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The Drug (Pricing) Wars: States, Preemption, and Unsustainable Prices

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It is no secret: the prices of prescription drugs in the United States are unsustainable. As a piercing example of the limits of America's incomplete and disordered health care nonsystem, the crisis has only worsened in recent years. Not only do drug prices exact a toll on America's consumers, but they also impact Americans' access to life-enhancing (and sometimes lifesaving) drugs. They constitute a real and present threat to the quality of health care in the United States in 2020 and beyond.

Recognizing this harm, states are increasingly operating in this space, seeking diverse regulatory solutions to better protect their citizens—from gouging statutes, to transparency laws, to formulary rules. In 2020, states operationalize multiple roles when it comes to prescription drug prices, and states' indispensability has highlighted the need to categorize and summarize these efforts and their roles. These roles include states that serve as mere payers; those that try to activate consumer tools; those that facilitate various marketplaces; those that oversee and review the prices and purchases that take place in their states; and, ultimately, those that seek to directly penalize and punish pharmaceutical companies who price their drugs at certain levels. Many states occupy multiple, complex, and overlapping roles simultaneously.

This Article undertakes that necessary review, observing that increased state regulatory action reflects a rising trend of state primacy in health policy. But it also observes a key limitation for state-centric regulation: state action is too often hamstrung by preemptive blocks that prevent various state solutions from taking effect. From ERISA, to the Dormant Commerce Clause, to the Department of Health and Human Services' waiver process, to federal patent

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preemption, these federal sources of law serve as a cumulative preemptive cap on necessary state action.

Besides the obvious harms, these regulatory clogs can be characterized as (1) functioning too often as antidemocratic, (2) weakening the regulatory structure, (3) injecting regulatory inconsistencies, and (4) lessening the chances of a satisfactory federal solution. Applying lessons from the environmental law context, this Article challenges the wisdom and legitimacy of these federal regulatory clogs in the midst of a pharmaceutical drug-cost crisis. In addition to identifying alternative pathways, this analysis suggests a reexamination of the various legal regimes that block state efforts in this area, all while millions of Americans currently face drug prices that they simply cannot afford.

INTRODUCTION

I think it is a moral requirement to make money when you can . . . to sell the product for the highest price.[1]
—Nirmal Mulye, President, Nostrum Pharmaceuticals

In 2017, Americans spent $333 billion on retail prescription drugs, up from $236 billion in 2007.[2] This amount, when expressed on a per capita basis, exceeds every other country on earth[3] and is more than double that of the United Kingdom and other European peer countries.[4] The cost phenomenon is due to one main reason: Americans spend more on drugs because the prices are higher.[5] That Americans' insurance is less comparatively protective is an additional cause, which ensures that the burden of cost is more directly felt by American citizens.[6]

In 2019, nearly one-fourth of people taking prescription drugs in the United States had a hard time affording the cost of prescription drugs,[7] and one in three uninsured Americans could not afford their medications.[8] Indeed, one-third of money donated using GoFundMe is raised for medical expenses,[9]

1. Wayne Drash, *Report: Pharma Exec Says He Had 'Moral Requirement' To Raise Drug Price 400%*, CNN, https://www.cnn.com/2018/09/11/health/drug-price-hike-moral-requirement-bn/index.html [https://perma.cc/GZV9-D4VJ] (last updated Sept. 12, 2018, 9:25 PM).

2. Alison Kodjak, *Prescription Drug Costs Driven by Manufacturer Price Hikes, Not Innovation*, NPR (Jan. 7, 2019, 5:04 PM), https://www.npr.org/sections/health-shots/2019/01/07/682986630/prescription-drug-costs-driven-by-manufacturer-price-hikes-not-innovation [https://perma.cc/5FRK-7L6N].

3. *See Pharmaceutical Spending*, ORG. FOR ECON. CO-OPERATION & DEV., https://data.oecd.org/healthres/pharmaceutical-spending.htm [https://perma.cc/ZJ7N-97QT] (choose "Total" and "US dollars/capita" from "Perspectives" dropdown and adjust "yearly" time range to 2017).

4. *See* Dana O. Sarnak, David Squires & Shawn Bishop, *Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier?*, COMMONWEALTH FUND (Oct. 5, 2017), https://www.commonwealthfund.org/publications/issue-briefs/2017/oct/paying-prescription-drugs-around-world-why-us-outlier [https://perma.cc/BV5V-R6DG].

5. *Id.*

6. *Id.*

7. *See Poll: Nearly 1 in 4 Americans Taking Prescription Drugs Say It's Difficult To Afford Their Medicines, Including Larger Shares Among Those with Health Issues, with Low Incomes and Nearing Medicare Age*, KAISER FAM. FOUND. (Mar. 1, 2019), https://www.kff.org/health-costs/press-release/poll-nearly-1-in-4-americans-taking-prescription-drugs-say-its-difficult-to-afford-medicines-including-larger-shares-with-low-incomes/ [https://perma.cc/4C6B-M337].

8. *See* Fiza Pirani, *One-Third of Uninsured Americans Can't Afford Their Medications, Study Finds*, ATLANTA J.-CONST. (Mar. 21, 2019), https://www.ajc.com/news/health-med-fit-science/one-third-uninsured-americans-can-afford-their-medications-study-finds/hu2WKzr3en4wNMPhgZtY9L/ [https://perma.cc/Z2ES-2DGA]; *see also* ROBIN A. COHEN, PETER BOERSMA & ANJEL VAHRATIAN, NAT'L CTR. FOR HEALTH STATS., STRATEGIES USED BY ADULTS AGED 18–64 TO REDUCE THEIR PRESCRIPTION DRUG COSTS, 2017, at 5 (2019), https://www.cdc.gov/nchs/data/data-briefs/db333-h.pdf [https://perma.cc/FM36-KNDN].

9. Nathan Heller, *The Hidden Cost of GoFundMe Health Care*, NEW YORKER (June 24, 2019), https://www.newyorker.com/magazine/2019/07/01/the-perverse-logic-of-gofundme-health-care

with thousands using the popular site to seek donations to cover the costs of their prescriptions.[10] Charities that assist patients in paying for their drug co-pays constitute a $10 billion industry.[11]

It is not an exaggeration to state that the costs of drugs in the United States have, in and of themselves, caused their own health care crisis.[12] In 2019, nearly thirty percent of Americans reported not taking a prescription drug as directed because of its cost.[13] Higher co-pays cause adherence rates to drop precipitously, and where pharmaceutical companies have offered free medications, adherence has noticeably improved.[14] With nonadherence to prescription drugs causing 125,000 deaths in the United States every year,[15] the exorbitant costs of prescription drugs cause harm that is more than just hypothetical.[16]

Indeed, the cause of the cost crisis is multifactorial: an increase in deductibles, a decrease in insurance benefits, and the rise of pharmacy benefit managers.[17] On top of this, there has been no federal holistic legal solution to regulate the costs pharmaceutical drug companies can charge. And although there are proposals, no complete solution appears to be immediately

[https://perma.cc/8EGZ-9A5N (dark archive)]. GoFundMe is an online platform that facilitates charitable giving. *See About GoFundMe*, GOFUNDME, https://www.gofundme.com/c/about-us [https://perma.cc/U2ND-HXSB].

10. *See* Lydia Ramsey Pflanzer, *People Are Raising Money for Routine Prescriptions with Sites Like GoFundMe*, BUS. INSIDER (Apr. 10, 2017, 4:21 PM), https://www.businessinsider.com/crowdfunding-for-prescription-medications-2017-4 [https://perma.cc/LXD6-VT4M].

11. Sarah Karlin-Smith, *Co-Pay Support Orgs Rank High Among Largest U.S. Charities*, POLITICO (May 15, 2017, 12:00 PM), https://www.politico.com/tipsheets/prescription-pulse/2017/05/co-pay-support-orgs-rank-high-among-largest-us-charities-220316 [https://perma.cc/FT2M-ERGP].

12. *See, e.g.*, Kari Paul, *Texas Woman Dies Because $116 Co-Pay for Flu Medication Was Too Expensive*, MARKETWATCH (Feb. 12, 2018, 7:21 PM), https://www.marketwatch.com/story/texas-woman-dies-after-refusing-to-spend-116-co-pay-for-flu-medication-2018-02-12 [https://perma.cc/9A96-8834] (telling the story of a woman who died after deciding not to pay for her medication and explaining that taking medicine incorrectly leads to 125,000 deaths per year).

13. *See* Jay Hancock, *Americans Ready To Crack Down on Drug Prices That Force Some To Skip Doses*, KAISER HEALTH NEWS (Mar. 1, 2019), https://khn.org/news/americans-ready-to-crack-down-on-drug-prices-that-force-some-to-skip-doses/ [https://perma.cc/2CJL-LF54]; *see also* Sarnak et al., *supra* note 4 (describing a similar statistic from previous years).

14. *See* Jane E. Brody, *The Cost of Not Taking Your Medicine*, N.Y. TIMES (Apr. 17, 2017), https://www.nytimes.com/2017/04/17/well/the-cost-of-not-taking-your-medicine.html [https://perma.cc/M8GA-ADUZ (dark archive)].

15. *Id.*

16. A 2019 Gallup poll found thirteen percent of those surveyed—or around thirty-four million American adults—"report[ed] knowing of at least one friend or family member in the past five years who died after not receiving needed medical treatment because they were unable to pay for it." Dan Witters, *Millions in U.S. Lost Someone Who Couldn't Afford Treatment*, GALLUP (Nov. 12, 2019), https://news.gallup.com/poll/268094/millions-lost-someone-couldn-afford-treatment.aspx [https://perma.cc/EKH7-D33B].

17. *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/C4GQ-2UU7].

forthcoming.[18] Instead of a legislative solution emanating from the United States Capitol, individual states are intent on taking the lead to solve the prescription-drug-cost crisis. Various pressures push states into occupying this role, and the federal government's inability to solve the problem has created a vacuum into which states have quickly stepped.

But state regulation in the space has proven tricky. States' attempts at regulation have been rebuffed by federal sources of power, yet the federal government offers no alternative solution to the prescription-drug-pricing crisis. These federal blocks have exacerbated the governance challenge that states with growing health care budgets are facing. They have also raised interesting questions about regulatory legitimacy and the appropriate limits of state power.

This Article delves into those state efforts by providing a nomenclature for state action in this space. It documents the primary federal blocks, or regulatory clogs, on state power that constitute cumulative preemption and have debilitated state efforts. One need only consult regulatory arguments—and particularly those concerns raised in environmental law scholarship—to note the potential damage done to the governing regime by a powerful but immobile federal government.

The substantial federal preemption of state efforts puts at risk the strength, consistency, legitimacy, and prospects for success for improving the regulatory structure that would inure following robust and creative state regulation. And besides just hampering state efforts, these federal blocks prevent any durable state solutions from taking hold, aggravating the prescription-drug-cost crisis for states and their citizens alike. This Article identifies those threats and their consequences and seeks to unearth a way forward.

This Article proceeds in three parts. Part I provides a holistic catalog and nomenclature of state efforts. Part II identifies regulatory clogs. And Part III, after consulting environmental law scholarship, summarizes the problems that are caused by the regulatory clogs. Before concluding, the Article also provides a brief analysis of alternative pathways for regulation that are not yet clogged or impeded. Ultimately, this effort is undertaken with a mindful eye toward reducing the costs that Americans are forced to pay for life-sustaining and lifesaving prescription drugs.

18. *See infra* notes 57–69 and accompanying text.

I. STATE PRIMACY IN PRESCRIPTION DRUG PRICING

In 2020, it is clear that states are the dominant actors in American health care. They serve as payers for health care services for their citizenry[19] and their most vulnerable citizens by determining the size and scope of their Medicaid programs.[20] They serve as organizers, constructing marketplaces for private activity[21] and determining the shape and focus of private insurance markets.[22] They act as sellers, selling insurance within the market—the very markets that they themselves have constructed.[23] And they act as participants—they serve as major employers who must pay for and provide health insurance for their employees.[24]

States do not just affect the conditions for health care delivery, they also exert regulatory power over the practice of medicine. They police the quality of care of providers practicing within their borders.[25] They regulate, serving as

19. *See Total Medicaid Spending*, KAISER FAM. FOUND., https://www.kff.org/medicaid/state-indicator/total-medicaid-spending [https://perma.cc/4KB9-GSSA] (showing the total Medicaid spending in fiscal year 2018 for the fifty states and the District of Columbia).

20. *See* Lola Fadulu, *Why States Want Certain Americans To Work for Medicaid*, ATLANTIC (Apr. 12, 2019), https://www.theatlantic.com/health/archive/2019/04/medicaid-work-requirements-seema-verma-cms/587026/ [https://perma.cc/VR5M-JMZS (dark archive)]; *Status of State Action on the Medicaid Expansion Decision*, KAISER FAM. FOUND., https://www.kff.org/health-reform/state-indicator/state-activity-around-expanding-medicaid-under-the-affordable-care-act/ [https://perma.cc/L7QS-ZT99] (showing that thirty-eight states, plus the District of Columbia, have chosen to expand Medicaid with a variety of tweaks and twists, while twelve have not chosen to expand Medicaid at all).

21. *See, e.g.*, Louise Norris, *Colorado Health Insurance Marketplace: History and News of the State's Exchange*, HEALTHINSURANCE.ORG (Aug. 12, 2020), https://www.healthinsurance.org/colorado-state-health-insurance-exchange/ [https://perma.cc/4R9S-YMN5] (documenting characteristics of Colorado's health insurance exchange marketplace).

22. *See* Ezekiel J. Emanuel, Joshua Sharfstein, Topher Spiro & Meghan O'Toole, *State Options To Control Health Care Costs and Improve Quality*, HEALTH AFFS.: HEALTH AFFS. BLOG (Apr. 28, 2016), https://www.healthaffairs.org/do/10.1377/hblog20160428.054672/full/ [https://perma.cc/5RFX-UKNZ].

23. *See, e.g.*, *Health CO-OP*, NAT'L ASS'N INS. COMM'RS, https://www.naic.org/cipr_topics/topic_health_co-op.htm [https://perma.cc/JQ9U-473Q] (last updated Feb. 12, 2020) (noting that one factor impacting the success of health insurance cooperatives is that they operate in a competitive marketplace).

24. *See Health Insurance*, PBS: HEALTHCARE CRISIS: WHO'S AT RISK?, https://www.pbs.org/healthcarecrisis/healthinsurance.html [https://perma.cc/GCD3-LEQB] (noting that the government as an employer provides coverage to 39.2 million people who work for federal, state, and local governments and the military).

25. *See* Drew Carlson & James N. Thompson, *The Role of State Medical Boards*, 7 AMA J. ETHICS: POL'Y F., 311, 311–13 (2005); *see, e.g.*, *The Mission of the Medical Board of California*, MED. BD. CAL., http://www.mbc.ca.gov [https://perma.cc/4W7L-J5MZ] ("The mission of the Medical Board of California is to protect health care consumers through the proper licensing and regulation of physicians and surgeons and certain allied health care professionals and through the vigorous, objective enforcement of the Medical Practice Act, and to promote access to quality medical care through the Board's licensing and regulatory functions.").

the primary entity to approve hospital additions[26] under state-issued certificate laws. And they are law enforcers—their prosecutors enforce their health care fraud laws, seeking to prevent fraud and abuse of their taxpayers.[27] In short, states operate on all sides of health care transactions.

While the future of the Affordable Care Act ("ACA")[28] remains tenuous, states continue to take a leading role in its operation.[29] Under the ACA, many states have undertaken additional oversight of health care markets.[30] In the wake of federal destruction, some are seeking to rebuild, or have rebuilt,[31]

26. *See, e.g.*, *Certificate of Need (CON)*, GA. DEP'T CMTY. HEALTH, https://dch.georgia.gov/certificate-need-con [https://perma.cc/2KAA-A2LG] ("Georgia began reviewing health care projects in 1975 . . . ."); *Duke Files Certificate of Need for Hospital Expansion*, DUKE HEALTH, https://corporate.dukehealth.org/news-listing/duke-files-certificate-need-hospital-expansion [https://perma.cc/4YSY-FUMT] (Jan. 20, 2016) ("We fully recognize that this [expansion] project is conditional upon the approval by the state . . . ."); *Submit a CON Application*, MICH. DEP'T HEALTH & HUM. SERVS., https://www.michigan.gov/mdhhs/0,5885,7-339-71551_2945_5106-120981--,00.html [https://perma.cc/NS5V-FWJN] (explaining Michigan's application process for a certificate of need).

27. *See, e.g.*, False Claims Act, ch. 367, 2001 Tenn. Pub. Acts 850 (codified at TENN. CODE. ANN. §§ 4–18–101 to –108 (LEXIS through 2020 Reg. 2d Extraordinary Sesss.)); False Claims Act, ch. 1, §§ 1-605 to 1-618, 108A-63.1, 108A-63, 2009 N.C. Sess. Laws 1518 (codified as amended at N.C. GEN. STAT. ANN. §§ 1-605 to 1-618, 108A-63.1, 108A-63 (2013) (LEXIS through Sess. Laws 2020-97 of the 2020 Reg. Sess. of the Gen. Assemb.)). According to U.S. Department of Health and Human Services' reviews in 2019, twenty-one states currently have False Claims Act statutes. *See State False Claims Act Reviews*, U.S. DEP'T HEALTH & HUM. SERVS. OFF. INSPECTOR GEN., https://oig.hhs.gov/fraud/state-false-claims-act-reviews/ [https://perma.cc/FXY7-Y375 (staff-uploaded archive)].

28. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered sections of U.S.C. titles 21, 25, 26, 29, and 42).

29. Plaintiffs, intent on destroying the ACA, are now on to another creative argument in *Texas v. United States*, 945 F.3d 355 (5th Cir. 2019), *cert. granted sub nom.* Texas v. California, 140 S. Ct. 1262 (Mar. 2, 2020) (mem.), literally pitting the states against the federal government (and, in fact, some states against other states). *Id.* at 375–76. In this litigation, states are arguing that congressional power is so limited under the commerce power that invalidating the tax penalty under the ACA knocked out its only constitutional basis, *see id.* at 390, an argument that has been met with a healthy dose of legal skepticism. *See* Nicholas Bagley, *Rise of the Know-Nothing Judge*, ATLANTIC (July 15, 2019), https://www.theatlantic.com/ideas/archive/2019/07/texas-v-us-rise-know-nothing-judge/593959/ [https://perma.cc/LW89-A4HQ (dark archive)]. After a Fifth Circuit decision that would have struck down the ACA, the U.S. Supreme Court granted certiorari in March of 2020. Texas v. California, 140 S. Ct. 1262, 1262 (Mar. 2, 2020) (mem.).

30. *See The Marketplace in Your State*, HEALTHCARE.GOV, https://www.healthcare.gov/marketplace-in-your-state/ [https://perma.cc/ZSE7-BBH8] (noting that some states have expanded their programs and listing states that maintain their own websites).

31. *See* John Myers, *California Gov. Gavin Newsom Has Signed His First Budget. Here's Where the $215 Billion Will Go*, L.A. TIMES (June 27, 2019, 5:27 PM), https://www.latimes.com/politics/la-pol-ca-california-government-spending-budget-20190627-htmlstory.html [https://perma.cc/62X9-QUER] ("Beginning Jan. 1, Californians will be required to have at least 'minimal essential coverage' for healthcare needs or face a cash penalty — a state version of the individual mandate that was abandoned by federal lawmakers.").

parts of the law.[32] In addition to providing structural oversight, others *participate* in the health care marketplace, overseeing nonprofit cooperatives that compete with private insurance plans to provide health insurance for yet more of their citizens.[33] And in the face of federal failure, states are operating with increasing frequency to bring down the prices of prescription drugs.[34]

A. *Causes of State Ubiquity*

Ten years into the ACA, states exert control over setting health policy.[35] They have explored new prescriptions—with great heterogeneity—for drug policy.[36] States' potent power to affect, and their resulting interest in, the cost of prescription drugs is due to three contemporary causes: (1) their budgets, (2) the courts, and (3) congressional inaction.

Budgets. America accounts for one of every twenty-five people on Earth but fifty percent of worldwide expenditures on prescription drugs.[37] Medicaid, the federal-state cooperative program that covers seventy-five million Americans,[38] accounts for nearly twenty percent of all states' general funds.[39] These budgets, which are required to be balanced at the state level,[40] are

32. *See* Bob Salsberg, *ACA Mandate Gone, but a Few States Still Require Coverage*, ASSOCIATED PRESS (Jan. 1, 2019), https://www.apnews.com/0f53160eb52a4a3991a9b758f7a8dda8 [https://perma.cc/97CZ-H7EZ] (noting that New Jersey and the District of Columbia "enacted laws replacing the federal mandate" and that Vermont's mandate is set to go into effect in 2020).

33. *See* NAT'L ASS'N INS. COMM'RS, *supra* note 23.

34. *See* Steven Findlay, *States Pass Record Number of Laws To Reel in Drug Prices*, KAISER HEALTH NEWS (Sept. 9, 2019), https://khn.org/news/states-pass-record-number-of-laws-to-reel-in-drug-prices/ [https://perma.cc/K7G7-43HD].

35. Abbe R. Gluck & Nicole Huberfeld, *What Is Federalism in Healthcare For?*, 70 STAN. L. REV. 1689, 1785 (2018) ("The ACA did offer states policy control—power that was enhanced by the ability to leverage the possibility of opting out to extract concessions from the federal government.").

36. *See* Sarah Lanford, *What States Did in 2019 To Address Health Coverage and Costs*, NAT'L ACAD. FOR STATE HEALTH POL'Y (Dec. 16, 2019), https://www.nashp.org/what-states-did-in-2019-to-address-health-coverage-and-costs [https://perma.cc/4SEW-C7FM] ("[S]tates continued to take steps to rein in drug costs, from passing legislation to create wholesale drug importation programs to regulating pharmacy benefit managers (PBMs) more aggressively.").

37. *See* Ezekiel J. Emanuel, *Democrats Are Having the Wrong Health Care Debate*, N.Y. TIMES (Aug. 2, 2019), https://www.nytimes.com/2019/08/02/opinion/democrats-health-care.html?action=click&module=Opinion&pgtype=Homepage [https://perma.cc/G2J6-Z4MP (dark archive)].

38. *See Medicaid Expansion Enrollment*, KAISER FAM. FOUND., https://www.kff.org/health-reform/state-indicator/medicaid-expansion-enrollment/ [https://perma.cc/GS7V-ND7D].

39. *See Medicaid's Share of State Budgets*, MEDICAID & CHIP PAYMENT & ACCESS COMM'N, https://www.macpac.gov/subtopic/medicaids-share-of-state-budgets/ [https://perma.cc/H77N-ALJU].

40. *See* Michelle Andrews, *States Join Fight To Lower Prescription Prices*, AARP: POL. & SOC'Y (Apr. 30, 2019), https://www.aarp.org/politics-society/advocacy/info-2019/states-fight-prescription-drug-prices.html [https://perma.cc/6YK4-H4W8]; Katherine Young, *Utilization and Spending Trends in Medicaid Outpatient Prescription Drugs*, KAISER FAM. FOUND. (Feb. 15, 2019), https://www.kff.org/medicaid/issue-brief/utilization-and-spending-trends-in-medicaid-outpatient-prescription-drugs/ [https://perma.cc/Y65S-GGBX] ("Because states must balance their budgets,

increasingly strained by the price of prescription drugs.[41] And money spent on health care is money that cannot be spent on other societal goods, like education.[42]

For example, Massachusetts' Medicaid program, MassHealth, has experienced a near-doubling of its prescription drug budget in recent years, from $1.1 billion in 2012 to $1.9 billion in 2017.[43] In 2018, that number was reportedly $2.2 billion.[44] The causes are identifiable. For example, about two dozen drugs in California make up almost half of the state's prescription drug budget.[45] It is true that net spending on prescription drugs in the Medicaid program has slowed in recent years, but gross spending continues to increase.[46] For some, the pricing challenge is being framed as a patient safety issue, especially where expensive drugs impact patient treatment compliance.[47]

ongoing increased spending on Medicaid prescription drugs is a policy concern, prompting states to consider ways to reduce drug spending.").

41. *See* Martha Bebinger, *Medicaid Drug Spending: A Power Struggle Between States, Federal Government*, U.S. NEWS & WORLD REP. (Sept. 21, 2018, 11:08 AM), https://www.usnews.com/news/healthcare-of-tomorrow/articles/2018-09-21/medicaid-drug-spending-a-power-struggle-between-states-federal-government [https://perma.cc/RF86-9KPB] ("Drugs are among the fastest-rising health care costs for many consumers and are a key reason health care spending dominates many state budgets — crowding out roads, schools and other priorities."); Alisa Chester & Ian Reynolds, *States Work To Curb Drug Spending: Tight Budgets Lead to New Approaches to Managing Costs*, GEO. UNIV. HEALTH POL'Y INST.: CTR. FOR CHILD. & FAMS. (Feb. 23, 2018), https://ccf.georgetown.edu/2018/02/23/states-work-to-curb-drug-spending-tight-budgets-lead-to-new-approaches-to-managing-costs/ [https://perma.cc/ZKX7-MUKQ] ("These rising costs have strained state budgets, leading policymakers to look for strategies—within Medicaid and beyond—to better manage spending while ensuring a patient's access to needed medications."); Shefali Luthra & Phil Galewitz, *In Florida, Drug Importation from Canada Finds New Champions, Old Snags*, KAISER HEALTH NEWS (Feb. 25, 2019), https://khn.org/news/in-florida-drug-re-importation-from-canada-finds-new-champions-old-snags/ [https://perma.cc/N75G-9PJH] (mentioning that some state "budgets are directly squeezed by climbing drug prices").

42. *See* Gabrielle Levy, *Increases in Medicaid Spending Come at the Expense of Higher Education: Study*, U.S. NEWS & WORLD REP. (May 1, 2018, 4:37 PM), https://www.usnews.com/news/national-news/articles/2018-05-01/increases-in-medicaid-spending-come-at-the-expense-of-higher-education-study [https://perma.cc/XD9N-BMKW].

43. *See* Jessica Bartlett, *State Report: Drug Benefit Managers Are Driving up Health Care Costs*, BOS. BUS. J. (June 5, 2019, 12:50 PM), https://www.bizjournals.com/boston/news/2019/06/05/state-reportsays-drug-benefit-managers-are-driving.html [https://perma.cc/7LRV-DFAR].

44. *See* Robert Pear, *Massachusetts, a Health Pioneer, Turns Its Focus to Drug Prices. It's in for a Fight.*, N.Y. TIMES (Mar. 31, 2018), https://www.nytimes.com/2018/03/31/us/politics/massachusetts-drug-costs-medicaid-waiver.html [https://perma.cc/B2V3-B8XA (dark archive)].

45. *See* Merrill Goozner, *California's Path To Lower Drug Prices*, MOD. HEALTHCARE (Jan. 8, 2019, 12:00 AM), https://www.modernhealthcare.com/article/20190108/BLOG/190109919/california-s-path-to-lower-drug-prices [https://perma.cc/9U7R-JK3X (dark archive)].

46. *See* MEDICAID & CHIP PAYMENT & ACCESS COMM'N, MEDICAID DRUG SPENDING TRENDS 1 (2019), https://www.macpac.gov/wp-content/uploads/2019/02/Medicaid-Drug-Spending-Trends.pdf [https://perma.cc/MN6Y-TV63].

47. *See* Wilson Ring, *States Look To Lower Drug Costs, Consider Canadian Imports*, ASSOCIATED PRESS (Feb. 11, 2018), https://apnews.com/84ca06724c4641689b367e2f4a9e1325/States-look-to-lower-drug-costs,-consider-Canadian-imports [https://perma.cc/9Z8U-KFSB] ("'The No. 1 threat to

Courts. Second, where harshening budgetary realities have forced states to pay more attention to the cost of health care for their citizens, newly understood Commerce Clause jurisprudence[48] has given states the ability to operate with more discretion and impunity in this area. In its biggest moment in 2012, a 5–4 Supreme Court vote invalidated the ACA's individual mandate under the Commerce Clause[49] but upheld the mandate under the tax and spending authority.[50] And, after the individual mandate penalty was zeroed out by Congress in late 2017,[51] the Fifth Circuit upheld a finding that the mandate penalty was unconstitutional in late 2019 before the Supreme Court granted certiorari.[52]

But in the same 2012 decision, the Supreme Court invalidated the mandatory nature of Medicaid expansion under the ACA by a 7–2 vote, holding that the expansion was unconstitutionally coercive on the states.[53] Overall, the opinion illustrated both the Court's new unfriendliness toward Commerce Clause jurisprudence[54] and a departure from Medicaid's history.[55] Both decisions hemmed in federal power, aggressively carving back Congress' right to legislate under the Commerce Clause.[56] States naturally felt empowered to step into the breach.

patient safety related to prescription drugs in our state is that the drugs are so expensive that people don't take them,' [Utah State Rep. Norm] Thurston said.").

48. Nat'l Fed'n of Indep. Bus. v. Sebelius, 567 U.S. 519, 582 (2012) ("The threatened loss of over 10 percent of a State's overall budget, in contrast, is economic dragooning that leaves the States with no real option but to acquiesce in the Medicaid expansion.").

49. *Id.* at 552–58.

50. *Id.* at 562–74.

51. *See* Robert Pear, *Without the Insurance Mandate, Health Care's Future May Be in Doubt*, N.Y. TIMES (Dec. 18, 2017), https://www.nytimes.com/2017/12/18/us/politics/tax-cut-obamacare-individual-mandate-repeal.html [https://perma.cc/TQ9Y-BD7G (dark archive)].

52. *See* Abby Goodnough, *Obamacare Insurance Mandate Is Struck Down by Federal Appeals Court*, N.Y. TIMES (Dec. 18, 2019), https://www.nytimes.com/2019/12/18/health/obamacare-mandate.html [https://perma.cc/34FG-HQAU (dark archive)] (last updated June 26, 2020); *see also* Texas v. United States, 945 F.3d 355, 369 (5th Cir. 2019), *cert. granted sub nom.* Texas v. California, 140 S. Ct. 1262 (Mar. 2, 2020) (mem.); Texas v. California, 140 S. Ct. 1262, 1262 (Mar. 2, 2020) (mem.) (granting certiorari).

53. *Sebelius*, 567 U.S. at 579–85.

54. *See* Jonathan L. Marshfield, *The Amendment Effect*, 98 B.U. L. REV. 55, 69 (2018) (arguing that Chief Justice Roberts's opinion "was a strategic choice aimed at effectuating broader doctrinal change in the Court's Commerce Clause jurisprudence").

55. *See* Nicole Huberfeld, *The Universality of Medicaid at Fifty*, 15 YALE J. HEALTH POL'Y L. & ETHICS 67, 72 (2015) ("Over time, Congress expanded Medicaid eligibility by requiring states to provide comprehensive medical coverage to children under age twenty-one; to expand coverage of the aged, blind, and disabled; to expand eligibility standards for pregnant women and for children; and to financially support drug coverage for people enrolled in both Medicare and Medicaid after the Medicare drug benefit was enacted.").

56. And it has not only been the *Sebelius* decision—other administrative-based policy solutions have been blocked by federal courts. A Trump administration plan—requiring all pharmaceutical companies to publicize their list prices in every television advertisement—was blocked from implementation by a federal court in 2019. Merck v. U.S. Dep't of Health & Hum. Servs., 385 F.

Congress. Finally, while no clear administrative solutions have been forthcoming,[57] perhaps it is Congress that has provided salient impetus for state action in the pharmaceutical drug space. While Congress publicizes public outrage over the cost of prescription drugs,[58] it has not passed any serious regulatory solution over the last decade.[59] Even though legislative solutions have been proposed,[60] beyond salvos, Congress has, to date, failed to address the root cause of the pharmaceutical cost crisis.[61] It has been stymied by infighting.[62]

Supp. 3d 81, 89–90 (D.D.C. 2019); *see also* Katie Thomas & Katie Rogers, *Judge Blocks Trump Rule Requiring Drug Companies To List Prices in TV Ads*, N.Y. TIMES (July 8, 2019), https://www.nytimes.com/2019/07/08/health/drug-prices-tv-ads-trump.html [https://perma.cc/KR7D-CTXZ (dark archive)]. As was the case in another prominent federal court decision that struck down a state-led antigouging effort, the court recognized the challenge of prescription drug pricing, before unceremoniously destroying the administration's attempt to shame drug companies. *Merck*, 385 F. Supp. 3d at 84 (noting that the court did not "take any view on the wisdom of requiring drug companies to disclose prices," and that the proposal "could be an effective tool in halting the rising cost of prescription drugs"). Even the judges striking down these proposed fixes attempt to distance themselves from the very impacts of their rulings. *See id.* ("[N]o matter how vexing the problem of spiraling drug costs may be, [the Department of Health and Human Services] cannot do more than what Congress has authorized. The responsibility rests with Congress to act in the first instance.").

57. *See* Emanuel, *supra* note 37.

58. *See* Halimah Abdullah, *'Pharma Bro' Shkreli Invokes the Fifth Before Congress*, NBC NEWS, https://www.nbcnews.com/news/us-news/pharma-bro-martin-shkreli-faces-congress-n511106 [https://perma.cc/ML4E-8UC5 (staff-uploaded archive)] (Feb. 4, 2016, 7:33 PM) ("[Rep. Elijah] Cummings [D-Md.] angrily yelled him [sic], 'It's not funny, Mr. Shkreli. People are dying. And they're getting sicker and sick[er].'"); Dylan Scott, *Congress Is Grilling Pharma CEOs. Here Are 8 Ideas for Bringing Down Drug Prices.*, VOX, https://www.vox.com/policy-and-politics/2019/1/14/18176707/congress-drug-prices-hearing-pharmaceutical-ceos [https://perma.cc/JP7B-W8PL (staff-uploaded archive)] (last updated Feb. 26, 2019, 10:30 AM); *Martin Shkreli Takes the 5th in Front of 'Imbeciles' on Congressional Committee, Infuriating Lawmakers*, CHI. TRIB. (Feb. 4, 2016, 3:33 PM), https://www.chicagotribune.com/business/ct-martin-shkreli-congressional-hearing-20160204-story.html [https://perma.cc/V4HA-QHSP]; Kelefa Sanneh, *Everyone Hates Martin Shkreli. Everyone Is Missing the Point*, NEW YORKER (Feb. 5, 2016), https://www.newyorker.com/culture/cultural-comment/everyone-hates-martin-shkreli-everyone-is-missing-the-point [https://perma.cc/HRF6-XZX9 (dark archive)].

59. *See* Jay Hancock, *Everyone Wants To Reduce Drug Prices. So Why Can't We Do It?*, N.Y. TIMES (Sept. 23, 2017), https://www.nytimes.com/2017/09/23/sunday-review/prescription-drugs-prices.html [https://perma.cc/HW7X-MB2S (dark archive)] ("Even powerful members of Congress from both parties have said that drug prices are too high. But any momentum to curtail prescription drug costs — a problem that a large number of Americans now believe government should solve — has been lost amid rancorous debates over replacing Obamacare and stalled amid roadblocks erected via lobbying and industry cash.").

60. *See* Prescription Drug Pricing Reduction Act, S. 2543, 116th Cong. (2019) (proposing legislation to "lower prescription drug prices" and "improve transparency" related to pharmaceutical practices); Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 116th Cong. (2019) (proposing legislation "[t]o establish a fair price negotiation program").

61. *See* Sheryl Gay Stolberg, *McConnell Promised To End Senate Gridlock. Instead, Republicans Are Stuck in Neutral.*, N.Y. TIMES (Aug. 3, 2019), https://www.nytimes.com/2019/08/03/us/politics/senate-votes-mcconnell.html [https://perma.cc/2NFJ-D65F (dark archive)] ("Seven months into a new era of divided government, the Republican-led Senate limped out of Washington this week after the fewest legislative debates of any in recent memory, without floor votes on issues that both parties

Inaction by Congress in this space is nothing new.[63] Proposed solutions to the prescription-pricing crisis are fraught with political risk,[64] industry attention, lobbying efforts,[65] and unavoidable complexity.[66] Unsurprisingly, coming up with a solution to address the cost of prescription drugs remains divisive in Congress.[67] And, as recent efforts have floundered,[68] no clear regulatory solutions are imminently forthcoming.[69]

view as urgent: the high cost of prescription drugs, a broken immigration system and crumbling infrastructure.").

62. *See* Adam Cancryn, *Liberals Fight Their Own Party over Drug Prices*, POLITICO, https://www.politico.com/story/2019/06/06/democrats-prescription-drug-prices-1497676 [http://perma.cc/U2RY-VDDR] (June 6, 2019, 10:36 AM); Emmarie Huetteman, *GOP Senators Distance Themselves from Grassley and Trump's Efforts To Cut Drug Prices*, KAISER HEALTH NEWS (July 25, 2019), https://khn.org/news/gop-senators-distance-themselves-from-grassley-and-trumps-efforts-to-cut-drug-prices/ [https://perma.cc/JTA9-HCVM]; Alex Pareene, *Do Democrats Actually Want To Make Drugs Cheaper?*, NEW REPUBLIC (June 3, 2019), https://newrepublic.com/article/154038/democrats-actually-want-make-drugs-cheaper [https://perma.cc/9TVX-J2L9 (dark archive)].

63. This is perhaps best illustrated by the cancellation of a 2016 proposed pilot that would have changed the way that Medicare Part B paid participating doctors for (often very expensive) drugs that are administered in-office. For a full explanation of the proposal, see Isaac D. Buck, *The Cost of High Prices: Embedding an Ethic of Expense into the Standard of Care*, 58 B.C. L. REV. 101, 130–34 (2017). This plan, which would have constituted a relatively minor regulatory step, was abruptly abandoned by the Obama administration—after criticism from both sides of the political aisle—in late 2016. *See* Zachary Brennan, *CMS Drops Medicare Part B Drug Payment Pilot*, REGUL. FOCUS (Dec. 16, 2016), https://www.raps.org/regulatory-focus™/news-articles/2016/12/cms-drops-medicare-part-b-drug-payment-pilot [https://perma.cc/7S9D-PU5C]; Rachel Dolan, *The Demise of the Part B Demo: Doom for Value-Based Payment?*, HEALTH AFFS.: HEALTH AFFS. BLOG (Dec. 27, 2016), https://www.healthaffairs.org/do/10.1377/hblog20161227.058082/full/ [http://perma.cc/6QJ9-FUUD (staff-uploaded archive)]; Ryan Grim & Jeffrey Young, *House Democrats Push Back on Obama Plan To Cut Drug Prices*, HUFFPOST, https://www.huffpost.com/entry/house-democrats-hhs-drug-prices_n_5720e639e4b0b49df6a9c93f [http://perma.cc/2ACY-FY7G] (Apr. 28, 2016). The proposal would have changed the reimbursement mechanism by beginning to move away from directly linking the doctor's profit to the overall cost of a drug—in an effort to remove the strong financial incentive that exists for physicians to prescribe more expensive drugs for their Medicare Part B patients. *See* Rachel E. Sachs, *Delinking Reimbursement*, 102 MINN. L. REV. 2307, 2308–14 (2018) [hereinafter Sachs, *Delinking Reimbursement*] (highlighting the importance in delinking the financial and reimbursement structure from the FDA-approval structure). The pilot was dropped after access concerns for Medicare beneficiaries were raised. *See* Brennan, *supra*.

64. *See, e.g.*, Katie Thomas & Reed Abelson, *How Trump's Latest Plan To Cut Drug Prices Will Affect You*, N.Y. TIMES (Feb. 5, 2019), https://www.nytimes.com/2019/02/05/health/drug-prices-rebates-sotu.html [https://perma.cc/MS9F-5W9U (dark archive)] (noting that a new proposed Trump administration rule will have "tricky" politics).

65. *See* Susan Scutti, *Big Pharma Spends Record Millions on Lobbying Amid Pressure To Lower Drug Prices*, CNN, https://www.cnn.com/2019/01/23/health/phrma-lobbying-costs-bn/index.html [https://perma.cc/NS68-3QFY] (last updated Jan. 24, 2019, 2:38 PM) (noting that the pharmaceutical industry lobbying was more than $27 million in 2018).

66. *See* Austin Frakt, *There Is No Single, Best Policy for Drug Prices*, N.Y. TIMES (July 15, 2019), https://www.nytimes.com/2019/07/15/upshot/lower-drug-prices-no-one-cure.html [https://perma.cc/R72H-3PRB (dark archive)] ("Although there appears to be a mandate to lower drug prices, it's an issue that defies a simple solution.").

67. *See* Li Zhou, *House Democrats' Internal Feud Over Prescription Drug Prices, Explained*, VOX (June 17, 2019, 8:20 AM), https://www.vox.com/policy-and-politics/2019/6/17/18650959/nancy-

B. *State Efforts To Secure Access to Prescription Drugs*

In health policy and regulation, a state's various roles are ubiquitous and multilayered. In one role, the state may be principally focused on paying for health care services and securing access for its indigent population, for example,[70] while in another, it may seek to ensure the enforcement of licensing and quality standards, which can have negative impacts on access.[71] In the prescription drug context, states may want to both guarantee patient access to expensive drugs *and* limit budgetary increases. These conflicts require states to achieve adequate balance between access and quality, free markets and government regulation, and private ingenuity and public options.

The differences in policy can be drastic. A policy that cuts back on the scope or breadth of Medicaid coverage will effectively reduce the state's financial burden for pharmaceutical prices.[72] This, in turn, would undoubtedly save the state money but could harm individual patients' finances if the policy increases cost sharing for its citizens. Similarly, an overbroad state policy that limits the types of drugs that can be sold in the state may save the state taxpayer dollars but may negatively impact citizens' health.[73]

States have an incentive to slow the increased financial impact on *state budgets* but may lack the same intense incentive to lower the *list price* of pharmaceutical drugs themselves. For example, in an effort to address a state's budgetary crisis caused by the price of pharmaceutical drugs, a state may seek to stop covering the drug in its Medicaid program. This may help alleviate the

pelosi-prescription-drug-prices-lloyd-doggett [https://perma.cc/E5M3-YJYW (staff-uploaded archive)] ("Reducing prescription drug prices was a key plank of House Democrats' platform during the 2018 midterms. More than six months into their term, however, a concrete bill has yet to emerge from House leadership on the subject . . . .").

68. *See* Jessie Hellmann, *White House Says Pelosi Plan To Lower Drug Prices 'Unworkable'*, HILL (Nov. 8, 2019, 12:10 PM), https://thehill.com/policy/healthcare/469608-white-house-calls-pelosis-plan-to-lower-drug-prices-unworkable-and-hyper [https://perma.cc/426Q-GL4G (staff-uploaded archive)].

69. *See* Caitlin Owens, *Congress Lukewarm on Helping Biosimilars*, AXIOS (June 12, 2019), https://www.axios.com/congress-lukewarm-on-helping-biosimilars-c5ced9a1-7b27-4ec3-897a-103c73f36c7b.html [https://perma.cc/B7A8-S9V9].

70. *See* Ashley Lopez, *Most Texans Want State To Expand Medicaid and Help Poor Get Health Care*, KAISER HEALTH NEWS (June 14, 2018), https://khn.org/news/most-texans-want-state-to-expand-medicaid-and-help-poor-get-health-care/ [https://perma.cc/G44G-KWV8].

71. *See, e.g.*, *In re* Guess, 327 N.C. 46, 48–54, 393 S.E.2d 833, 834–38 (1990) (evaluating licensing laws in the context of a licensed doctor practicing alternative medical therapies).

72. *See, e.g.*, Matthew Fleming & Phil Galewitz, *13 States Cut Medicaid To Balance Budgets*, KAISER HEALTH NEWS (July 24, 2012), https://khn.org/news/medicaid-cuts/ [https://perma.cc/MHL6-4FR4] ("Thirteen states are moving to cut Medicaid by reducing benefits, paying health providers less or tightening eligibility, even as the federal government prepares to expand the insurance program for the poor to as many as 17 million more people.").

73. *See, e.g.*, Phil Galewitz, *States Cut Medicaid Drug Benefits To Save Money*, KAISER HEALTH NEWS (July 24, 2012), https://khn.org/news/medicaid-cuts-sidebar/ [https://perma.cc/KDS9-9JJG].

state budgetary burden but would have a limited impact in addressing the overall burden of drug prices for all Americans.[74]

In an effort to provide a working nomenclature for the flurry of activity at the state level, the state's five primary roles—(1) payer, (2) consumer, (3) market facilitator, (4) overseer, and (5) regulator—are presented immediately below. These roles differ on the score of whether they can impact prescription drug prices—from the ambivalence of the payer to the hard power of the law brought to bear by the regulator—and, indeed, whether the state efforts are legally defensible.

1. State as Payer

First, and most prominently, states can operate as *passive funders* of health care services and products. In this role, states can simply—and often only—provide public funding for health care services and delivery for their citizens.[75] This role is characterized by passivity—not in that the state takes no action in the delivery of health care but that the state is largely ambivalent as to the prices of prescription drugs because they are required to cover them through their Medicaid programs.[76] Seemingly unconcerned with, or unable to achieve, global cost cutting or cost control, here the state is predominantly focused on the goal of securing and protecting access to health care for its citizens. To ensure this access, the state pays for health care products but may exercise little discretion in determining the types or costs of those products. In its most dramatic—and likely common—iteration, decisions that impact cost effectiveness are often left up to the whim of the patient or provider, and the state merely foots the bill.[77]

The state undertakes a number of actions in the spirit of its funder role. In addition to the state providing tax credits to pharmaceutical companies for research and development[78] and overseeing the operation of public mental

74. States may have a stronger incentive to seek to rein in prescription drug prices *because* of the severity of their budgetary challenges.

75. *See, e.g.*, *North Carolina Medicaid Program*, BENEFITS.GOV, https://www.benefits.gov/benefit/1390 [https://perma.cc/2LT6-SWNL].

76. *See* Sachs, *Delinking Reimbursement*, *supra* note 63, at 2309 ("In the United States, federal law requires Medicare and Medicaid to cover most, and in many cases all, FDA-approved drugs.").

77. *See* Isaac D. Buck, *Furthering the Fiduciary Metaphor: The Duty of Providers to the Payers of Medicare*, 104 CALIF. L. REV. 1043, 1068 (2016) ("[I]n many clinical scenarios, the provider retains unlimited discretion to choose among options that range in cost-effectiveness.").

78. *See* HEATHER POOLE, CONN. OFF. OF LEGIS. RSCH., SELECTED STATES' R&D TAX CREDITS 1–2 (2015), https://www.cga.ct.gov/2015/rpt/pdf/2015-R-0209.pdf [https://perma.cc/F5PH-M44Q] (comparing various states' exemptions); *How Effective Are State R&D Tax Credits?*, SSTI (Mar. 13, 2013), https://ssti.org/blog/how-effective-are-state-rd-tax-credits [https://perma.cc/E7SE-Q6YX] (summarizing how states compete for research and development jobs and economic development).

health facilities,[79] perhaps the most visible example of state health care funding is the role that the state plays in funding its Medicaid program.[80] This includes paying for Medicaid beneficiaries' prescription drugs.[81] In this role, states have discretion to determine *how much* coverage or funding they provide, often making decisions about scope and breadth of coverage for their most vulnerable public insurance beneficiaries.[82]

More generally, states have also taken actions that impact the number of citizens qualifying for Medicaid coverage. Since the passage of the ACA, a number of states have refused to expand access to Medicaid for their citizens.[83] Although shrinking, about thirty percent of states have not established or implemented Medicaid expansion under the ACA, leaving federal funding on the table in an era of tight budgets.[84] In addition to refusing to expand their Medicaid programs, states have also sought to impose additional burdens on citizens who are seeking to qualify for their state's Medicaid program. For example, states have been seeking to change the breadth of their Medicaid programs by structuring work requirements for their beneficiaries.[85] But these efforts—to this point—have been enjoined by federal courts.[86]

Aside from limiting enrollment in the preeminent, state-funded health insurance program, states can limit the number and/or type of services available to beneficiaries enrolled in the program. In addition to narrowing

79. *See, e.g.*, *State Mental Health Agency (SMHA) Per Capita Mental Health Services Expenditures*, KAISER FAM. FOUND., https://www.kff.org/other/state-indicator/smha-expenditures-per-capita/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D [https://perma.cc/K864-S7QY] (displaying the mental health service expenditures per individual state).

80. *See* MEDICAID & CHIP PAYMENT & ACCESS COMM'N, *supra* note 39.

81. *See, e.g.*, Isaac D. Buck, *States as Activists*, 39 J. LEGAL MED. 121, 126 (2019) [hereinafter Buck, *States as Activists*]; Pear, *supra* note 44 (noting Massachusetts's budget for prescription drug pricing now exceeds $2 billion annually).

82. *See* Galewitz, *supra* note 73.

83. *See Status of State Medicaid Expansion Decisions: Interactive Map*, KAISER FAM. FOUND. (Aug. 5, 2020), https://www.kff.org/medicaid/issue-brief/status-of-state-medicaid-expansion-decisions-interactive-map/ [https://perma.cc/5HG7-MHKZ].

84. *Id.*

85. *See* Vann R. Newkirk II, *The Fight Over Medicaid Begins in Kentucky*, ATLANTIC (June 29, 2018), https://www.theatlantic.com/politics/archive/2018/06/judge-halts-kentuckys-medicaid-work-requirements/564218/ [https://perma.cc/AJ7L-JPEJ (dark archive)]. Currently, the most prominent battlefield involves the fight over Medicaid work requirements. Kentucky's work requirements were approved by the Centers for Medicare and Medicaid Services in early 2018 but have been blocked by a federal court. *See id.*

86. *See, e.g.*, Stewart v. Azar, 366 F. Supp. 3d 125, 147–48, 156 (D.D.C. 2019) (enjoining Kentucky's effort to install work requirements within its Medicaid program), *appeal filed*, Stewart v. Azar, No. 19-5097 (D.C. Cir. Apr. 11, 2019). Kentucky has since rescinded its Medicaid work requirement waiver. *See Kentucky Officially Withdraws Its Medicaid Work Requirement Waiver*, ADVISORY BD. (Dec. 18, 2019), https://www.advisory.com/daily-briefing/2019/12/18/kentucky [https://perma.cc/52YP-VFE9].

coverage enrollment, states can also make that coverage shallower, as long as any changes comply with federal law.[87] In this way, state discretion is limited by federal law.[88]

Specifically, states are required to cover most drugs that are FDA approved—albeit at a discounted price.[89] But, as prices rise, "those fractional rebates no longer suffice to defray the burden of rising costs."[90] Three examples of limitations that make for shallower coverage for prescription drugs involve per-month-per-beneficiary limitations or caps, such as the one seen in Illinois; prior authorization; and automatic substitution laws.

Medicaid Prescription Caps. One way that a state can impact its prescription drug budget is to simply limit the number of prescriptions beneficiaries on Medicaid can access in the first place. Though a blunt instrument, a growing number of states have implemented so-called "Medicaid cap policies" for prescription drugs,[91] nearly doubling from twelve states in 2001 to twenty states in 2010.[92] Characterized as policies that limit the amount of prescription drugs a Medicaid beneficiary can receive over the course of a month, caps have been cost-cutting tools that states can deploy to shrink a state's prescription drug budget.[93]

87. *See* Huberfeld, *supra* note 55, at 79 ("Although the Medicaid Act has provided a baseline for states regarding standards for medical welfare, the program has allowed huge amounts of state variation within the federal rules so long as states have not provided less (on paper) than the federal statute requires.").

88. *See* 42 U.S.C. §§ 1396a–1396b-1(c) (defining the parameters that circumscribe state financial participation in and administration of medical assistance programs under federal law).

89. Rachel Sachs, *Your Weekly Reminder That FDA Approval and Insurance Coverage Are Often Linked*, BILL HEALTH BLOG (Nov. 30, 2016), https://blog.petrieflom.law.harvard.edu/2016/11/30/your-weekly-reminder-that-fda-approval-and-insurance-coverage-are-often-linked/ [https://perma.cc/3JAR-6EHA] ("Medicaid must cover essentially all FDA-approved drugs . . . .").

90. *See* Shefali Luthra, *Massachusetts Grabs Spotlight by Proposing New Twist on Medicaid Drug Coverage*, WASH. POST (Nov. 20, 2017), https://www.washingtonpost.com/national/health-science/massachusetts-grabs-spotlight-by-proposing-new-twist-on-medicaid-drug-coverage/2017/11/19/df4e7a52-cae7-11e7-aa96-54417592cf72_story.html?utm_term=.58aa0fc9ec1e [https://perma.cc/EL62-UP7R (dark archive)].

91. *See* Daniel A. Lieberman, Jennifer M. Polinski, Niteesh K. Choudhry, Jerry Avorn & Michael A. Fischer, *Medicaid Prescription Limits: Policy Trends and Comparative Impact on Utilization*, BMC HEALTH SERVS. RSCH., Jan. 15, 2016, at 1–2, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4714442/pdf/12913_2016_Article_1258.pdf [https://perma.cc/LZ97-WBSP].

92. *Id.*

93. *See, e.g.*, *Four Prescription Policy*, ILL. DEP'T HEALTHCARE & FAM. SERVS., https://www.illinois.gov/hfs/medicalproviders/pharmacy/pages/fourprescriptionpolicy.aspx [https://perma.cc/RJ38-GPU6] ("The four prescription policy was developed as a result of budget negotiations, but best-practices call for an annual review of the full regimen of prescriptions for any patient."). The policy also seeks to reduce unnecessary medications. *Id.* Starting in 2020, Illinois instituted a uniform preferred drug list. *See Heads Up! New Illinois Medicaid Prescription Drug Policy Coming Jan. 1, 2020*, AIDS FOUND. CHI. (Dec. 18, 2019), https://www.aidschicago.org/page/news/all-news/heads-up-new-illinois-medicaid-prescription-drug-policy-coming-jan-1-2020 [https://perma.cc/NF79-NGLN].

Unsurprisingly, these laws may save money for states (although this is disputed)[94] but may also negatively impact access. In addition to limiting health care access, these laws may change the type of health care services needed. For example, a recent study concluded that "caps decreased the use of preventive but not symptomatic essential medications."[95] But the laws also "shifted usage from branded drugs to generics, with considerable savings."[96]

The specific story of New Hampshire, an early adopter of caps, is informative. New Hampshire prevented its Medicaid beneficiaries from filling more than three medications per month starting in 1981.[97] This policy scrambled health care access, causing "decreased use of essential medications, increased nursing home admissions, and increased use of emergency services by patients with schizophrenia."[98] Nonetheless, the popularity of these cap laws among the states continues to grow.[99]

Since 2013, Illinois has limited the amount of prescriptions that each Medicaid beneficiary can have filled in a thirty-day period to four.[100] A number of types of drugs—including oncolytics and contraceptives—are exempted from the policy.[101] Further, Illinois has clearly noted that the policy "is not a 'hard' limit," and that "Medicaid patients can and should have access to medications that are medically necessary, even if they exceed four prescriptions per 30 days."[102] Correspondingly, according to Illinois Medicaid, "[t]he policy simply requires prior approval for prescriptions above the limit."[103]

A state's cap law is an example of state action that best characterizes a prescription policy that defines the state's role as payer. While these laws directly impact a state's Medicaid budget, they do not impact the overall list price of prescription drugs.[104] In this way, they are a particularly blunt instrument for a state seeking to cut its prescription drug budget. These cap

94. *See* NAT'L CMTY. PHARMACISTS ASS'N, EFFECTIVELY MANAGING A MEDICAID PHARMACY BENEFIT PROGRAM, http://www.ncpanet.org/pdf/leg/nov12/medicaid_manual.pdf [https://perma.cc/BZU6-X9XU (staff-uploaded archive)] ("Arbitrary medication caps rarely save money. Targeted, evidence-based precertification programs utilizing the best technology and step therapy are far more financially productive and produce better patient outcomes.").

95. Lieberman et al., *supra* note 91, at 1.

96. *See id.*

97. *See id.* at 8.

98. *See id.* at 2.

99. *See id.*

100. *See* ILL. DEP'T HEALTHCARE & FAM. SERVS., *supra* note 93.

101. *See id.*

102. *See id.*

103. *See id.*

104. A list price is the price initially listed for a drug before discounts and rebates are added. *See* Robert W. Dubois, *Rx Drug Costs: List Prices Versus Net Prices and the Importance of Staying Within the Data*, HEALTH AFFS.: HEALTH AFFS. BLOG (Mar. 13, 2019), https://www.healthaffairs.org/do/10.1377/hblog20190312.446522/full/ [https://perma.cc/SU7X-Y7ZP].

laws cut the budgets for states who impose these limits,[105] but they do so by limiting the amount of medically necessary prescriptions that are available to Medicaid beneficiaries. They also only apply to the Medicaid population, thereby lacking the hallmarks of an enduring and universal solution to the prescription-drug crisis.

Prior Authorization Laws. Another way states can attempt to limit the utilization of expensive drugs is through prior authorization laws. These programs allow Medicaid programs to trim the Medicaid budget by requiring that the provider seek preapproval before being allowed to prescribe a drug not on the preferred drug list for a Medicaid beneficiary.[106] While not much is known about the impact of these laws on access, recent studies have suggested that "prior authorization processes cause some beneficiaries and providers access and bureaucratic problems."[107]

Generic Substitution Laws. Generic substitution laws have proliferated throughout the country.[108] By 2018, forty-five states had automatic substitution laws, with the first signed by eight states in their 2013–14 legislative sessions.[109] These laws are also quite diverse: some mandate substitution—that is, if there is an interchangeable generic available, that the generic be substituted for the brand name drug.[110] Others give the pharmacist discretion to substitute generics.[111] Some require patient consent.[112] Notably, in order to be eligible, state laws require that the substitution products are deemed interchangeable by the FDA.[113] Substitution can save a substantial

105. *See* Lieberman et al., *supra* note 91, at 1 (noting that the laws led to decreases in spending for "preventive essential medications," "[b]rand cap implementation," and "medication classes with generic replacements").

106. *See Medicaid's Prescription Drug Benefit: Key Facts*, KAISER FAM. FOUND. (May 1, 2019), https://www.kff.org/medicaid/fact-sheet/medicaids-prescription-drug-benefit-key-facts/ [https://perma.cc/MNU8-HSUL].

107. *See* JANE TILLY & LINDA ELAM, KAISER COMM'N ON MEDICAID & THE UNINSURED, PRIOR AUTHORIZATION FOR MEDICAID PRESCRIPTION DRUGS IN FIVE STATES: LESSONS FOR POLICY MAKERS 1 (2003), http://files.kff.org/attachment/report-prior-authorization-for-medicaid-prescription-drugs-in [https://perma.cc/SY75-M98R].

108. *See* Richard Cauchi, *State Laws and Legislation Related to Biologic Medications and Substitution of Biosimilars*, NAT'L CONF. STATE LEGISLATURES (May 3, 2019), http://www.ncsl.org/research/health/state-laws-and-legislation-related-to-biologic-medications-and-substitution-of-biosimilars.aspx [https://perma.cc/6X7B-CTLH].

109. *Id.*

110. *See* Joseph S. Ross, *Therapeutic Substitution—Should It Be Systematic or Automatic?*, 176 JAMA INTERNAL MED. 776, 776 (2016) (highlighting the differences between automatic substitution and therapeutic substitution).

111. *Id.*

112. William H. Shrank, Niteesh K. Choudhry, Jessica Agnew-Blais, Alex D. Federman, Joshua N. Liberman, Jun Liu, Aaron S. Kesselheim, M. Alan Brookhart & Michael A. Fischer, *State Generic Substitution Laws Can Lower Drug Outlays Under Medicaid*, 29 HEALTH AFFS. 1383, 1384 (2010).

113. *See* Cauchi, *supra* note 108.

amount of money.[114] Widening the definition of what is interchangeable—including relying on therapeutic substitution, which would widen the availability of generic substitutions—could also save payers billions of dollars.[115]

* * *

The state as payer model can provide effective solutions for state budgets but often has a limited impact in affecting pharmaceutical drug prices from a holistic perspective. Nonetheless, states continue to rely on policy solutions that are from the payer paradigm. Concerns about access will likely follow those solutions.

2. State as Consumer

States can act as *consumers* of health care services and products. In this role, states are empowered, much like individual customers, to purchase health care services and products from the sellers of those products and services—hospitals, providers, and pharmaceutical companies. This role—which most commonly takes place in the context of the Medicaid program for states—empowers the state to act as would an insurance company. For example, the state of Arizona "purchases" services on behalf of its Medicaid beneficiaries just like an Arizona private insurer, such as BlueCross BlueShield, would.[116]

What differentiates the state as consumer from the state as a payer is that, in acting as a customer, the state adopts policy prescriptions that are geared toward actively forcing sellers to reduce prices. Instead of cutting services or constricting access to more expensive treatments or products—actions a state as payer would deploy—states as customers try to use their leverage to negotiate with providers and other sellers over pricing. In this role, state officials may be better positioned to accomplish the important goal of lowering the overall cost of health care without negatively impacting access.

Examples of the states-as-consumer paradigm can be seen in a flurry of new cost-efficiency efforts across the country.[117] Some of the states have moved on to so-called "outcomes-based purchasing," which allows the state to pay for drugs based on the clinical effectiveness of the product.[118] Others,

114. *See* Shrank et al., *supra* note 112, at 1383.

115. *See* Ross, *supra* note 110 (highlighting the differences between automatic substitution and therapeutic substitution). Also, Ross notes that nearly $75 billion could be saved in allowing a substitution of a within-class generic in lieu of only an interchangeable generic. *Id.*

116. *See* BLUECROSS BLUESHIELD OF ARIZ., EVERDAYHEALTH PPO (2017), https://www.azblue.com/~/media/azblue/files/employers/benefit-books/2017-ng1to50/2017-ste-e-group-everydayhealth-100-alliance-off-final--20172-0117.pdf?la=en [https://perma.cc/K2R8-XD8W].

117. *See infra* Section I.B.3 and accompanying text.

118. *See infra* notes 121–34 and accompanying text.

including Washington and Louisiana, have deployed "subscription" models in which the state pays a flat fee for unlimited access to particularly expensive drugs for its Medicaid beneficiaries and state prisoners.[119] And the Massachusetts model allows states to acquire more negotiating leverage through a formulary that is constructed based on price efficiency.[120] The three related models are summarized below.

Outcomes-Based Purchasing. In 2018, three states—Oklahoma,[121] Michigan,[122] and Colorado[123]—all received approval from the Centers for Medicare and Medicaid Services ("CMS") for so-called outcomes-based contracts with pharmaceutical companies. Outcomes-based contracts provide for the drug manufacturer to retain some of the financial risk of drug failure in an effort to save the state money.[124] Whatever the clinical goal, outcomes-based contracts allow the original drug price to remain "in place if a specified percentage of patients achieves the agreed-upon outcome. But if the outcome threshold is not met, the manufacturer refunds some of the original price to the payer."[125] The state is issued a rebate check if the drug does not perform as expected.[126]

In Oklahoma, drug companies whose drugs fail to perform as promised are required to pay a rebate that matches either the price of the drug or the cost of additional treatment needed after the drug's ineffectiveness.[127] Michigan's proposal, approved in late 2018, mirrors Oklahoma's approach in that it allows state officials "to leverage additional rebate agreements for

119. *See* Melinda Deslatte, *Louisiana Reaches 'Netflix-Model' Deal To Tackle Hepatitis C*, ASSOCIATED PRESS (June 26, 2019), https://www.apnews.com/bc074b5c06024926a5c58163de8bab9d [https://perma.cc/62JJ-BS7W]; Ricky Zipp, *Washington's Hepatitis C Subscription Model Approved by Medicaid Agency*, S&P GLOB. (June 13, 2019), https://www.spglobal.com/marketintelligence/en/news-insights/latest-news-headlines/washington-s-hepatitis-c-subscription-model-approved-by-medicaid-agency-52366464 [https://perma.cc/9CQX-7QQ8].

120. *See infra* notes 157–63 and accompanying text.

121. *See OHCA Receives OK for Drug Pricing Initiative*, OKLA. HEALTH CARE AUTH. (June 28, 2018), http://www.okhca.org/about.aspx?id=22227 [https://perma.cc/5654-KF3B].

122. *See* Susannah Luthi, *Medicaid OKs Michigan Waiver To Negotiate Drug Prices Based on Outcomes*, MOD. HEALTHCARE (Nov. 14, 2018, 12:00 AM), https://www.modernhealthcare.com/article/20181114/NEWS/181119978/medicaid-oks-michigan-waiver-to-negotiate-drug-prices-based-on-outcomes [https://perma.cc/E9T5-L7V5 (dark archive)].

123. *CMS OKs Colorado's Waiver for Medicaid Value-Based Purchasing*, MOD. HEALTHCARE (Feb. 25, 2019, 12:00 AM), https://www.modernhealthcare.com/article/20190225/NEWS/190229950/cms-oks-colorado-s-waiver-for-medicaid-value-based-purchasing [https://perma.cc/AA8C-S8G (dark archive)].

124. *See* ELIZABETH SEELEY & AARON S. KESSELHEIM, OUTCOMES-BASED PHARMACEUTICAL CONTRACTS: AN ANSWER TO HIGH U.S. DRUG SPENDING? 2 (2017), https://www.commonwealthfund.org/sites/default/files/documents/___media_files_publications_issue_brief_2017_sep_seeley_outcomes_based_pharma_contracts_ib.pdf [https://perma.cc/5KRQ-6SM7].

125. *Id.*

126. *See id.*

127. *See* OKLA. HEALTH CARE AUTH., *supra* note 121.

'outcomes-based' contracts with manufacturers."[128] Colorado followed suit in early 2019.[129]

But outcomes-based contracts have been far from a silver bullet.[130] A 2017 study concluded that these contracts could be plagued by a number of challenges—including that they would not (1) apply to a large subset of drugs, (2) sufficiently take into account patient health, (3) save patients' out-of-pocket costs, nor (4) save the state any money, among other concerns.[131]

Indeed, eight months after initial approval of the program, for example, Oklahoma had entered into only four contracts with pharmaceutical companies for treatments that covered only 1,700 patients—a shadow of the more than 800,000 Medicaid enrollees in the state.[132] The program faced "significant roadblocks," as drug companies seemed particularly reticent to enter into such agreements.[133] Coming up with specific definitions and determining when certain conditions under the program apply continues to pose a major challenge for state bureaucrats, impacting the program's overall effectiveness.[134]

The Subscription Model. In the summer of 2019, both Washington and Louisiana made news by receiving approval from CMS to enter into "subscription model[s]" to provide treatment for their residents with Hepatitis C.[135] Popularized in Australia in 2015, these models mirror popular

128. Luthi, *supra* note 122.

129. *See CMS OKs Colorado's Waiver for Medicaid Value-Based Purchasing*, *supra* note 123.

130. *See* Harris Meyer, *As a Cure for High Drug Prices, Outcomes-Based Deals Aren't Delivering Yet*, MOD. HEALTHCARE (Mar. 23, 2019, 1:00 AM), https://www.modernhealthcare.com/insurance/cure-high-drug-prices-outcomes-based-deals-arent-delivering-yet [https://perma.cc/6CCZ-4RZ9 (dark archive)]. Meyer relays that

> [I]nsurers and independent experts say outcomes-based contracting has made slow and uncertain progress since it was introduced in the past decade, with few if any published results. While it may help on the margins with some drugs, many observers doubt it offers a viable solution to the broad problem of prescription drug affordability in the U.S.

Id.

131. *See* SEELEY & KESSELHEIM, *supra* note 124, at 4–5.

132. Yusra Murad, *In Oklahoma, a Warning for Proponents of Value-Based Pharma Payment*, MORNING CONSULT (Feb. 6, 2019, 12:31 PM), https://morningconsult.com/2019/02/06/in-oklahoma-warning-proponents-value-based-pharma-payment/ [https://perma.cc/F7PA-PJN5].

133. *See id.*

134. *See id.*

135. *See CMS Approves Louisiana State Plan Amendment for Supplemental Rebate Agreements Using a Modified Subscription Model for Hepatitis C Therapies in Medicaid*, CTRS. FOR MEDICARE & MEDICAID SERVS. (June 26, 2019), https://www.cms.gov/newsroom/press-releases/cms-approves-louisiana-state-plan-amendment-supplemental-rebate-agreements-using-modified [https://perma.cc/CSN5-JDPG] [hereinafter *CMS Approves Louisiana State Plan*]; Eric Sagonowsky, *Washington Takes 'Netflix' Hep C Drug Pricing Further with Winner-Take-All Bidding*, FIERCEPHARMA (Jan. 28, 2019, 12:30 PM), https://www.fiercepharma.com/pharma/washington-seeks-proposals-for-winner-take-all-hep-c-deal [https://perma.cc/B3ZE-TXS2].

online streaming subscription services by allowing states to use an unlimited amount of drugs for a set period of time.[136] The model seems to be gaining traction at the state level and may provide a creative solution—at least for some drugs—to the cost crisis,[137] particularly because it does not negatively impact access to the drugs.

Starting on July 15, 2019, Louisiana began offering a generic form of Epclusa, a drug that treats Hepatitis C, to its Medicaid and prison populations.[138] Entering into an agreement with Asegua Therapeutics (a Gilead subsidiary), Louisiana was set to pay a flat annual fee for unlimited access to as much Epclusa as it needed.[139] Under this model, also referred to as "Netflix pricing" by the state's health secretary, Louisiana was set to pay $58 million annually for five years (a total of about $290 million), allowing the state—according to state officials—to treat more than thirty thousand individuals afflicted with the disease.[140]

The arrangement was hailed as an achievement by state officials, who said that Louisiana was unable to afford a traditional payment model to pay for Epclusa in the past because it would have cost the state more than $750 million annually.[141] CMS approved Louisiana's request for the plan, as supplemental rebates do not run afoul of the Medicaid best price rule.[142] Noting that CMS's approval could also be given to other states' similar plans, CMS Administrator Seema Verma also wrote that "CMS is committed to giving [states] flexibility to confront the challenges they face" in its approval.[143]

136. *See* Tina Rosenberg, *Treat Medicines Like Netflix Treats Shows*, N.Y. TIMES (Mar. 5, 2019), https://www.nytimes.com/2019/03/05/opinion/can-netflix-show-americans-how-to-cut-the-cost-of-drugs.html [https://perma.cc/9Y4F-3XCZ (dark archive)].

137. *See id.* ("Yet you can pay Netflix $8.99 and watch one movie or all 342 episodes (so far) of 'Grey's Anatomy.' Netflix doesn't care. Netflix and Hulu can do this because they sell products with a very low marginal cost. Movies and TV shows are expensive to make. But once that's done, each new stream costs Netflix little or nothing. Another product works in a similar way: medicine.").

138. *See* Deslatte, *supra* note 119.

139. *See id.*

140. *See id.*

141. *See id.*

142. *See* 42 C.F.R. § 447.505(d)(6) (2019) (stating that "[r]ebates under the national rebate agreement or a CMS-authorized supplemental rebate agreement paid to State Medicaid Agencies under 1927 of the Act" are excluded from the "[b]est price" requirement). CMS Administrator Seema Verma highlighted this in her letter that approved Louisiana's plan. *CMS Approves Louisiana State Plan*, *supra* note 135. Supplemental rebates are allowed under the Medicaid Drug Rebate Program with pharmaceutical companies and are "typically provided in exchange for preferential treatment on a state's preferred drug list." TARA O'NEILL HAYES, PRIMER: THE MEDICAID DRUG REBATE PROGRAM 5 (2019), https://www.americanactionforum.org/print/?url=https://www.americanactionforum.org/research/primer-the-medicaid-drug-rebate-program/ [https://perma.cc/49NB-7DMT].

143. *CMS Approves Louisiana State Plan*, *supra* note 135.

A month before Louisiana's approval, Washington received CMS approval for a similar plan.[144] Unlike Louisiana's, Washington's plan features a "winner take all" competitive bidding program.[145] The proposed plan would award the winning pharmaceutical-company bidder a contract that would allow the state unlimited access until 2023 for a set price.[146] The proposal would cover drug costs for a larger population, including Washington's Medicaid program beneficiaries, state prisoners, state employees, retirees, and teachers. [147] Individuals with state-purchased health insurance coverage constitute about 30,000 of Washington's 60,000 citizens who are infected with Hepatitis C.[148]

Medicaid Waivers and Other Direct Negotiations. In late 2017, Massachusetts attempted to use state discretion over its Medicaid program to inject consumer-based negotiation tools and filed a § 1115 waiver under the Medicaid Act.[149] This proposal would have given Massachusetts the authority to limit its drug formulary, which is the list of drugs that are covered by its Medicaid program.[150] In this way, Massachusetts would have been empowered with additional leverage to negotiate for steeper discounts in the drugs that its program ultimately covered.[151]

The upside of such a system would have allowed Massachusetts to achieve additional discounts, cutting the costs of pharmaceutical drugs without sacrificing access for its beneficiaries, largely because the proposal was set to provide coverage for at least one medication "per therapeutic class" and also had an appeals process for those whom off-formulary drugs were medically necessary.[152] This new proposal would have aligned Massachusetts's Medicaid

144. *See CMS Approves Washington State Plan Amendment Proposal To Allow Supplemental Rebates Involving a "Subscription" Model for Prescription Drug Payment in Medicaid*, CTRS. FOR MEDICARE & MEDICAID SERVS. (June 12, 2019), https://www.cms.gov/newsroom/press-releases/cms-approves-washington-state-plan-amendment-proposal-allow-supplemental-rebates-involving [https://perma.cc/4EJA-AKUB].

145. *See Washington State Requests 'Winner-Take-All' Hep C Drug Payment Models*, WCG: FDANEWS (Feb. 4, 2019), https://www.fdanews.com/articles/190086-washington-state-requests-winner-take-all-hep-c-drug-payment-models [https://perma.cc/YTX2-BH6E].

146. *See* Michael Ollove, *A Netflix Model for Hepatitis C: One Price, Unlimited Meds*, PEW CHARITABLE TRS. (Feb. 25, 2019), https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2019/02/25/a-netflix-model-for-hepatitis-c-one-price-unlimited-meds [https://perma.cc/X77W-KHHG].

147. *See id.*

148. *Eliminating Hepatitis C*, WASH. STATE HEALTH CARE AUTH., https://www.hca.wa.gov/about-hca/clinical-collaboration-and-initiatives/eliminating-hepatitis-c [https://perma.cc/DKG9-3PLV].

149. *See* Luthra, *supra* note 90.

150. *See id.*

151. *See* Max Nisen, *Massachussets Could Shake Up Drug Pricing*, BLOOMBERG BUSINESSWEEK (Sept. 28, 2017, 2:00 PM), https://www.bloomberg.com/news/articles/2017-09-28/masshealth-drug-waiver-plan-could-shake-up-pricing [https://perma.cc/L7H8-ZDYM (dark archive)].

152. *See* Luthra, *supra* note 90.

program with the coverage provided by private insurers and pharmacy benefit managers ("PBMs").[153] These entities "frequently decline to cover drugs for which there are cheaper alternatives."[154] Practically, eliminating a drug from coverage would entice the manufacturer to negotiate with the state for a more sustainable price, cutting costs for the state.[155] But after the formulary waiver was denied by CMS in 2018, Massachusetts moved on to other direct negotiation plans.[156]

Massachusetts legislators made news in the summer of 2019 after passing a bill that would start "direct negotiations with drug companies for high-priced drugs."[157] Under the proposed program, the governor would be able to begin negotiations with pharmaceutical companies if the drug costs more than $25,000 annually per patient or if the state pays more than $10 million annually for the drug.[158] According to Governor Charlie Baker, the prices of drugs in Massachusetts have "nearly doubled since 2012," and the new plan would give the governor a number of new tools should direct negotiations fail.[159] Interestingly, drugs that treat Hepatitis C are likely to fall within the ambit of the bill—including Epclusa, the drug that is the subject of Louisiana's subscription pricing plan.[160] Massachusetts spent more than $80 million on Epclusa in 2018.[161]

If negotiations do fail, under the state plan, the governor would be empowered to raise public pressure by suggesting a fairer price, establishing public hearings, or his office could ask the Massachusetts Health Policy Commission to establish a fair price.[162] But in the new Massachusetts program, there is no referral to the Massachusetts attorney general for unfair or excessive price increases.[163]

* * *

Empowering the state to leverage its market share in the health care marketplace to bring down the costs of prescription drugs encourages creative and effective solutions. Like the state-as-payer model, the state-as-consumer

153. *See* Nisen, *supra* note 151.

154. *Id.*

155. *See* Buck, *States as Activists*, *supra* note 81, at 133; Nisen, *supra* note 151.

156. For more on the story of Massachusetts, see *infra* Section II.C.

157. Martha Bebinger, *Massachusetts Moves To Negotiate Medicaid Drug Prices*, WBUR (July 22, 2019), https://www.wbur.org/commonhealth/2019/07/22/massachusetts-budget-drug-price-controls [https://perma.cc/7FUG-SWLG].

158. *Id.*

159. *Id.*

160. *Id.*; Deslatte, *supra* note 119 ("Louisiana will pay . . . for access to the generic form of the antiviral medication Epclusa . . . .").

161. Bebinger, *supra* note 157.

162. *Id.*

163. *Id.*

approaches of outcomes-based reimbursement, subscription models, and increased negotiation seem to address the state's burden for the cost of prescription drugs. In other words, the plans—at least to this point—are geared toward programs that are paid for by the state, like state Medicaid programs. A universal solution—a subscription plan or outcome-based reimbursement plan for all citizens in the state, regardless of payer—could be more effective in addressing drug prices. Nonetheless, these programs could constitute the first steps toward something more holistic and may spread to other payers if successful.

3. State as Market Facilitator

A state may aim to take a more agnostic role than the one it occupies in the customer paradigm and instead seek to improve the efficiency of health care delivery by improving the innerworkings of the marketplace. To assist providers and patients in making more cost-effective decisions, the state can support or mandate market-facilitating rules and initiatives.[164] The most prominent example of market-facilitating programs and rules regarding pharmaceutical drugs are price-transparency laws. While their effectiveness remains questionable, the laws are proliferating nationwide. The other example is wholesale importation, which opens up a new market to consumers.

This role seeks to protect citizens' access to health insurance and care, but—like the state-as-funder role—it remains largely passive. The success of these initiatives often depends on the voluntary participation of companies, patients, and providers in actually deploying decision aids that strive for cost-effectiveness and other price-transparency tools.[165] While these laws and programs seek to improve cost-effectiveness, most do not require a connection between increased transparency and clinical decision-making. A physician or patient can ignore the reported information at her own whim. As it goes

164. This can also be seen with new state laws that require providers to use decision aids in determining a course of treatment. *See, e.g.*, WASH. REV. CODE § 7.70.060(2)(c). The state is not mandating a particular course of action, nor pressuring providers to choose a particular course of treatment, but is seeking to improve the capacity for, and possibility of, reasonable and effective decision making. *See, e.g.*, *id.*

165. *See* Phil Galewitz, *Doctors Slow To Adopt Tech Tools That Might Save Patients Money on Drugs*, NPR (July 5, 2019, 5:00 AM), https://www.npr.org/sections/health-shots/2019/07/05/738283044/doctors-slow-to-adopt-tech-tools-that-might-save-patients-money-on-drugs [https://perma.cc/Q9AY-ARK6] ("Still, doctors have been slow to adopt the technology, sometimes because of concerns about getting bogged down in long discussions about drug costs. Humana, for example, introduced its drug pricing tool to its network of doctors in 2015. Today, fewer than 10% are using it, according to Humana officials.").

without saying, patients are free to ignore any of the market-facilitating tools that the state implements.[166]

A state's attempts to alleviate or solve its worst inefficiencies by trying to make the health care marketplace operate as would any other marketplace often suffer from serious challenges.[167] The state-as-facilitator role mirrors many of the changes brought about at the federal level by the ACA[168] by seeking to supercharge the power and functionality of the private market.[169] Similarly, these new pushes—mandating increased information and transparency but no pricing or spending limits—may also go a long way in explaining the law's shortcomings.[170] Perhaps legislative bodies' belief that patients simply need more information belies the data that suggests patients do not use or check pricing information, even when it is made available to them.[171] As a result, somewhat counterintuitively, increased availability of data does not lead to a reduction in the amount of health care expenditures for individuals.[172]

Beyond failing to impact individuals' decision making, these actions do not actively impact the *price* of services. In fact, the state in the facilitator role may operate with an agnosticism as to the overall price of drugs in the marketplace. And although facilitating initiatives may have varying effectiveness, states continue to implement programs intended to assist the functioning of the health care market.[173] Though this may hold some

166. *See* Helaine Olen, *A Failed Cure for Health Care Costs*, SLATE (Jan. 9, 2017, 9:40 PM), https://slate.com/business/2017/01/why-those-price-comparison-tools-to-reduce-medical-costs-dont-work.html [https://perma.cc/H2GV-VU87].

167. *Id.*

168. *See* Isaac D. Buck, *Affording Obamacare*, 71 HASTINGS L.J. 261, 271 (2020).

169. *Id.* at 270 ("It genetically engineers an artificial market by propping up *both* buyers and sellers.").

170. *Id.* at 287–88 (addressing some of the shortcomings in the law that the ACA has improved as well as areas where the ACA continues to lack leverage).

171. *See* Austin Frakt, *Price Transparency Is Nice. Just Don't Expect It To Cut Health Costs.*, N.Y. TIMES (Dec. 19, 2016), https://www.nytimes.com/2016/12/19/upshot/price-transparency-is-nice-just-dont-expect-it-to-cut-health-costs.html [https://perma.cc/C7C2-7SDC (dark archive)] ("The study found that price transparency did not reduce outpatient spending, even among patients with higher deductibles or who faced higher health care costs because of illness."). Further,

> "[h]ealth plans report that use of their price transparency tools is limited, with many enrollees unaware they exist. The vast majority of plans now provide pricing information to enrollees, but only 2 percent of them look at it. Aetna offers a price transparency tool to 94 percent of its commercial market enrollees, but only 3.5 percent use it."

Id.

172. *Id.* ("One study found that only 1 percent of residents of New Hampshire used the state's health care price comparison website over a three-year period.").

173. *See, e.g.*, Steven Findlay, *supra* note 34 ("The majority of states now have such transparency laws, and most post the data on public websites.").

regulatory promise, the federal government has sent mixed signals on its willingness to allow this type of regulatory solution.

"Transparency" Laws. Exemplifying the move to increase transparency in drug pricing, four states—Nevada, California, Vermont, and Louisiana—have passed legislation over the last few years. These actions do not include any penalty for providers, insurers, or hospitals that fail to use the drug-pricing information in making coverage or clinical decisions, so these transparency laws may have a limited impact on the global cost of pharmaceutical drugs. Nonetheless, in these four states, pharmaceutical companies are required to report pricing information—with some states requiring additional information—to state officials. These states' laws seek to publicize and/or track pharmaceutical drugs' price increases to various degrees, purportedly attempting to use the power of oversight and the disinfectant of publicity in the realm of prescription drug pricing. Whether these laws have a real impact on state budgets remains an open question.

In June of 2017, Nevada Governor Brian Sandoval signed a bill into law that forced "pharmaceutical companies to release insulin prices," which became the "country's strictest drug-price disclosure rule."[174] It specifically required the Department of Health and Human Services to compile a report disclosing the costs for "all forms of insulin," manufacturing costs for "producing the drug[s]," and research investments and projects.[175] This law's mandate targets PBMs, requiring them to "disclose what rebates they negotiate with diabetes drugmakers" and the discounts and rebates they receive.[176] It also applies beyond pharmaceutical companies and PBMs, requiring sales representatives to register with the state and nonprofits to report any funding received from pharmaceutical companies, PBMs, and insurance companies.[177]

The bill, which was a weaker, second iteration[178] growing out of the same effort to rein in insulin pricing, aimed to bring down the costs of insulin drugs

174. Jessie Bekker, *Sandoval Signs Bill To Increase Insulin Price Transparency*, LAS VEGAS REV.-J., https://www.reviewjournal.com/news/2017-legislature/sandoval-signs-bill-to-increase-insulin-price-transparency/ [https://perma.cc/X3BW-2VV2 (dark archive)] (June 15, 2017, 7:18 PM); Act of June 15, 2017, ch. 592, 2017 Nev. Stat. 4295, 4297 (codified as amended at NEV. REV. STAT. ANN. § 439B (2019) (LEXIS through all legislation from the 80th Reg. Sess. (2019), the 31st Spec. Sess. (2020), and the 32d Spec. Sess. (2020))).

175. §§ 3.6–4.3, 2017 Nev. Stat. at 4297–99; Bekker, *supra* note 174 (noting that the bill required the disclosure of "insulin prices, manufacturing costs, research investments and projects annually").

176. Lydia Ramsey Pflanzer, *Nevada Just Passed One of the Strictest Drug Pricing Transparency Laws in the Country*, BUS. INSIDER (June 15, 2017, 4:02 PM), http://www.businessinsider.com/nevada-passes-insulin-drug-pricing-transparency-bill-2017-6 [https://perma.cc/8653-JUHC]; *see also* § 4.2(1), 2017 Nev. Stat. at 4298.

177. §§ 4.6(1), 4.9(1)(a)(1), 2017 Nev. Stat. at 4300; Pflanzer, *supra* note 176.

178. Pflanzer, *supra* note 176. An original bill had capped the price of insulin drugs in the state. *Id.*

for the nearly 300,000 adults in Nevada living with diabetes.[179] The Pharmaceutical Research and Manufacturers of America ("PhRMA") and the Biotechnology Innovation Organization ("BIO") immediately sued Nevada in the late summer of 2017, alleging that the law was unconstitutional.[180] A federal district court judge denied a request for an injunction in the fall of 2017, finding a lack of immediate harm.[181] The lawsuit was dropped in the summer of 2018.[182] And since the insulin transparency law took effect, Nevada has further mandated the reporting of pricing for asthma medications.[183]

Similarly, California passed a law that requires companies to give sixty-day notice "prior to the planned effective date of [an] increase" in the "wholesale acquisition cost of a prescription drug," including the cumulative increases "within the previous two calendar years."[184] It has been called "the most comprehensive drug price transparency bill in the nation," requiring "drug makers to publicly justify big price hikes."[185] Further, under the law, health insurers are forced "to report what percentage of premium increases are due to drug prices."[186] If the pharmaceutical company failed to report this information, the state would impose civil monetary penalties, "but the bill

179. *Id.* (noting that about 281,000 adults have diabetes, which is 12% of the population and "another 39% [are] in the prediabetes stage").

180. *See* Eric Sagonowsky, *Pharma Strikes Back at Nevada Pricing Law with Lawsuit Alleging It's 'Unprecedented and Unconstitutional'*, FIERCEPHARMA (Sept. 6, 2017, 11:53 AM), https://www.fiercepharma.com/legal/pharma-takes-nevada-pricing-law-lawsuit-alleging-it-s-unprecedented-and-unconstitutional [https://perma.cc/C38E-35P7] ("The groups argue that the law 'interferes with the federal patent and trade-secret laws, deprives manufacturers of their property interest in their trade secrets, and improperly overrides the regulatory choices of every other state.'").

181. *See* Jessie Bekker, *Federal Judge Refuses To Halt Diabetes Drug Transparency Law*, LAS VEGAS REV.-J. (Oct. 17, 2017, 3:21 PM), https://www.reviewjournal.com/news/politics-and-government/nevada/federal-judge-refuses-to-halt-diabetes-drug-transparency-law/ [https://perma.cc/5N9Q-44KW (dark archive)].

182. *See* Colton Lochhead, *Nevada Governor Signs Law for Transparency in Asthma Drug Prices*, LAS VEGAS REV.-J. (May 30, 2019, 5:30 PM), https://www.reviewjournal.com/news/politics-and-government/2019-legislature/nevada-governor-signs-law-for-transparency-in-asthma-drug-prices-1676050/ [https://perma.cc/FEG5-EVH8 (dark archive)] (noting that "pharmaceutical companies . . . [have] hint[ed] at a possible lawsuit over the new law as well"). Since the early summer of 2019, Nevada has also been considering a new measure that would "set up an interim study to look at the costs of prescription drugs in Nevada and how things such as rebates, price reductions along the supply chain and other aspects play into the final charge to a patient." *Id.*

183. *Id.*

184. Act of Oct. 9, 2017, ch. 603, § 4, 2017 Cal. Stat. 4733, 4739 (codified at CAL. HEALTH & SAFETY CODE § 127677(a)–(b) (Westlaw current with urgency legislation through Ch. 372 of 2020 Reg. Sess.)).

185. April Dembosky, *California Governor Signs Law To Make Drug Pricing More Transparent*, NPR (Oct. 10, 2017, 3:25 PM), https://www.npr.org/sections/health-shots/2017/10/10/556896668/california-governor-signs-law-to-make-drug-pricing-more-transparent [https://perma.cc/HFL5-SU39].

186. *Id.*; *see also* § 6(c)(4)(A)(i), 2017 Cal. Stat. at 4744 (codified as amended at CAL. INS. CODE § 10181.45(c)(4)(A)(i) (Westlaw)), *amended by* 2020 Cal. Legis. Serv. ch. 184 (S.B. 1255) (Westlaw).

doesn't directly prohibit drug companies from price increases."[187] And like in Nevada, PhRMA has claimed that the law is unconstitutional, filing suit in U.S. district court in Sacramento in late 2017.[188] The law, which went into effect in January of 2018, "doesn't directly affect [the] prices" of drugs.[189] But "proponents [of the law] hope that advance warnings—and mandating that manufacturers justify the increases—will generate enough public pressure to hold down prices."[190] In the fall of 2019, the law led to the revelation that pharmaceutical companies raised the wholesale acquisition costs of their products by a median of nearly twenty-six percent from 2017 to 2019.[191]

Vermont was the first state to require the reporting of wholesale acquisition prices ("WACs"). Vermont's law required pharmaceutical companies to disclose price increase justifications to the state attorney general starting in 2016.[192] Interestingly, this law required that the information disclosed to the state attorney general be kept from public view and only allowed the attorney general's summaries to be made available to the public.[193] Thus, the state was powerless to either prevent or cap the price increases; the only remedy available to the state was a $10,000 fine to be used against pharmaceutical companies that failed to provide sufficient information in their reports.[194]

187. Kimberly Leonard, *California To Pass Drug Price Transparency Bill*, WASH. EXAM'R (Oct. 9, 2017, 11:01 AM), http://www.washingtonexaminer.com/california-to-pass-drug-price-transparency-bill/article/2636919 [https://perma.cc/U5L7-VV5T].

188. *See* Tracy Seipel, *Drug Companies Sue California Over Drug Pricing Transparency Law*, MERCURY NEWS, https://www.mercurynews.com/2017/12/08/drug-companies-sue-california-over-drug-pricing-transparency-law/ [https://perma.cc/F2HR-9MTS (dark archive)] (Jan. 2, 2018, 4:16 PM).

189. *See* Victoria Colliver, *California's Drug Transparency Law Yields Early Surprises*, POLITICO (Mar. 25, 2018, 7:30 PM), https://www.politico.com/story/2018/03/25/california-drug-transparency-law-440090 [https://perma.cc/433L-ZLTC].

190. *Id.*

191. *See* Shira Tarlo, *California's Drug Pricing Transparency Law Reveals Stunning Increases in Wholesale Prices*, SALON (Oct. 20, 2019, 10:30 PM), https://www.salon.com/2019/10/20/californias-drug-pricing-transparency-law-reveals-stunning-increases-in-wholesale-prices/ [https://perma.cc/26YH-ZG6W].

192. *See* Act of June 2, 2016, Pub. Act No. 165, § 4635(c)(1), 2016 Vt. Acts & Resolves 701, 702 (codified at VT. STAT. ANN. tit. 18, § 4635 (LEXIS current with Municipal Act M-11 of the 2019 Sess. (Adj. Sess.))) (requiring a "justification for the increase in the wholesale acquisition cost of [a] drug in a format that the Attorney General" finds appropriate); *see also* April McCullum, *VT Gets Drug Companies To Explain Prices*, BURLINGTON FREE PRESS, http://www.burlingtonfreepress.com/story/news/politics/government/2016/12/07/vt-gets-drug-companies-explain-prices/95040106/ [https://perma.cc/2JM4-HWKZ (dark archive)] (Dec. 8, 2016, 10:04 AM).

193. § 4635(d)–(e), 2016 Vt. Acts & Resolves at 702 (stating that the Attorney General "shall provide a report to the General Assembly").

194. § 4635(f), 2016 Vt. Acts & Resolves at 702; *see also* Peter Loftus, *Drug Pricing Report Shows Limits of Transparency Push*, WALL ST. J. (Dec. 31, 2016, 9:00 AM), https://www.wsj.com/articles/drug-pricing-report-shows-limits-of-transparency-push-1483192856 [https://perma.cc/GQ9D-32WB].

Nevertheless, Vermont's law required limited public disclosure of drugs that "had price increases of 15% in the past year, or 50% over the last five years."[195] In the first report in 2016, ten drugs fell into that category—many of which had increased more than 20% over the previous year, or that had increased more than 100% over the previous five years.[196] In 2017, the law had "yielded limited information," and "visibly frustrated" legislators considered changing the law to allow the public more access to the information.[197] This led to a "strengthening" of the law in 2018, adding new reporting requirements for insurers and drug manufacturers and requiring the formation of a working group that is charged with investigating pricing in an effort to identify savings for the state.[198]

Similarly, Louisiana passed a pair of drug-pricing transparency bills in the summer of 2017.[199] The bills mandated that pharmaceutical manufacturers that sold in the state disclose quarterly WAC prices to the Louisiana Board of Pharmacy[200] and that the Louisiana Board of Pharmacy "post on a website those WAC prices, organized by therapeutic category."[201] Further, the licensing boards were required to "advise [the prescribers] at least once annually of the opportunity to access this website."[202] Under the laws, PBMs

195. Lydia Ramsey Pflanzer, *'More Is Possible': A Bunch of States Are Taking On High Drug Prices, and It Could Start Hitting Drugmaker Profits*, BUS. INSIDER (June 4, 2017, 3:36 PM), https://www.businessinsider.com/states-with-drug-pricing-transparency-bills-2017-6 [https://perma.cc/65EQ-9EBB]; § 4635(b)(1), 2016 Vt. Acts & Resolves at 701–02.

196. *See* Zachary Brennan, *Vermont Drug Price Transparency: New Law Calls out Egregious Price Spikes*, REGUL. AFFS. PROS. SOC'Y (Dec. 6, 2016), http://www.raps.org/Regulatory-Focus/News/2016/12/06/26309/Vermont-Drug-Price-Transparency-New-Law-Calls-Out-Egregious-Price-Spikes/ [https://perma.cc/NA3M-4HEV] ("According to the latest report, of 87,248 national drug codes evaluated, 9.4% saw a more than 50% increase in the last five years and 4.6% saw more than 15% increase in the last year.").

197. *See* April McCullum, *Lawmakers: Vermont's New Drug Cost Law Is Lacking*, BURLINGTON FREE PRESS (Feb. 6, 2017, 2:11 PM), http://www.burlingtonfreepress.com/story/news/politics/government/2017/02/06/lawmakers-consider-updating-drug-cost-law/97465466/ [https://perma.cc/3YYA-UMP9 (dark archive)].

198. *See* Thomas Sullivan, *Vermont Passes Manufacturer and Insurer Pharmaceutical Cost Transparency—Strengthens Current Law*, POL'Y & MED., https://www.policymed.com/2018/06/vermont-legislation-state-revisits-manufacturer-cost-transparency-with-newly-signed-bill.html [https://perma.cc/QR4E-X66P] (last updated June 8, 2018).

199. *See* Erik Schulwolf, *Compromise Price Transparency Measures Enacted in Louisiana*, DRUG PRICING POL'Y WATCH (June 16, 2017), http://www.drugpricingpolicywatch.com/2017/06/16/compromise-price-transparency-measures-enacted-in-louisiana/ [https://perma.cc/GYL6-WQAN].

200. Act of June 14, 2017, Pub. Act. No. 220, § 2255.11, 2017 La. Acts 501, 501 (codified at LA. STAT. ANN. § 40:2255.11 (Westlaw through the 2020 1st Extraordinary Sess.)).

201. Thomas Sullivan, *Louisiana Price Transparency Measures Go into Effect . . . With an Interesting Twist*, POL'Y & MED., http://www.policymed.com/2017/09/louisiana-price-transparency-measures-go-into-effectwith-an-interesting-twist.html [https://perma.cc/R3KL-69QW] (last updated May 4, 2018) [hereinafter Sullivan, *Louisiana Price Transparency Measures Go into Effect*]; *see also* Act of June 14, 2017 Pub. Act No. 236, § 1251(A)(1)–(2), 2017 La. Acts 546, 546–47 (codified as amended at LA. STAT. ANN. § 37:1251 (Westlaw)).

202. § 1251(A)(5), 2017 La. Acts at 547.

were forced to report the rebates they received, and health insurers were required to report to beneficiaries when they received a better price than the beneficiary.[203]

Interestingly, the laws required the Board of Pharmacy to apply for, and receive, private grant funding to support the construction of the website.[204] Like in Nevada, these laws in Louisiana were watered-down versions of the original proposals that sought to impose additional pricing and cost disclosures.[205]

Wholesale Importation. In May of 2018, Vermont became the first state to pass a law that allowed the state to begin working toward achieving the importation of drugs from Canada.[206] Nonetheless, the law requires the state to seek approval from Health and Human Services ("HHS"), which has not yet occurred.[207] For his part, HHS Secretary Alex Azar has called drug importation plans a "gimmick" and has argued that "the U.S. government cannot adequately certify the safety of imported drugs."[208] Skeptics of such laws reference the safety critique, arguing that "American regulators can't effectively determine whether imported drugs meet the same safety standards as those sold directly in the United States."[209] By the end of 2019, Vermont had submitted an application and concept paper to the federal government in an effort to operationalize its importation program.[210]

203. *See* Maria Clark, *New Laws Take Aim at Prescription Drug Pricing in Louisiana*, NEW ORLEANS TIMES-PICAYUNE, https://www.nola.com/entertainment_life/health_fitness/article_bcc74d3a-851c-5466-9581-44ea7d67d96f.html [https://perma.cc/G97M-SW3J (staff-uploaded archive)] (July 12, 2019, 2:37 PM).

204. § 1251(C)(1), 2017 La. Acts at 548; *see also* Schulwolf, *supra* note 199; Sullivan, *Louisiana Price Transparency Measures Go Into Effect*, *supra* note 201 ("Within ten months of successful receipt of grand funds sufficient in amount to implement the provisions of this Section, the board shall make the drug pricing disclosure website available to prescribers.").

205. *See* Schulwolf, *supra* note 199.

206. *See* Shefali Luthra, *Vermont Legislators Pass a Drug Importation Law. So What?*, KAISER HEALTH NEWS (May 18, 2018), https://khn.org/news/vermont-legislators-pass-a-drug-importation-law-so-what/ [https://perma.cc/DY62-RXDZ].

207. Act of May 16, 2018, Pub. Act No. 133, § 4653(a), 2018 Vt. Acts & Resolves 244, 245 (codified at VT. STAT. ANN. tit. 18, § 4653(a) (LEXIS current with Municipal Act M-11 of the 2019 Sess. (Adj. Sess.))); *see* Luthra, *supra* note 206.

208. Luthra, *supra* note 206.

209. *Id.*

210. Trish Riley, *Vermont Submits Concept Paper to Trump Administration To Import Drugs from Canada*, NAT'L ACAD. FOR STATE HEALTH POL'Y (Dec. 3, 2019), https://www.nashp.org/vermont-submits-concept-paper-to-trump-administration-to-import-drugs-from-canada/ [https://perma.cc/SV7B-7WQB] ("[In 2019], Vermont Gov. Phil Scott submitted a concept paper to the federal government outlining the state's approach to implementing the first-in-the-nation drug importation law.").

By the summer of 2019, three more states had joined Vermont—Maine, Florida, and Colorado—with drug importation laws.[211] Even though the Trump administration signaled that it could support the laws[212] and has proposed a plan that would allow drugs from other countries to be sold in the United States,[213] HHS has never approved drug reimportation. And drug reimportation plans may have an enemy in the Canadian government: "[i]f Canadian prices are used to bring down American prices, drugmakers have a reason to just charge more up north."[214]

Nonetheless, the Trump administration made news in the summer of 2019, signaling that it was likely to approve two pathways that would make drug importation a reality.[215] This included the creation of a pilot program as well as drafting new safety rules and guidelines for pharmaceutical companies that wished to participate in importation.[216] A number of additional states debated bills to import drugs from Canada,[217] and more than half had proposed importation laws in 2019.[218]

* * *

While many states are operating in facilitator roles to improve the inner workings of the health care marketplace, the effectiveness of such efforts remains an open question. Drug transparency laws have limited utility, and drug importation plans—while attractive and simple—pose challenges, the most formidable of which is likely to be federal agency approval and potential legal review.[219] The state's role as facilitator—exemplified primarily by an agnostic view toward the cost of prescription drugs and federal threats—may constitute an uphill battle to directly solve the prescription-drug-cost crisis.

211. *See* Bill Chappell, *Trump Administration Plans To Allow Imports of Some Prescription Drugs from Canada*, NPR (July 31, 2019, 9:24 AM), https://www.npr.org/2019/07/31/746905508/trump-administration-plans-to-let-prescription-drugs-be-imported-to-u-s [https://perma.cc/CN5V-6VK5].

212. *Id.*

213. *See* Tami Luhby, *Trump Administration Proposes Allowing Imports of Certain Drugs from Canada*, CNN, https://www.cnn.com/2019/12/18/politics/us-drug-importation-canada/index.html [https://perma.cc/A2T3-3WHM] (Dec. 18, 2019, 4:28 PM).

214. *See* Luthra & Galewitz, *supra* note 41. Reimportation refers to the process of importing drugs that were manufactured domestically and then exported to other countries back into the United States. *See* Meredith Freed, Tricia Neuman & Juliette Cubanski, *10 FAQs on Prescription Drug Importation*, KAISER FAM. FOUND. (Oct. 8, 2020), https://www.kff.org/medicare/issue-brief/10-faqs-on-prescription-drug-importation/ [https://perma.cc/TW2J-J83M].

215. *See* Chappell, *supra* note 211.

216. *See id.*

217. *See Four More States Submit Bills To Import Prescription Drugs from Canada*, NAT'L ACAD. FOR STATE HEALTH POL'Y (Feb. 6, 2018), https://nashp.org/four-more-states-submit-bills-to-import-prescription-drugs-from-canada/ [https://perma.cc/4QY9-7JRY].

218. *See* Chappell, *supra* note 211.

219. *See id.* ("Wednesday's announcement marks the first step in the process. It could take years to implement the plans — which could also be challenged in court.").

4. State as Overseer

Beyond acting as a payer, consumer, or facilitator, a state may take on a more active role. Perhaps the state decides to directly *oversee* the prescription drug market—and its costs—and reviews the prices of products and ultimately has authority to either approve or block certain drug company proposals. This gives the state an enforcement role—it is not simply footing the bill, nor is it acting as would a private insurance company, negotiating the best price available for its beneficiaries. Instead, a state that occupies the oversight role is using its vast state apparatus to make sure the prices that are being set are reasonable.

The state is not setting prices directly, nor declaring certain prices illegal. Rather, a state occupying the oversight role is serving in a citizen-protective role. One could liken the state's role as overseer to its role occupied when regulating the price of public utilities within the state.[220] In that role, the state is influencing the price of utilities in an effort to protect its citizens while refraining from resorting to prosecution for actors who charge too much; similarly here, the state uses its ability to protect citizens from high drug prices through its police power.[221] This approach of protecting citizens rather than prosecuting violators is different from, although related to, the state adopting a consumer protection role.[222] It is exemplified by the drug commission model, which is illustrated by new programs in Maryland and Maine.

The Drug Commission Model. Just two years after passing an attention-grabbing anti-gouging law that would have applied to nonessential, noncompetitive generic drugs[223] had it not ultimately been struck down, the state of Maryland has now established a prescription drug affordability board.[224] The Maryland board is tasked with "evaluat[ing] the cost of particularly expensive medications, or those whose prices increase significantly."[225] If the board determines that the drug's price is too high, "it would set an upper payment limit for that medication for people covered by

220. *See* Nicholas Bagley, *Medicine as a Public Calling*, 114 MICH. L. REV. 57, 60 (2015).

221. *See id.* at 95–97, 99.

222. For an analysis that examines the consumer protection role in the context of prescription drug pricing, see Michelle M. Mello & Rebecca E. Wolitz, *Legal Strategies for Reining in "Unconscionable" Prices for Prescription Drugs*, 1143 NW. U. L. REV. 859, 859 (2020).

223. *See infra* Section I.B.5.

224. *See It's Maryland's Chance To Lead on Drug Prices*, BALT. SUN (Mar. 27, 2019, 11:05 AM), https://www.baltimoresun.com/opinion/editorial/bs-ed-0328-drug-cost-control-20190327-story.html [https://perma.cc/BGN7-HY9J (staff-uploaded dark archive)] [hereinafter *It's Maryland's Chance*]; Thomas Sullivan, *Maryland Creates Prescription Drug Affordability Board for Setting Price Caps*, POL'Y & MED., https://www.policymed.com/2019/06/maryland-creates-prescription-drug-affordability-board-for-setting-price-caps.html [https://perma.cc/7DLW-Z7W9] (last updated June 22, 2019).

225. *It's Maryland's Chance*, *supra* note 224.

state or local health care plans other than Medicaid."[226] It held its first meeting in January of 2020, with outreach meetings scheduled to be held in February.[227] Pennsylvania additionally proposed a drug affordability board in early 2020.[228]

Two additional details that relate to Maryland's program are important: first, the program could be expanded to "limit[] . . . all drug purchases in the state," and second, it could impact as many as 300,000 people.[229] It only applies to drugs with a starting price at $30,000 per year, a brand-name drug that experiences a $3,000 increase, or a generic drug that experiences a price increase of more than 200 percent.[230] Its first impactful work could go into effect in 2022 at the earliest.[231]

Maine has also established a drug affordability board.[232] This program will create a 5-member board tasked with creating "prescription drug spending targets for public entities based on a 10-year rolling average, accounting for inflation with spending reductions, and [will] provide methods for achieving lower prescription costs through measures such as bulk purchasing, leveraging multi-state purchasing, or negotiating specific rebate amounts."[233] The legislation requires that the board be empaneled in 2020,[234] and tasks the entity with devising plans and suggestions that would achieve cost savings for the state's public payers.[235] These plans could lead to an upper payment limit that would be set starting in 2022.[236]

226. *Id.*

227. *See* Bruce DePuyt, *Prescription Drug Affordability Panel Gets to Work*, MD. MATTERS (Jan. 13, 2020), https://www.marylandmatters.org/2020/01/13/prescription-drug-affordability-panel-gets-to-work/ [https://perma.cc/BLY7-99NR].

228. *See Pennsylvania Introduces Legislation To Form a Prescription Drug Affordability Board*, PA. HEALTH ACCESS NETWORK (Jan. 30, 2020), https://pahealthaccess.org/pennsylvania-introduces-legislation-to-form-a-prescription-drug-affordability-board/ [https://perma.cc/AV54-UALN].

229. *It's Maryland's Chance*, *supra* note 224.

230. Prescription Drug Affordability Board Act, ch. 692, § 21-2C-08(C), 2019 Md. Laws 4027, 4043–44 (codified as amended at MD. CODE ANN., HEALTH-GEN. § 21-2C-08(c) (LEXIS through legislation effective Oct. 1, 2020)).

231. *See* Kyle Blankenship, *Maryland, Massachusetts Statehouses Press Drug-Pricing Bills as Feds Founder*, FIERCEPHARMA (Apr. 12, 2019, 11:05 AM), https://www.fiercepharma.com/pharma/maryland-massachusetts-statehouses-take-lead-drug-pricing-bills-as-feds-founder [https://perma.cc/Z8Q3-DNMX].

232. Act of June 24, 2019, ch. 471, § 2041(1), 2019 Me. Laws 1214, 1214 (codified at ME. STAT. tit. 5, §§ 2041–2042 (Westlaw current with legislation through the 2019 2d Reg. Sess. of the 129th Leg.)) (establishing "[t]he Maine Prescription Drug Affordability Board . . . .").

233. Thomas Sullivan, *Maine Governor Signs Prescription Drug Reform into Law*, POL'Y & MED., https://www.policymed.com/2019/06/maine-governor-signs-prescription-drug-reform-into-law.html [https://perma.cc/Z9HG-5EW3] (last updated June 25, 2019); *see also* §§ 2041(2), 2042(1) Me. Laws at 1214, 1216.

234. *See* § 2041(6), 2019 Me. Laws at 1215.

235. § 2042(3), 2019 Me. Laws at 1217.

236. *See* Lev Facher, *Pharma Lobbyists Flooded Maryland To Block a Drug-Pricing Bill. Opponents Pushed Back—And Won*, STAT (Apr. 11, 2019), https://www.statnews.com/2019/04/11/pharma-

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The solution of the drug commission board appears promising but is untested to this point by courts. Indeed, the new legislation has been influenced by Maryland's past efforts to regulate drug prices.[237] Those efforts ended in the Fourth Circuit striking down Maryland's law,[238] which is the focus of the next section.

5. State as Regulator

Finally, the state can occupy the state-as-regulator role, 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. While a handful of states were considering passing anti-gouging legislation by the summer of 2019,[239] Maryland—and its controversial and ultimately struck-down law that was passed in 2017—is the prototypical example of a state that has empowered law enforcement to prosecute and punish pharmaceutical companies that have allegedly gouged its citizens for the price of prescription drugs. The story of Maryland is summarized below.

Anti-Gouging Legislation. In 2017, and without the governor's signature,[240] Maryland passed an anti-gouging law—legislation that applied to "essential off-patent or generic drug[s]."[241] This law prevented those who are engaged in a noncompetitive marketplace[242] from gouging consumers in the state. For

lobbyists-flooded-maryland-to-block-a-drug-pricing-bill-opponents-pushed-back-and-won/ [https://perma.cc/CVT2-S9H9].

237. *See* Jane Horvath, *Maryland Passes Nation's First Prescription Drug Affordability Board Legislation*, NAT'L ACAD. FOR STATE HEALTH POL'Y (Apr. 15, 2019), https://nashp.org/maryland-passes-nations-first-prescription-drug-affordability-board-legislation/ [https://perma.cc/AH3R-JEKB] (noting that the legislation will "phase-in" board authority due to concern about a court challenge following the strike down of its last drug pricing effort).

238. *See infra* Section I.B.5.

239. *See State Prescription Drug Legislative Tracker*, NAT'L ACAD. FOR STATE HEALTH POL'Y (July 18, 2019), https://www.nashp.org/wp-content/uploads/2019/12/Final-2019-Tracker-1-3-2020.pdf [https://perma.cc/9C48-YKBK] (identifying New Jersey, Virginia, and Indiana as states considering such legislation).

240. *See* Michael Dresser, *Hogan Lets Drug Price-Gouging Bill, Dozens of Others Become Law Without Signature*, BALT. SUN (May 26, 2017, 7:06 PM), http://www.baltimoresun.com/news/maryland/politics/bs-md-hogan-bill-decisions-20170526-story.html [https://perma.cc/U4GM-M4XM (staff uploaded dark archive)].

241. *See* David C. Gibbons & Jeffrey N. Wasserstein, *Maryland AG Seeks SCOTUS Review of Generics Price-Gouging Prohibition Struck Down by Fourth Circuit*, FDA L. BLOG (Oct. 26, 2018), http://www.fdalawblog.net/2018/10/maryland-ag-seeks-scotus-review-of-generics-price-gouging-prohibition-struck-down-by-fourth-circuit/ [https://perma.cc/FBU4-ZNK7].

242. This is defined as a market with three or fewer manufacturers who were competing. *See* Buck, *States as Activists*, *supra* note 81, at 131; Jeremy A. Greene & William V. Padula, *Targeting Unconscionable Prescription-Drug Prices — Maryland's Anti-Price-Gouging Law*, 377 NEW ENG. J. MED.

drugs that were "made available for sale in" Maryland, the law authorized the Maryland attorney general to sue manufacturers where a manufacturer committed an unconscionable increase in the price of a drug.[243] Under the law, the attorney general was empowered to prevent the price hike and freeze the original price, disgorge any profits, and seek civil penalties of up to $10,000.[244] Before doing so, however, the attorney general was required to "afford the manufacturer or distributor an opportunity to explain the basis of a price increase."[245]

Further, the statute did not define what type of price increase would constitute price gouging but did require the attorney general to show that the price increase was unconscionable and unjustified.[246] It also defined an "unconscionable increase" as an increase resulting in "consumers for whom the drug has been prescribed having no meaningful choice about whether to purchase the drug at an excessive price because of (1) the importance of the drug to their health, and (2) insufficient competition in the market for the drug."[247] Finally, "the attorney general was required to be notified of drug price increases of 50 percent or more 'in a given year for drugs that cost[] more than $80 per 30-day course.'"[248] The law went into effect in October of 2017,[249] but was declared unconstitutional by the Fourth Circuit in the spring of 2018.[250] A request for a rehearing *en banc* was rejected in the summer of 2018.[251] More on its unconstitutionality follows below.[252]

II. REGULATORY CLOGS

To date, four legal and administrative barriers have been erected to prevent states from regulating the price of prescription drugs. Their sources

102, 102 (2017), https://www.nejm.org/doi/10.1056/NEJMp1704907 [https://perma.cc/K7QB-7FZH (dark archive)].

243. *See* Buck, *States as Activists*, *supra* note 81, at 131; Greene & Padula, *supra* note 242, at 101.

244. *See* Buck, *States as Activists*, *supra* note 81, at 130–31.

245. *See* Green & Padula, *supra* note 242, at 102.

246. Buck, *States as Activists*, *supra* note 81, at 131; Green & Padula, *supra* note 242, at 102.

247. Gibbons & Wasserstein, *supra* note 241; *see also* Act of May 27, 2017, ch. 818, § 2-801(F), 2017 Md. Laws 4555, 4557–58 (codified as amended at MD. CODE ANN., HEALTH-GEN. § 2-801(f) (LEXIS through legislation effective Oct. 1, 2020)).

248. Buck, *States as Activists*, *supra* note 81, at 131.

249. *See* Michael Dresser, *Judge Refuses To Block Maryland Price-Gouging Law*, BALT. SUN (Sept. 29, 2017, 12:25 PM), https://www.baltimoresun.com/politics/bs-md-price-gouging-law-20170929-story.html [https://perma.cc/L8T4-YS7R (dark archive)].

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

251. *See* Ass'n for Accessible Meds. v. Frosh, 742 F. App'x 720, 720–21 (4th Cir. 2018) (mem.); Jeff Barker, *U.S. Supreme Court Denies Maryland Bid To Revive Law Aimed at Preventing 'Monstrous' Generic Drug Price Increases*, BALT. SUN (Feb. 19, 2019), https://www.baltimoresun.com/politics/bs-md-drug-price-gouging-decision-20190219-story.html [https://perma.cc/ P6JN-PTA9 (dark archive)].

252. *See infra* Section II.B.

vary. And the depths of these regulatory clogs make state efforts to successfully bring down the price of drugs all the more challenging; legislators must successfully navigate a thicket of overlapping laws with substantial preemptive power.

Interestingly, as opposed to a scenario in which the federal government explicitly seeks to limit state power in a regulatory space, none of these four legal regimes serves as an affirmative limitation. Thus, none of the regimes directs specific limitations on state pharmaceutical price regulation *per se*. In other words, none of these four regimes were created to reserve the power to regulate the prices of pharmaceutical drugs to the federal government. Instead, the resultant regulatory void—the states' inabilities to regulate pharmaceutical-drug prices—has been the result of a cumulative preemptive effect. For example, where one administrative agency process has blocked one pathway, another federal statute has blocked another avenue, with constitutional doctrine blocking yet another. To date, (1) ERISA, (2) the Dormant Commerce Clause, (3) CMS's federal waiver process, and (4) federal patent preemption have been used to limit state efforts in this space. All four are summarized below.

A. *ERISA*

First, there is the Employee Retirement Insurance Security Act of 1974 ("ERISA"),[253] which constitutes the most serious legislative threat to state action.[254] Most basically, ERISA prevents and invalidates state action that improperly "relates to" an employment-based private health insurance plan because the regulation of employee benefit plans is solely within the power of Congress.[255] In effect, ERISA creates a system of complete preemption in which the federal statute overpowers application of any state law that constitutes an impermissible connection with employer-based health insurance.[256] Work on ERISA's massive preemption effect—and the long, dark shadow it casts on health care policy solutions—has been the subject of incisive scholarly attention and is not the focus of this analysis.[257] Instead, this Article looks to the impediments that ERISA places before state regulation on prescription drug prices.

253. Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406, 88 Stat. 829 (1974) (codified as amended in scattered sections of 29 U.S.C.).

254. *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.").

255. *Id.* at 948 (Thomas, J., concurring) (quoting Egelhoff v. Egelhoff, 532 U.S. 141, 147 (2001)).

256. *Id.* at 946 (majority opinion) (holding that "a state law that enters a fundamental area of ERISA regulation and thereby counters the federal purpose" will be preempted).

257. *See* Erin C. Fuse Brown & Elizabeth Y. McCuskey, *Federalism, ERISA, and State Single-Payer Health Care*, 168 U. PA. L. REV. 389, 389 (2020).

ERISA has an undeniable impact on state efforts to regulate prescription drug prices, primarily because in seeking to regulate drug prices states promulgate laws that impact the cost sharing of private employer-based health insurance plans, particularly self-funded insurance plans.[258] When 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. Indeed, states have even run afoul of ERISA's preemption provisions by passing laws that have simply required price reporting to a state agency.[259] Thus, a state plan that impacts all payers in a state—for instance, a newly-proposed single-payer plan that limits the costs of all prescription drugs—is likely to impermissibly implicate ERISA because those state laws impact types of insurance plans that are always regulated by ERISA.[260] In this way, and with such a strong view of ERISA preemption, a state's options at holistically limiting prescription drug prices—at least as those regulations operate on health insurance—seem limited.

This is largely due to the fact that ERISA preempts "'any and all' state laws that 'relate to' employee benefit plans."[261] This provision mandates broad preemptive authority, constituting a much stronger impact than so-called floor preemption—the type of preemption that sets a federal floor and preempts weaker state regulation but allows states to regulate in a more rigorous way.[262] Because ERISA's preemptive effect is so powerful, perhaps the only way around the preemption provision besides amending ERISA is to make compliance with state rules that regulate pharmaceutical-drug prices voluntary.[263]

For this compelling reason, ERISA remains a block on the states' ability to regulate the cost of prescription drugs. Indeed, more than sixty percent of Americans with employer-based insurance are covered by self-funded plans

258. Self-funded plans are free of state regulation and are entirely governed by ERISA. *See* L. Darnell Weeden, *Tactical Self-Funded ERISA Employers Unnecessarily Threaten Employees' Right to an Independent Review of an HMO's Medical Necessity Determination with Preemption*, 77 ST. JOHN'S L. REV. 867, 868 (2003) ("As a general rule, ERISA's deemer clause prohibits a state from applying its insurance regulations to self-funded plans.").

259. A recent Eighth Circuit decision held that ERISA preempted an Iowa law that would have required pharmacy benefit managers to report payment methodology. *See* Pharm. Care Mgmt. Ass'n v. Gerhart, 852 F.3d 722, 731 (8th Cir. 2017).

260. *See Gobeille*, 136 S. Ct. at 953 (Ginsburg, J., dissenting) (quoting N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 656 (1995)) ("[A] law 'relates to' an employee benefit plan . . . if it has a connection with or reference to such a plan.").

261. *See* Fuse Brown & McCuskey, *supra* note 257, at 449.

262. *Id.* at 449–50.

263. *See* Alexandra M. Stecker, *The Great Divide: ERISA Integrity Versus State Desire To Hold Pharmacy Benefit Managers Accountable for Pharmaceutical Drug Pricing*, 44 J. CORP. L. 171, 184 (2018).

that are governed directly by ERISA.[264] Because of this concern, many state solutions are limited to devising answers to the challenges faced only by public payers in the state, most namely Medicaid.[265]

However, any solution only addressing the price of prescription drugs paid for by state Medicaid programs would be incomplete; California, a state with a large Medicaid population, still only covers one-third of state residents through its Medicaid program.[266] Further, about twenty percent of Tennesseans are on the state Medicaid program of TennCare.[267] Using state law to limit prices paid by Medicaid programs is unlikely to harm state cost control efforts but also seems unlikely to impact the overall list prices of prescription drugs.

B. *The Dormant Commerce Clause*

A court-made doctrine,[268] the Dormant Commerce Clause presents an additional challenge to states seeking to regulate the price of drugs; states that seek to limit the price of drugs must be particularly cognizant of the extraterritoriality doctrine within it.[269] State laws that seek to regulate drug costs that implicate transactions occurring outside of their state borders have been held to violate the Dormant Commerce Clause, largely because the doctrine prevents states from passing laws that evince an intent to regulate transactions in other states.[270]

The most prominent use of the Dormant Commerce Clause to strike down a state's effort is related to Maryland's effort in establishing its anti-gouging law.[271] In the Fourth Circuit's 2018 decision, the court noted that the

264. *See* Erin C. Fuse Brown & Ameet Sarpatwari, *Removing ERISA's Impediment to State Health Reform*, 378 NEW ENG. J. MED. 5, 6 (2018), https://www.nejm.org/doi/full/10.1056/NEJMp1709167 [https://perma.cc/6V3K-KS9Z (dark archive)].

265. Stecker, *supra* note 263, at 183 ("Instead of requiring entities under ERISA to report to state agencies, state legislatures can target entities outside the scope of ERISA.").

266. *See* Hattie Xu, *A Third of All Californians Depend on Medi-Cal. Here's Who They Are and Where They Live*, SACRAMENTO BEE, https://www.sacbee.com/news/local/health-and-medicine/article160786554.html [https://perma.cc/WX8P-BSS9] (July 20, 2017, 10:57 PM).

267. *See TennCare Overview*, DIV. TENNCARE, https://www.tn.gov/tenncare/information-statistics/tenncare-overview.html [https://perma.cc/8YBD-YMB2].

268. "Although the Constitution does not in terms limit the power of States to regulate commerce, we have long interpreted the Commerce Clause as an implicit restraint on state authority, even in the absence of a conflicting federal statute." United Haulers Ass'n v. Oneida-Herkimer Solid Waste Mgmt. Auth., 550 U.S. 330, 338 (2007).

269. *See* Ass'n for Accessible Meds. v. Frosh, 887 F.3d 664, 667 (4th Cir. 2018) ("The principle against extraterritoriality as it relates to the dormant commerce clause is derived from the notion that 'a State may not regulate commerce occurring wholly outside of its borders.'" quoting Star Sci., Inc. v. Beales, 278 F.3d 339, 355 (4th Cir. 2002)).

270. *Id.* at 670–72 ("[T]he Act effectively seeks to compel manufacturers and wholesalers to act in accordance with Maryland law outside of Maryland. This it cannot do.").

271. *See id.* at 674 (stating that "Maryland must address this [drug pricing] concern via a statute that complies with the dormant commerce clause" after striking down the state's antigouging statute).

Maryland law did not sufficiently limit its reach to sales that occurred wholly within Maryland.[272] Instead, the court concluded that the plain language of the Act—that the types of transactions that were under the purview of the Act applied to any "[e]ssential off-patent or generic drug" that was "made available for sale in [Maryland]"[273]—swept too far because the language was not limited to "sales that actually occur[red] within Maryland, nor [did] it restrict the Act's operation to the context of a resale transaction with a Maryland consumer."[274] On the narrow question of whether the specific language of the act appropriately limited the types of transactions over which it had an impact, the Fourth Circuit held that the language was insufficiently limited for purposes of dormant commerce analysis.

That holding would suggest that a new, more narrowly-tailored effort (like one that limits its application to sales made in Maryland to Maryland consumers, for instance), could pass constitutional muster, but the Fourth Circuit was sure to block additional regulatory pathways for future state efforts.[275] The court reasoned that "[e]ven if the Act did require a nexus to an actual sale in Maryland, it is nonetheless invalid because it still controls the price of transactions that occur wholly outside the state."[276] Because the law targeted manufacturers or wholesale distributors, and not "retailers that sell the drug directly to the consumer" and the price of the drug during "the initial sale of the drug," the court concluded that the Act targeted "upstream pricing and sale of prescription drugs"—transactions that occur outside of the state.[277] Even though the First Circuit upheld a similar statute that did not directly regulate out of state transactions involving manufacturers, and even though the Fourth Circuit acknowledged that Maryland's effort did "not establish a price schedule for prescription drugs, nor d[id] it aim to tie the prices charged for prescription drugs in Maryland to the prices at which those drugs are sold in other states," the law "attempt[ed] to dictate the price that may be charged elsewhere for a good."[278] This, the court noted, it could not do.[279]

The court went even further, calling the Maryland law a "price control" as opposed to an "upstream pricing impact," the latter of which is typically upheld under a Dormant Commerce Clause challenge.[280] Interestingly, the court differentiated previous scenarios from the Maryland law in an attempt to make the argument "that it 'regulate[d] the price of [an] out-of-state

272. *Id.* at 670–71.
273. *Id.* at 671.
274. *Id.*
275. *Id.*
276. *Id.*
277. *Id.*
278. *Id.* at 672.
279. *Id.*
280. *Id.*

transaction.'"[281] Finally, the court found that the act burdened interstate commerce because of the thorny problem of a second state establishing similar regulation. The court noted that "[i]f multiple states enacted this type of legislation, then a manufacturer may consummate a transaction in a state where the transaction is fully permissible, yet still be subject to an enforcement action in another state (such as Maryland) wholly unrelated to the transaction."[282] The Fourth Circuit's decision has illustrated the difficulty that states face when trying to regulate the price of drugs.

C. *Medicaid Waiver Requests*

Faced with ERISA and Dormant Commerce Clause challenges, it makes sense that states have fallen back on one area of health law and policy over which they (presumably) have tremendous discretion. Typically seen as an area of protected state innovation and dominion, states try to impact the price of prescription drugs through their Medicaid programs.[283] While regulatory solutions that focus solely on the state's Medicaid population lack the holistic solution to the problem of drug pricing, they still could presumably impact the prices that are charged while also holding down state budgets for Medicaid programs in an era of tightening coffers.

Nonetheless, CMS denied Massachusetts' waiver request, which would have allowed the state to establish a formulary within its Medicaid program in order to build in more cost-effectiveness.[284] Legal scholars have noted that any legal objections to the proposal seem to be pretextual and that perhaps CMS was waiting on congressional buy-in before approving such waivers.[285] For its

281. *Id.* (quoting Pharm. Rsch. & Mfrs. of Am. v. Walsh, 538 U.S. 644, 669 (2003)). Interestingly, the court differentiated the scenario where a state imposes a law that requires manufacturers to comply with a new escrow law and results in higher prices, impacting "purchasers in sales transactions that occur wholly outside [New York]," (upheld by the Second Circuit) from the Maryland law in *Frosh* because the law at issue in New York "was the result of natural market forces and was not artificially imposed by the laws of another state." *Id.* (quoting Freedom Holdings Inc. v. Spitzer, 357 F.3d 205, 220 (2d Cir. 2004)). In Maryland's effort, the court called it an attempt "to override prescription drug manufacturers' reaction to the market and to regulate the prices these manufacturers charge for their products," qualifying as a price control. *Id.*

282. *Id.* at 673.

283. "The [Medicaid] Act gives the States substantial discretion to choose the proper mix of amount, scope, and duration limitations on coverage, as long as care and services are provided in 'the best interests of the recipients.'" Alexander v. Choate, 469 U.S. 287, 303 (1985).

284. *See* 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/CY7A-GZWK (dark archive)] (describing the denial that prevented Massachusetts from establishing a "closed formulary structure" within its Medicaid program).

285. *See* Nicholas Bagley & Rachel Sachs, *Massachusetts Wants To Drive Down Medicaid Drug Costs: Why Is the Administration So Nervous*?, HEALTH AFFS.: HEALTH AFFS. BLOG (Apr. 5, 2018), https://www.healthaffairs.org/do/10.1377/hblog20180404.93363/full/ [https://perma.cc/WCY5-NAMZ] [hereinafter Bagley & Sachs, *Massachusetts Wants To Drive Down Medicaid*] ("Perhaps more

part, CMS noted that "it would have considered the waiver if it was a pilot or demonstration project," but the Massachusetts application was not proposed as such a project.[286] Scholars sharply criticized the decision to deny the waiver,[287] as CMS did not provide legal reasoning that explained the denial of the waiver.[288] Instead, CMS suggested that states that sought such waivers could get them approved if they gave up Medicaid's statutory discounts,[289] but it is highly unlikely that any state would opt for such a pathway.[290] Indeed, the Medicaid program provides statutory rebates, and most states achieve additional supplemental rebates with manufacturers.[291]

As a result, CMS has blocked another avenue for states to address pharmaceutical-drug pricing while limiting state power in an area that has historically been seen as extensive. This has occurred while the federal administration encourages states to use the Medicaid waiver process to construct work requirements in the Medicaid program[292] and to overhaul its

plausible is the idea that CMS wants congressional buy-in before taking a step—approving closed formularies—that would undermine the legislative bargain struck between rebates and coverage.").

286. Dickson, *supra* note 284.

287. *See* Katie Gudiksen, *Update on Massachusetts' Waiver Request To Use a Drug Formulary for Medicaid*, SOURCE (July 9, 2018), https://sourceonhealthcare.org/source-short-update-on-massachusetts-waiver-request-to-use-a-drug-formulary-for-medicaid/ [https://perma.cc/JP78-8V9G] ("If the federal government is serious about increasing pharmaceutical competition, they need to allow states to test different methods of bringing down prices, including using closed formularies, to force drug manufacturers to demonstrate the value of their products to patients.").

288. *See* Nicholas Bagley & Rachel E. Sachs, *Limiting State Flexibility in Drug Pricing*, 379 NEW ENG. J. MED. 1002, 1003 (2018), https://www.nejm.org/doi/full/10.1056/NEJMp1809358 [https://perma.cc/H745-4ZWT (dark archive)]. Bagley and Sachs further expand on CMS's failure to expand on the denial of the waiver:

> For example, the agency could have said—but didn't—that the waiver is bad policy. It could have said—but didn't—that the waiver contravenes the purposes of the Medicaid statute. It could have said—but didn't—that the agency lacks the resources to oversee a novel waiver like this one. CMS offered no explanation at all for the rejection . . . . From a legal perspective, that's a problem. Administrative law requires agencies to provide reasons for their actions.

Id.

289. *See* Rachel Sachs & Nicole Huberfeld, *The Problematic Law and Policy of Medicaid Block Grants*, HEALTH AFFS.: HEALTH AFFS. BLOG (July 24, 2019), https://www.healthaffairs.org/do/10.1377/hblog20190722.62519/full/ [https://perma.cc/DPE3-TY94] ("Although CMS did not explain the legal reasoning behind its denial, it did suggest that a state may choose to exclude drugs if it forgoes Medicaid's statutory discounts. This strategy, though, is unlikely to lead to savings larger than the program was able to obtain already. Only if a state severely restricts the drugs it will cover, and therefore severely restricts patients' access to care, could cost savings occur.").

290. *See* Bagley & Sachs, *Massachusetts Wants To Drive Down Medicaid*, *supra* note 285 (noting that Massachusetts and Arizona are the only states that have requested waivers).

291. *See* Rachel Dolan, *Understanding the Medicaid Prescription Drug Rebate Program*, KAISER FAM. FOUND. (Nov. 12, 2019), https://www.kff.org/medicaid/issue-brief/understanding-the-medicaid-prescription-drug-rebate-program/ [https://perma.cc/A9JA-QFJM].

292. Corin Cates-Carney, *Rural Seasonal Workers Worry About Montana Medicaid's Work Requirements*, NPR (Nov. 3, 2019, 8:10 AM), https://www.npr.org/sections/health-shots/

funding mechanism through block grant proposals,[293] which both face substantial legal hurdles.[294]

D. *Patent Law*

Finally, federal patent law can impact state efforts to regulate the pricing of pharmaceutical drugs.[295] Pay-for-delay bills are meant to outlaw the practice of pharmaceutical companies with lucrative patents from paying potential competitors to delay entry of alternative drugs into the market.[296] This is a prominent argument in the litigation surrounding California Bill AB 824,[297] which bans "pay-for-delay" deals.[298] The Association for Accessible Medicines ("AAM"), the plaintiff in the Maryland litigation, sued the state of California seeking a preliminary injunction and alleging a number of legal infirmities.[299] In that motion, which was denied on December 31, 2019,[300] AAM made a

2019/11/03/766115339/rural-seasonal-workers-worry-about-montana-medicaids-work-requirements [https://perma.cc/RME3-HRQU] ("The Trump administration . . . encourages states to add work requirements to Medicaid . . . ."). Medicaid work requirement proposals, which seek to limit the population covered by the Medicaid program, have been the subject of extensive litigation. While approved by CMS, to date, waiver requests have been blocked by federal courts as violative of the Medicaid statute. *See, e.g.*, Stewart v. Azar, 366 F. Supp. 3d 125, 145–48 (D.D.C. 2019), *appeal filed*, Stewart v. Azar, No. 19-5097 (D.C. Cir. Apr. 11, 2019).

293. *See* Nathaniel Weixel, *Trump Administration To Allow Medicaid Block Grants*, HILL (Jan. 30, 2020, 9:38 AM), https://thehill.com/policy/healthcare/480650-trump-administration-to-allow-medicaid-block-grants [https://perma.cc/AQ3L-FLYK].

294. *See, e.g.*, *Stewart*, 366 F. Supp. 3d at 145–48; Shira Stein, *Medicaid Block Grant Policy Could Face High Legal Hurdles*, BLOOMBERG L. (Jan. 28, 2020, 5:16 AM), https://news.bloomberglaw.com/health-law-and-business/medicaid-block-grant-policy-could-face-high-legal-hurdles [https://perma.cc/6XSW-YMYY].

295. *But see* Serena Lipski, *Excessive Pricing and Pharmaceuticals: Why the Federal Patent Act Does Not Preempt State Regulation of Pharmaceutical Prices*, 39 U. TOL. L. REV. 913, 914 (2008) ("Any implication that a state is prohibited from regulating pharmaceutical pricing at all, however, challenges core principles of federalism and the special role of the state as the primary source of laws promoting health and welfare. A state may directly regulate the price of pharmaceutical products, patented or not, as part of its general police power.").

296. *See* Michael Owens, *A Cure for Collusive Settlements: The Case for a Per Se Prohibition on Pay-for-Delay Agreements in Pharmaceutical Patent Litigation*, 78 MO. L. REV. 1353, 1353 (2013) ("Under a pay-for-delay agreement, a manufacturer of a brand-name pharmaceutical will settle patent infringement litigation by making payments to a defendant generic manufacturer in exchange for the generic manufacturer refraining from entering the market.").

297. Act of Oct. 7, 2019, 2019 Cal. Stat. ch. 531 (A.B. 824) (codified at CAL. HEALTH & SAFETY CODE §§ 134000–134002) (Westlaw current with urgency legislation through Ch. 372 of 2020 Reg. Sess.)).

298. *See* Phebe Hong, *Legal Challenges to California's Pay-for-Delay Ban*, BILL HEALTH (Oct. 17, 2019), https://blog.petrieflom.law.harvard.edu/2019/10/17/legal-challenges-to-californias-pay-for-delay-ban/ [https://perma.cc/TWP4-4X24] ("The AAM argues that the California law is unconstitutional because it regulates out-of-state transactions and is preempted by federal patent law.").

299. *See* Ass'n for Accessible Meds. v. Becerra, No. 2:19-cv-02281, 2019 WL 7370421, at *1–2 (E.D. Cal. Dec. 31, 2019), *vacated and remanded*, 822 F. App'x 532 (9th Cir. July 24, 2020).

300. *Id.* at *1.

number of legal arguments, one of which focused on the fact that California's law that banned pay-for-delay deals between pharmaceutical companies was preempted by federal patent law.[301]

In that case, the Eastern District of California agreed with the state that California's pay-for-delay law did not violate federal patent preemption because it did "not require determination of the validity of a patent and [did] not create patent-like protections."[302] The court also denied the argument that the law violated the Hatch-Waxman Act,[303] largely because the court found it "impossible to know if this law will have its intended effect, or as Plaintiff argue[d], will backfire, causing generic companies to cease filing [abbreviated new drug ("ANDA")] applications[304] and challenging patents held by brand-name drug companies."[305] Finally, the court denied a challenge related to the well-known case of *FTC v. Actavis*,[306] noting that "*Actavis* turns on questions of antitrust law, not patent law, and federal antitrust law does not preempt state antitrust law."[307] Nonetheless, states cannot specifically target patented pharmaceuticals, as that effort has been struck down before.[308]

Although the district court's decision was struck down by the Ninth Circuit exclusively due to issues with standing, and California's efforts to activate its pay-for-delay law are left unresolved, patent preemption remains a powerful tool that is intended to keep states from intervening in this space. Indeed, courts have routinely invalidated state efforts that have impermissibly conflicted with federal patent law.[309] A state law that governs the marketing, selling, and competition of a patented good—in this case, a pharmaceutical drug—has to contend with the concern that it will run afoul of patent preemption here.

301. *Id.* at *7.

302. *See id.*

303. Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 35 U.S.C. § 156).

304. An ANDA application is an "abbreviated new drug application," which is the application filed for a generic drug. *See Abbreviated New Drug Application (ANDA)*, FOOD & DRUG ADMIN. (May 22, 2019), https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda [https://perma.cc/APK5-MR9L]. "Generic drug applications are termed 'abbreviated' because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness." *Id.*

305. *Ass'n for Accessible Meds.*, 2019 WL 7370421, at *7

306. 570 U.S. 136 (2013).

307. *See Ass'n for Accessible Meds.*, 2019 WL 7370421, at *8.

308. *See, e.g.*, Biotechnology Indus. Org. v. District of Columbia, 496 F.3d 1362, 1371–74 (Fed. Cir. 2007).

309. *See, e.g.*, Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 152–57 (1989) ("[S]tate regulation of intellectual property must yield to the extent that it clashes with the balance struck by Congress in our patent laws."); Zenith Elecs. Corp. v. Exzec, Inc., 182 F.3d 1340, 1355 (Fed. Cir. 1999).

* * *

After canvassing the states' efforts and the formidable legal hurdles, Table 1 categorizes those observations. It also provides an assessment of the likelihood of success as well as notable drawbacks given the strength of the obstruction of particular regulatory strategies that states face.

What is notable about the various approaches, and their particular legal and policy-based risks, is that those in which the state appears to be engaging in the most effective interventions are most hamstrung by legal challenges. Efforts most free from legal challenge appear to be those that are either likelier to be ineffective or a partial solution to the drug-pricing problem. For example, the constitutionality of transparency laws does not appear to be in doubt, but the effectiveness of those laws is surely questionable. Subscription models appear to trigger no legal challenge, but they only deal (as currently constituted) with one drug for the Medicaid population. Worse, prescription drug caps and other efforts that narrow access are clearly protected within the state's police power but have negative impacts on population health. Maryland's effort—which empowered the state to bring the force of its power to bear to lower drug costs—was blocked by the Dormant Commerce Clause. These observations highlight the challenges facing states and the unenviable task of achieving regulatory success and meaningful improvement without drawing a substantial legal challenge.

Table 1: State Roles and Efforts To Impact Drug Pricing

Type	Specific Effort	Threat	Drawbacks/ Effectiveness
State as Payer	Prescription Drug Caps	None	Medicaid Only, Negative Clinical Impacts
State as Payer	Narrowing Access	None[310]	Medicaid Only, Negative Clinical Impacts
State as Customer	Subscription Model	None	Medicaid Only, Often One Drug
State as Customer	Outcomes-Based Contracts	None	Medicaid Only, Often One Drug
State as Customer	Direct Negotiations	Unknown	Medicaid Only
State as Customer	Medicaid Formularies	Blocked by Health and Human Services	Medicaid Only
State as Facilitator	Drug Importation	Unknown	All Payers, Unknown
State as Facilitator	Transparency Laws	None	All Payers, Limited Effectiveness
State as Overseer	Pricing Commissions	None	All Payers, Mixed (*see* MD v. NY)
State as Regulator	Anti-Gouging	Unconstitutional, Dormant Commerce	All Payers, Potentially Effective

III. THE PROBLEMS OF CUMULATIVE DRUG-PRICING PREEMPTION

Besides the concerns related to the balance of health care federalism—which is beyond the purview of this Article—the inability of states to regulate the price of pharmaceutical drugs raises two different species of concerns. The two species are encapsulated by (1) the legitimacy of the regulatory scheme, and (2) any normative values that are surfaced by this type of regulatory regime.

310. With the exception of injunctions against work requirements, like those seen in Kentucky. Other efforts that limit access to drugs for a state's Medicaid population do not face legal threats.

The first concern focuses on regulatory legitimacy. Indeed, eviscerating state power to regulate pharmaceutical-drug prices when the federal government has no forthcoming solution to the crisis—for example, blocking state efforts, whether by courts or a federal agency with no superseding federal solution—abdicates important congressional duties that would be responsive to concerns of the populace. More seriously, it raises important questions about whether those regulatory clogs are appropriate or whether they illustrate an illegitimate block on state power. Concerns referenced in other scholarly literature—particularly the concerns raised by "null" preemption from Professor Jonathan Remy Nash[311]—are worthwhile to consider in the context of pharmaceutical-drug pricing regulation as considered here. These concerns are made all the more important given the efforts by the drug-pricing industry to use preemption to block regulatory efforts and, correspondingly, a friendly U.S. Supreme Court.[312] This both raises the stakes over these fights and further incentivizes business interests to increasingly rely on the power of preemption.

The second species of concerns focuses on four normative interests raised by the impotency of states in this area. First, states' inabilities to regulate and answer to their citizens' demands raises antidemocratic concerns. Second, the elimination of state regulation makes the regulatory regime weaker. Third, and perhaps counterintuitively (to the extent state experimentation leads to diverse policy prescriptions), states' inability to regulate drug prices may lead to a *less* efficient and *less* consistent regulatory design over time. Fourth, there is a practical concern; the federal block seems to make it less likely that the crisis—evinced by the observation that prescription drugs cost too much for too many Americans—will actually be addressed. For these arguments, literature from administrative and environmental law scholarship—specifically from Professor William Buzbee—will be applied to the pharmaceutical-pricing challenge in an effort to show why the federal cap on state policymaking in this space is not only concerning but also damaging.

A. *Regulatory Legitimacy and Null Preemption*

In his 2010 law review article, Professor Jonathan Remy Nash observes and defines "null preemption," the phenomenon that occurs when the federal

311. *See generally* Jonathan Remy Nash, *Null Preemption*, 85 NOTRE DAME L. REV. 1015 (2010) (explaining null preemption and the concerns it raises).

312. *See* Sandra Zellmer, *Preemption by Stealth*, 45 HOUS. L. REV. 1659, 1703 (2009) ("As the states become more aggressive in filling gaps left by lax federal regulatory schemes and federal enforcement failures, for-profit corporations, developers, and other antiregulatory forces have become equally aggressive—and quite effective—in wielding preemption as an obstacle to the implementation of protective state regulations.").

government preempts state law but replaces it with nothing.[313] Ultimately arguing that the practice should be limited and that courts should "react skeptically to assertions of null preemption," Professor Nash provides a nomenclature for the practice throughout his piece.[314] That nomenclature—although specifically focused on environmental law—can be borrowed and imported into health law scholarship, particularly within the regulation of pharmaceutical-drug prices, to illuminate some startling findings.

At the center of Professor Nash's work is a concern about the legitimacy of a federal government that preempts all state action but replaces it with no concomitant federal regulation.[315] The legitimacy-based concerns raised by null preemption are likely to exacerbate the concerns he identifies as generally common to preemption, not the least of which is the harm to state dignity caused by preemption in these cases.[316] As he argues, and as is seen in the pharmaceutical drug context, a federal regime intent on blocking state efforts but unwilling to establish a superseding regulatory structure raises all the legitimacy concerns seen in occurrences of null preemption.

B. *Normative Concerns*

In his piece, *Federalism Hedging, Entrenchment, and the Climate Challenge*, Professor William W. Buzbee presents a compelling argument that supports state regulation in environmental law.[317] Although his expert focus is on environmental regulation with a specific emphasis on climate change, Professor Buzbee's insights and lessons can be easily translated and applied to health law and to the pharmaceutical-drug-cost crisis. Specifically, his

313. *See* Nash, *supra* note 311, at 1017.

314. *Id.* at 1016.

315. *Id.* at 1055–56.

> The legitimacy costs of null preemption to state governments are substantial. Federal preemption of state law is inconsistent with the dignity of states as sovereigns in any circumstance. The offense is of lesser magnitude where, under the constitutional scheme for allocation of power, the preemption lies in an area in which the federal government is seen to regulate more effectively or appropriately. In contrast, the offense to state dignity is surely heightened where the preemption is null preemption, and the federal government preempts state power to regulate without offering to do so on its own.

Id. at 1055.

316. *See id.* at 1055 ("Federal preemption of state law is inconsistent with the dignity of states as sovereigns in any circumstance." (citing Daniel J. Meltzer, *State Sovereign Immunity: Five Authors in Search of a Theory*, 75 NOTRE DAME L. REV. 1011, 1040–41 (2000))); *see also* Nina A. Mendelson, Chevron *and Preemption*, 102 MICH. L. REV. 737, 781 (2004) (observing that regulatory preemption of state law could "impose upon a state's dignity or a state's function as a policy 'laboratory' or center of democratic activity").

317. *See generally* William W. Buzbee, *Federalism Hedging, Entrenchment, and the Climate Challenge*, 2017 WIS. L. REV. 1037 (arguing the need for both state and federal regulation of climate change).

observations—and particularly those about the strength and consistency of a state-based regulatory framework—can be applied to the instant analysis and are highlighted below.

The imposition of various legal rules that have blocked state efforts to successfully regulate prescription drugs has led to four normative concerns about cumulative preemption: it (1) is antidemocratic, (2) weakens the strength of the regulatory regime overall, (3) injects inconsistency into the regulatory environment, and (4) decreases the changes of a durable and successful federal intervention. These four challenges—presented as four adjectives that highlight normative concerns with this type of regulatory regime—are presented in-depth below.

1. Antidemocratic

First, the most apparent concern evinced by the federal block on state regulation of drug prices is the impact of federal action on blocking the will of citizens. State action, which includes attempting to impose Medicaid formularies to gain more control over the cost of prescription drugs, passing new anti-gouging laws that give the state the ability to more powerfully regulate and prevent radical price increases, and allowing the state access to prescription drug-pricing data—are all undertaken in response to pressure from the citizenry.[318] Federal actions that block a state's ability to regulate in this space silence the voices of the citizens and "entirely deprive[] states of their ability to fulfill their sovereign obligation to protect their citizens."[319] This concern may be particularly pronounced when executive agencies and/or federal appellate courts are the sources of the antidemocratic actions.

Indeed, there are few issues featuring as much consensus among Americans. Nearly ten years after the passage of the ACA, citizens believe drug costs are too high.[320] This is a topic of broad agreement across the political spectrum.[321] A striking percentage of Americans skip taking doses of

318. *See* Mendelson, *supra* note 316, at 781 (referring to the state as a "center of democratic activity").

319. *See* Nash, *supra* note 311, at 1055.

320. *See* Jay Hancock, *Americans Ready To Crack Down on Drug Prices That Force Some To Skip Doses*, KAISER HEALTH NEWS (Mar. 1, 2019), https://khn.org/news/americans-ready-to-crack-down-on-drug-prices-that-force-some-to-skip-doses/ [https://perma.cc/9KRR-QMXP] ("By a 9-to-1 ratio, Republicans, Democrats and independents favor making drug companies show list prices in their advertising . . . ."); Ed Silverman, *Most Americans Believe Prescription Drug Prices Are Unreasonable*, STAT NEWS (Sept. 29, 2016), https://www.statnews.com/pharmalot/2016/09/29/americans-believe-drug-prices-unreasonable/ [https://perma.cc/8ZDW-S7PE] (noting that about 80% of Americans call prescription drug prices "unreasonable").

321. *See Poll: Majorities of Democrats, Republicans and Independents Support Actions To Lower Drug Costs, Including Allowing Americans To Buy Drugs from Canada*, KAISER FAM. FOUND. (May 1, 2017), https://www.kff.org/health-costs/press-release/poll-majorities-of-democrats-republicans-and-

medication in an effort to save money.[322] Consequently, wide majorities support additional efforts to improve access to medicines.[323] Of those polled, sixty-three percent stated that "there's not as much regulation as there should be to help limit the price of prescription drugs."[324] Nearly ninety percent of respondents supported government negotiations for the Medicare program, and eighty percent stated that Americans should be allowed to import drugs from Canada.[325] It is clear that the cap on state efforts, preventing them from adequately regulating pharmaceutical drugs, frustrates clear wishes of a vast majority of the citizenry.

2. Weaker

Overlapping regulation—between the federal and state levels—makes the regulatory structure stronger because it bolsters deterrence and forces the desired improvement by enforcing those regulations.[326] Put simply, it is more likely that two regulatory entities will uncover and punish illegality.[327] Overlapping regulation also achieves a level of redundancy in the regulatory structure, working to operationalize the fact that "another regulatory system reduces the possibility that certain undesirable behavior slips through the cracks."[328]

State and federal regulatory authorities also allow learning of best practices to occur.[329] Both horizontal and vertical feedback take place, improving the chance that the regulatory regimes can learn from one another. Federal intervention in this way, specifically intervention that blocks state efforts, can "short-circuit the evolution and spread of regulatory ideas."[330] Not only does it block states from trying out different regulatory solutions for eventual federal implementation, but it chills the learning that occurs *between states* when states are able to regulate.[331]

independents-support-actions-to-lower-drug-costs-including-allowing-americans-to-buy-drugs-from-canada/ [https://perma.cc/47XP-2RAF].

322. *See* Fuse Brown & Sarpatwari, *supra* note 264, at 6 (noting that twenty percent of Americans have skipped or delayed a pharmaceutical dosage due to cost).

323. *See* Alison Kodjak, *Poll: Americans Support Government Action To Curb Prescription Drug Prices*, NPR (Mar. 1, 2019, 3:00 AM), https://www.npr.org/sections/health-shots/2019/03/01/699086303/poll-americans-support-government-action-to-curb-prescription-drug-prices [https://perma.cc/X8BQ-ZXYY] (providing poll data suggesting respondents majorly favor proposals to lower drug costs).

324. *Id.*

325. *See id.*

326. *See* Buzbee, *supra* note 317, at 1050.

327. *Id.*; *see also* ROBERT A. SCHAPIRO, POLYPHONIC FEDERALISM: TOWARD THE PROTECTION OF FUNDAMENTAL RIGHTS 123–24, 154 (2009).

328. *See* Nash, *supra* note 311, at 1057.

329. *See* Buzbee, *supra* note 317, at 1050–51.

330. *See* Nash, *supra* note 311, at 1056–57.

331. *See* Jonathan H. Adler, *Interstate Competition and the Race to the Top*, 35 HARV. J.L. & PUB. POL'Y 89, 97 (2012) ("To the contrary, evidence suggests, at least in those areas not dominated by

3. Inconsistent

Striking down state efforts injects additional inconsistency into the regulatory regime. Consistency is important for the obvious reason of securing the stability of an interlocking federal regulatory state but also—as Professor Buzbee recognizes—for bringing other strengths to the regulatory environment. All can be applied to the pharmaceutical-drug-cost crisis.

First, Professor Buzbee notes that "regulatory success and stability will often depend on market and business innovations that over time will make regulatory burdens palatable."[332] In other words, new regulatory requirements often spur innovative actors who flock to a market in an effort to assist the targets of regulation in dealing with the newly created regulatory space. To apply this recognition to the instant analysis, this would suggest that increased state regulation of pharmaceutical-drug pricing would incentivize new innovators to create products that would enable drug companies to better handle new regulatory burdens. These may be companies that can handle the monitoring and compliance functions that would accompany any drug-pricing regulatory regime required by a state.

Second, and relatedly, once a regulatory regime takes hold, business interests are incentivized "to become political coalitions that oppose regulatory change that could unsettle their markets."[333] Once a state is permitted to regulate in the space, business interests push targeted entities to reshuffle their incentives so as to increasingly concretize the rising regulatory requirements, instantiating them within a business model and industry.[334] As is argued in the context of climate change, "businesses . . . have, over time, become increasingly invested in the new status quo and will defend it."[335]

Indeed, with no state regulation, the regulatory structure is wholly dependent on federal regulation, which can be fickle based on changes in presidential administration. As Professor Buzbee notes, overlapping state and federal regulation creates a sort of regulatory insurance. In this way, "federal regulatory instability or reversal will not result in the collapse of interdependent markets and businesses" and "[n]o single jurisdiction's regulatory reversals or instability will destroy the market or product category demand."[336] This is the fundamental value of consistency in a regulatory

federal intervention, that states learn from each other and move toward adopting superior environmental policies because of interactions with their neighbors."); Vicki C. Jackson, *Thayer, Holmes, Brandeis: Conceptions of Judicial Review, Factfinding, and Proportionality*, 130 HARV. L. REV. 2348, 2354–55 (2017) (observing that Justice Brandeis supported American federalism, which allows states to learn from one another).

332. Buzbee, *supra* note 317, at 1052.

333. *Id.* at 1053–54.

334. *Id.*

335. *Id.* at 1096.

336. *Id.* at 1056.

regime that allows both federal and state intervention. The "stops and starts" experienced in the effort to regulate drug prices have added to the inconsistency in this space.

4. Decreasing the Chance of Federal Intervention

Relatedly, state-based regulation is likely to increase the chance of successful federal intervention. In the first way, state regulation reduces the temperature of regulatory fight, making it less of a zero-sum battle between the industry and policymakers. Second, simply allowing states to regulate in this space—and, in some ways, irrespective of the regulatory success they ultimately experience—serves a communicative function to federal regulators, increasing pressure on them to act.

First, allowing states to regulate drug prices would defang the pharmaceutical industry's efforts to fight every attempt by the federal government with such vigor. As Professor Buzbee mentions, "[t]he rewards for fighting regulation will diminish if success leaves another layer of regulation, especially if that layer is made up of disparate state policies."[337] Indeed, because states are often prevented from regulating drug prices from the start, business interests face supercharged incentives to fight every federal effort, largely because the federal policy battle represents the whole ball game.[338]

A related observation is also worth mentioning. In addition to simply refraining from fighting holistic regulation, the existence of state regulation in the space may actually pressure industry actors to "come to the table" in search of a better federal solution. As Professor Buzbee mentions, "the mere possibility of more varied and possibly more onerous state regulation can reduce the risk of such federal policy reversal or even catalyze calls for federal regulation."[339] It may even be the case that the industry supports a federal law that improves on a state law that may be flawed.[340] Indeed, successful implementation of state regulation may not even be necessary, but the *ability* of states to regulate in the space is important. As noted, the threat of state regulation "creates incentives for greater commitment to the successful implementation of a federal law" by the industry.[341] A regulatory structure that robs the states of any potential ability to regulate eviscerates this positive effect.

337. *Id.* at 1057.

338. *See id.* at 1098 ("In fact, the regulatory payoff for regulatory obstruction at the federal level would be greater if that derailment promised a complete escape from regulation.").

339. *Id.* at 1056–57.

340. *See id.* at 1096.

341. *See id.* at 1099.

Finally, allowing the state to operate in the space may increase the chance of federal intervention—not only because allowing states to operate further encourages businesses to come to the negotiating table, but it also raises pressure on federal actors. In the face of state action, the costs of federal regulators not acting become greater. State action ratchets up political pressure on the federal government. It also serves as a viable channel, allowing and protecting the value of expression.[342]

In this vein, and as Professor Patti Zettler has noted in the context of FDA approval,[343] state action serves not just as a substantive exercise but also constitutes a communicative action. Indeed, state action here is important *not just* for whether it ultimately works—or, for the confines of this Article, is ever allowed to *potentially* work—but state action is important because of its communicative signal to the federal government.[344] In other words, states operating in this space create pressure on the federal government to act—pressure that mounts following an increasing number of state actions to bring down the price of prescription drugs. A system that frequently holds that states lack the power to regulate drug prices allows federal policymakers to hide in their inaction and delay any meaningful intervention. This argument would suggest that states that ultimately are unsuccessful in bringing down the cost of prescription drugs are still serving an important function by signaling to the federal government that this is a problem in need of a solution. But without durable state solutions, that important communicative function is silenced.

C. *Alternative Pathways*

Given the challenges that exist, it is worthwhile to contemplate particular regulatory channels and initiatives that still provide a potential way forward for states to regulate the price of prescription drugs. These potentials, currently unblocked, feature a cognizable argument as to which regulatory avenues are clearly within the state's power to establish. They are (1) professional regulation, (2) consumer protection, and (3) voluntary or softer-power regimes. All three are explored below.

Professional Regulation. In other areas within health law, states have unfettered discretion to regulate the practice of medicine. Indeed, states have plenary authority to govern licensing and disciplinary actions within their borders.[345] Through the use of their police power, states also have the ability

342. *See* Nash, *supra* note 311, at 1057.

343. *See generally* Patricia J. Zettler, *Pharmaceutical Federalism*, 92 IND. L.J. 845 (2017) (arguing that state drug regulation will drive federal action).

344. *See id.* at 895–900.

345. *See* Drew Carlson & James N. Thompson, *The Role of State Medical Boards*, AMA J. ETHICS POL'Y F. (Apr. 2005), https://journalofethics.ama-assn.org/article/role-state-medical-boards/2005-04

to regulate different facets of the practice of medicine, and can regulate how many and what pills they allow providers to prescribe.[346] It is conceivable that a state regulation that limits the types of drugs that the provider can prescribe, though impeding clinical discretion, could be used by states to prevent physicians from prescribing drugs that are too expensive.

Price Gouging Laws Focused on Consumer Protection and Lending Law. As Professors Becky Wolitz and Michelle Mello have argued,[347] states could deploy consumer protection statutes in a more robust way in an effort to protect citizens from unconscionable pricing while avoiding a void-for-vagueness challenge. These laws, typically well within states' domains, seek to impose externalities on manufacturers whose products harm citizens, much in the same way prescription drug prices harm those who are exposed to their high prices. Mello and Wolitz argue that lending laws offer a helpful analog but caution that "a state-level consumer protection law focused on generic drug prices is still risky."[348]

A Voluntary or Incentive-Based Solution. A third potential solution is to build a regulatory mechanism that is largely voluntary but which incentivizes participation. These systems would be free from the concerns over state regulation of the insurance marketplace but would seek to ratchet up pressure on prescription drug manufacturers who price their drugs at unsustainable levels. Different rewards, such as preferred tax status, could be awarded to prescription drug companies who act in a way the state wants to encourage. This would allow the state to avoid the challenges of ERISA, but it would face the challenge of being a regulatory solution that lacks any enforcement mechanism.

CONCLUSION

The prices of prescription drugs in the United States are unsustainable. Not only do they exact a painful cost on America's consumers, but they impact Americans' access to life-enhancing (and sometimes lifesaving) drugs. Recognizing this threat, states have attempted to regulate in this space to protect their citizens. States rely on multiple roles when it comes to prescription drug prices. Some act as payers, consumers, market facilitators, overseers, or regulators. Many occupy multiple roles simultaneously.

[https://perma.cc/E3QX-A9LM] ("The right to practice medicine is a privilege granted by each state.").

346. *See* Christine Vestal, *States Require Doctors To Use Prescription Drug Monitoring Systems for Patients*, WASH. POST (Jan. 15, 2018, 8:00 AM), https://www.washingtonpost.com/national/health-science/states-require-doctors-to-use-prescription-drug-monitoring-systems-for-patients/2018/01/12/c76807b8-f009-11e7-97bf-bba379b809ab_story.html [https://perma.cc/9BFC-DX95 (dark archive)].

347. *See* Mello & Wolitz, *supra* note 222, at 953–55.

348. *See id.* at 955–57.

Increased state action in this space reflects a rising trend of state primacy in health policy. But action on the ground is hamstrung, with a number of legal blocks preventing various state solutions from taking effect. From ERISA, to the Dormant Commerce Clause, to HHS's waiver process, federal sources of law serve as a cap on state action in this space. Besides the obvious harms, these regulatory clogs are antidemocratic, weaken the regulatory structure, inject inconsistencies, and are likely to lessen the chances of a satisfactory federal solution. This analysis suggests a rethinking of the current federally driven regulatory regime in an effort to finally make America's prescription drugs affordable.