No Moral Price: Leveraging Bayh-Dole to Uncover the True Cost of Innovation

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Federal regulators' inability to access drug-specific research and development ("R&D") costs constitutes a pressing issue requiring careful scrutiny. The absence of this data impairs regulatory solutions addressing extreme drug prices and leaves uncontested one of the most effective arguments that the pharmaceutical industry wields to ward off pricing regulation: the purported "chill to innovation." Rigorous evaluation of these statistics is essential to determining how to best structure drug prices to facilitate innovation. This Note presents a novel mechanism for acquiring this crucial information: the Bayh-Dole Act's "march-in" provision. This thus-far unused legislative provision endows certain federal agencies with the authority to fact-find. This Note asserts that the government should leverage this investigative function to obtain drug-specific R&D data, an endeavor that would significantly aid the creation of reasonable pricing benchmarks while sidestepping the risks associated with fully exercising march-in rights. This Note demonstrates the technical, political, and legal feasibility of this endeavor by analyzing relevant regulations, statutes, case law, and recent political developments. Americans have been forced to navigate the pharmaceutical realm at an informational handicap for long enough; it is time to level the playing field.

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INTRODUCTION

The federal government is currently faced with a pharmaceutical landscape increasingly out of balance: drug prices continue to rise, placing greater strain on patients,[1] as

1. *See* Grace Sparks et al., *Americans' Challenges with Health Care Costs*, KFF (Jan. 29, 2026), https://www.kff.org/health-costs/americans-challenges-with-health-care-costs/ [https://perma.cc/LZD8-N6JJ] ("About two-thirds of adults say they are either 'very worried' (32%) or 'somewhat worried' (34%) about being able to afford the cost of health care for themselves and their families. . . ."); *see also* Michael Erman, *Exclusive: Drugmakers Raise US Prices on 350 Medicines Despite Pressure from Trump*, REUTERS (Jan. 1, 2026, at 22:47 EST), https://www.reuters.com/business/healthcare-pharmaceuticals/drugmakers-raise-us-prices-350-medicines-despite-pressure-trump-2025-12-31/ [https://perma.cc/GH49-FJQM]

pharmaceutical companies increasingly strategize to prolong exclusivity and preserve pricing power.[2] Meanwhile, the output of genuinely innovative drugs slows,[3] despite the federal government funding a significant portion of the most uncertain and high-risk research.[4] Criticisms of the current drug development process abound, particularly the paying-twice critique, which contends that the public is forced to pay for the same drug twice, first at the outset of development and then again once it is commercialized.[5]

These issues are deeply intertwined with the U.S. patent system, which grants patentees the exclusive right to make, sell, and use approved drugs, thereby enabling private companies to charge monopoly prices.[6] In the pharmaceutical context, the right to exclude is deemed particularly necessary because the drug development process is lengthy and expensive.[7] Creating a drug requires decades of research and millions in funding, not only for the drugs that ultimately succeed, but also for all the failed

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("Drugmakers plan to raise U.S. prices on at least 350 branded medications . . . . The number of price increases for 2026 is up from the same point last year, when drugmakers unveiled plans for raises on more than 250 drugs.").

2. *See* Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. ON LEGIS. 499, 527 (2016) (defining evergreening, the practice of acquiring secondary patents on drugs for minor modifications that offer little therapeutic value but extend patent monopolies nonetheless); *see also* Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 167 (2016) (describing product hops, a practice similar to evergreening that allows companies to preserve pricing power by preventing implementation of generic substitution laws).

3. *See* Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J.L. & BIOSCIENCES 590, 597 (2018) ("78% of the drugs associated with new patents in the FDA's records were not new drugs coming on the market, but existing drugs.").

4. Rita C. Peters, *FDA: Early Stage Drug Development Costs Trigger Higher Drug Costs*, 42 PHARM. TECH. 20 (2018), https://www.pharmtech.com/view/fda-early-stage-drug-development-costs-trigger-higher-drug-costs [https://perma.cc/5CPB-XG39] (discussing how upstream drug development is more costly, uncertain, and prolonged); *see also Drug Development Process Step 1: Discovery and Development*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/patients/learn-about-drug-and-device-approvals/drug-development-process [https://perma.cc/B43P-PSL2] (last visited Mar. 24, 2026) ("At this stage . . . thousands of compounds may be potential candidates for development as a medical treatment."); Ekaterina Galkina Clery et al., *Contribution of NIH Funding to New Drug Approvals 2010-2016*, 115 PROCS. NAT'L ACAD. SCIS. 2329, 2329 (2018) (noting that NIH funding focused on general research rather than the creation of specific drugs).

5. *See* Lorelei Ritchie de Larena, *The Price of Progress: Are Universities Adding to the Cost?*, 43 HOUS. L. REV. 1373, 1383 (2007) (describing the paying-twice critique).

6. *See* 35 U.S.C. § 1; *see also* 35 U.S.C. § 154 ("Every patent shall contain . . . a grant to the patentee . . . the right to exclude others from making, using, offering for sale, or selling the invention . . . .").

7. Feldman, *supra* note 3, at 592 ("The processes of developing new drugs, conducting the clinical trials, obtaining FDA approval, and bringing the drugs to market are extraordinarily expensive.").

variants examined along the way.[8] Thus, at its core, a patent represents a bargain, offering exclusivity and monopoly pricing as quid pro quo for progress.[9] This balancing act is profoundly important, as monopoly pricing comes at the expense of affordability and accessibility of drugs.[10]

Oddly, although the patent system enables and justifies high drug prices based on the enormous investments that research and development ("R&D") requires,[11] the cost of R&D itself for any specific drug is shockingly opaque—even for federal regulators.[12]

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8. *See* CONG. BUDGET OFF., RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 2 (2021), https://www.cbo.gov/publication/57126 [https://perma.cc/Q7A5-P3VH] (stating that R&D estimates include "expenditures on drugs that do not make it past the laboratory-development stage, that enter clinical trials but fail in those trials or are withdrawn by the drugmaker for business reasons, or that are not approved by the FDA").

9. *See* U.S. CONST. art. I, § 8, cl. 8 ("The Congress shall have Power . . . To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries. . . ."); *see also* Kevin J. Hickey & Erin H. Ward, CONG. RSCH. SERV., R46679, THE ROLE OF PATENTS AND REGULATORY EXCLUSIVITIES IN DRUG PRICING 4–5 (2024) (describing the balancing act that is embodied by patents). This notion is also embedded in the jurisprudence of the patent system. *See* Edwards Lifesciences AG v. CoreValve, Inc., 699 F.3d 1305, 1314 (Fed. Cir. 2012) ("A patentee's right to exclude is a fundamental tenet of patent law."); Impression Prods., Inc. v. Lexmark Int'l, Inc., 581 U.S. 360, 362 (2017) ("The Patent Act gives patentees a limited exclusionary power. . . ."); Nichia Corp. v. Everlight Ams., Inc., 855 F.3d 1328, 1341 (Fed. Cir. 2017) ("Patent rights are property rights, and central to those rights is the right to exclude.").

10. "Patent protection affects the price of pharmaceuticals whereby price is a component in determining affordability and therefore access to existing medicines and industry investment in introducing or developing new medicines. A higher price would hinder access, but stimulate the development of new medicines through a higher R&D budget enabling patients to benefit from access to new medicines in the future." Inthira Yamabhai & Richard D. Smith, *A Review of the Health and Economic Implications of Patent Protection, with a Specific Focus on Thailand*, HEALTH & POL'Y RSCH. SYST., 3 (2012); *see also Prescription Drugs*, GEO. UNIV. HEALTH POL'Y INST., https://hpi.georgetown.edu/rxdrugs/ [https://perma.cc/FWE4-J5YW] (last visited May 18, 2026) ("More than 131 million people — 66 percent of all adults in the United States — use prescription drugs."); *see also* Hickey & Ward, *supra* note 9, at 2, 5 ("[S]tudies suggest that IP rights are among the most important factors driving high drug prices." In fact, it is "by design" that "IP rights may lead to increased prices for IP-protected goods or services. IP rights are often said to grant a temporary monopoly to the rights holder.").

11. *See, e.g.*, *Sudden Price Spikes in Decades-Old Prescription Drugs: Inside the Monopoly Business Model, Hearing Before the Special Comm. on Aging*, 114th Cong. 6 (2016) (statement of Howard Dorfman, Former Senior Vice President and General Counsel, Turing Pharmaceuticals) ("Pharmaceutical companies typically justify drug price increases, especially large rises, by expenditures such as [R&D]. . . .").

12. Not for lack of effort, either. For instance, government officials in the General Accounting Office (GAO) attempted to uncover this data through its contracts with private manufacturers. *See* Bowsher v. Merck & Co., 460 U.S. 824, 827–29 (1983) (summarizing litigation efforts of GAO to obtain underlying R&D cost data). In another instance, a different pharmaceutical company refused to hand over R&D expense data even upon congressional prompting. Staff of S. Comm. on Fin., 114th Cong., REPORT ON THE PRICE OF SOVALDI AND ITS IMPACT ON THE U.S. HEALTH CARE SYSTEM 3 (Comm. Print 2015) ("The

Aggregate figures, generalized averages, and the like are ubiquitous,[13] and yet comprehensive accounts of drug-specific R&D data are nowhere to be found.[14]

The inability of policymakers to access this information is alarming because this data is integrally tied to exorbitant drug pricing.[15] The absence of these figures means regulators are incapable of concretely assessing the relationship between R&D, innovation, and pricing regulations.[16] This, in turn, renders

company failed to provide sufficient information to determine how much additional cost it incurred to complete the development, finish the FDA approval process, and bring the drug to market."). Although Congress does have the ability to subpoena such records, it has failed to ever do so—no doubt due in part to the pharmaceutical industry's fervent efforts to ensure as much. *See* Bob Young & Michael Surrusco, *Rx R&D Myths: The Case Against the Drug Industry's R&D "Scare Card"*, PUB. CITIZEN ii (2001), https://www.citizen.org/wp-content/uploads/rdmyths.pdf [https://perma.cc/2QAC-A6AU] ("[I]n 1999-2000[,] the drug industry spent $262 million on federal lobbying, campaign contributions and ads for candidates . . . .").

13. *See generally* Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH & ECON. 20 (2016) (creating a general, average estimate for R&D costs per drug); Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH & ECON. 151 (2003) (same). Similarly, North Dakota, Vermont, Connecticut and Texas state laws, among others, require reports of aggregate company-wide R&D data. *See* H.B. 1032, 67th Leg., Reg. Sess. (N.D. 2021); 18 V.S.A. § 4635 (Vt. 2024); H.B. 5384, 144th Leg., Reg. Sess. (Conn. 2018); H.B. 2536, 86th Leg., Reg. Sess. (Tex. 2019).

14. *See, e.g.*, ARIELLA BAREL & LAUREL BOMAN, ENGELBERG CTR. ON INNOVATION, L. & POL'Y, *Clinical Trial Cost Transparency at the National Institutes of Health: Law and Policy Recommendations* 63 (2020), https://www.nyuengelberg.org/files/Clinical_Trial_Cost_Transparency_at_the_NIH-Law_and_Policy_Recommendations.pdf [https://perma.cc/D2PM-2HPF] (explaining that no existing data publication "currently accomplishes the goal of clinical trial cost transparency"); Frederick M. Abbott, *Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health*, 6 U.C. IRVINE L. REV. 281, 307–08 (2016) ("A major contribution . . . directed toward excessive pricing would be to require the . . . [pharmaceutical] industry to provide concrete data regarding the cost of R&D on individual drugs that are subject to assessment."); Donald W. Light et al., *Estimated Research & Development Costs of Rotavirus Vaccines*, 27 VACCINE 6627, 6632 (2009) (describing how uncovering the cost of R&D is hindered by "several limitations that stem from the undisclosed and closely held costs of developing vaccines"); *infra* Part II.D.1 (describing the limits of academic studies).

15. Hickey & Ward, *supra* note 9, at 2 ("[S]tudies suggest that IP rights are among the most important factors driving high drug prices.").

16. *See* CONG. BUDGET OFF., *supra* note 8, at 4–6 ("The relationship between [R&D spending and new drug approvals] is complex and variable . . . . [Moreover,] increase[s] in drug approvals does not, by itself, indicate the extent to which the new drugs are particularly innovative . . . . Additionally, not all R&D spending is directed toward development of new drugs."); *see also* Jeffrey Cheng et al., *Striking a Balance: Drug Prices, Profits and Incentives for Innovation*, BROOKINGS, https://www.brookings.edu/articles/striking-a-balance-drug-prices-profits-and-incentives-for-innovation/ [https://perma.cc/Q5KY-LQGQ] (last visited May 20, 2026) ("[E]conomists don't really know whether drug prices are too high, making policies aimed at lowering them hard to evaluate from a social welfare perspective . . . . Another key question in thinking about whether drug prices are too high is the extent to which innovation would respond to changes in prices.").

powerful regulatory solutions, such as congressionally mandated reasonable prices, risky and uncertain policy endeavors.[17] The policy challenge is compounded by the pharmaceutical industry's insistence that pricing control invariably chills innovation.[18] Meanwhile, federal agencies continue pouring billions of taxpayer dollars into R&D, with no recognition of such contributions once the drug hits the market.[19]

To address this significant issue, this Note proposes a novel use of an existing mechanism: the Bayh-Dole Act's march-in provision and its embedded fact-finding authority.[20] Although traditionally understood as a safeguard against failures to commercialize federally funded inventions, the march-in framework also equips federal agencies with substantial investigative authority that can be leveraged to obtain comprehensive, drug-specific R&D data.[21] Armed with this data, regulators can finally quantitatively evaluate the forces underlying the persistent issue of high drug pricing, bringing policymakers one step closer to creating an effective and sustainable solution.

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17. *See, e.g.*, WENDY H. SCHACHT, CONG. RSCH. SERV., RL32324, FEDERAL R&D, DRUG DISCOVERY, AND PRICING: INSIGHTS FROM THE NIH-UNIVERSITY-INDUSTRY RELATIONSHIP 16 (2012) (describing how the National Institutes of Health abandoned a reasonable pricing provision in response to significant industry backlash about the uncertainty this would produce).

18. *See, e.g.*, *Why Does the United States Pay, by Far, the Highest Prices in the World for Prescription Drugs?: Hearing Before the Subcomm. on Primary Health and Retirement of the Comm. on Health, Educ., Lab., & Pensions*, 118th Cong. 10, 21 (2024) [hereinafter Congressional Hearing 2024] (statement of Robert M. Davis, Chairman and CEO, Merck & Co., Inc.) ("If we disrupt an ecosystem that incentivizes robust investments in research, we put at risk not only the foundation of American leadership in pharmaceutical development but also the health and lives of countless people who would have benefitted from future discoveries."); *see also* NAM News Room, *J&J: Price Controls, PBMs Problematic*, NAT'L ASSOC. MFRS., https://nam.org/jj-price-controls-pbms- problematic-32150/ [https://perma.cc/QQY7-6RZW] (last visited May 19, 2026) ("Drug price controls will 'chill' critical innovation in pharmaceutical manufacturing and do nothing to address the underlying causes of high medication costs, Johnson & Johnson leaders said recently.").

19. Clery et al., *supra* note 4, at 2329 ("NIH funding contributed to every one of the [new molecular entities] approved from 2010–2016 and was focused primarily on the drug targets rather than on the NMEs themselves."); *Budget*, NAT'L INSTS. OF HEALTH, https://www.nih.gov/about-nih/organization/budget [http://perma.cc/7UZX-KG9G] (last visited May 21, 2026) ("The NIH invests most of its nearly $48 billion budget in medical research for the American people.").

20. *See* 35 U.S.C. § 203(a) (the march-in provision of the Bayh-Dole Act); *see also* 37 C.F.R. § 401.6 (2023) (regulations imbuing federal agencies with fact-finding powers).

21. *See* Amy Schofield, *The Demise of Bayh-Dole Protections Against the Pharmaceutical Industry's Abuses of Government-Funded Inventions*, 32 J.L. MED. & ETHICS 777, 780 (2004) ("[T]he regulations implementing the Act empower NIH to conduct extensive fact-finding.").

I. CRADLE TO MARKET: THE BROAD STROKES OF DRUG DEVELOPMENT

The cost of R&D for specific drugs is one of the most elusive topics in the pharmaceutical field—particularly as incurred by private companies in the late stages of drug development.[22] Astonishingly, even federal regulators lack sufficiently comprehensive access to this information.[23] The difficulty of obtaining drug-specific R&D data stems in part from the complex process of drug development.[24] To this end, Part I clarifies the different processes, statutes, and agencies involved in the creation of a drug. Part I.A briefly reviews the phases of drug development and their interaction with the patent system. Part I.B introduces the Bayh-Dole Act and examines its impact on this process.

A. THE DRUG DEVELOPMENT PROCESS

There are five stages of drug development: (1) discovery and development; (2) preclinical research; (3) clinical research; (4) FDA review; and (5) FDA post-market safety monitoring.[25] Each phase involves different regulatory agencies, expenses, and risks.[26] The patent process functions in tandem and ensures stakeholders

22. *See, e.g.*, Light et al., *supra* note 14, at 6632 (describing how efforts to uncover the cost of R&D are hindered by "several limitations that stem from the undisclosed and closely held costs of developing vaccines"); *see also* Kiu Tay-Teo et al., *Comparison of Sales Income and Research and Development Costs for FDA-Approved Cancer Drugs Sold by Originator Drug Companies*, JAMA NETWORK OPEN, Jan. 4, 2019 (examining R&D costs that notes general unavailability of relevant data); Vinay Prasad & Sham Mailankody, *Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval*, 177 JAMA INTERNAL MED. 1569, 1574 (2017) ("Ultimately, the greatest limitation to our analysis is one shared by all the prior analyses we have discussed: we still lack total R&D transparency.").

23. *See supra* note 12 and accompanying text.

24. *See* Hickey & Ward, *supra* note 9, at 6–28 (describing how various statutes, the FDA, and the U.S. PTO govern together the production of a drug); *see* U.S. FOOD & DRUG ADMIN., *supra* note 4, at 3 (describing the different phases of drug development; at just the clinical trials stage, for instance, phase two and three trials span one to four years).

25. U.S. FOOD & DRUG ADMIN., *supra* note 4; *see also Exploring the Five Phases of Drug Development*, THERMOFISHER SCI. (Oct. 23, 2023), https://www.patheon.com/us/en/insights-resources/blog/drug-development-phases.html [https://perma.cc/6V2M-97PE] ("[A] new drug must make it through five specific phases: 1) discovery and development, 2) preclinical research, 3) clinical research, 4) FDA review, and 5) safety monitoring.").

26. *See* Steven M. Ferguson & Uma S. Kaundinya, *Licensing the Technology: Biotechnology Commercialization Strategies Using University and Federal Labs*, *in* BIOTECH. ENTREPRENEURSHIP 185, 200 (Craig Shimasaki ed., 2020) (describing the various risk levels, expenses, and entities associated with each phase of drug development following federal funding grants for research).

obtain sufficient returns to continue R&D.[27] Part I.A explores these phases for drugs developed at least partially using federal funds, before discussing the implications of the pharmaceutical patents.

At the discovery and development stage, scientists conduct research that is core to the development of nearly all pharmaceuticals, but do so without a particular product in mind.[28] This generality and uncertainty make it one of the most expensive drug development phases.[29] The federal government, specifically the National Institutes of Health (NIH), is the largest funder of this early research, and often offers grants to universities, hospitals, and academic medical centers ("AMCs").[30] These institutions tend to file patents for their most promising drug discoveries near the end of this stage with the U.S. Patent and Trademark Office (USPTO).[31] Some refer to this first stage as the

27. Kevin J. Hickey, CONG. RSCH. SERV., IF12582, PRICING AND MARCH-IN RIGHTS UNDER THE BAYH-DOLE ACT, 3 (2024) (explaining how the patent process intersects with the drug development process and affects pricing).

28. Clery et al., *supra* note 4, at 2329 (noting that NIH funding was focused almost entirely on early stage research, it added that "NIH funding contributed to every one of the NMEs [new molecular entities] approved from 2010–2016 and was focused primarily on the drug targets rather than on the NMEs themselves"); *see also* Ferguson & Kaundinya, *supra* note 26, at 200 ("Most biotechnology products have some history of their R&D that can be traced back to a basic research institution, most often funded by federal grants."); U.S. FOOD & DRUG ADMIN., *supra* note 4 (describing how researchers discover new drugs).

29. Peters, *supra* note 4; *see also* U.S. FOOD & DRUG ADMIN., *supra* note 4 ("At this stage . . . thousands of compounds may be potential candidates for development as a medical treatment."); *see also* Clery et al., *supra* note 4, at 2333 (noting that NIH funding focused on general research rather than the creation of specific drugs).

30. CONG. BUDGET OFF., *supra* note 8 ("The federal government is the primary funder of basic research in biomedical sciences[, which] ultimately increases the supply of new drugs because drug companies rely on the findings from that research. . . ."); *see* Ferguson & Kaundinya, *supra* note 26, at 199–200 (describing how the NIH funds research at universities, hospitals, AMCs, and nonprofits).

31. Notably, as of 2013, inventors must be the first to file an application for their claimed invention to obtain a patent. *See* 35 U.S.C. § 102(a)–(b) (describing the filing requirement). This is why researchers tend to file a patent as early on as possible, typically toward the end of the discovery and development phase. *See* Rebecca S. Eisenberg, *The Role of the FDA in Innovation Policy*, 13 MICH. TELECOMM. & TECH. L. REV. 345, 357 (2007) ("[P]atents on drugs are typically issued in the early stages of product development, before . . . clinical trials. Much (or even all) of the terms of these initial patents may have expired by the time the products are brought to market. . . .").

"upstream" phase of drug development;[32] the "downstream" phase, in turn, refers to stages two through five.[33]

In stage two, these funding recipients typically license or assign their patented discoveries to small businesses or start-ups for preclinical research.[34] The businesses produce crucial safety information for each drug candidate that helps lower the risk of future investment.[35] Then, in stage three, larger pharmaceutical companies sublicense the patent rights, partner with the start-up, or acquire the start-up, taking over the final steps of commercialization, such as clinical trials.[36] These studies are often the most costly aspect of drug development for these companies, as they require examining the effect of drugs on people through clinical trials that can last anywhere from 5 to over 20 years.[37] The

32. *See* Hilde Stevens & Isabelle Huys, *Intellectual Property in Early-Phase Research Public—Private Partnerships in the Biomedical Sector*, *in* THE CAMBRIDGE HANDBOOK OF PUBLIC-PRIVATE PARTNERSHIPS, INTELLECTUAL PROPERTY GOVERNANCE, AND SUSTAINABLE DEVELOPMENT 109–40 (Margaret Chon, Pedro Roffe, & Ahmed Abdel-Latif eds., 2018) (specifying that upstream refers to early stage research, particularly drug development and discovery); *see also* Clery et al., *supra* note 4, at 2330 (distinguishing which phases of drug development are covered by the NIH); Peter Lee, *Toward a Distributive Commons in Patent Law*, WIS. L. REV. 917, 957 (2009) (describing how public funding, as through the NIH, deals primarily with upstream contributions; noting that the distinction between upstream and downstream is not always clear).

33. *See* Clery et al., *supra* note 4, at 2329 (describing how companies handle "applied preclinical research and clinical research, obtaining regulatory approval, and establishing the manufacturing, control, distribution, and marketing"); Lee, *supra* note 32, at 922 n.17 & 943–46 (noting that "downstream" typically refers to activities closer to applied technology).

34. *See* Ferguson & Kaundinya, *supra* note 26, at 205 ("Because the technologies coming from NIH or NIH funded research are most typically preclinical inventions, most licensees are early-stage companies or start-ups rather than larger firms that typically want more proven ideas for new products.").

35. *Id.* (discussing how, in the context of federally funded research, large pharmaceutical companies enter the picture when there is lower risk involved, in the sense that the drug may not be successfully commercialized); *see* U.S. FOOD & DRUG ADMIN., *supra* note 4 ("Before testing a drug in people, researchers must find out whether it has the potential to cause serious harm, also called toxicity."). These studies are smaller, relative to future clinical trials. *Id.*

36. *See* Ferguson & Kaundinya, *supra* note 26, at 205 ("When the licensee can sufficiently 'de-risk' the technology through its various efforts, these companies then sublicense, partner, or get acquired by larger biotech or pharmaceutical firms for the final, most expensive stages of development with the large company expected to sell the product once it reaches the market.").

37. *Id.* at 205–07 (describing clinical trials as the "final, most expensive stages of development" for pharmaceutical companies). For a more in-depth exploration of the different phases of clinical trials, see Stevens & Huys, *supra* note 32, at 109–40 (describing the distinctions between different phases of clinical trials); Dean G. Brown et al., *Clinical Development Times for Innovative Drugs*, 21 NATURE REVS. DRUG DISCOVERY 793, 793 (2022) (explaining that of the 405 drugs reviewed, "[d]evelopment times ranged from under 5 years to over 20").

likelihood that these studies will not lead to a marketable drug is lower at this stage, but more expensive if it does occur.[38] By the time FDA review rolls around in step four, the drug is nearly at the finish line.[39] During this stage, the FDA requires a New Drug Application ("NDA"), composed of all relevant information about the drug, from conception to clinical trials.[40] As the following section explains, the Bayh-Dole Act ("Bayh-Dole") produced this drug development process, fundamentally transforming the pharmaceutical landscape.[41]

B. INTRODUCING THE BAYH-DOLE ACT AND THE MARCH-IN RIGHTS PROVISION

Congress created Bayh-Dole in response to a particularly bleak pharmaceutical landscape: despite substantial federal funding of research at universities, nonprofits, and AMCs,[42] hardly any of the findings were ever commercialized due to strained resources and indecipherable patent policies.[43] Bayh-Dole successfully

38. *See* Ferguson & Kaundinya, *supra* note 26, at 205 (describing how the pharmaceutical company will typically enter the picture after original researchers have sufficiently "de-risked" the product by getting it past pre-clinical trials).

39. *See* U.S. FOOD & DRUG ADMIN., *supra* note 4 (explaining that this is the stage where companies can finally apply for FDA review and then begin dealing with marketing, labeling, etc.); THERMOFISHER SCI., *supra* note 25 ("If the drug is deemed safe and effective for its intended use, the FDA grants approval to manufacture, market, and distribute the drug in the United States.").

40. U.S. FOOD & DRUG ADMIN, *supra* note 4 ("A New Drug Application (NDA) tells the full story of a drug. Its purpose is to demonstrate that a drug is safe and effective for its intended use in the population studied."); *see also* THERMOFISHER SCI., *supra* note 25 (describing how NDAs are created).

41. Jocelyn Ulrich, *Word of the Month: The Bayh-Dole Act*, PHARMA. RSCH. & MFRS. AM. (Nov. 8, 2023), https://phrma.org/blog/word-of-the-month-the-bayh-dole-act [https://perma.cc/8VGH-WAY6] ("[T]he Bayh-Dole Act fundamentally changed how federally funded research gets turned into commercialized products.").

42. COMM. ON POL'YS FOR ALLOCATING HEALTH SCIS. RSCH. FUNDS, FUNDING HEALTH SCIENCES RESEARCH: A STRATEGY TO RESTORE BALANCE 37 (Floyd E. Bloom & Mark A. Randolph eds., 1990) ("The Public Health Service Act of 1944 . . . empowered NIH to support research on diseases other than cancer through extramural grant and fellowship programs," i.e., to non-governmental universities, nonprofits, and labs . . . Congress increased funding for scientific research dramatically between 1945 and 1970, when appropriations for NIH rose from $26 million to $4.8 billion in constant 1988 dollars.").

43. Ulrich, *supra* note 41 ("Prior to its passage, inventions arising from government-funded research often languished in bureaucratic red tape, rarely seeing the light of day."); *see The University and Small Business Patent Procedures Act: Hearings on S.414 Before the S. Judic. Comm.*, 96th Cong. 33 (1979) (statement of Sen. Orrin G. Hatch) ("Twenty-two different funding agencies dispose of patent rights on Government- financed research in 22 different ways. This is evidence that the present policies and procedures are seriously inadequate to meet the continuing and increasing need of stimulating private sector R&D

reconfigured this system by creating a single, uniform policy that offered universities, AMCs, and nonprofits the patent rights to inventions they created using federal funds.[44] Bayh-Dole also clearly sets forth an expectation that the subject invention be commercialized,[45] ideally by a U.S.-based small business.[46] In doing so, the Act unleashed the creative ability of thousands of institutions across the country, causing a dramatic increase in the number of new patents granted over the following decades.[47]

Bayh-Dole allocates rights for federally funded inventions through funding agreements, i.e., any grant, contract, or agreement between a federal agency and a contractor.[48] Contractors in the pharmaceutical context are often universities,

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supplemented by Federal assistance."); *see also* Ryan Whalen, Note, *The Bayh-Dole Act & Public Rights in Federally Funded Inventions: Will the Agencies Ever Go Marching in?*, 109 NW. U. L. REV. 1083, 1088 (2015) (capturing how the pharmaceutical industry also feared that "accepting federally funded R&D contracts potentially endangered background rights to the firms' previously patented inventions"); *see also* Comm. on Assessing the Value of Rsch. in Advancing Nat'l Goals, *Evolution of the U.S. Research Enterprise*, *in* FURTHERING AMERICA'S RESEARCH ENTERPRISE 30 n.4 (Richard F. Celeste, Ann Griswold & Miron L. Straf eds., 2014) ("Prior to the act, most inventions were owned by the federal government, although research performers could and did negotiate with funding agencies for the rights to patent and license federally funded inventions.").

44. Hearings on S. 414, *supra* note 43, at 33 ("The protection mandated by a uniform patent policy is now both appropriate and necessary."); *see* 35 U.S.C. § 200 ("It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development. . . ."); *see* Christine Chasse, Note, *Caps on Capsules: Prescription for Lower Drug Prices in the United States*, 75 FOOD & DRUG L.J. 280, 302–03 (2020) (describing how "the Bayh-Dole Act unlocked all the inventions and discoveries that had been made in laboratories throughout the United States with the help of taxpayers' money") (internal citation omitted).

45. 35 U.S.C. § 200 ("It is the policy and objective of the Congress . . . to promote the commercialization and public availability of inventions made in the United States by United States industry and labor.").

46. *See id.* ("It is the policy and objective of the Congress . . . to encourage maximum participation of small business firms in federally supported research and development efforts."); *see also* 35 U.S.C. § 204 (mandating that small businesses and nonprofits that obtain title to subject inventions may not license or assign said patent "unless such person agrees that any products embodying . . . or produced through the use of the subject invention will be manufactured substantially in the United States").

47. *See* Gabrielle Athanasia, *The Legacy of Bayh-Dole's Success on U.S. Global Competitiveness Today*, CTR. FOR STRATEGIC & INT'L STUDS. (Jan. 12, 2022), https://www.csis.org/blogs/perspectives-innovation/legacy-bayh-doles-success-us-global-competitiveness-today [https://perma.cc/DY5J-WD4Y] ("Since it was enacted in 1980, the Act has led to over $1.3 trillion in U.S. economic growth, created more than 4.2 million jobs across the country, and contributed to the success of over 11,000 new startup companies from universities throughout America.").

48. 35 U.S.C. § 201(b) (defining funding agreement as "any contract, grant, or cooperative agreement entered into between any Federal agency . . . and any contractor").

nonprofits, and AMCs.[49] Any invention that a contractor first thinks of or creates while working on a project sponsored by a funding agreement constitutes a "subject invention."[50] This definition materially narrows what is within Bayh-Dole's statutory reach.[51] For instance, imagine a start-up conducts preclinical research on a subject invention, and, in the process, discovers and develops a distinct but related drug. Although this downstream discovery also stems from federally funded research, Bayh-Dole obligations do not apply because the start-up is not sponsored by a funding agreement.[52]

Nonetheless, for discoveries that are covered by Bayh-Dole, the policy and objective of the Act expressly promote and expect commercialization,[53] ideally by a U.S.-based small business.[54] The Act's reporting requirements for contractors reinforce this mandate, enabling the agency administering the funding agreements (the "funding agency") to ensure that contractors fulfill

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49. 35 U.S.C. § 201(c) (defining contractor as "any person, small business firm, or nonprofit organization that is a party to a funding agreement"); *see* Ferguson & Kaundinya, *supra* note 26, at 199–200 (describing how AMCs, universities, and nonprofits frequently receive federal funds for research).

50. 35 U.S.C. § 201(e) (defining subject invention as "any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement").

51. *See id.* (defining subject invention); *see also March-in Rights - Implications from the COVID Pandemic*, BAKER BOTTS, https://www.bakerbotts.com/thought-leadership/publications/2022/october/march-in-rights-implications-from-the-covid-pandemic [https://perma.cc/SY4H-YPUR] (last visited May 18, 2026) ("March-in rights contain a further gatekeeping mechanism that must apply before the rights can even be considered: 'subject inventions.'").

52. *See* Ferguson & Kaundinya, *supra* note 26, at 213 (explaining that entities attempting to commercialize federally funded research via licensing agreements "do not require bioentrepreneurs to cross-license existing rights they may own, give up any product marketing rights, nor forsake any downstream developmental rights"); *see Creating a Utilization Report*, NAT'L INST. OF STANDARDS & TECH., https://www.nist.gov/iedison/iedison-organization-user-guide/utilization-reports/creating-utilization-report [https://perma.cc/25QR-Y59Q] (last visited May 14, 2026) (describing questions included in the reports such as identifying information of assignees and licensees of the subject invention's patents); *see also* Ferguson & Kaundinya, *supra* note 26, at 213 ("IP derived from new discoveries made with NIH-licensed tools will remain clear and unencumbered.").

53. 35 U.S.C. § 200 ("It is the policy and objective of the Congress . . . to promote the commercialization and public availability of inventions made in the United States by United States industry and labor.").

54. *See id.* ("It is the policy and objective of the Congress . . . to encourage maximum participation of small business firms in federally supported research and development efforts."); *see also* 35 U.S.C. § 204 (mandating that small businesses and nonprofits that obtain title to subject inventions may not license or assign said patent "unless such person agrees that any products embodying . . . or produced through the use of the subject invention will be manufactured substantially in the United States").

their Bayh-Dole obligations.[55] These include filing an invention report with the funding agency any time they create a subject invention;[56] timely filing a patent application with a "government interest statement" that acknowledges government funding;[57] and submitting a separate patent report to the funding agency.[58]

Even after the subject invention is transferred from start-ups to larger pharmaceutical companies for the remaining development,[59] the original contractors are still responsible for

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55. *See* 35 U.S.C. § 202 (describing the various kinds of information that must be reported to the funding agency).

56. *See Invention Reports*, NAT'L INST. OF STANDARDS & TECH., https://www.nist.gov/iedison/iedison-organization-user-guide/invention-reports [https://perma.cc/YXD8-FL8A] (last visited May 18, 2026) (explaining that subject inventions must be reported to the funding agency); *see also* 37 C.F.R. § 401.14(c)(1) (2018) ("The contractor will disclose each subject invention to the Federal agency within two months after the inventor discloses it in writing to contractor personnel responsible for patent matters."); 35 U.S.C. § 202(c)(1) (requiring every funding agreement to include a clause that states "the contractor disclose each subject invention to the Federal agency within a reasonable time after it becomes known to contractor personnel responsible for the administration of patent matters, and that the Federal Government may receive title to any subject invention not disclosed to it within such time").

57. *See* 35 U.S.C. § 202(c)(2) (requiring every funding agreement to include a clause that states "the contractor [will] make a written election within two years after disclosure to the Federal agency . . . whether the contractor will retain title to a subject invention"); 35 U.S.C. § 202(c)(3) (requiring every funding agreement to include a clause that states the "contractor electing rights in a subject invention agrees to file a patent application prior to the expiration of the 1-year period referred to in section 102(b)"); 35 U.S.C. § 202(c)(6) (requiring every funding agreement to include a clause that states "[a]n obligation on the part of the contractor . . . to include within the specification of such [patent] application and any patent issuing thereon, a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention").

58. *See* 37 C.F.R. § 401.14(c)(2) (2018) ("The contractor will elect in writing whether or not to retain title to any such invention by notifying the Federal agency within two years of disclosure to the Federal agency."); *see also Invention Reports*, NAT'L INST. OF STANDARDS & TECH., *supra* note 56 (explaining how to file a patent report); *see also* NIH Grants Policy Statement, NAT'L INSTS. OF HEALTH, https://grants.nih.gov/grants/policy/nihgps/html5/section_8/8.2.4_inventions_and_patents.htm, [https://perma.cc/4HPS-VL2J] (last visited May 18, 2026) ("The [grant] recipient must inform NIH of the filing date of its Initial Patent Application, the Initial Patent Application number and title and all subsequently filed patent applications."). Both the invention and patent report present a second requirement to disclose a new invention, separate from the government interest statement. *See id.* (indicating that funding agencies must be notified about patent applications, in addition to the USPTO).

59. This usually involves the licensing or assignment of the patent to the larger companies. There are special restrictions involved in assigning a patent, particularly if the contractor is a nonprofit. For more information, see 35 U.S.C. § 202(c)(7)(A). Additionally, it may be worth noting that this transaction, whether assignment or licensing, is usually led by the contractor's Technology Transfer Office. *See* Ferguson & Kaundinya, *supra* note 26, at 201 (explaining how technology transfer offices facilitate contracts between these organizations and private companies); *see also id.* at 205–06 (explaining that start-ups usually handle preclinical research while larger corporations handle the rest). The specifics of the transaction between the contractor and the start-up or the start-up and the large

ensuring the subject inventions are eventually commercialized.[60] This entails filing annual utilization reports that detail "any products made through the use of or embodying the subject invention," including the information of any licensees and manufacturers and their plans for bringing these products to market.[61] These reports are collected in iEdison, an online platform managed by the National Institute of Standards and Technology (NIST), which federal regulators can use to ensure federally-funded inventions are commercialized.[62]

As a final failsafe to enforce commercialization, Bayh-Dole also created march-in rights, which gave funding agencies the authority to require the patent holder grant a license to any responsible applicant.[63] If the patent holder refuses to do so, the federal government can grant licenses itself.[64] This extraordinary

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corporation can vary greatly, even within the realm of just licensing agreements. *Id.* at 208–11 (describing the different types of licensing agreements possible and their individual components).

60. *See* 37 C.F.R. § 401.14(h) (2018) ("The Contractor agrees to submit on request periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining such utilization that are being made by the contractor or its licensees or assignees.").

61. *Creating a Utilization Report*, NAT'L INST. OF STANDARDS & TECH., *supra* note 52.

62. *iEdison Organization User Guide*, NAT'L INST. OF STANDARDS & TECH., https://www.nist.gov/iedison/iedison-organization-user-guide [https://perma.cc/U8LX-YXM6] (last visited May 18, 2026) ("iEdison allows contractors, grantees, and other recipients of federal funding to comply with the reporting requirements of the Bayh-Dole Act.").

63. 35 U.S.C. § 203(a). The term "responsible applicant" is not defined anywhere in the statute, the implementing regulations, or any court decision. The best available guidance likely comes from the analogous federal procurement law concept of a "responsible" contractor or bidder, where courts and regulations have developed a multi-factor, agency-centered framework. *See* 48 C.F.R. § 9.104-1 (2019) (explaining the framework of criteria for determining that a contractor is "responsible"). The march-in provision is the end result of a looming fear that had pervaded the drafting of Bayh-Dole: a future in which the Act succeeded in facilitating the commercialization of federally funded research but without ensuring that the resulting inventions are meaningfully accessible to the public. *See The University and Small Business Patent Procedures Act: Hearings on S. 414 Before the Comm. on the Judiciary*, 96th Cong. 245 (1979) (statement of Howard Rose) (describing the principle of march-in rights as "insur[ing] that patents created in this manner are ultimately converted to a product or system for the benefit of the general public"); *see also id.* at 28 (statement of Sen. Bob Dole) ("When large amounts of taxpayers' money are directed to the research field, the public expects and deserves to reap the benefit of its investment in the form of products available for its consumption. When this fails to materialize, it is obvious that the Government has reneged on its promise."). Legislators designed the march-in provision in response to this concern, hoping to provide a last-resort source of protection to avoid a multi-billion dollar "give away." *Id.* at 227 (statement of Eric P. Schellin) (noting that opponents of the Bill have characterized it as "a vast giveaway").

64. 35 U.S.C. § 203(a) ("[T]he Federal agency under whose funding agreement the subject invention was made shall have the right . . . to require the contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or

violation of the typically sacrosanct American patent rights[65] is allowed in only four scenarios: (1) if the patent holder has not taken "effective steps to achieve practical application" within a "reasonable" amount of time;[66] (2) if there are "health or safety needs which are not reasonably satisfied" by the patent holder;[67] (3) if the patent holder has not "reasonably satisfied" federally mandated "requirements for public use";[68] or (4) if the patent holder fails to ensure that the products derived from the patent are substantially produced in the United States.[69] Thus, if somewhere downstream, a private company acquired a federally funded pharmaceutical but failed to make it publicly available, the government would be able to empower a different company to do so.

NIST has promulgated procedural regulations for marching-in, including informational requests and a hearing process.[70] Both

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exclusive license . . . and if the contractor, assignee, or exclusive licensee refuses such request, to grant such a license itself. . . .").

65. *See, e.g.*, Florida Prepaid Post-Secondary Educ. Expense Bd. v. Coll. Sav. Bank, 527 U.S. 627, 642 (1999) (explaining that patents constitute property and are shielded by due process); *see also* Oil States Energy Servs. v. Greene's Energy Grp., 584 U.S. 325, 344 (2018) (reaffirming that patent rights constitute property for the purposes of Due Process clause protection); Celgene Corp. v. Peter, 931 F.3d 1342, 1358 (Fed. Cir. 2019) (explaining that the Takings Clause also protects patents); Microsoft v. i4i Ltd., 564 U.S. 91, 111 (2011) (stating that the invalidity of patents must be demonstrated by clear and convincing evidence, the most strenuous civil standard of proof).

66. 35 U.S.C. § 203(a)(1).

67. 35 U.S.C. § 203(a)(2). What such health or safety needs might be remains unknown, as no agency or court has ever defined the phrase.

68. 35 U.S.C. § 203(a)(3). Oddly, although that statute states that these public use requirements will be specified by federal regulations, no agency has ever promulgated any such substantive regulations. *See* 37 C.F.R. § 401.14 and 401.16 (2018) (offering the only regulations that flesh out march-in rights).

69. 35 U.S.C. § 203(a)(4); *see also* 35 U.S.C. § 204 (mandating that anyone granted a patent or license through Bayh-Dole must agree that any products created through the patent "will be manufactured substantially in the United States[,]" though "the requirement . . . may be waived" under certain circumstances).

70. When an agency receives information that it believes would warrant exercising march-in rights, it may then informally consult with the contractor and request any information that it deems relevant. 37 C.F.R. § 401.6(a)(1) (2023). Assuming the agency decides to proceed, it must provide written notice to the contractor, who then has thirty days to provide any information or argument it wants in opposition to the march-in proceeding. 37 C.F.R. § 401.6(a)(1) (2023); *see also* 37 C.F.R. § 401.6(a)(3) (2023) ("Within 30 days after the receipt of the written notice of march-in, the contractor (assignee or exclusive licensee) may submit . . . information or argument in opposition to the proposed march-in."). The regulations also specify when the funding agency must provide notice to the contractor, what details must be included in the notice, whether the notice must be written, and timing for when it must be sent. 37 C.F.R. § 401.6(a)(1) (2023) (requiring agency to inform the contractor whether it will initiate a march-in proceeding within 120 days of the consultation); 37 C.F.R. § 401.6(a)(2) (2023) (explaining that if the head of the agency, or

empower funding agencies with investigative authority to ensure contractors have met their Bayh-Dole obligations.[71] Viewed in its entirety, the march-in rights provision speaks to a broader, essential principle: as a major sponsor of R&D, the public has a heightened stake in accessing inventions produced using public funds. Part II is dedicated to examining how R&D data can ultimately affect drug pricing.

II. THE NECESSITY AND LACK OF COMPREHENSIVE R&D DATA

The unavailability of end-to-end R&D data undermines regulatory efforts to address high drug prices while allowing one of the industry's most effective arguments to go largely unchallenged.[72] Part II demonstrates that generalized or company-wide estimates of R&D spending offer only limited utility in addressing this issue; drug-specific data is essential, particularly for already-commercialized drugs marked by severe unaffordability.[73] This information is crucial both to develop meaningful benchmarks for reasonable pharmaceutical pricing

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their designee, decides to initiate a march-in proceeding, they must provide written notice to the contractor, including the reasons for the proposed march-in, the field(s) of use that the agency is considering requiring licensing in, and all of the contractor's rights). If the contractor's information raises a genuine dispute over material facts, a "fact-finding" hearing begins, during which the contractor can again submit any facts, evidence, or testimony desired. 37 C.F.R. § 401.6(a)(3) (2023). Note that neither the Bayh-Dole Act nor its related regulations defines the phrase "field of use." Case law, however, has provided a useful definition: "Terms that limit a licensee's use of the licensed intellectual property to certain industries, markets, or products are referred to as 'field-of-use' restrictions." Medinol Ltd. v. Guidant Corp., 500 F. Supp. 2d 345, 348 n.14 (S.D.N.Y. 2007).

71. *See* Schofield, *supra* note 21, at 780 ("[T]he regulations implementing the Act empower NIH to conduct extensive fact-finding.").

72. As used in this Note, R&D expense data and the like refers to the total cost of bringing a drug to market, from early-stage research all the way to FDA approval.

73. *See* Olivier J. Wouters et al., *Association of Research and Development Investments with Treatment Costs for New Drugs Approved from 2009 to 2018*, JAMA NETWORK OPEN, Sep. 26, 2022, at 8 ("Drug companies should make further [R&D] data available to support their claims that high drug prices are needed to recover research and development investments, if they are to continue to use this argument to justify high prices."); *see also* Abbott, *supra* note 14, at 305 ("The cost of researching and developing originator pharmaceutical products is deliberately shrouded in mystery."). Cost-price methodology is especially useful for already commercialized drugs because people are already struggling to afford them. *See, e.g.*, *Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin, Hearing Before the H. Subcomm. Oversight and Investigations of the H. Comm. on Energy and Commerce*, 116th Cong. 58 (2019) (statement of Thomas Moriarty, Executive Vice President, Chief Policy and External Affairs Officer and General Counsel, CVS Health) [hereinafter *Priced Out Hearing*, Moriarty Statement] ("Over the last several years, list prices for insulin have increased nearly 50 percent. And over the last 10 years, the list price of one product, Lantus, rose by 184 percent.").

and to determine how the burdens of innovation were actually allocated among the various public and private actors involved in a drug's development.[74] The relevant underlying data already exists.[75] The real hurdle is obtaining access to it.[76]

Part II.A explains that the absence of drug-specific R&D expense data weakens potential regulatory mechanisms for addressing exorbitant drug pricing. Part II.B outlines how the pharmaceutical industry has leveraged the opacity of this data to hinder regulators by stirring up fears of adversely impacting innovation.[77] Having established the significance of R&D cost

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74. *See* Abbott, *supra* note 14, at 303 ("[T]he logical starting point for determining whether the price of a product is unfair is the manufacturer's cost of making the product."); *see also* CONG. BUDGET OFF., *supra* note 8 ("The relationship between [R&D spending and new drug approvals] is complex and variable . . . . [Moreover,] increase[s] in drug approvals does not, by itself, indicate the extent to which the new drugs are particularly innovative . . . . Additionally, not all R&D spending is directed toward development of new drugs."); *see also infra* Part III.B (explaining how the relative contributions of varying organizations in the drug development process is unverified).

75. At least two studies demonstrate that this information both exists and can be organized into clear accounts of R&D expenses because both studies have collected R&D data through anonymous surveys to pharmaceutical companies. *See* DiMasi et al. (2016), *supra* note 13, at 22–23; DiMasi et al. (2003), *supra* note 13, at 156–58.

76. *See* Abbott, *supra* note 14, at 307 ("A major contribution . . . directed toward excessive pricing would be to require the . . . [pharmaceutical] industry to provide concrete data regarding the cost of R&D on individual drugs that are subject to assessment."); Light et al., *supra* note 14, at 6632 ("[N]one of the cost estimates can be verified . . . suggest[ing] caution in accepting company claims of high R&D costs, unless those claims are backed by independently verified data."); Prasad & Mailankody, *supra* note 22, at 1574 ("[A]lthough we used SEC filings, which are subject to strict guidelines and regulation, it is possible that some companies overemphasized or underemphasized R&D costs through unintentional errors. Without access to primary company data, we cannot be sure."); Tay-Teo et al., *supra* note 22, at 8 ("First . . . [our analysis] is limited by the availability and accuracy of data presented in the companies' annual reports.").

77. *See, e.g.*, *Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin, Hearing Before the H. Subcomm. Oversight and Investigations of the H. Comm. on Energy and Commerce*, 116th Cong. 3 (2019) (written statement of Douglas J. Langa, Executive Vice President, North America Operations, and President of Novo Nordisk Inc.) [hereinafter *Priced Out Hearing*, Langa Written Statement] ("The innovative medicines and delivery systems we produce are the result of significant and ongoing investment in research and development."); *Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin, Hearing Before the H. Subcomm. Oversight and Investigations of the H. Comm. on Energy and Commerce*, 116th Cong. 5 (2019) (written statement of Michael B. Mason, Senior Vice President, Eli Lilly & Co.) [hereinafter *Priced Out Hearing*, Mason Written Statement] ("[P]harmaceutical companies raised list prices to . . . ensure that they are able to continue to fund lifesaving research and development."); *Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin, Hearing Before the H. Subcomm. Oversight and Investigations of the H. Comm. on Energy and Commerce*, 116th Cong. 107 (2019) (statement of Kathleen Tregoning, Executive Vice President for External Affairs, Sanofi) [hereinafter *Priced Out Hearing*, Tregoning Statement] (replying to the question "Does the price of insulin help offset the cost of research," answering that

data, Part II.C examines where along the drug development pipeline this information is available or obscured. Finally, Part II.D reveals how current efforts or tools to critically assess R&D data are insufficient.

A. COST-PRICE METHODOLOGY AND REGULATORY SOLUTIONS TO HIGH DRUG PRICES

The inability of regulators to access granular R&D expense data effectively removes from their toolkit a powerful avenue for dealing with high drug prices: the use of cost-price methodology. This, in turn, weakens other regulatory mechanisms for dealing with high drug prices, such as setting reasonable pricing benchmarks. Cost-price methodology is an effective analytical device for developing a factually informed baseline for reasonable drug pricing.[78] It involves contrasting the price of a drug with the cost of developing it, allowing regulators to decide for themselves what level of disparity is too high to be reasonable or too low to continue incentivizing innovation.[79] This is not to suggest that such a formula would be in any way simple nor even that a perfect balance exists, but rather that in cases of extraordinarily high drug prices, concrete and quantitative assessments of the disparities involved could be enough to encourage congressional action.[80]

"Revenues from all of our business, in part, go back to fund research and development across all areas.").

78. Abbott, *supra* note 14, at 302–03 (describing cost-price methodology); *see also* Evert A. Manders et al., *Drug Pricing Models, No 'One-Size-Fits-All' Approach: A Systematic Review and Critical Evaluation of Pricing Models in an Evolving Pharmaceutical Landscape*, 4 EUR. J. HEALTH & ECON. 683, 687 (2025) (providing a broad overview of different pricing models, including cost-based pricing and acknowledging that use of cost-based pricing is inhibited by the lack of granular R&D expense data). It is worth noting that pharmaceutical companies tend to prefer value-based pricing, which would focus on the preventative benefits of a medication. *See* Abbott, *supra* note 14, at 304 ("Therefore, in 'value' terms based on alternatives, even a high-priced medicine may be a 'bargain.'"); *see also, e.g.*, Staff of S. Comm. on Fin., *supra* note 12, at 45 (explaining how Gilead set drug prices based on the value of the drug because "[h]ealthcare reform has incentives to pay for value, which aligns with what sofosbuvir will deliver (even if it is not the least expensive agent)"). The issue with value-based pricing is that it is "essentially a hostage bargaining model," allowing companies to justify extremely high prices for any life-saving pharmaceutical. *See* Abbott, *supra* note 14, at 304.

79. *See* Abbott, *supra* note 14, at 302 ("[T]he logical starting point for determining whether the price of a product is unfair is the manufacturer's cost of making the product.").

80. "[T]he point is that in cases where pharmaceutical pricing is 'stratospheric,' a judge or jury may not need a finely tuned methodology for determining when a price is unfairly excessive. Taking advantage of the public by charging prices that far exceed what is reasonable is excessive." *Id.* at 317; *see, e.g.*, Light et al., *supra* note 14, at 6628–29

Moreover, obtaining drug-specific R&D costs could be a crucial first step toward one day creating a formula that balances affordability with the need to facilitate innovation.

There are other ways of determining a reasonable drug price, for instance by considering the price of the same drugs in other countries, or "reference pricing."[81] The Biden administration adopted this approach when it included a reasonable pricing provision in a contract for the development of future COVID-19 vaccines.[82] However, regulators may find that even the lowest price offered among nations is unreasonably high if analyzed with sufficient R&D data.[83] In addition, this method introduces a perverse incentive to price drugs as expensively as possible around the world.[84] A similar problem also plagues strategies that only invoke pricing regulation when drug prices exceed a certain threshold, again encouraging companies to price as expensively as possible, as soon as possible.[85] Cost-price analyses based on

(describing the different costs involved within the four phases of clinical trials alone, a useful illustration of the complexities of calculating R&D costs).

81. *See* Manders et al., *supra* note 78, at 686–91 (providing a broad overview of different pricing models); *see also* Nikhil Chaudhry & Reshma Ramachandran, *Reasonable Pricing Clauses: A First Step Toward Ensuring Taxpayers a Fair Return on Their Public R&D Investment*, PETRIE FLOM CTR. (Sep. 28, 2023), https://petrieflom.law.harvard.edu/2023/09/28/reasonable-pricing-clauses-a-first-step-toward-ensuring-taxpayers-a-fair-return-on-their-public-rd-investment/ [https://perma.cc/2KS8-GA96] (explaining reference pricing in the context of a Regeneron contract, which "us[ed] a 'Most Favored Nation' clause" to ensure that the prices of [the pharmaceuticals] would not exceed the price charged in other G7 countries); *see also* Abbott, *supra* note 14, at 303 n.18 (also defining reference pricing).

82. *See* Chaudhry & Ramachandran, *supra* note 81 ("[T]he Department of Health and Human Services announced . . . that it had successfully included a reasonable pricing provision in a $326M investment contract with Regeneron for development of a next generation monoclonal antibody therapy for COVID-19.").

83. *See* Abbott, *supra* note 14, at 305 (discussing why reference pricing "is not preferable to the cost versus price approach. It is entirely possible that the lowest baseline price (or the average) among a basket of markets is excessive, not least in the case of originator pharmaceutical products").

84. Jaime Espi et al., *WHO/HAI Project on Medicine Prices and Availability* (World Health Org., Working Paper No. 1, 2011), at 13 ("[I]t seems logical to conclude that one consequence of ERP [external reference pricing] is that it puts pressure on countries that are selected by others as a reference country to keep prices high, especially if they want an early market entry of new products.").

85. *See* Juliette Cubanski et al., *Explaining the Prescription Drug Provisions in the Inflation Reduction Act*, KFF, https://www.kff.org/medicare/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act/ [https://perma.cc/CK97-SC4M] (last visited May 19, 2026) ("Drug manufacturers may respond to the inflation rebates by increasing launch prices for drugs that come to market in the future."); *see also* Loren Adler, *Understanding the Bipartisan Senate Finance Prescription Drug Reform Package*, BROOKINGS INST., https://www.brookings.edu/articles/understanding-the-bipartisan-senate-finance-prescription-drug-reform-package/ [https://perma.cc/R4ZV-NJYJ] (last visited May 19, 2026) ("Knowing that they will be unable to increase a drug's list price faster

concrete R&D data per drug would avoid these issues while retaining the benefits of a reasonable price provision.[86]

Government regulators have attempted to create reasonable pricing requirements in the past.[87] In 1989, the NIH included a fair pricing condition in its R&D contracts with private manufacturers, defined as a price within the range of existing therapies.[88] The agency abandoned the clause within a decade in response to severe industry backlash, largely driven by the uncertainty of the pricing condition.[89] This outcome was not inevitable. Access to concrete R&D cost data and reliance on a cost-price methodology could have transformed the pricing condition from an indeterminate standard into a more administrable, evidence-based constraint.[90] Such grounding would have limited the clause's perceived breadth and weakened claims that it posed an unacceptable risk to industry participation.[91]

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than inflation, manufacturers will be incentivized to launch at a higher price than they otherwise would have.").

86. *See* Abbott, *supra* note 14, at 305 ("[C]ost-price methodology . . . is the most direct methodology for determining the profit of the supplier and therefore the most reasonable way to determine whether the price is higher than it should be.").

87. *See, e.g.*, SCHACHT, *supra* note 17, at 15–17 (describing a previous NIH attempt to include a fair pricing condition in contracts); *see also* Chaudhry & Ramachandran, *supra* note 81 (describing another recent instance of federal agencies including reasonable pricing clauses in contracts for drug development and manufacturing).

88. *See, e.g.*, SCHACHT, *supra* note 17, at 16 ("NIH reportedly was reluctant to make definitive decisions on pricing. At that time, reasonable pricing was defined as a price within the range of existing therapies.").

89. *Id.* ("Opponents of the clause argued that the uncertainty of the pricing clause exacerbated a process already fraught with risk."). Notably, the agency's change of heart was fueled by a concern that the industry would *perceive* the condition to be a barrier, rather than an actual decrease in collaboration. *See* Chaudhry & Ramachandran, *supra* note 81 (explaining that, although the number of agreements with the private sector were lower while the pricing clause was present, "this rebound effect was likely due to other confounding factors").

90. Other federal entities create such standards based on reasonableness across a wide variety of fields. *See, e.g.*, Petro Star Inc. v. Fed. Energy Regul. Comm'n, 166 F.4th 161, 171 (Fed. Cir. 2026) (describing how the Commissioner of the Federal Energy Regulatory Commission must set reasonable rates over the interstate transmission and wholesale sale of electric energy and natural gas, subject to back-end judicial scrutiny); *see also* Sw. Bell Tel. Co. v. F.C.C., 168 F.3d 1344, 1352 (D.C. Cir. 1999) (explaining how the Federal Communications Commission has broad discretion to charge just, reasonable, and non-discriminatory rates for interstate services).

91. "According to industry sources, not knowing what the determination of 'fair' pricing would be at the end of a long and expensive research, development, and commercialization process was a strong deterrent to entering into cooperative arrangements." SCHACHT, *supra* note 17, at 16. Granular R&D data, by enabling creation of a factually grounded baseline for reasonable pricing, could thus help regulators develop transparent, effective benchmarks for pricing, articulated prior to the inclusion of a reasonable pricing clause.

B. R&D'S DUAL ROLE IN INDUSTRY FRAMING AND REGULATORY RESPONSE

The pharmaceutical industry capitalizes on the lack of individualized R&D cost data in two separate but intertwined ways, leveraging fears of chilling innovation to ward off pricing regulation.[92] First, pharmaceutical companies often insist that exorbitant prices should be chalked up to their vast investments in R&D.[93] This assertion has been picked apart in congressional hearings and multiple studies.[94] Even assuming revenues must exceed R&D costs to sustain the industry, the enormous distance between expenditures and pricing suggests a far weaker link between the two than pharmaceutical companies claim.[95] The disparity between R&D expenditures and the amount spent on

92. *See Sudden Price Spikes in Decades-Old Prescription Drugs: Inside the Monopoly Business Model, Hearing Before the Special Comm. on Aging*, 114th Cong. 6 (2016) (statement of Howard Dorfman, Former Senior Vice President and General Counsel, Turing Pharmaceuticals) ("Pharmaceutical companies typically justify drug price increases, especially large rises, by expenditures such as research and development of the drug itself or a substitute, clinical trial work, or educational programs."); *see also* Nancy L. Yu et al., *R+D Costs for Pharmaceutical Companies Do Not Explain Elevated US Drug Prices*, HEALTH AFFS. (Mar. 7, 2017), https://www.healthaffairs.org/content/forefront/r-d-costs-pharmaceutical-companies-do-not-explain-elevated-us-drug-prices [https://perma.cc/RMV8-RGRE] ("[T]he pharmaceutical industry often explains that the higher prices they charge in the US provide them with the funds they need to conduct their high-risk research."). *Cf.* Jennifer L. Graber, Note, *Excessive Pricing of off-Patent Pharmaceuticals: Hatch It or Ratchet*, 92 N.Y.U. L. REV. 1146, 1152–53 (2017) ("Companies under scrutiny often justify ratcheting the prices of their drugs, claiming that they need to increase pharmaceutical prices to pay for research, development, and manufacturing costs.").

93. *See, e.g.*, *Priced Out Hearing*, Langa Written Statement, *supra* note 77, at 3 ("The innovative medicines and delivery systems we produce are the result of significant and ongoing investment in research and development."); *Priced Out Hearing*, Mason Written Statement, *supra* note 77, at 5 ("[P]harmaceutical companies raised list prices to . . . ensure that they are able to continue to fund lifesaving research and development."); *Priced Out Hearing*, Tregoning Statement, *supra* note 77, at 107 (replying to the question "[d]oes the price of insulin help offset the cost of research for future drugs?" that "[r]evenues from all of our business, in part, go back to fund research and development across all areas").

94. *Drug Pricing in America: A Prescription for Change, Part I: Hearing Before the Comm. on Fin.*, 116th Cong. 4, 20 (2019) [hereinafter Drug Pricing Congressional Hearing 2019] ("We found that typically a pharmaceutical corporation captured 1.7 times their global research and development spending from charging higher prices to U.S. patients, taxpayers, and insurers."); Light et al., *supra* note 14, at 6632 ("Based on reports from senior investigators and independent evidence, we have assembled evidence that R&D costs to the companies for rotavirus vaccines were much lower than commonly-touted average costs, even though the Phase III trials were much larger than usual.").

95. *See* Yu et al., *supra* note 92 ("To put the excess revenue in perspective, lowering the magnitude of the US premium to a level where it matches global R&D expenditures . . . would have saved US patients, businesses, and taxpayers approximately $40 billion in 2015, a year for which the Centers for Medicare and Medicaid Services (CMS) reported that total US spending on pharmaceuticals was $325 billion.").

self-enriching behaviors suggests a different explanation for high prices.[96] As an example, from just 2012 to 2021, "Johnson & Johnson spent $43 billion more on stock buybacks and dividends than research and development."[97] Simultaneously, drug prices have increased annually despite decreasing R&D expenses following FDA approval.[98] Observers have thus concluded that these high prices reflect the maximum that someone will pay when they have no other choice—not the cost of R&D.[99]

Second, the pharmaceutical industry claims that pricing controls will chill innovation by undermining the recovery of R&D costs, thereby disincentivizing future research.[100] This argument has been remarkably successful in warding off pricing regulation.[101] The immense cost and duration of clinical trials,

96. *See* Jishian Ravinthiran, *Profits Over Patients: Spending on Self-Enrichment Exceeds Research and Development Costs for Many Manufacturers of IRA Drugs*, PUB. CITIZEN (Jan. 18, 2024), https://www.citizen.org/article/profits-over-patients/ [https://perma.cc/7LXH-X66F] ("[T]hese corporations' own expenditures on self-enriching activities, including stock buybacks, dividends to shareholders, and executive compensation . . . far exceed their investments in innovation."); *see also* Congressional Hearing 2024, *supra* note 18, at 86–87 (noting that from just 2012 to 2021, "Johnson & Johnson spent $43 billion more on stock buybacks and dividends than research and development," while Merck & Co.'s spending on the same "exceeded its research and development costs by $3 billion").

97. Congressional Hearing 2024, *supra* note 18, at 80–85.

98. *See* Drug Pricing Congressional Hearing 2019, *supra* note 94, at 19 ("Once a drug has been approved by the FDA, there is minimal additional research and development costs so drug companies cannot justify price increases by claiming research and development costs." (citation omitted)); *see also* U.S. FOOD & DRUG ADMIN., *supra* note 4 (providing a detailed explanation of post-FDA approval procedures that could incur additional costs).

99. Congressional Hearing 2024, *supra* note 18, at 85–86 (concluding that drug pricing represents "the maximum that companies believe healthcare payers will pay for monopolized drugs with few if any adequate therapeutic alternatives").

100. *See, e.g.*, Congressional Hearing 2024, *supra* note 18, at 21 (statement of Robert M. Davis, Chairman and CEO, Merck & Co., Inc.) ("If we disrupt an ecosystem that incentivizes robust investments in research, we put at risk not only the foundation of American leadership in pharmaceutical development but also the health and lives of countless people who would have benefitted from future discoveries."); *see also* NAM News Room, *supra* note 18 ("Drug price controls will 'chill' critical innovation in pharmaceutical manufacturing and do nothing to address the underlying causes of high medication costs, Johnson & Johnson leaders said recently.").

101. This is illustrated by its repeated invocation through decades of policy debates. *See, e.g.*, *Comparative Pricing of Prescription Drugs Sold in the United States and Canada and the Effects on U.S. Customers, Hearing Before the S. Subcomm. on Com., Sci., and Transp.*, 107th Cong. 25 (2001) ("[P]harmaceutical companies claim the prices of new drugs are necessary to fund ongoing research and development."); *see also Hearings on International Enforcement of Intellectual Property Rights and American Competitiveness Before the S. Comm. on Fin.*, 110th Cong. 10–11 (2008) (testimony of Jeff Kindler, Chairman and CEO, Pfizer, Inc.) ("[P]rice controls and other restrictive practices in Europe and elsewhere stifled innovation . . . . [T]he range of other public policies effectively undermined those protections. As a result, the pharmaceutical industry in many of these countries has withered."); *Unsustainable Drug Prices: Testimony from the CEOs, Hearing Before the H.*

combined with the United States' reliance on pharmaceutical companies to conduct them, allow the pharmaceutical industry to frame threats to its bottom line as threats to innovation and public health.[102]

Closer scrutiny, however, reveals that the assertion is more like a series of untested assumptions stacked in a trench coat.[103] The claim presumes a direct causal relationship between R&D, innovation, and pricing regulation, ignoring the substantial nuance within each.[104] The actual relationship between R&D, innovation, and pricing regulation outcomes remains unclear, particularly in light of the federal government's substantial contributions to upstream research.[105] Access to granular R&D expense data would enable regulators to finally answer these questions quantitatively, putting to rest once and for all the ever-

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Comm. on Oversight & Gov't Reform, 116th Cong. 52 (2020) (statement of Dr. Giovanni Caforio, Chairman of the Board and Chief Executive Officer, Bristol Myers Squibb Co.) ("[O]ur objective is to have a system in which the reward for the investments we make in R&D is recognized . . . that's how we can fund very high-risk[,] lengthy[,] and costly R&D programs.").

102. *See, e.g.*, Petition for Writ of Certiorari at 2, AstraZeneca Pharms. v. Kennedy, No. 24-1819 (U.S. 2025) (describing a government effort to negotiate drug prices where the pharmaceutical company argued that "a regime of government price controls for critical medicines[ ] [would] upend[ ] the biopharmaceutical ecosystem and stall[ ] innovation and patient care").

103. *See* Wouters et al., *supra* note 73, at 8 ("Drug companies should supply further data to support claims that high drug prices are needed to recover [R&D] investments, if this argument will continue to be used to justify high prices."); *see also* Abbott, *supra* note 14, at 305 ("The cost of researching and developing originator pharmaceutical products is deliberately shrouded in mystery.").

104. *See WHO Publishes Pricing Policy Guideline to Improve Affordable Access to Medicine*, WORLD HEALTH ORG., (Sep. 8, 2020) https://www.who.int/news/item/28-09-2020-who-publishes-pricing-policy-guideline-to-improve-affordable-access-to-medicines [https://perma.cc/6LD5-DKRF] (describing ten different policy approaches to pricing regulation); *see supra* Part I.A (describing the complexity of the drug development process and the many organizations involved); Oriol de Solà-Morales et al., *Defining Innovation with Respect to New Medicines: A Systematic Review from a Payer Perspective*, 34 INT'L J. ASSESSMENT IN HEALTH CARE 224, 224 (2018) ("Overall, there was little agreement in the published literature on what characteristics of new medicines constitute rewardable innovation.").

105. CONG. BUDGET OFF., *supra* note 8 ("The relationship between [R&D spending and new drug approvals] is complex and variable . . . . [Moreover,] increase[s] in drug approvals does not, by itself, indicate the extent to which the new drugs are particularly innovative . . . . Additionally, not all R&D spending is directed toward development of new drugs."); *see also* Cheng et al., *supra* note 16 ("[E]conomists don't really know whether drug prices are too high, making policies aimed at lowering them hard to evaluate from a social welfare perspective . . . . Another key question in thinking about whether drug prices are too high is the extent to which innovation would respond to changes in prices.").

looming fear of a "chill to innovation"—if only regulators could access it.[106]

C. R&D EXPENSE DATA AND THE LIMITS OF CURRENT TRANSPARENCY

To the extent that any visibility into R&D costs exists, it is pieced together from indirect sources, which are inconsistent and only reveal aggregate figures.[107] Who is likely to possess drug-specific R&D cost data depends on the phase of drug development.[108] For the first stage of drug development, funding agencies can identify which grants contributed to a pharmaceutical product, but not how much of any given grant funded its specific R&D pathway.[109] Although the recipient likely has a sense of how funds are divvied up, that information is not gathered in RePORTER or iEdison.[110] For the second stage, R&D costs incurred by start-ups and small firms remain largely proprietary and are not disclosed in a sufficiently granular or systematic manner.[111]

The obscurity of latter phases of drug development is the crux of the transparency issue plaguing R&D.[112] While earlier

106. *See* Abbott, *supra* note 14, at 307 ("A major contribution . . . directed toward excessive pricing would be to require the . . . [pharmaceutical] industry to provide concrete data regarding the cost of R&D on individual drugs that are subject to assessment.").

107. Indirect sources include SEC disclosures and other occasional regulatory submissions. *See, e.g.*, Prasad & Mailankody, *supra* note 22, at 1575 (relying on SEC filings); *see also* Tay-Teo et al., *supra* note 22, at 1 (relying on global sales data and annual financial reports).

108. This is because so many different organizations are involved in the drug development process. *See supra* Part I.A (providing an overview of the drug development process).

109. The NIH RePORT, for instance, often focuses on grants more broadly, each of which might fund multiple studies. *See NIH RePORT Frequently Asked Questions*, NAT'L INSTS. OF HEALTH, https://report.nih.gov/faqs [https://perma.cc/Z3HZ-XWAH] (last visited May 20, 2026) (explaining that the database only offers "total costs" that for "multi-project grants" include "funding for all of the constituent subprojects").

110. *See id.* (explaining that the database can be used to check the number of grants awarded, the research focus of each, related studies and research papers published as a result).

111. *Appendix D: Congressional Access to Proprietary Pharmaceutical Industry Data*, *in* PHARMACEUTICAL R&D: COSTS, RISKS, AND REWARDS, TECHNOLOGY ASSESSMENT ADVISORY COUNCIL (1993) (attempts to obtain this data "is likely to be met by protests about the proprietary nature of the data"); *see, e.g.*, Tay-Teo et al., *supra* note 22, at 2 (attempting to analyze R&D data using public filings and sales figures, inhibited by the unverifiability of this information and inability to access underlying data).

112. *See, e.g.*, Letter from Docs. Without Borders/Médecins Sans Frontières (MSF) USA et al., to Eric Lander et al. (Jan. 31, 2022), https://dndi.org/wp-content/uploads/2022/02/

segments are also effectively insulated from scrutiny, none compare to the black box that pharmaceutical companies have so fervently and intentionally constructed around this R&D data.[113] Large pharmaceutical companies administering the last stages of R&D have refused to voluntarily provide their granular R&D data despite congressional requests.[114] Worsening the issue, these companies have the clearest insight into how tax credits, deductions, and offsets affect the R&D costs of clinical trials and FDA review[115]—information that is crucial to creating a comprehensive and accurate account of the cost of R&D.[116] These expenses underlie the core debates surrounding innovation, pricing, and regulatory intervention; it is these costs that are invoked to justify high prices, to whisper about the insidious chill to innovation, to ward off pricing regulation.[117] Yet, as it stands, no mechanism exists to access this crucial information.

Clinical-trial-cost-transparency-open-letter-January2022.pdf [https://perma.cc/3C8Q-JAW9] ("[P]harmaceutical and biotechnology companies are able to claim that the high costs of research and development (R&D), clinical trials in particular, justify high prices for drugs and other medical tools - yet they do not disclose these costs in any detail.").

113. *See Hearing on H.B. 1032 Before the H. Comm. on Hum. Servs.*, 67th Gen. Assemb. of N.D., Doc. 116, at 1 (N.D. Jan. 6, 2021) (statement of Jack T. McDonald) ("We are supportive of efforts to shed light on the black box that drug manufacturers are permitted to operate in with respect to their pricing."); *Appendix D: Congressional Access to Proprietary Pharmaceutical Industry Data*, *supra* note 111 ("[T]he pharmaceutical industry successfully battled GAO for a decade to prevent GAO from using these 'access to records' clauses to obtain information about individual companies' research, development, and marketing costs.").

114. Staff of S. Comm. on Fin., *supra* note 12, at 3 ("The company [Gilead] failed to provide sufficient information to determine how much additional cost it incurred to complete the development, finish the FDA approval process, and bring the drug [Sovaldi] to market.").

115. Logically, these companies must have the clearest insights into total R&D costs for clinical trials because they are the ones conducting the studies. "Enterprises in this industry must keep track of their expenses. Otherwise, planning and budgeting would be infeasible . . . . It is implausible that financial controllers provide 'blank checks' to research departments and do not examine expenditures. In short, while there may be a level of uncertainty regarding R&D costs, for the companies this is not a 'black box.'" Abbott, *supra* note 14, at 310.

116. MSF Access Campaign, *Roundtable: How Can Disclosing Clinical Trial Costs Increase Access to Medical Products? Summary Report* 3 (May 17, 2022), https://msfaccess.org/sites/default/files/2022-10/R%26D_TechBrief_DMSF-AC_CT%20Transparency_Summary%20Report_ENG_17_5_2022.pdf [https://perma.cc/2LFN-X284] ("Without full transparency of R&D costs from drug developers, it is not possible to determine the true costs of each stage of the R&D process for each drug, the total R&D cost, and which of these costs are related to clinical trials.").

117. When pharmaceutical companies tout R&D expenses to justify their pricing strategies, common sense dictates that they must be referring to the costs that *they* incurred, i.e., clinical trial costs and onwards. *Priced Out Hearing*, Langa Written Statement, *supra* note 77, at 3 ("The innovative medicines and delivery systems we produce are the result of significant and ongoing investment in research and development."); *Priced*

D. EXISTING AVENUES TO COLLECT R&D DATA ARE INADEQUATE

Scholars, state legislators, and federal regulators have all attempted to uncover R&D data before.[118] Unfortunately, none have produced sufficiently granular and comprehensive findings to fill the R&D information gap.[119] As this Section demonstrates, structural limitations are embedded within every existing avenue for acquiring such information. Academic studies lack access to verifiable underlying data and are constrained by methodological shortcomings. State legislation, while valuable for recognizing the importance of transparency, remains too narrow in scope and too limited in the type of information it can compel. Even federal regulation, which offered the strongest existing mechanism for obtaining drug-specific R&D data, falls short due to its limited applicability, aggregation methods, and incomplete accounting of public funding.

1. *The Limits of Academic Studies*

The limitations of studies trying to measure R&D costs highlight why publicly available resources are insufficient for assessing these costs.[120] First, some studies rely on anonymous surveys of pharmaceutical companies, which means they are unable to access or verify the underlying data on which their

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Out Hearing, Mason Written Statement, *supra* note 77, at 5 ("[P]harmaceutical companies raised list prices to . . . ensure that they are able to continue to fund lifesaving research and development."); *Priced Out Hearing*, Tregoning Statement, *supra* note 77, at 107 ("Revenues from all of our business, in part, go back to fund research and development across all areas.").

118. *See infra* notes 121, 137. State legislation, for instance, often had varying points of focus. *See, e.g.*, *Hearing on H.B. 272 Before the H. Health & Hum. Servs. Comm.*, 2020 Gen. Sess., at 44:00–55:00 (Utah Feb. 24, 2020) (statement of Rep. Paul Ray), https://le.utah.gov/av/committeeArchive.jsp?timelineID=158120 [https://perma.cc/2ZR7-KAZT] (describing the urgency of helping independent community pharmacies stay open). Similarly, academic studies were created to examine R&D costs in different contexts. *See, e.g.*, Light et al., *supra* note 14, at 6627 (examining R&D costs of Rotavirus vaccines); *see also* Prasad & Mailankody, *supra* note 22, at 1569 (examining R&D costs for cancer pharmaceuticals).

119. *See, e.g.*, H.B. 1032, 67th Leg. Assemb., Reg. Sess. (N.D. 2021) (enabling North Dakota to collect aggregate company-wide R&D expenses, rather than for specific drugs); *see also* DiMasi et al. (2016), *supra* note 13, at 21 (presenting a generalized average cost of R&D, rather than for specific drugs).

120. *See generally* Light et al., *supra* note 14; Prasad & Mailankody, *supra* note 22; Tay-Teo et al., *supra* note 22; DiMasi et al. (2016), *supra* note 13; DiMasi et al. (2003), *supra* note 13. That these studies span two decades and yet all are motivated by the same factors that gave rise to this Note demonstrates that high drug prices are a long-standing problem.

estimates depend.[121] Studies alternatively rest on self-reported data, which is equally unverifiable and concerning given researchers' connections to industry-funded organizations.[122] Even when granted direct access to pharmaceutical data,[123] academic scholarship has produced R&D cost estimates based on a generalized average, rather than in reference to specific drugs.[124] This presents a significant problem because the cost of developing a drug can vary drastically depending on, inter alia, the therapeutic area, clinical trial complexity, and the stage of development at which the drug was acquired.[125]

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121. *See* Light et al., *supra* note 14, at 6632 ("[N]one of the cost estimates can be verified . . . suggest[ing] caution in accepting company claims of high R&D costs, unless those claims are backed by independently verified data."); *see also* Prasad & Mailankody, *supra* note 22, at 1574 ("[A]lthough we used SEC filings, which are subject to strict guidelines and regulation, it is possible that some companies overemphasized or underemphasized R&D costs through unintentional errors. Without access to primary company data, we cannot be sure."); *see also* Tay-Teo et al., *supra* note 22, at 8 ("First . . . [our analysis] is limited by the availability and accuracy of data presented in the companies' annual reports.").

122. "The [DiMasi] analysis lacks transparency and is difficult to judge on its merits. It cannot be properly analyzed without knowing the specific drug products investigated, yet this has been deemed proprietary information and is governed by confidentiality agreements." Prasad & Mailankody, *supra* note 22, at 1573; *see also* Catherine Perloff, *Protestors Demand Center for the Study of Drug Development to Release Names of Pharmaceutical Funders*, TUFTS DAILY (Apr. 29, 2016), https://www.tuftsdaily.com/article/2016/04/protestors-demand-center-study-drug-development-release-names-pharmaceutical-funders [https://perma.cc/H7V6-H97S] ("[A]ctivists argue that the undisclosed pharmaceutical companies that fund his work may encourage him to report a high cost for drug development in order to fit the industry's agenda . . . ."); *see also* Prasad & Mailankody, *supra* note 22, at 1570 ("[The DiMasi] figure is more than 8 times higher than the $320.0 million (inflation adjusted for 2017 US dollars) estimate to develop one drug reached by the group Public Citizen. Given such divergent estimates, closer examination is warranted.").

123. DiMasi et al. (2016), *supra* note 13, at 22–23; DiMasi et al. (2003), *supra* note 13, at 156–58. Recall that both these studies had direct access to pharmaceutical data. Criticism aside, it is worth pointing out that this clearly demonstrates that this information both exists and can be organized into clear accounts of R&D expenses, if only the relevant underlying data were more transparent.

124. DiMasi et al. (2016), *supra* note 13, at 24 (presenting "[a]verage out-of-pocket clinical period costs for investigational compounds"); DiMasi et al. (2003), *supra* note 13, at 161 ("This estimate is a measure of the full resource cost needed, on average, for industry to discover and develop a new drug to the point of marketing approval.").

125. Phase III Clinical Trials: Definitive Guide & Case Studies, CCRPS (June 8, 2025), https://ccrps.org/clinical-research-blog/phase-iii-clinical-trials-definitive-guide-amp-case-studies [https://perma.cc/2UE5-6ZZ3] ("Per-patient costs vary widely depending on the therapeutic area, geographic regions involved, and trial complexity. . . ."); *see also* Aylin Sertkaya et al., *Costs of Drug Development and Research and Development Intensity in the US, 2000-2018*, JAMA NETWORK OPEN 1, 5 (June 28, 2024) (explaining that based on public resources alone, researchers found that the cost of R&D varied widely depending on therapeutic class and phase of development).

These studies can also employ techniques that inevitably inflate or distort estimates of R&D costs. For instance, they may only consider self-originating drugs, which refers to instances where the pharmaceutical company personally handled R&D from beginning to end.[126] The studies thus automatically excluded all drugs that were even partially federally funded, subtracting from final estimates vast public contributions.[127] They fail to account for the impact of tax breaks and employ an arguably inflated rate for cost of capital.[128] The remaining studies suffer from similar methodological flaws, including failures to account for tax adjustments; lack of development-phase distinctions or acquisition status; and exclusion of the cost of capital and the cost of failed compounds.[129]

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126. DiMasi et al. (2016), *supra* note 13, at 23 (defining focus on self-originating compounds); DiMasi et al. (2003), *supra* note 13, at 157 (explaining that self-originating excludes drugs "originated in government or academic labs"). The authors justify this exclusion by saying that it is unlikely many drugs originated in such contexts based on the number of registered patents that include government interest statements. *Id.* Their point is belied by the NIH's estimation of government contributions and widespread criticisms of severe underreporting of government contributions to new inventions. *See* Art Rai & Bhaven Sampat, *Accountability in Patenting of Federally Funding Research*, 20 NATURE BIOTECHNOLOGY 953, 956 (2013) ("[B]ecause about 60% of academic biomedical research was federally funded in the period between 1980 and 2007 . . . [the lack] of government interest statements provides prima facie evidence of under-disclosure.").

127. DiMasi et al. (2003), *supra* note 13, at 157 (explaining that self-originating excludes drugs "originated in government or academic labs"); *see* Clery et al., *supra* note 4, at 2329 ("NIH funding contributed to every one of the NMEs [new molecular entities] approved from 2010-2016. . . .").

128. Tax breaks can affect final R&D cost estimates by as much as 15%. Prasad & Mailankody, *supra* note 22, at 1574–75 ("Industry critics and journalists have repeatedly questioned the assumptions in the [DiMasi] study . . . argu[ing] its authors arbitrarily inflate the value placed on the cost of capital. . . ."). Cost of capital refers to "the potential financial returns had the money been used in other areas of investment with equal risk to drug development (i.e., opportunity cost)." Tay-Teo et al., *supra* note 22, at 2. As one researcher put it, the inclusion of cost of capital in R&D estimates is questionable at best because "[t]hese companies need to innovate to maintain profits; they are not in the business of simply investing funds." Light et al., *supra* note 14, at 6628. Moreover, the DiMasi articles use an 11% rate for cost of capital that "is much higher than the usual discount rates of 3–7% recommended in government cost-benefit guidelines." *Id.* at 6629 ("The 11% rate is often stated to be based on the pharmaceutical industry's expected rate of return, but in the real world of competitive markets, profits are never guaranteed; had a company invested in the American Exchange Pharmaceutical Index of stocks in December 1998 at $368, its value was $260 10 years later, an annual average loss of 3.4%.").

129. One, relying on SEC filings and offering drug-specific estimates, fails to account for tax adjustments, does not disaggregate costs by development phase, and does not indicate whether the drugs analyzed were self-originated or acquired. *See* Prasad & Mailankody, *supra* note 22, at 1574 (describing limitations of the study). Another, based on global sales data and annual financial reports, similarly omits the impact of tax-related offsets. *See* Tay-Teo et al., *supra* note 22 ("To this end, we undertook this study to quantify the income generated from the sales (i.e., sales income net of rebates and discounts but without

2. *The Limits of State Legislation*

Across the nation, states have implemented laws that enable the collection of R&D expense data.[130] While state legislation could help resolve the R&D issue, closer examination reveals three critical flaws. First, of the 14 relevant state laws, 7 only require reporting of aggregate company-level R&D costs.[131] Without drug-specific cost data, regulators cannot directly assess the relationship between pricing and R&D or compare pharmaceutical companies' expenditures against federal and intermediary investments, leaving them unable to pursue pricing regulation without persistent fears of chilling innovation.[132] Aggregate company-wide R&D costs, by definition, cannot resolve these issues.

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accounting for expenses and taxes) of cancer drugs. . . ."). A third, drawing on company reports and interviews with principal figures within the companies, provides drug-specific and phase-specific estimates but fails to incorporate the cost of capital, the cost of failed compounds, or tax adjustments. *See* Light et al., *supra* note 14, at 6630 ("As in all raw cost estimates, these are uncorrected for inflation, cost of capital, or failure of other vaccines projects.").

130. *See* H.B. 1032, 67th Leg., Reg. Sess. (N.D. 2021); 18 VT. STAT. ANN. 18 § 4635 (Vt. 2024); H.B. 5384, 144th Leg., Reg. Sess. (Conn. 2018); H.B. 2536, 86th Leg., Reg. Sess. (Tex. 2019); H.B. 272, 63d Leg., Reg. Sess. (Utah 2020); S.B. 689, 84th Leg., Reg. Sess. (W. Va. 2020); H.B. 2007, 141st Leg., Spec. Sess. (Va. 2021); H.B. 1224, 66th Leg., Reg. Sess. (Wash. 2019); S.B. 1550, 123d Leg., Reg. Sess. (Fla. 2023); H.B. 4005, 29th Leg., Reg. Sess. (Or. 2018); *see* L.D. 1406, 128th Leg., Reg. Sess. (Me. 2025); A. 1646, 219th Leg., Reg. Sess. (N.J. 2020); A. 4216, 221st Leg., Reg. Sess. (N.J. 2018); *cf.* H.B. 1418-FN, 165th Leg., Reg. Sess. (N.H. 2018) (creating a commission to study the potential impact R&D data on drug prices, but not a reporting requirement).

131. North Dakota, Vermont, Connecticut, Texas, Utah, West Virginia, and Virginia state laws require reports of aggregate company-wide R&D data. *See* H.B. 1032, 67th Leg., Reg. Sess. (N.D. 2021); 18 V.S.A. § 4635 (Ver. 2024); H.B. 5384, 144th Leg., Reg. Sess. (Conn. 2018); H.B. 2536, 86th Leg., Reg. Sess. (Tex. 2019); H.B. 272, 63d Leg., Reg. Sess. (Utah 2020); S.B. 689, 84th Leg., Reg. Sess. (W. Va. 2020); H.B. 2007, 141st Leg., Spec. Sess. (Va. 2021).

132. *See* Abbott, *supra* note 14, at 303 (describing cost-price methodology, which requires drug-specific R&D costs); *see also* MSF Access Campaign, *supra* note 116, at 3 ("Without full transparency of R&D costs from drug developers, it is not possible to determine the true costs of each stage of the R&D process for each drug, the total R&D cost, and which of these costs are related to clinical trials."). For further insight into these persistent fears of chilling innovation, see, e.g., Congressional Hearing 2024, *supra* note 18, at 21 (statement of Robert M. Davis, Chairman and CEO, Merck & Co., Inc.) ("If we disrupt an ecosystem that incentivizes robust investments in research, we put at risk not only the foundation of American leadership in pharmaceutical development but also the health and lives of countless people who would have benefitted from future discoveries."); *see also* NAM News Room, *supra* note 18 ("Drug price controls will 'chill' critical innovation in pharmaceutical manufacturing and do nothing to address the underlying causes of high medication costs, Johnson & Johnson leaders said recently.").

Second, all of these laws are only triggered if the price of the pharmaceutical increases by a certain amount or over a certain threshold.[133] Although the laws use drug-specific price hikes as a trigger, they stop short of requiring disclosure of the actual R&D costs associated with the specific drug whose price increased.[134] This approach creates a perverse incentive to price new drugs as expensively as possible, potentially causing more harm in the long-run.[135] If they work as intended, even the laws that are drug-specific will not provide any insight into R&D costs, let alone alleviate the burden caused by existing drugs that are already unaffordable.[136]

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133. *See, e.g.*, L.D. 1406, 128th Leg., Reg. Sess. (Me. 2025) (requiring reporting of R&D data for particular drugs upon a price increase or if the annual cost of the treatment is over $2,500); 18 VT. STAT. ANN. 18 § 4635(b)(1)(a) (2024) ("The Department of Vermont Health Access shall create annually a list of 10 prescription drugs on which the State spends significant health care dollars and for which the wholesale acquisition cost has increased by 50 percent or more over the past five years or by 15 percent or more during the previous calendar year. . . ."); H.B. 5384, 144th Leg., Reg. Sess. (Conn. 2018) (requiring manufacturer disclosure of "twenty-five most frequently prescribed outpatient prescription drugs; twenty-five outpatient prescription drugs that the health care plan covered at the greatest cost . . . twenty-five outpatient prescription drugs that experienced the greatest year-over-year increase in cost. . . ."); H.B. 2536, 86th Leg., Reg. Sess. (Tex. 2019) (requiring manufacturer disclosure following "an increase of 50 percent or more in wholesale acquisition cost of a drug with a wholesale acquisition cost of at least $100 for a 30-day supply"); H.B. 272, 63d Leg., Reg. Sess. (Utah 2020) (requiring manufacturer disclosure after increasing a drug's wholesale acquisition cost by a threshold amount set by the statute); *see, e.g.*, S.B. 689, 84th Leg., Reg. Sess. (W. Va. 2020) (requiring annual manufacturer reporting for drugs with a wholesale acquisition cost of at least $100 for a 30-day supply or that experienced specified wholesale acquisition cost increases).

134. *See, e.g.*, H.B. 272, 63d Leg., Reg. Sess. (Utah 2020) (enumerating 31A-47-103(1)(b)(i) to (v), which all entail drug-specific disclosure requirements, while subsection (v), which pertains to R&D costs, only requests aggregate data).

135. *See* Michael Erman, *Drugmakers to Raise U.S. Prices on Over 250 Medicines Starting January 1*, REUTERS (Dec. 31, 2024, at 7:21 AM EST), https://www.reuters.com/business/healthcare-pharmaceuticals/drugmakers-raise-us-prices-over-250-medicines-starting-jan-1-2024-12-31/ [https://perma.cc/M5RR-HSRW] (citing 3 Axis President Antonio Ciaccia, who said that "[d]rugmakers don't have much real estate any longer to increase prices over time, which means taking greater liberties on launch prices is really the only option they have in the face of expanded penalties for year-over-year price increases").

136. *See supra* notes 134–35 and accompanying text (explaining that existing laws assessing drug price hikes incentivize pharmaceutical companies to charge excessive prices at the outset to avoid triggering disclosure obligations and, even when a company is required to make a disclosure, it still doesn't have to provide disaggregated R&D data); Audrey Kearney et al., *Public Opinion on Prescription Drugs and Their Prices*, KFF (Mar. 31, 2026), https://www.kff.org/health-costs/public-opinion-on-prescription-drugs-and-their-prices/ [https://perma.cc/7NVP-63JS] ("Six in ten adults say they are worried about being able to afford their prescription drug costs . . . . Four in ten say they have had to take cost-saving measures, such as skipping doses, not filling prescriptions, or taking other measures due to costs.").

Third, the four laws that do require disclosure of drug-specific R&D data limit this obligation to drug manufacturers.[137] Although valuable, this information excludes R&D costs incurred during earlier stages of research.[138]

3. *The Limits of Federal Avenues*

The most relevant federal mechanism for collecting R&D data is the Medicare Drug Price Negotiation Program (MDPNP). The MDPNP statutorily empowers federal regulators to consider R&D data when determining what the "maximum fair price" should be for specific drugs.[139] Yet, the structural limitations of MDPNP severely constrain its ability to fill the R&D data gap.[140] First, MDPNP imposes stringent criteria for negotiation eligibility that significantly narrows which drugs it reaches.[141] For instance, only

137. S.B. 1550 § 499.026(3)(a)–(c), 123d Leg., Reg. Sess. (Fla. 2023) (instructing companies to list all drugs that had a price increase over a designated threshold in the last year and the factors that contributed to "each reportable drug price increase" including R&D costs); H.B. 1224 § 6(d), 66th Leg., Reg. Sess. (Wash. 2019) (requiring drug manufacturers to report the total R&D cost for each "covered drug"); *see* A. 4216 § 4(a) and (b)(2), 221st Leg., Reg. Sess. (N.J. 2024) (requiring the drug manufacturer to submit a list of critical prescription drugs, as defined by the bill, and R&D costs for each); A. 1646, 219th Leg., Reg. Sess. (N.J. 2020) (requiring the drug manufacturer to submit a list of critical prescription drugs, as defined by the bill, and R&D costs for each); *How Prescription Drug Prices Are Set: WAC, PBM Rebates, Patent Thickets, and the IRA Explained*, DRUG PATENT WATCH (Mar. 30, 2026), https://www.drugpatentwatch.com/blog/how-are-prescription-drug-prices-determined/ [https://perma.cc/3473-B55B] (explaining that manufacturers set list prices).

138. To the extent these manufacturers guided the drug through clinical trials and commercialization, the resulting disclosures could illuminate the most opaque stages of R&D. *See* BAREL & BOMAN, *supra* note 14, at 63 (explaining that no existing data publication "currently accomplishes the goal of clinical trial cost transparency"). Nonetheless, R&D data for the other components of the drug development process is still crucial to create a comprehensive picture of R&D costs.

139. *See* 42 U.S.C. § 1320f (creating the Drug Price Negotiation Program). This inclusion alone reflects a recognition that R&D data bears directly on pricing determinations, while the program's limitations simultaneously highlight the broader challenge of obtaining sufficiently granular and comprehensive expense data; *see* 42 U.S.C. § 1320f (a)(3) ("The Secretary shall . . . negotiate and, if applicable, renegotiate maximum fair prices for . . . selected drugs.").

140. Juliette Cubanski and Tricia Neuman, *Key Facts About Medicare Drug Price Negotiation*, KFF (Mar. 11, 2026), https://www.kff.org/medicare/key-facts-about-medicare-drug-price-negotiation/?entry=table-of- contents-in-2026-cms-selected-15-medicare-part-b-and-d-drugs-for-price-negotiation-with-negotiated-prices-taking-effect-in-2028 [https://perma.cc/Y25D-ZW5G] (describing how the list of selected drugs is chosen, including a multitude of requirements that severely narrow what is eligible for negotiation and in the R&D data collected).

141. 42 U.S.C. § 1320f-1 (listing criteria and exceptions for negotiation eligibility); *see also* 42 U.S.C. § 1320f-1(e)(1)(A) (limiting eligibility to where "at least 7 years will have elapsed since the date of . . . [FDA] approval"). Pharmaceuticals that are orphan drugs, low spending drugs, plasma derived drugs, or small biotech drugs are also excluded from

the top 15 drugs that constitute the highest total expenditures for Medicare fall under MDPNP, excluding many drugs that still require close scrutiny.[142] Second, MDPNP allows companies to aggregate costs for all products with the same active ingredient in their R&D expense calculation.[143] This is a significant issue because it allows companies to inflate R&D estimates by including the costs of developing later iterations of an already commercialized drug despite these later iterations providing little therapeutic value.[144] Third, although MDPNP considers federal

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negotiation. *See, e.g.*, 42 U.S.C. § 1320f-1(d)(2) (excluding low-spend and small biotech drugs); 42 U.S.C. § 1320f-1(e)(3) (excluding orphan drugs).

142. 42 U.S.C. § 1320f-1(b)(1) (instructing the government to rank drugs by price and select the most expensive ones). Note that highest total, referred to by the statute as "gross covered prescription drug costs" could refer to either the most expensive pharmaceuticals per patient or those that are most widely used, even if they are not all that expensive per unit. 42 U.S.C. § 1395w-115 (defining "gross covered prescription drug costs" as "costs incurred under the plan . . . directly related to the dispensing of covered [drugs] regardless of whether the plan or the individual pays for them"). For instance, because MDPNP selects drugs based on aggregate Medicare expenditures, high-cost therapies used by relatively few beneficiaries may fall outside the program if they do not generate sufficient total Medicare spending. *See* 42 U.S.C. § 1320f-1(d)(1)(A)–(B) (limiting eligibility to drugs with the "highest total spend"). While the top fifteen drugs certainly necessitate the most immediate attention, the remaining products on the list are hardly cheap. For instance, the 16th drug on the list of pharmaceuticals with the highest total spend required about $783 million in government expenditures, while the 15th drug, eligible for negotiation, cost about $786 million; even the lowest drug in the list required approximately $236 million in expenditures. *See Top 50 Negotiation-Eligible Drugs for Initial Price Applicability Year 2028*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/files/document/factsheet-medicare-top-50-negotiation-eligible-drug-list-ipay-2028.pdf [https://perma.cc/5NER-UZEA] (last visited June 2, 2026).

143. *See* 42 U.S.C. § 1320f-1(d)(3)(B) (instructing use of data "that is aggregated across dosage forms and strengths of the drug, including new formulations").

144. This practice is referred to as evergreening. *See* Feldman, *supra* note 3, at 601 (explaining that evergreening is the "acquisition of secondary patents on . . . minor modifications of pharmaceutical products . . . to unfairly extend the monopoly over the drug beyond the life of the initial patent"). For example, a company may invest significant resources to secure approval for a reformulated version of a drug, such as converting a hard-pill into a soft gel, even where the therapeutic advancement is marginal. *See, e.g.*, *The Evergreening Playbook: How Pharma Extends Drug Exclusivity — and What It Actually Costs*, DRUG PATENT WATCH (Mar. 8, 2026), https://www.drugpatentwatch.com/blog/the-evergreening-playbook-how-pharma-extends-drug-exclusivity-and-what-it-actually-costs/ [https://perma.cc/XVK6-V9FY] ("For a drug generating $4 billion per year, six additional months of exclusivity is worth roughly $2 billion in revenues — before accounting for the extended period's much higher margin (since there are no generic competitors)."). Admittedly, every drug chosen for MDPNP may not be subject to evergreening, but the practice isn't exactly rare. Researchers have found that evergreening is "endemic" to the industry, especially for blockbuster drugs: "Of the roughly 100 best-selling drugs, more than 70% had their protection extended at least once, with almost 50% having the protection cliff extended more than once." *See* Feldman, *supra* note 3, at 637 ("78% of the drugs associated with new patents . . . were not new drugs coming on the market, but existing drugs."). The chance, therefore, that such a pharmaceutical falls within the bucket of MDPNP drugs is hardly negligible.

grants in its R&D calculations, it limits this assessment to funding provided directly to pharmaceutical companies.[145] MDPNP estimates, therefore, do not offer a fully comprehensive account of R&D costs.[146]

The common thread across these efforts is the difficulty of tracing and verifying drug-specific R&D expenditures across the full drug development pipeline. And yet, a mechanism already exists that enables federal regulators to accomplish precisely this endeavor: Bayh-Dole's march-in rights provision.

III. UNMASKING THE COST OF INNOVATION USING MARCH-IN FACT-FINDING

This Note proposes that funding agencies invoke their investigative authority to directly request R&D data within a broader inquiry into the reasonableness of drug pricing—a modest iteration of proposals to use march-in rights for pricing control.[147]

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145. U.S. DEP'T OF HEALTH & HUMAN SERVS., CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE DRUG PRICE NEGOTIATION PROGRAM: FINAL GUIDANCE (2024), https://www.cms.gov/files/document/medicare-drug-price-negotiation-final-guidance-ipay-2027-and-manufacturer-effectuation-mfp-2026-2027.pdf [https://perma.cc/82NC-BDGJ] ("CMS confirms that the definition of prior Federal financial support does not include indirect funding such as that provided by a U.S. federal agency to a third party which then provided that funding to a Primary Manufacturer.").

146. Moreover, MDPNP's focus is on the drugs that Medicare spends the most on, not on those that public funding has invested the most in. *See* 42 U.S.C. § 1320f-1(d)(1)(A)–(B) (limiting eligibility to drugs with the "highest total spend"). Thus, the R&D data that it does collect may not be as well suited for assessing the relative contributions of everyone involved in the drug development process.

147. According to Bayh-Dole, march-in proceedings may be invoked if the contractor or their assignee or licensee fails to achieve practical application. 35 U.S.C. § 203(a)(1). A different statutory provision defines practical application to mean "the invention is being utilized and that its benefits are . . . available to the public on reasonable terms." 35 U.S.C. § 201(f). Thus, if the drug is only available on unreasonable terms, march-in rights may be invoked. Whether price counts as a material "reasonable term," however, is subject to significant debate. *See infra* Part III.B. While this proposal may initially seem like a bold exercise of agency authority, it is in fact a moderate iteration of a more aggressive approach that has already garnered substantial support: the use of march-in rights to compel licensing of patented drugs. *See, e.g.*, Jennifer Penman & Fran Quigley, *Better Late Than Never: How the U.S. Government Can & Should Use Bayh-Dole March-In Rights to Respond to the Medicines Access Crisis*, 54 WILLAMETTE L. REV. 171, 180 (2017) (advocating for the use of march-in rights to control pricing); *see also* Letter from Rep. Lloyd Doggett & 50 Members of Cong. to Sylvia Matthews Burwell, Sec'y, Dep't of Health & Hum. Servs., & Francis Collins, Dir., Nat'l Insts. of Health (Jan. 11, 2016), https://keionline.org/sites/default/files/Doggett-51member-MarchIn-11Jan2016.pdf [https://perma.cc/8A37-LLZN] (arguing that march-in rights should be used for pricing control); *see also* Letter from Xavier Becerra, Att'y Gen. of Cal., et al., to Alex M. Azar, Sec'y, U.S. Dep't of Health & Human Servs., et al. (Aug. 4, 2020), https://www.oag.ca.gov/system/files/attachments/press-docs/Remdesivir%20Letter%2020200804.pdf [https://perma.cc/QPD8-XLUW] (same). Use

Part III develops the practical, legal, and political dimensions of this proposal in four sections. Part III.A details how this proposal could work in practice and in combination with pre-existing agency systems. Note that the viability of this proposal hinges on a crucial underlying debate: whether exorbitant pricing triggers march-in rights.[148] Part III.B concludes that legislative history and statutory interpretation support the contention that pricing concerns are sufficient to invoke march-in rights. Part III.C reviews recent administrative developments to highlight the political feasibility of this proposal. Lastly, Part III.D contends with potential legal challenges, illustrating the improbability of their success.

A. LEVERAGING MARCH-IN FACT-FINDING

This section illustrates how funding agencies could leverage march-in procedures as a mechanism for R&D fact-finding. From the initial informal consultation to the independent fact-finding hearing, nearly every step in the march-in process centers on the funding agency's fact-finding role.[149] Although Bayh-Dole does not authorize agencies to directly subpoena information, the march-in procedures create at least three distinct opportunities for agencies to request information or for companies to submit information. The funding agency's informational request alone is likely to persuade companies to disclose R&D expenses because it would

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of agencies' fact-finding ability in the suggested manner would not infringe pre-existing monopolies nor set a precedent for forced government licensing as marching in would; it would simply allow the procurement of much needed information in a completely confidential setting, available solely to government officials.

148. *See infra* Part III.B (discussing the 'pricing as a term' debate in depth); *see, e.g.*, Peter S. Arno & Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed Upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 TUL. L. REV. 631, 651 (2001) ("The requirement for 'practical application' seems clearly to authorize the federal government to review the prices of drugs developed with public funding under Bayh-Dole terms and to mandate march-in when prices exceed a reasonable level."); *see also* Pharm. Rsch. & Mfrs. of Am. (PhRMA), Comment Letter on Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, (Feb. 6, 2024), https://www.regulations.gov/document/NIST-2023-0008-0633 [https://perma.cc/A8ND-9YUX] ("[I]ncorporat[ing] price into the consideration of two march-in criteria, practical application and health and safety needs, [is] contrary to Bayh-Dole's text and purpose (Section III). PhRMA rejects the premise that price should be a factor in the march-in analysis.").

149. *See* Schofield, *supra* note 21, at 780 ("[T]he regulations implementing the Act empower NIH to conduct extensive fact-finding.").

come in the context of a march-in investigation. The looming threat to their patent rights could be all the incentive companies need to comply.[150]

First, Bayh-Dole requires that the funding agency request an informal consultation and any relevant information if it thinks march-in rights may be needed.[151] R&D costs are certainly relevant, if only because high prices may truly be necessary to recoup the cost of R&D.[152] The funding agency may, therefore, directly request concrete R&D figures for contested drugs from companies; these organizations would arguably be incentivized to comply with these requests if only to end the inquiry there.

The second opportunity arises if the company does not provide a detailed accounting of R&D costs, at which point the funding

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150. The pharmaceutical industry's vehement opposition to the use of march-in rights evinces the likelihood that they will try at all costs to avoid a full-blown march-in proceeding. *See, e.g.*, Megan Van Etten, *Setting the Record Straight on the Bayh-Dole Act and March-In*, PHRMA (May 10, 2023), https://phrma.org/blog/setting-the-record-straight-on-the-bayh-dole-act-and-march-in [https://perma.cc/LJS6-AFHZ] ("Why would it be bad for the government to use march-in? In addition to not being sanctioned under the law, misusing the march-in provision would create a precedent that any product made with any level of government funding would be subject to march-in . . . stifling the same public-private innovation the Bayh-Dole Act was designed to accelerate."); *see also Misusing the Bayh-Dole Act's March-In Rights Is Not an Effective Way to Reduce Drug Prices*, COUNCIL FOR INNOVATION & PROGRESS (Jan. 29, 2024), https://c4ip.org/fact-check-misusing-the-bayh-dole-acts-march-in-rights-is-not-an-effective-way-to-reduce-drug-prices/ [https://perma.cc/P6XT-LAFD] ("Such government intervention would . . . introduce significant uncertainties and risks for inventors and investors, discouraging partnerships with government-funded research across the entire innovative ecosystem.").

151. "Whenever an agency receives information that it believes might warrant the exercise of march-in rights . . . it shall notify the contractor in writing (including electronic means) of the information and request an informal consultation and information relevant to the matter with the contractor to understand the nature of the issue. . . ." 37 C.F.R. § 401.6(a)(1) (2023).

152. This is not a far-fetched presumption. For instance, after increasing the price of the life-saving drug Daraprim from $13.50 per pill to $750 per pill, then-CEO Martin Shkreli of Turing Pharmaceuticals "defended the decision by telling Bloomberg News that newer versions of the drug needed to be developed . . . [and] that such research was extremely expensive." *See, e.g.*, Joanna Walters, *Martin Shkreli: Entrepreneur Defends Decision to Raise Price of Life-Saving Drug 50-Fold*, GUARDIAN (Sep. 22, 2015) https://www.theguardian.com/business/2015/sep/21/entrepreneur-defends-raise-price-daraprim-drug [https://perma.cc/5LNC-FEB4]. Similarly, Brystol-Myers Squibbs and Celgene increased the price of Revlimid, an essential cancer medication, twenty-two times since its initial release in 2005, eventually pricing the drug at $16,000 for a month of treatment by 2020; during a congressional hearing, CEOs of both companies explained that the price increases were a necessity for continued funding of R&D. *See Unsustainable Drug Prices: Testimony from the CEOs (Part I): Hearing Before the H. Comm. on Oversight & Reform*, 116th Cong. 55 (2020) (responding to a question regarding the impact of R&D on pricing, then-CEO of Bristol-Myers Squibb Giovanni Caforio replied "the need to obtain a return on our research and development investment is one of the important factors impacting the way we think about the price of medicines").

agency may still pursue march-in rights following further written notice.[153] This notice must explain why the agency is considering marching in, including the facts upon which the action would be based.[154] In such a notice, the agency could reiterate its pricing concerns and requests for granular R&D data. At this stage, the company has an even greater incentive to oblige because if it can raise a "genuine dispute over the material facts upon which the march-in is based," it would have the right to a fact-finding hearing.[155] If no such dispute is raised, the agency may indeed march-in, stripping the company of its patent monopoly altogether.[156] Pharmaceutical companies are likely to attribute their pricing to R&D costs of failed research projects across the company's portfolio, arguing that agencies should focus on portfolio-wide costs rather than drug-specific expenses.[157] This is a non-issue, as agencies can accept the relevance of portfolio-wide metrics without capitulating on their requests for drug-specific data; in fact, this may allow agencies to garner additional

153. *See* 37 C.F.R. § 401.6(a)(3) (2023) (implying that a fact-finding hearing must be offered only if there is a genuine dispute regarding the material facts, and that if there is no such dispute, the agency may proceed with exercising march-in rights).

154. *See* 37 C.F.R. § 401.6(a)(2) (2023) ("The notice shall state the reasons for the proposed march-in in terms sufficient to put the contractor on notice of the facts upon which the action would be based and shall specify the field or fields of use in which the agency is considering requiring licensing. The notice shall advise the contractor (assignee or exclusive licensee) of its rights, as set forth in this section and in any supplemental agency regulations.").

155. *See* 37 C.F.R. § 401.6(a)(3) (2023) ("If the information presented raises a genuine dispute over the material facts, the head of the agency or designee shall undertake or refer the matter to another official for fact-finding.").

156. *See id.* (implying that a fact-finding hearing must be offered only if there is a genuine dispute regarding the material facts, and that if there is no such dispute, the agency may proceed with exercising march-in rights). Recall also that the NIH may terminate a march-in proceeding at any time at its discretion, providing another reason for the company to satisfy the agency's request for information; indeed, the "genuine dispute" itself may be enough for the NIH to reconsider. *See* 37 C.F.R. § 401.6(a)(7) (2023) ("An agency may, at any time, terminate a march-in proceeding if it is satisfied that it does not wish to exercise march-in rights.").

157. Indeed, as they have. Brystol-Myers Squibbs and Celgene increased the price of Revlimid, an essential cancer medication, twenty-two times since its initial release in 2005, eventually pricing the drug at $16,000 for a month of treatment by 2020; during a congressional hearing, CEOs of both companies explained that the price increases were a necessity for continued funding of R&D. *See Unsustainable Drug Prices: Hearing*, *supra* note 152; *see also, e.g.*, *Priced Out Hearing*, Langa Written Statement, *supra* note 77, at 3 ("The innovative medicines and delivery systems we produce are the result of significant and ongoing investment in research and development."); *Priced Out Hearing*, Mason Written Statement, *supra* note 77, at 5 ("[P]harmaceutical companies raised list prices to . . . ensure that they are able to continue to fund lifesaving research and development.").

metrics.[158] What ultimately matters is ensuring that companies cannot evade scrutiny by invoking the abstract uncertainty of drug development.[159]

Funding agencies could also use iEdison to obtain R&D cost data from others involved in the drug development process, allowing regulators to at last create a comprehensive account of R&D costs.[160] As the current format of invention and patent reports enables regulators to trace what inventions were created under which grants, this would simply entail adding relevant questions about costs.[161] There are, however, three complicating factors.

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158. In fact, funding agencies could request both forms of information, allowing regulators to evaluate whether the price of Drug X bears a reasonable relationship to either its own development costs or the broader research ecosystem the company invokes in its defense. *See* 37 C.F.R. § 401.6(a)(1) (2023) ("Whenever an agency receives information that it believes might warrant the exercise of march-in rights . . . it shall notify the contractor in writing (including electronic means) of the information and request an informal consultation and information relevant to the matter with the contractor to understand the nature of the issue. . . .").

159. *See supra* Part II.A (explaining how the pharmaceutical industry centers R&D costs to justify exorbitant pricing); *see, e.g.*, *Unsustainable Drug Prices: Testimony from the CEOs, Hearing Before the H. Comm. on Oversight and Reforms*, 116th Cong. 11 (2020) (statement of Mark Alles, former CEO, Celgene) ("Since Revlimid's initial FDA approval, the company continued to invest several hundred million dollars into the research and development of this medicine . . . . As is common in drug development, some of these studies were not successful, did not succeed . . . . At Celgene, pricing decisions for our medicines were guided by . . . the continuous effort to discover new medicines and new uses for existing medicines, and the need for financial flexibility.").

160. *See* 37 C.F.R. § 401.14(h) (2023) ("The contractor also agrees to provide additional reports as may be requested by the agency in connection with any march-in proceeding undertaken by the agency."). As Florida State University Law Professor Frederick M. Abbott has described, it should not be impossible to put a number on the R&D costs of any given drug. *See* Abbott, *supra* note 14, at 281. These companies are businesses like any other; they must have budgets and financial projections. The very risk-assessments toted in arguments about rising prices reveal that individual companies have the kind of accounting sought after in this proposed fact-finding endeavor. *Id.* at 303; *see* DiMasi et al. (2016), *supra* note 13, at 22.

161. *See Creating a Utilization Report*, NAT'L INST. OF STANDARDS & TECH, *supra* note 52 (providing utilization reports that detail "any products made through the use of or embodying the subject invention," including the information of any licensees and manufacturers and their plans for bringing these products to market); *see also* NIH Grants Policy Statement, *supra* note 58 ("The [grant] recipient must inform NIH of the filing date of its Initial Patent Application, the Initial Patent Application number and title and all subsequently filed patent applications."). Furthermore, it's worth noting that researchers have already attempted to do so using publicly available records; their efforts were limited by the need to infer connections between grants and research for a specific drug, but using iEdison, the NIH would not face such constraints. *See* Bishal Gyawali et al., *Government Funding for the Development of Enzalutamide*, 11 JAMA ONCOLOGY 181, 182 (Dec. 19, 2024) (describing how researchers attempted to estimate public contributions to the drug by categorizing public grant information "based on the project location and investigators, award descriptions, and the linked published articles and abstracts").

First, additional measures are necessary to cure the pervasive underreporting of Bayh-Dole patents.[162] Although certain pharmaceuticals are now well known for the significant role that public funding played in their development, the vast majority of patented drugs supported by federal funding have not been reported as required.[163] Many solutions have already been proposed for this issue.[164]

Second, Bayh-Dole's statutory language and regulatory procedures strongly suggest that downstream developers, like start-ups and larger pharmaceutical companies, must comply with march-in proceedings.[165] Contractors do not have the capacity to commercialize products, which is the core mandate of Bayh-

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162. *See* Luis Gil Abinader, *Late Disclosures of Federal Funding in US Patents*, 12 J.L. & BIOSCIENCES 1, 13 (2025) ("[S]ignificant underreporting has occurred even for patents that should be on the NIH's radar due to separate acknowledgments made by other members of the same patent family."); *see also* Rai & Sampat, *supra* note 126, at 956 ("[B]ecause about 60% of academic biomedical research was federally funded in the period between 1980 and 2007 . . . the overall 43% incidence of government interest statements provides *prima facie* evidence of under-disclosure.").

163. Xtandi, a cancer drug currently sold for over $15,000 for a single month's supply, is one such example, although estimates of the total federal contribution vary. *See* Stacia Woodcock, *How Much Does Xtandi Cost Without Insurance?*, GOODRX (Feb. 18, 2026), https://www.goodrx.com/xtandi/how-much-does-xtandi-cost-without-insurance?srsltid=AfmBOop4vQXjRa6nnahGGIq2M3PoBQwSJPy31TZQ61Ltr8fJdw9zsXR9 [https://perma.cc/6MVU-BJP5] ("A 30-day supply of Xtandi can cost over $15,000 without insurance."); *see also* Gyawali et al., *supra* note 161, at 182 (estimating that public contributions to the development of Xtandi amounted to at least $74 million for the earliest stages of research); *see also* James Love, *KEI Reaction to Astellas Comment Regarding Public and Private Sector Contributions to the Development of Xtandi*, KNOWLEDGE ECOLOGY INST. (Feb. 15, 2022), https://www.keionline.org/37384 [https://perma.cc/S7L9-BTHH] (documenting pharmaceutical company Astellas' claim that "the U.S. government contributed approximately $500,000 to the initial discovery of the molecule that eventually became XTANDI").

164. *See, e.g.*, Abinader, *supra* note 162, at 28–30 (describing a number of possible solutions to cure underreporting). This would also have the added benefit of triggering another powerful Bayh-Dole provision, which states that if contractors do not disclose subject inventions within the required time period, the federal government may receive title. *See* 35 U.S.C. § 202(c)(1) ("[T]he Federal Government may receive title to any subject invention not disclosed to it within such time."). Note, however, that the NIH has been very unwilling to use this provision. *See* Abinader, *supra* note 162, at 20 ("NIH has on various occasions shown reluctance to take ownership of inventions from grantees who fail to comply with Bayh-Dole reporting requirements.").

165. *See* 35 U.S.C. § 200 ("It is the policy and objective of the Congress . . . to promote the commercialization and public availability of inventions made in the United States."); *see also* 37 C.F.R. § 401.6 (2023) (stating that the procedures apply to contractors *and* their assignees and licensees); *The University and Small Business Patent Procedures Act, Hearing on S.414 Before the Comm. on the Judiciary*, 96th Cong. 160 (1979) ("To be in a position to exercise these [march-in] rights a Government agency would have to stay involved in the plans and actions of its patent holders and check up on them.").

Dole.[166] The statutory scheme therefore must contemplate partnerships with private companies through eventual assignment or licensing of patents, suggesting that march-in requirements must carry over as well.[167] The march-in regulations reinforce this conclusion by repeatedly applying these procedures to assignees and licensees, not just contractors.[168]

Third, this proposal will not reach every blockbuster drug developed with federal funds. A single drug may be covered by multiple patents, not all of which qualify as Bayh-Dole "subject inventions."[169] Federally funded upstream research does not always translate into downstream Bayh-Dole coverage.[170]

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166. *See* 35 U.S.C. § 200 ("It is the policy and objective of the Congress . . . to promote the commercialization and public availability of inventions made in the United States"); *see also* Ferguson & Kaundinya, *supra* note 26, at 205 ("As is the case with universities, the NIH is not able to commercialize its discoveries even with its considerable size and resources—it relies instead upon partners . . . . Companies with access to the needed expertise and money are needed to undertake continued development of these inventions from the NIH or other research institutions into final products.").

167. This deduction is further supported by the language of the utilization reports, which requires contractors to explain their plans for commercialization, and within that, who they plan to license or assign the invention to. *Creating a Utilization Report*, NAT'L INST. OF STANDARDS & TECH., *supra* note 52. Researchers have come to similar conclusions: "Importantly, this last requirement and the resulting march-in rights do not only apply to the contractor." *See* Arno & Davis, *supra* note 148, at 648 ("The rights attach to the invention and any resulting patent. Thus, even if a patent is eventually granted to others, if it resulted from the original federal funding . . . the later patent should bear the legend and be subject to the entire Act.").

168. *See* 37 C.F.R. § 401.6(a)(2) (2023) ("A march-in proceeding shall be initiated by the issuance of a written notice by the agency to the contractor and its assignee or exclusive licensee, as applicable and if known to the agency . . . . The notice shall advise the contractor (assignee or exclusive licensee) of its rights. . . ."); *see* 37 C.F.R. § 401.6(a)(3) (2023) ("Within 30 days after the receipt of the written notice of march-in, the contractor (assignee or exclusive licensee) may submit in person, in writing, or through a representative, information or argument in opposition to the proposed march-in . . . . Any portion of the march-in proceeding, including a fact-finding hearing that involves testimony or evidence relating to the utilization . . . that [is] being made by the contractor, its assignee, or licensees shall be closed to the public. . . .").

169. *See* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-21-52, NIH SHOULD PUBLICLY REPORT MORE INFORMATION ABOUT THE LICENSING OF ITS INTELLECTUAL PROPERTY 19 (2020) ("FDA-approved drugs can involve multiple patented inventions, with HHS owned patents being one part of a portfolio of intellectual property used to commercialize a drug.").

170. *See* 35 U.S.C. § 201(f) ("The term 'subject invention' means any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement."); *see also* Lisa Larrimore Ouellette & Bhavan N. Sampat, *Using Bayh-Dole Act March-In Rights to Lower US Drug Prices*, 5 JAMA HEALTH F. 1, 2 (2024) ("March-in does not apply to privately funded inventions or to publicly funded inventions developed through intramural research such as at NIH labs (which are governed by the separate Stevenson-Wydler Act) . . . . March-in rights also do not apply to the large number of drugs for which the government contributed to drug development, when these contributions did not result in patents associated with the drug.").

Nonetheless, recent studies suggest that several blockbuster drugs developed with meaningful public support are within Bayh-Dole's statutory reach.[171] For instance, one article notes that there were at least three top-selling drugs for which late disclosures of government support were filed: Gleevec, Lyrica, and Prozac,[172] two of which were heavily criticized for exorbitant pricing.[173]

Even a comprehensive accounting of R&D costs for a single drug would represent a substantial improvement over the current state of pharmaceutical transparency.[174] Knowledge of R&D expenses is invaluable to creating a fair and accurate benchmark for drug pricing, allowing regulators to address the framework's greatly criticized failure to define "reasonable price."[175] This would help inform future pricing benchmarks, making any future use of march-in rights in pricing disputes more predictable.[176] Armed with R&D figures, regulators could directly compare private and public contributions to drug development and their relationship to pricing, at last quantitatively assessing the purported impact on innovation. Furthermore, this Note's proposal to leverage funding agencies' investigative authority is less likely to adversely affect innovation because such fact-finding need not require the full use of march-in proceedings.[177]

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171. *See* Abinader, *supra* note 162, at 13 ("[M]ore than 30 patents in the Orange Book have reported government interest statements."); *see also* Ouellette & Sampat, *supra* note 170, at 7 (finding that march-in rights apply to at least eighteen drugs).

172. *See* Ouellette & Sampat, *supra* note 170, at 7 (finding that march-in rights apply to at least eighteen drugs).

173. STAFF OF H. COMM ON OVERSIGHT AND REFORM, 116TH CONG., REPORT ON DRUG PRICING INVESTIGATION NOVARTIS—GLEEVEC 34 (Comm. Print 2020) (describing how Novartis has responded to criticisms regarding exorbitant pricing of Gleevec); *see also* Nicholas Florko, *Powerful Democrat Wants Pfizer to Explain Price Hikes for Lyrica, Its Nerve Pain Drug*, STAT (Dec. 19, 2018), https://www.statnews.com/2018/12/19/wyden-pfizer-lyrica-hikes/ [https://perma.cc/9YMS-QM82] (describing rapid and "egregious" price hikes of Lyrica).

174. *See* BAREL & BOMAN, *supra* note 14, at 63 (noting that no existing data publication "currently accomplishes the goal of clinical trial cost transparency").

175. *See* Ouellette & Sampat, *supra* note 170, at 5 (using Gleevec, Lyrica, and Prozac to illustrate issues with underreporting of government interest in patent filings).

176. *See, e.g.*, Pharmaceutical Research and Manufacturers of America, Comment Letter on NIST's Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights (Docket No. 2023-0008) (Feb. 6, 2024) [hereinafter PhRMA Comment Letter], at 16 ("[I]ncluding price in the analysis to determine whether march-in should be exercised under criterion 1 or 2 . . . opens up further uncertainty about the proper scope of march-in authority, which will cause negative effects on commercialization and innovation. . . .").

177. In the same vein, as data collection is less of an interference with patent rights than full seizure of title, concerns regarding its impact on innovation hold less weight.

The investigative functions encapsulated within the march-in provision are well suited for gathering comprehensive R&D expenditures per drug. The viability of this proposal, however, depends on whether pricing can trigger march-in rights.

B. DRUG PRICING IS A TRIGGER FOR MARCH-IN RIGHTS

Statutory language and legislative history demonstrate that at least one of the four statutory grounds for march-in provisions encompasses pricing concerns: when the contractor has failed to sufficiently pursue practical application.[178] According to Bayh-Dole, practical application requires the invention to be "utilized and . . . its benefits [to be] . . . available to the public on reasonable terms."[179] The essential inquiry is whether "reasonable terms" includes price.[180] The basic tenets of statutory interpretation, which require first considering the ordinary meaning of statutory language, strongly indicate that the grounds for invoking march-in rights include exorbitant pricing.[181] In cases spanning the country and a wide variety of legal areas, federal appellate and district courts alike have interpreted "reasonable terms" to include

178. 35 U.S.C. § 203(a)(1) (describing how the funding agency may march-in "if action is necessary because the contractor or assignee has not taken . . . effective steps to achieve practical application of the subject invention in such a field of use"). Advocates of using march-in rights to contend with high drug prices have also cited 35 U.S.C. § 203(a)(2)—specifically "action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor" to argue that a second scenario encompasses pricing concerns. Some have argued that this language naturally implicates pricing because unaffordability can render life-saving drugs inaccessible, leaving critical health and safety needs unmet. *See, e.g.*, *Civil Society Comments Re: March-in Rights Framework*, PUB. CITIZEN (Feb. 6, 2024), https://www.citizen.org/article/civil-society-comments-re-march-in-rights-framework/ [https://perma.cc/AJV4-PNGR] ("Excessive pricing of medicines can prevent public health and safety needs from being satisfied, and numerous march-in petitions have been presented to the federal government on this basis.").

179. 35 U.S.C. § 201(f).

180. *See, e.g.*, Arno & Davis, *supra* note 148, at 651 ("The requirement for 'practical application' seems clearly to authorize the federal government to review the prices of drugs . . . and to mandate march-in when prices exceed a reasonable level."); *see also* PhRMA Comment Letter, *supra* note 176, at 2 ("[I]ncorporat[ing] price into the consideration of two march-in criteria, practical application and health and safety needs, [is] contrary to Bayh-Dole's text and purpose (Section III). PhRMA rejects the premise that price should be a factor in the march-in analysis.").

181. Penman & Quigley, *supra* note 147, at 180 ("It does not take sophisticated legal analysis to decipher the plain meaning of phrases like 'reasonable terms' and 'health and safety needs.' It is well-settled law that words in statutes should be interpreted in line with their ordinary meaning.").

price.[182] To not include pricing within "reasonable terms" would go against the ordinary meaning of the phrase.[183]

Detractors, often consisting of members of the pharmaceutical industry, have argued that "practical application" only entails commercial availability, i.e., merely making the drug available on the market.[184] But, as scholars Jennifer Penman and Fran Quigley argue, drawing from the surplusage canon, this fails to explain why Congress would also include the phrase "reasonable terms."[185]

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182. Researchers Peter S. Arno and Michael H. Davis provide an excellent summary of this case law:

> In Byars v. Bluff City News Co., the United States Court of Appeals for the Sixth Circuit, recognizing that establishing "reasonable terms" is necessary to remedy a monopolistic market, noted that "[t]he difficulty of setting reasonable terms, especially price, should be a substantial factor" in how to proceed. Similarly, in American Liberty Oil Co. v. Federal Power Commission, the United States Court of Appeals for the Fifth Circuit, interpreting a statute that allows the Federal Power Commission to establish "reasonable terms and conditions," concluded that this meant that the "price . . . must be reasonable." In Commercial Solvents Corp. v. Mellon, the United States Court of Appeals for the D.C. Circuit addressed prices under a statute that demanded "reasonable terms as to quality, price and delivery"; this language shows that the word "terms" includes, as a matter of common sense, the element of price . . . . In Topps Chewing Gum, Inc. v. Major League Baseball Players Ass'n, the United States District Court for the Southern District of New York resolved a dispute between baseball players and a playing card company that had agreed to pay "commercially reasonable terms"; the court said, "I assume [commercially reasonable terms] means at a price higher than Topps currently pays under its player contracts." In United States v. United States Gypsum Co., the United States District Court for the D.C. Circuit held that "reasonable terms and conditions" includes prices.

Arno & Davis, *supra* note 148, at 650–51.

183. Penman & Quigley, *supra* note 147, at 185 ("[A] powerful and straightforward argument that the federal government could conclude that a drug is 'not available on reasonable terms' if its price is exorbitant . . . why would you read a statute written like that to exclude any consideration of prices?").

184. *See, e.g.*, PhRMA Comment Letter, *supra* note 176, at 7 ("Reading price into the practical application criterion would be contrary to the goals set out in the Act"); Biotechnology Innovation Organization, Comment Letter on Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights (Feb. 6, 2024) ("The march-in authority was not designed, for example, to regulate commercial conditions for marketing products or services, e.g., pricing or conditions of sale. Instead, its primary purpose was to rectify the unusual situation where there has been an inexcusable failure to commercialize the subject invention, i.e., lack of 'practical application.'").

185. *See* Penman & Quigley, *supra* note 147, at 185–86 ("If Congress had intended the only obligation of the license holder to be making the invention commercially available, it would have concluded its definition of 'practical application' with the requirement contained there that the invention be 'available to the public.' . . . Clearly, mere commercialization of the invention is not sufficient to meet a license holder's obligations.").

A plain reading of the statute and regulations suggests that merely commercializing a pharmaceutical is not enough to satisfy Bayh-Dole requirements.[186]

Legislative history further indicates that the phrase was always meant to include price due to long-term concerns about the windfall profits the act would otherwise create.[187] Legislators were well aware of the public significance of simply handing away patent rights to federally funded research with no limitations.[188] Multiple statements by members of Congress and witnesses affirm the widespread understanding that a pricing constraint would be necessary.[189] Notably, this interpretation is also supported by a large array of congresspeople,[190]

186. *Id.*

187. *See* Lee, *supra* note 32, at 957 ("As far back as 1947, the Attorney General reported that '[i]nventions financed with public funds should inure to the benefit of the public, and should not become a purely private monopoly under which the public may be charged for, or even denied, the use of technology which it has financed.' Thirty years later, in the debates surrounding the Bayh-Dole Act, members of Congress warned against unduly rewarding private companies without commensurate public benefit." (citation omitted)); *see also* Jerome H. Reichman, Testimony Before NIH Public Hearing on March-In Rights Under the Bayh-Dole Act 4 (May 23, 2004) [hereinafter *Reichman Testimony*] ("[T]he march-in provisions were added to ensure that patentees' did not abuse their position by making the products available to the public on unreasonable terms that could lead to 'windfall profits. . . .'").

188. *See* 126 CONG. REC. 29,898 (1980) (statement of Rep. Brown) ("I am aware of the concern that granting contractors exclusive rights to federally funded inventions is a 'give-away' of the taxpayers' property.").

189. *See Government Patent Policy: Hearing Before the Subcomm. on Sci., Rsch. and Tech. of the H. Comm. on Sci. and Tech.*, 96th Cong. 48, 54 (1979) (statement of Harry F. Manbeck) (noting that if a contractor "fails to supply the market adequately at a fair price, then there is reason for requiring it to license both the background patents and the patents stemming from the contract work"); Penman & Quigley, *supra* note 147, at 183 (citing *The Univ. & Small Business Patent Procedures Act: Hearings on S. 414 Before the Comm. on the Judiciary*, 96th Cong. 2, 153–54 (1979)) (testimony of Betsy Ancker-Johnson, Vice President, Gen. Motors Env't Activities Staff, Former Assistant Sec'y of Com.) ("[M]arch-in provisions protected not just against non-use of the invention but also against 'abuse' of the monopolies that were detrimental to 'the welfare of the people.'"); *id.* (citing *Hearings on S. 1215 Before the Subcomm. on Sci., Space, & Tech. of the S. Comm. on Com., Sci., & Transp.*, 96th Cong. 401 (1979)) ("Admiral H.G Rickover testified to Congress that the proposal was a multi-billion dollar giveaway."); *see also 1979 Comm. on the Judiciary Hearings*, *supra* note 63, at 44 (statement of Sen. Birch Bayh) ("[Bill criticism] comes from those that feel that this bill is a front to allow the large, wealthy, corporations to take advantage of Government research and thus to profit at taxpayer's expense. We thought we had drafted the bill in such a way that this was not possible.").

190. Letter from Members of Congress to Sylvia Matthews Burwell, Sec'y of Health & Human Servs. & Francis S. Collins, Dir. of the Nat'l Insts. of Health (Jan. 11, 2016), https://keionline.org/sites/default/files/Doggett-51member-MarchIn-11Jan2016.pdf [https://perma.cc/J4EF-RZ4Y].

state attorneys general,[191] academics, and other important stakeholders like the FTC.[192]

In contrast, others frequently argue that Bayh-Dole was never intended to regulate drug prices, based on an editorial written by Senators Birch Bayh and Bob Dole asserting that march-in rights could only be exercised where a federally funded invention had not been commercialized at all.[193] Their position is less decisive than often portrayed because five years earlier, Senator Bayh himself petitioned the NIH to march in on patents held by Johns Hopkins and Baxter Health Corporation, expressly citing "unreasonably high royalties and prices of medical care."[194] The force of the senators' later interpretation is further complicated by their undisclosed ties to pharmaceutical companies at the time of publication.[195]

Agency responses to such march-in petitions, however, present a far more significant obstacle: no funding agency has ever granted a petition requesting the exercise of march-in rights.[196] Funding

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191. Letter from States Attorneys General to Alex M. Azar, Sec'y of Health & Human Servs., Francis S. Collins, Dir. of the Nat'l Insts. of Health, and Stephen Hahn, Comm'r of the Food & Drug Admin. (Aug. 4, 2020), https://www.oag.ca.gov/system/files/attachments/press-docs/Remdesivir%20Letter%2020200804.pdf [https://perma.cc/JBG5-ELYQ].

192. Fed. Trade Comm'n, Comment Letter on Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights (Feb. 6, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/2024.02.06March-InRightsComment.pdf [https://perma.cc/4LCF-55LD].

193. *See* Birch Bayh & Bob Dole, *Our Law Helps People Get New Drugs Sooner*, WASH. POST (Apr. 10, 2002), https://www.washingtonpost.com/archive/opinions/2002/04/11/our-law-helps-patients-get-new-drugs-sooner/d814d22a-6e63-4f06-8da3-d9698552fa24/ [https://perma.cc/7WVB-73Y7]. The senators described the purpose of the legislation as enticing private companies to seek public-private partnerships rather than focusing solely on their own proprietary research. *Id.* They emphasized that the public garnered enormous benefits from such relationships, highlighting the significant private investments needed in addition to federal grants to commercialize pharmaceuticals. *Id.* Directly addressing the contested statutory ground, they maintained that the government's rights had been mischaracterized. *Id.* ("The ability of the government to revoke a license granted under the act is not contingent on the pricing of a resulting product . . . . The law instructs the government to revoke such licenses only when the private industry collaborator has not successfully commercialized the invention as a product.").

194. *See* Letter from Lloyd N. Cutler & Sen. Birch Bayh to Donna E. Shalala, Sec'y of the Dep't. of Health and Hum. Servs. (Mar. 3, 1997), https://www.keionline.org/wp-content/uploads/cellpro-request.pdf [https://perma.cc/L5EY-LUR6] (requesting the use of march-in rights on behalf of CellPro, Inc. over patents related to medical cell-separation devices held by Baxter Healthcare Corp. and Johns Hopkins University).

195. James Love, *Birch Bayh's Competing Interests and Evolving Views*, KNOWLEDGE ECOLOGY INT'L (Aug. 23, 2012), http://keionline.org/node/1537 [https://perma.cc/2AV4-MB8N] (noting that both senators were employed by firms that had several pharmaceutical companies as clients and were actively participating in contracts to sponsor pharmaceutical companies such as Pfizer).

196. The Knowledge Ecology International, an advocacy organization, offers an instructive and comprehensive history of march-in requests. *See Timeline Regarding Bayh-*

agencies have publicly rejected seven march-in petitions since 1997.[197] Four of these petitions expressly argued that pricing should factor into agency interpretations of "reasonable terms" when evaluating practical application and, separately, into assessments of whether health and safety needs had been reasonably satisfied.[198] For every contested drug, the NIH

Dole March-In Requests, KNOWLEDGE ECOLOGY INT'L, https://www.keionline.org/march-in-rights-timeline [https://perma.cc/P5VB-H629] (last visited May 13, 2026).

197. *See* Rejection of Petition for the Government to Exercise its March-In Rights Under the Bayh-Dole Act in Connection with Xalatan® 4 (Nat'l Insts. of Health Sep. 17, 2004), https://www.keionline.org/wp-content/uploads/March-in-xalatan.pdf [https://perma.cc/924C-YQBY] (finding that there were no grounds for marching in because practical application had been achieved and health needs were satisfied); Rejection of Petition for the Government to Exercise its March-In Rights under the Bayh-Dole Act in Connection with Norvir® 6 (Nat'l Insts. of Health July 29, 2004), https://www.essentialinventions.org/docs/usa-ritonavir/zerhouni29jul04.pdf [https://perma.cc/UU3N-GWXZ] (finding that the march-in provision had not been triggered); *see also Timeline Regard Bayh-Dole March-In Right Requests*, KNOWLEDGE ECOLOGY INT'L, https://www.keionline.org/march-in-rights-timeline [https://perma.cc/L868-A5KX] (last visited Aug. 3, 2026) ("The FTC declined to decide the march-in case filed by KEI on February 12, 2007, on the grounds that -because the Gilead voluntary license applied to developing countries- the harm was to U.S. taxpayers, not U.S. consumers, and harms caused to U.S. taxpayers for the misuse of publicly-funded inventions is not a cause of action in an U.S. antitrust case."); Rejection of Petition for the Government to Exercise its March-In Rights Under the Bayh-Dole Act in Connection with Fabrazyme® 9 (Nat'l Insts. Of Health Dec. 1, 2010), https://www.keionline.org/wp-content/uploads/francis_collins_rejection_fabrazyme_marchin_1dec2010.pdf [https://perma.cc/WXY5-RC26] (explaining that march-in rights were not warranted because exercising them would not resolve the issue identified by the petitioners, namely shortages of the contested drug); Rejection of Petition for the Government to Exercise its March-In Rights Under the Bayh-Dole Act in Connection with Norvir® 6 (Nat'l Insts. of Health Nov. 1, 2013), https://www.keionline.org/wp-content/uploads/Norvir_NIH_Signed_Determination_1Nov%202013.pdf [https://perma.cc/55UH-4KPZ] (explaining that use of march-in rights was not warranted because the practical application had been achieved); Rejection of Petition for the Government to Exercise its March-In Rights Under the Bayh-Dole Act in Connection Patents Owned by CellPro, Inc. 11 (Nat'l Insts. of Health Aug. 1, 1997), https://www.keionline.org/wp-content/uploads/2018/03/cellpro-marchin-1aug1997-Varmus.pdf [https://perma.cc/DYC2-ZKNW] (refusing to invoke march-in rights to aid CellPro in gaining more favorable commercial terms); Rejection of Petition for the Government to Exercise its March-In Rights Under the Bayh-Dole Act in Connection with Xtandi® 1 (Nat'l Insts. of Health June 20, 2016), https://www.keionline.org/wp-content/uploads/Final-Response-Goldman-6.20.2016.pdf [https://perma.cc/NP8D-KT7T] (refusing to invoke march-in rights because practical application had been achieved).

198. *See generally* Petition to Use Authority Under Bayh-Dole Act to Promote Access to Ritonavir (Nat'l Insts. of Health Jan. 29, 2004), https://www.essentialinventions.org/legal/norvir/norvir-29jan04petition.pdf [https://perma.cc/8BYZ-D226] (request by Essential Inventions for the use of march-in rights over patents related to latanoprost/Xalatan, marketed by Pfizer); *see also* Petition to the Nat'l Insts. of Health Off. of the Dir. (Nat'l Insts. of Health July 29, 2004) https://www.essentialinventions.org/docs/usa-ritonavir/zerhouni29jul04.pdf [https://perma.cc/F6AJ-3X5G] (request by Essential Inventions for the use of march-in rights over patents related to ritonavir, also known as Norvir, marketed by Abbott Laboratories); Request for March-In on Abbott Patents for Ritonavir (Nat'l Insts. of Health Oct. 25, 2012) https://www.keionline.org/wp-content/uploads/2012_Oct25_Ritionavir_

concluded that patent holders had achieved practical application based on the manufacture, practice, and operation of the invention; patentees' attainment or active pursuit of FDA approval; and their availability to the public.[199] The agency further reasoned that health and safety needs were satisfied so long as the drug was not in short supply.[200] Lastly, it explained that, given the enormous implications of drug pricing, it felt that such issues were best left to Congress to resolve.

These NIH decisions are not binding.[201] The NIH is permitted to change a view that it later determines was based on an incorrect legal interpretation.[202] An agency is required, however, to "examine relevant data and articulate a satisfactory explanation for its action" if it does change course.[203] In such a circumstance, the change-in-position doctrine indicates that a federal court's scope of review would be narrow and require "appropriate deference to agency decision-making."[204] With that said, because

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march_in_complaint.pdf [https://perma.cc/9DQF-QARN] (request by American Medical Students Association, Knowledge Ecology International, U.S. Public Interest Research Group, and the Universities Allied for Essential Medicines for the use of march-in rights over patents related to ritonavir/Norvir, marketed by Abbott and AbbVie); Letter from James Packard Love et al., Knowledge Econ. Int'l, to Hon. Sylvia Burwell, Sec'y of the Dep't. of Health and Hum. Servs. et al., (Jan. 14, 2016) https://www.keionline.org/wp-content/uploads/Xtandi-March-In-Request-Letter-14Jan2016.pdf [https://perma.cc/E4SG-38ES] (requesting the exercise of march-in rights over patents related to Xtandi and marketed by Astellas, at the behest of the Knowledge Ecology Institute and the Union for Affordable Cancer Treatment).

199. *See, e.g.*, Rejection of Petition to the Nat'l Insts. of Health (Nov. 1, 2013), https://www.keionline.org/wp-content/uploads/Norvir_NIH_Signed_Determination_1Nov%202013.pdf [https://perma.cc/5GUE-32PW] (finding that Norvir has reached practical application because it "has now been on the market as an FDA approved drug since 1995 . . . [and] [t]he Requestors have provided no information, and no information was identified to suggest that ritonavir [the contested drug] is in short supply").

200. Ironically, even when a drug was in short supply, the NIH still didn't march in because the company was "working diligently and in good faith to address the . . . shortage." Rejection of Petition to the Sec'y of Health and Hum. Servs., https://www.keionline.org/wp-content/uploads/francis_collins_rejection_fabrazyme_marchin_1dec2010.pdf [https://perma.cc/ZD33-YGFQ] (last visited May 13, 2026) (explaining that march-in rights were not warranted because exercising them would not resolve the issue identified by the petitioners, namely shortages of the contested drug, given the time-consuming nature of obtaining FDA approval).

201. *See* Good Samaritan Hosp. v. Shalala, 508 U.S. 402, 417 (1993) ("Indeed, '[a]n administrative agency is not disqualified from changing its mind. . . .'" (citation omitted)).

202. *See id.* ("[Agencies are] not estopped from changing a view [they] believe[ ] to have been grounded upon a mistaken legal interpretation.").

203. F.D.A. v. Wages & White Lion Invs., 604 U.S. 542, 567 (2025).

204. *See id.* (noting that under the change-in-position doctrine, "the scope of . . . review 'is narrow,' and reviewing courts must exercise appropriate deference to agency decisionmaking").

ambiguous statutory language is involved, such deference would likely be further limited per *Loper Bright*.[205]

The crux of the decision would likely boil down to the court's interpretation of the relevant statutory language.[206] As argued above, there is ample reason for any court to find that "practical application" encompasses so much more than the mere commercialization that the NIH has currently deemed adequate.[207] For instance, the lack of thoroughness present in these past NIH decisions may alone be probative, as the agency did not attempt to define "reasonable terms" or address the crucial phrase in even a single reply.[208] Some have argued that the absence of this analysis renders the agency's decisions prima facie invalid.[209]

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205. *See* Loper Bright Enters. v. Raimondo, 603 U.S. 369, 370 (2024) (articulating four factors to ascertain the appropriate level of deference: "the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control"). Consistency would be the obvious obstacle if judicial review were ever to come about, but in terms of thoroughness and validity, the NIH could surely build a strong case for changing its mind if it wanted to. Criticisms of undue influence in the NIH's past decisions could also play a role in justifying the change in position. "In April of 2016, when NIH director Francis Collins was asked . . . why he was reluctant to exercise Bayh-Dole licensing rights, Collins replied that he feared doing so would harm the agency's relationship with the drug companies." Penman & Quigley, *supra* note 147, at 201; *see also* Fran Quigley, *Tell Me How It Ends: The Path to Nationalizing the U.S. Pharmaceutical Industry*, 53 U. MICH. J.L. REFORM 755, 786–87 (2020) ("The explanation for this remarkable breach of duty is clear: the pharmaceutical industry has succeeded in a multi-decade process of regulatory capture. The industry's success is thanks to its generous campaign contributions, lobbying expenditures, and the revolving door between pharmaceutical management, federal agency leadership, and even congressional leadership.").

206. Even for ambiguous statutes, there is a "best" reading and in "the business of statutory interpretation, if it is not the best, it is not permissible." *Loper Bright*, 603 U.S. at 400 (further explaining that ambiguous statutory language must be interpreted by federal courts, rather than left up to agency construction).

207. Penman & Quigley, *supra* note 147, at 185–86 ("A plain reading of the statute and regulations suggests that 'mere commercialization of the invention is not sufficient to meet a license holder's obligations.'").

208. *See* Nat'l Insts. of Health, Office of the Dir., *In the Case of Xalatan® Manufactured by Pfizer, Inc.* 1 (Sep. 17, 2004), https://www.keionline.org/wp-content/uploads/March-in-xalatan.pdf [https://perma.cc/T42V-BBQW] (finding that there were no grounds for marching in without ever addressing the definition of "reasonable terms"); Nat'l Insts. of Health, Office of the Dir., *In the Case of Norvir® Manufactured by Abbott Laboratories, Inc.* 1 (July 29, 2004), https://www.essentialinventions.org/docs/usa-ritonavir/zerhouni 29jul04.pdf [https://perma.cc/3Z2B-4XHQ] (last visited May 13, 2026) (same); Nat'l Insts. of Health, Office of the Dir., *In the Case of Norvir® Manufactured by AbbVie* 1 (Nov. 1, 2013), https://www.keionline.org/wp-content/uploads/Norvir_NIH_Signed_Determination_1Nov% 202013.pdf [https://perma.cc/4ARM-QH76] (same).

209. *See* Schofield, *supra* note 21, at 779; *see also* F. M. Scherer, *The Political Economy of Patent Policy Reform in the United States*, 7 J. TELECOMM. & HIGH TECH. L. 167, 186 (2009) (discussing the NIH's interpretation: "[t]his seems an unreasonable interpretation of

The NIH's self-conscious articulation of its incompetence in investigating drug pricing is similarly unavailing.[210] The only entity that is statutorily authorized to exercise march-in rights is the funding agency.[211] Moreover, the march-in provision is one of the few protections that Bayh-Dole offers to protect the massive public investments at stake.[212] If "reasonable terms" includes pricing as a matter of statutory interpretation, agencies ought to consider the impact of drug pricing.[213] If the NIH does not feel well equipped to do so, it must take measures to change that.[214] The NIH cannot abdicate its responsibilities because it fears its own authority.

Nevertheless, looking solely at the NIH's past actions, the possibility of the NIH interpreting the march-in provision to include pricing concerns may seem unlikely. However, recent developments signal a change in the tide.

C. RECENT DEVELOPMENTS SUPPORT THE POLITICAL AND TECHNICAL FEASIBILITY OF THIS PROPOSAL

Recent regulatory action by the NIST—an agency authorized to promulgate Bayh-Dole regulations—suggests growing acceptance

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subparagraph (2) above even if not (1), but on such fuzzy constructs, reasonable people can disagree").

210. *See, e.g.*, *In the Case of Xalatan®*, *supra* note 208, at 6 ("The NIH believes that the issue of whether drug pricing should be consistent across the spectrum of developing countries is one that would be more appropriately addressed by Congress, as it considers these matters in a larger context.").

211. Recall that the funding agency is the only entity that *can* enforce the march-in provision. *See* 35 U.S.C. § 203(a) (singularly authorizing the funding agency to determine whether march-in rights should be used).

212. Other protections include the government's retained right to exercise licensing on a federally funded patent if contractors fail to make a timely disclosure. *See* 35 U.S.C. § 202(c)(1) ("[T]he Federal Government may receive title to any subject invention not disclosed to it within such time."). Much like march-in rights, however, federal agencies have never exercised this provision. *See* Abinader, *supra* note 162, at 20 ("When NIH detects possible reporting gaps, the agency apparently gives grantees several opportunities to cure them. The NIH appears to view taking patent ownership as a last-resort remedy, which should be used only when grantees refuse to address invention reporting failures.").

213. Recall that the funding agency is the only entity that *can* enforce the march-in provision. *See* 35 U.S.C. § 203(a) (singularly authorizing the funding agency to determine whether march-in rights should be used).

214. One scholar has argued that the presence of the fact-finding provision itself demonstrates that "the legislature intended that NIH, as the agency responsible for the public health, is the governmental entity best equipped to determine whether to march-in on the patentee's exclusive right." Peter Mikhail, *Hopkins v. CellPro: An Illustration That Patenting and Exclusive Licensing of Fundamental Science Is Not Always in the Public Interest*, 13 HARV. J.L. & TECH. 375, 391 (2000).

for pricing as a trigger for invoking march-in rights.[215] In 2023, the NIST promulgated a final rule related to the march-in provisions that omitted proposed language that would have expressly excluded pricing considerations.[216] In the same year, the NIST released for public comment a second draft regulation, demonstrating its marked change in attitude.[217] This draft regulation repeatedly instructed agencies to consider the reasonableness of pricing, including by comparison to the cost of R&D.[218]

Another recent development demonstrates that agencies are capable of invoking the investigative mechanism embedded in the march-in provision. On August 8, 2025, the Secretary of Commerce, Howard Lutnick, invoked march-in proceedings against Harvard University, initiating an informal consultation by

215. The Secretary of Commerce has delegated authority to the NIST to promulgate "regulations pertaining to the ownership of inventions made with federal funding." *See* POLICY & COORDINATION, NAT'L INST. OF STANDARDS & TECH., https://www.nist.gov/tpo/policy-coordination [https://perma.cc/5W4G-VTZU] (last updated Sep. 12, 2023); *see also* 35 U.S.C. § 206 (authorizing the Secretary of Commerce to promulgate regulations for Bayh-Dole). The draft framework suggests that the Biden administration viewed unreasonable drug pricing as a potential trigger for march-in rights.

216. In 2018, the NIST released a draft "green paper," which proposed explicitly stating in the march-in regulations that the provision should not be used to "control the market price of patented products." Emily G. Blevins & Kevin J. Hickey, CONG. RSCH. SERV., IF12582, PRICING AND MARCH-IN RIGHTS UNDER THE BAYH-DOLE ACT 2 (Dec. 3, 2024). Yet in 2021, when the NIST requested public comment on proposed language to actualize this recommendation, the agency was met with an outpouring of disapproval. *See* Rights to Federally Funded Inventions and Licensing of Government Owned Inventions, 88 Fed. Reg. 17730 (proposed Mar. 24, 2023) (codified at 37 C.F.R. pts. 401 and 404). In the 81,000 comments received, thousands voiced their opposition; as did President Joe Biden in an executive order urging the agency to not include the change, leading up to NIST's 2023 final rule. *Id.*

217. Rights to Federally Funded Inventions, *supra* note 216, at 85598 ("If the contractor or licensee has commercialized the product, but the price[s] . . . at which the product is currently offered to the public are not reasonable, agencies may need to further assess whether march-in is warranted."). This analysis further instructed agencies to consider "factors that unreasonably limit availability of the invention to the public[,]" such as "the reasonableness of the price and other terms at which the product is made available to end-users." *Id.*

218. For instance, the new framework instructed agencies to consider "factors that unreasonably limit availability of the invention to the public," such as "the reasonableness of the price." *Id.* This assessment of pricing, in turn, should reflect "the degree of investment, time, and regulatory requirements needed to bring the product to market," as well as any justification provided by the contractor or licensee. *Id.* at 85599. Perhaps most on point was one of the final questions it included, stating that funding agencies should consider "how [the] price point compares to the cost of developing and manufacturing the [product]." *Id.* at 85603.

letter.[219] This marks the first time any administration has initiated the march-in process, confirming that the fact-finding powers embedded within the march-in provision, and championed by this Note, are both functionally and politically feasible tools.[220]

D. POTENTIAL LEGAL OBJECTIONS TO USING THE MARCH-IN PROVISION'S FACT-FINDING PROCESS

If a funding agency were to act on this proposal, two legal challenges are likely: (i) a violation of the Takings Clause via the Fifth Amendment[221] and (ii) a violation of the Unconstitutional Conditions Doctrine.[222] As outlined below, it is unlikely that either of these challenges would succeed.

1. *Takings Clause*

Given the intensity with which R&D expense data is concealed, it is likely that pharmaceutical companies would contend that R&D expenditures are trade secrets, accordingly protected by the Takings Clause.[223] Determining "whether a taking has occurred is

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219. Image posted by Howard Lutnick (@howardlutnick), X, *Taxpayers deserve the benefit of the bargain. If Harvard won't honor the Bayh-Dole Act, then we will find someone who will* (Aug. 8, 2025), https://x.com/howardlutnick/status/1953967726135063023/photo/1 [https://perma.cc/3AT9-6T8Q]. The image posted by Secretary Lutnick was a letter to the President of Harvard University, Alan Garber. According to the letter, the Department of Commerce initiated the action to address "[f]ailures to comply with the requirements for timely disclosure and election of title . . . [f]ailures to comply with the preference for United States industry . . . and [f]ailures to take effective steps for practical application of subject inventions. . . ." *Id.*

220. Secretary Lutnick's letter demands that Harvard provide "a comprehensive list of all patents it has received stemming from federally funded research grants and [for it to] provide information sufficient to prove its compliance with the Bayh-Dole Act . . . ." *Supra* note 219. This sets a crucial precedent, placing the onus on the patent holder to demonstrate compliance.

221. *See infra* Part III.D.1.

222. *See infra* Part III.D.2.

223. *See* Microbix BioSystems, Inc. v. Biowhittaker, Inc., 172 F. Supp. 2d 665, 679 (D. Md. 2000) (concluding that a "fact finder could reasonably find that the information concerning . . . cost of . . . production is a trade secret"); *see also* EFCO Corp. v. Symons Corp., 219 F.3d 734, 741 (8th Cir. 2000) (finding, through the application of a near identical definition of trade secrets as in *Monsanto*, that the corporation's research and development costs fell within the definition of trade secret). The Takings Clause of the Fifth Amendment states that "private property [shall not] be taken for public use, without just compensation." U.S. CONST. amend. V. According to *Ruckelshaus v. Monsanto*, the only Supreme Court case to ever address an alleged taking of trade secrets, intangible property is protected by the Fifth Amendment, including data that might constitute trade secrets. *See* Pharm. Researchers & Mfrs. of Am. v. Stolfi, 153 F.4th 795, 833 (9th Cir. 2025) (*PhRMA*) (describing *Ruckelshaus v. Monsanto Co.* as the "only Supreme Court case addressing an alleged taking

essentially an ad hoc, factual inquiry."[224] Thus far, federal courts have stated that alleged takings of trade secrets constitute regulatory takings, requiring application of the three-factor *Penn Central* test.[225] In applying *Penn Central*, courts must consider: "(1) the regulation's interference with reasonable investment-backed expectations, (2) the economic impact of the regulation, and (3) the character of the government action."[226] The first factor is extremely important and typically dispositive.[227] A reasonable investment-backed expectation "must be more than a unilateral expectation or an abstract need."[228] In highly regulated industries, furthermore, reasonable expectations are necessarily tempered.[229] Also relevant in this inquiry is whether law or regulation provided notice of the disclosure requirement.[230]

The proposed investigative use of march-in rights to collect granular R&D data would likely survive such a challenge. Since it was promulgated in 1987, the regulatory language pertaining to fact-finding has remained wholly unchanged, despite amendments to the structure and other phrasing.[231] As one court emphasized, the pharmaceutical industry is "unquestionably an industry with a long history of government regulation."[232] Nor has government oversight been limited to health and safety concerns; transparency into R&D costs in particular has garnered sustained attention

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of trade secrets"); *see also id.* at 815–24 ("As a threshold matter, we note that manufacturers have a protectable property interest in their claimed trade secret information to the extent that the information is 'cognizable as a trade-secret property right under [state] law.'" (citing *Ruckelshaus v. Monsanto*, 467 U.S. 986, 1003–04 (1984))); *see also* Vanda Pharm., Inc. v. United States, 174 Fed. Cl. 513, 523 (Fed. Cl. 2025) ("Over forty years ago, the United States Supreme Court expressly extended Fifth Amendment protections to legally recognized trade secrets."); *see also* Gal-Or v. United States, 470 F. App'x 879, 884 (Fed Cir. 2012) ("It is undisputed that trade secrets are protected by the Taking Clause of the Fifth Amendment."). The level of secrecy involved defines the extent of the property right, so "information that is public knowledge or that is generally known in an industry cannot be a trade secret." *Ruckelshaus*, 467 U.S. at 1002.

224. *Ruckelshaus*, 467 U.S. at 1005.

225. *See generally* Penn Cent. Transp. Co. v. City of New York, 438 U.S. 104 (1978). The Ninth Circuit's *PhRMA* is the most recent, on point case available for such an analysis. 153 F.4th 795 (9th Cir. 2025). In *PhRMA*, pharmaceutical manufacturers objected to a state transparency law that required them to disclose information related to drug pricing, including R&D costs. *Id.* at 805–07. Notably, the relevant state agency could also make this data available to the public through an incorporated "public interest" exception. *Id.*

226. *PhRMA*, 153 F.4th at 834 (citing *Penn Cent.*, 438 U.S. at 124).

227. *Id.* at 838.

228. *Id.* at 834.

229. *Id.* at 835.

230. *Id.*; Ruckelshaus v. Monsanto Co., 467 U.S. 986, 990 (1984).

231. *See* 37 C.F.R. § 401.6 (2023) (website tracing amendments).

232. Pharm. Researchers & Mfrs. of Am. v. Stolfi, 153 F.4th 795, 835 (9th Cir. 2025).

from both state and federal legislatures and regulators.[233] Thus, pharmaceutical companies cannot claim to be surprised by a federal agency requesting such data.[234]

Furthermore, inquiries into R&D data are directly related to the purpose for which agency fact-finding is authorized—determining whether the exercise of march-in rights might be warranted.[235] If the march-in provision is triggered through 35 U.S.C. § 203(a)(1), the essential question is whether the pricing of the drug is a "reasonable term," such that the company has achieved "practical application."[236] R&D costs of a particular drug are rationally related, if not essential, to such an analysis, especially given the pharmaceutical industry's frequent claim that R&D investments drive drug pricing.[237] Thus, the regulations and statute provide notice of both the fact-finding authority of agencies and the potential use of it to obtain R&D expenditures.

The voluntary participation of these private entities is also crucial to note.[238] The private sector chose to benefit from the substantial patent opportunities created by Bayh-Dole. Pharmaceutical companies cannot plausibly claim that their investment-backed expectations are disrupted when agencies act pursuant to authority that existed at the time the companies entered the field.[239] In a similar case involving a drug

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233. *See supra* Part II.D.2 (describing multiple state transparency laws that enable inquiry into R&D costs); *see also* Staff of S. Comm. on Fin., *supra* note 12, at 22 (noting that Senate staff requested R&D data for a specific drug multiple times, all of which Gilead ignored).

234. *PhRMA*, 153 F.4th at 835 ("As a starting point, then, manufacturers ought to be aware of the heightened possibility that regulations may be enacted requiring disclosure of the exact type of information that may be commonly claimed as a trade secret under [the transparency law at issue].").

235. 37 C.F.R. § 401.6(a)(1) (2023).

236. 35 U.S.C. § 201(f) (march-in rights are warranted if "the Federal agency determines action is necessary because the contractor or assignee has not taken . . . effective steps to achieve practical application of the subject invention"); *see also* 35 U.S.C. § 203(a)(1) ("The term 'practical application' means to . . . establish that the invention is being utilized and that its benefits are . . . available to the public on reasonable terms.").

237. *See supra* Part II.A.

238. *See* Bristol Myers Squibb Co. v. Sec'y, 2025 WL 2537005, at *4 (3d Cir. Sep. 4, 2025).

239. Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1006–07 (1984) ("[Monsanto] can hardly argue that its reasonable investment-backed expectations are disturbed when EPA acts to use or disclose the data in a manner that was authorized by law at the time of the submission."). One could point to the historical disuse of the march-in provision, at least on the basis of pricing concerns, to suggest that this materially affected the industry's reasonable expectations. However, lack of precedent does not change the clear language of the regulations and statute delineating march-in proceedings, which demonstrate at a minimum that agency fact-finding would be a possibility.

transparency disclosure law, a court applying this analysis found that there was not a regulatory taking, even though it allowed public visibility of the collected data.[240] The far less disruptive, and entirely confidential, fact-finding endeavor envisioned above is thus likely to survive a Takings Clause challenge.[241]

2. *Unconstitutional Conditions Doctrine*

The Unconstitutional Conditions Doctrine forbids the government from "deny[ing] a benefit to a person on a basis that infringes his constitutionally protected interests."[242] A funding agency's investigation into the cost of R&D would be a natural component of a broader inquiry into the reasonableness of drug pricing. Nonetheless, affected companies could argue that such requests implicitly and impermissibly condition the continued benefit of the Bayh-Dole patent and/or the lack of march-in proceedings on the compelled provision of R&D data, violating their right to free speech.[243] Applying the Unconstitutional Conditions Doctrine in this context requires assessing whether the disclosure of R&D data would infringe on First Amendment doctrine.

First Amendment challenges are analyzed by first determining the type of speech at stake and the appropriate tier of scrutiny.[244] The agency action described above would likely be categorized as a government reporting requirement,[245] and the regulated speech

240. Pharm. Researchers & Mfrs. of Am. v. Stolfi, 153 F.4th 795, 805–07 (9th Cir. 2025) (explaining that the relevant state agency could also make the contested data available to the public through an incorporated "public interest exception").

241. 37 C.F.R. § 401.6(a)(4) (2023).

242. Perry v. Sindermann, 408 U.S. 593, 597 (1972) ("For at least a quarter-century, this Court has made clear that even though a person has no 'right' to a valuable governmental benefit and even though the government may deny him the benefit for any number of reasons, there are some reasons upon which the government may not rely.").

243. *PhRMA*, 153 F.4th at 810 ("Laws that require disclosures of information . . . are subject to First Amendment scrutiny.").

244. *See* DoorDash, Inc. v. City of New York, 789 F. Supp. 3d 337, 353 (S.D.N.Y. 2025) (explaining that because not all speech is entitled to equal importance, "the Court first considers the 'genre of speech involved'" (citation omitted)); *see also* Imperial Sovereign Ct. of Mont. v. Knudsen, 170 F.4th 820, 845 (9th Cir. 2026) (explaining that there are "longstanding and myriad precedents setting forth the tiered scrutiny analysis [that courts] . . . apply to a . . . claim challenging a law on the ground that it is an unconstitutional content-based restriction on speech.").

245. This is because it is akin to the many other "statutes and regulations that require regulated entities and individuals to report information to a government agency." *PhRMA*, 153 F.4th at 809.

would constitute commercial speech.[246] To the extent an agency's requests for R&D data urge companies "to speak a particular message," a court may also construe this as a content-based regulation of speech.[247] Content-based regulations compelling speech are typically presumptively unconstitutional, but a key exception applies for government disclosure requirements: *Zauderer* deferential review.[248] *Zauderer* held that such laws may survive First Amendment scrutiny so long as (i) the compelled information is purely factual and uncontroversial; (ii) the requirement is reasonably related to the government's interest; and (iii) the requirement is not unjustified or unduly burdensome.[249]

March-in based fact-finding is likely to satisfy these criteria. Regarding the first factor, agency inquiries into drug-specific R&D data would call upon concrete numerical figures—factual by definition.[250] Although such accounts could be controversial, the confidentiality mandated by the march-in regulations renders this point moot.[251] As for the second factor, drug-specific R&D data is

246. This is because the requested information would "communicate product-specific economic information." Pharm. Researchers & Mfrs. of Am. v. Stolfi, 153 F.4th 795, 819 (9th Cir. 2025).

247. Nat'l Inst. of Fam. & Life Advocs. v. Becerra, 585 U.S. 755, 766 (2018) ("The licensed notice is a content-based regulation of speech. By compelling individuals to speak a particular message, such notices 'alte[r] the content of [their] speech.'" (citation omitted)).

248. *See* Zauderer v. Off. of Disciplinary Couns., 471 U.S. 626, 651 (1985) (holding that disclosure requirements compelling "purely factual and uncontroversial information" in commercial speech survive First Amendment scrutiny if reasonably related to the government's interest and not unjustified or unduly burdensome); *see also Becerra*, 585 U.S. at 768–69, 776 (offering a more recent articulation of the *Zauderer* standard).

249. *See Zauderer*, 471 U.S. at 651 (articulating the three requirements for a lower level of scrutiny). In creating this standard, the Court reasoned that "constitutionally protected interest[s] in not providing any particular factual information . . . is minimal" and that "disclosure requirements tread much more narrowly on . . . [one's] interests than do flat prohibitions on speech").

250. *See, e.g.*, Hercules, Inc. v. E.P.A., 598 F.2d 91, 109–10 (D.C. Cir. 1978) (explicitly labeling the agency's work producing quantitative discharge limits as "EPA's factual determinations leading to the numerical standard," treating the underlying numerical inquiry as a factual matter subject to deferential review rather than independent judicial recalculation); *see also* Settling Devotional Claimants v. Copyright Royalty, 797 F.3d 1106, 1121 (D.C. Cir. 2015) (holding that "[a]n agency's choice of a particular number or percentage is not reviewable for exact precision, but simply for broad reasonableness"—a further signal that numerical agency determinations occupy the domain of fact, not law).

251. *See* 37 C.F.R. § 401.6(a)(4) (2023) ("[A]gencies shall not disclose any such information obtained during a march-in proceeding to persons outside the government. . . ."). In the original articulation of the uncontroversial requirement, the Court was faced with a disclosure law that would make such data publicly available. *Zauderer*, 471 U.S. at 651 (establishing an uncontroversial requirement in the context of advertising). This constitutes a constitutional violation even under *Zauderer* because it

not merely reasonably related to the government's interests—it is essential.[252] The absence of this information weakens desperately needed regulatory solutions and renders it nearly impossible for regulators to quantitatively assess the impact of pricing regulation on innovation.[253] Lastly, access to this information would conversely strengthen regulatory solutions, offering an adequate justification against the backdrop of exorbitant drug prices.[254] Nor could companies plausibly claim that disclosure of such figures is unduly burdensome when there is abundant evidence that this data is within their grasp.[255]

CONCLUSION

"There is no moral price. There is no moral amount of profit . . . . Their job is to make a profit. It is actually against the law for them not to maximize their profit." This statement, offered by Senator Rand Paul of Kentucky in defense of rising drug prices during a congressional hearing, reflects a central tension

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essentially forces companies to "publicly condemn" themselves. *See* Nat'l Assoc. of Mfrs. v. S.E.C., 800 F.3d 518, 530 (D.C. Cir. 2015) ("Requiring a company to publicly condemn itself is undoubtedly a more 'effective' way for the government to stigmatize and shape behavior than for the government to have to convey its views itself, but that makes the requirement more constitutionally offensive, not less so." (citation omitted)). Where the sole audience is federal regulators, thereby removing the potential impact on commerciality, contentiousness calculations must change.

252. *See supra* Part II.A.

253. Borrowing again from *PhRMA*, this interest is not "transparency for its own sake" but critically connected to the "significant informational asymmetries" that characterize the pharmaceutical drug market and which the "State has a substantial interest in reducing." Pharm. Researchers & Mfrs. of Am. v. Stolfi, 153 F.4th 795, 823 (9th Cir. 2025). That the government is a "direct purchaser of pharmaceutical drugs and a major payer in the health care system" makes this "particularly true." *Id.* Furthermore, this data would allow regulators to assess relative contributions to drug development, crucial for understanding the impact of pricing regulations on innovation because it elucidates how the burdens of innovations have been shouldered.

254. *See* MSF Access Campaign, *supra* note 116 ("Without full transparency of R&D costs from drug developers, it is not possible to determine the true costs of each stage of the R&D process for each drug, the total R&D cost, and which of these costs are related to clinical trials.").

255. As Florida State University Law Professor Frederick M. Abbott has described, it shouldn't be impossible to put a number on the R&D costs of any given drug. *See* Abbott, *supra* note 14, at 281. These companies are businesses like any other; they must have budgets and financial projections. The very risk-assessments toted in arguments about rising prices reveal that individual companies have the kind of accounting sought after in this proposed fact-finding endeavor. *See id.* at 303; *see also* DiMasi et al. (2016), *supra* note 13, at 22.

underlying modern drug pricing debates.[256] Patents grant exclusionary rights precisely so private actors may reap monopoly profits sufficient to incentivize innovation.[257] Yet this rationale collides with the human right to health, which demands access to the very life-saving medicines that patents render inaccessible.[258] These competing regimes are tolerated because intellectual property law is presumed to produce a greater social good—continuous medical innovation.[259] But that justification cannot be limitless. There may not be a moral price, but there is certainly a functionally effective one.

Federal regulators cannot meaningfully evaluate the relationship between innovation, public investment, and drug pricing while remaining blind to the actual costs of pharmaceutical R&D. This Note demonstrates that Bayh-Dole's march-in framework offers a viable mechanism for addressing this problem. The Act's investigative procedures equip funding agencies with the authority necessary to obtain drug-specific R&D expenditures within broader inquiries into the reasonableness of pharmaceutical pricing.[260] Leveraging this fact-finding authority

256. Congressional Hearing 2024, *supra* note 18, at 80–85 (statement of Sen. Rand Paul).

257. *See* 128 CONG. REC. H6983 (daily ed. Sep. 15, 1982) (statement of Rep. Waxman) ("A patent is a monopoly, and when anyone holds a monopoly that person has the ability or that company has the ability to charge the highest price because there is no one else in competition, and as a matter of public policy we, under the patent law, give that protection to the person who has put money into research and development for an innovative and new product."); *see also* Hickey & Ward, *supra* note 9 ("Patents are typically justified by a utilitarian rationale that exclusive rights are necessary to provide incentives to produce new creative works and technological inventions.").

258. *See* Jennifer Anna Sellin, *Does One Size Fit All? Patents, the Right to Health, and Access to Medicines*, 62 NETH. INT'L. L. REV. 445, 448 (2014) (explaining how the use of patent protection in the pharmaceutical field is paradoxical); *see also* Govind Persad, *Examining Pharmaceutical Exceptionalism: Intellectual Property, Practical Expediency, and Global Health*, 18 YALE J. HEALTH POL'Y, L. & ETHICS 157, 161–62 (2019) (discussing the United Nations Secretary-General's 2016 High Level Panel on Access to Medicines, debating whether international intellectual property rights agreements conflicted with the human right to health and access to life-saving medication).

259. *See* Krishna Frkovic, *Intellectual Property Rights as a Barrier for Developing Countries to Access a Covid-19 Vaccine*, 26 MARQ. INTELL. PROP. & INNOVATION L. REV. 47, 58 (2022) (citing U.N. Comm. on Econ., Soc. & Cultural Rights, *General Comment No. 14: The Right to the Highest Attainable Standard of Health*, U.N. Doc. E/C.12/2000/4 (Aug. 11, 2000)) (describing the coexistence theory, which "asserts that patent law and human rights law are distinct but share a basic concern in defining the optimal amount of patent protection required to incentivize and practice socially useful innovation").

260. *See* 37 C.F.R. § 401.6 (2023) (listing the march-in regulations); *see also supra* Part III.A (explaining how to leverage march-in procedures as a mechanism for R&D fact-finding).

would furnish regulators with the concrete data necessary to develop evidence-based pricing benchmarks, quantitatively assess claims about innovation, and better protect the public's stake in federally funded inventions. At minimum, the public should not be forced to accept assertions about the necessity of exorbitant drug prices on faith alone. Americans have been navigating the pharmaceutical realm at an informational handicap for far too long. It is time to level the playing field.