https://perma.cc/NLT7-BJQN].

75. Jensen, *supra* note 74, at 12.

76. Farah Stockman, Opinion, *Our Drug Supply Is Sick. How Can We Fix It?*, N.Y. TIMES (Sept. 18, 2021), https://www.nytimes.com/2021/09/18/opinion/drug-market-prescription-generic.html [https://perma.cc/ZQQ5-NKCQ].

77. *Id.*

numerous drugs."[78] Closures will likely continue to happen in the future as the generic drug industry sees massive consolidation. In 2017, for example, just four companies produced more than 50 percent of all generic drugs.[79]

As drug manufacturing is increasingly outsourced, the potential for more frequent shortages arises. Drugs are made up of two components: (1) the active pharmaceutical ingredient (API), which is the central ingredient that produces the intended effect of the medication; and (2) the excipient, which is a non-drug substance, such as lactose or mineral oil, that helps deliver the medication to a person's system.[80] Of the top one hundred generic medicines consumed in the United States, 83 percent did not have a domestic source of an API, and 11 percent had only one domestic source.[81] Of the forty-seven most-prescribed antivirals, 97 percent had no domestic source of an API, and the other 3 percent had only one domestic source.[82] When there are manufacturing issues in another country, the FDA lacks the capabilities to prevent a shortage. For example, a 2016 explosion at a chemical plant in China led to a global shortage of an intravenous antibiotic because the plant was likely the world's sole source of the active ingredient used to make it.[83]

Once a shortage occurs, there is only so much the government can do via regulation to help fix the problem, even in the United States. The FDA cannot compel a pharmaceutical manufacturer to resume or increase production of any drug.[84] However, the FDA can work with the current manufacturer to investigate the cause of supply chain issues, expedite inspections and reviews to approve new sources of the drug more quickly, assess the extent of the shortage, and encourage competitors to increase production to cover the shortfall.[85]

78. DRUG SHORTAGES 2020, *supra* note 72.

79. Robin Feldman, *Drug Companies Keep Merging. Why That's Bad for Consumers and Innovation.*, WASH. POST (Apr. 6, 2021, 6:00 AM) https://www.washingtonpost.com/outlook/2021/04/06/drug-companies-keep-merging-why-thats-bad-consumers-innovation/ [https://perma.cc/7QQ8-KTAE].

80. Kathlyn Stone, *What Is an Active Pharmaceutical Ingredient (API)?*, VERYWELL HEALTH (July 27, 2022), https://www.verywellhealth.com/api-active-pharmaceutical-ingredient-2663020/ [https://perma.cc/5V67-2TMP].

81. Jill Young Miller, *Study: US Health Security at Risk Because of Medicine Manufacturing Limits*, OLIN BLOG (Aug. 5, 2021), https://olinblog.wustl.edu/?s=us+active+pharmaceutical [https://perma.cc/Y4RW-74E8].

82. *Id.*

83. Stockman, *supra* note 76.

84. Tessema et al., *supra* note 32, at 1030.

85. DRUG SHORTAGES 2020, *supra* note 72, at 13–14.

Manufacturers must report shortages to the FDA, which maintains a list of the shortages and discontinuations.[86] The FDA perhaps has improved its ability to help prevent drug shortages. At the height of the drug shortage crisis in 2011, there were 250 shortages, while during the COVID-19 crisis in 2020 there were forty-three drug shortages.[87] The FDA estimates that it successfully prevented 199 drug shortages during the 2020 calendar year.[88]

The FDA became much more flexible with its power during the COVID-19 pandemic in 2020. To support the medical system, the FDA expedited reviews of drug applications and used "regulatory flexibility" to increase COVID drug supplies.[89] Of course, there were added complications during the pandemic due to global supply chain disruptions and the flurry of drug treatments for the virus. For example, physicians desperate for effective treatments began prescribing hydroxychloroquine, an anti-parasitic used to treat and prevent malaria, touted by the then-President Donald Trump as an effective preventative drug for COVID-19.[90] Although the FDA authorized hydroxychloroquine for emergency use and some hospital protocols encouraged doctors to consider the drug for patients, the preliminary results of a large controlled trial did not find it to be an effective treatment.[91] This confusion led to global hydroxychloroquine shortages, and "[p]atients who could not access their antimalarial drugs faced worse physical and mental health outcomes as a result."[92]

The global and domestic supply of drugs and their active ingredients is precarious. Manufacturing issues can lead to a lower supply of

86. *FDA Drug Shortages*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/drugshortages/ [https://perma.cc/Q3LA-5RVH].

87. DRUG SHORTAGES 2020, *supra* note 72.

88. *Id.* at 3.

89. Lianna Matt McLernon, *FDA Went Flexible to Mitigate Shortages During COVID-19*, CTR. FOR INFECTIOUS DISEASE RSCH. & POL'Y (July 7, 2021), https://www.cidrap.umn.edu/news-perspective/2021/07/fda-went-flexible-mitigate-shortages-during-covid-19 [https://perma.cc/48TT-7DER].

90. *See* Linda Qiu, *Trump's Inaccurate Claims on Hydroxychloroquine*, N.Y. TIMES (June 20, 2020) https://www.nytimes.com/2020/05/21/us/politics/trump-fact-check-hydroxychloroquine-coronavirus-.html?searchResultPosition=3 [https://perma.cc/CF4N-2RLQ]; Susan Dominus, *The Covid Drug Wars That Pitted Doctor vs. Doctor*, N.Y. TIMES (Aug. 5, 2020), https://www.nytimes.com/2020/08/05/magazine/covid-drug-wars-doctors.html [https://perma.cc/2EKV-NEAA].

91. Dominus, *supra* note 90.

92. Press Release, Am. Coll. Rheumatology, Patients Reported International Hydroxychloroquine Shortages Due to COVID-19 (Nov. 6, 2020), https://www.rheumatology.org/About-Us/Newsroom/Press-Releases/ID/1121 [https://perma.cc/B9MU-98RP].

drugs for the same demand, which can cause increases in drug pricing for pharmaceutical purchasers and consumers.

2. Anticompetitive Behavior

There are two main ways companies make decisions or engage in anticompetitive behavior that directly cause increased generic drug prices. First, generic manufacturers can choose to enter the market where there is little to no competition and set a high price for the drug. One example of this is Mylan and its acquired product EpiPen discussed in the introduction to this Note.[93]

In 2016, the U.S. Senate Special Committee on Aging produced a bipartisan report investigating the problem of high generic drug prices.[94] The report contained detailed case studies of four companies that "followed a business model (with some variation) that enabled them to identify and acquire off-patent sole-source drugs over which they could exercise de facto monopoly pricing power, and then impose and protect astronomical price increases."[95] The report identified five elements in this business model in the table reprinted below:[96]

Sole-Source. The company acquired a *sole-source drug*, for which there was only one manufacturer, and therefore faces no immediate competition, maintaining monopoly power over its pricing.
Gold Standard. The company ensured the drug was considered the *gold standard*—the best drug available for the condition it treats, ensuring that physicians would continue to prescribe the drug, even if the price increased.
Small Market. The company selected a drug that served a *small market*, which were not attractive to competitors and which had dependent patient populations that were too small to organize effective opposition, giving the companies more latitude on pricing.
Closed Distribution. The company controlled access to the drug through a *closed distribution system* or specialty pharmacy where a drug could not be obtained through normal channels, or the company used another means to make it difficult for competitors to enter the market.
Price Gouging. Lastly, the company engaged in *price gouging*, maximizing profits by jacking up prices as high as possible. All of the drugs investigated had been off-patent for decades, and none of the four companies had invested a penny in research and development to create or to significantly improve the drugs. Further, the Committee found that the companies faced no meaningful increases in production or distribution costs.

93. *See* discussion *supra* notes 9–24 and accompanying text.

94. SUSAN M. COLLINS & CLAIRE MCCASKILL, SPECIAL COMM. ON AGING, U.S. SENATE, SUDDEN PRICE SPIKES IN OFF-PATENT PRESCRIPTION DRUGS 13 (2016) [hereinafter SPECIAL COMMITTEE ON AGING REPORT].

95. *Id.* at 4.

96. *Id.*

One of these companies was Turing Pharmaceuticals, run by the infamous hedge fund manager Martin Shkreli, the "Pharma Bro."[97] Since 1953, Daraprim has been used to treat a parasitic infection that is especially dangerous for people who are immunocompromised, such as those with HIV or those who have recently had organ transplants.[98] There was no generic version of this drug available; however, Daraprim, whose patents had long expired, was only being sold for $13.50 a pill.[99] Turing Pharmaceuticals acquired the rights to the drug in 2015 and raised the list price 5,000 percent to $750 a pill overnight.[100] Per a deal with the previous manufacturer, Daraprim was in "restricted distribution," which could "reduce, if not eliminate, the opportunity for a second generic entrant to furnish sufficient quantities of the drug to patients in order to complete the necessary bioequivalence studies required for FDA approval."[101] In other words, restricted or closed distribution channels make it hard for generic manufacturers to get ahold of the drug to examine it and formulate a biosimilar version.

At the time, Shkreli said that the drug was so infrequently used that the price increase would not affect many people or the health system as a whole, and that the profits would be used to develop more treatments for the parasitic infection.[102] Later, Shkreli explained on a radio show that he was maximizing profits as he was supposed to by law, that the price increase was merely "business," and that no one would have to pay full price except for insurance companies (although he did allow that insurance companies may pass on some of the price to the consumer).[103] Turing's controlled distribution tactics prevented

97. *Id.* at 4, 7.

98. Sydney Lupkin, *A Decade Marked by Outrage Over Drug Prices*, NPR (Dec. 31, 2019, 1:16 PM), https://www.npr.org/sections/health-shots/2019/12/31/792617538/a-decade-marked-by-outrage-over-drug-prices [https://perma.cc/EQN2-PPHN].

99. *Id.*

100. *Id.*

101. SPECIAL COMMITTEE ON AGING REPORT, *supra* note 94, at 37 (quoting written testimony from Howard Dorfman, former General Counsel of Turing Pharmaceuticals).

102. Andrew Pollack, *Drug Goes From $13.50 a Tablet to $750, Overnight*, N.Y. TIMES (Sept. 20, 2015), https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html [https://perma.cc/24HR-U45E]. However, other physicians interviewed by Congress said Daraprim as prescribed was already a highly effective treatment, and a new drug was not urgently needed. SPECIAL COMMITTEE ON AGING REPORT, *supra* note 94, at 41.

103. Breakfast Club, *Martin Shkreli Interview at The Breakfast Club Power 105.1 (02/03/2016)*, YOUTUBE, at 08:00 (Feb. 3, 2016), https://www.youtube.com/watch?v=JTNOWSKMS10 [https://perma.cc/8XVX-R6VC]. Interestingly, in recent years, Shkreli became the subject of media suggesting that public opinion surrounding his behavior may have softened. *See* Stephanie Clifford, *The Journalist and the Pharma Bro*, ELLE (Dec. 20, 2020),

some hospitals from carrying Daraprim, and one doctor stated that many hospitals with access to the drug would find it too expensive to carry.[104] The FDA was able to approve a generic version of the pill five years later, in 2020.[105] However, as of September 9, 2020, the price of Daraprim still remained at $750.[106]

Companies can also make the decision to organize with other companies to artificially keep the price of certain generic drugs high. A massive antitrust case brought by forty-four state attorneys general is going through the court system at the time of writing.[107] The suit seeks damages from pharmaceutical companies and individual company executives under various antitrust consumer protection laws.[108] The complaint alleges that "competitors in the generic drug industry would systematically and routinely communicate with one another directly, divvy up customers to create an artificial equilibrium in the market, and then maintain anticompetitively high prices."[109] The complaint specifically singles out Teva Pharmaceuticals as the leader of the co-conspirators and says that together the group of companies "embarked on one of the most egregious and damaging price-fixing conspiracies in the history of the United States."[110] Allegedly, Teva significantly raised prices on 112 of their drugs over a nineteen-month period, and colluded with their competitors on at least eighty-six of them.[111] On April 4, 2014, over six manufacturers raised the prices of twenty-two generic drugs by as much as 185 percent.[112] Additionally, on July 3, 2013, Teva decided to raise the price of twenty-one drugs by as much as 2,762 percent.[113] A few weeks after the April 4 price increases went into effect, Teva's own executive calculated a net

https://www.elle.com/life-love/a35021224/martin-shkreli-christie-smythe-pharma-bro-journalist/ [https://perma.cc/RXJ2-6XJ3]; PHARMA BRO (1091 Pictures 2021).

104. Pollack, *supra* note 102.

105. Shelby Lin Erdman & Jamie Gumbrecht, *FDA Approves Generic Form of $750 Pill Daraprim*, CNN (Feb. 29, 2020), https://www.cnn.com/2020/02/29/health/daraprim-generic-version/index.html [https://perma.cc/LK6Y-NABP].

106. Andrew Siddons, *Drug Price Spikes Still Unchecked, Five Years After Controversy*, ROLL CALL (Sept. 9, 2020, 6:02 AM), https://www.rollcall.com/2020/09/09/drug-price-spikes-still-unchecked-five-years-after-controversy [https://perma.cc/KM82-U3B9].

107. *See In re* Generic Pharm. Pricing Antitrust Litig., 368 F. Supp. 3d 814, 822 (E.D. Pa. 2019).

108. Complaint at 1–9, Connecticut v. Teva Pharma. USA, No. 19-cv-00710-MPS, 2019 WL 2126100, at *1–9 (D. Conn. May 10, 2019) [hereinafter Complaint].

109. *Id.* at 2.

110. *Id.*

111. *Id.* at 3.

112. Tessema et al., *supra* note 32, at 1035.

113. *Id.*

increase in sales to Teva of roughly $214 million per year as a result.[114] The same executive calculated that "as a result of the July 3 price increases, plus Pravastatin and one other drug, [there] was a staggering $937,079,079 (nearly $1 billion) *per quarter* [increase in sales revenue] to Teva."[115] This was possible for a number of reasons, but the main one was that giant pharmaceutical companies often had total market share of the drugs and could easily collude with one another.[116]

There have been other recent antitrust cases, some of which have been from the pharmaceutical industry regulating itself.[117] Thus, collusion in this way is risky for the drug manufacturers, but profits made by these efforts may outweigh the risk of government prosecution.

II. LEGAL LANDSCAPE ENABLING CURRENT MARKET CONDITIONS

The legal system as it currently stands is ineffective in controlling market conditions that threaten patient access to critical drugs. Because there is underenforcement by federal policy, states must attempt to regulate the industry. However, states face serious legal impediments to more aggressive regulatory fixes. Because there is little preventative regulation, state and federal governments must spend ample time and resources prosecuting illegal behavior after the harm is already done to the health care system.[118] Additionally, regulation cannot address certain aspects of this problem, like a low supply of drugs due to lack of competitor interest.

The federal government has not been able to pass cohesive legislation that can help regulate the price of generic drugs and the pharmaceutical industry until very recently. For example, "at least fifty separate pieces of legislation that seek to control prescription drug prices were introduced in the Senate and the U.S. House of Representatives in 2019."[119] The executive branch has also made calls to action. President Trump unveiled policies to lower prescription drug prices, which ultimately were delayed and struck down by courts.[120] President

114. Complaint, *supra* note 108, at 239.

115. *Id.* at 211.

116. For example, for one price-fixed generic drug, Teva had 65 percent of the market share and another manufacturer, Lupin Pharmaceuticals, had 35 percent of the market share. *Id.* at 52.

117. *See* Michael S. Sinha et al., *Antitrust, Market Exclusivity, and Transparency in the Pharmaceutical Industry*, 319 J. AM. MED. ASS'N 2271, 2271 (2018).

118. *See, e.g.*, Complaint, *supra* note 108.

119. Gill, *supra* note 51.

120. Juliette Cubanski et al., *A Status Report on Prescription Drug Policies and Proposals at the Start of the Biden Administration*, KAISER FAM. FOUND. (Feb. 11, 2021),

Biden made drug pricing policy a central part of his agenda and was successful in passing a sweeping bill that includes drug pricing reform for Medicare.[121] The bill enables the federal health secretary to negotiate certain drug prices for Medicare and caps the out-of-pocket prescription drug costs for people on Medicare at $2,000 a year, effective starting in 2025.[122] These new policies will cut Medicare drug costs by an estimated $287 billion over ten years.[123] Although this legislation is likely to help millions of Americans, it could take years to find out if these policies are successful, and they are only aimed at Medicare recipients, leaving millions of Americans without drug pricing protections.

In the absence of cohesive federal policy, states must attempt to create their own to prevent certain corporate behavior or try to change the way the government functions as a consumer of prescription drugs, like in the context of Medicaid. However, state laws are often preempted, and regulatory efforts are often blocked by courts as seen below.

The state has many roles in its interactions with the pharmaceutical industry. Professor Isaac D. Buck, in his article *The Drug (Pricing) Wars: States, Preemption, And Unsustainable Prices*, identifies the state as a payer, consumer, market facilitator, overseer, and regulator.[124] The most important "hat" the state wears when trying to control drug prices is as a regulator "in which the state emboldens and unleashes its most powerful arm—that of prosecutorial legal enforcement—to punish pharmaceutical companies for charging too much for their prescription drugs."[125]

States often have a difficult time passing legislation regulating drug pricing because of challenges coming from the pharmaceutical industry that assert the legislation violates federal law. As Professor Isaac Buck explains, there are four main regulatory clogs that states

https://www.kff.org/medicare/issue-brief/a-status-report-on-prescription-drug-policies-and-proposals-at-the-start-of-the-biden-administration/ [https://perma.cc/QMT5-DXBG].

121. Inflation Reduction Act of 2022, H.R. 5376, 117th Cong. (2022).

122. Barbara Sprunt, *Biden Signs Sweeping Climate, Health Care, Tax Bill into Law*, NPR (Aug. 16, 2022, 4:35 PM), https://www.npr.org/2022/08/16/1117709411/biden-signs-sweeping-climate-health-care-tax-bill-into-law [https://perma.cc/L5B3-AN75].

123. *Estimated Budgetary Effects of Subtitle I of Reconciliation Recommendations for Prescription Drug Legislation*, CONG. BUDGET OFF. (July 8, 2022), https://www.cbo.gov/publication/58290 [https://perma.cc/DY68-ETXW].

124. Isaac D. Buck, *The Drug (Pricing) Wars: States, Preemption, and Unsustainable Prices*, 99 N.C. L. REV. 167, 180 (2020).

125. *Id.* at 201.

often face when passing drug pricing legislation: ERISA, Medicaid Waiver Requests, patent law generally, and the dormant Commerce Clause.[126]

ERISA. The Employee Retirement Insurance Security Act of 1974 (ERISA),[127] limits state power when attempting to regulate private insurance plans.[128] As applied to the pharmaceutical industry, "[w]hen states interfere with the prices that can be charged to insurance companies by drug companies, ERISA is likely to be activated to block the state efforts."[129] ERISA is broadly preemptive: "[a]lthough federal law typically displaces conflicting state law in cases where compliance with state law would make compliance with the federal law impossible, ERISA goes further, broadly preempting 'any and all' state laws that relate to an ERISA plan, regardless of whether they conflict with existing federal laws."[130] Around 60 percent of Americans with employer-based coverage have private insurance plans that are covered by ERISA.[131] An example of state legislation that is preempted by ERISA a requirement for PBMs (the "middlemen" of the drug distribution process) to disclose their pricing markups to consumers or regulators.[132] Because of ERISA, states often make policy that affects only Medicaid or other state and local health plans.

Medicaid Waiver Requests. States are frequently blocked from regulating private insurance per ERISA, but they do have more control over public insurance, like Medicaid.[133] States traditionally have ample regulatory power over Medicaid; however, they are still subject to federal guidelines. States must get waivers from the federal agency Centers for Medicare & Medicaid Services (CMS) "to test new or existing ways to deliver and pay for health care services in Medicaid."[134] In 2018, Massachusetts was denied a waiver request "to establish its own drug formulary similar to private insurance companies" by

126. *Id.* at 202–11.

127. Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406, 88 Stat. 829 (1974).

128. *See* Gobeille v. Liberty Mut. Ins. Co., 136 S. Ct. 936, 946 (2016) ("ERISA pre-empts a state law that regulates a key facet of plan administration even if the state law exercises a traditional state power.").

129. Buck, *supra* note 124, at 204.

130. Brown & Sarpatwari, *supra* note 50.

131. *Id.*

132. *Id.*

133. Buck, *supra* note 124, at 207.

134. *State Waivers List*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/index.html [https://perma.cc/S5UN-ZVUV].

determining which drug its Medicaid would cover.[135] There was not a legal explanation for the denial, and some scholars suggest it may have been a political decision by CMS.[136]

Patent Law. The process of introducing generic drugs into the market begins once certain patents for brand-name drugs expire, which is why generic drugs are also called "off-patent" drugs. This process can be undermined by a strategy in the industry known as "pay-for-delay," in which brand-name companies sue generic manufacturers about to enter the market for patent infringement to ultimately reach a settlement agreement paying the generic company to keep its drug off the market so that the brand-name company can keep its price high.[137] In 2019, California passed AB 824[138] as an attempt to increase antitrust scrutiny of these schemes.[139] The Association of Accessible Medicines, a pharmaceutical trade organization, sued in federal court arguing the law attempts to regulate interstate commerce, clashing with the Commerce Clause.[140] As of December 2021, the law has been temporarily enjoined.[141]

Dormant Commerce Clause. The dormant Commerce Clause is a court made doctrine that interprets the Commerce Clause as implicitly restraining state authority "even in the absence of a conflicting federal statute."[142] States cannot regulate in a way that discriminates against interstate commerce unless they prove that there was no other alternative to protect legitimate state interests.[143] In practical terms, this means that states cannot facially or inadvertently regulate the activities of companies outside of the state. Anti-price gouging laws have been blocked by the dormant Commerce Clause legal theory. For example,

135. Virgil Dickson, *CMS Denies Massachusetts' Request to Choose Which Drugs Medicaid Covers*, MOD. HEALTHCARE (June 27, 2018, 1:00 AM), https://www.modernhealthcare.com/article/20180627/NEWS/180629925/cms-denies-massachusetts-request-to-choose-which-drugs-medicaid-covers [https://perma.cc/CPT2-FSSW].

136. Buck, *supra* note 124, at 207–08.

137. *See* Kevin Wallentine, Note, *Shifting the Burden on Pay-For-Delay Challenges: Analyzing AB 824's Effects on Reverse Payment Settlements and Drug Costs*, 54 LOY. L.A. L. REV. 367, 369 (2020).

138. Assemb. B. 824, 2019–2020 Leg., Reg. Sess. (Cal. 2019).

139. Wallentine, *supra* note 137, at 369–70 ("[AB 824] shifts the burden to the settling companies to prove their arrangement is not anticompetitive.").

140. Nick Cahill, *Judge Halts California Ban on 'Pay to Delay' Pharma Deals*, COURTHOUSE NEWS SERV. (Dec. 9, 2021), https://www.courthousenews.com/judge-halts-california-ban-on-pay-to-delay-pharma-deals [https://perma.cc/BC3S-LH9Y].

141. *Id.*

142. United Haulers Ass'n Inc., v. Oneida-Herkimer Solid Waste Mgmt. Auth., 550 U.S. 330, 338 (2007).

143. Dean Milk Co. v. City of Madison, 340 U.S. 349, 354 (1951).

the Fourth Circuit applied the dormant Commerce Clause to Maryland's anti-gouging law, which would prohibit unconscionable or excessive prices for prescription drugs.[144] The court held that the law violated the dormant Commerce Clause because "the Act effectively seeks to compel manufacturers and wholesalers to act in accordance with Maryland law outside of Maryland."[145]

On the other hand, some drug price-transparency laws have survived dormant Commerce Clause challenges. California passed a drug price-transparency bill in 2017, SB 17.[146] The bill essentially requires insurers and manufacturers to disclose various aspects of drug pricing information, including notifying purchasers before a price increase of over 16 percent over a two-year-period when the drug's wholesale price is over forty dollars.[147] This information would have already been public, but SB 17 made it easier for the information to be collected and aggregated.[148] Predictably, the pharmaceutical industry challenged this law, and in January 2021, a court ruled and upheld the legality of the law holding the facts precluded summary judgement on dormant Commerce Clause and First Amendment claims.[149] While the litigation was ongoing, California was able to collect pricing data.[150] From 2017 through the first quarter of 2019, drug prices continued to spike.[151] The "wholesale acquisition cost" of generic drugs saw a 37.6 percent increase during that time.[152] This suggests that states enacting price-transparency laws do not, at this time, have a significant impact on drug pricing.

144. Ass'n for Accessible Meds. v. Frosh, 887 F.3d 664, 674 (4th Cir. 2018).

145. *Id.* at 672. The Court further explained the burden on the drug companies: "If Maryland compels manufacturers to sell prescription drugs in the initial transaction at a particular price, but another state imposes a different price, then manufacturers could not comply with both laws in a single transaction. The manufacturer's compliance would require more than modification of their distribution systems; it would force them to enter a separate transaction for each state in order to tailor their conduct so as not to violate any states' price restrictions." *Id.* at 673–74.

146. CAL. HEALTH & SAFETY CODE § 1367 (2022).

147. Jaime S. King & Katherine L. Gudiksen, *Health Law: SB 17 and State Regulation of Drug Pricing*, 3 JUDGES' BOOK 71, 72–73 (2019).

148. *Id.* at 73.

149. Pharm. Rsch. & Mfrs. of Am. v. David, 510 F. Supp. 3d 891 (E.D. Cal. 2021), *aff'd*, No. 21-16312, 2022 WL 2915588, at *2 (9th Cir. July 25, 2022).

150. Barbara Feder Ostrov & Harriet Blair Rowan, *California's New Transparency Law Shows Staggering Rise in Wholesale Drug Prices*, L.A. TIMES (Oct. 11, 2019, 6:00 AM), https://www.latimes.com/business/story/2019-10-11/californias-new-transparency-law-shows-staggering-rise-in-wholesale-drug-prices [https://perma.cc/C96R-KK5D].

151. *Id.*

152. *Id.* (The cost of a generic liquid version of Prozac rose from nine dollars to sixty-nine dollars in the first quarter of 2019, an increase of 667 percent).

Because so many of these state regulatory attempts have failed, both the state and federal government must patch the regulatory holes in the law with antitrust, fraud, and consumer protection prosecution after harm has already been done to the healthcare system. *United States ex rel. Sanofi-Aventis US LLC v. Mylan Inc.*,[153] the EpiPen fraud case, and *In re Generic Pharmaceuticals Pricing Antitrust Litigation*[154] are examples. These cases take many years to litigate and cost millions of dollars, and they do not clearly deter anticompetitive behavior.

III. THE STATE AS A SELLER: PUBLIC DRUG MANUFACTURING

The public manufacturing of generic drugs is an evolving policy idea that separates the government from its regulatory role. Public generic drug manufacturing occurs when the government becomes a market participant (a seller) in the pharmaceutical industry. This Part will highlight different examples of how this participation can look in theory and practice.

In 2020, California passed Senate Bill 852, the California Affordable Drug Manufacturing Act of 2020 (referred to as "CADMA" in this Note).[155] This first-in-the-nation law will eventually allow the state to develop its own line of generic drugs.[156] The initial plan, however, is for California to contract out the manufacturing of select drugs while maintaining control over pricing and distribution.[157]

The legislation's stated goal is to "increase competition, lower prices, and address shortages in the market for generic prescription drugs, to reduce the cost of prescription drugs for public and private purchasers, taxpayers, and consumers, and to increase patient access to affordable drugs."[158] To do so, the California Health and Human Services Agency (CHHSA) must enter into partnerships with "a payer, state governmental agency, group purchasing organization, nonprofit organization, or other entity resulting in the production or distribution of generic prescription drugs, with the intent that these drugs be made widely available to public and private purchasers, providers and

153. No. 16-CV-1157 (D. Mass. Nov. 16, 2017) (Bloomberg, Court Dockets).

154. 368 F. Supp. 3d 814 (E.D. Pa. 2019).

155. CAL. HEALTH & SAFETY CODE § 127690 (2022).

156. April Dembosky, *California Governor Signs a Bill to Allow State to Develop Generic Drugs*, NPR (Sept. 29, 2020, 3:57 PM), https://www.npr.org/2020/09/29/918317455/california-governor-signs-a-bill-to-allow-state-to-develop-generic-drugs [https://perma.cc/4G7E-QNNK].

157. *Id.*

158. CAL. HEALTH & SAFETY CODE § 127692(a) (2022).

suppliers."[159] CHHSA, which is initially spearheading the program, must pick generics that will result in cost savings and price transparency.[160] Specifically, CHHSA must select generics "that have the greatest impact on lowering drug costs to patients, increasing competition and addressing shortages in the prescription drug market, improving public health, or reducing the cost of prescription drugs to public and private purchasers."[161] The agency specifically must prioritize drugs for chronic and high cost conditions and drugs that can be delivered through mail order.[162] This bill was introduced right before the COVID-19 pandemic, and supply chain issues that occurred during the crisis became pertinent to the drafting of the legislation. In a senate floor analysis, lawmakers cited having a reliable supply chain of drugs during emergencies as important in helping the state prepare for the next pandemic.[163]

CADMA, for the most part, remains rather broad in scope; however, the law specifies that at least one form of insulin be produced, as long as there is a way to manufacture a more affordable form.[164] A few years after the passage of CADMA on July 7, 2022, California Governor Gavin Newsom publicly announced that California would be making its own insulin.[165] Included in the $308 billion state budget Newsom signed a month earlier was $100 million for this project: $50 million toward the development of low cost insulin products and $50 million to a California-based insulin manufacturing facility that would "provide new, high-paying jobs and a stronger supply chain for the drug."[166] No manufacturing partner had yet been contracted, but

159. *Id.* § 127692(a)–(b).

160. *Id.* § 127693(b)(1), (4).

161. *Id.* § 127693(b)(5).

162. *Id.* § 127693(c)(3).

163. S. Rules Comm. on S.B. 852, 2019–20 Leg., Reg. Sess. 4 (Cal. 2020) (senate floor analysis, Aug. 31, 2020).

164. CAL. HEALTH & SAFETY CODE § 127693(c)(2) (2022). CHHSA is supposed to investigate and make a report to the legislature including "[a] description of the status of all drugs targeted under this chapter" and "the feasibility of directly manufacturing generic prescription drugs and selling generic prescription drugs at a fair price. The report shall include an analysis of governance structure options for manufacturing functions, including chartering a private organization, a public-private partnership, or a public board of directors" in 2022 and 2023 respectively, although these reports are not required to be made public. *Id.* § 127694(a)–(c) (referencing section 9795 of the California Government Code); *id.* § 127695(a)(1).

165. Gavin Newsom (@GavinNewsom), TWITTER (July 7, 2022, 12:09 PM), https://twitter.com/GavinNewsom/status/1545122879649374209 [https://perma.cc/DF65-5TJQ].

166. Timothy Bella, *California Will Make Its Own Insulin to Fight Drug's High Prices, Newsom Says*, WASH. POST (July 8, 2022, 10:39 AM), https://www.washingtonpost.com/health/2022/07/08/california-insulin-newsom-drug-prices/ [https://perma.cc/66XB-8K4X].

California planned on starting insulin manufacturing within a couple of years while "working to identify other generic drugs it could bring to market, targeting those that [were] expensive or in short supply."[167]

There are good reasons to make insulin a priority. Insulin has long been the face of rising generic drug prices and has garnered outrage in the general public.[168] The outrage is reasonable: the most commonly used forms of insulin cost ten times more in the United States than in any other developed country.[169] Insurance companies may not even put any form of insulin on their tier one formularies, meaning that the patient has to pay more out-of-pocket expenses than they would for other generic drugs.[170] One of the main reasons that prices have remained high even though insulin has been available for the last one hundred years is that, until recently, three pharmaceutical companies maintained a "virtual monopoly" on the drug, so there has been limited competition in the market.[171] Novo Nordisk, Sanofi-Aventis, and Eli Lilly, among others, are facing legal consequences connected to the high prices of their insulin.[172] For example, there is an ongoing antitrust class action suit alleging a fraudulent price-fixing scheme among two of the three companies.[173] As 10.2 percent of the United States adult population has been diagnosed with diabetes and many more are expected to be living undiagnosed,[174] insulin pricing is a huge public health concern.

167. Angela Hart, *California Aims to Slash Insulin Prices and Challenge Big Pharma. Can it Succeed?*, L.A. TIMES (June 6, 2022, 5:00 AM), https://www.latimes.com/california/story/2022-06-06/california-aims-to-slash-insulin-prices-and-challenge-big-pharma [https://perma.cc/6XCJ-KUN6].

168. *See, e.g.*, Danielle Ofri, Opinion, *The Insulin Wars*, N.Y. TIMES (Jan. 18, 2019), https://www.nytimes.com/2019/01/18/opinion/cost-insurance-diabetes-insulin.html [https://perma.cc/EF5Z-B2GP] (referring to insulin pricing as "infuriating" and even using the word "war" to describe the conflict with insurance companies to get patients affordable drugs).

169. Emily Rauhala, *American Diabetics Are Crossing Borders into Canada in Order to Get Life-Saving Insulin*, THE INDEPENDENT (July 1, 2019, 1:43 PM), https://www.independent.co.uk/news/long_reads/diabetes-insulin-prices-drugs-fda-pharmaceuticals-us-canada-a8961816.html [https://perma.cc/3N68-KU63].

170. Ofri, *supra* note 168.

171. S. Vincent Rajkumar, *The High Cost of Insulin in the United States: An Urgent Call to Action*, 95 MAYO CLINIC PROC. 22, 23 (2020). Other reasons include a vulnerable population that is willing to pay high costs for a drug, patent abuse, barriers to biosimilar entry, and middlemen who benefit from a higher list price. *Id.*

172. Sinha et al., *supra* note 117, at 2272.

173. *See In re* Insulin Pricing Litig., No. 3:17-cv-0699-BRM-LHG, 2019 WL 643709, at *1–2 (D.N.J. Feb. 15, 2019).

174. CTRS. FOR DISEASE CONTROL, NATIONAL DIABETES STATISTICS REPORT 2020: ESTIMATES OF DIABETES AND ITS BURDEN IN THE UNITED STATES 2–3 (2020).

A public manufacturing bill has also been proposed federally, which gives more insight into how public manufacturing could work on a larger scale. In 2018, Senator Elizabeth Warren and Representative Jan Schakowsky introduced the Affordable Drug Manufacturing Act,[175] and then reintroduced the bill in 2019.[176] The goal of the bill is to "increase competition and lower prices for consumers."[177] Whereas the California law, CADMA, solely identifies insulin to be produced under the law at this time, the expanded federal proposal requires at least the production of insulin, naloxone (a nasal spray that can reverse the effects of an opioid overdose), and antibiotics.[178] An accompanying report by the Congresswomen outlined conditions in which public manufacturing of a generic drug could occur: (1) no company is marketing the drug; (2) only one or two companies are marketing the drug, and the price has spiked; (3) only one or two companies are marketing the drug, and the drug is in shortage; or (4) only one or two companies are marketing the drug, the price is a barrier to patient access, and the drug is listed as an "essential medicine" by the World Health Organization.[179] The report then named four hundred different off-patent drugs that fit into one of these categories.[180] This was an ambitious proposal, but of course, the federal government has many more resources to exercise broad manufacturing power than states do.

In the last few decades, there has been successful public manufacturing in America on a small scale to fill gaps in the marketplace. This has happened on the state level. Since 2003, California has been manufacturing a drug called BabyBIG®, the only treatment for infant botulism, a gastrointestinal condition caused by exposure to certain

175. Affordable Drug Manufacturing Act of 2020, S. 3162, 116th Cong. (2020); *see also* Elizabeth Warren, Opinion, *It's Time to Let the Government Manufacture Generic Drugs*, WASH. POST (Dec. 17, 2018, 9:00 PM), https://www.washingtonpost.com/opinions/elizabeth-warren-its-time-to-let-the-government-manufacture-generic-drugs/2018/12/17/66bc0fb0-023f-11e9-b5df-5d3874f1ac36_story.html [https://perma.cc/ASA7-CULZ].

176. *See* Press Release, Elizabeth Warren, Schakowsky, Warren Reintroduce Affordable Drug Manufacturing Act, Legislation to Radically Reduce Drug Prices Through Public Manufacturing of Prescription Drugs (Dec. 20, 2019), https://www.warren.senate.gov/newsroom/press-releases/schakowsky-warren-reintroduce-affordable-drug-manufacturing-act-legislation-to-radically-reduce-drug-prices-through-public-manufacturing-of-prescription-drugs [https://perma.cc/D2ZE-6EJG].

177. *See* OFFS. OF SEN. ELIZABETH WARREN & REP. JAN SCHAKOWSKY, COSTLY CURES: THE BROKEN GENERIC DRUG MARKET AND THE URGENT NEED FOR THE AFFORDABLE DRUG MANUFACTURING ACT 2 (2019) [hereinafter COSTLY CURES].

178. *Id.*

179. *Id.* at 11.

180. *Id.* at 2.

toxins.[181] This drug has been used to treat more than 2,100 infant botulism cases across the country resulting in more than $153 million of avoided hospital costs for affected families.[182] Additionally, according to a February 2020 set of recommendations to the New Mexico Interagency Pharmaceutical Purchasing Council, both Massachusetts and Michigan Departments of Health have operated vaccine manufacturing facilities in the past.[183]

In 2020, the U.S. government contracted with several pharmaceutical companies to quickly develop vaccines against COVID-19 that would ultimately become available free of charge for eligible Americans.[184] However, the government acted as merely a consumer in this situation by funding research and buying doses of the vaccines while not maintaining any rights regarding pricing, distribution, or manufacturing, even though it gave the pharmaceutical companies billions of dollars to get the vaccines to market.[185] Although this was a unique situation, having critical infrastructure set up with public manufacturing could help with future pharmaceutical emergencies.

IV. EFFICACY OF PUBLIC MANUFACTURING

The public manufacturing of drugs is likely an effective, if not necessary, policy proposal to improve access to essential prescription

181. Jay L. Hoecker, *How Can I Protect My Baby from Infant Botulism?*, MAYO CLINIC (July 7, 2020), https://www.mayoclinic.org/healthy-lifestyle/infant-and-toddler-health/expert-answers/infant-botulism/faq-20058477 [https://web.archive.org/web/20220313095223/https://www.mayoclinic.org/healthy-lifestyle/infant-and-toddler-health/expert-answers/infant-botulism/faq-20058477]; S. Rules Comm. on S.B. 852, 2019–2020 Leg., Reg. Sess. 7 (Cal. 2020) (senate floor analysis, Aug. 31, 2020). "Federal law permits and California law requires CDPH [California Department of Public Health], as the sponsor of Baby BIG®, to charge a fee for BabyBIG® in order to meet but not exceed the IBTPP operational expenses, including the developmental and ongoing production costs of BabyBIG®." *Id.*

182. *What Is BabyBig?*, INFANT BOTULISM TREATMENT & PREVENTION PROGRAM, https://www.infantbotulism.org/general/babybig.php [https://perma.cc/PK62-T5K8].

183. JANE HORVATH, REPORT TO THE NEW MEXICO INTERAGENCY PHARMACEUTICAL PURCHASING COUNCIL: RECOMMENDATIONS FOR THE WORK OF THE COUNCIL 23 (2020).

184. *See generally* SIMI V. SIDDALINGAIAH, CONG. RSCH. SERV., IN11560, OPERATION WARP SPEED CONTRACTS FOR COVID-19 VACCINES AND ANCILLARY VACCINATION MATERIALS 1 (2021), https://crsreports.congress.gov/product/pdf/IN/IN11560 [https://perma.cc/4CCQ-ZSJJ] (outlining the contract values with seven pharmaceutical companies including Pfizer/BioNTech and Moderna).

185. *See* Matina Stevis-Gridneff et al., *A European Official Reveals a Secret: The U.S. Is Paying More for Coronavirus Vaccines*, N.Y. TIMES (June 9, 2021), https://www.nytimes.com/2020/12/18/upshot/coronavirus-vaccines-prices-europe-united-states.html [https://perma.cc/W2KX-3KMY]; Jonathan Saltzman, *The US Government Has Now Paid Moderna $6b for Vaccine Effort*, BOSTON GLOBE (Apr. 29, 2021, 9:47 AM), https://www.bostonglobe.com/2021/04/29/nation/us-government-has-now-given-moderna-6b-vaccine-effort/ [https://perma.cc/CLU2-E5M5].

drugs. In the absence of strong federal drug policy, states should consider implementing public manufacturing for two main reasons. First, because the state is entering the market rather than working around it, the state will not face regulatory roadblocks. The state can act independently of the federal government in this area. Second, public manufacturing protects consumers from price changes brought on by market conditions. The state can produce and stockpile drugs on U.S. soil, thus protecting against certain drug shortages that can happen from the reliance on an international supply. Additionally, the state is insulated from certain market pressures as it does not seek to increase shareholder value through greater profit margins of its product, so the state can bring more competition to the market.

A. Evading Regulatory Challenges

Federal drug manufacturing could be very effective for creating stability for the supply chain and pricing of commonly used generic drugs.[186] However, without the federal government pushing a policy like the Affordable Drug Manufacturing Act, states can look to pass similar legislation as California has done. Public manufacturing legislation could be effective at circumnavigating certain legal forces because it bypasses common regulatory blocks that have halted or complicated state attempts at drug pricing regulation in the past.

ERISA. With public manufacturing, the state is not mandating anything in relation to private insurers or the competitor manufacturing companies. The goal of the state is to make their prices lower than other generic competitors so that they can be a competitive market participant. Ideally, private insurers would cover the state-manufactured drug, and the less expensive generic would become the preferred drug on the patient's insurance plan and at the pharmacy.

Medicaid Waiver Requests. States entering the business of public manufacturing are operating separately from their roles regarding Medicaid and would not need to utilize Medicaid waiver requests. However, states could choose to get creative with state-manufactured drugs and Medicaid strategy. CADMA, for example, does not detail how California may instruct Medi-Cal (California's Medicaid program) in accordance with any drugs it manufactures, but it could, in theory, require Medi-Cal to cover or prioritize California manufactured drugs.

186. *See* COSTLY CURES *supra* note 177, at 7.

Patent Law. The benefits of public manufacturing of generic drugs include the fact that the state would not have to navigate federal patent law, as theoretically all the drugs the state would be considering are off patent. If a manufacturing system was already in place, perhaps states in the future could utilize their own supply chain for the manufacturing of novel drugs, like a new vaccine for the next pandemic.

Dormant Commerce Clause. Public manufacturing legislation would not run into this regulatory clog as the state is not attempting to regulate other generic manufacturers that may reside out of the state, nor artificially influence the prices those manufacturers must set. Additionally, the market participation exception to the dormant Commerce Clause may protect further activities the state may decide to do pertaining to public manufacturing. The Supreme Court has held, "[n]othing in the purposes animating the Commerce Clause prohibits a State, in the absence of congressional action, from participating in the market and exercising the right to favor its own citizens over others."[187] A state which is merely entering the market is different from a state discriminating against citizens in other states in violation of the Commerce Clause by prohibiting or burdensomely regulating natural functions of interstate commerce.[188] Even if the state contracts with a private company to manufacture drugs, they are still acting as a market participant.

Although it seems possible that states could limit their drug distribution networks within the state, it would be possible for a state to export their drugs to other states. As mentioned above, BabyBIG®, which is manufactured by the state of California, is available nationally.[189]

Although not necessary to survive a dormant Commerce Clause challenge, another related (and ambitious) policy idea is to have a group of participating states manufacture different drugs and band together to create a drug-share distribution network across state lines.

In the absence of federal legislation to control generic drug pricing, state policies funding public manufacturing should not face common legal challenges to regulation as the state assumes the role that another private company entering the market would. Additionally, if the state had significant market share of certain popular drugs, the

187. Hughes v. Alexandria Scrap Corp., 426 U.S. 794, 810 (1976).
188. *Id.* at 805–06.
189. *What Is BabyBig*, *supra* note 182.

need to fill the policy gaps with aggressive antitrust prosecution against bad actors may lessen, and more patients could receive affordable medication before there are prolonged legal battles.

B. Market Forces

The public manufacturing of drugs in the United States is necessary policy in preventing drug shortages, a major reason for price spikes.[190] There is a consensus about the need to bring drug manufacturing back to the United States to prevent changes to the global drug supply chain that the United States cannot control, especially after the COVID-19 pandemic. For example, the Vice President and Director of Governance Studies at the Brookings Institution, Darrell M. West, wrote that one of the most fundamental challenges the United States faces moving forward after the pandemic is the fact that most essential medicines come from outside of the country.[191]

The vulnerabilities of the U.S. pharmaceutical supply chain are a federal policy concern. The U.S. Department of Health and Human Services (HHS) committed $60 million to "increase domestic manufacturing capacity for API [to] help reduce reliance on global supply chains for medications that are in shortage, particularly during times of increased public health need."[192] A White House report that set forth policy recommendations to secure the drug supply chain advocated "[b]oosting local production and fostering international cooperation," "[p]romoting research and development that establishes innovative manufacturing processes and production technologies to strengthen supply chain resilience," and "[c]reating robust quality

190. *See* discussion *infra* Section I.B.1.

191. Darrell M. West, *Time to Make Essential Medicines Within the United States*, BROOKINGS (June 14, 2021), https://www.brookings.edu/blog/techtank/2021/06/14/time-to-make-essential-medicines-within-the-united-states/ [https://perma.cc/J6EP-PU32]. Citing a Washington University Olin School of Business report, West suggests, among other ideas, "reduc[ing] reliance upon foreign manufacturers and develop[ing] U.S. drug manufacturing capabilities." *Id.*; *see also* Eric Edwards, *The U.S. Needs to Reimagine Its Pharma Supply Chain*, HARV. BUS. REV. (Aug. 12, 2021), https://hbr.org/2021/08/the-u-s-needs-to-reimagine-its-pharma-supply-chain [https://perma.cc/BBU3-Z4PC] ("Given the fragility of the global supply chain, the logical response should be to create a domestic supply of key ingredients. However, due to challenging economics associated with many of these essential medicine ingredients, there has been limited private investment in domestic capacity. Many of these medicines are viewed more as commodities than strategic assets critical to the health of our country.").

192. Press Release, U.S. Dep't of Health & Hum. Servs., Biden Administration Recommends Policy Changes to Secure U.S. Pharmaceutical Supply Chain (June 8, 2021), https://www.hhs.gov/about/news/2021/06/08/biden-administration-recommends-policy-changes-secure-us-pharmaceutical-supply-chain.html [https://perma.cc/6RCU-SPMZ].

management maturity to ensure consistent and reliable drug manufacturing and quality performance."[193] The report suggests a variety of policy initiatives aimed at incentivizing and assisting American companies in increasing production and maintaining larger stockpiles of drugs.[194]

The public manufacturing of drugs on American soil can supplement other initiatives to help and incentivize the private sector. The federal government could send resources directly to states that are manufacturing and stockpiling widely used or especially vulnerable drugs, rather than spending the money on oversight initiatives of private companies for key drugs. As discussed briefly above about the ability of governments to also consider producing patented drugs, it would benefit the federal government or a state government to own large-scale manufacturing capabilities or to have manufacturing deals in place in case there is a unique emergency shortage situation or a new pandemic. This would allow for a quick production turnaround without the need to negotiate a contract with a new manufacturing partner. Additionally, government-controlled drug manufacturing could ensure the safety of those specific drugs.[195]

Public manufacturing of drugs could also help with competition issues in the marketplace. The first competition issue that can affect drug pricing, discussed in Section II.B, is when too many generic competitors enter the market, which lowers the price of the drug. As a result, companies no longer find it profitable to make. When they subsequently exit the market, prices can rise as remaining companies try to leverage their market share. If a state had drug manufacturing capabilities set up or contracted out, it could monitor these situations to see when competitors are exiting the market for a certain drug, and then step in to start producing the vulnerable drug. If the state was already manufacturing the drug, these market changes theoretically would not happen in the first place. As governments do not seek profit in the same way corporations do, their version of a drug should maintain a stable price.

193. *Id.*

194. THE WHITE HOUSE, BUILDING RESILIENT SUPPLY CHAINS, REVITALIZING AMERICAN MANUFACTURING, AND FOSTERING BROAD-BASED GROWTH 240–49 (2021).

195. Stockman, *supra* note 76 ("Major companies have been caught faking and manipulating the data that is supposed to prove that drugs are effective and safe. Probable carcinogens have been discovered in the drug supply.").

The second competition issue previously discussed is that when a drug does not attract competitors at all because fewer patients use the prescription, there is an indication to the market that profits will not be high. This situation complicates how public manufacturing can assist the consumer in receiving better access to necessary medication. States would have to evaluate what is more important to them between two seemingly contradictory paths forward: either choosing to manufacture drugs that are used by a high number of people and are vulnerable to price spikes for various market reasons, or choosing drugs that are vulnerable for the very reason that there is not a high demand in the marketplace and thus companies are not willing to compete for market share. Evaluating the hierarchy of actionable vulnerabilities in the market could expend many resources and leave the government open to public criticism. As discussed, the Schakowsky/Warren federal bill outlines criteria for choosing which drugs to manufacture and does not use the number of prescriptions as an evaluative tool.[196] Additionally, California already decided to manufacture the infant botulism drug which has a limited market but seems to be providing a much-needed service to patients. Another policy idea—regardless of how many patients use the drug—is to create an incentive program or actual requirement that manufacturers who want to cease production on a single source drug must warn the government so that the state with manufacturing capabilities can start the process of bringing that drug into production.

Finally, the public manufacturing of drugs could protect consumers from higher prices caused by collusion between private manufacturers. It is safe to say that state governments, or the federal government, are unlikely to participate in a price-fixing scheme with other drug manufacturing entities. The drugs that make price-fixing worth a manufacturer's exposure to liability are likely popular drugs that will make a lot of money for the company, like insulin. Therefore, if public manufacturing legislation covers popular drugs with few competitors, the price of that drug should be shielded from spikes as a result of collusive measures. Although the government could make a profit off their manufactured drugs, they are not required to report to

196. The bill's four manufacturing targets are listed again here: (1) no company is marketing the drug; (2) only one or two companies are marketing the drug, and the price has spiked; (3) only one or two companies are marketing the drug, and the drug is in shortage; or (4) only one or two companies are marketing the drug, the price is a barrier to patient access, and the drug is listed as an "essential medicine" by the World Health Organization. COSTLY CURES, *supra* note 177.

shareholders or increase profit margins, and thus, drug prices should remain stable unless production conditions change in a way that affects manufacturing costs.

C. Private Sector Success

One critique of public drug manufacturing is that the government could face the same industry dynamics, like PBMs and other third-party mark-ups, that prevent lower costs to consumers. Another potential trepidation is that drugs will not be able to be manufactured for lower prices than they are already. Recent private and nonprofit sector initiatives indicate how those concerns play out in practice.

One example of an organization finding success working outside of the traditional pharmaceutical industry is a nonprofit organization called Civica RX.[197] Civica's mission is to "reduce and prevent drug shortages and the price spikes that can accompany them" in order to make generic medications more affordable.[198] Civica is funded by a group of hospital administrators and philanthropists, creating a "buyers club."[199] Members agree on which drugs they want, and Civica contracts with generic manufacturers to produce them.[200] To combat drug shortages:

> [Civica] sources drugs from the United States and Europe so it has more visibility into the supply chain. It stockpiles several months of supply, bucking the trend of just-in-time manufacturing. And it supplies drugs that the market has failed to reliably produce. Today, it counts more than 50 health systems as members—over a third of all licensed hospital beds in the United States.[201]

Civica also has plans to build its own factory in Virginia to produce its own sterile injectable drugs.[202] Civica's members pay prices that

197. *Why Civica?*, CIVICA RX, https://civicarx.org/#TALKING_POINTS [https://perma.cc/FQL5-Z2NU].

198. *Id.*

199. Stockman, *supra* note 76.

200. *Id.*

201. *Id.*

202. Carter Dredge & Stefan Scholtes, *The Health Care Utility Model: A Novel Approach to Doing Business*, NEJM CATALYST (July 8, 2021), https://catalyst.nejm.org/doi/full/10.1056/CAT.21.0189 [https://perma.cc/4EGN-TE86].

are competitive rather than uniquely low, in order to ensure price chain stability, which in turn provides a "peace of mind."[203]

The next example is the Mark Cuban Cost Plus Drug Company (Cost Plus Drugs), an online pharmacy launched in early 2022.[204] Cost Plus Drugs purchases over one hundred medications directly from manufacturers and focuses on drugs on the FDA's shortage list.[205] The Cost Plus Drugs website explains exactly how it prices its products.[206] Cost Plus Drugs takes a 15 percent markup on the purchased price for operation costs, and then adds a $3 pharmacy fee.[207] The website also displays the difference between the retail price and the Cost Plus Drugs price. For example, the website says the generic for Epzicom, used to treat HIV, retails for $1,096.20 but is sold at Cost Plus Drugs for $57.60.[208] The generic for Abilify, used to treat mental health illnesses, retails for $677.70 but is sold with Cost Plus Drugs for $6.[209] Cost Plus Drugs does not take insurance but contends that in most cases, their price is still lower than the price a consumer would pay with insurance at the pharmacy.[210] Critics contend that limited drug offerings and a cash-only business model lessen the "disruptive impact" of the company.[211] However, the cash-only business provides a valuable option for the uninsured and those with high deductibles who may have to pay full price for their medication. Cost Plus Drugs is also building its own manufacturing plant in Texas to further address drug shortages and price gouging.[212]

---

203. Stockman, *supra* note 76.

204. *See* Lisa Kim, *Billionaire Mark Cuban Opens Online Pharmacy to Provide Affordable Generic Drugs*, FORBES (Apr. 14, 2022), https://www.forbes.com/sites/lisakim/2022/01/20/billionaire-mark-cuban-opens-online-pharmacy-to-provide-affordable-generic-drugs/?sh=4db0fad83e4a [https://perma.cc/DD6W-RGJ5].

205. Joshua Cohen, *Mark Cuban's Online Pharmacy Projected to Disrupt the Prescription Drug Market, but There Are a Few Caveats*, FORBES (Feb. 3, 2022, 9:51 AM), https://www.forbes.com/sites/joshuacohen/2022/02/03/mark-cubans-online-pharmacy-projected-to-disrupt-the-prescription-drug-market-but-with-caveats [https://perma.cc/R32B-49X3].

206. *See* MARK CUBAN COST PLUS DRUG COMPANY, https://costplusdrugs.com/ [https://perma.cc/DX9X-QPR7].

207. *Our Mission*, MARK CUBAN COST PLUS DRUG CO., https://costplusdrugs.com/mission/ [https://perma.cc/59EB-UT65].

208. *Medications*, MARK CUBAN COST PLUS DRUGS CO., https://costplusdrugs.com/medications/ [https://perma.cc/J6BC-BF8M].

209. *Id.*

210. MARK CUBAN COST PLUS DRUG COMPANY, *supra* note 206

211. Cohen, *supra* note 205.

212. David Seeley, *Mark Cuban Cost Plus Drug Co. Tops Out Its Deep Ellum Facility*, DALLAS INNOVATES (Feb. 2, 2022), https://dallasinnovates.com/mark-cuban-cost-plus-drug-co-tops-out-its-deep-ellum-facility/ [https://perma.cc/9MRA-YCW3].

Civica demonstrates that hospitals want a more stable drug supply and provides one method of achieving that goal, although it has not necessarily reduced prices. Cost Plus Drugs reveals that certain popular and vulnerable drugs likely can be sold for lower prices while being profitable.[213]

The success of these companies has been noticed, and California considered both companies as the potential partner for their public manufacturing initiative.[214] Civica had independently announced earlier that it was preparing to produce a biosimilar insulin and is "in talks" with California as well as other states to partner.[215] Cost Plus Drugs was at one point in talks with California but is no longer.[216]

Governments could supplement or partner with private sector disruption agents like Civica and Cost Plus Drugs, reaching a larger market and potentially providing better channels of distribution for increased numbers of consumers. Governments can achieve massive scale; however, there is always the concern that the bureaucratic structure of the government may impede the goal of getting less expensive drugs quickly to the consumer.

V. CONCLUSION

Plagued by adverse market conditions and anticompetitive behavior among companies that impact the consumer, the pharmaceutical industry as it exists can restrict access to medication. Federal and state regulation has been inadequate to fully address these issues. The public manufacturing of drugs is one important policy solution governments can implement to protect against drug shortages, anticompetitive behavior, and other competition issues.

Governments choosing to manufacture generic drugs will have to make decisions about which drugs are prioritized. The government cannot, and should not, take over the entire pharmaceutical industry.[217]

213. Jemima McEvoy, *Mark Cuban Considering Leaving Shark Tank as He Bets His Legacy on Low-Cost Drugs*, FORBES (Sept. 26, 2022, 6:30 AM), https://www.forbes.com/sites/jemimamcevoy/2022/09/26/mark-cuban-considering-leaving-shark-tank—-new-venture-focuses-on-selling-low-cost-drugs/?sh=56f5b574caa6 [https://perma.cc/S79D-KUNV] ("Cost Plus Drugs already claims more than a million customers and says it is growing at a rate of about 10% each week, on track to be profitable in 2023.").

214. Hart, *supra* note 167.

215. *Id.*

216. *Id.*

217. Although, that idea has been proposed. *See generally* Fran Quigley, *Tell Me How It Ends: The Path to Nationalizing the U.S. Pharmaceutical Industry*, 53 U. MICH. J.L. REFORM 755 (2020) (proposing legal pathways for nationalizing the pharmaceutical industry).

The private sector must continue innovating and formulating new drug therapies. However, the generic drug industry, by its very nature, is not innovative. On the federal level, it has been estimated that "[p]olicies to improve competition or reduce prices for off-patent drugs lacking generic competition would save the federal government around $1–2 billion annually."[218] The public manufacturing of drugs can be achieved by a government setting up manufacturing operations itself or contracting with licensed manufacturers to do so, as California's law requires.[219] The success of the California Affordable Drug Manufacturing Act will not become apparent for many years, but the passage of this law is a crucial step in the government's experimentation with ways to improve the health of our healthcare system.

218. Benjamin N. Rome & Aaron S. Kesselheim, *Federal Spending on Off-Patent Drugs That Lack Generic Competition*, 36 J. GEN. INTERNAL MED. 821, 822 (2021).

219. CAL. HEALTH & SAFETY CODE § 127692(a) (2022).