DRUG DEALING: MAKING PUBLIC PHARMA WORK

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ABSTRACT

The U.S. market for prescription drugs is failing many Americans. Drug prices in the United States are nearly three times higher than in comparable countries, and evidence shows that patients regularly forego essential medicines because they cannot afford them. Additionally, shortages of important medicines are common. In partial response, California recently passed a law to enable public manufacture and distribution of medicines, starting with insulin, a drug needed by many diabetics in the state. Several other states, as well as the federal government, are considering similar action to drive down prices of older drugs and to help resolve shortages. Public production could yield important benefits, but there are legal obstacles to overcome at every step, from developing the product at the bench to getting it to the patient. This Article maps the primary legal and logistical issues facing public pharmaceutical programs—from intellectual property barriers and PBM-driven market manipulation to regulatory hurdles like FDA registration, ERISA preemption, and product liability. We also propose ways to overcome these obstacles. We focus especially on a troubling reality: even if states succeed in producing affordable, high-quality public medicines, they may still struggle to get them to the millions of patients who need them. After all, private generic manufacturers already face major obstacles in breaking through distribution bottlenecks to deliver lower-cost options. But states have tools that private firms lack. Armed with legislative, regulatory, and contractual authority, states can encourage—or require—market intermediaries to carry public products, expanding access at scale. In doing so, they may also help dismantle the bottlenecks that constrain private generic competition more broadly.

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INTRODUCTION

Prescription drug pricing and access are serious problems in the United States today. Drug prices are, on average, three times higher than in other developed nations, with insulin products similarly (if not more) disproportionately priced.[1] Expenditures on prescription drugs are also

1. ANDREW W. MULCAHY, DANIEL SCHWAM & SUSAN L. LOVEJOY, OFF. ASSISTANT SEC'Y FOR PLAN. & EVALUATION, U.S. DEP'T HEALTH & HUM. SERVS., INTERNATIONAL PRESCRIPTION DRUG PRICE COMPARISONS: ESTIMATES USING 2022 DATA 3 (2024), https://aspe.hhs.gov/sites/default/files/

increasing annually,[2] with spending rising by 9.4% to $633.5 billion in 2022 alone.[3] Pricing, however, is not the only impediment to access. Increasingly, hospitals and pharmacies have reported drug shortages,[4] due to supply chain issues and abrupt discontinuation of essential medications by private manufacturers, leaving patients with few alternatives.[5]

The public health consequences of these pricing and access issues are far-reaching. More than one in four adults taking prescription drugs have reported difficulties paying for and accessing medications,[6] leading many to

documents/8e057b0a094e6f9b9d01171fce6698f4/international-price-comparisons.pdf [https://perma.cc/AY4R-6Q7X]; ANDREW W. MULCAHY, DANIEL SCHWAM & NATE EDENFIELD, OFF. ASSISTANT SEC'Y FOR PLAN. & EVALUATION, U.S. DEP'T HEALTH & HUM. SERVS., COMPARING INSULIN PRICES IN THE U.S. TO OTHER COUNTRIES 16 (2020), https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//196281/Comparing-Insulin-Prices.pdf [https://perma.cc/6PD6-BTET]. Notably, these analyses primarily use gross prices, as those are more readily available than net prices. While we recognize that these prices are not the prices that all patients (or even most patients) pay at the pharmacy counter, list prices are the publicly posted prices for these drugs that are paid by some patients. In addition, these claims survive sensitivity analyses that attempt to adjust for this missing net price data. *See, e.g.*, MULCAHY et al., *supra*, at ix.

2. ARIELLE BOSWORTH, STEVEN SHEINGOLD, KENNETH FINEGOLD, NANCY DE LEW & BENJAMIN D. SOMMERS, OFF. ASSISTANT SEC'Y FOR PLAN. & EVALUATION, U.S. DEP'T HEALTH & HUM. SERVS., PRICE INCREASES FOR PRESCRIPTION DRUGS, 2016–2022 (2022), https://aspe.hhs.gov/sites/default/files/documents/e9d5bb190056eb94483b774b53d512b4/price-tracking-brief.pdf [https://perma.cc/3A4E-9PZE].

3. Eric M. Tichy et al., *National Trends in Prescription Drug Expenditures and Projections for 2023*, 80 AM. J. HEALTH-SYS. PHARMACY 899, 899 (2023).

4. ERIN R. FOX & MICHAEL GANIO, AM. SOC'Y HEALTH-SYS. PHARMACISTS, NATIONAL DRUG SHORTAGES: JANUARY 2001 - DECEMBER 2024 (2025), https://www.ashp.org/-/media/assets/drug-shortages/docs/2024/2024-Drug-Shortages-Survey.pdf [https://perma.cc/8ZZP-5QPJ]; AM. SOC'Y HEALTH-SYS. PHARMACISTS, SEVERITY AND IMPACT OF STERILE INJECTABLE DRUG SHORTAGES (2022), https://www.ashp.org/-/media/assets/drug-shortages/docs/ASHP-Sterile-Injectable-Drug-Shortages-March 2022.pdf [https://perma.cc/V5LR-XMWY]; Michelle P. Lin, Carmen Vargas-Torres, Janice Shin-Kim, Jacqueline Tin & Erin Fox, *Nearly All Thirty Most Frequently Used Emergency Department Drugs Experienced Shortages from 2006–2019*, 53 AM. J. EMERGENCY MED. 135, 136–38 (2022); Bharath Krishnamurthy & Megha Parikh, *Drug Prices and Shortages Jeopardize Patient Access to Quality Hospital Care*, AM. HOSP. ASS'N (May 22, 2024, 8:27 AM), https://www.aha.org/news/blog/2024-05-22-drug-prices-and-shortages-jeopardize-patient-access-quality-hospital-care [https://perma.cc/9WZZ-5KMT].

5. David Dayen, *Novo Nordisk Discontinues Insulin Medication After Cutting Its Price*, AM. PROSPECT (Mar. 14, 2024), https://prospect.org/health/2024-03-14-novo-nordisk-discontinues-insulin-levemir [https://perma.cc/CP27-B2V6]; TRINIDAD BELECHE ET AL., OFF. ASSISTANT SEC'Y PLAN. & EVALUATION, U.S. DEP'T OF HEALTH & HUM. SERVS., IMPACT OF DRUG SHORTAGES ON PATIENTS IN THE UNITED STATES: A CASE STUDY OF THREE DRUGS (2024), https://www.ncbi.nlm.nih.gov/books/NBK608930/pdf/Bookshelf_NBK608930.pdf [https://perma.cc/AF9D-VYDU]; Melissa Barber, Athena Sofides & Reshma Ramchandran, *Counting on Insulin Manufacturers to Do the Right Thing Is Not a Good Policy Prescription to Avert Shortages*, HEALTH AFFS. FOREFRONT (July 12, 2024), https://www.healthaffairs.org/content/forefront/counting-insulin-manufacturers-do-right-thing-not-good-policy-prescription-avert [https://perma.cc/BJD3-SC68]; *Legislative Proposals to Prevent and Respond to Generic Drug Shortages: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 118th Cong. (2023) (written testimony of Melissa Barber, Postdoctoral Fellow, Yale University), https://d1dth6e84htgma.cloudfront.net/Melissa_Barber_Witness_Testimony_09_14_23_1aa206816e.pdf [https://perma.cc/LQ6Q-Z7ZE].

6. Grace Sparks, Ashley Kirzinger, Alex Montero, Isabelle Valdes & Liz Hamel, *Public Opinion on Prescription Drugs and Their Prices*, KAISER FAM. FOUND. (Oct. 4, 2024), https://www.kff.org/health-costs/poll-finding/public-opinion-on-prescription-drugs-and-their-prices [https://perma.cc/3X6Z-UVBS].

ration use or skip doses.[7] These problems undermine individual care and strain the entire healthcare system, as patients endure avoidable complications and preventable crises.[8] High costs also force governments to make tough budgetary tradeoffs, diverting funds to healthcare subsidies at the expense of other vital public priorities.[9] For many essential drugs, the prescription drug market is in a constant state of failure.

Scholars have attributed this ongoing crisis to several overlapping factors, including abuses of drug companies' monopoly power,[10] fragmentation of the pharmaceutical supply chain,[11] and dynamics of consolidation in the sector.[12] Fundamentally, there is a structural tension between the prevailing strategy for commercialization of new, expensive medicines—which relies on firms seeking profits bolstered by exclusive rights—and the trend toward more mandatory and universal coverage of medicines. Firms can leverage laws intended to help ensure access into excessive pricing power.[13]

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7. *See id.*; Deidre McPhillips, *Drug Costs Lead Millions in the US to Not Take Medications as Prescribed, According to CDC*, CNN (June 2, 2023, 7:13 AM), https://www.cnn.com/2023/06/02/health/prescription-drug-costs-rationing/index.html [https://perma.cc/HF9X-G6JH]; Andrew Hantel, Mark Siegler, Fay Hlubocky, Kevin Colgan & Christopher K. Daugherty, *Prevalence and Severity of Rationing During Drug Shortages: A National Survey of Health System Pharmacists*, 179 JAMA INTERNAL MED. 710, 710 (2019); Jonathan Minh Phuong, Jonathan Penm, Betty Chaar, Lachlan Daniel Oldfield & Rebekah Moles, *The Impacts of Medication Shortages on Patient Outcomes: A Scoping Review*, 14 PLOS ONE, issue no. 5, May 2019, art. no. e0215837, 2019, https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0215837 [https://perma.cc/DMM7-4EZ2]; Adam Gaffney, David U. Himmelstein & Steffie Woolhandler, *Prevalence and Correlates of Patient Rationing of Insulin in the United States: A National Survey*, 175 ANNALS INTERNAL MED. 1623, 1625 (2022); Annabelle E. Wilcox et al., *Navigating Barriers to Affording and Obtaining Insulin and Diabetes Supplies*, 15 J. DIABETES 71, 73–74 (2023).

8. Phuong et al., *supra* note 7; McPhillips, *supra* note 7.

9. *See* Alan M. Garber & Jonathan Skinner, *Is American Health Care Uniquely Inefficient?*, 22 J. ECON. PERSPS. 27, 28 (2008). For example, a 59% increase in health care costs in Massachusetts between 2001 and 2011 resulted in a 15% reduction in the state budget for public education, 23% reduction for infrastructure and housing, and 11% reduction in public safety resources. *See* Amitabh Chandra, *Healthy, Wealthy, and Wise: Improving the Productivity of Massachusetts' Health Care Spending*, HARV. KENNEDY SCH. POL'Y BRIEFS 3 (May 2012), https://www.hks.harvard.edu/sites/default/files/centers/taubman/files/healthy_final.pdf [https://perma.cc/H39H-LKWZ].

10. *See* Mark A. Lemley & Bhaven Sampat, Essay, *Is the Patent Office a Rubber Stamp?*, 58 EMORY L.J. 181, 182 (2008); Erika Lietzan & Kristina M.L. Acri née Lybecker, *Distorted Drug Patents*, 95 WASH. L. REV. 1317, 1319–21 (2020); Olga Gurgula, *Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene?*, 51 INT'L REV. INTELL. PROP. & COMPETITION L. 1062, 1063–64 (2020).

11. *See* Roger Lee Mendoza, *Continuity and Change in the Drug Supply Chain: Actors, Actions, and Aversions*, 24 J. MED. ECON. 689, 695 (2021); Andrew D. Goldsmith & Francisco E. Varela, *Fragmentation in the Biopharmaceutical Industry*, 22 DRUG DISCOVERY TODAY 433, 434–35 (2017). *See generally* Rachel E. Sachs, *Integrating Health Innovation Policy*, 34 HARV. J.L. & TECH. 57 (2020) (discussing the implications of fragmentation in the U.S. healthcare supply chain on innovation in new pharmaceutical technologies).

12. *See* Mariana P. Socal, Kiefer Ahn, Jeremy A. Greene & Gerard F. Anderson, *Competition and Vulnerabilities in the Global Supply Chain for US Generic Active Pharmaceutical Ingredients*, 42 HEALTH AFFS. 407, 412 (2023); Chintan V. Dave, Aaron S. Kesselheim, Erin R. Fox, Peihua Qiu & Abraham Hartzema, *High Generic Drug Prices and Market Competition: A Retrospective Cohort Study*, 167 ANNALS INTERNAL MED. 145, 145 (2017).

13. *See* Hannah Brennan, Amy Kapczynski, Christine H. Monahan & Zain Rizvi, *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275, 285–86 (2016).

Much has already been written about the myriad abuses of the patent system, and the statutory and regulatory tools available to mitigate some of these abuses.[14] Measures have also been proposed—and some are underway—to increase transparency in drug pricing[15] and to protect consumers using antitrust and consumer protection laws.[16] Further, the recently enacted Inflation Reduction Act allows the federal government to negotiate the prices of a limited set of high-cost drugs for Medicare beneficiaries, and demand rebates for drugs where the price increases faster than inflation.[17] The negotiation program is, however, under sustained assault from industry, and several bills have recently been proposed to weaken its requirements.[18] These initiatives, while promising, have yet to resolve the systemic failures of an underregulated market that allows private manufacturers to set mostly unchecked prices and to abruptly cease

14. *See supra* note 10 and accompanying text; Brennan et al., *supra* note 13, at 294–99; Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1677–81 (2003); Linda P. Nussbaum & John D. Radice, *Where Do We Go Now? The Hatch-Waxman Act Twenty-Five Years Later: Successes, Failures, and Prescriptions for the Future*, 41 RUTGERS L.J. 229, 239, 244 (2009); Christopher J. Morten & Charles Duan, *Who's Afraid of Section 1498? A Case for Government Patent Use in Pandemics and Other National Crises*, 23 YALE J.L. & TECH. 1, 50 (2020); David Orozco, *Administrative Patent Levers*, 117 PENN. ST. L. REV. 1, 15, 30 (2012); *cf.* Mark D. Janis, *Patent Abolitionism*, 17 BERKELEY TECH. L.J. 899, 903 (2002).

15. *See Prescription Drug Pricing Transparency Law Comparison Chart*, NAT'L ACAD. FOR STATE HEALTH POL'Y (Dec. 7, 2023), https://nashp.org/state-tracker/prescription-drug-pricing-transparency-law-comparison-chart [https://perma.cc/W5PK-L2XW]. Many of these regulations around drug-pricing transparency are also tied to legislation imposing fiduciary responsibilities on pharmacy benefit managers (PBMs), such as the recently enacted statute in New York which requires PBMs operating in the state to act "for the best interests of the covered individual, and the health plan or provider." *See* S. 3762, 204th Leg., 2021–2022 Reg. Sess. (N.Y. 2021). Other states, including Arkansas, California, Louisiana, and Maine, also have enacted such legislation. *See* Victoria Bailey, *GAO: States Enact Own Regulations to Address Pharmacy Benefit Managers*, TECHTARGET (Apr. 17, 2024), https://healthpayerintelligence.com/news/gao-states-enact-own-regulations-to-address-pharmacy-benefit-managers [https://perma.cc/LAU5-HZEC]. For a view of fiduciary responsibilities that should attach to entities that were designed to serve the public and not corporate shareholders, see generally Aneil Kovvali & Joshua C. Macey, *The Corporate Governance of Public Utilities*, 40 YALE J. ON REGUL. 569 (2023).

16. *See* Herbert Hovenkamp, Mark Janis & Mark A. Lemley, *Anticompetitive Settlement of Intellectual Property Disputes*, 87 MINN. L. REV. 1719, 1720 (2003); Arthur Allen, *A More Aggressive FTC Is Starting to Target Drug Mergers and Industry Middlemen*, KFF HEALTH NEWS (May 22, 2023), https://kffhealthnews.org/news/article/a-more-aggressive-ftc-is-starting-to-target-drug-mergers-and-industry-middlemen [https://perma.cc/XDV7-G7KG]; Complaint, *In re* Caremark Rx, LLC, No. 9437 (F.T.C. Sept. 20, 2024); *cf.* Robin C. Feldman, *The Insufficiency of Antitrust Analysis for Patent Misuse*, 55 HASTINGS L.J. 399, 400 (2003) (arguing that antitrust solutions may seem compelling, but lack the ability to adequately address issues related to patent misuse).

17. Inflation Reduction Act of 2022, Pub. L. No. 117-169, §§ 11001-02, 11101-02, 136 Stat. 1818, 1833, 1865–77; Press Release, The White House, Fact Sheet: Biden-Harris Administration Announces New, Lower Prices for First Ten Drugs Selected for Medicare Price Negotiation to Lower Costs for Millions of Americans (Aug. 15, 2024), https://bidenwhitehouse.archives.gov/briefing-room/statements-releases/2024/08/15/fact-sheet-biden-harris-administration-announces-new-lower-prices-for-first-ten-drugs-selected-for-medicare-price-negotiation-to-lower-costs-for-millions-of-americans [https://perma.cc/ZG2B-26DK].

18. *See* Rachel Cohrs Zhang, *Pharma Giants, Government Spar in Court Over Medicare Drug Price Negotiation*, STAT NEWS (Mar. 7, 2024), https://www.statnews.com/2024/03/07/medicare-drug-prices-negotiation-oral-arguments-hearing [https://perma.cc/SD29-PSPJ]; *see also* H.R. 1492, 119th Cong. (2025); H.R. 1672, 119th Cong. (2025).

production when financially expedient. The market for prescription drugs needs a broader cure to address the issues that the status quo has generated.

It is principally to confront the issue at a systemic level and to imagine a new "industrial policy"[19] for the pharmaceutical sector that there has been increasing interest in "public production"—establishing a public supply chain or "option"[20] for essential medicines.[21] In its most expansive form, public production refers to a pipeline where state or federal governments lead *all* stages of the pharmaceutical supply chain, from research and development (R&D) to manufacture to distribution. Public investment in early-stage R&D is long-standing and deeply embedded in the drug development ecosystem.[22] The U.S. National Institutes of Health (NIH) has been the largest funder of biomedical R&D globally,[23] and almost every

19. *See* Amy Kapczynski & Joel Michaels, *Administering a Democratic Industrial Policy*, 18 HARV. L. & POL'Y REV. 279, 281 (2024); MARC JARSULIC, CTR. FOR AM. PROGRESS, INDUSTRIAL POLICY TO REDUCE PRESCRIPTION GENERIC DRUG SHORTAGES (2024), https://www.americanprogress.org/article/industrial-policy-to-reduce-prescription-generic-drug-shortages [https://perma.cc/JS86-78PC].

20. GANESH SITARAMAN & ANNE L. ALSTOTT, THE PUBLIC OPTION: HOW TO EXPAND FREEDOM, INCREASE OPPORTUNITY, AND PROMOTE EQUALITY 22–23 (2019).

21. For academic perspectives promoting the public production of drugs, see Shweta Kumar, *Formulating Public Pharma*, 110 CORNELL L. REV. (forthcoming 2025); Jane Kaufman, *Beyond Regulation: Competition in the Pharmaceutical Industry and the Public Manufacturing of Drugs*, 56 LOY. L.A. L. REV. 331 (2023); Fran Quigley, *Tell Me How It Ends: The Path to Nationalizing the U.S. Pharmaceutical Industry*, 53 U. MICH. J.L. REFORM 755 (2020); Dan Liljenquist, Ge Bai & Gerard F. Anderson, *Addressing Generic-Drug Market Failures — The Case for Establishing a Nonprofit Manufacturer*, 378 NEW ENG. J. MED. 1857 (2018); Alex Moss, Dana Brown & S. Sean Tu, *Use of Public Research and Manufacturing Enterprises to Lower Prescription Drug Prices and Increase Innovation*, 52 J.L. MED. & ETHICS 750 (2024); Ameet Sarpatwari, Dana Brown & Aaron S. Kesselheim, *Development of a National Public Pharmaceutical Research and Development Institute*, 47 J.L. MED. & ETHICS 225 (2019); Phebe Hong, Aaron S. Kesselheim & Ameet Sarpatwari, *Transformative Models to Promote Prescription Drug Innovation and Access: A Landscape Analysis*, 19 YALE J. HEALTH POL'Y, L. & ETHICS 56 (2020); Jing Luo, Ameet Sarpatwari & Aaron S. Kesselheim, *Regulatory Solutions to the Problem of High Generic Drug Costs*, 2 OPEN F. INFECTIOUS DISEASES, issue no. 4, Fall 2015, art no. ofv179, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4685151/pdf/ [https://perma.cc/TJ4L-RDEF]; Szymon Jarosławski, Mondher Toumi, Pascal Auquier & Claude Dussart, *Non-Profit Drug Research and Development at a Crossroads*, 35 PHARM. RSCH., issue no. 2, Mar. 2018, art. no. 52; Szymon Jarosławski & Mondher Toumi, *Non-Profit Drug Research and Development: The Case Study of Genethon*, 7 J. MKT. ACCESS & HEALTH POL'Y, issue. no. 1, Nov. 2018, art. no. 1545514, https://www.tandfonline.com/doi/epdf/10.1080/20016689.2018.1545514 [https://perma.cc/3TDR-WTC4]; DANA BROWN, DEMOCRACY COLLABORATIVE, MEDICINE FOR ALL: THE CASE FOR A PUBLIC OPTION IN THE PHARMACEUTICAL INDUSTRY (2019), https://thenextsystem.org/sites/default/files/2019-09/MedicineforAll_WEB.pdf [https://perma.cc/L3DL-V9KW].

22. *See* Nisha Gaind, *How the NIH Dominates the World's Health Research — In Charts*, 639 NATURE 554 (2025). This system has come under profound attack in the first few months of the Trump Administration, with potentially devastating downstream implications for biomedical research in the United States and around the world. *See* MINORITY STAFF OF S. COMM. ON HEALTH, EDUC., LAB. & PENSIONS, TRUMP'S WAR ON SCIENCE 1 (2025), https://www.sanders.senate.gov/wp-content/uploads/HELP-Committee-Minority-Report-Trumps-War-on-Science.pdf [https://perma.cc/5R4R-26KD]; Richard G. Frank & Sherry Glied, *The Trump Administration's NIH and FDA Cuts Will Negatively Impact Patients*, BROOKINGS INST. (May 14, 2025), https://www.brookings.edu/articles/the-trump-administrations-nih-and-fda-cuts-will-negatively-impact-patients [https://perma.cc/GG6Z-5FKT].

23. Roderik F. Viergever & Thom C.C. Hendriks, *The 10 Largest Public and Philanthropic Funders of Health Research in the World: What They Fund and How They Distribute Their Funds*, 14 HEALTH RSCH. POL'Y & SYS., Feb. 2016, art no. 12, https://health-policy-systems.biomedcentral.com/articles/10.1186/s12961-015-0074-z [https://perma.cc/7Q5R-ZLNC].

drug approved by the Food and Drug Administration (FDA) from 2010 to 2019 received some early-stage research support from NIH funding.[24] However, the state is currently largely absent in drug manufacturing and distribution. As a consequence, the state cannot reap all of the benefits associated with public R&D, or proactively meet demand not met in the market for important medicines.

Most discussions of public production by scholars,[25] advocates,[26] and legislators[27] have primarily focused on expanding the state's role in these latter stages, through public manufacturing and distribution. Even this narrower scope of state involvement—on which this Article will primarily focus—may offer many possible benefits. As scholars such as Dana Brown, Tom Latkowski, Ameet Sarpatwari, Aaron Kesselheim, and Shweta Kumar have argued, public manufacturing can allow states to close "access gaps" created by both drug pricing and drug shortages and develop public-sector knowledge around manufacturing processes.[28] Additionally, as we discuss below in Part II, increasing state involvement in distribution through existing networks will not only facilitate market entry for public products, but may also lead to broader, systemic changes that ease market entry for other private, generic manufacturers. Thus, a public manufacturing and distribution supply chain has the potential to fundamentally alter the status quo.

Public production has well-established precedent.[29] When the private sector has failed to meet public health needs, state and federal governments have sometimes stepped in at pivotal moments to close the gap. At the federal level, the Union Army established facilities in Philadelphia and Astoria to produce more than a hundred medicines for use by the Army during the Civil War.[30] Similarly, during World War II, the U.S. Office of Scientific Research and Development's Committee on Medical Research and the U.S. Department of Agriculture's Northern Regional Research

24. *See* Ekaterina Galkina Cleary, Matthew J. Jackson, Edward W. Zhou & Fred D. Ledley, *Comparison of Research Spending on New Drug Approvals by the National Institutes of Health vs the Pharmaceutical Industry, 2010–2019*, 4 JAMA HEALTH F., issue no. 4, Apr. 2023, art. no. e230511, https://jamanetwork.com/journals/jama-healthforum/articlepdf/2804378/galkina_cleary_2023_oi_230016_1682539099.62802.pdf [https://perma.cc/YR7Z-JH3C].

25. *See, e.g.*, Moss et al., *supra* note 21, at 750.

26. *See, e.g.*, Quinn Nichols, Nicole Koonce & Allison Hardt, *The Movement for Public Production of Insulin Continues to Grow in the United States*, T1 INT'L (June 12, 2024, 7:40 PM), https://www.t1international.com/blog/2024/06/12/movement-public-insulin-production-continues-grow-united-states [https://perma.cc/86VA-WSF7].

27. *See* Affordable Drug Manufacturing Act of 2023, S. 3398, 118th Cong.

28. DANA BROWN & TOM LATKOWSKI, DEMOCRACY POL'Y NETWORK, DEMOCRACY COLLABORATIVE & T1INT'L, PUBLIC PHARMACEUTICALS: STATE POLICY KIT (Dec. 2022), https://static1.squarespace.com/static/62f41050584b40607baef690/t/63992dceb17a723edcbb9d1e/1670983118927/PUB_Public+Pharmaceuticals+State+Policy+Kit.pdf [https://perma.cc/9XEV-G36P]; Sarpatwari et al., *supra* note 21, at 226; Kumar, *supra* note 21 (manuscript at 8–9).

29. *See* BROWN & LATKOWSKI, *supra* note 28.

30. *See generally* GEORGE WINSTON SMITH, MEDICINES FOR THE UNION ARMY: THE UNITED STATES ARMY LABORATORIES DURING THE CIVIL WAR (1962) (detailing the work of the army's Medical Department during the Civil War to manufacture and distribute medicines).

Laboratory were instrumental in developing the processes necessary for the industrial production of penicillin, while the War Production Board built production facilities to mass produce the antibiotic for soldiers abroad.[31] At the state level, the Michigan State Department of Health manufactured an anthrax vaccine for the Pentagon from 1964 to 1995.[32] MassBiologics, based in Massachusetts, has served as a public manufacturer for over a century, producing vaccines, biologics, and gene therapies to this day.[33]

Around the world, public production has played a vital role alongside the private sector, particularly for medicines with limited commercial appeal. Sweden, for example, has operated a public, state-owned manufacturer and retailer since the 1970s for medicines that private manufacturers do not produce due to size or logistical constraints.[34] Brazil[35] and India[36] have engaged in public production efforts to manufacture drugs that are either unaffordable or unavailable in the private sector. Likewise, Cuba manufactures and distributes medicines for its domestic health system, exports medicines to other countries, and has even been successful in developing novel drugs, including the world's first vaccine for lung cancer, which is currently in clinical trials in the United States.[37]

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31. Peter Neushul, *Science, Government, and the Mass Production of Penicillin*, 48 J. HIST. MED. & ALLIED SCIS. 371, 372 (1993).

32. Nicholas Wade, *A Vaccine That Experts Say Is Effective*, N.Y. TIMES (Dec. 16, 1997), https://www.nytimes.com/1997/12/16/us/a-vaccine-that-experts-say-is-effective.html [https://perma.cc/D7MM-WETG].

33. *History*, UMASS CHAN MED. SCH.: MASSBIOLOGICS, https://www.umassmed.edu/massbiologics/about/history [https://perma.cc/325D-TPUX].

34. *Our Role in the Society*, APOTEK PRODUKTION & LABOROTORIER, https://www.apl.se /in-english/about-apl/our-role-in-the-society.html [https://perma.cc/4HYJ-ST6U].

35. Maurice Cassier & Marilena Correa, *Patents, Innovation and Public Health: Brazilian Public-Sector Laboratories' Experience in Copying AIDS Drugs*, *in* ECONOMICS OF AIDS AND ACCESS TO HIV/AIDS CARE IN DEVELOPING COUNTRIES: ISSUES AND CHALLENGES 89 (Jean-Paul Moatti et al. eds., 2003); Tatiana Aragão Figueiredo, Renato Gonçalves Fialho Neto & Jorge Lima de Magalhães, *The Public Production of Medicines in Brazil*, 26 CIÊNCIA & SAÚDE COLETIVA 3423, 3424 (2d Supp. 2021); Vera Lucia Luiza, Gabriela Costa Chaves, Tayná Marques Torres Barboza, Luciana de Paula Barros Gonçalves & Eric G. Stobbaerts, *Challenges in a Product Development Partnership: A Malaria Treatment Case Study.* 22 CIÊNCIA & SAÚDE COLETIVA 2197, 2197 (2017); Isabela Ribeiro et al., *New, Improved Treatments for Chagas Disease: From the R&D Pipeline to the Patients.* 3 PLOS NEGLECTED TROPICAL DISEASES, issue no. 7, July 2009, art. no. e484, https://doi.org/10.1371/journal.pntd.0000484 [https://perma.cc/2KHN-RAYB]; Maria Alice Rosa Ribeiro, *Saúde Pública e as Empresas Químico-Farmacêuticas*, 7 HISTÓRIA, CIÊNCIAS, SAÚDE-MANGUINHOS 607 (2001); Luana Dandara, *Maior Surto de Meningite do País, na Década de 1970, Foi Marcado Pela Desinformação,* FIOCRUZ (Nov. 17, 2022, 10:43 AM), https://fiocruz.br/noticia/2022/11/maior-surto-de-meningite-do-pais-na-decada-de-1970-foi-marcado-pela-desinformacao [https://perma.cc/93C3-E4GC]; FUNDAÇÃO OSWALDO CRUZ, ORGANIZAÇÃO PAN-AMERICANA DA SAÚDE, PANORAMA DA PRODUÇÃO LOCAL DE MEDICAMENTOS NO BRASIL: DESAFIOS E VULNERABILIDADES (2023), https://iris.paho.org/handle/10665.2/57897 [https://perma.cc/PRW8-CEAX]; *The Shortage of Benznidazole Leaves Thousands of Chagas Patients Without Treatment*, MÉDICINS SANS FRONTIÈRES: ACCESS CAMPAIGN (2011), https://msfaccess.org/sites/default/files/MSF_assets/NegDis/Docs/Chagas_Briefing_BZD%20shortage%20briefing_ENG_2011.pdf [https://perma.cc/EBX6-GJ3C].

36. *Hindustan Antibiotics Limited*, GOV'T OF INDIA: DEP'T OF PHARMS., https://pharmaceuticals.gov.in/hindustan-antibiotics-limited [https://perma.cc/QUJ5-CMLL].

37. Omar Everleny Perez Villanueva & Juan Carlos Albizu-Campos Espiñeira, *The Development of Cuba's Biotechnology: Mechanisms and Challenges*, 51 J.L. MED. & ETHICS 136, 137 (2023); Sally

Given both domestic and international precedents, the renewed interest in launching public production initiatives comes as no surprise. In 2020, California enacted the Affordable Drug Manufacturing Act of 2020 to empower the state to publicly manufacture and distribute generic drugs at low cost.[38] The state recently entered into an agreement with a non-profit entity, Civica, to begin production of a low-cost, generic insulin,[39] and there are plans to expand the program to naloxone.[40] Similar initiatives are also being considered (or have recently been considered) in Maine,[41] Michigan,[42] Washington,[43] and New York.[44] At the federal level, Senator Elizabeth Warren and Congresswoman Jan Schakowsky have advanced a bicameral Affordable Drug Manufacturing Act, which envisions creating a federal Office of Drug Manufacturing to publicly manufacture prescription drugs.[45]

Public production of pharmaceuticals presents an exciting opportunity, but one that will encounter challenges. One major challenge to public manufacturing is patent protections on medicines.[46] Recent public

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H. Jacobs, *A Souvenir Smuggled Home from Cuba: A Cancer Vaccine*, N.Y. TIMES (Nov. 14, 2016), https://www.nytimes.com/2016/11/15/health/cancer-vaccine-cuba-medical-tourism.html [https://perma.cc/SYG3-L3FU]. Clinical trials are currently enrolling patients. *See A Vaccine (CIMAvax-EGF) for the Prevention of Lung Cancer Development or Recurrence*, CLINICALTRIALS.GOV (May 2, 2025), https://clinicaltrials.gov/study/NCT04298606 [https://perma.cc/YDY2-B4HR].

38. California Affordable Drug Manufacturing Act of 2020, 2020 Cal. Legis. Serv. Ch. 207 (West) (codified at CAL. HEALTH & SAFETY CODE §§ 127690 et seq. (West 2024)); *see* Emma Bowman, *California Enters a Contract to Make Its Own Affordable Insulin*, NPR (Mar. 19, 2023, 2:16 PM), https://www.npr.org/2023/03/19/1164572757/california-contract-cheap-insulin-calrx [https://perma.cc/GM8M-J3E5]; Nichols et al., *supra* note 26.

39. *See* Press Release, Civica, California Selects Civica Rx as Its Insulin Manufacturing Partner (Mar. 18, 2023), https://civicarx.org/california-selects-civica-rx-as-its-insulin-manufacturing-partner [https://perma.cc/2Z5U-4ZHK]; Bowman, *supra* note 38.

40. *California to Purchase CalRx Branded Over-the-Counter Naloxone for $24*, CAL. DEP'T OF HEALTH CARE SERVS.: OPIOID RESPONSE (Apr. 29, 2024), https://californiaopioidresponse.org/california-to-purchase-calrx-branded-over-the-counter-naloxone-for-24 [https://perma.cc/NP3U-QUQN].

41. *See 2024 State Legislation to Lower Prescription Drug Costs*, NAT'L ACAD. FOR STATE HEALTH POL'Y (Jan. 7, 2025), https://nashp.org/state-tracker/2024-state-legislation-to-lower-pharmaceutical-costs [https://perma.cc/LKY6-64FU] (choose "other" from dropdown; then scroll down in the body until the row for LD 1793 is visible).

42. Press Release, Gov. Gretchen Whitmer, Whitmer Signs Executive Directive Aimed at Lowering Costs, Manufacturing Insulin in Michigan (Oct. 3, 2022), https://www.michigan.gov/whitmer/news/press-releases/2022/10/03/whitmer-signs-executive-directive-aimed-at-lowering-costs [https://perma.cc/D2CZ-FV2V].

43. *See* OFF. POL'Y & LEG. RELS., WASH. STATE DEP'T PUB. HEALTH, MANUFACTURING GENERIC DRUGS (2019), https://app.leg.wa.gov/ReportsToTheLegislature/Home/GetPDF?fileName=Manufacturing%20Generic%20Drug%20Report_899c9be4-ed5b-41b7-96c2-4f8a9a7cc3ef.pdf [https://perma.cc/Z5MW-QPC6].

44. Karen DeWitt, *Senate Proposal Would Make New York a Manufacturer for Some Generic Drugs, Including Insulin*, N.Y. NOW (Feb. 1, 2024), https://nynow.wmht.org/blogs/politics/senate-proposal-would-make-new-york-a-manufacturer-for-some-generic-drugs-including-insulin [https://perma.cc/93W5-YBMS].

45. *See* Affordable Drug Manufacturing Act of 2023, S. 3398, 118th Cong.; Affordable Drug Manufacturing Act of 2023, H.R. 6607, 118th Cong.; Elizabeth Warren, Opinion, *It's Time to Let the Government Manufacture Generic Drugs*, WASH. POST (Dec. 17, 2018), https://www.washingtonpost.com/opinions/elizabeth-warren-its-time-to-let-the-government-manufacture-generic-drugs/2018/12/17/66bc0fb0-023f-11e9-b5df-5d3874f1ac36_story.html [https://perma.cc/2B7W-MKZY].

46. *See* Kumar, *supra* note 21, at 7–8; BROWN, *supra* note 21, at 16–17.

production efforts have therefore targeted older drugs with fewer patent hurdles.[47] However, as we will describe, patents can still pose obstacles even for older medicines—and the potential benefits of producing newer drugs are significant. For these reasons, we outline strategies for navigating patent barriers here.

The existing literature has, however, tended to assume that if states can circumvent or override patent barriers and produce high quality, affordable medicines, they will automatically reach patients. Little attention has been paid to the legal, regulatory, and logistical challenges associated with the *distribution* of public-sector drugs, especially drugs for which there is significant competition in the private sector.[48] This may reflect a deeper assumption—rooted in the influence of neoclassical economics on policy and legal thinking—that markets naturally self-correct and effortlessly match buyers with sellers.[49] But the pharmaceutical market belies this picture. Generic competitors often struggle to enter markets and distribute cheaper alternatives. For example, manufacturers often block or delay generic entry for profitable drugs by obtaining secondary patents and engaging in pay-for-delay settlements.[50] Even if generics navigate around

47. California's CalRx program, for example, will manufacture generic and biosimilar drugs. Audrey Stienon, *Public Pharma's Biggest Barrier*, AM. PROSPECT (Jan. 5, 2024), https://prospect.org/health/2024-01-05-public-pharmas-biggest-barrier [https://perma.cc/8RSA-EVV2].

48. *See supra* note 21. There is some literature on pharmacy benefit managers (PBMs), but this literature either does not contemplate the impact of PBMs on public production or does not explore it in detail. *See, e.g.*, Robin Feldman, Viewpoint, *CalRx Biosimilar Insulin: California's Initiative to Enter the Insulin Market*, 183 JAMA INTERNAL MED. 1043 (2023); Giovanna Crozier-Fitzgerald, *The Benefit Is in the Details: How Pharmacy Benefit Managers Have Reaped Profits from Insulin's Increasing List Price and Remained Unscathed, Until Now*, 29 WIDENER L. REV. 97 (2023); Earl L. Carter, *Pulling Back the Curtain on PBMs: A Path Towards Affordable Prescription Drugs*, 59 HARV. J. ON LEGIS. 257 (2022); Kwanghyuk Yoo, *Interaction of Human Rights Law and Competition Law: The Right to Access to Medicines and Consumer Welfare in the U.S. Pharmaceutical Sector*, 43 VT. L. REV. 123 (2018); Kwanghyuk Yoo, *Pharmacy Benefit Managers and Generic Pharmaceuticals Pricing Conspiracy: Unveiling Lock-in Mechanisms, Structural Shortcomings and Antitrust Evidence*, 64 S.D. L. REV. 43 (2019); Joanna Shepherd, *Pharmacy Benefit Managers, Rebates, and Drug Prices: Conflicts of Interest in the Market for Prescription Drugs*, 38 YALE L. & POL'Y REV. 360 (2020); Joshua P. Cohen, *PBMs and a Medicare Prescription Drug Benefit*, 55 FOOD & DRUG L.J. 311 (2000).

49. For a discussion about the pervasiveness of such assumptions, see generally ELIZABETH POPP BERMAN, THINKING LIKE AN ECONOMIST: HOW EFFICIENCY REPLACED EQUALITY IN U.S. PUBLIC POLICY (2022) (detailing how an economic style of reasoning took hold in recent U.S. policy fora); Jedediah Britton-Purdy, David Singh Grewal, Amy Kapczynski & K. Sabeel Rahman, *Building a Law-and-Political-Economy Framework: Beyond the Twentieth-Century Synthesis*, 129 YALE L.J. 1784 (2020) (describing the influence of neoliberalism in law and legal discourse in recent decades).

50. When a generic competitor moves to enter the market for a lucrative drug, the drug's manufacturer will often "pay-for-delay," entering into a settlement agreement in patent litigation to delay the generic drug's entry. These settlements guarantee the original drug's manufacturer more time with a monopoly in the market. *Pay-for-Delay: When Drug Companies Agree Not to Compete*, FED. TRADE COMM'N, https://www.ftc.gov/news-events/topics/competition-enforcement/pay-delay [https://perma.cc/XB98-XMF3]. Manufacturers also frequently obtain "secondary patents," or patents on various aspects of the drug beside the active compound, in order to extend the life of their patent protection. *See* Gurgula, *supra* note 10, at 1067; *see also* Amy Kapczynski, Chan Park & Bhaven Sampat, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, 7 PLOS ONE, issue no. 12, Dec. 2012, art. no. e49470, https:// journals.plos.org/plosone/article?id=10.1371/journal.pone.0049470 [https://perma.cc/P7EZ-LPSN] (documenting the prevalence of secondary patents).

patent barriers, brand-name manufacturers can still negotiate with insurers and pharmacy benefit managers to restrict the uptake of generics—undermining access for consumers.[51] Anticipating these entry and distribution barriers and crafting strategies to circumvent them will be essential for the success of any public production initiative.

In Part I, we first describe the market for prescription drugs, outlining how the market is structured to maximize profit for private manufacturers, often at the expense of patients. Part II then discusses how public production could both fit into and disrupt this status quo by highlighting two examples of drugs well-positioned for public manufacturing—penicillin G benzathine and insulin.[52] Our selection of these examples is intentional. Penicillin G benzathine offers an example of an off-patent drug with limited private competition that likely will face minimal challenges to manufacture or market entry and distribution. By contrast, insulin represents one of the most complicated cases for market entry, with entrenched manufacturers that are highly motivated to block new competitors and protect their profits. Using these examples, we identify how states can leverage their unique position as both a market participant and a market regulator to facilitate market entry for public products.

This Article identifies the primary chokepoints for public manufacturing and distribution, especially for products like insulin which are a source of significant profits for private firms. We propose legal and policymaking tools uniquely available to the state to break through these chokepoints. We address the wide range of legal issues that must be navigated, from bench to patient—addressing the selection of drugs and manufacturing strategies,

51. An example of this is Viatris's long-acting generic insulin product, Semglee, which despite a list price 50% below the other long-acting insulins on the market, secured no formulary placements with large PBMs. *See infra* Section II.B.3; Complaint at 24–25, *In re* Caremark Rx, LLC, No. 9437 (F.T.C. Sept. 20, 2024); Tori Marsh & Lauren Chase, *Insulin Costs Plummet: A Decade-Long High Comes to an End*, GOODRX (Jan. 15, 2025), https://www.goodrx.com/healthcare-access/research/how-much-does-insulin-cost-compare-brands [https://perma.cc/DJ2C-VLYW] (detailing a launch price of less than $0.15 per unit for Semglee, less than half of the prices depicted for other comparable insulins); Lauren Joszt, *Payer Controls Limiting Semglee Uptake Despite Patient Demand*, AJMC (July 18, 2023), https://www.ajmc.com/view/payer-controls-limiting-semglee-uptake-despite-patient-demand [https://perma.cc/8Z6Z-YHAJ].

52. Insulin has been chosen as an example here for a few reasons. First, despite molecules that have been off patent for years, generic products do not have significant market share in the United States. *See* Jeremy A. Greene & Kevin R. Riggs, *Why Is There No Generic Insulin? Historical Origins of a Modern Problem*, 372 NEW ENG. J. MED. 1171, 1171–72 (2015). Second, insulin has been the subject of sustained national attention, and affordability crises in insulin have dire consequences. *See* MATT MCCONNELL, HUM. RTS. WATCH, "IF I'M OUT OF INSULIN, I'M GOING TO DIE": UNITED STATES' LACK OF REGULATION FUELS CRISIS OF UNAFFORDABLE INSULIN (2022), https://www.hrw.org/report/2022/04/12/if-im-out-insulin-im-going-die/united-states-lack-regulation-fuels-crisis [https://perma.cc/EX8W-G5LJ]; Ken Alltucker, *As Insulin Shortages Persist, What Diabetes Patients Can Do*, USA TODAY (Oct. 24, 2024, 5:24 PM), https://www.usatoday.com/story/news/health/2024/10/24/insulin-shortage-2024-ozempic-diabetes/75821654007 [https://perma.cc/4JJG-WSHA]. Finally, insulin is particularly subject to manufacturer and PBM actions to control the market, due to the need for insurers to cover a suite of insulin products and not just one drug. *See infra* Section II.B.3. We also primarily focus on state initiatives, because they are either already underway or have been proposed in several states. *See supra* notes 38–47 and accompanying text. While national initiatives to manufacture generic drugs have been proposed, they are likely less feasible in the current political and administrative law climate.

and describing the measures needed to ensure that public production can reach patients at scale (and how these should be configured to avoid challenges on antitrust, dormant Commerce Clause, and ERISA preemption grounds). We close with a discussion of measures needed to ensure drug interchangeability and address product liability concerns. We conclude that public manufacturing and distribution can, if carefully crafted, not only directly serve patients in need, but may, along the way, also help reform some of the market failures endemic to the prescription drug market.

I. STRUCTURE OF THE PRIVATE PHARMACEUTICAL MARKET

The U.S. market for prescription drugs is extraordinarily complex and shares little in common with an idealized "competitive market." Its complexity is easier to appreciate when compared to something simpler, like a farmer's market where shoppers buy directly from farmers. If one stand charges too much, shoppers can easily seek an alternative at the next stand or their local grocery store. The prescription drug market, on the other hand, is quite different. Patients often urgently need a medication but have no alternative source—since patents and data exclusivity frequently grant a single manufacturer monopoly control until those protections expire.[53] And even for drugs without patents or data exclusivities, manufacturers can use other anticompetitive practices, such as reverse payments and "pay-for-delay" settlements, loss-leader pricing, and product hops to create barriers to keep generic competitors out and limit alternatives for patients.[54]

53. The United States grants a range of exclusivities that prevent regulatory authorities from granting market approval to low-cost generics (market exclusivities) or prevent competitors from using reference product data (data exclusivities). These include New Chemical Entity (NCE), 21 U.S.C. §§ 355(c)(3)(E)(ii), (j)(5)(F)(ii); New Clinical Study (for an original or supplemental new drug application), 21 U.S.C. §§ 355(c)(3)(E)(iii), (j)(5)(F)(iii); Orphan Drug, 21 U.S.C. § 360cc(a)(2); Qualified Infectious Disease Product, 21 U.S.C. § 355f(a); Pediatric, 21 U.S.C. § 355a(b); and Biologic exclusivities, 42 U.S.C. § 262(k)(7). *See Potential Market Exclusivity Granted During U.S. Regulatory Approval Process*, IPD ANALYTICS (Dec. 23, 2021), https://www.ipdanalytics.com/post/potential-exclusivity-granted-during-us-regulatory-approval-process [https://perma.cc/P42D-WS33]; U.S. FOOD & DRUG ADMIN., REFERENCE PRODUCT EXCLUSIVITY FOR BIOLOGICAL PRODUCTS FILED UNDER SECTION 351(A) OF THE PHS ACT (2014) (No. FDA-2013-D-1165); *Frequently Asked Questions on Patents and Exclusivity*, U.S. FOOD & DRUG ADMIN. (Feb. 5, 2020), https://www.fda.gov/drugs/development-approval-process-drugs/frequently-asked-questions-patents-and-exclusivity [https://perma.cc/UEZ6-L6CE].

While there may be a situation where there are two innovator drugs in a class at one time (for example, Eliquis and Xarelto), it is not uncommon for there to be only one innovator drug in a class (for example, aducanumab when it was first introduced) or only one drug that is preferred by a patient (often true of insulin, which is burdensome to adjust once a patient is stable on a particular drug/set of drugs). For Eliquis and Xarelto, see Antonio Gómez-Outes, Ma Luisa Suárez-Gea, Ramón Lecumberri, Ana Isabel Terleira-Fernández & Emilio Vargas-Castrillón, *Direct-Acting Oral Anticoagulants: Pharmacology, Indications, Management, and Future Perspectives*, 95 EUR. J. HAEMATOLOGY 389, 389 (2015). For more on aducanumab, see generally Steven Woloshin & Aaron S. Kesselheim, *What to Know About the Alzheimer's Drug Aducanumab (Aduhelm)*, 182 JAMA INTERNAL MED. 892 (2022).

54. For pay-for-delay, see *Pay-for-Delay: When Drug Companies Agree Not to Compete*, *supra* note 50; Sandeep Vaheesan, *Antitrust Has a Generic-Drug Problem*, THE ATLANTIC (June 15, 2023), https://www.theatlantic.com/ideas/archive/2023/06/pharmaceutical-generic-drugs-pay-for-delay/674

Adding to the complexity, the prescription drug market is layered with intermediaries—including pharmacies, insurers, and pharmacy benefit managers (PBMs)—which together form a tangled and opaque supply chain between manufacturers and patients. Although manufacturers set the list price for their drugs, they neither receive payment from, nor negotiate prices directly with consumers. Instead, manufacturers primarily interact with PBMs, and sometimes insurers.[55] In most cases, consumers only pay a discounted price—the co-pay—and do not know the price paid to the manufacturer or the pharmacy that dispensed the medication.[56] Even the pharmacist generally does not know the "real" price of each drug—they might dispense the drug at multiple different prices, even within the same day, based on different consumers' insurance coverage.[57] Depending on the patient, several payers might contribute to the drug costs, masking the net price, while distributing the profits among the various intermediaries.[58] This high degree of fragmentation prevents any meaningful coordination to decrease prices, and perversely rewards each actor for pursuing their own profit, often at the expense of patients.

Given the pharmaceutical market's complexity and opacity, public production initiatives must approach market entry with careful strategic planning. This Part describes the pharmaceutical supply chain in detail, from drug development and manufacturing to distribution and consumer access. This summary will not only illustrate the fragmented and inefficient nature of the pharmaceutical market but also preview key areas where public manufacturing and distribution will encounter challenges—which will be discussed in greater detail in Part II.

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410 [https://perma.cc/PT5R-DHEH]. For product hopping, see Tobin Klusty, *A Legal Test for the Pharmaceutical Company Practice of "Product Hopping*,*"* 17 AM. MED. ASS'N J. ETHICS 760, 760 (2015). For loss-leader pricing, see *The Economics of Generic Drug Pricing Strategies: A Comprehensive Analysis*, DRUGPATENTWATCH (May 9, 2025), https://www.drugpatentwatch.com/blog/the-economics-of-generic-drug-pricing-strategies-a-comprehensive-analysis [https://perma.cc/6FP3-VCT6].

55. Many organizations have drawn complicated diagrams to illustrate this point. For one example, see Rachel Dolan & Marina Tian, *Pricing and Payment for Medicaid Prescription Drugs*, KAISER FAM. FOUND. (Jan. 23, 2020), https://www.kff.org/medicaid/issue-brief/pricing-and-payment-for-medicaid-prescription-drugs [https://perma.cc/GM8M-WWND].

56. *See* MEDPAC, DATA BOOK: HEALTH CARE SPENDING AND THE MEDICARE PROGRAM 161 (2024), https://www.medpac.gov/wp-content/uploads/2024/07/July2024_MedPAC_DataBook_Sec10_SEC.pdf [https://perma.cc/HX4B-KR95] (describing the portion of drug costs that consumers typically pay).

57. *See* Alex Evans, *How Does Drug Pricing Work in the U.S.?*, GOODRX (Sept. 19, 2023), https://www.goodrx.com/hcp-articles/providers/how-does-drug-pricing-work-in-the-us [https://perma.cc/V25C-AJVL]; *cf.* SAM HUGHES & NICOLE RAPFOGEL, CTR. FOR AM. PROGRESS, FOLLOWING THE MONEY: UNTANGLING U.S. PRESCRIPTION DRUG FINANCING (2023), https://www.americanprogress.org/article/following-the-money-untangling-u-s-prescription-drug-financing [https://perma.cc/5DLK-HATR] (describing both a complicated flow of money among pharmaceutical stakeholders and the agreements for payment between PBMs and pharmacies).

58. *See, e.g.*, Dolan & Tian, *supra* note 55. As depicted in Figure 1, even where the consumer typically does not have a copay, two different entities paid the pharmacy, and three more entities exchanged money with those two payers. *Id.*

A. Overview of Drug Development and Manufacturing

Drug research and development begins with early-stage research aimed at identifying potential therapeutic targets and testing candidate compounds in cell cultures and animal models.[59] Public funding plays a pivotal role in this early-stage research.[60] In 2014, basic research accounted for $13.6 billion, or 54% of total drug research spending by NIH, whereas the private industry invested less than half of that—just $6.3 billion.[61] In fact, 99.4% of drugs approved by the FDA from 2010 to 2019 received some early-stage research support from NIH funding.[62] While basic research is disproportionately undertaken through public research funds, federal labs have further developed drugs from bench to product: the U.S. Army laboratories, for example, have developed and manufactured vaccines for Eastern equine encephalitis, Q fever, tularemia, Venezuelan equine encephalitis, Rift Valley fever, Argentine hemorrhagic fever, Chikungunya, and West Nile virus.[63]

Promising candidates from basic research must then undergo clinical trials to determine safety, establish appropriate dosages, and evaluate efficacy in humans. In most cases, the private sector takes over at the clinical trial stage.[64] Although federal grant recipients may elect to retain title to any resulting intellectual property,[65] pharmaceutical companies often exclusively license patents on products developed with public funds and conduct the necessary clinical trials and regulatory approvals to bring the drug to market. But public investments in clinical trials are still substantial,

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59. Such targets may include enzymes, receptors, transporters, biological pathways for disease progression, hormones, mutated or overexpressed genes linked to disease. *See generally* Zi-Chang Jia et al., *The Art of Finding the Right Drug Target: Emerging Methods and Strategies*, 76 PHARMACOLOGICAL REVS. 896 (2024).

60. Ekaterina G. Cleary, Jennifer M. Beierlein, Navleen Surjit Khanuja, Laura M. McNamee & Fred D. Ledley, *Contribution of NIH Funding to New Drug Approvals 2010–2016*, 115 PROCEEDINGS NAT. ACAD. SCIS. 2329, 2332–33 (2018); Bhaven N. Sampat & Frank R. Lichtenberg, *What Are the Respective Roles of the Public and Private Sectors in Pharmaceutical Innovation?*, 30 HEALTH AFFS. 332, 336 (2011); Ranjana Chakravarthy, Kristina Cotter, Joseph DiMasi, Christopher-Paul Milne & Nils Wendel, *Public- and Private-Sector Contributions to the Research and Development of the Most Transformational Drugs in the Past 25 Years: From Theory to Therapy*, 50 THERAPEUTIC INNOVATION & REGUL. SCI. 759, 767 (2016).

61. U.S. GOV'T ACCOUNTABILITY OFF., DRUG INDUSTRY: PROFITS, RESEARCH AND DEVELOPMENT SPENDING, AND MERGER AND ACQUISITION DEALS 34–37 (2017) (No. GAO-18-40).

62. *See* Cleary et al., *supra* note 24.

63. PROTECTING OUR FORCES: IMPROVING VACCINE ACQUISITION AND AVAILABILITY IN THE U.S. MILITARY 12–13 (Stanley M. Lemon, Susan Thaul, Salem Fisseha & Heather C. O'Maonaigh, eds., 2002); MARY R. DEUTSCH, VACCINE ACQUISITION STRATEGIES: THE FORCE PROTECTION GAMBLE 10 (2003), https://apps.dtic.mil/sti/tr/pdf/ADA415423.pdf [https://perma.cc/AQU8-KKTH].

64. This public-private division was a result of historical developments after World War II. Following the unprecedented bench-to-production World War II effort, Vannevar Bush, the director of the Office of Scientific Research and Development and architect of postwar science policy, focused on public funding for basic research, leaving private industry to gap fill on the manufacturing end. *See* VANNEVAR BUSH, SCIENCE: THE ENDLESS FRONTIER 17–20 (1945), https://nsf-gov-resources.nsf.gov/2023-04/EndlessFrontier75th_w.pdf; Maurice R. Hilleman, *The Business of Science and the Science of Business in the Quest for an AIDS Vaccine*, 17 VACCINE 1211, 1211–13 (1999).

65. *See* 35 U.S.C §§ 201–02.

particularly for drugs with smaller commercial markets. For example, bedaquiline, a drug for multi-drug resistant tuberculosis received between $455 and $747 million in public investments for clinical trials, whereas the private sector contributed between $90 to $240 million.[66] In addition to direct funding, the federal government provides additional subsidies to the private sector through tax incentives, including research credits[67] and more generous orphan drug credits for development of drugs for rare diseases. [68]

All products must then go through an involved approval process at the FDA. There are different pathways for FDA approval depending on whether the drug is an entirely new product or a generic or biosimilar version of an existing drug. For a new molecule or a new delivery system, manufacturers must generally file a new drug application and provide clinical trial data demonstrating the product's safety and efficacy.[69] (Biologics, or drugs made from living organisms (including insulin), have a parallel process,[70] which includes additional attention to the drugs' manufacturing process because the resulting biologics are highly variable based on small changes in such processes.[71])

For generic drugs,[72] manufacturers must file an abbreviated new drug application, and for "biosimilar" versions of larger-molecule "biologic" drugs, manufacturers file a Section 351(k) BLA application.[73] A key element of the generic drug approval process is ensuring interchangeability—if the manufacturer can prove that their drug is effectively the same, or "interchangeable," with the drug being replicated (called the "reference product"), then pharmacists can substitute the newly approved generic for the innovator drug at the pharmacy counter.[74] This allows generic drugs to quickly pick up market share. Biosimilar approval has historically required expensive and time-consuming clinical trials to establish equivalence. While the FDA and other regulators are increasingly moving to remove this requirement and instead approve biosimilars on the basis of

66. Dzintars Gotham, Lindsay McKenna, Mike Frick & Erica Lessem, *Public Investments in the Clinical Development of Bedaquiline*, 15 PLOS ONE, issue no. 9, Sept. 2020, art. no. e0239118, https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0239118 [https://perma.cc/K75V-EPHA].

67. 26 U.S.C. § 41.

68. Qualified clinical testing expenses are expenses defined in 26 U.S.C. § 45C(b).

69. *See* 21 U.S.C. § 355(b) (2024). If the innovation is simply a new dosage form, manufacturers can use the simpler 505(b)(2) pathway. *See* 21 U.S.C. § 355(b)(2).

70. Biologic approvals are governed by the Section 351(a) biologic license application for new drugs. *See* 42 U.S.C. § 262.

71. *Id.*; *see also Regulatory Knowledge Guide for Biological Products*, NIH SEED (Mar. 2024), https://seed.nih.gov/sites/default/files/2024-03/Regulatory-Knowledge-Guide-Biological-Products.pdf [https://perma.cc/4J7N-CEL3] (describing in Section 9.2 biologic-specific considerations).

72. Where there is an applicable data exclusivity protection, manufacturers seeking to enter the market may struggle to launch their product with the relevant FDA approval. *See infra* Section II.A.3.

73. *See* 21 U.S.C. § 355(j); *see also Abbreviated New Drug Application (ANDA)*, U.S. FOOD & DRUG ADMIN. (Mar. 28, 2025), https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda [https://perma.cc/W25X-QMVH]. For biosimilars, see 42 U.S.C. § 262(k).

74. *See* Considerations in Demonstrating Interchangeability with a Reference Product: Update; Draft Guidance for Industry; Availability, 89 Fed. Reg. 52060 (June 21, 2024) (describing updates to the interchangeability standard for biologic products, which would include insulin).

physicochemical and in vitro biological comparison, the high cost of these studies has dampened the biosimilar pipeline.[75]

This research and regulatory process may appear relatively straightforward, but conducting clinical trials and gaining FDA approval is one of the most costly elements of drug development.[76] Despite significant public investment in clinical trials and the FDA approval process, manufacturers sometimes justify high initial prices for new drugs based on their private investments at these stages.[77] High prices, in turn, are sustained by data exclusivities, whose grants are justified as necessary to incentivize research.[78]

B. Overview of Distribution

After FDA approval, manufacturers need to get their products to consumers, most of whom have insurance coverage. Over a third of Americans are publicly insured (by programs like Medicare, Medicaid, and the Veterans Affairs (VA) program).[79] To access one of these public insurance programs, a manufacturer generally needs to make their drug available to *all* federal programs.[80] Each public program has slightly different administrative requirements for entry and ongoing compliance,[81] and each operates on a different timeline.[82] States may negotiate with

75. Erik Doevendans, Peter van Meer & Huub Schellekens, *The Devolution of Biosimilars Regulations*, 43 NATURE BIOTECHNOLOGY 19, 20–21 (2025); Sampat & Lichtenberg, *supra* note 60, at 334 (detailing that not many biosimilar applications are filed).

76. *See* Talha Syed, *Does Pharma Need Patents?*, 134 YALE L.J. 2038, 2045–46 (2025); P. Sydney Engle, Note, *Prescribing a Change to the FDA's Drug Labeling Rules After the 21st Century Cures Act*, 72 DUKE L.J. 861, 870–71 (2023).

77. Christopher M. Holman, *In Defense of Secondary Pharmaceutical Patents: A Response to the UN's Guidelines for Pharmaceutical Patent Examination*, 50 IND. L. REV. 759, 807–08 (2017).

78. *See supra* note 54.

79. KATHERINE KEISLER-STARKEY, LISA N. BUNCH & RACHEL A. LINDSTROM, U.S. CENSUS BUREAU, HEALTH INSURANCE COVERAGE IN THE UNITED STATES: 2022 (2023), https://www.census.gov/library/publications/2023/demo/p60-281.html [https://perma.cc/3PTG-ZS88].

80. For example, a contract with the VA and the 340B program is required for Medicaid. Participation in the national Medicaid rebate program is required to be eligible for payment through Medicare Part B. *See* 42 U.S.C. § 1396r-8.

81. *See supra* note 80 and accompanying text; *Manufacturer Resources*, HEALTH RES. & SERVS. ADMIN. (Aug. 2024), https://www.hrsa.gov/opa/manufacturers [https://perma.cc/5DKK-97N9] (describing ongoing reporting required for the 340B program); Vanessa S. Duran & Jennifer R. Shapiro, *Medicare Part D Manufacturer Discount Program Final Guidance*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Nov. 17, 2023), https://www.cms.gov/files/document/manufacturer-discount-program-final-guidance.pdf-0 [https://perma.cc/8TLA-8P5M] (detailing reporting and audits for manufacturers participating in the Part D Coverage Gap Discount Program).

82. For example, to get a VA contract, a new public manufacturer will need to first sign an interim agreement to supply the VA drugs while negotiating and completing the paperwork for a VA schedule contract. *See Law 102-585, Veterans Health Care Act of 1992*, U.S. DEP'T VETERANS AFFS.: OFF. OF PROCUREMENT, ACQUISITION & LOGISTICS (Nov. 4, 2024), https://www.va.gov/opal/nac/fss/publicLaw.asp#one [https://perma.cc/C5GC-K74A]. To enter the 340B program, a manufacturer would need to sign an agreement, gain access to the 340B online system for reporting, and provide periodic updates on the manufacturer's information. *See* 42 U.S.C. § 1396r-8. Once a manufacturer has completed agreements with 340B and the VA, they will need to complete a National Drug Rebate Agreement to

manufacturers separately for additional rebates or discounts for the state's Medicaid program.[83] Hospitals have the option to negotiate additional discounts through the 340B program as well.[84]

Both public and private insurers use PBMs as an intermediary with drug manufacturers to negotiate drug prices and formulary placement on behalf of insurance companies and their beneficiaries.[85] PBMs thus create and manage the "formularies" that define which medicines are covered. They negotiate with manufacturers, often creating complex formulary rules and tiers that influence the drugs that patients and doctors choose. These intentional placement choices determine whether and how consumers will be able to use their insurance coverage to access a drug at the pharmacy counter.[86] For structural reasons detailed below, new market entrants cannot realistically expect to avoid dealing with PBMs when selling to consumers with insurance. And because the vast majority of consumers access prescription drugs through insurance coverage,[87] understanding PBMs and their impact on the prescription drug market will be critical to any distribution strategy for a new drug.

PBMs' middleman role in negotiations is ripe for abuse, as many scholars have described.[88] Because PBMs control whether competing manufacturers'

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offer the drug in Medicaid. *See Medicaid National Drug Rebate Agreement (NDRA)*, MEDICAID.GOV (Dec. 29, 2022), https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/medicaid-national-drug-rebate-agreement-ndra/index.html [https://perma.cc/Q87Y-PSHJ].

83. Elizabeth Williams, Anna Mudumala, Robin Rudowitz & Alice Burns, *Medicaid Financing: The Basics*, KAISER FAM. FOUND. (Jan. 29, 2025), https://www.kff.org/medicaid/issue-brief/medicaid-financing-the-basics [https://perma.cc/G2XE-N6WQ]; 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/JE7L-FEZ9].

84. *See* 42 U.S.C. § 256b(a)(10); Stephen Barlas, Commentary, *Health Care Reform Bill Expands Access to Section 340B Discounted Drugs for Hospitals*, 35 PHARMACY & THERAPEUTICS 632, 634 (2010).

85. T. Joseph Mattingly II, David A. Hyman & Ge Bai, *Pharmacy Benefit Managers: History, Business Practices, Economics and Policy*, 4 JAMA HEALTH F., issue no. 11, Nov. 2023, art. no. e233804, https://jamanetwork.com/journals/jama-health-forum/fullarticle/2811344 [https://perma.cc/32GK-BEJM]; *see also* Kristi Martin, *What Pharmacy Benefit Managers Do, and How They Contribute to Drug Spending*, COMMONWEALTH FUND (Mar. 17, 2025), https://www.commonwealthfund.org/publications/explainer/2025/mar/what-pharmacy-benefit-managers-do-how-they-contribute-drug-spending [https://perma.cc/N7C6-AQFV].

86. *See* Mattingly et al., supra note 85 ("Formulary design has a direct effect on whether patients can obtain prescribed medications and the associated out-of-pocket spending."). For Medicare and Medicaid, the CMS regulatory process noted above would be needed in addition to negotiation with PBMs to provide a new drug to Medicare and Medicaid patients. *See supra* notes 81–84 and accompanying text. For private insurance outside these programs, there might be some state requirements regarding drug plans, but not a drug approval or registration system. In private insurance, PBMs are the primary gatekeepers of the formulary. *See* Nicole Rapfogel, *5 Things to Know About Pharmacy Benefit Managers*, CENTER AM. PROGRESS (Mar. 13, 2024), https://www.americanprogress.org/article/5-things-to-know-about-pharmacy-benefit-managers [https://perma.cc/5LJ9-XUV4].

87. *See, e.g.*, *infra* note 145 and accompanying text.

88. For an academic discussion of PBMs, see Sheva J. Sanders & Jessica C. Wheeler, *Trading Pain for Gain: Addressing Misaligned Interests in Prescription Drug Benefit Administration*, 55 U. MICH. J.L. REFORM 423 (2022); Carter, *supra* note 48; James C. Robinson, *Pharmacy Benefit Management: The Cost of Drug Price Rebates*, 51 J.L. MED & ETHICS 52 (2023). For other discussions

drugs will be placed on an insurance plan's formulary (albeit within regulatory limits), PBMs can leverage formulary placement and restrictions (like prior authorization or step therapy[89]) to negotiate discounts and rebates from manufacturers.[90] PBMs were expected to use this power to generate savings for insurers and patients. But their profit model means that it is sometimes more lucrative for them to restrict or entirely foreclose formulary access for low-cost generics that—*because* of their low cost—cannot offer the same volume of rebates.[91]

The structure and power of PBMs allow them to very effectively manipulate the market for prescription drugs. PBMs profit by pocketing a portion of the discount they negotiate from manufacturers. For example, if the list price of a drug is $100, and the PBM secures a $60 rebate, it shares some of that discount with the insurer and keeps the rest.[92] This model creates a perverse incentive: the higher the list price, and the bigger the rebate, the more the PBM earns. If the price of the same drug jumps to $200, and the final cost remains $40—now with a $160 rebate—the PBM ends up with a larger cut. A congressional committee report on PBM activity showed that PBMs are aware of this dynamic: most major PBMs have a business committee as well as a clinical committee that reviews their formularies, and PBMs often intentionally choose higher cost medications for their formularies to maximize their rebate potential.[93] PBMs thus significantly contribute to rising list prices and slow the adoption rates of lower-cost, generic drugs.[94] Manufacturers are also aware of and take advantage of this setup—if the drug stops being profitable, or is less profitable than another

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of PBMs and their impact, see Matthew Fiedler, Loren Adler & Richard G. Frank, *A Brief Look at Current Debates About Pharmacy Benefit Managers*, BROOKINGS (Sept. 7, 2023), https://www.brookings.edu/articles/a-brief-look-at-current-debates-about-pharmacy-benefit-managers [https://perma.cc/AN94-JDZR].

89. Prior authorization is a requirement that a clinical expert from the insurance company review a prescription before it is filled. Step therapy is a requirement that a patient try another drug or therapy before accessing the prescribed therapy. *See, e.g.*, *Prior Authorization and Step Therapy Coverage Criteria*, BLUE CROSS BLUE SHIELD OF MICH. (May 2025), https://www.bcbsm.com/amslibs/content/dam/public/consumer/forms-documents/pharmacy/prior-authorization-and-step-therapy-guidelines.pdf [https://perma.cc/7FP9-HDAE].

90. James T. Kenney & Shellie Keast, *A Primer on Brand-Name Prescription Drug Contracting*, 30 J. MANAGED CARE & SPECIALTY PHARMACY 507, 507 (2024).

91. *See* H. COMM. ON OVERSIGHT & ACCOUNTABILITY, THE ROLE OF PHARMACY BENEFIT MANAGERS IN PRESCRIPTION DRUG MARKETS 32–33 (2024), https://oversight.house.gov/wp-content/uploads/2024/07/PBM-Report-FINAL-with-Redactions.pdf [https://perma.cc/P7F3-9FS7] (providing an example where Express Scripts detailed how it would shift claims from lower-cost drugs to more lucrative, high-cost drugs; for example, shifting patients from Humira (an older drug) to Enbrel or Cimzla).

92. Rebecca Robbins & Reed Abelson, *The Opaque Industry Secretly Inflating Prices for Prescription Drugs*, N.Y. TIMES (June 21, 2024), https://www.nytimes.com/2024/06/21/business/prescription-drug-costs-pbm.html [https://perma.cc/UN7M-UBTM].

93. *See* HOUSE COMM. ON OVERSIGHT & ACCOUNTABILITY, *supra* note 91, at 31–33. PBMs also receive a premium from manufacturers for negotiating with them, and take a cut of the rebates, or discounts, that manufacturers pay to insurance plans for favorable formulary placement. *See* Robbins & Abelson, *supra* note 92.

94. HOUSE COMM. ON OVERSIGHT & ACCOUNTABILITY, *supra* note 91, at 35–36.

product, a manufacturer can take the drug off the market at will, even if there is no other production source for that drug.

Alarmingly, PBMs also operate as a black box. Federal regulators do not have any oversight over manufacturers' relationship with PBMs,[95] and most states have only minimal oversight.[96] PBMs' profit structure, rebates, and business model are not fully transparent to anyone in the system. This lack of transparency makes it hard for consumers and insurers to know what a drug actually costs and difficult for new competitors to negotiate entry terms.

Concerns have been raised about PBM actions, and some regulatory changes have been proposed to change PBM behavior.[97] The largest PBMs are also currently the subject of both federal and state antitrust investigations for potential anticompetitive practices.[98] However, PBMs are a central intermediary today, and generally cannot practically be bypassed, particularly in the short-term.

Without these intermediaries, drug manufacturers would have to negotiate with each individual insurance plan, and vice versa—an enormous task. For branded drug manufacturers, PBMs provide a vast and lucrative market for their products,[99] and can helpfully deter market penetration for generics. For insurers, PBMs run much of the operational structure for prescription drug plans, often paying for drugs at the pharmacy counter and handling claim processing on the insurance company's behalf.[100] While some of the largest insurance companies have brought these functions in-

95. The FDA does not oversee plan operations, only drug approval; CMS has contractual relationships with private plans, but those plans are the entities that contract with the PBMs. CMS does not have an explicit role in regulating PBM action, outside of what the agency does to regulate plan activity. For more on the FDA's statutory mandate, see 21 U.S.C. ch. 9, subch. V (detailing the FDA's role in regulating drugs and devices, which is focused on approval of drugs). For CMS's mandate, see 42 U.S.C. ch. 7, subchs. XVIII & XIX (laying out the statutory foundation and requirements for Medicare and Medicaid). While federal legislation to regulate PBMs has been proposed, nothing substantive has passed that would allow federal oversight of these organizations.

96. Most states have provisions that prevent pharmacy gag clauses, but only twenty-seven states require reporting of rebate information, and only sixteen states prohibit spread pricing. *See State Pharmacy Benefit Manager Legislation*, NAT'L ACAD. FOR STATE HEALTH POL'Y (Oct. 21, 2024), https://nashp.org/state-tracker/state-pharmacy-benefit-manager-legislation [https://perma.cc/H755-4CDP].

97. *See* Robbins & Abelson, *supra* note 92; HOUSE COMM. ON OVERSIGHT & ACCOUNTABILITY, *supra* note 91, at 46. For examples of efforts to regulate PBMs, see *State Pharmacy Benefit Manager Legislation*, *supra* note 96.

98. *See infra* Section II.B.3.b.

99. *See* Mattingly, Hyman & Bai, *supra* note 85. Once a drug is on the market, its marginal cost of production is typically low, but manufacturers guard their patents and exclusive rights closely and will often develop secondary patents or slightly better formulations of the same drug in order to hold on to market exclusivity for as long as possible. *See* Kerstin Noëlle Vokinger, Aaron S. Kesselheim, Jerry Avorn, & Ameet Sarpatwari, *Strategies That Delay Market Entry of Generic Drugs*, 177 JAMA INTERNAL MED. 1665, 1666–67 (2017); Aaron S. Kesselheim, Jerry Avorn & Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 J. AM. MED. ASS'N 858, 861 (2016). PBMs aid and abet this dynamic, because it offers them more opportunities to gather rebates on high-priced drugs. *See* Robbins & Abelson, *supra* note 92.

100. *See* Mattingly et al., *supra* note 85, at 3–5; Martin, *supra* note 85 ("PBMs operate at the center of a complex distribution chain for prescription drugs, connecting drug manufacturers, payers, pharmacies, and patients. PBMs perform many functions within this chain[.]").

house by purchasing PBMs (e.g., Optum and United, Express Scripts and Cigna), many smaller insurance companies still contract with independent PBMs (or, the large insurer's in-house PBMs) to provide these services.[101] Insurance companies also sign multi-year contracts with PBMs,[102] making them legally and operationally difficult to replace. As a result, neither drug manufacturers nor insurance companies would be eager to take actions that would damage their relationships with PBMs.

C. Providing Drugs to Patients

In the pharmacy, patients often have little information or choice, which further fuels the problem of high prices. Remarkably, it is sometimes the case that it is cheaper for patients to pay out of pocket—but few patients think to ask about this, and PBMs and pharmacies sometimes suppress this information.[103] The formulary structure may also disincentivize patients from taking the drug that is the lowest cost to the system as a whole, for example, if copays are similar for drugs with different net costs.[104] Generics will be cheaper for the system but will not necessarily be cheaper to the patient at the point of sale if they are excluded from or disadvantaged by the insurance formulary, or deemed to not be interchangeable by the FDA. In such cases, many states prohibit pharmacists from substituting the generic drug at the counter.[105]

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101. *See, e.g.*, *Pharmacy and Prescription Drug Benefits*, UNITEDHEALTHCARE, https://www.uhc.com/member-resources/pharmacy-benefits [https://perma.cc/T4A7-7YLY] ("You may see the name Optum Rx on your prescription benefits. This is the UnitedHealthcare pharmacy service provider."); Peter High, *A View from Inside Cigna's $67 Billion Acquisition of Express Scripts*, FORBES (July 8, 2019, 9:19 AM), https://www.forbes.com/sites/peterhigh/2019/07/08/a-view-from-inside-cignas-67-billion-acquisition-of-express-scripts [https://perma.cc/QP8J-5UQP]; *see also Audit of Vertically Integrated Medicare Part D Sponsors*, U.S. DEP'T HEALTH & HUM. SERVS.: OFF. INSPECTOR GEN., https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000849.asp [https://perma.cc/B26F-GR4D]. For an example of a small plan using one of the large plan's PBMs, see *Coming January 1, 2025: CCA's New Pharmacy Benefit Manager—Here's What to Know*, COMMONWEALTH CARE ALLIANCE (July 29, 2024), https://www.commonwealthcarealliance.org/provider-news/coming-january-1-2025-ccas-new-pharmacy-benefit-manager-heres-what-to-know [https://perma.cc/7K7U-2MW6] (detailing CCA's PBM transition to CVS Caremark).

102. *See* Scott McEachern & Patrick Cambel, *PBM Contracts: Understand Then Optimize*, MILLIMAN (Aug. 2, 2020), https://us.milliman.com/en/insight/pbm-contracts-understand-then-optimize [https://perma.cc/N9CY-J67T] ("Typical contracts with PBMs are structured under a three-year master agreement negotiated at the time of implementing the PBM[.]").

103. Some states have banned these "gag clauses," that restrict pharmacists from telling a patient that the drug they are seeking is cheaper without insurance. *Trending Now: State Legislation That Bans Pharmacy Benefit Managers' "Gag Clauses,"* NAT'L ACAD. FOR STATE HEALTH POL'Y (Jan. 30, 2018), https://nashp.org/trending-now-state-legislation-that-bans-pharmacy-benefit-managers-gag-clauses [https://perma.cc/MF9Q-B2S7].

104. Formularies vary but typically have between 3–5 tiers. Preferred brand drugs typically sit on tier 2 or 3 and have a cost between $37 and $45. *See How Do Drug Tiers Work?*, BLUE CROSS BLUE SHIELD OF MICH., https://www.bcbsm.com/medicare/help/using-your-plan/drug-tiers [https://perma.cc/Z46F-GXVU].

105. *See infra* notes 273–75 and accompanying text; *supra* notes 73–75 and accompanying text.

Because PBMs are hidden middlemen in the prescription drug market, their impact is not always considered,[106] especially in discussions of public production. However, any new entrant in the prescription drug market, especially in a drug category that has an expensive, lucrative competitor drug that is widely used, will have to contend with the role that PBMs and other manufacturers play to keep cheaper drugs out and more expensive drugs in.

II. CONCEPTUALIZING A PUBLIC PRODUCTION SUPPLY CHAIN

Given the complexity of the pharmaceutical market, how can public production scale effectively to reach large numbers of patients and deliver the promised cost and health benefits? We systematically outline the challenges—and potential solutions—that public entities must navigate, from designing a product to ensuring it reaches patients at the pharmacy counter.

We begin by examining the structure of public manufacturing and the role of intellectual property and data exclusivity in shaping which drugs are viable candidates for public production. We then address the critical challenge of distribution—particularly in markets where drugs are highly profitable and private firms have strong incentives to block public alternatives. Using case studies of two candidate drugs for public production, penicillin G benzathine and insulin, we demonstrate these points, as well as how states can leverage their regulatory and legislative tools to overcome roadblocks. Finally, we turn to additional considerations (and potential liabilities) around consumer access and use, including measures that states can take to ensure interchangeability of their products at the pharmacy counter and tort liabilities in the event of injuries stemming from public products. Although public entities will need to proactively consider and design around a wide range of potential issues, these challenges, we conclude, are surmountable.

A. Bench to Product: Challenges and Solutions to Drug Manufacturing

This Section focuses on legal considerations for states and the federal government as they establish a public manufacturing program. We focus on two major decision points: (1) determining the formal entity that manufactures in the public's name; and (2) securing freedom to operate in a field where intellectual property rights and data exclusivity claims are common. We propose that while the federal government is well-positioned to manufacture in-house, states may need to initially rely on third-party

106. *See, e.g.*, Josh Feng & Luca Maini, *Demand Inertia and the Hidden Impact of Pharmacy Benefit Managers*, 70 MGMT. SCI. 8940, 8940 (2024). PBMs are coming under increasing scrutiny. *See* Complaint at 3, *In re* Caremark Rx, LLC, No. 9437 (F.T.C. Sept. 20, 2024); Complaint at 70–72, Texas v. Eli Lilly and Co., No. D-1-GN-24-007930 (Tex. Dist. Ct. Oct. 3, 2024); Robbins & Abelson, *supra* note 92.

entities as they build capital and capacity to transition to fully public manufacturing. And, both states and the federal government may be able to exercise unique statutory and immunity privileges to overcome or design around intellectual property (IP) protections and data exclusivities that would otherwise be prohibitive for generic manufacturers.

1. Developing a Public Manufacturing Apparatus

In designing a public manufacturing initiative, states or the federal government can opt to either internally develop the capacity to manufacture their products within existing or newly chartered public institutions—as at least one federal bill has proposed[107]—or contract with a third party to produce products—as California is choosing to do with a non-profit drug firm called Civica, a non-profit venture, with experience in and established facilities for large-scale manufacturing.[108] The choice is an important one, requiring a consideration of factors such as cost, political risk, and institutional capacity.[109]

Operationally, the federal government is better positioned to carry out manufacturing initiatives, including in-house ones, than most states because of the potential for larger capital investment through Congressional appropriations,[110] the ability to "internalize" benefits to patients across the

107. Affordable Drug Manufacturing Act of 2023, S. 3398, 118th Cong. § 2 (proposing the establishment of an Office of Drug Manufacturing within the Department of Health and Human Services (HHS) with the potential to manufacture prescription drugs such as "insulin, asthma and chronic obstructive pulmonary disease (COPD) inhalers, naloxone, epinephrine auto-injectors, and antibiotics"). The Act also would allow HHS to contract with third-party entities if needed, "with [a] preference for nonprofit entities . . . ." *Id.*

108. *See Solving Drug Shortages Through Dedicated Manufacturing*, CIVICARX, https://civicarx.org/wp-content/uploads/2024/12/Civica-Manufacturing-2Pager-24-1203.pdf [https://perma.cc/3TV3-N7PE] (discussing Civica's manufacturing capacity to produce ninety million vials and fifty million pre-filled syringes of essential medications per year and experience with manufacturing three dozen medications); Taryn Luna & Emily Alpert Reyes, *Newsom Announces $50-Million Contract to Make California's Own Brand of Insulin*, L.A. TIMES (Mar. 18, 2023, 2:07 PM), https://www.latimes.com/california/story/2023-03-18/newsom-announces-50m-contract-to-make-californias-own-brand-of-insulin [https://perma.cc/P2BG-S7VT]. California's legislation does, however, leave open the possibility for direct manufacture by the state. *See* CAL. HEALTH & SAFETY CODE § 127694.1 (West 2024).

109. *See* BROWN, *supra* note 21, at 39–55.

110. For example, Congress appropriated a $2.5 billion budget to support a new public research and development initiative for pharmaceuticals in Advanced Research Projects Agency for Health. *See* Jocelyn Kaiser, *Looking to Gamble, Newest U.S. Health Agency Places First Research Bets*, SCIENCE (Oct. 10, 2023, 4:55 PM), https://www.science.org/content/article/looking-gamble-newest-u-s-health-agnecy-places-first-research-bets [https://perma.cc/PLD9-YTGE]. And, the Affordable Drug Manufacturing Act, if passed, would "authorize[] to be appropriated such sums as may be necessary to carry out" the Act, *see* Affordable Drug Manufacturing Act of 2023, S. 3398, 118th Cong. § 2, in contrast to the $50 million initial investment California has made for insulin manufacturing with CiviaRx, *see* Kevin Dunleavy, *California Invests $50M to Partner with Civica Rx on Insulin Manufacturing*, FIERCE PHARMA (Mar. 20, 2023, 11:45 AM), https://www.fiercepharma.com/manufacturing/california-invests-50m-partner-civica-rx-insulin-manufacturing [https://perma.cc/JS6P-HK3E].

country, and institutional experience in public manufacturing.[111] States such as California, with a large economy and substantial number of publicly-operated biomedical institutions and universities,[112] and Massachusetts, with an existing public-manufacturing facility in MassBiologics,[113] may also have the institutional capacity to operate state-run manufacturing, and stand to gain enough to make a project locally worthwhile. For many other states, however, cost and capacity may pose more of a challenge.[114]

Contracting with non-profit, third-party entities may require fewer up-front resources, and enable even smaller states to jumpstart public manufacturing, where local benefits are sufficient to justify the cost. California's contract between its Department of Health Care Access and Information (HCAI) and Civica offers an example of this approach.[115] The joint public manufacturing venture will be overseen by a Board of Directors, equally staffed by HCAI and Civica, allowing for the state to have joint decision-making authority over drug selection, manufacturing, regulatory approval, and commercialization.[116]

However, as some have cautioned, states should not become overly dependent on such partnerships in the long run because even a "nonprofit status is no guarantee that they will always uphold the broader public interest" and "in other corners of the health care market, nonprofits are just as concerned with maximizing income."[117] States can, however, use this initial joint venture to develop institutional knowledge and experience, before transitioning to a fully state-operated manufacturing and distribution scheme, which may well help bring costs down and render programs more sustainable by cutting out a middleman and gaining better access to information about production and the supply chain.

2. Overcoming Intellectual Property Barriers

Public manufacturing initiatives must also make strategic choices about which drugs to produce. Projected health benefits and cost savings will be key factors, along with the practical feasibility of securing a stable supply.

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111. The federal government has significant public-sector involvement not just in the pharmaceutical space, *see supra* notes 60–63 and accompanying text, but also in other contexts such as utilities, finance, and defense, *see* Aneil Kovvali & Joshua C. Macey, *Private Profits and Public Business*, 103 TEX. L. REV. 711, 730–752 (2025).

112. BROWN, *supra* note 21, at 50.

113. *See Facilities*, UMASS CHAN MED. SCH.: MASSBIOLOGICS, https://www.umassmed.edu/massbiologics/about/facilities [https://perma.cc/48HS-N8J5].

114. Dana Brown has suggested that states could rely on "capitalization funds from a variety of sources, including general obligation bonds, state loans, and possible equity financing" if they choose to establish state-run manufacturing facilities. BROWN, *supra* note 21, at 51.

115. *See* STANDARD AGREEMENT BETWEEN CAL. DEP'T OF HEALTH CARE ACCESS & INFO. AND CIVICA FOUNDATION (2023), https://calrx.ca.gov//uploads/2023/03/Fully-Executed-22-23025-Civica-Foundation-1.pdf [https://perma.cc/5D88-ZSMQ] [hereinafter STANDARD AGREEMENT].

116. *Id.* at 4–6.

117. Stienon, *supra* note 47. For example, COVID vaccine manufacturers like Moderna entered into partnerships with the government to develop the vaccine, only to then quadruple the price. *See id.*

However, the primary legal concern during the drug selection stage is intellectual property, as the need to navigate exclusive rights can significantly affect the cost, feasibility, and even the design of the final product.

Although public manufacturers may prefer to steer clear of newer drugs with IP complications, aggressive patenting by firms means that even older drugs may not be entirely free of patent risk.[118] Pharmaceutical companies commonly blanket successful products with dozens or even hundreds of patents,[119] a strategy known as "patent thicketing" or "evergreening."[120] Patents are available not just for active therapeutic ingredients, but also for salts and polymorphic forms, formulations and dosages, combination products, and delivery devices like auto-injectors or inhalers.[121]

Some trivial secondary patents can be designed around, such as by developing a different device to deliver the same product. The viability of these workarounds, however, will hinge on both technical factors and the intricate interplay between patent law and regulatory frameworks.[122] For example, a dosage or isomer patent may be impossible to work around if it covers the only FDA-approved form of a drug, and the integration of delivery devices into the drug approval process can make substituting a device difficult.[123] Just as importantly, generic substitution laws—along with patient preferences and habits—can make introducing a modified version of a drug unattractive. Broadly speaking, even seemingly trivial patents, like patents on inhaler caps, can interact with the regulatory and marketing environment in ways that allow them to effectively deter competition for years.[124]

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118. *See* Aaron S. Kesselheim, Jerry Avorn & Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA 858, 859–60 (2016) (explaining the role of exclusivities in the problem of high prices); Kumar, *supra* note 21, at 7–8.

119. I-MAK, OVERPATENTED, OVERPRICED: CURBING PATENT ABUSE: TACKLING THE ROOT OF THE DRUG PRICING CRISIS 3 (2022), https://www.i-mak.org/wp-content/uploads/2022/09/Overpatented-Overpriced-2022-FINAL.pdf [https://perma.cc/R65Z-M6YN].

120. Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J.L. & BIOSCIENCES 590, 596 (2018) (defining evergreening as the practice of "artificially extending the life of a patent or other exclusivity by obtaining additional protections to extend the monopoly period"); Jeffrey Wu & Claire Wan-Chiung Cheng, *Into the Woods: A Biologic Patent Thicket Analysis*, 19 CHI.-KENT J. INTELL. PROP. 93, 109 (2019).

121. *See* Kapczynski et al., *supra* note 50.

122. Stephanie H. Choi et al., *Generic Drug Device Combination Products: Regulatory and Scientific Considerations*, 554 INT'L J. PHARMACEUTICS 443, 443 (2018).

123. *Id.* at 449; William B. Feldman, Doni Bloomfield, Reed F. Beall & Aaron S. Kesselheim, *Patents and Regulatory Exclusivities on Inhalers for Asthma and COPD, 1986–2020*, 41 HEALTH AFFS. 787, 787–88 (2022). Notably, if a public entity challenges the validity of a patent in court, the manufacturer could countersue and receive an automatic thirty-month stay preventing generic entry. *See* 21 U.S.C. § 355; Sunand Kannappan, Jonathan J. Darrow, Aaron S. Kesselheim, & Reed F. Beall, *The Timing of 30-month Stay Expirations and Generic Entry: A Cohort Study of First Generics, 2013–2020*, 14 CLINICAL & TRANSLATIONAL SCI. 1917, 1918 (2021). In addition to embroiling the state in litigation efforts to challenge a weak patent, this stay also prevents the state from even moving forward with an FDA approval application while challenging the relevant patent. *Id.* Government patent use provides remedies for the federal government and those acting on its behalf. *See* Brennan et al., *supra* note 13, at 281–83.

124. Feldman et al., *supra* note 123, at 794.

Private firms seeking the ability to legally manufacture, import, or sell a patented product must either obtain licenses (unlikely to be granted for lucrative products), or challenge exclusive rights that they believe invalid.[125] It is not uncommon for generic firms to seek to invalidate patents to enter the market, and Congress created incentives for them to do so through the Hatch-Waxman Act, which allows generic companies a 180-day exclusivity period if they successfully become the first entrant.[126]

Public entities can pursue freedom to operate in the same fashion—but they have powerful tools not available to the private sector. Under the Bayh-Dole Act, the federal government can "march-in" on patents arising from federally funded research and license them to third parties.[127] However, Bayh-Dole rights have narrow scope, because there are very few publicly funded medicines that have *only* patents subject to Bayh-Dole rights.[128] Secondary patents will in most cases block the ability of Bayh-Dole rights alone to enable access to research funded with federal dollars.

More important, and far more powerful, are the government patent use rights held by the federal government. Section 1498 is a codified and expanded version of a long-standing rule that operates similarly to eminent domain right.[129] Under this law, the federal government and its contractors can use *any* patent, and need only pay reasonable compensation in exchange—commonly a royalty of a few percent.[130] The rule helps prevent hold-up and address excessive pricing, and the federal government has relied on it frequently—both historically and today—in areas like defense procurement.[131]

Section 1498 can be used in conjunction with Bayh-Dole,[132] but also can be used independently, because the right applies to all patents. There remains some uncertainty about the royalty rates that courts would assign if the federal government were to manufacture lucrative, patented medicines using this right.[133] However, courts have suggested that a lost profits

125. 35 U.S.C. § 271 ("[W]hoever *without authority* makes . . . any patented invention . . . infringes the patent." (emphasis added)); 35 U.S.C. §§ 311, 321 (describing the process for challenging a patent).

126. 21 U.S.C. § 355(j)(5)(B)(iv). Collusive deals settling such patent invalidity suits are also common and have been recently targeted under competition law. *See generally* FTC v. Actavis, Inc., 570 U.S. 136 (2013).

127. 35 U.S.C. § 203; 35 U.S.C. § 202(c)(4).

128. Lisa Larrimore Ouellette & Bhaven N. Sampat, *Using Bayh-Dole Act March-In Rights to Lower US Drug Prices*, 5 JAMA HEALTH F., issue no. 11, Nov. 2024, art. no. e243775, https://jamanetwork.com/journals/jama-health-forum/fullarticle/2825385 [https://perma.cc/CCV5-RBKN].

129. 28 U.S.C. § 1498 (providing that if a patent is "used or manufactured by or for the United States without license of the owner thereof . . . the owner's remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture"); *see also* Brennan et al., *supra* note 13, at 298–99; Morten & Duan, *supra* note 14, at 11–13.

130. Brennan et al., *supra* note 13, 305–07.

131. *Id.* at 301–03.

132. Amy Kapczynski, *Realizing Public Rights Through Government Patent Use*, 49 J.L. MED. & ETHICS 34, 36 (2021).

133. Brennan et al., *supra* note 13, at 310–15.

approach is generally inappropriate under this provision; instead, either a small fixed percent royalty, or a more complex approach that seeks to ensure companies recoup their risk-adjusted R&D costs (discounted for public funding and other markets where they will recoup that investment) would be more appropriate.[134] Importantly, Section 1498 does not overcome data exclusivity, as discussed next, so where data exclusivities pose an impediment, public entities must either themselves generate data to bypass the exclusivity or wait until the period ends.[135]

Use under Section 1498 must be both "for" the federal government, and authorized by the federal government under the statute.[136] State manufacturers could, however, benefit from the right if given express authority from the federal government, for example in a contract to supply a federal program like Medicare or Medicaid.[137] Where state manufacturers seek to serve other markets, without an express contract or authorization from the federal government, they might instead seek to invoke their own sovereign immunity to patent infringement under the Eleventh Amendment.[138] Although the possibility of injunctions under *Ex Parte Young* would remain a concern, as Shweta Kumar has argued, states would have stronger arguments for immunity if they provided adequate remedies in state court, such as by providing compensation through state eminent domain laws or passing state laws analogous to Section 1498.[139] Federal and state manufacturing initiatives will need to address IP concerns early on and develop strategies—and a budget—to generate freedom to operate, with these distinctive government rights in mind.

3. Data Exclusivity Challenges

Data exclusivity protections for innovator drugs could potentially create additional challenges for manufacturing. Generic manufacturers normally rely on clinical trial data submitted by the original reference drug to receive approval as a generic equivalent (or a biosimilar). However, two issues can arise. First, data exclusivities granted by the FDA can prevent generic

134. *Id.* at 311–12.

135. *Id.* at 340–45.

136. *Id.* at 330; JOSEPH ADAMCZYK, ADRIENNE LEWIS & SHIVANI MORRISON, N.Y.U. TECH. L. & POL'Y CLINIC, § 1498: A GUIDE TO GOVERNMENT PATENT USE 17–19 (Christopher Morten ed., 2021), https://prep4all.org/wp-content/uploads/2021/01/P4A-1498-A-Guide-to-Government-Patent-Use.pdf [https://perma.cc/FMU4-6947]; *see also* 28 U.S.C. § 1498 (applying only where an invention is "used or manufactured by or for the United States").

137. TVI Energy Corp. v. Blane, 806 F.2d 1057, 1060 (Fed. Cir. 1986) (inferring use for the federal government where use was pursuant to a government contract); Hughes Aircraft Co. v. United States, 534 F.2d 889, 901 (Ct. Cl. 1976) (addressing the "authorization by" prong).

138. Kumar, *supra* note 21, at 44–45; *see also* Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank, 527 U.S. 627, 630 (1999). Congress could, however, abrogate states' sovereign immunity as well, if there were evidence of widespread and persistent infringement. *See* Kumar, *supra* note 21, at 46–47; Allen v. Cooper, 589 U.S. 248, 264 (2020).

139. Kumar, *supra* note 21, at 49 (noting that offering a state forum and remedies for patent infringement by the states could reduce the necessity of a federal forum, or foreclose the option of a federal forum altogether); *see also Ex parte* Young, 209 U.S. 123, 165 (1908).

manufacturers from using this data to support their application, even if the patents on the drug have expired.[140] In such instances, data exclusivities would limit the ability of public production initiatives to seek regulatory approval of their manufactured products. Without the reference product's clinical trial data, a public producer manufacturing an equivalent drug would have no way to demonstrate the safety or efficacy of their new equivalent product.

These challenges counsel in favor of primarily selecting drugs for manufacture that do not have relevant data exclusivity protections. Of course, as with IP, this may not always be desirable, and there may be instances when the public health needs of the state require a public alternative regardless of these exclusivity concerns.[141] In these instances, states may be able to secure emergency authorizations from the FDA or partner with compounding pharmacies to manufacture the drug through FDA exemptions, subject to specific regulatory requirements for manufacturing quality.[142]

On a structural level, increasing state involvement in clinical trials during drug development could also obviate the need for tax incentives and exclusivities currently offered to private manufacturers and allow the government to retain ownership over clinical trial data. There is at least federal capacity for both manufacturing batches needed for clinical trials and for conducting trials—the Pilot Bioproduction Facility at the Walter Reed Army Institute of Research specializes in manufacturing small batches of vaccines and biologics for clinical trials;[143] and public institutions like the VA hospital network could serve as trial centers. Therefore, a more expansive version of public production—one that also expands state involvement in late-stage R&D—could present the most robust approach to override these monopoly concerns.

B. Product to Pharmacy: Challenges and Solutions to Drug Distribution

Even if states successfully navigate the challenges to drug manufacture, they will have to contend with the weblike structure of PBMs, insurance plans, and pharmacies to get their products to consumers. This Section focuses on these challenges. First, we argue that distribution schemes that bypass PBMs—such as through direct sale to insurers, hospitals, or consumers—are unlikely to achieve sufficient economies of scale and broad access to the public product without PBMs and insurance. Second, we propose that the distribution challenges will vary based on whether the publicly manufactured drug is in a lucrative drug class for private firms.

140. *See* Syed, *supra* note 76, 2084–85.

141. Kumar, *supra* note 21, at 31.

142. *Id.* at 39–40; *see also* Brennan et al, *supra* note 13, at 340–45 (discussing the FDA's enforcement discretion and the potential use of new drug application filings and 505(b)(2) applications).

143. *Pilot Bioproduction Facility*, WALTER REED ARMY INST. RSCH., https://wrair.health.mil/Collaborate/Pilot-Bioproduction-Facility/About-Us [https://perma.cc/VLQ7-TNM2].

Two selected examples, penicillin G benzathine and insulin, demonstrate that incentives for PBMs and private manufacturers to limit entry for public products will differ by drug type. Finally, we conclude that states are uniquely positioned to overcome these challenges by leveraging regulatory and legislative tools to innovate around these barriers. Some proposed solutions will not only benefit market entry for public products but also create a more favorable environment for other generic manufacturers seeking to introduce low-cost products.

1. The Inevitability of the Pharmacy Benefit Manager (PBM) Problem

Much of the current literature on public production proposes that public initiatives can distribute their products directly to consumers and hospitals, bypassing PBMs and insurers altogether.[144] This may be possible for certain products, as we will describe. However, for most drugs, public manufacturers will likely not be able to achieve economies of scale and reach a significant number of patients without going through PBMs.

Selling directly to consumers would be one way to bypass PBMs, but this is harder than it seems. Most patients have insurance and pay their prescription drug costs using that insurance.[145] Paying out of pocket is often more expensive—and even when patients are aware of direct-to-consumer options, the hassle of navigating them can be a deterrent. Even a major player in the direct-to-consumer prescription drug space like GoodRx, which offers discounts for a number of different drugs, especially generic drugs, reaches only 4% of total consumers in the market.[146] This approach

144. *See, e.g.*, Liljenquist et al., *supra* note 48, at 1858; Kaufman, *supra* note 21, at 365–67; BROWN, *supra* note 21, at 54–55.

145. *See* Juliette Cubanski, Matthew Rae, Katherine Young & Anthony Damico, *How Does Prescription Drug Spending and Use Compare Across Large Employer Plans, Medicare Part D, and Medicaid?*, KAISER FAM. FOUND. (May 20, 2019), https://www.kff.org/medicare/issue-brief/how-does-prescription-drug-spending-and-use-compare-across-large-employer-plans-medicare-part-d-and-medicaid [https://perma.cc/C7B5-3CTU] (depicting in Figure 1 that most U.S. retail prescription drug spending is through private insurance, Medicare, and Medicaid).

146. In the second quarter of 2024, GoodRx reported seven million consumers, and transactions revenue of $146.7 million. *See* Press Release, GoodRx, GoodRx Reports Second Quarter 2024 Results (Aug. 8, 2024), https://investors.goodrx.com/news-releases/news-release-details/goodrx-reports-second-quarter-2024-results [https://perma.cc/L8MJ-ULTC]. This seems impressive at first blush—but the United States spent over $600 billion on drugs in 2021, of which $421 billion was on retail drugs. *See* OFF. OF SCIENCE & DATA POL'Y, ISSUE BRIEF: TRENDS IN PRESCRIPTION DRUG SPENDING, 2016–2022 (2022), https://aspe.hhs.gov/sites/default/files/documents/88c547c976e915fc31fe2c6903ac0bc9/sdp-trends-prescription-drug-spending.pdf [https://perma.cc/648D-HDZ8]. Not accounting for the increase in spending from 2021 to 2024, and only considering retail drugs, this means that GoodRx has cornered around 0.1% of the national prescription drug market through direct-to-consumer sales. GoodRx mostly deals in lower-cost drugs, so an argument can be made that this figure understates GoodRx's market share by focusing on revenue rather than volume. But even looking at their consumer base does not improve the case—nearly 162 million people in the United States consume at least one prescription drug, so GoodRx's seven million customers account for only about 4% of the total consumers in the market. *See Therapeutic Drug Use*, CDC NAT'L CTR. FOR HEALTH STATS. (Jan. 10, 2025), https://www.cdc.gov/nchs/fastats/drug-use-therapeutic.htm [https://perma.cc/GU4F-6THZ]; Stella U. Ogunwole, Megan

is only likely to be successful where a drug is extremely expensive, such that the cost of a generic product without insurance is still lower than the reference product with insurance.

Even a state willing to make a medicine available at no cost directly to patients would face a dilemma: How, precisely, would a state *reach* such patients? Patients and doctors would need not just to know about the alternative, but the state would need to build a not-for-profit supply chain. Today, there is no such supply chain, even to public hospitals and federally qualified health clinics, outside of a few special domains such as childhood vaccines.[147]

There may, however, be areas where government entities occupy the core market that policymakers want to reach. For example, California has discussed manufacturing a public version of naloxone, an anti-overdose drug, because it is needed by publicly run entities, including public schools, that need to regularly replenish stocks that expire.[148] These are promising areas where public production can have an impact quickly, and without navigating some of the complexities inherent in products like insulin.

It may also be possible to quickly construct supply chains for drugs that are only dispensed in the hospital. Hospitals are, in fact, the primary consumers of Civica's non-CalRx products currently.[149] While hospitals make up an overall small portion of the prescription drug market,[150] states

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A. Rabe, Andrew W. Roberts & Zoe Caplan, *U.S. Adult Population Grew Faster than Nation's Total Population from 2010 to 2020: Population Under Age 18 Declined Last Decade*, U.S. CENSUS BUREAU (Aug. 12, 2021), https://www.census.gov/library/stories/2021/08/united-states-adult-population-grew-faster-than-nations-total-population-from-2010-to-2020.html [https://perma.cc/E6GH-AFHN].

147. Congress enacted the Vaccine for Children's program in 1993, which allocates funds for the CDC to purchase pediatric vaccines from private manufacturers. The agency then distributes the vaccine to local health departments, which then make the vaccines available for free to Medicaid-eligible or uninsured children receiving care at either public or private hospitals and clinics. Nearly half of the total pediatric vaccine supply—more than seventy-five million doses—is subsidized through Vaccines for Children. *See* Lauren Roper, Mary Ann Kirkconnell Hall & Amanda Cohn, *Overview of the United States' Immunization Program*, 224 J. INFECTIOUS DISEASES S443, S444 (Suppl. 4 2021). With a concerted effort, broader public supply chains can be built—COVID vaccines provide one example. *See generally* Chad P. Bown & Thomas J. Bollyky, *How COVID-19 Vaccine Supply Chains Emerged in the Midst of a Pandemic*, 45 WORLD ECON. 468 (2022) (describing how COVID manufacturing supply chains emerged through public efforts such as Operation Warp Speed in the United States). But there is currently no general-purpose procurement or distribution structure for medicines that a public manufacturer could use.

148. Sophia Bollag, *California Finally Has a Contract to Make Its Own Insulin. Next Up: Naloxone*, S.F. CHRON. (Mar. 18, 2023, 12:44 PM), https://www.sfchronicle.com/politics/article/california-insulin-naloxone-17843496.php [https://perma.cc/MBP2-WZEX].

149. *See Nearly 80 Quality Generic Medications Accessible to Member Hospitals*, CIVICA (2024), https://civicarx.org/medications/#hospital [https://perma.cc/V9A7-R2C5]. Civica's 80 drugs developed for hospital use far outnumber the Civica drugs sold OTC. *See Affordable and Available Generic Medications and Biosimilars*, CIVICASCRIPT (2025), https://civicascript.com/our-products [https://perma.cc/2GYH-MSXE].

150. *See* OFF. ASSISTANT SEC'Y FOR PLAN. & EVALUATION, *supra* note 2, at 4 (finding that hospitals accounted for $39 billion in drug spending in 2016, while retail and mail order pharmacies accounted for about $300 billion).

might, like Civica, be able to serve these markets directly.[151] Selling public products primarily to hospitals would not, however, lower costs or ensure accessibility of non-hospital drugs—and hospitals commonly buy different products than patients receive at the pharmacy.[152]

Could the state go directly to insurance companies instead? This too presents problems. As noted above, insurance companies are significantly reliant on PBMs.[153] Aside from the insurance companies that own their own PBMs—primarily the larger, more sophisticated plans—most insurance plans will not risk their relationships with PBMs to negotiate separately with a public manufacturer, even if the cost savings are significant to the system. And plans that do enter these negotiations could expect a massive reduction in rebates in that class of drugs from private manufacturers and their PBMs, which could offset any cost-savings the public product could offer.[154]

Because direct-to-consumer, direct-to-hospital, or direct-to-insurance options would limit the market that a public product could reach and limit

151. *See supra* note 149. However, hospitals use intermediaries that are structured similarly to PBMs (buying on behalf of numerous hospitals in order to achieve bulk discounts and taking a cut of the discounts) and could have similar dynamics and business practices, such as long-term contracts that might make it difficult for a new supplier to break into the market. *See* Emma Boswell Dean, Reekarl Pierre, Samuel Carter & Amelia M. Bond, *Role of Supply Chain Intermediaries in Steering Hospital Product Choice: Group Purchasing Organizations and Biosimilars*, 2 HEALTH AFFS. SCHOLAR, issue no. 6, June 2024, art. no. qxae067, https://pubmed.ncbi.nlm.nih.gov/38841720/ [https://perma.cc/D66L-SQ79]; Kevin A. Schulman, *Understanding the History of Group Purchasing Organizations and Pharmacy Benefit Managers*, HEALTH AFFS. FOREFRONT (Dec. 1, 2023), https://www.healthaffairs.org/content/forefront/understanding-history-group-purchasing-organizations-and-pharmacy-benefit-managers [https://perma.cc/JY4J-DHZU]. For more on Civica's business model and practices, see Carter Dredge & Stefan Scholtes, Commentary, *The Health Care Utility Model: A Novel Approach to Doing Business*, NEJM CATALYST (July 8, 2021), https://civicarx.org/wp-content/uploads/2023/09/CIVICA-NEJM-Catalyst-Feature.pdf [https://perma.cc/KR4A-G5M3].

152. Insulin is one example of this. While hospitals do use insulin products that patients can get at a retail pharmacy (like Novolog), they also use Myxredlin, an intravenous insulin product. Myxredlin is only relevant for use in a hospital or institutional setting, and while hospitals would want to order this formulation, public production of it would not help patients struggling with high outpatient drug costs. *See* U.S. FOOD & DRUG ADMIN, HIGHLIGHTS OF PRESCRIBING INFORMATION: MYXREDLIN (June 2019), https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/208157s000lbl.pdf [https://perma.cc/CB3H-8DMQ]; *Myxredlin*, GOODRX (June 20, 2022), https://www.goodrx.com/myxredlin/what-is [https://perma.cc/9W36-XZVF].

153. *See supra* notes 85–102 and accompanying text.

154. There is one recent example that seems counter to this conventional wisdom: Blue Shield of California's negotiations with a biosimilar manufacturer of Humira, Fresenius Kabi. However, even in that deal, Blue Shield of California used an intermediary, Evio Pharmacy Solutions, to broker the deal, suggesting that insurance companies largely still do not have the capacity in house to conduct in-depth pharmaceutical manufacturer negotiations. *See* Paige Minemyer, *Blue Shield of California Inks Deal to Buy Humira Biosimilar Directly from Manufacturer*, FIERCE HEALTHCARE (Oct. 2, 2024, 3:00 PM), https://www.fiercehealthcare.com/payers/blue-shield-california-inks-deal-buy-humira-biosimilar-directly-manufacturer [https://perma.cc/GRH9-9SXE]. Additionally, Blue Shield of California is committed more broadly to splitting up its PBM functions among multiple contractors and taking a more active role in drug plan management, which explains the plan's willingness to go around traditional PBM middlemen for this transaction. While Blue Shield of California has said that this new PBM structure will save the plan millions in drug costs, it is far from industry standard and will need to show results before other plans follow suit. *See* Rebecca Pifer, *Blue Shield of California Is Promising a Simpler, Cheaper Pharmacy Benefits Model. Can It Deliver?*, HEALTHCARE DIVE (Oct. 26, 2023), https://www.healthcaredive.com/news/blue-shield-california-pharmacy-benefits-cvs-caremark-pbm-disruption/694620 [https://perma.cc/R6KU-HBCG].

the impact on pricing and access issues, any public initiative will inevitably have to contend with PBMs for many important products. States will, we describe below, find it fairly easy to supply drugs that are in noncompetitive drug classes through PBMs. But they will have to leverage their unique status as a market participant and market regulator to disrupt entrenched manufacturer-PBM relationships when manufacturing products for which private companies are invested in maintaining their market share.

2. When PBMs and Firms Have Less to Lose: The Simpler Case of Penicillin G Benzathine

Penicillin G benzathine (PGB) is an archetypical case of a drug that could be publicly manufactured and distributed without significant PBM or drug company pushback.[155] The drug has been in shortage both in the United States and globally since at least 2005,[156] and pediatric formulations of the drug have been discontinued altogether.[157] The public health implications are significant: shortages have thwarted global efforts to address adult syphilis and especially mother-to-child transmission of syphilis, for which PGB is the only effective treatment.[158] Syphilis cases in the U.S. have increased by 80%, from 115,000 in 2018 to 207,000 in 2022, partly due to these shortages.[159] Shortages also have significant implications for military preparedness, because the drug is routinely administered prophylactically to

155. *Bicillin L-A: Penicillin G Benzathine Injection, Suspension*, PFIZER (Oct. 2023), https://labeling.pfizer.com/ShowLabeling.aspx?id=691 [https://perma.cc/Z258-5NHF] (describing indications including upper respiratory infections, susceptive streptococci, trepenomal diseases (syphilis, yaws, bejel, pinta), and rheumatic fever).

156. *See* Rosemary Wyber, Kathryn Taubert, Stephen Marko & Edward L. Kaplan, *Benzathine Penicillin G for the Management of RHD: Concerns About Quality and Access, and Opportunities for Intervention and Improvement*, 8 GLOBAL HEART 227, 228–29 (2013) (describing shortages). For the current shortage, see *Health Advisory: Extension of Long-Acting Benzathine Penicillin G (Bicillin L-A) Shortage*, CAL. DEP'T OF PUB. HEALTH (Mar. 18, 2024), https://www.cdph.ca.gov/Programs/OPA/Pages/CAHAN/Extension-of-Long-Acting-Benzathine-Penicillin-G-Bicillin-L-A-Shortage.aspx [https://perma.cc/8N9A-39CG].

157. *See* Letter from Kevin Martyn, Portfolio Director, Opioids and Pre-Filled Syringes, Pfizer Hospital, to the public (June 12, 2023), https://www.fda.gov/media/169427/download [https://perma.cc/8N9A-39CG].

158. *See Ensuring Demand and Supply of Benzathine Penicillin to Treat Syphilis*, WORLD HEALTH ORGANIZATION: GLOBAL SEXUALLY TRANSMITTED INFECTIONS PROGRAMME, https://www.who.int/teams/global-hiv-hepatitis-and-stis-programmes/stis/treatment/shortages-of-penicillin [https://perma.cc/CG2P-6D64]; *see also* Stephen Nurse-Findlay et al., *Shortage of Benzathine Penicillin for Prevention of Mother-to-Child Transmission of Syphilis: An Evaluation from Multi-Country Surveys and Stakeholder Interviews*, 14 PLOS MEDICINE, issue no. 12, Dec. 2017, art. no. e1002473, https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002473 [https://perma.cc/JM2E-D6Q3].

159. *See* Press Release, Ctrs. for Disease Control, 2022 U.S. Syphilis Cases Reach Highest Numbers Since the 1950s (Jan. 30, 2024), https://www.cdc.gov/nchhstp/newsroom/releases/2024/sti-surveillance-report-2022.html [https://perma.cc/5BHQ-JU8W]; Catherine Sweeney, *A Drug Shortage Makes It Harder to Treat a Surge in Syphilis Cases*, NPR (Feb. 20, 2024, 5:09 AM), https://www.npr.org/2024/02/20/1232605853/a-drug-shortage-makes-it-harder-to-treat-a-surge-in-syphilis-cases [https://perma.cc/KG8Q-KFVN].

recruits during boot camp.[160] The national security impact of PGB shortages was underscored in a 2024 Senate Armed Services Committee hearing, where public manufacturing was proposed as a solution to ensure a stable supply.[161]

Why has such an important drug remained consistently in shortage for a decade? It is not for lack of awareness: in recent years, the FDA has launched a Strategic Plan for Preventing and Mitigating Drug Shortages and convened an Agency Drug Shortages Task Force;[162] and the White House has put forward a Supply Chain Disruptions Task Force and a Council on Supply Chain Resilience.[163] The vulnerability of PGB to shortages stems largely from the fact that despite a global demand for the drug, PGB has not stimulated a robust, multi-source market and only has one supplier in the United States: King Pharmaceuticals (a subsidiary of Pfizer).[164] There may be several reasons for this. First, PGB is an off-patent drug with, until increases in recent years, a low purchase price, which may disincentivize additional manufacturers from investing in production.[165] Second, the largest demand segment—rheumatic heart disease—is concentrated in low-income countries where consumers have limited purchasing power and may

160. Benjamin Ryan, *Antibiotic Shortage Could Worsen Syphilis Epidemic*, N.Y. TIMES (July 7, 2023), https://www.nytimes.com/2023/07/07/health/syphilis-epidemic-antibiotic-shortage-pfizer.html [https://perma.cc/Z4Z5-J5U9].

161. *Hearing to Receive Testimony on the Department of Defense's Efforts to Ensure Servicemembers' Access to Safe, High-Quality Pharmaceuticals Before the Subcomm. on Personnel of the S. Comm. on Armed Services*, 118th Cong. 47–49 (2024) (statement of Melissa Barber, Postdoctoral Fellow, Yale University).

162. *See* U.S. FOOD & DRUG ADMIN., STRATEGIC PLAN FOR PREVENTING AND MITIGATING DRUG SHORTAGES (2013), https://www.fda.gov/media/86907/download [https://perma.cc/FM6Z-C63N]; *Agency Drug Shortages Task Force*, U.S. FOOD & DRUG ADMIN. (Oct. 30, 2019), https://www.fda.gov/drugs/drug-shortages/agency-drug-shortages-task-force [https://perma.cc/8PJ4-9HHK].

163. Press Release, The White House, Fact Sheet: Biden-Harris Administration Announces Supply Chain Disruptions Task Force to Address Short-Term Supply Chain Discontinuities (June 8, 2021), https://bidenwhitehouse.archives.gov/briefing-room/statements-releases/2021/06/08/fact-sheet-biden-harris-administration-announces-supply-chain-disruptions-task-force-to-address-short-term-supply-chain-discontinuities [https://perma.cc/HBA8-FT6Z]; Press Release, The White House, Facts Sheet: President Biden Announces New Actions to Strengthen America's Supply Chains, Lower Costs for Families, and Secure Key Sectors (Nov. 27, 2023), https://bidenwhitehouse.archives.gov/briefing-room/statements-releases/2023/11/27/fact-sheet-president-biden-announces-new-actions-to-strengthen-americas-supply-chains-lower-costs-for-families-and-secure-key-sectors/ [https://perma.cc/H679-DC72].

164. *See Drugs@FDA: FDA-Approved Drugs*, U.S. FOOD & DRUG ADMIN. (Jan. 25, 2021), https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=050141 [https://perma.cc/66DA-XRKN]; Wyber et al., *supra* note 156, at 228. Prices paid by Veterans Affairs have increased from $188 per 10 pack of injections in 2012 to $954 in 2024; STI clinics unable to benefit from the VA's bulk purchasing report price increases from $300 in the mid-1990s to $6500 in 2023. *Compare VA FSS Pharm Prices*, U.S. DEP'T OF VETERANS AFFAIRS: OFF. OF PROCUREMENT, ACQUISITION & LOGISTICS (2024), https://web.archive.org/web/20240926212542/https:/www.va.gov/opal/docs/nac/fss/vaFssPharmPrices.xlsx (2024 price in line 18756), *with OALC Freedom of Information Act Requests*, U.S. DEP'T OF VETERANS AFFAIRS (2025), https://www.va.gov/opal/docs/foia/vaFssPharmPrices20250401.xlsx [https://perma.cc/K7NP-F34D] (line 20312 of the April 1, 2025 download provides the comparable 2012 price).

165. *See Ensuring Demand and Supply of Benzathine Penicillin to Treat Syphilis*, *supra* note 158. Although some have attributed shortages to low margins, this explanation does not hold up to closer scrutiny: Shortages have persisted or worsened despite steep price hikes. As an example, private sector prices are discussed above. *See* Ryan, *supra* note 160.

opt for older and cheaper alternatives instead.[166] Third, manufacturing constraints may also play a role, as key suppliers of component products in the supply chain have exited the global market.[167] Pfizer itself has attributed the shortages to increased global demand for the drug,[168] but stakeholders have pointed to Pfizer's failure to successfully execute a promised shortages mitigation plan and questioned why the company did not adequately forecast demand in line with epidemiological data demonstrating increases in syphilis incidence.[169]

The public health and military importance of PGB, combined with the lack of private sector enthusiasm for producing it, makes the drug an ideal candidate for public manufacturing. Manufacturing sterile injectables is more capital-intensive and challenging than tablets, but the public sector has proven capable of quality manufacturing of similar products.[170] Given Pfizer's failure to meet demand and its decision to stop manufacturing pediatric formulations,[171] it seems likely that Pfizer does not see the product as particularly profitable, and would therefore not be expected to undercut or aggressively compete against a public production effort. Lack of manufacturer pushback would allow a PBM to freely negotiate with a public entity without concern of losing rebates or damaging its relationship with Pfizer for other drugs. Additionally, since the drug is clinically important, PBMs and insurers would likely be excited to have a reliable manufacturer in this market. In other words, for a PBM, a public source of PGB would provide value with few drawbacks. Distribution through the existing PBM-insurer networks would therefore pose limited challenges for PGB and other similarly situated drugs.

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166. Frederic Seghers et al., *Securing the Supply of Benzathine Penicillin, A Global Perspective on Risks and Mitigation Strategies to Prevent Future Shortages*, 16 INT'L HEALTH 279, 280 (2024); Rosemary Wyber, Timothy D. Johnson & Bhavini Patel, *Supply of Benzathine Penicillin G: The 20-Year Experience in Australia*, 39 AUSTL. & N.Z. J. PUB. HEALTH 506, 506 (2015); *see also Ensuring Demand and Supply of Benzathine Penicillin to Treat Syphilis*, *supra* note 158.

167. *See* Anna S. Bartoo, Mary A. Gilmer & Eric M. Tichy, *Antimicrobial Shortages: A Global Issue Impacting Infectious Diseases*, 80 CLINICAL INFECTIOUS DISEASES 249, 249–50 (2025).

168. *See* Letter from Kevin Martyn, *supra* note 157.

169. In a letter to the White House Drug Shortage Task Force, thirty-nine organizations criticized Pfizer:

> Given that the company's 2017 plans to avoid future shortages have failed, we are also eager to learn more about what the company plans to do differently to safeguard against additional shortages. We are also highly skeptical of the company's attempts to primarily blame the shortage on increasing demand, which appears to unfairly deflect blame to communities affected by syphilis. However, trends in syphilis rates are clear and demand has been and will continue to increase for the foreseeable future; if Pfizer was truly caught completely off guard, it raises significant questions about the competency of the company to forecast obvious infectious disease trends.

Press Release, Nat'l Coal. STD Dirs., National Coalition Letter Urges White House Taks Force Intervention on Syphilis Drug Shortage (Oct. 2, 2023), https://www.ncsddc.org/national-coalition-letter-urges-white-house-task-force-intervention-on-syphilis-drug-shortage [https://perma.cc/KXT2-AFVS].

170. The public sector manufactured penicillin. *See* Neushul, *supra* note 31, at 372. More recently, Walter Reed Army Institute of Research and the state of Michigan have manufactured vaccines. *See* Wade, *supra* note 32; DEUTSCH, *supra* note 63, at 10.

171. *See* Letter from Kevin Martyn, *supra* note 157.

3. Overcoming the PBM Problem: The Complex Case of Insulin

Insulin exemplifies the kind of drug where public production efforts will face steeper challenges in distribution.[172] Like PGB, insulin is a (mostly) off-patent drug; the existing patents are primarily secondary patents on particular formulations or devices, not patents on the innovator molecule itself.[173] In part due to the monopoly protections afforded by these secondary patents, the insulin market is dominated by three private manufacturers with large portfolios of insulin products.[174] These manufacturers, especially Eli Lilly and Novo Nordisk, generate significant profits from insulin—and they will not easily cede market share to a public product.[175]

To resist public competition in the market for insulin, private manufacturers can leverage their relationships with PBMs in a variety of ways. First, as discussed in Part I, manufacturers provide large rebates to PBMs in exchange for advantageous formulary placement of their profitable products such as insulin.[176] Through these contracts, manufacturers and PBMs significantly influence which products are utilized most by patients on insurance.[177] Bypassing or violating these contracts would be costly to

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172. Insulin refers to the hormone. Insulin is a naturally occurring molecule, but contemporary insulin markets are dominated by biosynthetic human insulin as well as modified analogues. We use "insulin" here because public initiatives like CalRx are developing several formulations, including both long-acting and short-acting insulins in both vial and pen forms.

173. *See, e.g.*, Anders Olsen et al., *Patents and Regulatory Exclusivities on FDA-Approved Insulin Products: A Longitudinal Database Study, 1986–2019*, PLOS MED., issue no. 11, Nov. 2023, art. no. e1004309, https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1004309 [https://perma.cc/2NGG-TWW8].

174. Ryan Knox, *Insulin Insulated: Barriers to Competition and Affordability in the United States Insulin Market*, 7 J.L. & BIOSCIENCES 1, 7 (2020).

175. In 2022, Eli Lilly reported global revenue of $3.8 billion in its top three insulin products alone. By comparison, the entire global penicillin market, including all manufacturers and products (of which PGB is only one part), is only about $8 billion total—suggesting insulin is significantly more lucrative. *Compare* ELI LILLY & CO., ANNUAL REPORT (FORM 10-K), at 46 (2023), https://investor.lilly.com/static-files/40a0ac65-967f-419c-a7a0-ac806c796999 [https://perma.cc/4AEV-WMUE], *with Penicillin Drug Market Research, 2032*, ALLIED MKT. RSCH. (June 2023), https://www.alliedmarketresearch.com/penicillin-drug-market-A110795 [https://perma.cc/KP26-DSYK]. Pfizer does not include Bicillin, its injectable PGB, in its description of top products in investor materials. *See, e.g.*, PFIZER INC., QUARTERLY REPORT (FORM 10-Q) (Mar. 2025), https://s206.q4cdn.com/795948973/files/doc_financials/2025/q1/6be0bc09-ff03-4e04-9b54-13ceb601b05e.pdf [https://perma.cc/G3DP-9VLW]. In addition, PGB is only indicated for a few conditions, and represents a small number of penicillin prescriptions. *See* Shaffi Fazaludeen Koya, Senthil Ganesh, Katherine Klemperer, Prashant Yadav & Anthony McDonnell, *Injectable Antibiotic Use in India: Public-private Share in Volume and Cost*, 9 WELLCOME OPEN RSCH., Feb. 2024, art. no. 70 (Feb. 19, 2024), https://doi.org/10.12688/wellcomeopenres.20633.1 [https://perma.cc/G5JV-YNZZ].

176. *See, e.g.*, Complaint at 3, *In re* Caremark Rx, LLC, No. 9437 (F.T.C. Sept. 20, 2024); Complaint at 70–72, Texas v. Eli Lilly & Co., No. D-1-GN-24-007940 (Tex. Dist. Ct. Oct. 3, 2024).

177. For example, to get a rebate from a manufacturer, a PBM might be required to put that drug on a "tier" of a formulary that ensures it is a first choice. Or the rebate deal might require the drug company's drug to be made structurally preferable to other products such that it could be prescribed or dispensed without prior insurance company authorization. Were PBMs to place any competing public product on the same, or better, tier as the manufacturers' drugs, PBMs could receive fewer rebates and manufacturers may even be able to cut or pull their rebates altogether (if the manufacturers negotiated

both PBMs and insurers, particularly because profits via rebates for many drugs (not just one formulation of insulin) could be affected.[178] As a result of these contracts, PBMs and insurers would likely be uninterested in negotiating with a new manufacturer for the same product, even (and perhaps especially) if it is cheaper.

Regulatory requirements also can make it difficult for a firm to enter a market with a single product. Consumer protection regulations established for public insurance programs specify that a certain number of drugs or drug formulations must be covered in each drug class. The Centers for Medicare & Medicaid Services (CMS) has formulary requirements that all Medicare Part D plans must cover a broad enough set of insulins to offer patients products that will meet their needs.[179] In other drug classes, CMS may have similar requirements, or may specify that a drug that is singular, first-in-class, shall be covered by all plans.[180] These regulations were developed to solve an important problem in a private market: They ensure that plans provide comprehensive drug coverage, where they otherwise might cut corners and opt not to cover drugs for certain chronic conditions. But they also have the side effect of providing manufacturers with significant bargaining power in negotiations with PBMs. Some manufacturers' drugs are, quite literally, indispensable for regulatory compliance.[181]

For insulin, therefore, a public production effort would have to cover the full suite of insulin products—rather than just, say, one long-acting insulin formulation—before it can replace a large private manufacturer on a formulary. Developing this full suite may not be feasible for many public

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to be the only products in a class on a specific tier). *See* H. COMM. ON OVERSIGHT & ACCOUNTABILITY, *supra* note 91, at 33 (describing how Express Scripts urged account teams not to talk about Humira due to "rebate impacts," suggesting that rebate documents are detailed, highly complicated contracts where PBMs and manufacturers have reciprocal commitments); Complaint at 2, *In re* Caremark Rx, LLC, No. 9437 (F.T.C. Sept. 20, 2024) (describing exclusionary formularies); *see generally* Anne M. Sydor, Emily Bergin, Jonathan Kay, Erik Stone & Robert Popovian, *Modeling the Effects of Formulary Exclusions: How Many Patients Could Be Affected by a Specific Exclusion?*, 11 J. HEALTH ECON. & OUTCOMES RSCH. 86 (2024) (same).

178. *See* Complaint at 78–80, Texas v. Eli Lilly & Co., No. D-1-GN-24-007940 (Text. Dist. Ct. Oct. 3, 2024) (discussing how PBMs make money on higher list prices by negotiating prime formulary placement for manufacturers' drugs). Notably, if a manufacturer agrees with a PBM to place all its drugs on a preferred tier in exchange for additional rebates, and then the PBM places another drug on that same tier, the PBM could lose rebates for all the first manufacturer's drugs on that tier. *Id.*

179. CMS's specific formulary requirements are not generally published publicly. However, the Part D Senior Savings Model provided requirements for participating plans for insulin. *See* CTR. FOR MEDICARE & MEDICAID INNOVATION, PART D SENIOR SAVINGS MODEL CY 2023 REQUEST FOR APPLICATIONS FOR PART D SPONSORS 9, https://www.cms.gov/priorities/innovation/media/document/partd-senior-sav-cy23-sponsor-rfa [https://perma.cc/F853-6T9L].

180. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE PRESCRIPTION DRUG BENEFIT MANUAL § 30.2.1 (2016), https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf [https://perma.cc/PJ94-AKDG].

181. Manufacturers are aware of, and take full advantage of, this bargaining power. Of the drugs selected for the inaugural year of the Medicare Drug Negotiation Program, all of the drugs included other than insulin are on-patent, sole-source lucrative drugs. These drugs were selected based largely on total expenditures by the Medicare program. *See Medicare Drug Price Negotiation: Selected Drugs and Negotiated Prices*, CMS.GOV (May 23, 2025, 12:54 PM), https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation [https://perma.cc/T64Q-VMWW].

production initiatives.[182] For example, CalRx has only announced plans to develop three insulin formulations, not an entire slate of products.[183] As such, PBMs will not want to risk their relationships and rebate amounts with the large private manufacturers simply to add one or two public insulin formulations. If they do, they either will find themselves paying the full, sticker cost of privately manufactured insulin products (and any bundled products) as manufacturers withdraw their rebates—a highly undesirable prospect—or will risk regulatory noncompliance in their formulary design, which could be catastrophic for the PBM and the insurance plan.

Notably, the constraints described above assume a key detail: that PBMs and plans actually *want* to cover a lower cost drug. In reality, this assumption may not be true. Higher-cost drugs mean PBMs get additional dollars to (at best) enhance the value of their plans by lowering drug costs to entice patients, or (at worst) pad their own profits.[184] Under the rebate structure, PBMs do not directly bear the burden of high list prices—the costs are instead borne by Medicare or the private insurer.[185] And employers or individuals only see this price indirectly as steadily growing monthly plan premiums.[186] The key intermediaries that exist to help reduce costs paradoxically may have little interest in doing so without new regulatory action.

As a result of these dynamics, private manufacturers have tried—and failed—to introduce alternatives to insulin products at a lower list price. Afrezza, a fast-acting inhalable insulin, is an example.[187] Introduced at a price of $0.68 per insulin unit, it has struggled to get onto many formularies.[188] By the end of 2023, Afrezza had more than doubled its list

182. California's new public production initiative, as an example, is starting with three insulins—glargine, lispro, and aspart—which would not be enough to fill a formulary. *See* California Selects Civica Rx as Its Insulin Manufacturing Partner, *supra* note 39.

183. *See* Bowman, *supra* note 38. These formulations alone would not satisfy the requirements for plan participation in the PDSS Model, which requires more than three insulin formulations. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 179, at 9.

184. *See supra* Section I.B.

185. *See* MEDPAC, PAYMENT BASICS: PART D PAYMENT SYSTEM 2–3 (2021), https://www.medpac.gov/wp-content/uploads/2021/11/medpac_payment_basics_21_partd_final_sec.pdf [https://perma.cc/EDF4-URHY].

186. *See* Gary Claxton, Matthew Rae, Anthony Damico, Aubrey Winger & Emma Wager, *Health Benefits in 2024: Higher Premiums Persist, Employer Strategies for GLP-1 Coverage and Family-Building Benefits*, 43 HEALTH AFFS. 1491, 1497–98 (2024); Giuliana Grossi, *Prescription Costs and Inflation Drive 2025 Health Insurance Premium Hikes*, AJMC (Aug. 14, 2024), https://www.ajmc.com/view/prescription-costs-and-inflation-drive-2025-health-insurance-premium-hikes [https://perma.cc/2P5U-433G]. *But see generally* Salpy Kanimian & Vivian Ho, *Why Does the Cost of Employer-sponsored Coverage Keep Rising?*, 2 HEALTH AFFS. SCHOLAR, issue no. 6, June 2024, art no. qxae078 (June 4, 2024), https://academic.oup.com/healthaffairsscholar/article-pdf/2/6/qxae078/58319280/qxae078.pdf [https://perma.cc/N7EY-GCLQ] (describing the contribution of other rising healthcare costs to increases in premiums).

187. *See Developing Life More Humann*, MANNKIND (2024), https://mannkindcorp.com/pipeline [https://perma.cc/LK2R-CJSX].

188. Mannkind's manufacturer code (included in every National Drug Code package code for their drugs) is 47918. *See National Drug Code Database search for "Afrezza,"* U.S. FOOD & DRUG ADMIN. (Mar. 28, 2025), https://dps.fda.gov/ndc/searchresult?selection=finished_product&content=

price, to $1.52 per insulin unit.[189] This move was almost certainly influenced by the manufacturer's desire to be able to influence uptake by offering higher rebates to PBMs. Similarly, Semglee, an interchangeable biosimilar to long-acting insulin products,[190] has struggled to get onto formularies.[191] These two examples illustrate the stronghold that the largest insulin manufacturers and PBMs have in the (for them, highly profitable) insulin market.

Any publicly manufactured insulin product—and other public products seeking to disrupt a lucrative market—will face these same challenges to formulary uptake and distribution. Private generic manufacturers have limited tools to alter this status quo, but states have a unique status in the market—they are not just market participants but also have the ability to act as market regulators. By leveraging this authority, public production initiatives can level the playing field and may also make the market ultimately more competitive for other entrants.

a. Short-Term Reforms: Leveraging the State's Legislative and Regulatory Apparatus

As a start, public initiatives could add requirements to their standard contracts with PBMs (or Medicaid managed care plans) that Medicaid cover the public drug product, or that Medicaid plans negotiate in good faith with the public initiative to provide coverage of the drug.[192] Notably, all integrated plans that provide care for dual eligible beneficiaries (those entitled to both Medicare and Medicaid coverage) are already required to

proprietaryname&type=afrezza [https://perma.cc/3N32-NMHB]. Cross-comparing this manufacturer code with CMS formulary data, Mannkind's manufacturer number appears on fewer than five distinct formularies. *See Quarterly Prescription Drug Plan Formulary, Pharmacy Network, and Pricing Information*, DATA.CMS.GOV (May 2025), https://data.cms.gov/provider-summary-by-type-of-service/medicare-part-d-prescribers/quarterly-prescription-drug-plan-formulary-pharmacy-network-and-pricing-information [https://perma.cc/2ULR-YK4V]; *see also* Tori Marsh & Lauren Chase, *Insulin Costs Plummet: A Decade-Long High Comes to an End*, GOODRX (Jan. 15, 2025), https://www.goodrx.com/healthcare-access/research/how-much-does-insulin-cost-compare-brands [https://perma.cc/E6LM-DTK2] (detailing the price of Afrezza); Tracy Staton, *MannKind Turns to Digital, Social Media to Spread the Word on Afrezza's Relaunch*, FIERCE PHARMA (Aug. 15, 2016, 9:27 AM), https://www.fiercepharma.com/marketing/mannkind-turns-to-digital-social-media-to-spread-word-afrezza-s-relaunch [https://perma.cc/QZG6-EK94] ("The company is also zeroing in on some known obstacles. Faced with prior authorization requirements from payers, it set up a patient reimbursement hub . . . ."); Andrew Smith, *MannKind: Path to Afrezza Survival Involves Lower Prices to Woo Payers*, 22 AM. J. MANAGED CARE SP137 (Special Ed. 4 2016).

189. *See* Marsh, *supra* note 188.

190. *See, e.g.*, Bob Herman, *The New Generic Insulin Isn't as Cheap as You Thought*, AXIOS (Nov. 17, 2021), https://www.axios.com/2021/11/17/the-new-generic-insulin-isnt-as-cheap-as-you-thought [https://perma.cc/S4U9-G9KU]. For the long-acting nature of Semglee and its interchangeability with Lantus, see generally SEMGLEE, https://www.semglee.com [https://perma.cc/S894-DAEY].

191. *See* Complaint at 24–25, *In re* Caremark Rx, LLC, No. 9437 (F.T.C. Sept. 20, 2024).

192. California negotiates its own discounts on Medicaid drugs. *See* CAL. HEALTH & SAFETY CODE § 130509 (West 2025).

contract with the state where they are providing Medicaid.[193] States can therefore add provisions requiring coverage of the public product into contracts with these plans. These contractual provisions would force PBMs to the table and could help ensure formulary placement for the public product. Because receiving favorable formulary access can be critical to the public drug's market penetration and sustainability, these intermediate solutions can provide runway for the longer-term solutions discussed later. States can also help public manufacturing efforts get to scale initially by selectively purchasing the publicly manufactured drug for state hospitals, prisons, transitional living facilities, and other state programs that directly purchase and utilize drugs without use of a private PBM.[194]

State initiated public production efforts may also be able to leverage federal partnerships in implementing these solutions. The federal government, and in particular the CMS Center for Medicare and Medicaid Innovation (CMMI) and the Center for Medicaid and CHIP Services, can provide states with waivers for certain federal requirements in Medicaid or other federal plan formulary coverage requirements.[195] With CMMI in particular, states could work with federal counterparts to propose models that waive certain requirements statewide, broadening the market for a new public production initiative or advancing public health efforts for a particular chronic condition.[196]

Finally, states that already have regulatory relationships with PBMs could leverage those regulations to ensure fair access to the drug market for public products. States may be able to require that PBMs negotiate in good faith with all willing manufacturers or impose transparency and oversight requirements on PBM practices.[197] Alternatively, states could explore creating a public PBM option, which would operate without the profit-driven motives of private PBMs and be much more receptive to granting

193. *See, e.g.*, VA. DEP'T OF MED. ASSISTANCE SERVS., DUAL SPECIAL NEEDS PLAN (D-SNP) CONTRACT (2024), https://www.dmas.virginia.gov/media/6141/final-2024-mippa-fbde.pdf [https://perma.cc/YTS2-R85L]; CAL. DEP'T OF HEALTH CARE SERVS., DUAL SPECIAL NEEDS PLANS CONTRACT AND POLICY GUIDE, (2023), https://www.dhcs.ca.gov/provgovpart/Pages/Dual-Special-Needs-Plans-(D-SNP)-Contract-and-Program-Guide.aspx [https://perma.cc/AP2D-97RH].

194. *See, e.g.*, *Statewide Pharmaceutical Program*, CAL. DEP'T OF GEN. SERVS.: PROCUREMENT DIV., https://www.dgs.ca.gov/PD/About/Page-Content/PD-Branch-Intro-Accordion-List/Acquisitions/Statewide-Pharmaceutical-Program [https://perma.cc/T8P7-VKTN].

195. *See About Section 1115 Demonstrations*, MEDICAID.GOV, https://www.medicaid.gov/medicaid/section-1115-demonstrations/about-section-1115-demonstrations/index.html [https://perma.cc/F2GV-QKKJ]; 42 U.S.C. § 1315a(d)(1) (describing CMMI's waiver authority).

196. CMMI has a division focused specifically on state-partnership models. *See, e.g.*, *Maryland Total Cost of Care Model*, CMS.GOV, https://www.cms.gov/priorities/innovation/innovation-models/md-tccm [https://perma.cc/7US6-6WC7]. Notably, models chosen would need to reduce expenditures or improve clinical outcomes over time in order to avoid being terminated. *See* 42 U.S.C. § 1315(b)(3) (describing criteria for termination of models). This should not be an issue for public manufacturing initiatives, which could manufacture a lower-cost product that would save Medicare dollars.

197. For a survey of actions states have already taken to regulate PBM actions, see *2024 State Legislation to Lower Prescription Drug Costs*, *supra* note 41; CARELONRX, Q2 2024 STATE AND FEDERAL REGULATORY AND LEGISLATIVE ACTIVITY UPDATE (2024), https://www.carelonrx.com/content/dam/digital/carelon/crx-assets/documents/2Q2024-federal-and-state-legislative-activity-report.pdf [https://perma.cc/772H-46YS].

formulary access for generics and publicly manufactured drugs. Further, states such as West Virginia and Kentucky have created carveouts to their state Medicaid programs such that a single PBM serves the managed care organizations.[198] As a condition for receiving the PBM contract for the managed care organizations, states could implement standardized drug lists for coverage, to include requirements for low-cost generics and public products.

b. Legal Considerations for States in Enacting Legislative and Regulatory Changes

As states take steps to facilitate market entry, private entities may challenge the state's authority to implement these policies. Historically, market-coordination and regulation efforts by the state have faced legal challenges under the dormant Commerce Clause, antitrust laws, and Employee Retirement Income Security Act (ERISA) preemption.[199] As this Section presents, such challenges should not pose a hurdle to the adaptations we have proposed to ensure uptake of public production.

i. Dormant Commerce Clause

The dormant Commerce Clause prohibits states from discriminating against out-of-state entities engaged in interstate commerce.[200] This prohibition applies not only to facial or express discrimination, but also to

198. *See* Press Release, Nat'l Cmty. Pharmacists Ass'n, West Virginia Medicaid Saves $54.4 Million with Prescription Drug Carve-Out (Mar 12, 2019), https://ncpa.org/newsroom/news-releases/2019/03/13/west-virginia-medicaid-saves-%2454.4-million-with-prescription-drug-carve-out [https://perma.cc/7MSQ-HHPS]; Press Release, Nat'l Cmty. Pharmacists Ass'n, Kentucky Saved $282 Million with Single PBM (Nov. 8, 2023), https://ncpa.org/newsroom/qam/2023/11/08/kentucky-saved-282-million-single-pbm [https://perma.cc/K3WU-E3YN]. Managed care organizations are entities, typically health insurance companies, that contract with a state Medicaid program to provide care for Medicaid beneficiaries in exchange for a per-enrollee monthly or annual payment where the insurer manages the risk. *See* Elizabeth Hinton & Jada Raphael, *10 Things to Know About Medicaid Managed Care*, KFF (Feb. 27, 2025), https://www.kff.org/medicaid/issue-brief/10-things-to-know-about-medicaid-managed-care [https://perma.cc/23YE-9W3G].

199. *See, e.g.*, Pharm. Rsch. & Mfrs. of Am. v. Walsh, 538 U.S. 644, 653–56 (2003) (alleging that a Maine program setting conditions for manufacturers to participate in the state Medicaid program violated the dormant Commerce Clause). For cases using antitrust law to challenge state price restraints or conditions on sales, see, for example, Parker v. Brown, 317 U.S. 341, 346 (1943); Town of Hallie v. City of Eau Claire, 471 U.S. 34 (1985); S. Motor Carriers Rate Conf., Inc. v. United States, 471 U.S. 48 (1985); Cal. Retail Liquor Dealers Ass'n v. Midcal Aluminum, Inc., 445 U.S. 97 (1980). For cases where PBMs tried to use ERISA to argue preemption of state regulation efforts, see Rutledge v. Pharm. Care Mgmt. Ass'n, 592 U.S. 80, 88–89 (2020); Pharm. Care Mgmt. Ass'n v. Wehbi, 18 F.4th 956 (8th Cir. 2021).

200. The doctrine derives from *Gibbons v. Ogden*, which involved a New York state statute that provided a monopoly over all steamboat traffic in New York waters to two individuals. 22 U.S. (9 Wheat.) 1, 3–4 (1824). The Court held that the state regulation conflicted with a federal statute authorizing the licensing of steamboats for intercoastal trade and was therefore preempted. *Id.* at 81–84. Although *Gibbons* involved an active conflict between federal and state law, the Court, in subsequent cases, began to expand the reach of the Commerce Clause to cases where state regulations "burden[ed] . . . [the] business of other States," even when there no express federal regulation on the subject. Guy v. Baltimore, 100 U.S. 434, 443 (1880).

acts that have discriminatory effects.[201] But the dormant Commerce Clause will not preclude laws facilitating public production if they equally apply to and burden in-state and out-of-state entities, and states can take advantage of exceptions for states acting as market participants.

Although commentators have frequently criticized cases involving the dormant Commerce Clause as inconsistent and confusing,[202] recent Supreme Court decisions have clarified that the doctrine applies differently based on whether the state passes legislation regulating the market or directly participates as a seller or purchaser of services in the market. States seeking to regulate a market—such as by prescribing conditions that PBMs must meet to participate in Medicaid—must do so in a way that applies even-handedly to *all* actors in the market, both in-state and out-of-state counterparts.[203] This means that states cannot impose regulations or conditions on out-of-state actors that also do not also apply to in-state counterparts.[204] Nor can states limit prices that can be charged for products in the state based on prices charged out of state.[205]

By contrast, a state that merely "participa[tes] in the market" as a seller and purchaser of goods and services[206]—such as by negotiating the contract terms for purchase of public products for state hospitals—is not constrained by the dormant Commerce Clause at all. This is because "[t]here is no indication of a constitutional plan to limit the ability of the States themselves to operate freely in the free market."[207] Just as "trader[s] or manufacturer[s]" have "independent discretion" in their choice of business partners, states can choose the "parties with whom [they] will deal," regardless of whether these choices would disfavor out-of-state competitors.[208]

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201. *See* Maine v. Taylor, 477 U.S. 131, 138 (1986).

202. *See, e.g.*, Note, *The Dormant Commerce Clause and Moral Complicity in a National Marketplace*, 137 HARV. L. REV. 980, 981 (2024) ("Throughout its doctrinal history, the dormant commerce clause has engendered confusion and skepticism as the Court and scholars have struggled to derive sufficient principles to guide its application."); Stanley E. Cox, *Garbage In, Garbage Out: Court Confusion About the Dormant Commerce Clause*, 50 OKLA. L. REV. 155, 157 (1997); Thomas W. Merrill, *Toward a Principled Interpretation of the Commerce Clause*, 22 HARV. J.L. PUB. POL'Y 31, 33 (1998); Michael S. Knoll & Ruth Mason, Bibb *Balancing: Regulatory Mismatches Under the Dormant Commerce Clause*, 91 GEO. WASH. L. REV. 1, 14 (2023).

203. Nat'l Pork Producers Council v. Ross, 598 U.S. 356, 369–71 (2023). The Court called this the "antidiscrimination principle" at the "very core" of the dormant Commerce Clause. *Id.* Other factors that have been considered include whether the regulation advances a "legitimate local purpose" and whether a state targets market transactions that occur wholly out-of-state. *See Walsh*, 538 U.S. at 669–70.

204. *Nat'l Pork Producers Council,* 598 U.S. at 370.

205. *Id.* at 371–73; *see also* Healy v. Beer Inst., 491 U.S. 324, 337 (1989) (invalidating a Connecticut statute that restricted out-of-state beer vendors from charging Connecticut consumers prices higher than those charged in neighboring states); Ass'n for Accessible Meds. v. Frosh, 887 F.3d 664, 670–72 (4th Cir. 2018) (invalidating a Maryland statute that set price limits for in-state sales based on acquisition prices paid out-of-state).

206. Hughes v. Alexandria Scrap Corp., 426 U.S. 794, 810 (1976).

207. Reeves, Inc. v. Stake, 447 U.S. 429, 437 (1980).

208. *Id.* at 438–40. In fact, states frequently favor their own citizens when they act as a "market participant," such as by preferentially hiring in-state residents, *see* White v. Mass. Council of Constr. Emps., Inc., 460 U.S. 204, 205–06 (1983) (challenging a local government's decision to preferentially employ in-state workers in a city-funded construction project), or preferentially entering into contracts

State regulations aimed at facilitating formulary access for publicly manufactured medicines can be tailored to avoid conflict with the dormant Commerce Clause. For example, states could legislatively require PBMs serving Medicaid to cover publicly manufactured drugs, as long as the statute does not mandate that the PBM favor in-state manufacturers or impose these conditions selectively on out-of-state PBMs. In fact, challenges to similar regulations brought on dormant Commerce Clause grounds have already failed. Maine, for example, legislatively required manufacturers to negotiate rebates on prescription drugs as a condition for favorable Medicaid coverage.[209] The Supreme Court rejected a dormant Commerce Clause challenge, holding that the policy even-handedly burdened both in-state and out-of-state manufacturers, affected only negotiations and transactions occurring within the state, and furthered the state's legitimate interest in consumer access.[210] Similarly, if states leverage their market power in Medicaid to compel formulary access for publicly manufactured drugs, the regulation would equally burden private manufacturers in-state and out-of-state and therefore not implicate the dormant Commerce Clause.

States can also leverage the market participant exception to preferentially purchase publicly manufactured drugs or negotiate contract terms aimed at achieving market access for public products. This exception should squarely protect a state that preferentially purchases public drugs for its publicly operated hospitals, clinics, and points-of-care, for example.

ii. Federal Antitrust Law

The regulatory strategies we suggest are also unlikely to run afoul of federal antitrust laws. Consider if state hospitals and other institutions enter into exclusive arrangements for publicly manufactured drugs,[211] if state initiatives set prices well below cost,[212] or if states restrict which plans and PBMs can compete for Medicaid contracts.[213] If undertaken by private actors, these measures might well "impose restrictions[,] . . . . confer

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to purchase goods from in-state manufacturers, *see Reeves*, 447 U.S. at 431–32 (challenging a state-owned cement plant's decision to limit sales exclusively to residents of the state during a cement shortage).

209. Pharm. Rsch. & Mfrs. of Am. v. Walsh, 538 U.S. 644, 653–55 (2003).

210. *Id.* at 669–70.

211. *See* Standard Oil Co. v. United States, 337 U.S. 293, 314–15 (1949) (finding exclusive supply contracts to be in violation of federal antitrust laws by stifling competition from both in-state and out-of-state competitors). *But see* Tampa Elec. Co. v. Nashville Coal Co., 365 U.S. 320, 334–35 (1961) (upholding an exclusive dealing arrangement because it would not substantially lessen competition).

212. *See* Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209, 222–24 (1993) (holding that undercutting prices may be an antitrust violation if the "prices complained of are below an appropriate measure of its rival's costs" and the competitor has a "dangerous probability[] of recouping its investment in below-cost prices").

213. *See, e.g.*, Rectrix Aerodome Ctrs., Inc. v. Barnstable Mun. Airport Comm'n, 534 F. Supp. 2d 201, 202–03 (D. Mass. 2008), *aff'd*, 610 F.3d 8 (1st Cir. 2010) (challenging local regulations which limited the parties that could supply jet fuel at an airport).

exclusive or shared rights to dominate a market, or otherwise limit competition to achieve public objectives"[214] and so raise antitrust concerns.[215] However, states have never been held to the same standard as private parties because states establish the entitlements that structure markets and competition. As such, states are exempt from antitrust restrictions in shaping the conditions of competition, including conditions on market entry[216] and sales,[217] under the state antitrust immunity doctrine.[218]

To claim immunity, state action must be authorized by or in furtherance of a state statute that either "clearly contemplate[s]" or "foresee[s]" the potential for "anticompetitive conduct."[219] For example, in *Rectrix Aerodome*, a state statute allowed the municipality to "determine the terms and conditions under which contracts may be executed" and to "determine the charges or rentals for the use of any . . . services" in a local airport.[220] The First Circuit affirmed that the statute embodied a sufficiently "articulated policy of displacing competition" and therefore allowed the municipality to limit the parties that could sell jet fuel in a local airport, despite the anticompetitive effects.[221] Accordingly, state initiatives can avoid antitrust scrutiny for manufacturing and distribution decisions, such as those described above, if the statute establishing the initiative endows the state with latitude and discretion in its implementation. California's statute establishing its public production initiative does this, authorizing the state to "enter into partnerships resulting in the production or distribution of generic prescription drugs, *with the intent that these drugs be made widely available* to public and private purchasers . . . and pharmacies."[222] This language manifests an intention for the state and its intermediaries to take necessary measures to make public drugs "widely available." So downstream measures to advance this policy should be immune to antitrust challenge.

State-action immunity even extends to third parties delegated to enforce legislation, such as a non-profit like Civica. If a state chose to delegate

214. N.C. State Bd. of Dental Exam'rs v. FTC, 574 U.S. 494, 503 (2015).

215. Town of Hallie v. City of Eau Claire, 471 U.S. 34, 41–42 (1985); Parker v. Brown, 317 U.S. 341, 350 (1943).

216. The Court, for example, has upheld state regulations preventing advertisements by lawyers because they "reflect[ed] a clear articulation of the State's policy with regard to professional behavior," Bates v. State Bar of Ariz., 433 U.S. 350, 362 (1977), and regulations requiring state approval of the location of new automobile dealerships because the state clearly expressed its goal to "displace unfettered business freedom in the matter of the establishment and relocation of automobile dealerships," New Motor Vehicle Bd. of Cal. v. Orrin W. Fox Co., 439 U.S. 96, 109 (1978).

217. *See, e.g.*, *Parker*, 317 U.S. at 348–51 (rejecting an antitrust challenge to California's Agricultural Prorate Act that placed restrictions on how and when raisin packers could sell their products in order to stabilize the distribution prices for raisins).

218. *Id*. at 350–51.

219. *Town of Hallie*, 471 U.S. at 41.

220. Rectrix Aerodome Ctrs., Inc. v. Barnstable Mun. Comm'n, 534 F. Supp. 2d 201, 203–04 (D. Mass. 2008) (citing MASS. GEN. LAWS ch. 90, § 51H (2008)), *aff'd*, 610 F.3d 8 (1st Cir. 2010).

221. *Id.* at 203.

222. CAL. HEALTH & SAFETY CODE §§ 127690–127696 (West 2024) (emphasis added).

manufacturing and distribution to a third party, the third party would be able to enter into exclusive contracts and arrangements or set prices well below cost, just as the state can. However, for the immunity to extend to non-state actors, the state must not only enable but also "actively supervise[]" the third party's conduct.[223] "Active supervision" requires the state to "have and exercise power to review particular anticompetitive acts" of the third-party entity and to "disapprove [of actions] that fail to accord with state policy."[224] For example, in *Midcal*, the Court did not extend state-action immunity to private actors who were authorized by statute to set prices for wines because the state did not have any role in negotiating the prices, reviewing the reasonableness of the price schedules, or regulating the terms of the contract.[225] By contrast, in *Southern Motor Carriers*, the Court upheld a statute authorizing private carriers to set fixed prices because the rates would be reviewed and approved by a state agency.[226] Therefore, as long as a state statute authorizes anticompetitive conduct and the state exercises oversight—such as by requiring politically accountable, government officials to sit on the board and have a say in the substantive operations[227]—the state-action immunity doctrine would protect even private parties acting on the state's behest to further public production. States could model their arrangement after the CalRx-Civica arrangement, where the Board of Directors is composed of an equal number of individuals appointed by the state and by Civica. This allows the state to exert oversight and decision-making authority over all aspects of manufacturing and commercialization.[228]

Some scholars and lower courts have proposed that the antitrust immunity should apply with less force when a state acts in a proprietary capacity in the market and uses a state statute to advance its own position as a "competitor" in the market.[229] For example, in *Allright Colorado*, four shuttle bus operators accused the city of Denver of violating antitrust laws because the city operated its own shuttle bus service and authorized more

223. Cal. Retail Liquor Dealers Ass'n v. Midcal Aluminum, Inc., 445 U.S. 97, 105 (1980) (quoting City of Lafayette v. La. Power & Light Co., 435 U.S. 389, 410 (1978)).

224. Patrick v. Burget, 486 U.S. 94, 101 (1988).

225. *Midcal*, 445 U.S. at 105. The Court determined that the statute merely "cast[] . . . a gauzy cloak of state involvement over what is essentially a private price-fixing arrangement" that therefore could not be exempt from federal antitrust laws. *Id.* at 106.

226. S. Motor Carriers Rate Conf., Inc. v. United States, 471 U.S. 48, 65 (1985).

227. *See* N.C. State Bd. of Dental Exam'rs v. FTC, 574 U.S. 494, 515 (2015) ("Active supervision need not entail day-to-day involvement in an agency's operations or micromanagement of its every decision."). However, a state official must be able to "review the substance of the anticompetitive decision" and be able to "veto or modify particular decisions to ensure they accord with state policy." *Id*.

228. *See* STANDARD AGREEMENT, *supra* note 115, at 4 ("[T]he Parties will establish a joint steering committee (the 'JSC') to coordinate and oversee the Development, Manufacture and Commercialization of the Products . . . . The JSC will be composed of an equal number of representatives from each Party [the state and CivicaRx] and who have the appropriate and direct knowledge and expertise and requisite decision-making authority.").

229. *See* Jarod M. Bona & Luke A. Wake, *The Market-Participant Exception to State-Action Immunity from Antitrust Liability*, 23 J. ANTITRUST & UNFAIR COMPETITION L. 156, 163 (2014); *infra* notes 233–234 and accompanying text.

favorable pick-up locations and routes for its own service over those of private competitors.[230] Likewise, in the public production context, a party could allege that regulations aimed at favoring market entry for publicly produced drugs should be exempt from immunity because the state would have dual interests both as a regulator and as a participant in the prescription drug market. While there is some support for this position in Supreme Court dicta,[231] the Court itself has never expressly invalidated state regulations under the Sherman Antitrust Act relying on such a rationale.[232] Many courts of appeals have also expressly rejected such an exception.[233] Circuits that do recognize a potential exception have set an exceptionally high threshold: They apply the exception only when the state acts as a buyer or seller in a private market, no statute authorizes the anticompetitive market relationship, and the market relationship is not in service of a traditional governmental function or for public benefit.[234] Because public production

230. Allright Colo., Inc. v. City of Denver, 937 F.2d 1502, 1509–11 (10th Cir. 1991). The Tenth Circuit rejected the allegation, holding that "[t]he City's additional status as a possible competitor, or its possible engagement in a 'proprietary' activity" is not controlling. *Id.* at 1510.

231. *See* City of Columbia v. Omni Outdoor Advert., Inc., 499 U.S. 365, 374–75 (1991) ("[T]his immunity does not necessarily obtain where the State acts not in a regulatory capacity, but as a commercial participant in a given market."); City of Lafayette v. La. Power & Light Co., 435 U.S. 389, 418, 424 (1978) (Burger, C.J., concurring) (proposing that Supreme Court precedents do not "suggest[] that a proprietary enterprise with the inherent capacity for economically disruptive anticompetitive effects should be exempt from the Sherman Act merely because it is organized under state law as a municipality" because "the running of a business enterprise is not an integral operation in the area of traditional government functions").

232. Only in a case involving the Robinson-Patman Act, which prohibits price discrimination, has the Supreme Court invoked a potential market-participant exception for antitrust laws. In *Abbott Laboratories*, the Court held that the state's purchase of drugs from manufacturers at prices lower than those charged to private pharmacies violated the Act because the state was "compet[ing] in the private retail market" as a market participant and not as a "state sovereign[]." Jefferson Cnty. Pharm. Ass'n, Inc. v. Abbott Lab'ys, 460 U.S. 150, 154 & n.6 (1983).

233. At least the First, Eighth, Ninth, and Tenth Circuits do not recognize a market participant exception. *See* Rectrix Aerodome Ctrs., Inc. v. Barnstable Mun. Airport Comm'n, 534 F. Supp. 2d 201, 206 (D. Mass. 2008), *aff'd*, 610 F.3d 8 (1st Cir. 2010) ("Although Rectrix raises the market participant exception, it does not cite to any case (nor can the court find one) that has applied the exception to reject a claim of state action immunity."); Paragould Cablevision, Inc. v. City of Paragould, 930 F.2d 1310, 1313 (8th Cir. 1991) ("[T]he market participant exception is merely a suggestion and is not a rule of law."); AmeriCare MedServices, Inc. v. City of Anaheim, 735 F. App'x 473, 474 & n.1 (9th Cir. 2018) (rejecting an antitrust challenge to Anaheim's exclusive contracts with ambulance companies to serve the city's emergency medical needs because the circuit had "decline[d] to adopt . . . a market-participant exception"); *Allright Colo., Inc*, 937 F.2d at 1510 ("The fact that the City is also in some sense a [market] competitor of plaintiffs does not alter the basic test for state action immunity . . . . The City's additional status as a possible competitor, or its possible engagement in a 'proprietary' activity, is not determinative.").

234. For example, a challenge against a public university's requirement for students to stay on-campus in dormitories was rejected because the university was furthering "governmental interests" in providing the "educational benefits of a 'living and learning' environment" and because the legislature had enacted policy—that public universities "shall provide . . . student living facilities" which envisioned that universities could impose on-campus residency requirements. Edinboro Coll. Park Apartments v. Edinboro Univ. Found., 850 F.3d 567, 579, 581 (3d Cir. 2017). By contrast, a state's revenue-sharing arrangement with a marketing firm for a publicly-owned entertainment venue was deemed to be "less entitled to immunity" because it involved a commercial "entertainment contract[]" that did not provide a public benefit and because there was no enacted statute authorizing the municipality to "engage in conduct that logically could result in the suppression of competition." Delta

initiatives will proceed through state legislation and because provision of essential medicines advances public benefit,[235] it is unlikely that an antitrust challenge on such grounds would succeed under current law.

iii. ERISA

State regulatory and legislative actions regulating PBMs to promote public production initiatives could face an ERISA preemption challenge if they constrain how certain employer-sponsored healthcare plans may be structured. Under ERISA, state laws that have "an 'impermissible connection' with" or "reference to" some national, employer-sponsored healthcare plans—also known as ERISA plans—are preempted.[236] Our proposed adaptations in Section II.B aimed at PBMs can be narrowly tailored to avoid an impermissible connection with an ERISA plan, the primary relevant ERISA prohibition.[237]

States will want to ensure that any regulations targeting PBMs are limited such that they do not impermissibly impact ERISA plans. The *Rutledge* Court reasoned that regulations that require specific benefits or bind plan administrators to certain rules or reporting requirements—either directly, or by creating requirements for third-party administrators—are preempted because of an "impermissible connection with" an ERISA plan.[238] So ERISA preemption could be a threat to the extent that states enact legislation or regulation requiring *all* PBMs to negotiate to provide the public product, or mandating a certain formulary structure or placement for the public product that *all* PBMs must follow.[239] However, the *Rutledge* Court held that a law requiring PBMs to adhere to a certain cost structure in purchases with pharmacies was not preempted, suggesting that narrowly

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Turner, Ltd. v. Grand Rapids-Kent Cnty. Convention/Arena Auth., 600 F. Supp. 2d 920, 926, 929 (W.D. Mich. 2009).

235. *Cf. AmeriCare MedServices, Inc.*, 735 F. App'x 473 (holding that a state contracting for ambulance services was advancing public interest).

236. *See* Gobeille v. Liberty Mut. Ins. Co., 577 U.S. 312, 320, 319 (2016) (first quoting Egelhoff v. Egelhoff, 532 U.S. 141, 148 (2001); then quoting N.Y. State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 656 (1995)); *see also* 29 U.S.C. § 1001. States are able to regulate insurance within their state, but have very limited ability to regulate self-funded employer plans. Self-funded employer plans are plans where the employer pays for the benefits directly, i.e., the employer pays all the health costs for their employees, rather than paying monthly plan premiums to an insurance company.

237. Under *Rutledge*, only regulations that exclusively act on ERISA plans or where ERISA plans are essential to the law's operation fall under the "reference to" prohibition. Rutledge v. Pharm. Care Mgmt. Ass'n, 592 U.S. 80, 88–89 (2020). The Court further held in *Rutledge* that a law acting on PBMs regardless of their relationship with ERISA plans is not subject to this prong of the test. *Id.* As a result, this part of the test is likely to be irrelevant to the interventions recommended here.

238. *Id.*

239. *See id.* at 86–87 ("ERISA is therefore primarily concerned with pre-empting laws that require providers to structure benefit plans in particular ways, such as by requiring payment of specific benefits, or by binding plan administrators to specific rules for determining beneficiary status[.]" (citations omitted)).

tailored operational rules are permissible.[240] Regulations that require a particular pharmacy network structure, set of benefits, or coverage rules for all plans would likely be preempted, as the *Rutledge* Court suggested and the Tenth Circuit recently held.[241] To avoid ERISA issues, states should focus on regulating PBM operational behaviors—like their interactions with pharmacies and manufacturers—to promote fairness in negotiations and pricing without impermissibly regulating plan structure.

c. Long-Term Reforms Aimed at PBM Structure and Governance

While we have thus far primarily focused on identifying immediate legislative and regulatory solutions available to the state to coordinate market entry, we conclude this Section by briefly proposing longer-term systemic reforms targeting PBM structure and governance. Specifically, Congress could pass federal legislation regulating PBMs, or the Federal Trade Commission (FTC) and/or state attorneys general could more aggressively utilize potential antitrust enforcement authority to target anticompetitive PBM practices. These changes could facilitate market entry for public production initiatives, and for generic or biosimilar firms as a whole.

With PBMs receiving more public attention and scrutiny, bipartisan interest in enacting federal reforms has grown. Federal legislation has been introduced that would require PBMs to publicly disclose rebates and fees, including those not passed on to consumers;[242] prohibit PBMs from charging health plans higher than the amount reimbursed to the pharmacy;[243] and delink service fees charged by PBMs from the list price of a drug or the value of rebates and discounts.[244] Such legislation, if enacted, could certainly disincentivize some of the perverse practices we have described around formulary access and list pricing. However, additional legislation targeting the process of negotiation between PBMs and manufacturers—such as limiting or eliminating exclusionary contracting practices and drug rebates—will be required to structurally modify PBM behavior. For example, drug rebates from manufacturers to PBMs are currently not considered "kickbacks" under the federal Anti-Kickback

240. *See id.* at 83; *see also* Pharm. Care Mgmt. Ass'n v. Wehbi, 18 F.4th 956, 968–69 (8th Cir. 2021) (similarly holding that PBM regulations were not preempted by ERISA).

241. Pharm. Care Mgmt. Ass'n v. Mulready, 78 F.4th 1183, 1187 (10th Cir. 2023); *see also* Pharm. Care Mgmt. Ass'n v. District of Columbia, 613 F.3d 179, 183–85 (D.C. Cir. 2010) (holding that certain rules for PBMs, including requiring them to act as fiduciaries and pass on any benefits, were preempted by ERISA). The Tenth Circuit reasoned that these requirements substantially limited how plans could be structured, which would impact self-funded employer plans that use PBMs and were therefore preempted. *Mulready*, 78 F.4th at 1195–96.

242. Pharmacy Benefit Manager Sunshine and Accountability Act, H.R. 2816, 118th Cong. (2023).

243. Protecting Patients Against PBM Abuses Act, H.R. 2880, 118th Cong. (2023).

244. DRUG Act, H.R. 6283, 118th Cong. (2023).

Statute because of a statutory safe harbor provision,[245] even though the law was expressly designed to prevent entities from making decisions about which healthcare services and products are offered or covered based on financial incentives.[246] A 2020 finalized rule by the Office of Inspector General would remove at least part of the safe harbor for manufacturer drug rebates—although it would still allow PBMs to condition rebates for a drug on formulary position.[247] However, recent legislation has delayed implementation of the rule until 2032.[248] Designating drug rebates as kickbacks and preventing manufacturers from conditioning rebates and fees on formulary placement would allow oversight of "rebate traps"[249] and prevent decisions over formulary placements to be made based on financial incentives offered by manufacturers.

Alternatively, the FTC could compel changes to PBM behavior by exercising enforcement authority under Section 5 of the FTC Act (FTCA).[250] To date, antitrust lawsuits targeting PBMs have failed under the Sherman Antitrust Act because courts have evaluated potential violations primarily under the "rule of reason" test.[251] Operationalized in response to a conservative critique of antitrust law as deterring the free market, the rule of reason standard imposes heavy burdens on plaintiffs to show anticompetitive harm, and has been extremely permissive to market-

245. The statute exempts "a discount or other reduction in price obtained by a provider of services . . . if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity. . . ." 42 U.S.C. § 1320a-7b(b)(3).

246. Sheva J. Sanders & Jessica C. Wheeler, *Trading Pain for Gain: Addressing Misaligned Interests in Prescription Drug Benefit Administration*, 55 U. MICH. J.L. REFORM 423, 465 (2022).

247. Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals, 85 Fed. Reg. 76666 (Nov. 30, 2020) (to be codified at 42 C.F.R. pt. 1001). The rule would only allow manufacturers to: (1) offer rebates if the full value of the price reduction is passed on to the dispensing pharmacy or the beneficiary and (2) provide service fees to PBMs based on fair market value. *Id.* Notably, the rule clarified that conditioning price reductions on formulary placement would still be allowed because "rebates paid by drug manufacturers to or through PBMs to buy formulary position are not reductions in price." *Id.* at 76683.

248. *See* Juliette Cubanski, Tricia Neuman & Meredith Freed, *Explaining the Prescription Drug Provisions in the Inflation Reduction Act*, KAISER FAM. FOUND. (Jan. 24, 2023), https://www.kff.org/medicare/issue-brief/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act [https://perma.cc/8CBQ-3WEC] (noting that the IRA "further delays implementation of the November 2020 final rule issued by the Trump Administration that would have eliminated rebates negotiated between drug manufacturers and pharmacy benefit managers . . . by removing the safe harbor protection currently extended to these rebate arrangements" until 2032).

249. FED. TRADE COMM'N, REPORT ON REBATE WALLS 2–3 (2021), https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-report-rebate-walls/federal_trade_commission_report_on_rebate_walls_.pdf [https://perma.cc/H4TZ-U2SM].

250. 15 U.S.C. § 45(5)(a).

251. *See, e.g.*, *In re* EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig., 44 F.4th 959, 983 (10th Cir. 2022) (holding that "exclusive dealing contracts are not disfavored by antitrust laws" and, paradoxically, that such contracts are "often entered into for entirely procompetitive reasons"); Eisai, Inc. v. Sanofi Aventis U.S., LLC, 821 F.3d 394, 408 (3d Cir. 2016) (rejecting an antitrust claim against Sanofi's practice of contractually restricting hospitals from favoring competing drugs on their formularies); Shire US, Inc. v. Allergan, Inc., 375 F. Supp. 3d. 538 (D.N.J. 2019) (rejecting an antitrust claim against Allergan's exclusionary contracting practices that limited Shire's competing product to "non-preferred" formulary lists).

manipulating conduct by large firms.[252] By contrast, the FTCA—which only allows enforcement action by the FTC—has the potential to reach "unfair" competitive conduct that would otherwise survive the Sherman Act's rule of reason test.[253] In a recent policy statement, the FTC suggested that "exclusive dealing arrangements" and "loyalty rebates," which have thus far survived scrutiny under the Sherman Act, may "have the tendency to ripen into violations" of the FTCA "by virtue of [the pharmaceutical] industry conditions."[254] And, notably, in September 2024, the FTC brought an antitrust action under Section 5 against the three largest PBMs, alleging that the PBMs' preferential exclusion of low-cost and generic alternatives from formularies is anticompetitive and burdens consumers with high drug prices.[255]

The FTC's challenge, if successful, could force PBMs to reconsider exclusionary contracting and rebate practices that pose major hurdles to market entry for any low-cost and generic alternative. However, it remains to be seen whether courts will be receptive to the FTC's broad interpretation of the coverage of Section 5. In fact, as recently as 2015, the Obama administration's FTC indicated that conduct evaluated under the FTCA must follow the same rule of reason approach of the Sherman Act, a guidance that was only revoked under the Biden administration.[256] Thus, the

252. *See* Andrew I. Gavil & Steven C. Salop, *Probability, Presumptions and Evidentiary Burdens in Antitrust Analysis: Revitalizing the Rule of Reason for Exclusionary Conduct*, 168 U. PA. L. REV. 2107, 2112–13 (2020); Maurice E. Stucke, *Does the Rule of Reason Violate the Rule of Law?*, 42 U.C. DAVIS L. REV. 1375, 1421 (2009) (criticizing the rule of reason for "its inaccuracy, its poor administrability, its subjectivity, its lack of transparency, and its yielding inconsistent results").

253. *See* FTC v. R.F. Keppel & Bro., Inc., 291 U.S. 304, 310 (1934) (noting that the FTCA reaches conduct beyond those "which are forbidden at common law or which are likely to grow into violations of the Sherman Act"); FTC v. Motion Picture Advert. Serv. Co., 344 U.S. 392, 394–95 (1953) (suggesting that Congress "designed [the FTCA] to supplement and bolster the Sherman Act"); FTC v. Brown Shoe Co., 384 U.S. 316, 320–21 (1966) (holding that the FTC "has broad powers to declare trade practices unfair" under the FTCA); FTC v. Ind. Fed'n of Dentists, 476 U.S. 447, 454 (1986) (noting that the FTCA's standard of "unfairness" is "an elusive one, encompassing not only practices that violate the Sherman Act").

254. FED. TRADE COMM'N, POLICY STATEMENT REGARDING THE SCOPE OF UNFAIR METHODS OF COMPETITION UNDER SECTION 5 OF THE FEDERAL TRADE COMMISSION ACT 13 (2022), https://www.ftc.gov/system/files/ftc_gov/pdf/P221202Section5PolicyStatement.pdf [https://perma.cc/MWS6-UB6R].

255. Complaint at 35, *In re* Caremark Rx, LLC, No. 9437 (F.T.C. 2024).

256. FED. TRADE COMM'N, STATEMENT OF CHAIR LINA M. KHAN JOINED BY COMMISSIONER ROHIT CHOPRA AND COMMISSIONER REBECCA KELLY SLAUGHTER ON THE WITHDRAWAL OF THE STATEMENT OF ENFORCEMENT PRINCIPLES REGARDING "UNFAIR METHODS OF COMPETITION" UNDER SECTION 5 OF THE FTC ACT 4 (2021), https://www.ftc.gov/system/files/documents/public_statements/1591498/final_statement_of_chair_khan_joined_by_rc_and_rks_on_section_5_0.pdf [https://perma.cc/MWS6-UB6R]. The Trump administration's FTC has not yet made its position clear on whether they will maintain the broader interpretation of Section 5. However, in his confirmation hearings to be the FTC Commissioner, Mark Meador suggested that at least with regards to content moderation, the FTC will address antitrust behavior through "two avenues," including "the antitrust laws" and "on the consumer protection side . . . the FTC Act." Taylor M. Owings, Maureen Ohlhausen, Jamillia P. Ferris, Jeffrey C. Bank & Elizabeth Wentross, *Enforcement Priorities of President Trump's DOJ and FTC Begin to Take Shape*, WILSON SONSINI (Feb. 26, 2025), https://www.wsgr.com/en/insights/enforcement-priorities-of-president-trumps-doj-and-ftc-begin-to-take-shape.html [https://perma.cc/QGG7-PFRV].

FTC will have to contend with how courts now interpret "unfair competition" under the FTCA, an interpretive choice that may sustain or completely foreclose any such future challenges.[257] Even if a court were to adopt the FTC's interpretation, the fact-intensive, time-consuming, and expensive nature of antitrust litigation limits the number of challenges that can be brought[258]—and therefore the deterrent effect on PBMs. Further, given that actions under Section 5 can only be instigated by the FTC, PBMs may escape scrutiny altogether in a changed political environment if the FTC once again reverts to earlier administrations' narrowed construction of Section 5.

In the absence of federal intervention, there may be opportunities to discipline PBM behaviors using state antitrust and consumer protection laws. In an empirical study of state attorneys general offices, "[p]articipants ranked prescription drug affordability as a high-priority issue for the AG's office . . . [despite] several major competing priorities at the time the interviews were conducted, including the COVID-19 pandemic[] [and] opioid litigation."[259] And despite increasing political polarization, state AGs view prescription drug affordability and antitrust enforcement as a "rare bipartisan issue."[260] Accordingly, several state AGs have recently turned their attention to investigating PBM practices.[261] As of this writing, lawsuits

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This suggests at least some willingness to leverage Section 5 for consumer protection purposes. The FTC has also already announced that it will continue the Biden administration's merger guidelines, which increased a focus on consumer protection when assessing mergers in the healthcare industry. *See* Press Release, Fed. Trade Comm'n, FTC Chairman Andrew N. Ferguson Announces that the FTC and DOJ's Joint 2023 Merger Guidelines Are in Effect, Fed. Trade Comm'n (Feb. 18, 2025), https://www.ftc.gov/news-events/news/press-releases/2025/02/ftc-chairman-andrew-n-ferguson-announces-ftc-dojs-joint-2023-merger-guidelines-are-effect [https://perma.cc/BQ8M-MU9M].

257. Although the Supreme Court's recent decision in *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024), may affect how a court reviews the FTC's interpretation of Section 5, the Supreme Court has previously held that Congress left "[i]n large measure the task of defining 'unfair methods of competition' . . . [up] to the Commission." FTC v. Texaco Inc., 393 U.S. 223, 225 (1968); FTC v. Nat'l Lead Co., 352 U.S. 419, 428–29 (1957) (holding that the FTC has "wide discretion in determining the type of order that is necessary to bring an end to the unfair practices found to exist" because the Commission has "wide latitude for judgment" (internal quotations and citations omitted)); Lina M. Khan, *Section 5 in Action: Reinvigorating the FTC Act and the Rule of Law*, 11 J. ANTITRUST ENFT. 149, 152 (2023) ("Congress . . . tasked the FTC with concretizing the meaning of 'unfair methods of competition' through litigation and rulemaking, informed by the agency's expertise and ability to do rigorous research into real-world market and evolving business practices."). Accordingly, when bringing an antitrust enforcement action under Section 5, "courts are to give some deference to the Commission's informed judgment that a particular commercial practice is to be condemned as 'unfair.'" *Ind. Fed'n of Dentists*, 476 U.S. at 454.

258. *See* Rohit Chopra & Lina M. Khan, *The Case for "Unfair Methods of Competition" Rulemaking*, 87 U. CHI. L. REV. 357, 372 (2020) (describing the FTC as an "agency with scarce resources" that is asked to undertake "many years of intense and expensive litigation").

259. Michelle M. Mello, Trish Riley & Rachel E. Sachs, *The Role of State Attorneys General in Improving Prescription Drug Affordability*, 95 S. CAL. L. REV. 595, 627 (2022).

260. *Id.* at 633.

261. In addition to lawsuits against PBMs, state AGs have also targeted other actors. For example, a multistate action against price-fixing by manufacturers to artificially inflate prices of generic drugs is ongoing—with two of the manufacturers settling in October 2024. Press Release, Off. of the Att'y Gen. of Conn., Attorney General Tong Announces Significant Updates in Multistate Litigation Against

have separately been initiated in at least California,[262] Ohio,[263] Hawaii,[264] Texas,[265] Mississippi,[266] and Vermont[267] targeting PBM formulary design and rebate practices as violations of state antitrust and consumer protection laws. Although some of these lawsuits have encountered procedural and substantive hurdles,[268] they hold promise because state laws may be "more expansive than the federal antitrust laws in terms of the amount and quality of prohibited conduct."[269] Forty-nine states have statutes mirroring the FTC Act's Section 5 prohibition on "unfair" deceptive acts and practices and many of these statutes explicitly direct courts to "defer[] to the FTC's and federal courts' interpretations of the FTC Act" in determining their reach.[270] State lawsuits may therefore be complementary to FTC's investigation—or even the primary vehicle—to hold PBMs accountable for practices that incentivize inflated list prices and limit market entry.[271] Affirmative litigation, especially if brought as multistate actions, may also compel PBMs to broadly change their practices and induce the federal government

Generic Drug Manufacturers Over Conspiracies to Inflate Prices and Limit Competition (Oct. 31, 2024), https://portal.ct.gov/ag/press-releases/2024-press-releases/attorney-general-tong-announces-updates-in-litigation-against-generic-drug-manufacturers [https://perma.cc/D73W-J8Z7]. And seven states, in collaboration with the FTC, successfully brought an antitrust lawsuit against Martin Shkreli for blocking generic competition against Daraprim—an off-patent drug the price of which Shkreli raised 4,000% overnight—by preventing competitors from obtaining an essential ingredient used to manufacture the drug. *See* Fed. Trade Comm'n v. Shkreli, 581 F. Supp. 3d 579 (S.D.N.Y. 2022).

262. Complaint, People v. Eli Lilly & Co., No. 23-CV-01929-SPG-SK (Cal. Super. Ct. Jan. 12, 2023).

263. Complaint, State v. Ascent Health Servs. LLC, No. 23-CV-H-03-0179 (Ohio Ct. C.P. Mar. 27, 2023).

264. Complaint, State v. CaremarkPCS Health, L.L.C., No. 1CCV-23-0001281 (Haw. Cir. Ct. Oct. 4, 2023).

265. Complaint, State v. Eli Lilly & Co., No. D-1-GN-24-007940 (Tex. Dist. Ct. Oct. 3, 2024).

266. Complaint, State v. Eli Lilly & Co., No. 21-CV-00738 (Miss. Ch. Ct. Sept. 24, 2021).

267. Complaint, State v. Evernorth Health, Inc., No. 24-CV-02759 (Vt. Sup. Ct. July 17, 2024).

268. Several of the lawsuits, including those brought by the attorneys general for California and Ohio, have been procedurally stalled as the parties disagree over whether the case should be litigated in state or federal court. *See* California v. CaremarkPCS Health LLC, Nos. 23-55597 & 23-55599, 2024 WL 3770326 (9th Cir. Aug. 13, 2024) (reversing a district court decision that remanded the case back to state court); Marty Schladen, *Ohio Antitrust Suit Against Drug Middlemen Hovers Between Courts*, OHIO CAP. J. (Feb. 1, 2024, 5:00 AM), https://ohiocapitaljournal.com/2024/02/01/ohio-antitrust-suit-against-drug-middlemen-hovers-between-courts [https://perma.cc/AZC5-PUXT]. The Hawaii lawsuit suffered a setback after a district court granted a motion to dismiss for failure to plead unfair acts and practices, but allowed the state to offer an amended complaint. *See* Hawai'i *ex rel.* Lopez v. CaremarkPCS Health, L.L.C., No. 23-CV-00464, 2024 WL 4625719, at *12 (D. Haw. Oct. 30, 2024). Additional challenges at the state level include limited resources and budgets, especially for smaller states, as well as unsettled law around the reach of state statutes, the potential for federal preemption, and dormant Commerce Clause restraints. *See* Mello et al., *supra* note 259, at 635–36, 638–40.

269. *Guide to Antirust Laws*, WASH. STATE OFF. OF THE ATT'Y GEN., https://www.atg.wa.gov/antitrustguide.aspx [https://perma.cc/QXW8-9CGA].

270. Babette Boliek, *The States and Antitrust Law*, 7 J.L. & INNOVATION 134, 148 n.32, 151 (2024) (collecting statutes from forty-nine states that mirror Section 5's unfair deceptive acts and practices provision). For example, in *Epic Games*, the Ninth Circuit found that Apple's restrictions on mobile applications, such as "requiring in-app purchases on iOS devices to use Apple's in-app payment processor" did not violate the Sherman Act but did violate California's state antitrust law. Epic Games, Inc. v. Apple, Inc., 67 F.4th 946, 966 (9th Cir. 2023).

271. As the Supreme Court has recognized, "Congress intended the federal antitrust laws to supplement, not displace, state antitrust remedies." California v. ARC Am. Corp., 490 U.S. 93, 102 (1989).

to "take a more active regulatory approach," as was the case with multistate tobacco and opioid litigation.[272] The resolution of the early state test cases will be crucial to determine whether antitrust litigation can be the panacea, absent legislative change, to alter PBM behavior.

C. Pharmacy to Patient: Challenges and Solutions Surrounding Consumer Access and Use

We conclude with a brief discussion of considerations for public initiatives at the point-of-sale—including maximizing consumer uptake through drug interchangeability—and the potential for product liability risks after consumer use. These considerations should be accounted for early in the production process—for example, drug interchangeability will be important during product development and manufacturing—but they will only become relevant once the public initiative has launched a product that can reach patients at the pharmacy.

1. Drug Interchangeability and Discounts at the Pharmacy Counter

Although ensuring formulary access will likely be the primary hurdle for market penetration, public initiatives can take additional measures to maximize access, including ensuring interchangeability for their products. Public entities will want to ensure that the FDA deems their drug to be interchangeable with a particular reference product, which will involve making strategic choices during manufacturing and when seeking FDA approval.[273] In addition, states should review their pharmacy interchangeability regulations to ensure that pharmacists can substitute a public product when it is cheaper for the consumer and the system. In California, for example, pharmacies can only replace a reference product if the generic drug is cheaper for the consumer.[274] A private manufacturer would therefore only have to drop the consumer's out-of-pocket price for their product—not even the actual list price incurred by the system—to match that of the public drug to avoid substitution at the pharmacy counter. California could amend this rule by allowing pharmacists to always substitute for the public product if the two products are the same price for the consumer or requiring that the pharmacy substitute for the drug with the

272. PAUL NOLETTE, FEDERALISM ON TRIAL: STATE ATTORNEYS GENERAL AND NATIONAL POLICYMAKING IN CONTEMPORARY AMERICA 23 (2015); Cheryl Healton, *The Tobacco Master Settlement Agreement—Strategic Lessons for Addressing Public Health Problems*, 379 NEW ENG. J. MED. 997 (2018); Mello et al., *supra* note 259, at 615 (discussing that the opioid settlements "have typically combined monetary awards with provisions requiring the companies to change their conduct going forward"). The multistate litigation against tobacco manufacturers resulted in a settlement agreement where the manufacturers accepted increased costs of cigarettes, restrictions on tobacco marketing, and establishment of smoking prevention programs. *See The Master Settlement Agreement*, NAT'L ASS'N OF ATT'YS GEN., https://www.naag.org/our-work/naag-center-for-tobacco-and-public-health/the-master-settlement-agreement [https://perma.cc/UET6-LEBU].

273. *See supra* Section I.A.

274. CAL. BUS. & PROF. CODE § 4073 (West 2024).

lower list price—which will almost always be the public product—as long as the price paid by the consumer is the same. The latter may be a more attractive option because private manufacturers may be willing to lower the cost incurred directly by the consumer to match the public product but may be unwilling to drop their list prices as this would affect their profits.

Of course, even with this rule adjustment, large private manufacturers could undercut the low costs of a public product temporarily to protect their market share, given their financial capacity to provide additional discounts.[275] In such instances, public entities will need to have the flexibility to create new discounts or drop the price of the product further. As noted above, public initiatives are not profit-seeking ventures and even incurring losses per unit can be justified if doing so services larger goals of lowering overall costs for the consumer and the system as a whole, or otherwise improving drug access, for example by addressing shortages.

2. Product Liability

Will states, or their contractors, make high quality medicines? We have little doubt that they can, given the historical and comparative examples cited above. For better or worse, states will face tort liability if their products cause harm. Although states generally enjoy sovereign immunity, most states and the federal government have waived sovereign immunity for tort claims, with limited exceptions.[276] Therefore, states and non-state entities alike can incur liability for injuries arising from drug design defects, manufacturing defects, or labeling defects.[277]

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275. In 2023 alone, Novo Nordisk reported over DKK 83 billion in net profit. *See* NOVO NORDISK, ANNUAL REPORT 2023, https://www.novonordisk.com/content/dam/nncorp/global/en/investors/irmaterial/annual_report/2024/novo-nordisk-annual-report-2023.pdf [https://perma.cc/F6SQ-BYJV].

276. 28 U.S.C. § 2674 ("The United States shall be liable, respecting the provisions of this title relating to tort claims, in the same manner and to the same extent as a private individual under like circumstances . . . ."). For a list of state statutes waiving immunity for tort claims, see *State Sovereign Immunity and Tort Liability in All 50 States*, MATTHIESEN, WICKER & LEHRER, S.C. (Aug. 29, 2024), https://www.mwl-law.com/wp-content/uploads/2018/02/STATE-SOVEREIGN-IMMUNITY-AND-TORT-LIABILITY-CHART-00220857x9EBBF.pdf [https://perma.cc/ZLF6-K25Y].

277. The extent of liability, however, may vary based on whether the state manufactures branded, patented drugs versus generic drugs because of federal preemption under the Federal Food, Drug, and Cosmetic Act (FDCA). The Supreme Court has interpreted the FDCA as preempting state tort claims alleging drug design defects and labeling defects for generic drugs, but not for branded drugs. *See* PLIVA, Inc. v. Mensing, 564 U.S. 604, 612–13, 618, 625 (2011) (acknowledging that this distinction "makes little sense"); *id.* at 643 (Sotomayor, J., dissenting) ("If a consumer takes a brand-name drug, she can sue the manufacturer for inadequate warnings . . . . If, however, she takes a generic drug, . . . she now has no right to sue."); Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 493 (2013) (holding that a "straightforward application of pre-emption law" bars state design defect claims from being brought against generic manufacturers, but not against branded manufacturers because generic manufacturers cannot "alter a product's design"). The Court has not indicated whether the FDCA preempts manufacturing defect claims, either for off-patent or patented drugs. Thus, a state may only be liable for manufacturing defects if it produces off-patent drugs, but may be liable for design defects, manufacturing defects, and labeling defects for patented products.

There is a significant literature criticizing the U.S. reliance on tort liability to both prevent and remedy harm.[278] The question of whether such liability is desirable here is beyond our scope, but we close by noting that Congress has suspended tort law in favor of other administrative schemes before. In the 1970s and 1980s, childhood vaccine manufacturers faced an avalanche of product liability litigation which, given the sizable liabilities, proved threatening to private manufacturers.[279] In response, Congress enacted the National Childhood Vaccine Injury Act (NCVIA), which created a no-fault compensation system for vaccine injuries through administrative adjudication, while exempting vaccine manufacturers from state tort claims.[280] Public manufacturers might be included under the law, and similar amendments or alternatives to tort liability may be created both at the state and federal level if circumstances warrant it.

CONCLUSION

Public production of pharmaceuticals could meaningfully improve access for patients struggling with the high cost of medicines and medicine shortages, even if it were limited to older and largely off-patent medicines. But implementing such programs requires running a gauntlet of legal issues—all that require attention and but are surmountable, as described here. We identify the biggest barriers to reaching significant numbers of patents with publicly produced medicines, illustrating how the state can leverage its unique status as a sovereign and a market participant to overcome bottlenecks, and anticipating legal challenges that may be raised as states confront the status quo.

Public production initiatives can, we believe, succeed with attention to these issues, and both meet critical health needs of patients and possibly help solve market access problems for private competitors if they do so by making structural changes to the way PBMs operate. This provides an important and underappreciated justification for public production itself: the

278. *See, e.g.*, Ellen S. Pryor, *Part of the Whole: Tort Law's Compensatory Failures Through a Wider Lens*, 27 REV. LITIG. 307, 307 nn.1–3 (2008) (collecting sources describing various criticisms of tort law, including failures of economic justice, compensation, and equity); Rick Swedloff, *Uncompensated Torts*, 28 GA. ST. U. L. REV. 721, 723–25 (2012) (providing examples of injuries that lack remedies because of the structure of tort law); Alexander B. Lemann, *Coercive Insurance and the Soul of Tort Law*, 105 GEO. L.J. 55, 57 (2016) (discussing scholarly criticism of tort law as an inefficient system for compensating victims); Martha Chamallas, *The Architecture of Bias: Deep Structures in Tort Law*, 146 U. PA. L. REV. 463, 467 (1998) (proposing that "tort law devalues or undervalues the lives, activities, and potential" of certain groups).

279. *See* Bruesewitz v. Wyeth LLC, 562 U.S. 223, 226–28 (2011) (summarizing the history leading up to the enactment of the National Childhood Vaccine Injury Act); Elizabeth C. Scott, *The National Childhood Vaccine Injury Act Turns Fifteen*, 56 FOOD & DRUG L.J. 351, 354 (2001).

280. National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (codified as amended at 42 U.S.C. § 300aa-1 to -34). No-fault compensation schemes for vaccine injuries are also the norm in many other countries. *See* Randy G. Mungwira et al., *Global Landscape of No-fault Compensation Programmes for Vaccine Injuries: A Review and Survey of Implementing Countries*, 15 PLOS ONE, issue no. 5, May 2020, art. no. e0233334, at 2, https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0233334 [https://perma.cc/3P8X-E77Z].

state can leverage unique legislative and regulatory tools that are unavailable to the private sector to counteract the concentrated power of market intermediaries, improve market structure, and expand access to medicines, particularly for those most in need.