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Article

What We Are Owed

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Historically, the United States has been the largest public funder of biomedical innovation in the world, yet public contributions to drug research and development ("R&D") do not necessarily translate into affordable medications. The Inflation Reduction Act presents an opportunity to reconsider the relationship between public funding and public returns by requiring the consideration of federal funding as a factor in the Medicare Drug Price Negotiation Program ("MDPNP"). However, neither the statute nor agency guidance articulate clear normative principles for what the public is owed based on our contributions to drug R&D. This Article makes two key contributions. First, it offers an original scholarly analysis of the MDPNP's "prior Federal financial support" factor, critically examining the Program's treatment of federal funding in fair drug pricing. Second, it evaluates a range of fairness principles and argues that policymakers should explore a principle of proportionality as the default for allocating benefits from public contributions to drug R&D. By establishing a default in favor of proportional fairness, this approach ensures that public returns are meaningfully aligned with public contributions, flexibility is maintained to protect biomedical innovation, public confidence in institutions can be bolstered, and what we—the public—are owed is better secured. This Article charts a path toward a more equitable and accountable recognition of public contributions to privatized medical innovations within existing agency authority.

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INTRODUCTION

Historically, the United States has been the largest public funder of biomedical innovation in the world,[1] playing an important role in the development of many therapies.[2] Public financing of COVID-19 vaccines, estimated at nearly $32 *billion*,[3] is perhaps the most prominent recent example. Yet, public funding of drug research and development ("R&D") extends far beyond the pandemic. Studies have shown that "[e]very new drug marketed in the U.S. from 2010 to 2016 was related to some previous National Institutes of Health (NIH) supported research, and a quarter of new drugs are linked to late stage public funding through an academic research center or one of its private spin-off companies."[4] Public funding of life-changing drugs is pervasive and can often be substantial.

Yet, public funding does not ensure that the public has access to these interventions at an affordable, or even reasonable price.[5] This disconnect has fueled perennial debates about the pricing of drugs with privatized public

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[1] *Grants & Funding*, NAT'L INST. HEALTH, https://www.nih.gov/grants-funding (last visited Sept. 17, 2025).

[2] *See, e.g.*, Hussain S. Lalani, Sarosh Nagar, Ameet Sarpatwari, Rachel E. Barenie, Jerry Avorn, Benjamin N. Rome & Aaron S. Kesselheim, *US Public Investment in Development of mRNA Covid-19 Vaccines: Retrospective Cohort Study*, 380 BMJ 1, 5–6 (2023) [hereinafter *US Investment in Covid-19 Vaccines*] (concluding that government investment in mRNA vaccines saved millions of lives and noting other areas of significant public investment).

[3] *Id.* at 1.

[4] *Id.* (citing studies including Ekaterina Galkina Cleary, Jennifer M. Beierlein, Navleen Surjit Khanuja, Laura M. McNamee & Fred D. Ledley, *Contribution of NIH Funding to New Drug Approvals 2010–2016*, 115 PROC. NAT'L ACAD. SCI. U.S.A. 2329, 2329–30 (2018) and Rahul K. Nayak, Jerry Avorn & Aaron S. Kesselheim, *Public Sector Financial Support for Late Stage Discovery of New Drugs in the United States: Cohort Study*, 367 BMJ 1, 1 (2019).

[5] *See, e.g.*, STAFF OF S. HEALTH, EDUC., LAB., & PENSIONS COMM., 118TH CONG., PUBLIC INVESTMENT, PRIVATE GREED (Comm. Print 2023), https://www.sanders.senate.gov/wp-content/uploads/Public-Medicines-Report-6.9.23.pdf (explaining that pharmaceutical companies sell drugs to U.S. consumers at exorbinant prices despite being funded by taxpayers).

support.[6] From controversy over the "Moderna" vaccine[7] to inaccessible HIV medications[8] and outrage over expensive cancer treatments,[9] there is widespread moral criticism that drug prices[10] are too high given public contributions. This critique is often framed in terms of the public "'paying twice'—first, for the research and, second, through the above-market pricing of resulting privatized products."[11] Such criticisms have been made by those in nonprofit organizations, in academia, and in government.[12] This longstanding ethical outrage, however, has not yet found either its reflection or its effective redress in the law. With a few exceptions, federal public support for drug R&D historically has been of little legal or practical consequence for ensuring fair pricing of government-supported drugs.[13]

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[6] *See, e.g.*, Bhaven N. Sampat, *Whose Drugs Are These?*, 36 ISSUES SCI. & TECH. 42, 42–43, 48 (2020) (describing the history of the debate about government support of drug innovation and ongoing concerns regarding drug pricing); *see generally* Rebecca E. Wolitz, *The Pay-Twice Critique, Government Funding, and Reasonable Pricing Clauses*, 39 J. LEGAL MED. 177 (2019) [hereinafter Wolitz, *The Pay-Twice Critique*] (analyzing the "pay-twice" critique of government-subsidized research and development of prescription medications); Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1663–66 (1996) (outlining the history of legislative policy towards patenting of government-sponsored research and noting the implication of potentially "paying-twice").

[7] *Key Facts Senators Need to Know Before the Moderna Hearing*, PUB. CITIZEN (Mar. 10, 2023), https://www.citizen.org/article/key-facts-senators-need-to-know-before-the-moderna-hearing.

[8] Wolitz, *The Pay-Twice Critique*, *supra* note 6, at 193–94.

[9] Julie Steenhuysen, Ahmed Aboulenein & Aditya Samal, *US Declines to Force Lower Price on Cancer Drug Xtandi*, REUTERS (Mar. 22, 2023, 1:29 PM), https://www.reuters.com/business/healthcare-pharmaceuticals/us-declines-force-lower-price-cancer-drug-xtandi-2023-03-21.

[10] Drug "prices" of course are not uniform in reference. Among other nuances, there is a difference between prices paid by patients—their out-of-pocket costs—and prices received by drug manufacturers.

[11] Wolitz, *The Pay-Twice Critique, supra* note 6, at 178.

[12] Robert Pear, *'Paying Twice': A Push for Affordable Prices for Taxpayer-Funded Drugs*, N.Y. TIMES (May 28, 2018), https://www.nytimes.com/2018/05/28/us/politics/drug-prices.html (noting views of those in academia and government); Peter Maybarduk, *Paying Twice for a Vaccine: Moderna is Taking Taxpayers for a Ride*, PUB. CITIZEN (Aug. 5, 2020), https://www.citizen.org/news/paying-twice-for-a-vaccine-moderna-is-taking-taxpayers-for-a-ride; Press Release, Bernie Sanders, Senator for Vermont, NEWS: New Report Shows How Badly Big Pharma is Ripping Off American People With Publicly Funded Medications (June 12, 2023), https://www.sanders.senate.gov/press-releases/news-new-report-shows-how-badly-big-pharma-is-ripping-off-american-people-with-publicly-funded-medications.

[13] As a result, over the years, proposals for reform have proliferated. *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 (2001) (discussing Bayh-Dole march-in provisions); Travis Whitfill & Mariana Mazzucato, *Offer Taxpayers a Fairer Shake*, 39 ISSUES SCI. & TECH. 51 (2023) (arguing for reasonable pricing clauses, an equity model, and requirements to reinvest in research); Charles Silver & David A. Hyman, *Pharmaceutical Pricing When Success Has Many Parents*, 37 YALE J. ON REG. 855, 879 (2020) (advocating for royalties as reflecting the "obvious solution" should "the government want[] a better deal"); MARIANA MAZZUCATO, HEIDI CHOW, SAOIRSE FITZPATRICK, ANDREA LAPLANE, TIZIANA MASINI, DIARMAID MCDONALD, VICTOR ROY & ELLEN 'T HOEN, UCL INST. FOR INNOVATION & PUB. PURPOSE, THE PEOPLE'S PRESCRIPTION: RE-IMAGINING HEALTH INNOVATION TO DELIVER PUBLIC VALUE 8–9 (2018) [hereinafter THE PEOPLE'S PRESCRIPTION] (arguing for several interventions). Other approaches—like increasing direct government research or nationalizing drug development—aim to avoid these thorny issues entirely. *See, e.g.*, Paul Sorum, Christopher Stein, Danielle Wales & David Pratt, *A Proposal to Increase Value and Equity in the Development and Distribution of New Pharmaceuticals*, 52 INT'L J. HEALTH SERVS. 363 (2022) (proposing increased direct

The Inflation Reduction Act's ("IRA") Medicare Drug Price Negotiation Program ("MDPNP," or the "Program")[14] marks a change in this entrenched legal neglect and offers the possibility of revisiting existing relationships between public funding and public return. The culmination of decades of advocacy for fairer drug pricing writ large, the IRA mandates (among other requirements) that the Centers for Medicare & Medicaid Services ("CMS") must consider a drug's "prior Federal financial support" when evaluating fair pricing within the MDPNP.[15] The IRA thus provides, not only undeniable statutory *recognition* of a link between federal funding for drug R&D and the fairness of that drug's pricing, but agency authority to *act* on that link in defining what constitutes a fair price. This recognition and grant of agency authority are both significant and promising.

Though the MDPNP is a much-needed step in the right direction for tackling the high prices of prescription medications, regardless of funding source, focusing on this constituent component of federal funding exposes an underlying theoretical vulnerability. CMS's authority is broad, but its consideration of the specific factor of federal support appears to be not yet grounded in an obvious normative principle. The statutory text and subsequent agency guidance offer limited insight into how the agency *is* conceptualizing the significance of public contributions—let alone how the significance of public support *should* be conceptualized. This issue is both critical for the implementation of this new statutory framework and transcends it.

What, precisely, are we—the public—owed when it comes to the allocation of benefits derived from drugs researched and developed with public support? Although a general sense that the public is being treated unfairly permeates public discourse, the precise nature of this alleged wrong demands investigation and definition. Policymakers need a systematic, normative approach that will advance efforts to answer foundational questions of fairness in a principled way.

This Article gains traction on this timely yet longstanding issue by making two significant contributions to the literature. First, as the MDPNP is new, there is an important opportunity to shape its evolution. This Article provides a scholarly analysis of the factor of federal funding within the

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government involvement in drug development and distribution through new agency); Ameet Sarpatwari, Jerry Avorn & Aaron S. Kesselheim, *Accounting for US Public Funding in Drug Development: How Can We Better Balance Access, Affordability, and Innovation?*, 371 BMJ 1 (2020) (advocating for direct government involvement in drug development); Ameet Sarpatwari, Dana Brown & Aaron S. Kesselheim, *Development of a National Public Pharmaceutical Research and Development Institute*, 47 J. L. MED. & ETHICS 225 (2019) (proposing a "national public pharmaceutical R&D institute"); Mariana Mazzucato, Henry Lishi Li & Ara Darzi, *Is It Time to Nationalise the Pharmaceutical Industry?*, 368 BMJ 1 (2020) (arguing that a greater role for state ownership in the pharmaceutical industry would serve public interests).

[14] Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1818, 1833–64, § 11001–11004 (2022) (Medicare drug price negotiation provisions).

[15] 42 U.S.C.A. § 1320f-3(e)(1)(C) (Westlaw through Pub. L. 119-36).

MDPNP. This analysis reveals that, while CMS enjoys broad authority to account for federal support in the pricing of selected drugs, much about its approach is presently opaque. Neither the statutory framework nor agency guidance offers a clear, normative vision for how this factor should be systematically interpreted or applied.

This omission leaves a significant theoretical gap which presents an opportunity for normative and policy experimentation. The Program's application to a small number of drugs, constrained focus on drug-pricing, and ex post interventions suggest that the MDPNP is ill-suited to serve as the primary vehicle for addressing broader fairness concerns related to public investment. Nevertheless, even if it cannot fully resolve questions of a fair return on public investment, the MDPNP can play a meaningful role in clarifying what kinds of public contributions ought to matter and why. This Article argues that by drawing on a principle of proportionality—roughly, the idea that the benefits one receives from a joint endeavor ought to be calibrated to what one contributes—CMS could strengthen the transparency and legitimacy of its implementation of the federal funding factor. In so doing, it could further help develop tools and practices for informing more systematic approaches of utility beyond the MDPNP. Thus, consideration of federal funding within the MDPNP offers critical initial steps—as both a proof of concept and a backstop—toward a broader rethinking of how to ensure that the public is treated fairly, given its contributions to drug R&D.

This Article's second main contribution in arriving at a principle of proportionality is its effort to move beyond the contingencies of current law and offer a more enduring theoretical analysis. In the abstract, a well-designed framework for drug development and distribution should strive to optimize for three goals.[16] First, it should promote the creation of as many "new, clinically valuable, safe, and effective medications" as possible.[17] Second, it should facilitate the widespread "dissemination of those drugs to all who need and want them."[18] Third, the pursuit of these first two goals should be subject to a constraint of fairness.[19] Ideally, we would have effective and safe treatments or preventives for every human ailment, those interventions would be widely accessible, and the ways by which we achieve innovation and access would be fair.[20] Within this broader normative scheme, concerns about what the public is owed in return for its contributions to drug R&D can be framed as one dimension of this fairness

[16] Rebecca E. Wolitz, Drug Manufacturers, Pricing, and Ethical Obligations 215 (Dec. 2021) (Ph.D. dissertation, Yale University), https://elischolar.library.yale.edu/cgi/viewcontent.cgi?article=1440&context=gsas_dissertations [hereinafter Wolitz, Drug Manufacturers].

[17] *Id.*

[18] *Id.*

[19] *Id.*

[20] *Id.*

constraint. Not just any conduct in the development of new drugs is morally permissible, and both instrumental and intrinsic reasons support treating the recognition and reward of public contributions as an issue of fairness—one that deserves serious scholarly and political attention.

Concerns of fairness are not merely theoretical. They not only bear on who has access to medicines on what terms, but further the integrity of our institutions. Whether ultimately found to be credible or perceived, allegations of unfairness to the public are disregarded at risk. The public's investment in biomedical research is under unprecedented attack.[21] While recent proposals to restructure or reduce NIH's budget stem from a range of motivations—many ideologically driven—they echo broader themes central to debates about drug pricing and a fair allocation of returns on public investment. In his testimony on the President's Fiscal Year 2026 Budget, the Secretary of Health and Human Services, Robert Kennedy Jr., repeatedly emphasized the need for "accountability" and "restoring . . . public trust," particularly at NIH.[22] "Americans need to trust that we are good stewards of the dollars they give us."[23] That trust presumably extends to a good faith willingness to engage directly with concerns about whether the public receives a fair share of rewards from its contributions to drug R&D. *Even if* the existing system ultimately *is* fair, dismissing these concerns risks deepening public skepticism. By contrast, acknowledging and addressing such concerns in an accountable, transparent, and morally-justified manner may bolster confidence in public research institutions at this critical juncture.

What, however, does it mean for the public to be treated fairly in this context? Moral debate surrounding a fair allocation of benefits from government-supported medications requires theoretical development. This Article seeks not only to articulate and make explicit the sometimes implicit principles undergirding complaints of unfairness regarding government-supported medications, but also to subject them to scrutiny. It aims to uncover whether there is a principle which ought to be taken seriously, and, if so, how policymakers might employ a more systematic and workable moral approach.

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[21] *See, e.g.*, Jonathan Wosen, *Senators Push Back on Trump's Proposed $18 Billion NIH Budget Cut*, STAT+ (June 10, 2025), https://www.statnews.com/2025/06/10/nih-senators-push-back-on-2026-trump-budget-jay-bhattacharya (discussing proposed dramatic funding cuts of nearly 40%).

[22] *HHS Testimony on the President's Fiscal Year 2026 Budget Before the Subcomm. on Health of the H. Comm. on Energy & Com.*, 119th Cong. (June 24, 2025), https://www.hhs.gov/about/agencies/asl/testimony/2025/06/24/the-presidents-fiscal-year-2026-budget.html (statement of Robert F. Kennedy, Jr., Secretary, U.S. Dept. of Health & Hum. Servs.).

[23] *Id.* Notably, the Biden Administration was also concerned with themes of restoring public trust in HHS. *See, e.g.*, Dan Diamond, *'I Can't Go Toe to Toe with Social Media.' Top U.S. Health Official Reflects, Regrets*, WASH. POST (Jan. 13, 2025), https://www.washingtonpost.com/health/2025/01/12/xavier-becerra-hhs-secretary (identifying social media as a challenge to restoring public trust in the public health agencies).

Fairness is a "big tent,"[24] and this Article argues that there are at least three categories of unfairness alleged in the current allocation of benefits from government-supported medications. These are unfairness pertaining to: (1) the failed discharge of government obligations; (2) the high prices paid for publicly funded medications in the U.S., compared with prices paid in other high-income countries; and (3) substantive defects in the transactional terms of the relationships between the federal government and private drug manufacturers. Teasing apart these analytically discrete strands clarifies that the essential complaint of unfairness centers on the third category. The key question, then, is how to conceptualize what renders an allocation of benefits unfair in this context.

This Article argues that policymakers should explore grounding a determination of a fair return on public investments in a principle of proportionality. This principle should be utilized as an initial default. Establishing a *default* in favor of proportional fairness maintains flexibility by permitting deviations while demonstrating respect for treating all parties fairly. It further provides a forcing function to improve transparency and accountability surrounding public contributions to drug R&D.

Before proceeding, however, an important clarification is in order. Focusing on the linkage between public funding and fairness in drug pricing or other public returns does *not* imply that concerns about drug pricing arise *only* when the government has contributed to a drug's development. Fair pricing matters regardless of a drug's funding lineage, and public funding is unlikely to be the sole criterion by which fair pricing should be assessed. This inquiry instead isolates one prevalent and intuitive concern: that something feels *distinctly* unfair when a drug is very expensive, yet the public helped pay for its creation. The aim is to take this fairness intuition seriously and evaluate what, if anything, morally follows. Thus, this narrower inquiry should not be understood as rejecting broader efforts to regulate or negotiate drug prices more comprehensively—for example, by expanding the reach of the MDPNP within Medicare or beyond. If anything, greater attention to fairness in the context of publicly funded drugs may encourage increased reflection on these issues more generally.

This Article deepens ongoing debates about an appropriate return on public investments and the implications of public funding for the pricing of biomedical innovations. It proceeds in four parts. Part I examines the pervasive ways in which public funding supports biomedical R&D and the general historical insignificance as a legal matter of public funding for drug pricing and accessibility. Part II then turns to the new and evolving real-world opportunity for U.S. government officials to account for the moral significance of public support through the MDPNP. It analyzes the

[24] *See, e.g.*, Wolitz, Drug Manufacturers, *supra* note 16, at 149 ("This sampling of allegations demonstrates that 'unfairness' is a big tent.").

Program's federal funding factor. Moving beyond the specifics of this statutory scheme, Part III undertakes a broader inquiry into claims of unfairness regarding the pricing of publicly supported medications. This Part identifies and analyzes three overarching moral concerns: government entitlements, comparative unfairness with foreign payers, and transactional fairness. It lays the groundwork for organizing an approach around a principle of proportionality. Part IV proposes that policymakers explore a principle of proportionality as the moral, and therefore legal, default for evaluating fairness in the allocation of benefits from publicly supported medications. This analysis concludes with tentative recommendations for determining relevant contributions, relevant outputs, the form that government returns on investment should take, and institutional questions with which policymakers will need to grapple—before circling back to how a principle of proportionality might ultimately fit within the MDPNP.

I. THE PRIVATIZATION OF PUBLIC FUNDING

This Part provides a brief overview of sources of federal public support for drug R&D followed by an analysis of this funding's legal bearing on considerations of fair drug pricing.

A. *Sources and Typology of Federal Public Support for Drug R&D*

To better understand the normative significance—if any—of public funding for drug pricing policymaking, it is first important to better understand where public funding comes from and the forms which it takes. Public funding—meaning government funding—for drug R&D is provided by both states and the federal government.[25] Most commonly, however, controversies about U.S. drug pricing and public funding center on federal public funding. Several federal agencies support biomedical research and consequently drug R&D. Within the Department of Defense, for instance, the Army has been involved in vaccine development for both the Zika and COVID-19 viruses.[26] Discussions of federal funding, however, most often

[25] *See, e.g.*, *Frequently Asked Questions (FAQs)*, CAL. INST. FOR REGENERATIVE MED., https://www.cirm.ca.gov/about-cirm/cirm-faq (last visited Nov. 3, 2024) (stating that $3 billion in funding was granted for stem cell research upon the passing of Propositino 71 in 2004); *Making Prescription Drugs More Affordable for Californians*, CALRX, https://calrx.ca.gov (last visited Nov. 3, 2024) (noting California's investment in developing biosimilar insulin); *Budget*, NAT'L INST. OF HEALTH, https://www.nih.gov/about-nih/organization/budget (last visited Sept. 17, 2025) (noting NIH's overall budget, not specifically that associated with drug R&D).

[26] *See, e.g.*, Letter from Richard J. Durbin, Sherrod Brown, Bernard Sanders, Richard Blumenthal, Edward J. Markey & Angus S. King, Jr., U.S. Sens., to Robert M. Speer, Acting Sec'y., U.S. Army (June 26, 2017), https://www.keionline.org/wp-content/uploads/Senate-Letter-to-Army-re-Zika-Vaccine-Sanofi.pdf ("[T]he U.S. Army—in collaboration with the [NIH]—spearheaded efforts to research and develop a Zika vaccine."); Walter Reed Army Inst. of Rsch., *Preclinical Studies Support Army's Pan–Coronavirus Vaccine Development Strategy*, U.S. ARMY (Dec. 16, 2021), https://www.army.mil/article/252890/preclinical_studies_support_armys_pan_coronavirus_vaccine_development_strategy (discussing the results of a U.S. Army preclinical study for a COVID-19 vaccine).

focus on the National Institutes of Health (NIH). Though the future of NIH funding has been uncertain,[27] with an annual budget of nearly $48 billion,[28] the NIH historically has been "the largest public funder of biomedical research in the world."[29]

The NIH's knowledge-based mission is "to enhance health, lengthen life, and reduce illness and disability."[30] It supports eventual drug R&D through a variety of mechanisms. Of its annual $48 billion in funding, the NIH allocates approximately eleven percent to in-house research conducted by NIH scientists.[31] This knowledge production is disseminated through scientific publications and various agreements to share intellectual property.[32] The majority of the NIH's budget, however—eighty-two percent—is devoted to extramural research, meaning research occurring outside of the NIH.[33] The NIH has primarily supported extramural research through direct grants to outside researchers and institutions.[34] Grants support a range of activities from constructing new research facilities[35] to supporting new scientists and clinical trials.[36] The level of involvement by the NIH and its scientists varies across awards. For awards involving "cooperative agreements," for instance, "NIH staff provide oversight, coordination, or facilitation that goes substantially beyond what would normally be needed . . . ."[37] The NIH also supports drug R&D through other mechanisms, including material transfer agreements and cooperative research and development agreements ("CRADAs").[38] Under a CRADA, for example, the federal government can contribute non-financial resources to collaborate with an outside party, who may contribute resources, including funding.[39]

Congress further supports drug R&D through tax incentives. Scholars highlight three as being or having been the most important for drug R&D. These are: (1) a tax credit for increasing research activities; (2) the ability to write off certain R&D costs immediately; and (3) the orphan drug tax credit,

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[27] *See, e.g.*, Wosen, *supra* note 21.

[28] *Budget*, *supra* note 25.

[29] *Grants & Funding*, *supra* note 1 (basing the claim on the FY 2022 $45B budget).

[30] *Mission and Goals*, NAT'L INST. OF HEALTH, https://www.nih.gov/about-nih/mission-goals (last visited Sept. 17, 2025) [hereinafter *NIH Mission and Goals*].

[31] *Budget*, *supra* note 25.

[32] *See, e.g.*, *Research Tools Policy*, NAT'L INST. OF HEALTH, https://grants.nih.gov/policy-and-compliance/policy-topics/sharing-policies/other/research-tools (last visited Sept. 17, 2025) (explaining principles and guidelines for appropriate dissemination by funding recipients).

[33] *Budget*, *supra* note 25.

[34] *Id.*

[35] *See Activity Codes*, NAT'L INST. OF HEALTH, https://grants.nih.gov/funding/activity-codes (last visited Nov. 6, 2024) (including a funding category, C06, titled "Construction and Modernization" providing federal funds for construction of new research facilities).

[36] *See, e.g.*, *id.* (illustrating funding categories for new scientists at K01 and new clinical trials at R34).

[37] *Cooperative Agreements (U)*, NAT'L INST. OF ALLERGY & INFECTIOUS DISEASES, NIH, https://www.niaid.nih.gov/grants-contracts/cooperative-agreements (last visited Nov. 3, 2024).

[38] *CRADA & MTA FAQs*, NAT'L INST. OF HEALTH, https://www.techtransfer.nih.gov/faqs/crada-mta-faqs (last visited Nov. 3, 2024).

[39] 15 U.S.C. § 3710a(d)(1).

which permits "firms to claim a tax credit for [twenty-five] percent of their clinical testing expenses for rare diseases . . . ."[40]

To the extent that taxpayer *support* of drug R&D is construed broadly as *incentives*, advanced market commitments for therapeutic products and government insurance coverage are arguably forms of public support as well.[41] The U.S. government, for example—through Operation Warp Speed—made huge advanced market commitments to buy, largely, COVID-19 vaccines but also other therapies, pending those products successfully receiving Emergency Use Authorization or approval from the Food and Drug Administration ("FDA").[42] Innovation scholars point out that the presence of government health insurance programs, with robust prescription drug coverage, function as an incentive for drug development as well.[43]

The federal government thus supports drug R&D through a variety of mechanisms. To what extent, then, are drugs "publicly supported"? As one might imagine, the answer depends.[44] The answer ranges from every drug[45] to various subsets,[46] depending upon how "public funding" is construed.

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[40] LISA LARRIMORE OUELLETTE, WIPO, IP AND ACCESS TO PUBLICLY FUNDED RESEARCH RESULTS IN HEALTH EMERGENCIES: US POLICY, LAW AND PRACTICE 10–11 (2024) (discussing U.S. Internal Revenue Code Sections 41, 174, and 45C); *see also* Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents-Prizes Debate*, 92 TEX. L. REV. 303, 321–25 (2013) (discussing Sections 174 and 41); Mirit Eyal-Cohen & Ana Santos Rutschman, *Promoting Vaccine Innovation*, 83 OH. ST. L.J. 1003, 1007 (2022) (reviewing existing tax incentives and arguing that "tax law can help promote socially beneficial innovation"). U.S. DEP'T OF THE TREASURY, TAX EXPENDITURES paras. 7–8, 135 (Mar. 11, 2024) (describing expensing of research and experimentation expenditures, credit for increasing research activities, and orphan drug credit). Notably, Section 174 had lapsed, but passage of the "One Big Beautiful Bill Act" restores immediate expensing of domestic R&D costs. *See generally* Gian Pazzia & Paul McVoy, *KBKG Tax Insight: One Big Beautiful Bill – 2025 Tax Changes and Summary Chart*, KBKG (July 4, 2025), https://www.kbkg.com/feature/house-passes-tax-bill-sending-to-president-for-signature (noting the Act impact on Section 174).

[41] OUELLETTE, *supra* note 40, at 4.

[42] *Id.* at 19; *see also* Nicholson Price, Rachel Sachs, Jacob S. Sherkow & Lisa Larrimore Ouellette, *Are COVID-19 Vaccine Advance Purchases a Form of Vaccine Nationalism, an Effective Spur to Innovation or Something in Between?*, WRITTEN DESCRIPTION (Aug. 5, 2020), https://writtendescription.blogspot.com/2020/08/are-covid-19-vaccine-advance-purchases.html (stating that the U.S. government was pre-purchasing promising vaccines in large quantities). Some argue that at least some government contracts were not conditioned on EUA or approval in which case risks would be even further reduced. Christopher J. Morten, *The NIH-Moderna Vaccine: Public Science, Private Profit, and Lessons for the Future*, 51 J.L., MED. & ETHICS 35, 36 (2023) (drawing on work of Ameet Sarpatwari).

[43] *See, e.g.*, Mark A. Lemley, Lisa Larrimore Ouellette & Rachel E. Sachs, *The Medicare Innovation Subsidy*, 95 N.Y.U. L. REV. 75, 106 (2020) ("From an incentive perspective, reimbursement programs can function as market-based prizes . . . .").

[44] *See* OUELLETTE, *supra* note 40, at 4 (noting a lack of consensus on "when a particular innovation should be considered 'publicly funded,'" but observing under a "broad definition . . . *every* new medical product that reaches the US public is at least partially publicly funded").

[45] Ekaterina Galkina Cleary, Jennifer M. Beierlein, Navleen Surjit Khanuja, Laura M. McNamee & Fred D. Ledly, *Contribution of NIH Funding to New Drug Approvals 2010–2016*, 115 PROC. NAT'L ACAD. SCIS. U.S.A. 2329, 2330 (2018).

[46] *See, e.g.*, Rahul K. Nayak, Jerry Avorn & Aaron S. Kesselheim, *Public Sector Financial Support for Late Stage Discovery of New Drugs in the United States: Cohort Study*, 367 BMJ 1, 8 (2019), (finding that approximately 25% of FDA-approved drugs received late-stage government support); Lisa Larrimore Ouellette & Bhaven N. Sampat, *Using Bayh-Dole Act March-In Rights to Lower US Drug Prices*, 5 JAMA HEALTH FORUM 1, 1 (Nov. 1, 2024) (finding that 2% of new molecular entities approved between 1985 and 2022 were completely covered by Bayh-Dole march-in rights).

At its broadest, accounting for the knowledge the federal government produces, *every* drug can be said to be publicly supported. Focusing on publication citations, one study, for instance, found that every new molecular entity approved by the FDA between 2010 and 2016 was at least indirectly associated with NIH-funded research.[47] The majority of this research pertained to the drugs' biological targets (i.e., basic research) as opposed to the drug itself.[48]

Other studies that assess public support for medications use more constrained criteria, such as whether a patent can be traced to NIH research funding.[49] One such study found that while all 313 FDA-approved drugs in its sample were linked to NIH-funded basic or applied research, only thirty-four of these drugs were protected by patents that directly derived from NIH-funded research.[50] Another study looked at whether a drug had either a patent with a government interest statement or its manufacturer claimed a tax credit.[51] Some include public funds used to purchase an intervention.[52]

Still other studies focus on the contributions of the public and private sectors at different stages of research. Some studies argue that public funding plays a significant role in late-stage research, particularly for the most therapeutically important drugs that gain FDA approval.[53] Others emphasize that private sector funding is the most significant determinant of FDA approval, underscoring that while public funding is crucial, private investment is often the decisive factor in bringing a drug to market.[54] Determining whether any *given* drug is "publicly supported" is a fact-intensive analysis involving case-by-case assessments. Thus, in addition to studies seeking to make larger scale observations about contribution patterns, many studies focus on individual drugs.[55]

Regardless of one's views on the importance of *public* funding, the substantial contributions of the private sector cannot be overlooked. Even if, for instance, at least 25% of new molecular entities had late-stage public

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[47] Cleary, Beierlein, Khanuja, McNamee & Ledley, *supra* note 45, at 2330.

[48] *Id.*

[49] Fred D. Ledley & Ekaterina Galkina Cleary, *NIH Funding for Patents that Contribute to Market Exclusivity of Drugs Approved 2010–2019 and the Public Interest Protections of Bayh-Dole*, 18 PLOS ONE 1, 3 (2023).

[50] *Id.* at 5.

[51] OFF. OF THE ASSISTANT SEC'Y FOR PLANNING & EVALUATION, DEP'T OF HEALTH & HUM. SERVS., MEDICARE DRUG PRICE NEGOTIATION PROGRAM: UNDERSTANDING DEVELOPMENT AND TRENDS IN UTILIZATION AND SPENDING FOR THE SELECTED DRUGS 8 (2023).

[52] *US Investment in COVID-19 Vaccines*, *supra* note 2, at 1.

[53] Nayak, Avorn & Kesselheim, *supra* note 46, at 1.

[54] Duane Schulthess, Harry P. Bowen, Robert Popovian, Daniel Gassull, Augustine Zhang & Joe Hammang, *The Relative Contributions of NIH and Private Sector Funding to the Approval of New Biopharmaceuticals*, 57 THERAPEUTIC INNOVATION & REGUL. SCI. 160, 166 (2023) [hereinafter *Relative Contributions*].

[55] *See, e.g.*, *US Investment in COVID-19 Vaccines*, *supra* note 2, at 1 (estimating public contributions to COVID-19 vaccines at $31.9 billion); Rachel E. Barenie, Jerry Avorn, Frazer A. Tessema & Aaron S. Kesselheim, *Public Funding for Transformative Drugs: The Case of Sofosbuvir*, 26 DRUG DISCOV. TODAY 273, 273 (2021) (estimating $60.9 million in NIH funding for sofosbuvir).

sector contributions, this still suggests the prominent role of private sector contributions.[56] Consensus exists that private sector spending on drug R&D is presently essential and significant in both absolute and relative terms.[57]

This Article does not attempt to exhaustively review the extensive empirical literature on drug R&D funding, but this brief overview tees up two key issues. First, acknowledging public contributions (however one ultimately counts them) does not undermine the importance of private sector contributions. Yet, it is possible to credit the private sector while striving for a more equitable approach that appropriately values the inputs of *all* stakeholders.

Second, if one is concerned about the public being treated fairly, given its contributions to drug R&D, what forms of public support *should* "count"—and, more fundamentally, what moral principle explains *why* public support should count at all? Policymakers need a systematic moral approach to assess the significance of public contributions to drug R&D. Developing such an approach is crucial for clarifying what constitutes a fair allocation of rewards between public and private contributors and providing practical guidance to decisionmakers. Part III undertakes the first step along this path to exploring what "fairness" might plausibly mean in this context. First, however, what *legal* significance does the presence of public funding for drug R&D have for concerns about a fair allocation of rewards and, in particular, concerns regarding drug pricing?

B. *The General Insignificance of Public Funding Under the Law*

Momentarily setting aside the MDPNP, under existing law,[58] federal public support for drug R&D is of limited practical consequence for both concerns about pricing as well as direct financial returns on the government's investments.[59] Focusing here on access to and the pricing of successful medications, federal funding with respect to these considerations is largely no-strings-attached. No statutory provision—with the possible exception of march-in rights discussed below—mandates that drugs supported by federal funding must be affordable or even reasonably priced.[60] Tax incentives, grant funding, licensing, or other kinds of government

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[56] Nayak, Avorn & Kesselheim, *supra* note 46, at 8.

[57] *See, e.g.*, *Relative Contributions*, *supra* note 54 (collecting studies); *see also* OUELLETTE, *supra* note 40, at 4 ("Most of these innovations, however, also depend on even more substantial private-sector investment, particularly for clinical trials and other late-stage expenses.").

[58] This Section discusses the applicable legal regime *except* for the MDPNP. *See* discussion *infra* Part II.

[59] While no statutory provision requires a royalty, *if* a royalty is involved there are rules as to how that royalty must be divided. 15 U.S.C. § 3710c(a)(1); *see also* 35 U.S.C. § 202(c)(7).

[60] The Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020, Pub. L. No. 116-123, 134 Stat. 146 (2020) may be a possible exception though it is unclear what additional authority it offers. It states: "*Provided further*, That the Secretary may take such measures authorized under current law to ensure that vaccines, therapeutics, and diagnostics developed from funds provided in this Act will be affordable in the commercial market." *Id.* at 149 (emphasis in original).

support through collaboration generally impart no pricing obligations upon recipients.[61] There is no requirement, for instance, that an orphan drug be priced reasonably for the manufacturer to claim the associated tax credit.[62] Likewise for recipients of extramural NIH grants.

This general lack of legal emphasis on the reasonable pricing of new government supported medications is by design. A constellation of federal laws pertaining to government patenting and licensing practices from the 1980s give recipients of federal funding or technology transfers near carte blanche regarding eventual technology accessibility. Though controversial, this was a deliberate policy choice thought to further the public's interest in the creation and commercialization of new technologies.[63] Private actors, it was thought, would be more effective at generating and commercializing new technologies.[64] Thus, the Bayh-Dole Act—the most prominent of these laws—moved the U.S. toward giving away patent rights over the research it funded.[65] Extramural grant recipients could now retain patent rights for themselves over federally funded research to exercise more or less as they saw fit.[66] Other contemporaneous federal laws focused on government intramural research, mandating a mission of technology transfer as well as establishing new mechanisms for facilitating these goals under CRADAs.[67]

This existing statutory scheme is largely hands-off regarding the reasonable pricing of the drugs it helped to develop, but it is not completely disinterested. After all, among the stated policy objectives of the Bayh-Dole Act is "to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions."[68] As such, the government *does* retain several robust rights in the technologies it supports. For both extramural grants and intramural technology transfer through CRADAs, the U.S. government retains a "nonexclusive, nontransferrable [sic], irrevocable, paid-up license"[69] as well as what are known as "march-in rights."[70]

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[61] Fair pricing clauses and NIH intramural access plans are discussed below.

[62] An orphan drug is a drug that treats a "rare disease or condition" impacting fewer than 200,000 people or a drug for a condition impacting greater than 200,000 people, but for which there is "no reasonable expectation" for cost recoupment from sales in the U.S. 21 U.S.C. § 360bb(a)(2).

[63] For detailed history, see Eisenberg, *supra* note 6, at 1665.

[64] W. Nicholson Price II, *Grants*, 34 BERKELEY TECH. L.J. 1, 15–16 (2019); Wolitz, *The Pay-Twice Critique*, *supra* note 6, at 181.

[65] Eisenberg, *supra* note 6, at 1665–66, 1676.

[66] *Id.* at 1708; Wolitz, *The Pay-Twice Critique, supra* note 6, at 181.

[67] Wolitz, *The Pay-Twice Critique, supra* note 6, at 181.

[68] 35 U.S.C. § 200.

[69] 35 U.S.C. § 202(c)(4); 15 U.S.C. § 3710a(b)(1)(A).

[70] 35 U.S.C. § 203; *see also* 15 U.S.C. § 3710a(b)(1)(B)–(C) (describing similar).

March-in rights, in particular, have been a widely discussed safety valve for promoting better access to publicly funded medications.[71] These rights empower the government to provide additional licenses of a federally supported technology to others if certain conditions are met.[72] Among these possible circumstances are the need to "meet" or "alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees"[73] or in the case of CRADAs, the "collaborating party."[74]

There has been longstanding debate, however, about what kinds of situations ought to trigger march-in rights.[75] Arguments have largely sorted into two camps—those arguing that the focus should be exclusively on instances of failed product commercialization, and others arguing that the pricing of products, insofar as they impact accessibility, ought to count too.[76] Despite the plain meaning of march-in provisions to presumably include concern for the pricing and accessibility of government supported medications,[77] the NIH historically has fallen into the former camp. As of this writing, the NIH has not yet exercised these rights.[78] Further, and for march-in petitions brought based on pricing concerns, the NIH has asserted that access concerns on the basis of price are not within its mission nor statutory authorities.[79] On the NIH's interpretation, simply having a drug be

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[71] *See, e.g.*, Arno & Davis, *supra* note 13, at 659 (describing march-in rights as a mechanism to benefit taxypayers by ensuring inventions are sold at reasonable prices).

[72] 35 U.S.C. § 203(a); 15 U.S.C. § 3710a(b)(1)(C).

[73] 15 U.S.C. § 3710a(b)(1)(C); 35 U.S.C. § 203(a)(2).

[74] 15 U.S.C. § 3710a(b)(1)(C).

[75] *See, e.g.*, Carolyn L. Treasure, Jerry Avorn & Aaron S. Kesselheim, *Do March-In Rights Ensure Access to Medical Products Arising from Federally Funded Research? A Qualitative Study*, 93 MILBANK Q. 761, 764, 776 (2015) (noting a lack of clarity surrounding the scope of applicability of march-in rights and finding two major perspectives); Lisa Larrimore Ouellette & Bhaven N. Sampat, *The Feasibility of Using Bayh-Doyle March-In Rights to Lower Drug Prices: An Update* 3 (Nat'l Bureau of Econ. Rsch., Working Paper No. 32217, 2024) [hereinafter Ouellette & Sampat, *Update*] (describing legal debates as to the circumstances in which march-in rights apply); Nat'l Inst. of Standards & Tech. (NIST), Request for Information Regarding the Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights, 88 Fed. Reg. 85593, 85593–95 (Dec. 8, 2023) [hereinafter NIST Request] (requesting public comment on relevant factors to determine when march-in rights should be exercised).

[76] *See, e.g.*, Treasure, Avorn & Kesselheim, *supra* note 74, at 776–81 (describing the two arguments); Ouellette & Sampat, *Update*, *supra* note 74, at 3 (discussing the debate on when march-in rights apply); NIST Request, *supra* note 74, at 85594 (noting prior NIST notice of proposed rulemaking which would have excluded march-in exclusively on the basis of product pricing and now seeking consensus that balances the promotion of public utilization).

[77] *See* Arno & Davis, *supra* note 13, at 659–60 (describing Congress's purported concerns with including march-in rights); Treasure, Avorn & Kesselheim, *supra* note 75, at 782 ("The legislative history of the Bayh-Dole Act and the plain language of the statute establish that the "reasonable terms" should take price into account . . . .").

[78] *See, e.g.*, Ouellette & Sampat, *Update*, *supra* note 75, at 3 (observing while march-in rights have not been exercised, they have been used as a threat); Treasure, Avorn & Kesselheim, *supra* note 75, at 779 (noting government reluctance to utilize march-in rights).

[79] *See, e.g.*, ELIAS A. ZERHOUNI, NAT'L INSTS. OF HEALTH OFF. OF THE DIR., IN THE CASE OF NORVIR MANUFACTURED BY ABBOTT LABORATORIES, INC. 6 (2004) (deferring drug pricing concerns to Congress); Treasure, Avorn & Kesselheim, *supra* note 75, at 779, 782 (noting NIH's apparent reluctance to interfere with issues of drug pricing).

"available for use by patients" and "actively marketed" by the drug manufacturer qualifies as meeting "health or safety needs as required by the Bayh-Dole Act."[80]

The scope of march-in rights has received renewed attention. The first Trump Administration—despite commitments to addressing drug pricing—proposed a rule that would have restricted agencies' authority to march in based on product pricing.[81] Under the Biden Administration, the National Institute of Standards and Technology chose not to finalize this rule, yet the NIH continued to decline marching-in solely based on concerns about a drug's price.[82] In December 2023, however, the Biden Administration requested comments on a new draft framework.[83] Among its goals was to clarify "the prerequisites for exercising march-in" rights.[84] In significant contrast to the NIH's historical approach, the price of a product would figure prominently in guiding agency decision-making on whether to march in.[85] Under the second Trump Administration, this draft guidance has been "sitting in limbo" with some speculating that the President will ultimately "do away with" it.[86]

However, even if the current administration were to adopt this friendlier-to-access interpretation which arguably better aligns with statutory text,[87] march-in rights are unlikely to provide a momentous check on private corporate power when it comes to drug pricing.[88] This tool only applies to situations involving the presence of specific public-sector patents.[89] Any given drug, however, is protected by numerous patents, and only a small percentage of these patents trace their lineage to government-supported research in the relevant way. Even *if* one patent is a public-sector patent, if the others are not, the federal government would not be able to issue additional licenses for those non-covered patents.[90]

A recent study suggests that the universe of drugs where *all* patents are public-sector is small. Of 883 small-molecule drugs approved by the FDA

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[80] ZERHOUNI, *supra* note 79, at 6.

[81] NIST Request, *supra* note 75, at 85594.

[82] *See* Letter from Lawrence A. Tabak, Acting Director, Nat'l Inst. of Health, to Robert Sachs & Clare Love (Mar. 21, 2023), https://www.techtransfer.nih.gov/sites/default/files/documents/pdfs/NIH_Decision_Xtandi_March-In_Request (2023).

[83] NIST Request, *supra* note 75, at 85593.

[84] *Id.* at 85594.

[85] *Id.* at 85598–99.

[86] Jack Corrigan & Vikram Venkatram, *Trump Should Not Abandon March-In Rights*, NAT'L INT. (Apr. 28, 2025), https://nationalinterest.org/blog/techland/trump-should-not-abandon-march-in-rights.

[87] NIST Request, *supra* note 75, at 85598 (including reasonableness of price as relevant).

[88] *See* Treasure, Avorn & Kesselheim, *supra* note 75, at 782–83 (suggesting march-in rights may not be an effective tool to respond to drug pricing concerns).

[89] Ouellette & Sampat, *supra* note 46, at 2; *see also* Ledley & Cleary, *supra* note 49, at 10 (suggesting that Bayh-Doyle's protections are limited in scope).

[90] That is, under march-in rights; government patent use would be available under 28 U.S.C. §1498. *See, e.g.*, Rachel Sachs, Symposium Remarks, *Whether and How the U.S. Government Should Exercise Its Compulsory Licensing Authority Under 28 U.S.C. § 1498 and the Bayh-Dole Act*, 11 N.Y.U. J. INTELL. PROP. & ENT. L. (2021) (discussing the reach of 28 U.S.C. § 1498).

from 1985–2022, it found that only 9.1% of these drugs had at least one public-sector patent, and a mere 2% had *all* its patents subject to Bayh-Dole march-in rights.[91] Thus, the authors conclude: "March-in rights are not relevant for most drugs. If policymakers want to lower prices for a broader array of drugs, they should thus focus on other policies."[92]

Potentially evolving agency statutory interpretation of march-in rights aside, the Biden Administration, and most recently the second Trump Administration, have put forward other policies of relevance to drug pricing and public funding. The Biden Administration, for example, had experimented with the use of fair pricing clauses. Fair pricing clauses, roughly, are contractual provisions that place "pricing limitation[s] on the exercise of license or patent rights governing a federally funded medication" in order to improve patient access.[93] As with many access-to-medications tools, this was an existing strategy.[94] The NIH experimented with a reasonable pricing clause in the context of CRADAs beginning in 1989 in response to public outrage over the price of important HIV medications that had been developed using taxpayer funding.[95] By 1995, this clause was abandoned due to its perceived interference with private sector collaborations, and therefore it was thought the NIH's innovation mission.[96] Evidence supporting this position, however, appears weak.[97]

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[91] Ouellette & Sampat, *supra* note 46, at 5 tbl.2.

[92] *Id.* at 7.

[93] Wolitz, *The Pay-Twice Critique, supra* note 6, at 190.

[94] *See, e.g.*, Rachel Sachs, *Understanding the Democrats' Drug Pricing Package*, HEALTH AFFS. (Aug. 10, 2022), https://www.healthaffairs.org/content/forefront/understanding-democrats-drug-pricing-package (observing that the idea of permitting Medicare to negotiate drug prices was part of the Clinton health care plan in the early 1990s).

[95] Wolitz, *The Pay-Twice Critique*, *supra* note 6, at 193–94.

[96] *Id.* at 197.

[97] *Id.*; Ameet Sarpatwari, Allison K. LaPidus & Aaron S. Kesselheim, *Revisiting the National Institutes of Health Fair Pricing Condition: Promoting the Affordability of Drugs Developed with Government Support*, 172 ANNALS INTERNAL MED. 348, 348 (2020). *But see* NAT'L INSTS. OF HEALTH, THE NIH EXPERIENCE WITH THE REASONABLE PRICING CLAUSE IN CRADAS FY1990-1995 at 2 (Nov. 15, 2021) (describing considerations leading to the abandonment of this policy). Researchers have called on NIH to prioritize the improved collection and availability of data to better access NIH policies. *See, e.g.*, Maya M. Durvasula, Lisa Larrimore Ouellette & Bhaven N. Sampat, Comment Letter on Request for Information on Draft NIH Intramural Research Program Policy: Promoting Equity Through Access Planning 4–5 (July 22, 2024), https://law.stanford.edu/publications/response-to-request-for-information-on-draft-nih-intramural-research-program-policy-promoting-equity-through-access-planning (stating that limited evidence exists regarding policies and has been limited to anecdotes).

Though some skepticism of their effectiveness is warranted,[98] fair pricing clauses are intuitively compelling and of some political popularity.[99] Academics and politicians alike have called for their inclusion in funding contracts and other agreements with the federal government.[100] Scholars have urged their reformulation to reflect the lessons learned from the NIH's previous experiment.[101]

In December 2023, the Biden Administration revived use of reasonable pricing clauses through their inclusion in certain Administration for Strategic Preparedness and Response ("ASPR") contracts.[102] "[F]air pricing [will be] a standard part of contract negotiations for medical products developed or purchased as part of [the ASPR's] commitment to obtain best value for the U.S. taxpayer."[103] Commitment to this general policy grew out of earlier fair pricing provisions that were secured between ASPR's Biomedical Advanced Research and Development Authority ("BARDA") and the extension of its partnership with Regeneron Pharmaceuticals, Inc. to develop monoclonal antibodies.[104] This clause stated that "if a new product [to be developed by the drug manufacturer] is commercialized, its list price in the United States will be equal to or less than its retail price in comparable

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[98] Wolitz, *The Pay-Twice Critique, supra* note 6, at 179; *see also* Jorge L. Contreras, *"In the Public Interest": University Technology Transfer and the Nine Points Document - An Empirical Assessment*, 13 U.C. IRVINE L. REV. 435, 503 (2023) (suggesting omission of access to medicines terms from contractual clauses); Holly Fernandez Lynch, Rena M. Conti & Jorge L. Contreras, *Industry Price Guarantees for Publicly Funded Medicines: Learning from Project NextGen for Pandemics and Beyond*, 11 J. L. & BIOSCIS. 1, 3–4 (2024) (describing the government's pricing clause with Regeneron as "legally porous").

[99] Sarpatwari, LaPidus & Kesselheim, *supra* note 97, at 348; Nikhil Chaudhry & Reshma Ramachandran, *Reasonable Pricing Clauses: A First Step Toward Ensuring Taxpayers a Fair Return on Their Public R&D Investment*, HARVARD PETRIE-FLOM CTR.: BILL OF HEALTH (Sept. 28, 2023), https://blog.petrieflom.law.harvard.edu/2023/09/28/reasonable-pricing-clauses-a-first-step-toward-ensuring-taxpayers-a-fair-return-on-their-public-rd-investment.

[100] *See, e.g.*, Aaron S. Kesselheim, *Improving Competition to Lower U.S. Prescription Drug Costs*, *in* WASH. CTR. FOR EQUITABLE GROWTH, VISION 2020: EVIDENCE FOR A STRONGER ECONOMY 21, 23 (2020) (recommending policy changes to effectuate affordable drug prices); Press Release, Bernie Sanders, Senator for Vermont, NEWS: Sanders Statement on White House Proposal to Consider Price as a Factor in Breaking Patent Monopolies on Some Taxpayer-Funded Prescription Drugs (Dec. 7, 2023), https://www.sanders.senate.gov/press-releases/news-sanders-statement-on-white-house-proposal-to-consider-price-as-a-factor-in-breaking-patent-monopolies-on-some-taxpayer-funded-prescription-drugs (encouraging the government to increase use of reasonable pricing clauses in contracts with the pharmaceutical industry); Wolitz, *The Pay-Twice Critique*, *supra* note 6, at 179 (describing reasonable pricing clauses as a tool to address the pay-twice critique); THE PEOPLE'S PRESCRIPTION, *supra* note 13, at 39–42 (outlining proposed conditionalities that could be placed on public investments, including conditions for access and affordability).

[101] Wolitz, *The Pay-Twice Critique, supra* note 6, at 198. *See* Robin Feldman & Zachary Rosen, *NIH Licensing Would Benefit from Free-Market Provisions*, 51 J.L., MED. & ETHICS 24, 25–26 (2023) (describing free-market provisions that the government might deploy).

[102] Press Release, The White House, FACT SHEET: Biden-Harris Administration Announces Dozens of Pharma Companies Raised Prices Faster than Inflation, Triggering Medicare Rebates (Dec. 14, 2023) [hereinafter Biden-Harris Pharma Inflation Announcement], https://www.bidenwhitehouse.archives.gov/briefing-room/statements-releases/2023/12/14/fact-sheet-biden-harris-administration-announces-dozens-of-pharma-companies-raised-prices-faster-than-inflation-triggering-medicare-rebates.

[103] *Id.*

[104] *Id.*

markets globally."[105] Though use of these clauses was viewed as "a necessary step toward ensuring that American taxpayers receive a fairer return on their investment for essential therapies,"[106] this policy only applied to agreements within ASPR. This led to calls for such clauses to be adopted across all agencies, including the NIH.[107]

While the second Trump Administration's stance on this specific Biden-era ASPR clause is unclear, it has vocally embraced similar "most-favored nation" price comparisons for its approach to drug pricing reform, often citing American taxpayer support for drug R&D.[108] In a May 2025 Executive Order, President Trump stated: "The United States has less than five percent of the world's population and yet funds around three quarters of global pharmaceutical profits."[109] Calling this an "egregious imbalance" facilitated by "generous public subsidies for research and development primarily through the National Institutes of Health" and through "robust public financing of prescription drug consumption," President Trump ordered agency officials to work with drug manufacturers to ensure that American patients have access to drugs at prices "in line with comparably developed nations."[110] Notably, most-favored nation pricing under this order appears to apply to all drugs, not only those construed to have been taxpayer supported.[111] Based on this Executive Order, the Trump Administration has been negotiating individual drug pricing agreements with drug manufacturers and has established a direct to consumer website, TrumpRx.gov.[112]

Beyond fair pricing clauses and President Trump's new most-favored nation pricing order, the Biden Administration had also begun experimenting with yet a different mechanism for improved accessibility of NIH-funded

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[105] Press Release, U.S. Dep't of Health & Hum. Servs., HHS Announces Details of Partnership with Regeneron to Develop Life-Saving Monoclonal Antibodies (Sept. 8, 2023) [hereinafter HHS Announcement], https://www.hhs.gov/about/news/2023/09/08/hhs-announces-details-partnership-regeneron-develop-life-saving-monoclonal-antibodies.html.

[106] Chaudhry & Ramachandran, *supra* note 99.

[107] Press Release, Bernie Sanders, Senator for Vermont, NEWS: Sanders Statement on Biden Administration's New Reasonable Pricing Policy (Dec. 14, 2023), https://www.sanders.senate.gov/press-releases/news-sanders-statement-on-biden-administrations-new-reasonable-pricing-policy.

[108] Exec. Order No. 14,297, 90 Fed. Reg. 20749, 20749 (May 12, 2025).

[109] *Id.*

[110] *Id.* at 20749–50.

[111] *Id.* at 20749.

[112] *Fact Sheet: President Donald J. Trump Announces Major Developments in Bringing Most Favored Nation Pricing to American Patients*, THE WHITE HOUSE (Nov. 6, 2025), https://www.whitehouse.gov/fact-sheets/2025/11/fact-sheet-president-donald-j-trump-announces-major-developments-in-bringing-most-favored-nation-pricing-to-american-patients (providing update on status of the administration's efforts to bring most-favored nation pricing to Americans); *Trump Rx*, https://trumprx.gov (last visited Dec. 31, 2025) (explaining that in January 2026, TrumpRX will "connect[] patients directly with the best prices."). Some have expressed skepticism of these efforts calling them "underwhelming" and "more window dressing than the transformational sorts of reforms that are needed." Sydney Lupkin, *President Announces TrumpRx Website for Drugs, and Pricing Deal with Pfizer* (Sept. 20, 2025, 6:55 PM), https://www.npr.org/sections/shots-health-news/2025/09/30/nxs1-5558432/drug-prices-trumprx-pfizer (quoting Ameet Sarpatwari).

drugs: "Access Plans."[113] Applicable to its intramural research program, the NIH proposed developing a new policy that would require licensees of government-owned technologies to develop an "Access Plan" "as a means to prospectively address downstream access challenges."[114] Acknowledging that patients often struggle to access the medications they need due to their expense, the NIH decided to "explor[e] how it might leverage partnerships to further enhance health through the biomedical research it funds."[115] These plans would take a flexible approach and be tailored according to specific circumstances including the stage of an invention's development.[116] The NIH had finalized its proposal and issued a new access plan policy in January 2025.[117] This policy applied to all licenses of intramural technologies "that would authorize the commercialization of drugs, biologics (including vaccines), or devices for the prevention, diagnosis, or treatment of human disease."[118] While the current administration initially delayed this policy from going into effect,[119] it ended up rescinding and replacing it with their own version incorporating only "minor revisions to the text."[120] No access plans at this time appear to be publicly available.[121]

While many of these efforts originated under the Biden Administration, drug pricing remains a prominent issue for the second Trump Administration. It is unclear whether—and to what extent—the current administration successfully will advance these or other policies. Nonetheless, there is ongoing interest in exploring new approaches to improve patient access to government-supported medications. These notable efforts, however, are nascent and thus far fairly circumscribed if not in conception, in implementation. One final important statutory scheme remains to be discussed: The Inflation Reduction Act.

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[113] Request for Information on Draft Request for Information on Draft NIH Intramural Research Program Policy: Promoting Equity Through Access Planning, 89 Fed. Reg. 45003, 45003 (May 22, 2024).

[114] *Id.* at 45004.

[115] *Id.*

[116] *Id.*

[117] NAT'L INSTS. OF HEALTH, OFF. OF THE DIR., NOT-OD-25-062, NIH INTRAMURAL RESEARCH PROGRAM ACCESS PLANNING POLICY (Jan. 10, 2025), *replaced by* NOT-OD-25-136 (July 24, 2025) (reissuing the policy to "facilitate alignment with the [Trump] Administration's priorities").

[118] *Id.* Biologics are complex medicines "that generally come from living organisms." *Biosimilar and Interchangeable Biologics: More Treatment Choices,* FDA (Aug. 17, 2023), https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices. Biosimilars are biologics that are "highly similar to another biologic that is already FDA-approved." *Id*.

[119] NAT'L INSTS. OF HEALTH, OFF. OF THE DIR., IMPLEMENTATION UPDATE: DELAYED EFFECTIVE DATE FOR THE NIH INTRAMURAL RESEARCH PROGRAM ACCESS PLANNING POLICY, NOT-OD-25-079 (Mar. 28, 2025).

[120] NAT'L INSTS. OF HEALTH, OFF. OF THE DIR., NOT-OD-25-062, NIH INTRAMURAL RESEARCH PROGRAM ACCESS PLANNING POLICY (Jan. 10, 2025), *rescinded and replaced by* NOT-OD-25-136 (July 24, 2025).

[121] *Id*. This policy applies to license applications submitted on or after October 1, 2025, and delays submission of a non-confidential version of an access plan until three months after FDA approval.

II. THE INFLATION REDUCTION ACT'S FAIR PRICING FRAMEWORK

This Part provides a brief introduction to the Medicare Drug Price Negotiation Program followed by an analysis of this Program's inclusion of considerations of federal funding for fair drug pricing.

A. *An Overview of the Medicare Drug Price Negotiation Program*

Signed into law in August of 2022, the Inflation Reduction Act ("IRA") is relevant to many different sectors of the economy.[122] Within healthcare, however, it is groundbreaking for its impact on prescription drugs purchased through Medicare.[123] To better understand applicable sections of the IRA dealing with publicly supported medications, some background on prescription drug coverage under Medicare offers important context.

Medicare is a government insurance program that covers people who are 65 years of age or older, some people who are younger and disabled, and people with end-stage renal disease.[124] A complex government program, Medicare is comprised of several different parts, but those most relevant for prescription medications are Medicare Parts B and D.[125] Among other things, Part B covers doctors' visits including drugs provided in this setting (such as infusions).[126] Part D, by contrast, pertains to coverage of prescription drugs picked up at a pharmacy.[127]

Originally, Medicare did not include the kind of prescription drug coverage now offered under Part D.[128] Congress added this coverage in 2003.[129] When doing so, it included a controversial provision known as the "noninterference clause."[130] This clause prohibited HHS from directly negotiating the prices of covered drugs with drug manufacturers.[131] Instead,

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[122] Inflation Reduction Act of 2022 Pub. L. No. 117-169, 136 Stat. 1818.

[123] Press Release, CMS Newsroom, Commemorating the 2nd Anniversary of the Biden-Harris Lower Cost Prescription Drug Law (Aug. 16, 2024), https://www.cms.gov/newsroom/press-releases/commemorating-2nd-anniversary-biden-harris-lower-cost-prescription-drug-law.

[124] 42 U.S.C.A. § 1395c.

[125] *See, e.g.*, Lemley, Ouellette & Sachs, *supra* note 43, at 82.

[126] *Prescription Drugs (Outpatient)*, MEDICARE, https://www.medicare.gov/coverage/prescription-drugs-outpatient (last visited Oct. 4, 2025).

[127] *What's Medicare Drug Coverage (Part D)?*, MEDICARE, https://www.medicare.gov/drug-coverage-part-d (last visited Oct. 4, 2025).

[128] *CMS' Program History*, CMS, https://www.cms.gov/about-cms/who-we-are/history (last visited Oct. 4, 2025).

[129] *Id.*

[130] 42 U.S.C.A. § 1395w-111(i). *See, e.g.*, Theodore T. Lee, Abbe R. Gluck & Gregory D. Curfman, *The Politics of Medicare and Drug-Price Negotiation (Updated)*, HEALTH AFFS., http://healthaffairs.org/blog/2016/09/19/the-politics-of-medicare-and-drug-price-negotiation (Oct. 20, 2016) (describing the "noninterference clause" as a bargaining chip shaped by drug manufacturers that barred Medicare from negotiating drug prices or establishing its own formulary or pricing system).

[131] 42 U.S.C.A. § 1395w-111(i). Note that the Inflation Reduction Act "amends the noninterference clause by adding an exception that requires the Secretary of HHS to negotiate with pharmaceutical companies (on behalf of Medicare)" for a small number of drugs on the market for a specific number of years. Eli Y. Adashi, Daniel P. O'Mahony & I. Glenn Cohen, *The Inflation Reduction Act: Recasting the Medicare Prescription Drug Plans*, 64 AM. J. PREVENTIVE MED. 936, 936 (2023).

Part D was designed such that there would be competing private sector plans offering Part D coverage, and it would be these plans that were empowered to negotiate.[132] This design was controversial because it prevented the federal government from leveraging its purchasing power as bargainer with drug manufacturers, instead dispersing and fracturing that power.[133] With high drug prices remaining a chronic source of frustration and hardship for Americans, the following decades saw repeated bipartisan support for Congress to permit direct government drug price negotiations.[134]

This longstanding push to permit Medicare to directly negotiate drug prices culminated in the drug price negotiation provisions found in the IRA. While the IRA's Medicare prescription drug provisions include several important revisions to the program,[135] this Article's focus is on the negotiation program. Under the IRA, CMS is now empowered to directly negotiate drug prices for Medicare with drug manufacturers.[136] This is a remarkable and significant policy shift.

A place to begin with unpacking the Medicare Drug Price Negotiation Program ("MDPNP," or the "Program") is to understand to which drugs it applies. The Program does not apply to all drugs. Rather, the Secretary may only directly negotiate the prices for a subset. To qualify for the possibility of negotiation, a drug must be "single-source" meaning that it does not have generic or biosimilar competition.[137] The drug must also be a certain number of years out from receiving FDA approval or licensure. For small molecule drugs, the drug has to have been on the market for at least seven years.[138] For biologics, the drug has to have been on the market for at least eleven years.[139] Certain drugs are also excluded even if they would otherwise meet these criteria.[140]

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[132] *See* Rebecca E. Wolitz, *A Corporate Duty to Rescue: Biopharmaceutical Companies and Access to Medications*, 94 IND. L.J. 1163, 1218 (2019) (discussing how pharmaceutical industry influence shaped rules limiting government negotiation of drug prices).

[133] *Id.*

[134] Ashley Kirzinger, Audrey Kearney, Mellisha Stokes, Liz Hamel & Mollyann Brodie, *The Public Weighs In On Medicare Drug Negotiations*, KFF (Oct. 12, 2021), https://www.kff.org/health-costs/poll-finding/public-weighs-in-on-medicare-drug-negotiations.

[135] *See* Juliette Cubanski, Tricia Neuman, & Meredith Freed, *Explaining the Prescription Drug Provisions in the Inflation Reduction Act*, KFF (Jan. 24, 2023), https://www.kff.org/medicare/explaining-the-prescription-drug-provisions-in-the-inflation-reduction-act (discussing several provisions in the IRA that lower prescription drug costs and reduce federal spending).

[136] 42 U.S.C.A. § 1320f(a)(3).

[137] 42 U.S.C.A. § 1320f-1(e); *see also* CTRS. FOR MEDICARE & MEDICAID SERVS., FACT SHEET: KEY INFORMATION ON THE PROCESS FOR THE FIRST ROUND OF NEGOTIATIONS FOR THE MEDICARE DRUG PRICE NEGOTIATION PROGRAM 1 (Sept. 2023) [hereinafter CMS NEGOTIATIONS FACT SHEET] (discussing single source drugs as defined in The Inflation Reduction Act (2022).

[138] 42 U.S.C.A. § 1320f-1(e)(A)(ii).

[139] 42 U.S.C.A. § 1320f-1(e)(B)(ii).

[140] For example, certain orphan drugs are excluded. 42 U.S.C.A. § 1320f-1(e)(3)(A). Congress recently expanded the orphan drug exclusion. *See, e.g.*, *Key Inflation Reduction Act Amendment Broadens U.S. Protection for Orphan Drugs*, SIDLEY (July 15, 2025), https://www.sidley.com/en/insights/newsupdates/2025/07/key-inflation-reduction-act-amendment-broadens-us-protection-for-orphan-drugs; Pub. L. No. 119-21, 139 Stat. 72, 320-321 (2025).

Of these qualifying single-source drugs, CMS then determines which ones are "negotiation eligible." To determine this, for example in 2023, the first year of the Program's operation (meaning the legwork done for negotiated prices that go into effect in 2026, or "Initial Price Applicability Year" ("IPAY") 2026), CMS ranked the top fifty qualifying single-source drugs by gross Part D coverage expenditures.[141] It then picked the ten drugs on this list with the highest total gross part D costs, after excluding any biologics where biosimilars were expected to enter the market.[142] For this first year, CMS could only negotiate qualifying single-source Part D drugs, but the law expands over time to include Part B as well.[143] The number of drugs that can be selected also scales up over time,[144] rising to twenty Part B and Part D drugs for 2029 and beyond.[145]

Once CMS identifies drugs for price negotiations, drug manufacturers decide whether they will participate in the negotiations.[146] Supposing the process moves forward—and there are strong incentives for it to do so (thus far, *all* drug manufacturers of selected drugs have chosen to participate)[147]—CMS will collect information from drug companies and the public, eventually making an initial proposed offer of a "maximum fair price" for the listed drugs.[148] The statute provides a series of deadlines for the parties to negotiate counteroffers, and for CMS to publish both the negotiated prices and an explanation for those prices.[149] Negotiated prices for IPAY 2026 go

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[141] CMS NEGOTIATIONS FACT SHEET, *supra* note 136. Subsequent years follow the same or similar procedure described herein. *See, e.g.*, *Medicare Drug Price Negotiation Program: Selexted Drugs for Initial Price Applicability Year 2027* (Jan. 2025), https://www.cms.gov/files/document/factsheet-medicare-negotiation-selected-drug-list-ipay-2027.pdf (describing drug selection process for IPAY 2027); Memorandum from Chris Klomp, Deputy Administrator and Director, Center for Medicare, Dep't of Health & Hum. Servs., on Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2028 and Manufacturer Effectuation of the Maximum Fair Price in 2026, 2027, and 2028 to Interested Parties 161-63 § 30 (Sept. 30, 2025) (describing adjusted process for drug selection for initial price applicability year 2028, which is the first year to incorporate Part B drugs) [hereinafter IPAY 2028 Final Guidance].

[142] CMS NEGOTIATIONS FACT SHEET, *supra* note 137.

[143] 42 U.S.C.A. § 1320f-1(a).

[144] *Id.*

[145] *Id.*

[146] CMS NEGOTIATIONS FACT SHEET, *supra* note 137, at 2.

[147] 26 U.S.C. §5000D (describing taxes on program noncompliance); Press Release, The White House, Biden-Harris Administration Takes Major Step Forward in Lowering Health Care Costs; Announces Manufacturers Participating in Drug Price Negotiation Program (Oct. 3, 2023), https://bidenwhitehouse.archives.gov/briefing-room/statements-releases/2023/10/03/biden-harris-administration-takes-major-step-forward-in-lowering-health-care-costs-announces-manufacturers-participating-in-drug-price-negotiation-program (noting 100% participation in the first year of the program); *CMS Announces Manufacturer Participation in Second Cycle of Medicare Drug Price Negotiation*, CMS (Mar. 14, 2025), https://www.cms.gov/newsroom/fact-sheets/cms-announces-manufacturer-participation-second-cycle-medicare-drug-price-negotiation (noting signed agreements with manufacturers of the 15 drugs selected for the second program cycle).

[148] CMS NEGOTIATIONS FACT SHEET, *supra* note 137, at 1–2, 5.

[149] *See id.* (providing deadlines, milestones, and timeline for negotiation).

into effect on January 1, 2026.[150] With some modifications in the timeline, each subsequent year of the Program follows a similar cadence.[151]

Fundamental to the MDPNP is the government's determination of a "maximum fair price." A complex statutory and regulatory framework guide the government's process. In terms of a high-level overview, beginning with the statute, the Secretary "shall consider" a number of factors in generating its offers and counteroffers.[152] These factors are grouped into two categories: (1) "manufacturer-specific data" which is submitted by the manufacturer; and (2) factors regarding "evidence about alternative treatments."[153] Each category has a list of enumerated factors for consideration.[154]

Importantly, while there is an explicit list of factors for consideration, there is no statutory mandate as to *how* individual factors are to be weighted or balanced against one another. CMS thus has crafted a methodology that starts with the factors pertaining to the selected drug's clinical benefit and value (the second category), and then adjusts its determination based on the manufacturer specific factors (the first category).[155] In its IPAY 2026 Guidance, CMS explained that it first identifies therapeutic alternatives (which in this case are cabined to other drugs or biologics),[156] and then uses Medicare prices for these alternatives to derive a starting point.[157] CMS then evaluates the clinical benefit of the selected drug including as compared to therapeutic alternatives.[158] Following this, it makes adjustments in accordance with the manufacturer-specific factors.[159] Using all of these

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[150] *Id.*

[151] *See, e.g.*, CTRS. FOR MEDICARE & MEDICAID SERVS., FACT SHEET: MEDICARE DRUG PRICE NEGOTIATION PROGRAM FINAL GUIDANCE FOR 2027 AND MANUFACTURER EFFECTUATION OF THE MFP IN 2026 AND 2027, at 4–5 (2024); CTRS. FOR MEDICARE & MEDICAID SERVS., FACT SHEET: MEDICARE DRUG PRICE NEGOTIATION PROGRAM FINAL GUIDANCE FOR INITIAL PRICE APPLICABILITY YEAR 2028 AND MANUFACTURER EFFECTUATION OF THE MFP IN 2026, 2027, AND 2028, at 3–4 (2025).

[152] 42 U.S.C.A. § 1320f-3(e).

[153] *Id.*

[154] *Id.*

[155] Memorandum from Meena Seshamani, Deputy Administrator and Director, Center for Medicare, Dep't of Health & Hum. Servs., on Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 to Interested Parties 144–45 § 60.3 (June 30, 2023) [hereinafter IPAY 2026 Guidance]; *see also* IPAY 2028 Final Guidance, *supra* note 141, at 285-86 § 60.3.

[156] *Id.*; *see also* Memorandum from Meena Seshamani, Deputy Administrator and Director, Center for Medicare, Dep't of Health & Hum. Servs., on Medicare Drug Price Negotiation Program: Final Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price in 2026 and 2027 to Interested Parties 91, 252 § 60.3 (2024) [hereinafter IPAY 2027 Guidance]; IPAY 2028 Final Guidance, *supra* note 141, at 87.

[157] IPAY 2026 Guidance, *supra* note 155, at 146 § 60.3.2. If there is no therapeutic alternative, then CMS would look to the lower of the FSS or Big Four prices. *Id.* at 147. Notably, the precise details of CMS' approach to deriving this initial starting price have evolved with each program year. IPAY 2028 Final Guidance, *supra* note 141, at 288 § 60.3.2 (describing evolution of procedures for indentifying prices for therapeutic alternatives over time).

[158] IPAY 2026 Guidance, *supra* note 155, at 144 § 60.3.

[159] *Id.* at 145 § 60.3.

factors, CMS generates an initial price to offer drug manufacturers.[160] Subsequent guidance documents retain the shape of this core methodology.[161]

By statute, the Secretary cannot make maximum fair price offers that exceed a certain ceiling.[162] There are some nuances depending upon whether a drug is Part B or Part D, but generally, the negotiated price cannot be higher than previous net or average prices paid by Medicare or a certain percentage of the drug's non-federal average manufacturer price ("FAMP") (the average price that wholesalers pay manufacturers), whichever is lower.[163] The percentage of the non-FAMP price varies with time since FDA approval or licensure. It ranges from 40% for the oldest drugs to 75% for the newest drugs.[164]

B. *The Factor of Federal Funding*

With this overview in place, we can now focus on how public support for a selected drug's R&D figures into the MDPNP. The IRA's maximum fair price framework incorporates consideration of public funding as a factor under the category of "manufacturer-specific data."[165] As articulated by the statute, these data are to be collected for mandatory consideration by the Secretary in "determining . . . offers and counteroffers."[166] The following "manufacturer-specific data" are considered: [167]

> (A) Research and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped research and development costs.
>
> (B) Current unit costs of production and distribution of the drug.
>
> (C) Prior Federal financial support for novel therapeutic discovery and development with respect to the drug.
>
> (D) Data on pending and approved patent applications, exclusivities recognized by the Food and Drug Administration, and applications and approvals under

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[160] *Id.*

[161] *See* IPAY 2027 Guidance, *supra* note 156, at 252 § 60.3. IPAY 2028 Final Guidance, *supra* note 141, at 285–86 § 60.3.

[162] 42 U.S.C.A. § 1320f-3(c)(1).

[163] *Id.*; *see also* Juliette Cubanski, *FAQs About the Inflation Reduction Act's Medicare Drug Price Negotiation Program*, KFF (Jan. 23, 2025), https://www.kff.org/medicare/issue-brief/faqs-about-the-inflation-reduction-acts-medicare-drug-price-negotiation-program (describing how the IRA sets maximum fair prices).

[164] 42 U.S.C.A. § 1320f-3(c)(3).

[165] 42 U.S.C.A. § 1320f-3(e)(1).

[166] *Id.*

[167] 42 U.S.C. § 1320f-3(e)(1).

> section 355(c) of Title 21 or section 262(A)[168] of this title for the drug.
>
> (E) Market data and revenue and sales volume data for the drug in the United States.

Though the IRA directs CMS to consider public financing of a drug within its framework for determining a fair price for negotiated drugs, the statute is silent as to this factor's key terms. The statute does not define "prior Federal financial support," nor does it appear to define "novel therapeutic discovery and development."[169] As discussed in Part I, the federal government supports drug R&D in numerous ways, financial and otherwise. Moreover, entities beyond the federal government—for instance, states and non-profits—support drug R&D as well. Thus, restricting CMS' consideration of public support to "prior *Federal financial* support" appears intended as a restriction of sorts—but to what extent?[170]

Congress has left CMS to fill in these interpretive details. Over the past few years CMS has asserted a capacious definition of what constitutes "Federal financial support" in its guidance documents. The most recent definition, found in the IPAY 2028 Final Guidance, states:

> "Federal financial support for novel therapeutic discovery and development" refers to tax credits, direct financial support, grants or contracts, in-kind contributions (e.g., support in the form of office/laboratory space or equipment), *and any other funds provided by the federal government that support discovery, research, and/or development related to the selected drug*.[171]

At first glance, this definition appears extremely broad, and it is broader than the definition offered by CMS in its IPAY 2026 Guidance.[172] The IPAY 2027 Guidance had explicitly added "in-kind contributions,"[173] which is again replicated in the IPAY 2028 Final Guidance above quoted. While as

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[168] *See* 21 U.S.C. § 355(c) (statutory framework pertaining to FDA approval of small-molecule drugs); *see also* 42 U.S.C. § 262(A) (statutory framework pertaining to FDA licensure of biological products).

[169] 42 U.S.C. § 1320f-3(e)(1)(C).

[170] *Id.* (emphasis added). Note that Congress further restricts examining federal funding "with respect to the drug" which could raise additional complications if prior federal support funded multiple drugs. *Id.*

[171] IPAY 2028 Final Guidance, *supra* note 141, at 369–70 (emphasis added). This portion of the IPAY 2028 definition is identical to the 2027 version. IPAY 2027 Guidance, *supra* note 156, at 309.

[172] *Compare* IPAY 2026 Guidance, *supra* note 155, at 194 ("'Federal financial support for novel therapeutic discovery and development' refers to tax credits, direct financial support, grants or contracts, and any other funds provided by the federal government that support discovery, research, and/or development related to the selected drug.") *with* IPAY 2027 Guidance, *supra* note 156, at 154–55 (describing the broadening the definition of federal financial support to include in-kind contributions).

[173] IPAY 2027 Guidance, *supra* note 156, at 154–55 (stating that CMS "broadened" the 2026 revised program guidance definition to include in-kind contributions due to its experience with data submissions).

a *logical* matter there is little reason to *exclude* in-kind contributions from a substantive perspective—focusing on the text—one would, at least prima facie, think that in-kind contributions would be differentiated from financial contributions. Yet, CMS includes "in-kind contributions" under the umbrella of "financial" support, thereby blurring this distinction. Furthermore, the inclusion of a catch-all clause, "any other funds" supporting R&D "related to the selected drug," is capacious.[174] It is unclear what the term "funds" means. Thus, this clause arguably only excludes funding—however ultimately defined—from non-federal sources. Any kind and manner of federal support for drug R&D—for example, indirect funding—at least prima facie—appears to be fair game within the four corners of the definition's text.

Reinforcing this broad understanding of "Federal financial support," CMS has repeatedly declined invitations to restrict its scope.[175] For example, some commenters proposed that federal financial support should exclude tax credits and be restricted to products with a patent possessing a government interest statement or federal agency assignee.[176] CMS declined these recommendations asserting: "[t]he federal government supports drug research through tax incentives" and "[t]he statute does not require that CMS only consider direct expenditures in prior Federal financial support or only government interest patents." [177] In other words, the statute is broad, and CMS will be faithful to the statute.

These broad definitions, however, should not distract from the other ways in which CMS arguably has, at least historically, acted in a more conservative manner. The agency continues to finetune both its interpretation and the scope of federal support eligible for consideration under the Program. In its IPAY 2027 Guidance, for example, CMS imposed some explicit limitations on qualifying federal support. FDA priority review vouchers was one exclusion.[178] CMS stated that the purpose of such vouchers is to expedite review and emphasized that there is no dollar amount associated with them unless they are sold to a different drug manufacturer.[179] Even if one ultimately agrees, this stated rationale invites scrutiny. What principle undergirds this line? Do priority review vouchers not offer a form of federal support for bringing a new drug to market?

Other agency interpretational constraints that could ultimately bear on how fairly government support is being assessed within the larger MDPNP

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[174] IPAY 2028 Final Guidance, *supra* note 141, at 369–70; IPAY 2027 Guidance, *supra* note 156, at 309. This catch-all clause was present in the 2026 Revised Guidance as well. IPAY 2026 Guidance, *supra* note 155, at 194.

[175] IPAY 2026 Guidance, *supra* note 155, at 88–89; IPAY 2027 Guidance, *supra* note 156, at 154–55; IPAY 2028 Final Guidance, *supra* note 141, at 149 ("CMS declines to further revise the series of terms on prior Federal financial support.").

[176] *See, e.g.*, IPAY 2026 Guidance, *supra* note 155, at 88.

[177] *Id.* at 88–89.

[178] IPAY 2027 Guidance, *supra* note 156, at 154–55.

[179] *Id.* at 155.

scheme are more ambiguous and subtle, yet potentially profound. Unlike in its previous guidance,[180] CMS states in the IPAY 2027 Guidance that federal support filtered through a third party will not count for the purposes of its analysis: "CMS confirms that the definition of prior Federal financial support *does not include indirect funding* <u>*such as*</u> that provided by a U.S. federal agency to a third party *which then provided that funding* to a Primary Manufacturer."[181]

It is unclear how capaciously this exclusion should be understood. On the narrower side, suppose researchers at a university receive an NIH grant. Does this exclusion only pertain to instances in which those researchers directly pass along that grant money to a drug manufacturer? This would seem to be the plain meaning. Yet, given the "such as," does CMS intend here to remove the *entire* category of indirect funding from consideration?[182] If so, this would appear a significant limitation on understanding the scope of "prior Federal financial support." Many drugs, including some of the most important drugs, trace their lineage back to academic research centers which receive significant federal support.[183] Moreover, indirect funding through government support of basic and pre-clinical research, as discussed earlier, is often included in studies of the extent to which a drug is deemed to have been the beneficiary of public investment.

Questions about indirect funding intersect meaningfully with questions about what qualifies as "*prior* Federal financial support." Through this term, CMS in the IPAY 2027 Guidance introduced practical temporal limitations that could effectively restrict qualifying funding without clarifying those precise boundaries within the substantive definition itself. This approach potentially permits CMS to delicately sidestep some difficult questions about indirect funding that might otherwise qualify if the timeline were broader.

How, then, does CMS define *prior* Federal financial support in the IPAY 2027 Guidance? "Prior" means federal support:

> [I]ssued during the time period from when initial research began (as defined . . . in the R&D Costs subsection), or when the drug was acquired by the Primary Manufacturer, whichever is later, to the day through the date the most recent NDA / BLA was approved for the selected drug.[184]

The *starting point* for considering the relevance of any federal financial support thus begins either when the initial research on the drug began *or* at the time of a drug's acquisition by a drug manufacturer. The period *closes* when the FDA permits the drug to be sold. The endpoint of this period is clear and remains static for either case. It is important, however, to

[180] IPAY 2026 Guidance, *supra* note 155, at 88–89.
[181] IPAY 2027 Guidance, *supra* note 156, at 154 (emphasis added).
[182] As distinguished from federal support for indirect costs, which are to be included.
[183] Nayak, Avorn & Kesselheim, *supra* note 46, at 9 tbl.5.
[184] IPAY 2027 Guidance, *supra* note 156, at 309.

disaggregate the two scenarios that demarcate the beginning of the relevant period. CMS's approach outlined here may facilitate predictability, but at the cost of a fuller picture relevant to considerations of fairness.

Taking them in reverse order, the IPAY 2027 Guidance states that CMS will not count *any* federal funding that supported a drug's R&D prior to the time of its acquisition by a drug manufacturer, supposing there was an acquisition. This approach may reflect pragmatic considerations: perhaps the primary drug manufacturer does not have access to this information.[185] Nevertheless, this appears to mean that if, for example, a primary drug manufacturer acquired the rights to a drug during a Phase III trial, any federal support prior to that point in time is wiped clean from the slate. It simply does not count.[186] While this is a hypothetical example, it underscores the impact of this carveout—not only in excluding sources that might otherwise qualify as federal support under the statute, but also contributions that *should* count.

Not all drugs, however, involve acquisitions. For non-acquisitions under the IPAY 2027 Guidance, "when initial research began" is the relevant starting point, but the phrase "initial research" only appears twice in this document and is never clearly defined. One reference appears in the definition of prior federal financial support, and the other appears, in passing, in the definition section for "R&D: Basic Pre-Clinical Research Costs."[187] This definition, too, is difficult to parse.[188] This ambiguity regarding "when the initial research began" likely reflects CMS's desire to preserve its discretion as well as conceptual challenges. Indeed, CMS hints at this challenge, stating in a footnote: "CMS acknowledges that the exact date of initial discovery might not be known, but Primary Manufacturers should use their best estimate."[189]

To address this uncertainty, the agency offers practical guidance to drug manufacturers. If, for some reason, the basic pre-clinical research period "cannot be calculated"—or, given the footnote, estimated—CMS directs the manufacturer to count fifty-two months backwards from the day before the first IND application went into effect.[190] CMS arrived at fifty-two months because it deemed this number to "represent[] a solid average across studies" for how long a drug's pre-clinical phase lasts.[191]

Fifty-two months, of course, is just four years and four months—a period that may be far shorter than that used in studies tracing the lineage of

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[185] CMS distinguishes the "Primary Manufacturer" from others. If a primary manufacturer acquired the drug from another entity, it may or may not have access to information about what support was received by that entity. *See id.* at 187.

[186] *Id.* at 155.

[187] *Id.* at 304, 309 (searched using the computer function Command+F).

[188] *Id.* at 304–05 (defining "basic pre-clinical research costs").

[189] *Id.* at 304 n.160.

[190] *Id.* at 304.

[191] *Id.* at 304 n.162.

a drug's federal support. Estimates of federal support, for example, for sofosbuvir (the game-changing Hepatitis C treatment, Sovaldi) note "direct" (as well as indirect) NIH funding beginning in 1993.[192] This is fourteen years prior to when the researchers observe that sofosbuvir was discovered (2007), and sixteen years prior to the date of initial Phase I trials (2009).[193]

Moreover, to the extent it could be gamed, the fifty-two-month default potentially risks undermining the broader public policy aim of arriving at pricing assessments that are fair. Determining the timing of when an initial discovery occurs is inherently ambiguous and open to interpretation. This creates an incentive for drug manufacturers to rely on the fifty-two-month cutoff when doing so aligns with their private interests.[194] As a result, the default is likely to be strategically used, potentially sidelining more thorough evaluations that would better reflect the public's contributions and advance the policy's intent.

The IPAY 2028 Final Guidance definition omits explicitly defining "prior" federal financial support[195] and the document does not mention the phrase "indirect funding." The instructions for the associated Negotiation Data Elements Information Collection Request (ICR) Form, however, suggest that CMS's approach on these matters (albeit with some modifications) is generally in accordance with the IPAY 2027 Guidance.[196] The ICR directs the Primary Manufacturer to "include all prior Federal financial support" that contributed to the selected drug's R&D costs, but *only* funding provided to the Primary Manufacturer.[197] Likewise, regarding the relevant timeline, Primary Manufacturers are to report funding they have "received during the time period from when initial research began, or when the drug was acquired by the Primary Manufacturer, whichever is later," but now the end date for relevant information extends to the end of the current calendar year.[198] The IPAY 2028 Final Guidance and associated draft ICR form further omit the fifty-two month look-back period.[199] Its definition now also incorporates a new bullet point stating: "Direct prior federal financial support costs are costs

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[192] Barenie, Avorn, Tessema & Kesselheim, *supra* note 55, at 275–76.

[193] *Id.* at 274, 279.

[194] *See* Omar Qureshi, Reshma Ramachandran, Melissa Barber & Joseph S. Ross, Comment on IPAY 2027 Draft Guidance, *in* Public Comments: Medicare Drug Price Negotiation Draft Guidance 981 (July 2, 2024), https://www.cms.gov/files/document/public-comments-medicare-drug-price-negotiation-draft-guidance.pdf (expressing concern that manufacturers will default to fifty-two month cutoff, and explaining that doing so risks excluding a disproportionate amount of public investment).

[195] IPAY 2028 Final Guidance, *supra* note 141, at 369–70.

[196] Drug Price Negotiation for Initial Price Applicability Year 2028 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request (ICR) Forms (CMS-10849, OMB 0938-1452) at 23 (Nov. 24, 2025), https://web.archive.org/web/20250223025815/https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-10849 [hereinafter CMS 2028 ICR] (providing a draft version subject to a 30-day comment period which closed on December 24, 2025).

[197] *Id.*

[198] *Id.*

[199] IPAY 2028 Final Guidance, *supra* note 141, at 7 (discussing changes to definitions related to R&D costs, including removal of "instructions for the time periods of the data reported").

that can be specifically attributed to the discovery, pre-clinical development, and clinical trials of indications of the selected drug."[200] The word "specifically" is not further defined.

Prima facie, the IPAY 2028 Final Guidance seems to avoid at least some of the conceptual and normative challenges faced by its predecessor. In particular, to the extent CMS will not utilize a fifty-two-month lookback as part of its assessments of federal funding for IPAY 2028, this definition may offer more inclusive parameters—even if less predictable in some instances—than those articulated for IPAY 2027. Beyond this, the IPAY 2028 approach to "prior Federal financial support" remains broadly consistent with past guidance. It remains to be seen, however, precisely how the IPAY 2028 program cycle will implement this definition in practice.

CMS's definitions and responses in its guidance documents and ICRs notwithstanding, there is very little additional information currently publicly available to better understand how federal support itself is evaluated, as well as factored into the overall maximum fair price assessment.[201] CMS is statutorily required to provide a public explanation of selected drugs' maximum fair prices based on its consideration of the various statutory factors.[202] In providing these narrative summaries and underlying data, CMS has repeatedly emphasized that it would be balancing competing considerations of transparency and confidentiality.[203] Among other things, the public, through a narrative explanation could expect to have an idea of those factors "that had the greatest impact in determining the MFP . . . ."[204] Further, under CMS's confidentiality approach, the agency said it would treat information regarding prior federal funding as "non-proprietary" on the grounds that such data are publicly accessible.[205] By contrast, CMS would presume that other data, such as R&D costs and recoupment information—which may be essential for contextualizing the role of prior federal support—*are* proprietary.[206]

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[200] *Id.* at 370.

[201] *See, e.g.*, Amgen Comment on IPAY 2028 Draft Guidance (June 26, 2025), *in* Public Comments: Medicare Drug Price Negotiation Draft Guidance 151 (Sept. 30, 2025), https://edit.cms.gov/files/document/public-comments-ipay-2028-draft-guidance.pdf ("CMS has not concretely explained how federal financial support will impact initial offers, stating only that the agency 'will consider the extent to which the Primary Manufacturer benefited from Federal financial support with respect to the selected drug' and 'may consider adjusting the preliminary price downward if funding for the discovery and development of the drug was received from Federal sources.' This guidance offers negligible insight into how CMS may consider this information, and the lack of clear standards heightens the risk of inconsistent agency determinations across selected drugs and across years.").

[202] 42 U.S.C.A. § 1320f-4(a)(2).

[203] *See, e.g.*, IPAY 2026 Guidance, *supra* note 155, at 36.

[204] *Id.* at 163. The agency has used identical language across IPAY guidance documents. *See, e.g.*, IPAY 2028 Final Guidance *supra* note 141, at 313 (reflecting this language).

[205] IPAY 2026 Guidance, *supra* note 155, at 123; IPAY 2027 Guidance, *supra* note 156, at 193; IPAY 2028 Final Guidance, *supra* note 141, at 204 (adding now the condition that "CMS will treat prior Federal financial support…that are public available as non-proprietary").

[206] IPAY 2026 Guidance, *supra* note 155, at 123; IPAY 2027 Guidance, *supra* note 156, at 193; IPAY 2028 Final Guidance, *supra* note 141, at 204.

Unfortunately, regarding the factor of federal support the released IPAY 2026 explanatory documents are not illuminating.[207] The summary MFP explanation documents merely use boilerplate language acknowledging that CMS collected information about and considered a drug's prior federal support.[208] Likewise, the underlying manufacturer data released regarding prior federal funding—when it is filled in—is heavily redacted.[209] Of the ten selected drugs, not once is an unredacted dollar amount for federal support included in the released manufacturer provided data.[210] Consequently, these MFP explanation documents provide almost no information to the public about how CMS, in practice, has factored in considerations of public funding.

Beyond these explanatory documents, there is little else to go on. Regarding adjustments to the preliminary price based on the five categories of manufacturer provided data, CMS has said that it will consider this information "in totality and apply an upward adjustment, downward adjustment, or no adjustment to the preliminary price. To do this, CMS may consider each factor in isolation or in combination with other factors."[211] Other than observing that the agency is here reserving for itself great "flexibility,"[212] this offers little insight into CMS's actual process or methodology.

Further, though CMS provides "illustrative" examples in its guidance documents for each factor, its remarks regarding prior federal financial support are far from clarifying. CMS simply states that it:

> will consider the extent to which the Primary Manufacturer benefited from Federal financial support with respect to the selected drug. For example, CMS *may* consider adjusting the

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[207] *Selected Drugs and Negotiated Prices: Selected Drug List for Initial Price Applicability Year 2026 MFP Explanations*, CMS, https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/selected-drugs-and-negotiated-prices (last visited Sept. 23, 2025).

[208] *Compare* CTRS. FOR MEDICARE & MEDICAID SERVS., MAXIMUM FAIR PRICE (MFP) EXPLANATION FOR JANUVIA 5–6 *with* CTRS. FOR MEDICARE & MEDICAID SERVS., MAXIMUM FAIR PRICE (MFP) EXPLANATION FOR ELIQUIS 5–6 (demonstrating boilerplate language for manufacturer-specific data typical of these documents).

[209] *See, e.g.*, CTRS. FOR MEDICARE & MEDICAID SERVS., REDACTED DATA SUBMITTED BY THE PRIMARY MANUFACTURER AND OTHER INTERESTED PARTIES FOR JANUVIA 26–27 (showing significant data redactions including for federal financial support); CTRS. FOR MEDICARE & MEDICAID SERVS., REDACTED DATA SUBMITTED BY THE PRIMARY MANUFACTURER AND OTHER INTERESTED PARTIES FOR NOVOLOG/FIASP 26–30 (same).

[210] *Selected Drugs and Negotiated Prices: Selected Drug List for Initial Price Applicability Year 2026 MFP Explanations*, CMS, https://www.cms.gov/priorities/medicare-prescription-drug-affordability/overview/medicare-drug-price-negotiation-program/selected-drugs-and-negotiated-prices (last visited Sept. 23, 2025) (linking to detailed documents for ten selected drugs).

[211] IPAY 2027 Guidance, *supra* note 156, at 259. Similar language is found in IPAY 2028 Final Guidance, *supra* note 141, at 294.

[212] *See, e.g.*, IPAY 2027 Guidance, *supra* note 156, at 99.

> preliminary price downward if funding for the discovery and development of the drug was received from Federal sources.[213]

But how exactly is the "extent" of benefit from federal support to be measured? The agency currently offers no insights.

In sum, under statutory provisions and regulatory guidance, CMS both reserves for itself great latitude *in principle* given its definitions, yet indicates potentially significant exclusions *in practical application*. The agency's definition of "Federal financial support of novel therapeutic discovery and development" as a component part of generating a maximum fair price is arguably inclusive of all or nearly all kinds of federal contributions. This definition, however, appears to be in some tension with the agency's approach detailed for IPAY 2027 regarding the status of indirect federal funding and its interpretation of which funding counts as "prior." The 2027 interpretation remains somewhat ambiguous yet possesses the potential to significantly curtail the inclusion of federal funding for consideration. The IPAY 2028 Final Guidance may be more more inclusive and flexible, but largely appears to echo past approaches.

Beyond intricacies in evaluating the factor of federal support itself, how CMS utilizes the federal support it *does* deem relevant in its overall analysis is currently a black box. Although CMS has a statutory obligation to consider a selected drug's prior federal financial support, this consideration may ultimately yield no practical effect. CMS makes clear that it is *not* compelled to do anything with this information. By stating that it only "may" make a downward adjustment to the preliminary price based on prior federal support, CMS essentially reserves the right to insulate its offers to drug manufacturers from the impact of such information.

Regardless, the MDPNP is a seismic policy shift. This statutory framework is especially groundbreaking in its explicit engagement with the role of federal support in drug R&D. Many feel that the public has been underserved in this regard by previous legislative and regulatory frameworks. This statutory scheme is an opportunity to examine and address the status quo. The public now has legal recognition that federal support for drug R&D does seem to matter for the fair pricing of successful medications and an agency possesses authority to act accordingly.

Yet, significant normative questions remain for consideration. While one might attempt to piece together a systematic normative approach from the statute and regulatory guidance, CMS does not articulate the underlying principles guiding its treatment of "prior Federal financial support." Nor are such principles obvious. For example, the agency has not offered clarification from a moral standpoint as to why certain forms of support, such as tax credits, should be included while others should be excluded. Why

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[213] IPAY 2028 Final Guidance, *supra* note 141, at 294 (emphasis added); IPAY 2027 Guidance, *supra* note 155, at 260.

think, for instance, that either all or some indirect funding to those beyond the Primary Manufacturer should not count? Moreover, explicit guidance on how CMS *should* account for prior federal funding within its overarching negotiations regarding a drug's maximum fair price is lacking.

Raising these questions is not a critique of the statute nor of CMS. The agency is admirably navigating a complex mandate within real-world time constraints. Rather, these inquiries are meant to underscore the central issue that applies to, yet transcends, this—or any—contingent statutory or regulatory scheme: what is the public owed by way of a return for its support of drug R&D? The evolving framework of the MDPNP is an invitation and opportunity to address this fundamental question.

III. UNDERSTANDING CRITICISMS OF NO-STRINGS-ATTACHED PUBLIC FUNDING

A legal regime that permits drug manufacturers to charge whatever the market will bear with minimal, if toothless, restraints is deeply morally troubling. This moral sentiment is especially acute when a drug's R&D has been publicly supported. Yet, what precisely—if anything—makes such circumstances seem unfair?

The specific normative connection between public support and drug pricing remains underexplored and calls for a more systematic moral approach. [214] This issue invites broader reconsideration of background moral principles and demands serious engagement for policy development. Clarifying this connection is essential for evaluating how legal rules, policies, and proposals might succeed or fail.

Reflection as well as a close examination of criticisms identifies at least three categories of unfairness suggesting that drug prices are problematic given public contributions. These are claims of unfairness based on: (1) government entitlements, (2) comparative unfairness with foreign payers, and (3) transactional fairness. Each is discussed and analyzed in turn. Though there is some intersection between these categories, it is helpful to keep them analytically distinct. Before considering these moral criticisms however, a preliminary issue must be addressed: who is the "we" in "what are *we* owed?"

A. *A Brief Word About "We"*

The phrase *what we are owed* necessarily raises the question: who constitutes the "we"? "We" as used in this Article refers primarily to taxpayers. When critics contend that high drug prices are unfair given public contributions, they generally presuppose that the public—through

[214] *See generally*, Mariana Mazzucato, *Rethinking Innovation in Drugs: A Pathway to Health for All*, 51 J. L., MED. & ETHICS 16 (2023) (explaining the need for a reconfiguration of the drug innovation model to ensure equitable access to innovations).

tax dollars—has played a material role and is therefore entitled to some form of return.[215]

This characterization of "we," however, is imperfect. Not all taxpayers are alike. Drug manufacturers pay taxes—are they treated unfairly as a member of the public?[216] Further, is it *only* taxpayers who have a claim to benefit from government spending? What of the American, for instance, who earns too little to pay taxes? Despite these potential limitations, this framing is expedient for present purposes. Focusing on what is owed to the taxpaying public provides an analytically useful approach for assessing fairness in the allocation of benefits derived from publicly funded research. Complexities in the definition of "we" can be folded in later.

The following analysis generally adopts a further simplifying assumption. It discusses interactions between the public and drug manufacturers as if they occur directly, without intermediaries. While this abstraction to bilateral relationships does not reflect the full complexity of drug research, development, and commercialization, it elucidates the discussion of core allocation principles. Any conclusions will need to be calibrated for intermediaries.

B. *Government Obligations*

Criticisms of drug pricing in the context of taxpayer contributions can intertwine concerns about public contributions to drug R&D with a broader expectation that the government has an obligation to ensure prescription medicines are reasonably priced for those who need them.[217] Such concerns may reflect a belief that "there is some kind of background entitlement to necessities, of which medications are included, that goes unrealized or is

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[215] *See, e.g.*, Sanders, *supra* note 107 ("American taxpayers should not be thanked for the world-leading investments they have put into the research and development of prescription drugs by being charged, by far, the highest prices in the world for the medicine they need.").

[216] Though taxpayers, drug manufacturers are not similarly situated to a taxpayer patient being excluded from the benefits of public investments. Further, there is ongoing inquiry into U.S. tax avoidance strategies utilized by this sector. *See, e.g.*, Ian Gary, *US Pharma Investors Deserve Transparency to Understand Tax Risks*, BLOOMBERG L. (May 19, 2025, 4:30 AM), https://news.bloomberglaw.com/privacy-and-data-security/pharma-tax-avoidance-should-make-us-want-eus-transparency-rules (explaining the tax avoidance strategies of pharmaceutical companies and arguing for increased transparency).

[217] *See, e.g.*, Press Release, Patients for Affordable Drugs, Taxpayers and U.S. Patients Pay Twice for Kite's New CAR-T Drug (Oct. 18, 2017), https://www.patientsforaffordabledrugs.org/2017/10/18/taxpayers-and-us-patients-pay-twice-for-kites-new-car-t-drug (discussing taxpayer contributions and observing it is "time we focus on maximizing access and affordability for patients"); Govind C. Persad, *Pricing Drugs Fairly*, 62 WM. & MARY L. REV. 929, 953–54 (2021) (noting that "individual affordability" and "[a]ffordability to society" are separate considerations and observing that "[c]oncerns about individual affordability have instead motivated some to take the position that some or all medicines should be free to patients."). *But see* Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Policy Pluralism*, 128 YALE L.J. 544, 547–49 (2019) (arguing that innovation incentives and allocation mechanisms should be distinguished).

transgressed and *this* is what seems unfair. . . ."[218] Thus, one potential driver of moral dissatisfaction that gets glossed as an unfairness regarding public contributions may be concern regarding—for lack of a better term—a "welfare unfairness."[219]

The concept of a government obligation to provide access to prescription medications has engendered significant discussion throughout the world. The Universal Declaration of Human Rights recognizes a right to health (including "medical care"),[220] as do many human rights treaties.[221] An important example is The International Covenant on Economic, Social and Cultural Rights ("ICESCR").[222] The ICESCR includes a right to health that has been interpreted as including an embedded right to access medications with a corresponding government obligation.[223] State parties to ICESCR are understood, at the least, to have a "core obligation . . . [t]o provide essential drugs" as defined by the World Health Organization.[224]

The United States, though a signatory to the ICESCR, has not ratified this Covenant[225] and, in contrast to other countries, it does not possess an explicit national constitutional provision regarding a right to health, let alone healthcare.[226] Nonetheless, recent severe budget cuts notwithstanding,[227]

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[218] Wolitz, Drug Manufacturers, *supra* note 16, at 169 (emphasis in original); *see also* Baruch Brody, *Public Goods and Fair Prices: Balancing Technological Innovation with Social Well-Being*, 26 HASTINGS CTR. REP. 5, 10 (1996) (arguing that permitting the market to set drug prices is "mistaken").

[219] Wolitz, Drug Manufacturers, *supra* note 16, at 169; *see also* Brody, *supra* note 218, at 10 (querying how we ought to set drug pricing policies under "some general social mechanism").

[220] G.A. Res. 217 (III) A, Universal Declaration of Human Rights art. 25 (Dec. 10, 1948).

[221] *See, e.g.*, *Human Rights*, WORLD HEALTH ORG. (Dec. 1, 2023) https://www.who.int/news-room/fact-sheets/detail/human-rights-and-health (listing human rights treaties which include a right to health); *see also* Eleanor D. Kinney, *The International Human Right to Health: What Does this Mean for Our Nation and World?*, 34 IND. L. REV. 1457, 1459–62 (2001) (describing some of the international treaties which include a right to health, as well as some international agencies and regional organizations, which promote the right to health).

[222] G.A. Res. 2200A (XXI), International Covenant on Economic, Social and Cultural Rights art. 12 (Dec. 16, 1966) ("The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.").

[223] U.N., Econ. & Social Council, Comm. on Econ., Soc. & Cultural Rts., Substantive Issues Arising in the Implementation of the Int'l Covenant on Econ., Soc. & Cultural Rts. ¶ 43(d), U.N. Doc. E/C.12/2000/4 (Aug. 11, 2000) [hereinafter General Comment on ICESCR]; Suerie Moon, *Respecting the Right to Access to Medicines: Implications of the UN Guiding Principles on Business and Human Rights for the Pharmaceutical Industry*, 15 HEALTH & HUM. RTS. 32, 34 (2013); Katrina Perehudoff, *Universal Access to Essential Medicines as Part of the Right to Health: A Cross-National Comparison of National Laws, Medicines Policies, and Health System Indicators*, 13 GLOB. HEALTH ACTION 1, 2 (2020).

[224] General Comment on ICESCR, *supra* note 223, at ¶ 43.

[225] Scott Busby, *Whither the United States on Economic, Social, and Cultural Rights?*, CTR. FOR STRATEGIC & INT'L STUDS. 2 (Oct. 2024), https://www.csis.org/analysis/whither-united-states-economic-social-and-cultural-rights.

[226] Paul Hunt (Special Rapporteur of the Commission on Human Rights), *Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, ¶ 15, U.N. Doc. A/59/422 (Oct. 8, 2004) ("The right to health is also enshrined in numerous national constitutions: over 100 constitutional provisions include the right to health, the right to health care, or health-related rights such as the right to a healthy environment."); Elizabeth Weeks Leonard, *State Constitutionalism and the Right to Health Care*, 12 J. CONST. L. 1325, 1329 (2010).

[227] President Trump's "signature tax and spending legislation" signed into law on July 4, 2025 cuts

federal programs such as Medicare, Medicaid, and the Children's Health Insurance Program provide access to healthcare—including prescription medications—for certain populations, including older adults, low-income families, and children, reflecting a partial incorporation of health access considerations at the federal level.[228] Additionally, some U.S. state constitutions include provisions that reference health or healthcare as a right.[229] Generally speaking, however, in the United States, arguments for recognizing a right to health—let alone a legal right that specifically encompasses access to medications—whether grounded in human, constitutional, or statutory rights, have been bitterly contested.[230]

Though the existence and scope of a background entitlement to health—and more specifically, access (of some kind) to medications—remains highly politicized and contested, this need not impede our analysis. Suppose that there *is* a government obligation to ensure that the public has access to reasonably priced prescription drugs. If such an obligation exists, whether grounded in human rights or constitutional principles, it would presumably apply to all medications within scope, regardless of a drug's R&D lineage. Under such assumptions, if a patient needed a medication that was, for instance, wholly developed by a private drug manufacturer, this fact would not relieve the government of its obligations.

This general welfare obligation, however, should be disaggregated from a separate sense of unfairness that appears to arise when the public supports a drug's R&D. While a general obligation to provide access to medications may speak to a broader societal expectation, if not entitlement, it does not seem to fully capture the *particular* moral concern that attaches to medications developed with public funds. Focusing solely on a government obligation to ensure affordable access or reasonable prices therefore may obscure the additional, distinct moral issue posed by the current allocation of public and private rights in drugs that benefited from public investment. The "real" issue may not merely be a failure on behalf of the government to fulfill general healthcare entitlements, but rather an injustice tied specifically to the share or kind of returns enjoyed by the public on publicly supported drugs.

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nearly $1 trillion from Medicaid and institutes "other health policy changes." Sareen Habeshian, *Trump's Spending Bill Cuts Medicaid: Here's What it's Called in Your State*, AXIOS (July 8, 2025), https://www.axios.com/2025/07/08/medicaid-cuts-states.

[228] *See generally* BARBARA S. KLEES, ERIC T. ECKSTEIN II & CATHERINE A. CURTIS, BRIEF SUMMARIES OF MEDICARE & MEDICAID: TITLE XVIII AND TITLE XIX OF THE SOCIAL SECURITY ACT (2024), (describing Medicare and Medicaid programs); *Medicaid & CHIP: The Children's Health Insurance Program (CHIP)*, HEALTHCARE. GOV, https://www.healthcare.gov/medicaid-chip/childrens-health-insurance-program (last visited Sept. 19, 2025) (explaining how CHIP works).

[229] Elizabeth Weeks Leonard, *State Constitutionalism and the Right to Health Care*, 12 J. CONST. L. 1325, 1347 (2010).

[230] *See, e.g.*, Peter Sullivan, *Hill GOP Sets Sights on Scrapping Drug Price Talks*, AXIOS (Sep. 17, 2024), https://www.axios.com/2024/09/17/trump-drug-prices-gop-concerns (observing Republican calls to undermine the IRA's negotiation provisions).

This distinction suggests a potential blurring of issues. Once separated, one may recognize two distinct concerns: (1) a general background government obligation to ensure access to reasonably priced prescription medications, and (2) an additional unfairness associated specifically with publicly supported drugs. The relevant question then is how these two senses of unfairness fit together. *If* the latter presents a distinct moral wrong layered onto a governmental failure to fulfill its broader obligation, what are the normative implications for government policy at the intersection of public funding and drug pricing? One such implication might be that the presence of an underlying entitlement could bear on the form of public return the government should demand in its negotiations with drug manufacturers, perhaps by seeking price concessions as a form of return on public investment.

The form that appropriate rewards should take will be discussed further in Part IV. For now, however, it is critical to maintain focus on the central issue. While it seems reasonably clear that a distinct sense of unfairness attaches to drugs developed with public support, the precise nature of this unfairness remains elusive. Framing the critique solely in terms of governmental welfare obligations does not fully capture the underlying issue. Accordingly, it is useful at this stage to acknowledge yet set aside these broader welfare-based criticisms, as they apply irrespective of the fact or degree of public funding. The focus here is to distill and analyze the particular sense of unfairness that critics associate with the pricing of drugs developed with public support.

C. *Comparative Unfairness with Foreign Payers*

Another type of purported unfairness centers the disparity between U.S. prescription drug prices and those in other countries. A common argument holds that the U.S. healthcare system and its patients bear a disproportionate burden of subsidizing not only the development of innovative drugs but also access to these drugs in other developed nations where prices are lower. [231] This notion of foreign "free-riding" is frequently invoked as evidence of the inequitable treatment of the American public, particularly when discussing drugs that benefit from public support.[232]

Claims of purported free-riding off public support based on international pricing disparities are frequently made by members of both political parties.[233] The Biden Administration, for example, as we saw, keyed its

[231] Exec. Order No. 14,297, *supra* note 108, at 20749 (describing this as an "egregious imbalance"); Julie Rovner, *Trump Highlights Health Agenda with Vow to Lower 'Unfair' Drug Prices*, NBC NEWS (Feb. 6, 2019, 10:03 AM), https://www.nbcnews.com/health/health-news/trump-highlights-health-agenda-vow-lower-unfair-drug-prices-n968281; Wolitz, Drug Manufacturers, *supra* note 16, at 144–45.

[232] *See, e.g.*, Exec. Order No. 14,297, *supra* note 108, at 20749 ("The inflated prices in the United States fuel global innovation while foreign health systems get a free ride."); Rovner, *supra* note 231 (quoting Trump statement describing this as a "problem of global freeloading").

[233] Also, such claims have historically often arisen in debates over Bayh-Dole march-in rights. *See,*

ASPR reasonable pricing clause to foreign prices.[234] Commenting on this clause, Senator Sanders observed, "American taxpayers should not be thanked for the world-leading investments they have put into the research and development of prescription drugs by being charged, by far, the highest prices in the world for the medicine they need."[235] Claims of foreign free-riding have also been an on-going theme of both Trump Administrations.[236] A recent White House fact sheet states:

> Drug manufacturers discount their products to gain access to foreign markets and then subsidize those discounts through high prices charged in America—in essence, Americans are subsidizing drug-manufacturer profits and foreign health systems, despite drug manufacturers benefiting from generous research subsidies and enormous healthcare spending by the U.S. Government.[237]

Thus, perhaps unsurprisingly, focus on comparing foreign and domestic drug prices has generated a variety of proposals that not only benchmark against foreign prices as a general matter,[238] but specifically within the

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e.g., Treasure, Avorn & Kesselheim, *supra* note 75, at 773–74 (providing examples of march-in petitions which cited the higher prices Americans were paying for drugs as compared to foreign consumers as evidence of the need for march-in rights to be exercised); *see also* Comments of Aaron S. Kesselheim with Anushka Bhaskar, In the Matter of Request for Information Regarding the Draft Interagency Guidance
Framework for Considering the Exercise of March-In Rights, at 9 (Feb. 6, 2024), https://downloads.regulations.gov/NIST-2023-0008-0767/attachment_1.pdf (citing Senate Report 115–25, Armed Services Committee).

[234] Biden-Harris Pharma Inflation Announcement, *supra* note 102.

[235] Sanders, *supra* note 107.

[236] *See generally*, Exec. Order No. 14,297, *supra* note 108 (comparing inflated drug prices in the United States to lower costs in other developed nations); Exec. Order No. 13,948, 85 Fed. Reg. 59649 (Sept. 13, 2020) (arguing that "Americans finance much of the biopharmaceutical innovation that the world depends on" leading to "bargain prices" for others and calling this "unfair"); Rovner, *supra* note 231 (calling for Congress to address issues of unfair global free-riding).

[237] *Fact Sheet: President Donald J. Trump Announces Actions to Put American Patients First by Lowering Drug Prices and Stopping Foreign Free-Riding on American Pharmaceutical Innovation*, WHITE HOUSE (May 12, 2025), https://www.whitehouse.gov/fact-sheets/2025/05/fact-sheet-president-donald-j-trump-announces-actions-to-put-american-patients-first-by-lowering-drug-prices-and-stopping-foreign-free-riding-on-american-pharmaceutical-innovation.

[238] *See, e.g.*, Exec. Order No. 14,297, *supra* note 108, at 20749–50 (calling for American prices to be brought in line with those of comparably developed nations); *President Donald J. Trump's Blueprint to Lower Drug Prices*, WHITE HOUSE (May 11, 2018), https://trumpwhitehouse.archives.gov/briefings-statements/president-donald-j-trumps-blueprint-lower-drug-prices (discussing high drug prices for Americans and related "foreign freeloading"); Exec. Order No. 13,948, *supra* note 236, at 59649 (proposing to minimize international price disparities by adopting a "most-favored-nation price" for Medicare Parts B and D); Exec. Order No. 13,939, 85 Fed. Reg. 45759 (July 24, 2020) (permitting drug importation and citing pricing disparities with other countries); Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 116th Cong. (2019) (proposing HHS drug price negotiation program based on international price benchmarks); Michelle M. Mello & Rebecca E. Wolitz, *Legal Strategies for Reining in "Unconscionable" Prices for Prescription Drugs*, 114 NW. U. L. REV. 859, 867–87 (2020) (discussing various federal and state drug pricing bills, many of which incorporate international benchmarks); *see also The National Academy for State Health Policy's Proposal for State-Based International Reference Pricing*

context of publicly supported medications.[239] Such policies strive "to keep Americans from paying unfair prices for the care they need"[240] and "ensure that Americans are not paying more than people in other wealthy countries for the health security-related medicines their tax dollars support."[241]

Though common, these criticisms of U.S. drug prices blur several distinct issues that merit separation. The first pertains to the identities of the actors alleged to be behaving unfairly. The second, more fundamental, issue pertains to the nature of the unfairness being alleged. Each is discussed in turn.

Criticisms of unfairness grounded in foreign drug pricing tend to obscure the roles of the key actors allegedly contributing to this unfairness. At a high level, three primary actors should be distinguished: (1) drug manufacturers, (2) foreign governments, or payers, and (3) the U.S. government. Regarding unfairness perpetrated by drug manufacturers, these companies are frequently criticized for pricing practices that purportedly undervalue U.S. public contributions to a drug's R&D. Meanwhile, foreign governments are accused of "free-riding" on American investments by having the same drugs be available within their countries at lower prices. Finally, the U.S. government, given its plenary regulatory power, plays a ubiquitous role in these allegations of unfairness by *permitting* domestic policies that may either fail to acknowledge the public's contribution or otherwise disadvantage the U.S. public relative to patients in other countries.

Disaggregating these actors is essential to foreground the relationship that matters most for present purposes: the one between the U.S. government—as the public's representative and fiduciary—and private drug manufacturers. Framing the debate around cross-border price differences shifts attention away from this relationship to the activities of foreign countries. While politically expedient, invoking foreign "free-riding" on American investments risks obscuring the core issue: whether U.S. law and policy adequately serve the American public's interests vis-à-vis drug manufacturers.

The second distinction that ought to be made pertains to the nature of the unfairness. Focusing on foreign prices emphasizes a distinct kind of comparative unfairness—the idea that American patients pay significantly more for drugs than patients in other developed countries. The U.S. public

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for Prescription Drugs, NAT'L ACAD. FOR STATE HEALTH POL'Y (Aug. 10, 2020), https://nashp.org/the-national-academy-for-state-health-policys-proposal-for-state-based-international-reference-pricing-for-prescription-drugs (proposing policy for states to utilize international reference pricing).

[239] *See, e.g.*, Assembly No. 2671, 219th Leg. (N.J. 2020) (calling for international pricing benchmarks for drugs, biologics, and other health care technology developed directly or indirectly supported by the federal or state government); HHS Announcement, *supra* note 105 (announcing commitment by Regeneron for commercialized BARDA funded products to benchmark U.S. list prices against prices in other high income countries); S. 1681, 115th Cong. § 1(b) (2017) (proposal requiring federally funded drug developers to enter into reasonable pricing agreements with Secretary of HHS where reasonable pricing is benchmarked against prices in other countries).

[240] Biden-Harris Pharma Inflation Announcement, *supra* note 102.

[241] *White House Takes Additional Steps Towards Fairer Pricing for Drugs Developed With Taxpayer Funding*, PUB. CITIZEN (Dec. 14, 2023), https://www.citizen.org/news/white-house-takes-additional-steps-towards-fairer-pricing-for-drugs-developed-with-taxpayer-funding.

is alleged to be getting a raw deal *relative to* purchasers in other countries that did not contribute to a drug's development.[242]

Yet, are fairness concerns regarding public investments in drug R&D at their core fully captured by foreign price comparisons? Consider the following: suppose a drug developed with U.S. public support was sold to Americans at the same price as to Germans, who provided no such support. Equality of pricing across borders—or nondiscrimination in pricing—does not mean that prices are fair.[243] Equal prices might be generally unfair to both Americans and Germans, and, more significantly, they might be particularly unfair to Americans *given their prior public support of the drug's R&D*. Is it not *this* sense that is the first-order concern? It is understandable to be aggrieved, if not outraged, when others get a better price. Charges of unfairness about comparative pricing disparities, however, could arise regardless of the drug's funding lineage.

The unique unfairness issue at the core of moral indignation over the pricing of *publicly supported drugs* thus does not seem to be simply a matter of comparative foreign pricing. Rather, it appears to be the notion that the public is getting a "raw deal"[244] vis-à-vis a private drug manufacturer *because* the drug in question was developed with public support. For these reasons, the political preoccupation with the prices paid in other countries—within the context of purported unfairness to the American public *on the basis of publicly supported medications*—though politically expedient, appears to be a second-order issue. It seems more a (potential) insult *added to* an injury as opposed to the core injury itself. It weaves together separate strands of unfairness claims that ought to be kept distinct.

One might, moreover, take issue with the comparative claim taken on its own apart from any considerations of public funding. Claims of comparative unfairness and consequently the proliferation of proposals for redress through mandated equality of pricing across countries, though prima facie plausible, should not be accepted uncritically. Subscribing to this purported unfairness assumes a lot that requires a defense. Presumably, the idea that underlies such claims is that what makes an unequal price unfair is the sheer fact that another country believed to be sufficiently like us in the relevant ways gets a better price.[245] But are the United States and other high-income countries sufficiently alike when it comes to prescription drug purchasing?

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[242] Of course, one possible implication of this is *not* that drugs necessarily should be cheaper for Americans, but that foreign drugs should be *more* expensive.

[243] Wolitz, Drug Manufacturers, *supra* note 16, at 189–90; *see also* Persad, *supra* note 217, at 949–50 (rejecting the view that price discrimination is necessarily unfair).

[244] Rebecca Wolitz, *Recent Litigation Developments Regarding Drug Pricing and Access*, STAN. L. SCH.: L. & BIOSCIS. BLOG (Jan. 3, 2020), https://law.stanford.edu/2020/01/03/recent-litigation-developments-regarding-drug-pricing-and-access.

[245] *See* Wolitz, *The Pay-Twice Critique*, *supra* note 6, at 209 ("This interpretation of reasonable pricing incorporates a moral principle that like ought to be treated alike." (internal quotation marks and citations omitted)).

What factors ought to be relied upon as relevant in making comparisons between the United States and other countries for these purposes?

Further, even if there are sufficient similarities, why focus on equalizing the *price* of a drug across countries? For the sake of the argument, suppose advocates for equality with foreign prices subscribe to an underlying principle along the lines of, "if each patient in need of the drug (whether, for instance, American or German) is a moral equal, each patient should be treated equally by the drug manufacturer."[246] There is little reason to think, however, that equal treatment by a drug manufacturer requires uniform pricing. To the contrary, "[w]hat really seems to matter from a comparative fairness perspective is the fair treatment of patients relative to their welfare and not relative to the *prices* they pay for their medications."[247] It does not take much imagination to understand that given vast inequalities in background economic circumstances, the price of a drug can have disparate impacts on patient welfare, both across countries and within countries. Equalizing the price of medications in terms of dollars spent is not the same as equalizing patient welfare.[248]

Nonetheless, the political and practical appeal of comparative fairness claims is understandable. This approach appeals to an intuitive principle of fairness—that like should be treated alike[249]—which can gain broad political traction when the complexities are not closely examined. Moreover, such a focus can deflect scrutiny from the actions of drug manufacturers and the U.S. government by introducing other countries as potential wrong-doers who "free-ride" on American investments through lower prices.

This focus on foreign price benchmarking also offers the promise of a simplified pricing strategy; it is a shorthand. It outsources the determination of fair drug prices to other countries and aligns U.S. prices accordingly. Such a strategy capitalizes on the labor, data, and resource-intensive efforts already invested in foreign drug pricing assessments.[250] However, this also means that the U.S. system may import values and other assumptions that may imperfectly align with the American context.[251]

While there may be merit to claims of comparative unfairness based on disparities in foreign pricing, this is a secondary issue. The central issue

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[246] For a discussion of this principle, see Wolitz, Drug Manufacturers, *supra* note 16, at 189.

[247] *Id.* (emphasis in original).

[248] *Id.*

[249] Wolitz, *The Pay-Twice Critique*, *supra* note 6, at 209.

[250] *See generally* Leah Z. Rand, G.J. Melendez-Torres & Aaron S. Kesselheim, *Alternatives to the Quality-Adjusted Life Year: How Well Do They Address Common Criticisms?*, 58 HEALTH SERVS. RSCH. 433 (2023) (discussing other countries' approaches to health technology assessments and their responsiveness to criticisms of Quality Adjusted Life Years (QALYs)).

[251] For example, countries measure the health value of interventions in different ways. The use of QALYs has been a point of contention in the U.S. *See* Christen Linke Young, Richard G. Frank & Rachel Sachs, *International Reference Pricing for Prescription Drugs*, BROOKINGS (July 9, 2025), https://www.brookings.edu/articles/international-reference-pricing-for-prescription-drugs (explaining concern that use of QALYs may "undervalue treatments for certain kinds of conditions and discriminate against people with disabilities.").

concerns drug manufacturers' and the U.S. government's purported failure to account for the public's contributions to drug R&D. A focus on comparative price disparities risks conflating these distinct issues. Thus, comparative price concerns, while potentially relevant, should be viewed as secondary to the primary issue: securing a fair allocation of returns given public support.

D. *Transactional Fairness*

Having discussed government obligations and claims of comparative unfairness due to higher drug prices in the U.S. than in other countries, I now turn to the question of transactional fairness. In debates over the cost of publicly funded medications, the primary "unfairness" concern is often a perceived imbalance in the allocation of benefits. Many claim that the public is "getting fleeced," or partaking in a "bad deal," with drug manufacturers taking advantage of the U.S. government and hence the public.[252] This perception of unfairness stems from a belief that "[a]nother party is purportedly benefiting more than it should, and taxpayers are benefiting less than they should in light of taxpayer contributions to the underlying product."[253] The core issue is a concern for moral defect in the arrangement itself: an unfair distribution of benefits and burdens as between the parties.[254]

The key question, then, is what constitutes an unfair distribution of benefits and burdens? As others have noted, there has generally been a deficit in attention to deciphering what precisely constitutes a normatively justifiable allocation of public rewards.[255] Given this unique context where market principles are not wholly at play, what moral principles should guide this assessment? There are many candidate allocation principles one could draw on. Here, I discuss five. An allocation of benefits and burdens derived from a successful drug might be considered unfair if it: (1) involves "paying twice," (2) involves excessive incentives, (3) fails to recoup costs, (4) is unequal, or (5) is disproportional. The structure of each sub-section is as follows: each proposed principle is first articulated, followed by an analysis.

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[252] Wolitz, *The Pay-Twice Critique*, *supra* note 6, at 184 (internal quotation marks omitted).

[253] *Id.* at 184–85. While for ease of exposition, I refer to this as "transactional unfairness," this phenomenon is not strictly confined to agreements such as grants, CRADAs, licensing terms, etc. Tax credits and deductions provided by Congress are not contractual in this sense, and yet they may still trigger a sentiment that taxpayers are treated unfairly.

[254] There may be procedural problems with these arrangements. This Article focuses on substantive ones.

[255] Andrea Laplane & Mariana Mazzucato, *Socializing the Risks and Rewards of Public Investments: Economic, Policy, and Legal Issues*, 49 RSCH. POL'Y 1, 3 (2020).

1. *Paying Twice*

A common slogan in debates about the pricing of publicly supported medications is the "pay-twice critique."[256] This critique argues that the public purportedly pays twice for its medications—"first, for the research and, second, through the above-market pricing of resulting privatized products."[257] Although imprecise,[258] this critique highlights a key fairness concern: the *double-counting* of R&D costs. What may strike many as unfair about expensive, publicly supported medications is the perceived passing along of costs that were already subsidized.

A first candidate fair allocation principle, then, is what I will call the *principle of public subsidy exclusion*. This principle holds that for an allocation of benefits and burdens from a government-supported medication to be fair between the government and a drug manufacturer, the manufacturer must, *at the very least*, exclude public funding from the drug's price; fairness requires manufacturers to refrain from charging for R&D costs already covered by public funding. In other words, prices for publicly funded drugs should reflect public contributions to that drug's R&D in a specific way; the core idea is that *drug manufacturers should not charge for costs already covered by the public*. If drug manufacturers *are* permitted to pass along such costs, the public is treated unfairly by a distribution of benefits and burdens that reflects a double payment by the public for medications that they already subsidized. Drug manufacturers, meanwhile, are perceived as receiving a windfall from their public partner relative to their R&D costs.[259]

To illustrate with easy numbers, suppose a drug's R&D costs total $1,000, split evenly between a drug manufacturer and the federal government. The manufacturer invests $500, and the government provides a $500 grant. When the drug reaches the market and patients struggle to afford it, the manufacturer justifies its price by claiming it reflects the full $1,000 in R&D. According to the principle of public subsidy exclusion, passing along the full $1,000 would be unfair because it double-charges patients for the $500 already funded by public support.

As demands of fairness go, a principle of public subsidy exclusion is modest. At its core, it simply requires that drug manufacturers exercise minimal restraint. This principle acts as a safeguard against inequitable practices, analogous perhaps to a scenario where two friends agree to "split" the cost of a vacation rental, but one fails to disclose a negotiated discount and charges the other the full share. Similarly, the principle calls on drug manufacturers to avoid inappropriately shifting costs onto their joint

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[256] Wolitz, *The Pay-Twice Critique*, *supra* note 6, at 178.

[257] *Id.*

[258] For a discussion on the questions raised by this critique, see *id.* at 183–89.

[259] *See, e.g.*, THE PEOPLE'S PRESCRIPTION, *supra* note 13, at 17–19 (2018) (discussing how public bodies pay large portions of drug R&D costs without a guarantee that the drugs will be accessible).

collaborator, the public funder. A distribution of benefits and burdens between a drug manufacturer and the public—other things equal—that involves such cost-shifting, under this principle, is unfair.

Is the principle of public subsidy exclusion a good guiding principle for determining if the allocation of benefits between the government and a private drug manufacturer is fair? Three potential counterarguments emerge. First, the principle might be criticized as irrelevant: drug prices are not set in a way that reflects costs. If prices are not actually set by reference to R&D costs, how is it that public contributions would have an important role to play in allocational fairness? Two additional counterarguments point in opposite directions. This principle might be criticized at once for being too weak *and* too strong. Each counterargument is considered in turn.

A first criticism of a principle of public subsidy exclusion points out that the principle appears to implicitly assume that drug prices are set with an eye toward R&D costs, however the details of those costs are filled out.[260] Yet, as a matter of real-world practice, this is not how drug prices are determined. In the U.S., drug manufacturers enjoy significant discretion in setting prices, which are typically driven by profit maximization rather than cost recovery.[261] Former CEOs of major pharmaceutical companies have disclaimed cost-recoupment as a primary driver of pricing,[262] and academic research likewise substantiates the lack of an association. For example, one recent study concluded:

> The lack of association between research and development investments and list prices of drugs was not unexpected, given that pharmaceutical firms aim to maximize profits based on consumers' willingness to pay. This study offers empirical evidence that, in the US, drug companies charge what the market will bear.[263]

It thus might be argued that the principle of public subsidy exclusion is misdirected. If prices are not tied to R&D costs, the rationale for ensuring

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[260] There is considerable debate over costs. *See* Mello & Wolitz, *supra* note 238, at 950–51 (2020) (discussing various challenges in determining drug costs drawing on a discussion of public utilities rate regulation).

[261] *See, e.g.*, Rebecca E. Wolitz, *States, Preemption, and Patented Drug Prices*, 52 SETON HALL L. REV. 385, 404–06 (2021) [hereinafter Wolitz, *Preemption*] (collecting citations regarding pricing and R&D costs).

[262] *See* Ezekiel J. Emanuel, *Big Pharma's Go-To Defense of Soaring Drug Prices Doesn't Add Up*, ATLANTIC (Mar. 23, 2019), https://www.theatlantic.com/health/archive/2019/03/drug-prices-high-cost-research-and-development/585253 (citing former pharmaceutical executives' explanations of how drug prices are set); Wolitz, *Preemption*, *supra* note 261, at 416 n.161 (noting Novartis' defense of the $2.1 million price of Zolgensma as based on value).

[263] Olivier J. Wouters, Lucas A. Berenbrok, Meiqi He, Yihan Li & Inmaculada Hernandez, *Association of Research and Development Investments with Treatment Costs for New Drugs Approved from 2009 to 2018*, JAMA NETWORK: OPEN (Sept. 26, 2022), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2796669.

the exclusion of "double-counting" public subsidies in price-setting as a fairness principle is undermined.

This counterargument can be addressed rather quickly. Drug manufacturers frequently rely on R&D cost-based justifications to defend high prices, arguing that high prices are necessary to sustain innovation.[264] While one might be inclined to dismiss such arguments merely as self-serving rhetoric given the source, R&D cost-based justifications are further used to justify existing intellectual property policies. Patent and marketing exclusivities, if not others, are routinely framed as "provid[ing] opportunities for pharmaceutical companies to recoup their R&D investments in new drugs by limiting competition . . . ."[265] If R&D costs are used to justify prices to the public, this implicitly acknowledges the normative appeal of aligning pricing with R&D costs as relevant to considerations of pricing fairness.[266] Thus, if R&D costs are *not* completely covered by the drug manufacturer, and instead some of those costs derive from public contributions, those public contributions appear at least prima facie relevant to deciphering whether a drug's price is fair to the public. Consequently, without more, drug manufacturers and others cannot credibly dismiss the principle of public subsidy exclusion as irrelevant to questions of fairness to the public due to how prices are actually set.[267]

A second counterargument to the principle of public subsidy exclusion is that it offers an insufficiently robust standard of fairness. It underpowers an allocation of benefits to the government given that the principle merely requires that drug manufacturers exclude publicly subsidized R&D costs from the prices they charge for resulting products. While this addresses

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[264] *See, e.g.*, Nancy L. Yu, Zachary Helms & Peter B. Bach, *R&D Costs for Pharmaceutical Companies Do Not Explain Elevated US Drug Prices*, HEALTH AFFS. (Mar. 7, 2017), https://www.healthaffairs.org/do/10.1377/hblog20170307.059036/full (testing claim that premium prices paid by U.S. patients and taxpayers are required to fund drug R&D); Michael A. Carrier & Genevieve Tung, *The Industry That Cries Wolf: Pharma and Innovation*, STAT (Sept. 26, 2019), https://www.statnews.com/2019/09/26/innovation-boy-cried-wolf-pharma-industry (arguing that drug companies should crying "Innovation Wolf" each time Congress seeks to pass reasonable legislation); Wolitz, *Preemption*, *supra* note 261, at 401–02 (noting "mantra" that reducing drug prices necessarily leads to less innovative therapies); Am. Enter. Inst., *Sec. Alex M. Azar II: Fixing Health Care | LIVE STREAM*, YOUTUBE at 4:47 (May 16, 2018), https://www.youtube.com/watch?v=JuybD710fMs&t=1429s (refuting claim that Americans can have "new cures or affordable prices but not both . . . .").

[265] U.S. GOV'T ACCOUNTABILITY OFF., GAO-21-52, BIOMEDICAL RESEARCH: NIH SHOULD PUBLICLY REPORT MORE INFORMATION ABOUT THE LICENSING OF ITS INTELLECTUAL PROPERTY 14 (2020).

[266] Of course, suggesting that costs are relevant to fair drug pricing does not imply that they are the *only* thing that matters. As I argue elsewhere, "cost-plus pricing as an approach to determining unfairly high drug pricing gets a mixed review. An unfairness argument derived from patient accessibility cannot support the conclusion that prices in excess of the cost-plus price are necessarily unfair." Wolitz, Drug Manufacturers, *supra* note 16, at 192. A cost-plus-reasonable-profit approach has further been criticized from an innovation policy perspective for its "fail[ure] to align private incentives with social objectives," instead providing "the same incentive, in risk-adjusted terms, for *any* R&D investment." Daniel J. Hemel & Lisa Larrimore Ouellette, *Valuing Medical Innovation*, 75 STAN. L. REV. 517, 580 (2023) (emphasis in original).

[267] Moreover, and more simply, even if prices are not actually set in accordance with R&D costs, this does not imply that they ought not have a role to play.

"double-counting," it does little to ensure that the public receives a return on its investments. Should not the public be entitled to more than the avoidance of duplicative charges? The principle of public subsidy exclusion appears to set the bar too low. It provides a backstop against one kind of potentially unfair conduct but does not affirmatively *ensure* that the resultant allocation *is* fair, all things considered.

Conversely, a third counterargument takes the opposite line of attack. This line of argument suggests that the principle is too strong given its simplistic focus on duplicative costs. Drug R&D, it might be argued, is not appropriately analogous to two friends splitting the costs of a vacation rental. Analogizing in this way obscures the larger context in which an allocation principle is embedded—the government's background objective of bringing new, important drugs to market.[268] Going back to the example of $1,000 R&D costs split between a drug manufacturer and the government, suppose that without the government's contribution of $500, the drug would not have been invented. If the drug manufacturer still passes along the full $1,000 to patient-consumers through the drug's price, is this unfair? One can imagine the drug manufacturer *and* the government arguing in this instance: "Of course, it is not unfair! That $500 grant was *necessary* for the drug to exist. If it was necessary, how could that be unfair?"

The focus on the $500 grant, of course, obscures the other possible innovation incentives at play: intellectual property rights, marketing exclusivities, insurance reimbursement, etc. The relevant question, then—this interlocuter asserts—is not whether it is unfair that the prices patients and insurers pay reflect greater than or equal to a double charge of the manufacturer's costs. Rather, the question is, given the collection of incentives that are available to the drug manufacturer, is the price being charged fair in light of the government's objective that this technology should exist in the first place?

Considering these criticisms, though rhetorically powerful through the slogan of "paying twice," the underlying principle of public subsidy exclusion is too blunt an instrument for offering meaningful guidance on a fair distribution of benefits. Perhaps most forcefully, this principle fails to clarify why "duplicative" costs are necessarily unfair if they are required to adequately incentivize new drug innovation. Without more, the principle of public subsidy exclusion oversimplifies the complex interplay of public and private contributions to drug R&D and its implications for a fair allocation of benefits.

2. *Excessive Incentives*

Government support for drug R&D is offered in the service of facilitating the existence of these drugs in the first place. Whether the

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[268] *See, e.g.*, *NIH Mission and Goals*, *supra* note 30 (emphasizing scientific and health-related goals).

government offers a direct grant, a tax credit, a patent, a license, etc., these are all incentives so that the public can have a drug that will ideally improve social welfare.[269] The goal of the government is that the world will be a better place for having these drugs in it. Consequently, a dominant interpretation of applicable law like the Bayh-Dole march-in provisions is that the mere eventual commercialization of a successful technology is all that the government ought to require for these relationships between the government and a private party to be considered fair.[270]

This focus on innovation incentives therefore suggests a second principle through which to understand whether the relationship between the government and a third party is fair: a principle of excessive incentives. A *principle of excessive incentives* allocates benefits based on whether a drug has come to market that otherwise would not; it assumes that the drug would not have come to be but for the government's contribution. A distribution of benefits and burdens among the parties, on this view, is fair for the public (via the government) so long as the government does not overpay through the incentives it offers.[271] Importantly, the principle of excessive incentives does not demand winners. It is not considered unfair to the public if a government-supported project fails. After all, many roads that seem initially promising are unsuccessful.[272]

A principle of excessive incentives is attractive. Few, I suspect, would disagree that it is wasteful to overspend for an outcome that could have been obtained more cheaply. No one wants to overpay for things, and this seems especially true when government support for drug R&D is involved. The government, as a steward of scarce taxpayer resources, has an obligation not to waste them. In resource-constrained healthcare settings, inefficient spending compels individuals and institutions to make high-stakes choices without any compelling countervailing justification.[273] Patients may be forced to choose between their prescriptions and rent.[274] Likewise, at the institutional level, wasteful spending tightens already constrained budgets, potentially requiring difficult trade-offs that might have otherwise been

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[269] *See generally* Hemel & Ouellette, *Innovation Policy Pluralism*, *supra* note 217 (discussing IP and non-IP incentives); Christopher Buccafusco & Jonathan S. Masur, *Drugs, Patents, and Well-Being*, 98 WASH. U. L. REV. 1403, 1404 (2021) ("the ultimate end of patent law should be to spur innovations that improve human welfare—innovations that make people better off").

[270] *See, e.g.*, ZERHOUNI, *supra* note 79, at 2, 4–5 (finding that drug was sufficiently accessible to the public); Treasure, Avorn & Kesselheim, *supra* note 75, at 779–80 (discussing commercialization view as well as concerns regarding the possible impracticality of applying march-in rights).

[271] Wolitz, *The Pay-Twice Critique*, *supra* note 6, at 185 (citing Daniel J. Hemel & Lisa Larrimore Ouellette, *Bayh-Dole Beyond Borders*, 4 J.L. & BIOSCIS. 282, 288 (2017)).

[272] *See, e.g.*, Helen Dowden & Jamie Munro, *Trends in Clinical Success Rates and Therapeutic Focus*, 18 NATURE REVS. DRUG DISC. 495–96 (2019).

[273] *See* Wolitz, *Preemption*, *supra* note 261, at 394–96 (discussing possible injustice and inefficiency of drug pricing at the intersection of the patent scheme); Wolitz, Drug Manufacturers, *supra* note 16, at 173–74 (discussing possible injustice of drug pricing "above affordability").

[274] Wolitz, *Preemption*, *supra* note 261, at 395.

avoided.[275] Thus, inefficiently allocating scarce government resources given seemingly bottomless un- or underfunded needs is not merely wasteful but unfair.

Misuse of government resources certainly seems unfair to the public, but at least two large questions arise about the principle of excessive incentives. First, why think that a fair allocation of rewards for the public is merely the existence or commercialization of a new drug? Second, and more fundamentally, why think that this principle gets traction on the specific fair allocation issue that concerns this Article's inquiry?

To the first question, in a capitalist society innovation policy is dominantly organized around private actors and market incentives.[276] On this view, if a medical intervention is not already being researched and developed, it is because there is a lack of economic incentives available through the market.[277] However, as has been well discussed in the literature, market incentives do not always well align with urgent medical needs.[278] There are various ways that incentives (mixed with existing law) can fail to bring about high social value medical interventions.[279] Neglected diseases, for instance, are those diseases where there is great need and possibility for new interventions from a public health perspective, but absent some government intervention, an economically unattractive proposition for private for-profit actors.[280]

Given the role of market incentives in innovation policy, and the presence of various market failures from a health perspective, the prevailing traditional wisdom has been to view the government as occupying a supporting role in innovation policy as market-failure fixer.[281] This role as "market-fixer" offers a rationale for why the law has been structured in a way that demands very little by way of direct benefit sharing from private sector beneficiaries of government support.[282] It assumes that as a fix is needed to correct for an existing failure, this is the discrete role that the government plays. It aims to correct for the failure, so that a new drug might be invented and commercialized—or, at least, to stimulate efforts for a *chance* that this may

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[275] *Id.*

[276] Laplane & Mazzucato, *supra* note 255, at 2.

[277] *See, e.g.*, Buccafusco & Masur, *supra* note 269, at 1405 (observing the underproduction of certain drugs because they primarily serve people who cannot afford them).

[278] *Id.*; Hemel & Ouellette, *Valuing Medical Innovation*, *supra* note 266, at 517, 520–24; Amy Kapczynski & Talha Syed, *The Continuum of Excludability and the Limits of Patents*, 122 YALE L.J. 1900, 1911, 1942 (2013).

[279] *See generally* Hemel & Ouellette, *Valuing Medical Innovation*, *supra* note 266; Rachel E. Sachs, *Prizing Insurance: Prescription Drug Insurance as Innovation Incentive*, 30 HARV. J.L. & TECH. 153, 157 (2016).

[280] Sachs, *supra* note 279, at 157; *see also* Matiangai Sirleaf, *Disposable Lives: COVID-19, Vaccines, and the Uprising*, 121 COLUM. L. REV. F. 71, 90–91 (2021) (noting that market incentives can be ill-suited for pharmaceuticals, particularly vaccines, and comparing R&D timelines for the Ebola virus and COVID-19).

[281] Laplane & Mazzucato, *supra* note 255, at 1–3.

[282] *See id.* at 2–3.

be the case. For the government to ask for anything more by way of benefits for its efforts, on this view, would be counterproductive; it would undermine the whole point of the exercise,[283] leaving the market failure in place.[284] Moreover, with this view of the government acting as merely a "corrector" built into the law, the law appears to tacitly assume that the government does not spend excessively on these "fixes."

Furthermore, as adherents of this view point out, when a drug *does* successfully make it to market, the government gets more than simply the benefit of the drug's existence qua drug. It anticipates a suite of indirect benefits such as increased tax revenue, increased employment, improved public health, knowledge spillovers, etc.[285] In a report about the Bayh-Dole Act, for instance, the Congressional Research Service summarized Congress' view of a removed draft recoupment provision "as an unnecessary obstacle" and that "Congress accepted as satisfactory the anticipated payback to the country through increased revenues from taxes on profits, new jobs created, improved productivity, and economic growth."[286]

Part I demonstrated that U.S. law and policy is structured in a way that reflects these assumptions about the proper role of the government and the appropriate demands it may make upon private actors. By largely failing to account for direct benefits that ought to derive from public contributions to drug development, it appears to implicitly assume away the possibility of an unfair distribution based on the provision of these innovation incentives. Nevertheless, for decades, innovation policy scholars have questioned this regime in the vein of a principle of excessive incentives, asking whether the existing U.S. regime gets things "right" by way of the collective package of incentives it offers.[287] There has been ample criticism.[288]

I want to suggest, however, as important as these issues are, they can be orthogonal, rather than central, to the primary fairness question that concerns this inquiry—what the public is owed as a matter of fairness, when it has already contributed to the R&D of a new drug. This is so for two reasons.

First, the focus on innovation incentives, albeit important and related, most dominantly concerns a fair allocation issue distinct from that which is the focus of this Article. Second, even if the government gets the incentive

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[283] *See, e.g.*, OUELLETTE, *supra* note 40, at 13 (discussing how public funding presently aims to correct market failures rather than fully cover R&D costs).

[284] *Id.* (arguing for example that if "a given drug was 13 percent publicly funded does not mean that the manufacturer's private rewards should be reduced by 13 percent—such a reduction would merely reinstate the market distortions that public funding should be targeted to correct").

[285] DEP'T OF HEALTH & HUM. SERVS., NIH RESPONSE TO THE CONFERENCE REPORT REQUEST FOR A PLAN TO ENSURE TAXPAYERS' INTERESTS ARE PROTECTED 11 (2001). *See* Laplane & Mazzucato, *supra* note 255, at 2.

[286] WENDY H. SCHACHT, CONG. RSCH. SERV., RL32076, THE BAYH-DOLE ACT: SELECTED ISSUES IN PATENT POLICY AND THE COMMERCIALIZATION OF TECHNOLOGY 16 (2012).

[287] Eisenberg, *supra* note 6, at 1665–70; Lisa Larrimore Ouellette & Rebecca Weires, *University Patenting: Is Private Law Serving Public Values?*, 2019 MICH. ST. L. REV. 1329, 1333–34 (2019).

[288] *See, e.g.*, Morten, *supra* note 42, at 36–38 (examining the government's role in developing the Moderna vaccine and arguing that negotiations were "botched").

package *just* right, meaning it does not overpay by way of incentives for a new drug to be invented and commercialized, this does not mean that the government necessarily exhausts its claims—as a matter of transactional fairness—to receiving direct benefits from its contribution. Not all contributions presumably are market "corrections," nor should we assume that all contributions are alike.[289] Government contributions to improve or facilitate a market for biomedical interventions do not universally foreclose the government's moral claim to "additional" direct benefits. Each issue is discussed below.

Focusing first on whether innovation incentives are excessive at the intersection of relegating the government to the role of "market corrector" at best obscures, and at worst conflates, two distinct questions of allocational fairness to the public. In debates over the allocation of benefits of publicly supported innovation, it appears crucial to distinguish between two related but distinct concerns: (1) the fair allocation of scarce public funds to incentivize projects, and (2) the fair allocation of rewards *derived from* those publicly supported projects.

Both allocation issues are important, and both can involve treating the public unfairly. Few would dispute that the inefficient use of scarce government funds through excessive incentives is unfair. The efficiency of contributions is central to Problem 1. If the government overpays to induce development, it unfairly misallocates resources.

A principle of excessive incentives, however, seems to have less to say about Problem 2. What does inefficient spending on research priorities have to do with the question, *once public funds have been expended, what is it fair for the government to demand in return*? Paying excessively (or not) to incentivize a new drug may illuminate Problem 1, but it does not offer a complete answer to Problem 2.[290] While avoiding overpayment is a crucial question of fairness understood as efficiency, efficiency alone does not guarantee that the benefits of a successful drug are fairly shared between public and private contributors. As a guide for Problem 2, a principle of excessive incentives should therefore be rejected.

A deeper question, however, remains: even if a principle of excessive incentives ought to be rejected for determining what the public is owed from its support of drug R&D, in what way *should* concerns about innovation incentives impact an assessment of a fair allocation of benefits?

The issue of innovation incentives is relevant insofar as one does not want to undermine the government's overarching goal of ensuring that a

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[289] As discussed below, this gloss of the government as only a "market fixer" is contestable. Laplane & Mazzucato, *supra* note 255, at 1–2, 4.

[290] To be sure, the questions are related, but they are not coextensive. Drug manufacturers, for instance, may view total incentives as a bundle—combining both anticipated forms of public support and anticipated back-end obligations, such as pricing concessions or revenue sharing. But even if the same underlying facts are relevant to both inquiries, they serve different normative functions depending upon the question being asked.

socially valuable technology comes to market. While there will undoubtedly be debate about the details, there is likely broad consensus on this higher-level point. Suppose, for example, the government were truly faced with a choice between requiring a direct "return," such as cost recoupment, or ensuring that a drug comes to market. If the government viewed the prospective drug as socially valuable, absent additional facts, it seems not only reasonable to conclude—but many *would* likely conclude—that the government should forgo requiring a direct benefit in the service of this larger mission.

Potential trade-offs between innovation and access are well known to patent law.[291] Reservations about focusing on a fair allocation of benefits to the government from publicly supported medications bear structural similarities. The suggestion seems to be that concerns about fairness (as expressed through demands for direct benefits) and concerns about adequate innovation incentives are oppositional, or antagonistic; we may not be able to have both. And, if forced to choose, the public, through its government institutions, should privilege the "first-order" [292] concern of fostering the development of new, socially valuable technologies. After all, if the inventions are not invented, there will be nothing to allocate.[293]

This framing—and existing legal defaults—works for as far as it goes. However, it risks extending the underlying assumptions too far. It appears to assume that *all* government contributions are alike. Yet the problems that government support addresses presumably are diverse. Not all market "failures" are the same.[294]

Though this is an imperfect characterization, presumably there are important differences between government interventions designed to correct what might be described as a "complete" market failure—where, absent government action, there would be no chance a drug would come to market—and government interventions that lack such a dire economic profile. The government may contribute to drug R&D for many reasons beyond such

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[291] *See, e.g.*, Lemley, Ouellette & Sachs, *supra* note 43, at 108–09 (discussing how patent policy tolerates impediments to patient access on the grounds that patents are required to create new drugs).

[292] OUELLETTE, *supra* note 40, at 14. ("[T]he extent to which medical innovations are 'publicly funded' should not distract policymakers from the key first-order goals of biomedical innovation policy: saving lives and improving health, including by better aligning innovation incentives with social value and increasing access to valuable medical technologies.").

[293] Importantly, innovation losses should not be measured solely by the number of forgone drugs. What matters is a new policy's impact on forgone drugs of new clinical value. *See, e.g.*, *Reducing Prescription Drug Prices: How Competition Can Make Medications Affordable for Patients: Hearing Before the S. Comm. on the Judiciary* 9–10, 118th Cong. (2024) (testimony of Rachel E. Sachs, Professor of Law, Washington University in St. Louis), https://www.judiciary.senate.gov/imo/media/doc/2024-10-29_-_testimony_-_sachs.pdf (emphasizing that evaluations of innovation should center patients by focusing on clinical value rather than the sheer number of new drugs developed).

[294] Additional conceptual and policy work beyond the scope of this paper will be required to draw justifiable lines in the way suggested by this analysis. This work will elucidate empirically the size of each category of the government's role—information that, regardless of its outcome—will be of great benefit to informing public discourse. Establishing a default presumption based on proportionality, as argued in Part IV.E., would generate an additional incentive for this work.

circumstances. For instance, it may be motivated by its own priorities to accelerate progress in a particular area even though there is a functioning market or to address partial inefficiencies. A distinction along these lines might be illustrated by comparing government support for neglected disease treatments, where private incentives are entirely (or nearly entirely) absent, with government efforts to expedite the development of vaccines for widespread dangerous pathogens, where private markets may be functional but require optimization.[295] Mariana Mazzucato and colleagues make this fundamental point: it is too limiting to think of the government as "merely" a market fixer.[296] To do so fails to fully capture how the government behaves.[297] Depicting the government as only a market fixer overlooks the transformative role it plays as a market "co-creat[or]," actively shaping and co-creating markets to align innovation with public health priorities.[298]

If this reasoning is correct, recognizing and appreciating a broader governmental role can have significant implications for transactional fairness and what the public is owed.[299] Depicting the government's role as narrowly focused on fixing market failures assumes away the diversity of government interventions and risks rendering questions of allocational fairness to the public unimportant, if not invisible. Current U.S. legal defaults largely reflect this narrow conception, treating government support for drug R&D as if it addresses only "true" market failures where requiring direct benefits might jeopardize the viability of the underlying biomedical project. This overlooks scenarios where public support for drug R&D may be better glossed as making contributions as a co-investor or as a market creator, not just a fixer.[300] If the government's contributions are inaccurately or inappropriately glossed as

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[295] Frank Mueller-Langer, *Neglected Infectious Diseases: Are Push and Pull Incentive Mechanisms Suitable for Promoting Drug Development Research?*, 8 HEALTH ECON., POL'Y & L. 185, 186–87 (2013); U.S. GOV'T ACCOUNTABILITY OFF., GAO-21-319, OPERATION WARP SPEED: ACCELERATED COVID-19 VACCINE DEVELOPMENT STATUS AND EFFORTS TO ADDRESS MANUFACTURING CHALLENGES 1 (2021).

[296] *See* THE PEOPLE'S PRESCRIPTION, *supra* note 13, at 11 (arguing that governments should not be viewed merely as passive market fixers, but as active market shapers with the power to strategically design and incentivize better health innovation systems); Laplane & Mazzucato, *supra* note 255, at 2–3 (arguing that the traditional view of government as a passive "market fixer" is too limited, since public funding and institutional rules not only correct market failures but also shape innovation, define reward distribution, and create the conditions for economic growth and social returns).

[297] *See* Laplane & Mazzucato, *supra* note 254, at 2 (arguing that conventional views overlook how states actively shape markets by conceiving a limited government role); THE PEOPLE'S PRESCRIPTION, *supra* note 13, at 11 (suggesting that governments design and incentivize health innovation);

[298] *See* THE PEOPLE'S PRESCRIPTION, *supra* note 13, at 22 (emphasizing that public value is created when governments and citizens shape markets together); Laplane & Mazzucato, *supra* note 255, at 4 (arguing that government is not merely external to markets but an entrepreneurial actor that creates and shapes them in collaboration with the private sector).

[299] *See* THE PEOPLE'S PRESCRIPTION, *supra* note 13, at 42 (discussing what governments should demand).

[300] Laplane & Mazzucato, *supra* note 255, at 4.

merely fixing a market, this assumption generates "a pattern of socializing risks while privatizing rewards"[301] that treats the public unfairly.[302]

For these reasons, the public needs a normative principle that—while deeply sensitive to concerns about innovation incentives—is not blinded by them. It needs a principle that does not assume away any and all consideration of what a fair distribution of direct benefits might look like. The search for a more compelling moral principle continues.

3. *Cost-recoupment*

The idea of cost-recoupment is a recurring theme in discussions of how to address the perceived unfairness to the American public from expensive, publicly supported medications. A *principle of cost recoupment* holds that *if* a publicly supported drug reaches some to-be-defined level of commercial success, for the allocation of benefits and burdens to be fair, the government should at the very least recoup the value of its investments. In other words, under such circumstances, it would be *unfair* for the government to lose money on its contributions; it should emerge more or less financially neutral. Recoupment could be implemented through many different instrumentalities. It might mean that a drug's price is "discounted" to reflect the government's contribution.[303] It could also mean the return of funds to an agency for financing other projects, or it could be deposited into a general fund.[304]

Recoupment has long been mentioned in academic circles and enjoyed some political salience.[305] A recoupment provision was considered in the lead up to the Bayh-Dole Act's passage. Focusing not on drugs nor drug prices, this "Return of Government Investment" provision, § 204 of Senate Bill 414, more commonly known as the "payback" provision, "figured prominently" in Congressional discussions of the Bayh-Dole Act.[306] It was referenced "repeatedly in order to deflect those who argued that the proposed legislation amounted to a giveaway of taxpayer property."[307]

The proposed § 204 Bayh-Dole provision, involved setting a threshold for profits earned over a particular time from a federally supported invention. Once that threshold was met, the recipient of federal funds would need to remit a certain percentage of those profits back to the United States.

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[301] *Id.*

[302] And, if the narrower vision is generally accurate, the details of why should be disclosed to the public in a way that is understandable, accountable, and transparent.

[303] *See* SCHACHT, *supra* note 286, at 14–16; Steven R. Salbu, *AIDS and Drug Pricing: In Search of a Policy*, 71 WASH. U. L.Q. 691, 725 (1993).

[304] *See, e.g.*, CAL. CODE REGS. tit. 17, § 100608(b) (2014) (requiring commercialized entities in California to deposit a portion of their net commercial revenue into a general fund).

[305] *See generally* Matthew Herder, *Asking for Money Back—Chilling Commercialization or Recouping Public Trust in the Context of Stem Cell Research?*, 9 COLUM. SCI. & TECH. L. REV. 203 (2008).

[306] *Id.* at 207–08.

[307] *Id.* at 208.

The amount of money that could be recouped by the federal government, however, was capped at the amount of its investment through the underlying funding agreement.[308]

While the recoupment provision was discussed extensively in the legislative history,[309] and politically important for those resistant to the larger Bayh-Dole Act framework,[310] the provision quietly disappeared at the eleventh hour.[311] According to some, it is unclear precisely why.[312] Others attribute the provision's removal to being an "unnecessary obstacle . . . [and] burden to working with the government" and "particularly difficult to administer."[313]

More recently, CIRM—the California stem cell initiative mentioned above—has been noted for including "recoupment provisions."[314] Generally, these provisions regard "revenue-sharing"[315] rather than strictly "recoupment," given that they may go beyond reinstating the state's initial investment.[316] The CIRM revenue-sharing provisions have evolved over time.[317] An earlier approach included a recoupment provision, capping "[t]otal payments" to the State of California at "three times the total amount of the CIRM Grant or Grants" and described it as "payback in the form of a royalty."[318] The most recent version applicable to commercializing entities outlines a 0.1% royalty rate per $1 million of CIRM awards over ten years or up to nine times the amount of the grant, whichever occurs sooner.[319] Revenue shared with California is to be deposited into the State's General

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[308] S. REP. NO. 96–480, at 9 (1979).

[309] *See, e.g.*, *id.* (discussing proposed section 204); Herder, *supra* note 305, at 208–11.

[310] Herder, *supra* note 305, at 208.

[311] *Id.* at 211.

[312] *Id.* at 211–12.

[313] SCHACHT, *supra* note 286, at 16.

[314] *See generally* Herder, *supra* note 305 (discussing the recoupment portion of CIRM).

[315] *See* INST. OF MED., THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE: SCIENCE, GOVERNANCE, AND THE PURSUIT OF CURES 111 (Nat'l Acad. Press., 2013) (discussing CIRM's intellectual property regulations calling for "revenue sharing").

[316] CAL. HEALTH & SAFETY CODE § 125290.30(j) (West 2025).

[317] Depending upon the grant year, different regulatory provisions apply. *Compare* CAL. CODE REGS. tit. 17, § 100408 (West 2025) *and* CAL. CODE REGS. tit. 17, § 100608 (West 2025) *with* CAL. CODE REGS. tit. 17, § 100650 (West 2025). The most recent revenue-sharing provisions incorporate "The CIRM Intellectual Property Policy for CIRM Awards, dated September 5, 2018 . . . by reference" and apply to awards executed on or after that date. CAL. CODE REGS. tit. 17, § 100650(b) (West 2025); *see also* CAL. INST. FOR REGENERATIVE MED., INTELLECTUAL PROPERTY AND REVENUE SHARING REQUIREMENTS FOR NOTICE OF AWARDS EXECUTED ON OR AFTER SEPTEMBER 5, 2018: FREQUENTLY ASKED QUESTIONS (2018), https://www.cirm.ca.gov/wp-content/uploads/archive/files/about_cirm/IP%20FAQ%202018%20v3.pdf (describing changes made to the CIRM process effective in 2018).

[318] CAL. CODE REGS. tit. 17, § 100408(b)(1) (West 2025).

[319] CAL. INST. FOR REGENERATIVE MED., INTELLECTUAL PROPERTY POLICY FOR CIRM AWARDS 11 (2018) (found in VIII(A)(1) and incorporated by reference by CAL. CODE REGS. tit. 17, § 100650(b) (West 2025)), https://www.cirm.ca.gov/wp-content/uploads/archive/files/funding_page/IP%20Policy%20Effective%20September%205%2C%2018.pdf?; *see also* CAL. CODE REGS. tit. 17, § 100608(b)(1) (West 2025) (reflecting the similar language).

Fund,[320] and "to the extent permitted by law" will be used to offset the costs of providing California patients with access to products developed with CIRM funding as well as certain costs for research participants.[321] According to California's nonpartisan Legislative Analyst's Office, as of 2020, CIRM-funded inventions "provided [a] total of approximately $350,000 to the state" through revenue sharing provisions.[322]

The principle of cost recoupment offers a relatively modest conception of what fairness requires. Excepting perhaps the CIRM example which contains some hybrid features, the *principle* simply seeks to restore the public, via its government, to its pre-investment financial position (or equivalent). Under this principle, a fair allocation of benefits works to ensure that the public is no worse off than it was before its contribution—a goal of reinstating the government to its original position—at least for sufficiently successful projects.

Several considerations recommend this principle. First, it preemptively addresses concerns for innovation incentives. The principle as well as proposed provisions in practice, include profit or revenue thresholds beyond which recoupment applies. No doubt there will be debate about how to set such thresholds, and presumably they will vary on a case-by-case basis. The important point is that in so doing it can be structured in a way that strives not to undermine the underlying innovation mission.

Second, albeit modestly, cost-recoupment targets a concern of private-party free-riding. When a publicly funded drug becomes commercially successful, cost-recoupment ensures that scarce taxpayer dollars are not used to subsidize private profits without first recovering the public's contributions. Restoring the public to its pre-contribution position, whether through direct repayment or its equivalent through another mechanism, reflects a baseline expectation of fairness.

Third, the identity of the contributor as a *public* funder only reinforces the justification for cost-recoupment as a matter of fairness. As the steward of public resources, the government bears an obligation to taxpayers to manage those resources responsibly. This, presumably, includes avoiding unnecessary losses and ensuring that public contributions are fairly compensated. By recouping its costs, the government not only avoids leaving a share of financial benefits on the table to which it is fairly entitled, but also restores funds that can be reinvested towards other worthy projects within the remit of its public mission.[323] Cost-recoupment is therefore

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[320] CAL. HEALTH & SAFETY CODE § 125290.30(j)(1) (West 2025); *see also* CAL. INST. FOR REGENERATIVE MED., INTELLECTUAL PROPERTY POLICY FOR CIRM AWARDS 11 (2018) (found in VIII(A) and incorporated by reference by CAL. CODE REGS. tit. 17, § 100650(b) (West 2025)); CAL. CODE REGS. tit. 17, § 100608(b) (West 2025).

[321] CAL. HEALTH & SAFETY CODE § 125290.30(j)(1) (West 2025).

[322] LEGIS. ANALYST'S OFF., PROPOSITION 14 AUTHORIZES BONDS CONTINUING STEM CELL RESEARCH: INITIATIVE STATUTE 2 (2020).

[323] Laplane & Mazzucato, *supra* note 255, at 4.

consistent with the government's role as both a fiduciary for taxpayer dollars and a catalyst for furthering the public good. It serves as an important accountability mechanism.

Having clarified how the principle of cost recoupment can account for innovation incentives, this heads off a counterargument that the principle is too strong. But what of it being too weak? Some might argue that this modest principle fails due to its modesty. It does not go far enough: is not the public owed more than merely recouping its costs on a commercially successful drug?

Consider a hypothetical drug, "TabletX," developed with substantial public funding. Suppose the NIH provides $100 million in grants for early-stage research and clinical trials, which reduces the risk of the project and generates critical knowledge that enables the drug's eventual success. A private pharmaceutical company, "DrugCo," licenses this research and invests an additional $1.2 billion in later-stage trials, manufacturing, and marketing. TabletX becomes a blockbuster drug, generating $12 billion in profit over its first five years on the market.

Under the *principle of cost recoupment*, DrugCo might be required to reimburse the NIH for its $100 million investment once TabletX reaches a specified profitability threshold. This works to safeguard the government—and by extension, taxpayers—against incurring a financial loss on this particular drug. Importantly, further, it strives to ensure that any required cost recoupment does not work across purposes for bringing TabletX to market in the first instance. The allocation of benefits, however, remains highly favorable to DrugCo. After repaying the $100 million, and accounting for its own $1.2 billion investment, DrugCo retains $10.7 billion in profits. In contrast, the public receives no share of the remaining profits, despite contributing approximately 7.7% of the R&D costs and assuming much of the financial risk in its early stages.

This hypothetical underscores that fairness concerns persist even in the presence of cost-recoupment. Recoupment prevents taxpayer dollars from subsidizing private profits at an unnecessary loss, but it does not secure any share of the profits generated from commercially successful drugs. The public's role in enabling the success of TabletX is reduced to financial neutrality, while DrugCo captures nearly all the economic rewards.

In response, a proponent of mere cost-recoupment might argue that this focus on *direct* benefits is too myopic. The public, after all, greatly benefits indirectly from its investments in drug development, such as through knowledge spillovers, job creation, and increased tax revenues.[324] If one

[324] *See, e.g.*, DEP'T OF HEALTH & HUM. SERVS., *supra* note 284, at 9, app. 8 at 5 (describing how communities benefit from local biomedical research investments); DEP'T OF HEALTH & HUM. SERVS., REPORT TO CONGRESS ON AFFORDABILITY OF INVENTIONS AND PRODUCTS 1 (2004) (explaining that "The NIH contributes to the affordability of inventions and products by conducting and funding medical research" that may lead to new drugs and devices which improve human health).

widens the lens and looks at the *indirect* benefits that redound from the government's investments, the distribution—it might be argued—overwhelmingly skews towards the government and for this reason is inherently fair.[325]

Indirect benefits deriving from publicly supported biomedical research are significant, important, and the defining motivation for public devotion of funds to research in the first instance. For several reasons, however, public contributions can deserve direct recognition and rewards, not merely diffuse or uncertain indirect benefits. Indirect benefits do not necessarily negate the need for direct public returns and therefore should not be summarily dismissed.

First, indirect benefits can be speculative or unrealized in practice. While indirect benefits such as job creation, knowledge-spillovers, and tax revenues are often cited as justification for public investment, these returns may not fairly compensate taxpayers. For example, knowledge spillovers may disproportionately benefit private actors who consolidate their market dominance through patenting practices that inhibit follow-on inventions.[326] Likewise, corporate tax evasion can impede the government's "redistributive function," thereby undermining broader economic gains that might otherwise benefit the public.[327]

Second, conversely, indirect benefits are not exclusive to the government or the public. They flow from a joint project and apply to the collective, including private-sector actors. The private sector, for instance, benefits from a healthier workforce, an expanded market for its products, and foundational knowledge generated by publicly funded research. This may create an unjustified asymmetry: the public is expected to be content with taking its returns almost exclusively in the form of shared, indirect benefits, while private actors enjoy both indirect benefits *and* substantial direct financial gains. While there may be situations where direct benefit sharing is inappropriate or might be bargained away, there lacks an obvious justification—from the perspective of fairness—for making the absence of direct public returns the default. Failure to provide appropriate direct benefits (or a compelling justification for its absence) to the public can marginalize its role as a contributor to projects of great value and, absent additional facts, may be fundamentally unfair.[328]

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[325] *See* DEP'T OF HEALTH & HUM. SERVS., *supra* note 285, at 11–12 (referencing studies which demonstrate the government's return on its investments in research).

[326] Laplane & Mazzucato, *supra* note 255, at 5.

[327] *Id.*

[328] Some might be concerned that the opportunity for direct benefits might skew research priorities. For instance, it might compel NIH to gravitate away from researching diseases that primarily impact the poor. While vigilance would be required to guard against this institutional possibility, conceptually, this worry highlights the importance of disaggregating the two fairness problems discussed above. The government is not in the business of making money. Money-making should not motivate the setting of its research priorities. Once those priorities have been implemented and investments made, however, the

A principle of cost recoupment falls short of direct benefit-sharing because it is not benefit-sharing at all. It is merely a stop-loss mechanism, ensuring that public investments are repaid but offering no share of potentially significant financial gains generated by publicly supported research. At its core, cost recoupment's modesty reflects a constrained vision of fairness that does not secure equitable treatment for public contributions. While it strives to make the government whole, it does not address the fundamental question of whether the public is entitled to a share of the substantial financial gains that result from its investments. For public funding to reflect a fairer allocation of benefits, a more ambitious principle may be necessary—one that explicitly acknowledges the public as a contributor of significant value in drug R&D and correspondingly demands direct compensation in alignment with those contributions. Cost recoupment, though a step forward, risks rendering public contributions undercompensated and undervalued.

4. *Inequality*

Whereas a principle of cost recoupment may undervalue the government's contributions, a more robust principle for consideration of the fair allocation of benefits from a shared drug R&D enterprise might be a *principle of equality*. A fair distribution of benefits under this principle would require an equal sharing of benefits among all participating parties. Thus, for instance, if a drug manufacturer and the government both supported an eventually successful drug's R&D, and the drug had profits of $1 million, each party would be entitled to an equal share. The drug manufacturer and the government would each have a claim to $500,000 in profits. Under this principle, this even split would be a fair distribution of benefits.

A principle of equality has its appeal. Fairness in many aspects of life appears to, rightfully, require strict equality. The fair distribution of rights to citizens demands strict equality in order to convey the equal status citizens hold in relation to one another. Business or collaborative relationships also sometimes involve this feature of equal status among participating parties. With general partnerships, for example, the *default* rule often holds that partners are to split profits and losses equally.[329]

While an evaluation of the government's support for a drug is case-dependent, and there may be instances where a collaboration between the government and a drug manufacturer is akin to a general partnership in spirit, application of a principle of equality in the distribution of benefits seems generally inapt. Suppose one party contributes far more to the endeavor than

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prospect of direct benefits appears an appropriate part of a conversation regarding a fair allocation of benefits.

[329] *See, e.g.*, DEL. CODE ANN. tit. 6, § 15-401(b) (West 2023) ("Each partner is entitled to an equal share of the partnership profits and is chargeable with a share of the partnership losses in proportion to the partner's share of the profits.").

the other. If the government contributes thirty percent of a drug's R&D costs and a drug manufacturer contributes seventy percent, does it still seem fair that both the government and the drug manufacturer share equally in the profits? Likewise, if the drug manufacturer contributes one percent and the government contributes ninety-nine percent, does a principle of strict equality in the distribution of benefits yield a fair result? Absent additional facts, a moment's reflection suggests not. If one party puts in one percent of the work and resources required to research, develop, and bring a drug to market, it would seem extremely unfair for them to enjoy fifty percent of the profits. It seems unfair because the party seems not to deserve to share equally in the profits of the project given their lower (and meagre) contribution. For these reasons, a principle of equality may be rejected as an allocational mechanism.

5. *Proportionality*

A principle of cost recoupment might undercompensate the public by forgoing a share of benefits to which it has a justified interest. Likewise, a principle of equality might overcompensate, demanding an unfairly large share of benefits to which the public has no right. What seems missing from these proposed distribution schemes is that the share of benefits to be distributed from those collectively derived is poorly calibrated to the parties' respective contributions. In other words, as a matter of fairness, it seems there ought to be a relationship between what one invests through resources, labor, expertise, etc., into a joint enterprise and what one gets out. A strong contender for understanding what that relationship ought to be is a *principle of proportionality*: the value of the benefits each party derives from a joint enterprise—when there are benefits to be distributed—ought to be proportional to the value of each party's respective contributions.[330]

[330] *Cf.* ROBERT P. MERGES, JUSTIFYING INTELLECTUAL PROPERTY (2011). Merges offers a detailed discussion of proportionality, identifying it as one of four "midlevel principles" of intellectual property law. *Id.* at 150. His account resonates with the principle articulated here insofar as it states that "reward…ought to be proportional…to contribution," *see id.* at 278–79, yet the focus of Merges' formulation appears generally distinct. Merges' principle of proportionality is not concerned with allocating returns among joint contributors (whether public or private); rather, it emphasizes proportionality as a constraint on the misuse of excessive intellectual property rights. As Merges explains, "[t]he size or scope of an IP right ought to be proportional to the value or significance of the work covered by the right. This is the proportionality principle." *Id.* at 150. Elsewhere, he elaborates that "proportionality is the idea that a property right ought to be reasonably related to something socially useful and valuable. Where the unregulated market price of a property right moves radically out of alignment with underlying social utility, an institutional response is called for . . . ." *Id.* at 181. Speaking specifically of pharmaceutical patents, Merges writes: "If the structure of pharmaceutical patent law, together with the entire regulatory and competitive environment of the pharmaceutical industry, leads to excessive rewards in light of the benefits conferred, then the economic power of pharmaceutical patents can be trimmed back so as to restore a better sense of proportion. . . . Disproportionate reward coupled with grave suffering makes a powerful case for this." *Id.* at 279.

Philosophically, a principle of fairness grounded in proportionality has a long, distinguished heritage dating back to Aristotle.[331] "[W]hen a distribution is made from the common stock, it will follow the same ratio as that between the amounts which the several persons have contributed to the common stock . . . and the injustice opposed to justice of this kind is a violation of this proportion."[332] In other words, what someone is due as a matter of fairness is tied to their efforts and merit.[333] Going back to the example from above, a principle of proportionality explains why one might bristle at the idea that someone who contributes ten percent to a joint project should automatically be entitled to fifty percent of the project's spoils upon its success. The intuition is that—at least absent additional facts—the party who put in ten percent does not *deserve* fifty percent.

Moral desert is the normative underpinning of a principle of proportionality. It explains why, as a moral matter, a proportional distribution of benefits appears to be a fair one. A principle of proportionality is compelling given an underlying sense that moral desert matters for just outcomes. Writing more broadly, for instance, about moral desert's place writ large within moral theory, Shelly Kagan observes:

> Most of us, I think, are attracted to the idea that a plausible moral theory will tell us to be sensitive to these differences. For if people differ in terms of how morally deserving they are, then they differ in terms of what they *deserve*. And other things being equal, at least, it is important for people to get what they deserve. Thus an adequate moral theory should include an account of moral desert. Or so it seems to me.[334]

So, too, it seems, with the localized issue considered here. Inadequate consideration of moral desert is what appears to fundamentally ground criticisms of the current status quo when it comes to high prices for drugs researched and developed with public contributions.

There is a scholarly and political preoccupation with parsing origin stories and discerning how much and what kind of federal government resources contributed to a drug's R&D.[335] As discussed, answers to these empirical questions ultimately turn on contested judgments about what kinds

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[331] *See* ARISTOTLE, THE NICOMACHEAN ETHICS, bk. V, at 273 (H. Rackham trans., Harvard Univ. Press rev. ed. 1934) (discussing proportionality); *see also* SHELLY KAGAN, THE GEOMETRY OF DESERT 355, 643 n.11 (Oxford Univ. Press, 2012) (discussing a ratio comparative view of desert); Emily Crawford, *Proportionality*, *in* MAX PLANCK ENCYCLOPEDIA OF PUBLIC INTERNATIONAL LAW ¶ B3 (2011) (explaining the historical development of proportionality as a concept by tracing it back to Aristotle).

[332] ARISTOTLE, *supra* note 331, at 273.

[333] Given the specialized subject matter—contributions to drug R&D—I put aside larger complications regarding moral luck and free will.

[334] KAGAN, *supra* note 331, at 3 (emphasis in original).

[335] *See supra* Part I.A (discussing sources of federal government support of drug R&D).

of support should count. But, while such investigations can serve additional ends,[336] these efforts suggest a deep normative concern: relative contributions matter because they bear on what one morally deserves. The focus on identifying and quantifying contributory shares implies an underlying belief that benefits should track contributions. At baseline, those who contribute to a joint endeavor are owed a corresponding share of its rewards.

Thus, regardless of whether it is ultimately well-justified, the core of the criticism under consideration is that we, the public, purportedly deserve more than what the status quo offers by way of direct benefits because our contributions are not being fairly taken into account. What does it mean for public contributions to be fairly accounted for? It means, as a starting point, our contributions should provide a proportional mapping to our benefits. If the public, via the government, supports a successful new drug, yet at the end of the day it receives a share of benefits inconsistent with its contributions, the government receives a return on investment that appears to be less than what it deserves. Likewise, the drug manufacturer receives a return on *their* investment that *exceeds* what it deserves. The respective returns are disproportionate.

Yet, what exactly does it mean for a return to be "proportional"? What does a principle of proportionality involve?

In the context of interest, CIRM—the California stem cell funding agency mentioned earlier—offers an example (albeit a limited one) of proportionality in practice. CIRM historically has embraced provisions for benefit sharing that provide: "If funding sources in addition to CIRM were used in the creation of a CIRM-funded patented invention, the return to the State of California of any resultant revenues *shall be proportionate to the support provided by CIRM* for the discovery of the invention."[337] Insights into the motivation for relying on a principle of proportionality when multiple funding sources are at play do not appear to be publicly available. Further, though operative for older awards, this clause was not included in the streamlined policies applicable to awards executed post September 5, 2018.[338] Nevertheless, CIRM more generally glosses its revenue-sharing policies as grounded in a form of proportionality because this is what it views as fair to taxpayers. As the Institute explains, "CIRM has attempted to develop a revenue-sharing scheme which is easy to implement and *fair to*

[336] OUELLETTE, *supra* note 40, at 13–14.

[337] CAL. CODE REGS. tit. 17, § 100308(c) (West 2025) (emphasis added); *see also* CAL. CODE REGS. tit. 17, § 100408(a)(2) (West 2025) (also endorsing a proportional revenue sharing system).

[338] CAL. INST. FOR REGENERATIVE MED., *supra* note 319, at 11 (including a revenue sharing policy in part VIII, incorporated by reference CAL. CODE REGS. tit. 17, § 100650(b) (West 2025), that does not implement the proportionality adjustment).

the taxpayers of California so the revenue sharing provisions are *directly proportional to the CIRM award* ([0.1%] per $1 million of funding)."[339]

More generally, however, the law operationalizes a principle of proportionality through a number of doctrines, yet the precise meaning and features vary with the context.[340] There is a large cross-national body of literature on the topic.[341] Many of these doctrines, however—for instance, in constitutional or criminal law, where the focus is on constraints on state power to impose burdens on others or the appropriate structuring of criminal punishments—are of more limited relevance here.[342] Other areas, where a principle of proportionality is at play, are highly relevant to the benefit-sharing question before us. Some have referred to this kind of proportionality as "quantitative proportionality," indicating that "a specific arithmetic operation" is drawn on to determine whether a return is proportional.[343]

Within American law, limited partnership law and patent law offer examples where a principle of proportionality is drawn on to distribute benefits from a collective endeavor. With limited partnerships, for example, a default rule allocates distributions to partners based on each partner's contributions, thereby embracing a "proportional treatment requirement."[344]

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[339] CAL. INST. FOR REGENERATIVE MED., *supra* note 317, at 2 (emphasis added). CIRM's articulation of proportionality on the basis of its 0.1% return varies from the form of proportionality argued for here as it does not appear to account for the relative investments of others. Separately, it is notable, that CIRM also requires access plans from award recipients. *Id*. at 4.

[340] Among other areas of the law, proportionality shows up in criminal law, constitutional law, and European Union law. *See, e.g.*, Franz Bauer, *Proportionality in Private Law: An Analytical Framework, in* PROPORTIONALITY IN PRIVATE LAW 15, 17 (Franz Bauer & Ben Kohler eds., 2023) (comparing and contrasting the features of proportionality depending on the context). Themes of proportionality are further threaded throughout intellectual property law. *See e.g.* MERGES, JUSTIFYING INTELLECTUAL PROPERTY, *supra* note 330, at 8 (observing that "[p]roportionality shows up in all sorts of IP rules, from infringement and remedies issues in copyright, to the requirements of patentability, to various trademark doctrines."); ANNETTE KUR, NARI LEE, & ANNA TISCHNER, FAIRNESS IN INTELLECTUAL PROPERTY LAW 398 (2024) (discussing predominantly intellectual property laws in Europe and observing that "[t]he concept of fairness in remuneration reflects such a problem of disproportionality. Specific rules of that kind are set forth in copyright and patent law.").

[341] Vicki C. Jackson, *Being Proportional About Proportionality*, 21 CONST. COMMENT. 803, 804 (2004).

[342] *See, e.g.*, Vicki C. Jackson, *Constitutional Law in an Age of Proportionality*, 124 YALE L.J. 3094, 3098 (2015) (defining proportionality in a constitutional law context); Crawford, *supra* note 331, at ¶ A1 (providing an umbrella definition of proportionality); *see also* Youngjae Lee, *Why Proportionality Matters*, 160 U. PENN. L. REV. 1835 (2012) (discussing proportionality and criminal punishment).

[343] Bauer, *supra* note 340, at 17–18.

[344] REVISED UNIF. LTD. P'SHIP ACT § 503 (Unif. Law Comm'n) (2014) (revised 2013); *id.* at 19 (comment describing § 503(a) as having a "proportional treatment requirement").

Proportionality is also familiar to patent law.[345] One relevant area has to do with "FRAND" (fair, reasonable, and non-discriminatory) royalty rates for standard essential patents ("SEPs"), which are patents protecting an invention required for compliance with a technical standard—for example, wireless communication protocols used in smartphones.[346] These standards, developed by a standard development organization ("SDO"), ensure interoperability between devices and across firms.[347] Because SEP holders can potentially gatekeep others from complying with a technical standard, SDOs often require participating SEP holders to commit to licensing on FRAND terms.[348]

Proportionality can play a role in determining what constitutes a fair or reasonable royalty. Under a "top-down" approach advocated for by scholars and used by some courts,[349] "the aggregate royalty for all SEPs covering a particular standard is first calculated, after which an appropriate portion is allocated to the claiming SEP holder."[350] While a more idealized proportionality analysis would assess the value each SEP contributes to the standard, courts often resort to "numerical proportionality" for practical reasons. [351] Under this method, "royalties are allocated on the basis of one-patent-one-share."[352] Particularly given the context—that each SEP is purportedly essential—it can sometimes be difficult to discern if any one patent is more important than the others. Thus, each SEP holder receives a share of the aggregate royalty in proportion to their number of SEPs, blending ideas of proportionality with equality.

Beyond SEPs, proportionality arises within the broader context of patent infringement and damages. When an infringer has made use of another's patent, but that patent is but one of many applicable to a product—and in the modern world, a single product could be comprised of hundreds or even thousands of component parts with attendant patents—courts deploy a

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[345] In addition to the examples of SEPs and apportionment, there is some indication in the context of 28 U.S.C. § 1498 that courts may consider government contributions to the development of a patented technology in determining a reasonable royalty. Joseph Adamczyk, Adrienne Lewis & Shivani Morrison, *§ 1498: A Guide to Government Patent Use, a Path to Licensing and Distributing Generic Drugs* 29 (Christopher Morten ed., July 20, 2021) (unpublished white paper) (available online at https://ssrn.com/abstract=3882823). Though a principle of proportionality as articulated in this Article does not appear to be at play here, reducing what the government pays for use of a technology to which it has contributed is resonant.

[346] Mark A. Lemley & Timothy Simcoe, *How Essential Are Standard-Essential Patents?*, 104 CORNELL L. REV. 607, 607–09 (2019).

[347] Jorge L. Contreras, *Global Rate Setting: A Solution for Standards-Essential Patents?*, 94 WASH. L. REV. 701, 703–04 (2019).

[348] *Id.* at 704.

[349] *Id.* at 715–16.

[350] *Id.* at 713.

[351] *Id.* at 720.

[352] *Id.*

proportionality principle known as "apportionment" in determining damages.[353] Apportionment is also reflected in the Patent Act as well.[354]

Apportionment considers the infringer's profits derived from the product as a whole and then "apportions" as damages the share that is attributable to the infringed patent.[355] Apportioning damages "encourages innovation without allowing patentees a windfall: the patentee receives fair value for their invention without capturing the value of technology they did not invent."[356] This doctrine is designed "to ensure that damages awards reflect the value of the inventor's contribution, 'and no more.'"[357] The failure to apportion has significant legal and economic implications[358] for innovation incentives and the "bargain" presented by patent law of trading public disclosure for a period of exclusivity.[359] Yet, apportionment and its underlying principle of proportionality is fundamentally also about fairness. Absent additional facts, it would be *unfair* for the patent holder to collect damages based on the entirety of an invention to which it only contributed a component part. To permit such awards would be to provide the patent holder with an "unjustified windfall"[360]—in other words, more than it deserves.

Benefit allocations based on a principle of proportionality are thus familiar both as a matter of theory and law. It is the often implicit principle that presents itself when reflecting on what the significance of public support should be for a drug's eventual pricing and accessibility. Further, an appeal to proportionality is at times made explicit. Critics of government innovation policy across all sectors (for example, William Lazonick and Mariana Mazzucato) advocate for a "risk-reward nexus" to ensure government returns are commensurate with its investments in innovation.[361] In a similar vein,

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[353] William F. Lee & Mark A. Lemley, *The Broken Balance: How "Built-in Apportionment" and the Failure to Apply* Daubert *Have Distorted Patent Infringement Damages*, 37 HARV. J.L. & TECH. 255, 259, 268–69 (2024).

[354] 35 U.S.C. § 284; *see also* Lee & Lemley, *supra* note 353, at 269 (discussing how apportionment is embodied in the Patent Act itself).

[355] Lee & Lemley, *supra* note 353, at 269.

[356] *Id.* at 258.

[357] Christopher S. Storm, *Measuring the Inventor's Contribution*, 21 U.N.H. L. REV. 167, 205 (2022) (citation omitted).

[358] Lee & Lemley, *supra* note 353, at 270.

[359] *Id.* at 258.

[360] *Id.*

[361] William Lazonick & Mariana Mazzucato, *The Risk-Reward Nexus in the Innovation-Inequality Relationship: Who Takes the Risks? Who Gets the Rewards?*, 22 INDUS. & CORP. CHANGE 1093, 1094–96, 1096 n.3 (2013) (discussing a "risk-reward-nexus" (RRN) with an equitable RRN reflecting rewards that "are proportional to the risks taken" and "a division of the gains from innovation in proportion to the productive contributions that different actors have made to the innovation process."); *see also* Laplane & Mazzucato, *supra* note 255, at 9–10 (drawing on risk-reward nexus).

Peter Lee has argued that the scope of distributive demands made by public institutions, such as the NIH, should correspond to public contributions.[362]

More recently, public comments submitted to CMS regarding the 2027 MDPNP Draft Guidance included a few that drew on an underlying endorsement of a principle of proportionality for agency assessment of the factor of "prior Federal financial support." A group from the Center for Integration of Science and Industry at Bentley University encouraged CMS to interpret the manufacturer-related factors in a manner that accounts for both "public (federal) and private (manufacturer) investments," to ensure that returns are "commensurate with the scale and risk" of each party's contributions. [363] Likewise, a *drug manufacturer* recommended an agency interpretation of this factor based on the idea of proportionality.[364] In its comments to CMS, Astellas Pharma US, Inc. included a section entitled, "CMS should not disproportionately weigh federal financial support in developing MFP offers."[365] After observing a lack of clarity surrounding the factor of federal funding, Astellas goes on to argue:

> Federal financial support may be early in the discovery phase and eclipsed by ongoing investment in a product. We recommend that CMS look at Federal financial support in the context of the total R&D costs incurred for the selected drug and consider – at most – a *proportional adjustment in the preliminary price*. For example, if prior federal financial support represented 1% of the total investment required to develop a new drug, to the extent CMS considers adjusting the preliminary price downward as a result of such funding, it should do so in a proportional manner by adjusting the preliminary price downward by no more than 1%.[366]

That a drug manufacturer—particularly one who has sued CMS, taking the position in litigation that the MDPNP "not only is bad policy, it is

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[362] Peter Lee, *Toward a Distributive Commons in Patent Law*, 2009 WIS. L. REV. 917, 1001 (2009) ("A consistent theme of the accommodation strategies profiled here is balance: distributive claims by a public institution on a value-added health technology must be proportional to its contributions.").

[363] Letter from Fred Ledley, Edward Zhou & Paul Chaves da Silva, Ctr. for Integration of Sci. & Indus., Bentley Univ., *in* Comment Letters on the Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027 (Oct. 10, 2024), https://www.cms.gov/files/document/public-comments-medicare-drug-price-negotiation-draft-guidance.pdf [hereinafter MDPNP IPAY 2027 Comment Letters].

[364] Letter from Astellas Pharma US, Inc., *in* MDPNP IPAY 2027 Comment Letters, *supra* note 363. Other drug companies take a more resistant posture. Eli Lilly, for example, argues that existing accounting methods do not separate out federal support thereby creating a "new and material data capture and reporting burden." Letter from Eli Lilly & Co., *in* MDPNP IPAY 2027 Comment Letters, *supra* note 363. Eli Lilly further remarked on the difficulty of discerning indirect federal funding. *Id.*

[365] Letter from Astellas Pharma US, Inc., *in* MDPNP IPAY 2027 Comment Letters, *supra* note 363.

[366] *Id.* (emphasis added).

unconstitutional"[367]—has suggested an approach based on proportionality is notable.

While this support might concern some drug accessibility advocates about the merits of the principle itself, a better interpretation is that it underscores the intuitive appeal of the principle. Proportionality aligns with the defense of the status quo by private actors ("we're the ones doing most of the work, therefore we should be the ones to realize most of the gains").[368] This alignment is precisely why the principle should be attractive to industry, which would be the anticipated source of resistance to reforms embracing a principle of proportionality. If they—private actors—*are* doing most of the work, they should receive most of the gains. This, however, does not foreclose—and to the contrary promotes—recognition of public contributions; it highlights the necessity of delivering on what the public is due in accordance with their contributions as a moral and practical matter. As will be discussed further below, there is uncertainty whether returns to the public are in fact disproportional. The task is to create both the conditions under which a proportionality-based approach might be possible and a consensus-based understanding of how best to operationalize a workable version of the principle itself. Regardless, the overarching goal of any legal reform is fairness *to everyone*.

Thus, proportionality's potential political palatability is significant. It offers a foundation around which policymakers can build consensus. CMS, to preserve its authority and flexibility, has not embraced proportionality for guiding price adjustments based on the MDPNP factor of federal funding given a lack of statutory requirement for such an approach.[369] It does, however, draw on ideas of proportionality within the factor of prior federal financial support for apportioning indirect costs (e.g. operating and overhead costs) and federal support shared with another entity.[370] That CMS already incorporates ideas of proportionality in these ancillary details lends credence to proportionality's viability and soundness as a distributional principle. As a guiding principle for allocating benefits from shared endeavors, proportionality remains highly attractive.

The fact that multiple stakeholders support proportionality indicates its potential for political acceptance and new policy development. A workable version of proportionality promises to both determine and deliver on what the public is owed. Grounded in notions of moral desert, proportionality

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[367] Complaint at 3, Astellas Pharma US, Inc. v. U.S. Dep't of Health & Hum. Servs., No. 1:23-cv-04578 (N.D. Ill. July 14, 2023) (voluntarily dismissed by Astellas Pharma US, Sept. 6, 2023).

[368] Lazonick & Mazzucato, *supra* note 361, at 1097 (noting invocation of free-market ideology to claim that since private actors take all the risks they should get all the rewards).

[369] *See* IPAY 2027 Guidance, *supra* note 156, at 99.

[370] CMS 2028 ICR *supra* note 196, at 24–25. Regarding shared prior federal financial support, "the Primary Manufacturer must report support received only for costs the Primay Manufacturer incurred. Expenses should be allocated across entities based on each entity's respective stake in the selected drug's discovery and development." *Id*. at 25.

provides a plausible framework to address perceived—if not actual—injustices in the current legal regime governing government contributions to drug R&D. In so doing, it will work to help restore public trust in important government institutions. For these reasons, a principle of proportionality should be further explored.

IV. MOVING TOWARD OPERATIONALIZING A PRINCIPLE OF PROPORTIONALITY

Suppose one is inclined to accept a principle of proportionality as the underlying fairness principle that ought to guide a division of benefits between the government and a private party jointly engaged in drug R&D. Identifying and accepting a principle of proportionality as a matter of theory is only the first step. Many important questions remain open in order to eventually operationalize such a principle. These critical questions straddle the theoretical, institutional, and practical. They concern how proportionality should apply as a moral matter in this context as well as how a workable version of this principle might fit in with existing institutions and law. All such questions are inherently complex, and their full treatment must necessarily be reserved for future work. The aim of this Section, therefore, is to chart a systematic path forward. *If* policymakers are to take a principle of proportionality seriously, *what* are the underlying questions with which they must engage? And, *if* they engage with these questions, how should they begin to answer them? This Section systematically maps these questions as well as contributes some tentative, high-level suggestions for the direction that the answers could take.

Policymakers must engage with the following issues: (1) What exactly must be proportional? (2) What ought to count as a contribution for determining a party's relative investments? (3) What ought to count as a benefit for determining a party's relative returns? (4) How can a principle of proportionality respect considerations of fairness while not undermining concerns for innovation incentives? (5) In what way ought drug-pricing concessions or affordability concerns figure into the form a return to the government ought to take? (6) How might proportionality be incorporated into the existing legal regime—in particular, the MDPNP—and what complexities might it encounter? Each of these issues is discussed below.

A. *What Must Be Proportional?*

A first question policymakers will need to decide is what exactly proportionality measures. In other words, what must be "in proportion"? What should be the focus?

The "quantitative" approach implicit in the discussion above is tolerably straightforward. The basic skeletal model appears to be the following. Under a principle of proportionality, a fair distribution of benefits requires benefit-

sharing among all participating parties in accordance with the monetary value of their proportional contributions to a project's overall costs. Suppose that the government's contributions of support for a drug's R&D amount to 30% of the total costs, and a drug manufacturer contributes the remaining 70%. Under a principle of proportionality, a fair distribution of benefits tracks these proportional contributions; the government would be entitled to 30% of the drug's profits and the drug manufacturer would be entitled to 70%. Thus, once the parties' relative contributions to the project's overall costs are determined, the overall benefits are distributed using a proportion that mirrors their contribution ratio.

Centering a proportionality analysis on cost contributions is an intuitive first pass at understanding the nature of a principle of proportionality in this context. Yet, there are complexities that this simple model does not account for. This simple skeletal model is a fundamentally *comparative* understanding of the principle in that it is relational. On this understanding, a fair—or proportional—outcome is based on a comparison of each party's respective contributions; the distribution of benefits is contingent upon the share of each party.

Yet, there are *noncomparative* or hybrid features of the drug R&D enterprise that might be relevant as well.[371] Two candidate features that appear relevant for determining whether an allocation is disproportionate are the level of risk assumed by a party as well as the "criticality" of the party's contribution. Regarding risk, the level of risk assumed might be evaluated intrinsically as the potential losses a party faces, regardless of the losses any other contributor faces. Contributions made during the riskiest early stages of a project—when success is uncertain and failure is most likely—might deserve greater weight in proportionality calculations, justifying a larger share of rewards. Indeed, it is often the riskier nature of drug development in general that is cited as necessitating the industry's larger returns to private actors.[372] While public contributions occur at all stages of drug R&D, they are predominantly front-loaded where outcomes are uncertain and risk is greatest.[373] The government is often the first investor, reducing the risk of a project and getting it to a point where it is then handed off to the private

[371] This accords with discussions of moral desert generally, *see, e.g.*, KAGAN, *supra* note 331, as well as considerations of proportionality in, for instance, criminal punishment, *see, e.g.*, Lee, *supra* note 342.

[372] *See, e.g.*, U.S. CONG., OFF. OF TECH. ASSESSMENT, OTA-H-522, PHARMACEUTICAL R&D: COSTS, RISKS, AND REWARDS 7–9 (1993) (stating that risky R&D should earn more than safe investments); Neeraj Sood, Karen Mulligan & Kimberly Zhong, *Do Companies in the Pharmaceutical Supply Chain Earn Excess Returns?*, 21 INT'L J. HEALTH ECON. & MGMT. 99, 100 (2021).

[373] *See, e.g.*, Ledley & Cleary, *supra* note 49, at 7 (discussing a study confirming that "a large majority of NIH funding focuses on basic research, rather than applied").

sector for further development at a far less risky stage.[374] It is plausible to think that this risk should be accounted for in distributing direct benefits back to the government.[375]

Another feature that may be relevant to proportionality is the degree to which a contribution was critical to the project's success. Criticality might be considered independent of its financial cost and independent of the contributions of others. A contribution deemed indispensable could warrant greater recognition. It is unclear, however, what metrics might be used to discern and value this feature.

A final version of the proportionality principle likely should account for additional features such as risk and the criticality of contributions.[376] Adjustments to the simple cost-based model could, for instance, assign weighted values to riskier or more critical contributions, incorporating both comparative and noncomparative factors into the analysis. While cost-based approaches are easier (though not easy) to quantify and implement, accounting for risk and criticality might better capture the nuances of fairness in joint endeavors. Introducing these factors, however, also complicates the framework, raising additional questions about how to measure and integrate them effectively. Importantly, a final version of the proportionality principle will also require robust safeguards against gaming as well.[377]

For now, I set these complexities aside assuming something like the adoption of the cost-based model. Despite its limitations—its exclusive reliance on unadjusted monetary contributions or their equivalent—this model provides a valuable starting point for exploring the principle of proportionality. Even within this relatively simple model, there remain significant conceptual and operational challenges to consider.

B. *Determining Relevant Contributions*

After refining what exactly must be proportional, policymakers must turn their attention to defining the scope of "relevant" public contributions. They need to develop a principled approach to determining which inputs count and which do not. As detailed in Part I, the U.S. government supports biomedical R&D in a variety of ways. By some measures, *all* FDA-approved drugs are publicly supported. Should all forms of support, however, count as a relevant contribution as a matter of fairness? Normatively and practically, there need to be some limits. From a moral perspective, not all

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[374] *See, e.g.*, Laplane & Mazzucato, *supra* note 255, at 1–2 (noting that government takes early R&D risks before private firms step in).

[375] *Id.*

[376] Other potentially relevant features might include the creativity of the contribution or the effort expended.

[377] *See* Mello & Wolitz, *supra* note 238, at 864. For example, what will count as "legitimate" costs, and will that definition be resilient to manipulation?

contributions may be significant enough or of the "right" kind to warrant a reward. Further, from a practical perspective, some limits must be set with an eye to administrability; a principle of proportionality must be workable for government officials and others involved in its implementation.

The core of the proportionality principle is that a fair allocation is ultimately grounded in what is deserved—those who contribute to an outcome should receive benefits proportional to their contributions. The challenge, then, is to determine which government contributions merit a reward and which are too attenuated to justify a claim on the resulting benefits. Some contributions, while indirectly helpful, are too far removed from the successful outcome of a drug's development to warrant inclusion in a fairness calculation. That a researcher has clean water to drink, albeit likely critical to her ability to do her work, does not mean that the town's municipal water department has a proportional claim to her successful invention.[378]

Any affirmative proposal may have trouble at the margins, and again, at this stage, any suggestions herein are tentative and high-level. Yet, public policymakers might consider developing a fairness standard where contributions should count as relevant if they directly advance or reduce the risk of the R&D of a specific new technology.[379] This standard helps clarify which contributions deserve recognition and which are too far removed from the direct innovation process to warrant a share of the resulting benefits.

Based on the proposed standard, government support that includes funding directly tied to patents or other intellectual property arising from government-supported research should count. For example, if the NIH provides a grant for a specific drug's clinical trials and that drug is eventually commercialized, the government's contribution clearly advances the drug's development and reduces risks to the private sector's investment. This is a direct contribution deserving of a proportional return on the drug's commercial success.

Advanced Market Commitments ("AMCs") also fall into the category of relevant contributions. AMCs provide guaranteed markets for products that are still in development, reducing the financial risk of investment and incentivizing innovation.[380] Because AMCs directly reduce the risks of the

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[378] Let alone the administrability challenges of figuring out a proportional contribution based on water consumption.

[379] While it is hard to discern exactly how this will be implemented, the additional bullet point in the IPAY 2028 Final Guidance defining "direct basic pre-clinical research costs" as "costs that can be specifically attributed to the discovery and pre-clinical development of the selected drug" appears to embrace a similar idea. IPAY 2028 Final Guidance, *supra* note 141, at 206 (emphasis added). As observed earlier, however, CMS only considers federal support provided to the Primary Manufacturer, which is a significant limitation and departure from the suggestion above articulated.

[380] *See, e.g.*, *US Investment in Covid-19 Vaccines*, *supra* note 2, at 1, 7 (explaining that government advance purchase guarantees reduced financial risk for vaccine developers); Ana Santos Rutschman, *The COVID-19 Vaccine Race: Intellectual Property, Collaboration(s), Nationalism and Misinformation*, 64 WASH. U. J.L. & POL'Y 167, 191 (2021) (same).

development process for a specific intervention, they should be included in the fairness calculation.

Alternatively, contributions like government insurance reimbursement should not count, unless it takes on the features of an AMC by guaranteeing a market in a way that directly incentivizes the development of a specific technology. While insurance reimbursement helps ensure broader access to medications, it does not involve government investment in, nor risk reduction of, a specific drug's R&D process.

Support for basic research raises thornier questions. While undeniably valuable to the broader scientific community, it may be too attenuated from the development of a specific drug. For instance, if the government funds basic research in molecular biology, that research may ultimately contribute to the general understanding of biological processes—but does it represent a direct financial risk or targeted investment in the R&D of a particular drug? To the extent it does not, it should not count toward the allocation of proportional direct benefits.

To illustrate this point, consider an analogy: a student completing a successful research project. Suppose the student relied on the university library for access to books and academic journals, which were crucial to the research process. While the library provided essential support, its contribution was general, serving all students and not tailored to this student's specific project. The library benefits an entire community of users and is not specifically targeted at the unique success of any individual student's work. As such, it would not seem entitled to a proportional share of the rewards from the success of the student's research.

This analogy parallels the role of government funding for basic research. Basic research, like the university library, contributes to the advancement of general knowledge and supports a wide range of scientific endeavors. Likewise, a municipal water department ensures access to clean water for everyone, not just researchers. While crucial to the overall scientific endeavor, to the extent that neither directly targeted the R&D of a specific drug, such contributions seem too indirect to justify a *proportional* share of the rewards from any one drug's success. Of course, even if a proportional share of rewards might be unjustified or administratively impractical for such indirect contributions, this does not necessarily foreclose the possibility that these contributions appropriately ought to demand some sort of alternative recognition or renumeration.

By applying a standard that focuses on direct contributions to the R&D process, public policymakers can better delineate which forms of government support deserve to be rewarded within the context of a proportional benefit-sharing scheme. Contributions, including direct grants for drugs, the claiming of certain tax credits, funding tied to patent exclusivity, and AMCs are directly tied to the success of specific drugs and therefore merit a share of the resulting benefits, absent compelling reasons

to the contrary. In contrast, more attenuated forms of support, like insurance reimbursement and perhaps scientific publications regarding basic research—while valuable in their own right—may not warrant inclusion in this fairness analysis. This standard—though again, tentative—strives to provide a balanced approach to determining which contributions deserve recognition in a proportional allocation of direct benefits as well as which are practically workable for public policymakers to implement.

C. *Determining Relevant Benefits*

In addition to determining relevant contributions, policymakers will also need to develop a standard for determining relevant benefits. What kind of benefits ought to count for distributional purposes in a proportionality analysis? Profits derived from the sale of a successful drug are an obvious candidate for inclusion. But what about other kinds of benefits, such as improved health or economic outcomes resulting from a drug's success? In other words, the indirect benefits discussed earlier.[381] The NIH, for instance, emphasizes its societal impact on its website, noting:

> NIH-supported research leads to improvements in health that can bolster the economy, improve productivity, and reduce the costly burden of illness in the U.S. and worldwide. NIH funding also spurs economic growth, both by supporting jobs in research and by generating biomedical innovations that lead to growth in the biotechnology sector.[382]

Social returns, including improved health outcomes and economic activity, from a new drug can be immense.[383] Indeed, that is the underlying objective. From a public policy and innovation perspective, the goal is to align public and private spending in ways that bring the most socially-valuable health interventions to market.[384] For example, estimates of the social return on COVID-19 vaccines are beyond impressive.[385] A study that considered *all* such vaccines in aggregate, taking into account lives saved, adverse health outcomes averted, and reversal of economic losses due to containment measures, estimates that the social benefit of these vaccines was

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[381] *See supra* Part III.D.

[382] NAT'L INST. OF HEALTH, SERVING SOCIETY (May 7, 2025), https://www.nih.gov/about-nih/impact-nih-research/serving-society.

[383] *See, e.g.*, Carsten Fink, *Calculating Private and Social Returns to COVID-19 Vaccine Innovation* 2 (World Intell. Prop. Org., Econ. Rsch. Working Paper No. 68, 2022).

[384] *See* Hemel & Ouellette, *Innovation Policy Pluralism*, *supra* note 217, at 550, 593 (arguing that policymakers can "match," "mix," or "layer" IP and non-IP tools to promote socially desirable innovation outcomes); Buccafusco & Masur, *supra* note 269, at 1404–06 (describing potential reform to incentives offered through patent law based on the incorporation of QALYs or hedonic psychology.

[385] Fink, *supra* note 383, at 2.

$70.5 *trillion*.[386] This social return exceeded the private return to drug manufacturers by a factor of 887.[387]

As previously discussed, anticipated social returns are an essential consideration in guiding government decisions allocating scarce taxpayer resources. However, the role social returns should play in determining a *proportional* allocation of benefits between contributing parties post-investment is less clear. Two considerations suggest additional reflection on how they ought to be included in a proportionality-based framework.

First, prima facie it seems there should be a symmetrical approach to proportionality's consideration of which contributions and benefits are deemed relevant. If some *contributions* are excluded for being too indirect, similar considerations counsel a comparable approach to *benefits*. Departures from such symmetry would require justification. Depending upon the specifics, this could greatly reduce the scope of social benefits included as relevant.

Second, mirroring remarks above, social returns benefit society at large—not any one party. Yet to the extent discussions of drug R&D often implicitly assume that these societal benefits belong solely on the government's side of the ledger, this assumption appears in tension with the nature of social returns, which are broadly shared. Allocating them exclusively to the government risks skewing proportionality calculations and could potentially diminish the government's claim to benefits. For instance, if a social return of $70.5 trillion were credited only to the government under a proportionality principle, the government might paradoxically owe the drug manufacturer additional compensation. These considerations strongly suggest the need for careful reflection on an appropriate methodology for how to think about social benefits in the first instance as well as how to include consideration of social benefits in a proportionality framework.[388] A government-sponsored, publicly accountable, and transparent exercise of this nature would be highly valuable in itself, regardless of whether its results ultimately expanded or reduced the viability of claims to direct public returns.

D. *Promoting Fairness and Innovation*

Private firms have no entitlement to more than their fair share of profits from a project that has been supported with public contributions. Taking fairness seriously is inherently and instrumentally valuable. Intrinsically, all

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[386] *Id.* at 1–2, 9.

[387] *Id.* at 1, 14.

[388] Exploring such an approach is beyond the scope of this paper, but at least one related framework has been suggested based on the idea of "total stakeholder value." Edward W. Zhou, Paula G. Chaves da Silva, Debbie Quijada & Fred D. Ledley, *Considering Returns on Federal Investment in the Negotiated "Maximum Fair Price" of Drugs Under the Inflation Reduction Act: An Analysis* 17–18 (Inst. for Econ. Thinking, Working Paper No. 219, 2024).

parties deserve to be treated fairly. There are serious questions as to whether all parties are currently being treated fairly by distributions made under the existing legal regime. Adopting a principle of proportionality holds the promise of moving law and policy closer to circumstances under which the public either receives fairer returns based on its contributions or comes to better understand *why* the distributions it does receive are in fact fair.

Instrumentally, the equitable treatment of all parties is essential for sustaining long-term faith in the U.S. government as a worthy steward of public resources spent on drug R&D. The perception that the U.S. government is leaving its fair share of benefits on the table in its interactions with private actors undermines trust in public institutions as promoters of the public's interests. Further, the opportunity costs of forgone benefits could be significant. Deprivation of a fair share of benefits leaves additional resources to which the government is entitled untapped—resources that could be spent on new research or lowering drug costs, among many other potential uses that serve the public good. In the face of both great need and scarce resources, such a failure to procure what is owed would be unconscionable. Considerations of fairness to all contributors, including the public, should not be treated as merely ancillary.

Fairness, however, is of course not the only consideration at play. As discussed at length above, discussions of allocational fairness occur within the context of governmental, legally enshrined missions to promote innovation and commercialize new biomedical technologies. There is no denying the importance of this mission. A distributional fairness principle that undermines government-provided incentives for drug R&D is neither helpful nor the objective. Deploying a proportionality principle, therefore, must be sensitive to the context in which it is operationalized—an overarching government scheme to advance biomedical innovation for the good of the public.

At the same time, the government receiving a proportional share of benefits from a government-supported drug does not *necessarily* imply that innovation incentives will be rendered inadequate. Consideration of innovation incentives and distributional fairness, at least as a matter of theory, can peaceably coexist. One should not assume that concerns for innovation necessarily crowd out concerns for fairness. For these reasons, those who would eschew the government taking its fair share of rewards for a drug supported with taxpayer dollars should have the burden of making the affirmative case for why a deviation from a fair allocation—based on a principle of proportionality—is necessary. Proportionality, as explained in the next Section, should be established as the legal default.

E. *A New Default for Promoting Accountability*

Law and policymakers should adopt a presumption in favor of fairness and should do so by exploring a principle of proportionality. Public

contributions to drug R&D should be presumed to merit proportional benefits. Importantly, as a presumption, this revised default maintains necessary flexibility. It would apply unless it can be affirmatively shown, on a case-by-case basis, that providing such benefits would undermine the scientific enterprise.

Shifting the burden to prioritize fairness to the public marks a significant departure from the current legal framework, which largely ignores questions of fairness by assuming the problem away. Entrenched through political lobbying, institutional inertia, and assumptions about the role of government contributions which may not hold universally, the existing default presumes that public investments in drug R&D do not warrant proportional direct benefits. Establishing a new default would ensure that fairness concerns—what we, the public, are owed—are given the consideration and weight they deserve within our legal and policy frameworks. The public's entitlement to direct benefits would become the presumed baseline.

The U.S. needs an approach that balances appropriate consideration of public and private contributions to drug R&D while remaining sensitive to broader innovation policy concerns. Embracing proportionality as the legal and policy default holds promise for achieving this balance. At least three key reasons support rethinking the current approach and adopting a presumption in favor of a more equitable allocation of benefits through proportionality.

First, a default of proportionality demonstrates respect for *fairness to all parties*. Public contributions deserve recognition as part of a principled approach to ensuring equitable benefit-sharing. Treating the public fairly is not merely ancillary. Establishing a new default would demonstrate an essential commitment to justice within existing legal and policy frameworks.

Second, to be sure, a governmental commitment to providing the public with a fair—i.e., proportional—return on its contributions to drug R&D could theoretically be achieved *without changing any default*. Significant political and institutional headwinds, however, suggest the ineffectiveness of this route. The existing approach has been the model for decades, yet it has failed to adequately acknowledge and address profound concerns about fairness in public discourse. Flipping the default offers a new pathway that may not only better align with normative commitments, but is sensitive to these practical realities.

Finally, truth matters. Even if the public is already receiving a "fair" return on their investments, establishing a default of proportionality facilitates a forcing function to *promote transparency and accountability* on behalf of public actors. Powerful feelings and rhetoric aside, it is often difficult to know if the benefits the public receives from its contributions to drug R&D are fair. It certainly *seems* to many that we, the public, are not

getting what we are owed, yet it can be hard to know for sure—individual cases perhaps notwithstanding.[389]

The reasons for this epistemological problem are two-fold. U.S. innovation policy requires a moral principle—one that plausibly enjoys broad consensus—for determining when a distribution is fair to the public. That principle is articulated and, at least for initial purposes, defended. A principle of proportionality—albeit once suitably spelled out in its details—can plausibly provide this normative guidance.

Bolstering the lack of clearly articulated normative principles, however, has been a failure of governmental transparency and accountability. The public does not have easy, let alone routine, nor sometimes even *any* effective access to the information that would help it better understand what the public contributes and whether the returns it receives are proportional—i.e., fair. This is a well-known bottleneck. One recent government report, for instance, concluded that despite nearly $200 billion spent by the NIH on biomedical research between 2017 and 2021, "the extent to which NIH contributes to drug development is difficult to measure and not well understood."[390] Other government reports have likewise observed that existing legally required data reporting metrics are "inadequate" for enabling the public to assess a number of different issues surrounding U.S. technology transfer, including "how exclusive and nonexclusive licensing affects patient access to the resulting drugs."[391] Disaggregated licensing information about royalty rates, income, or other payments can be hard, if not impossible, to come by.[392] Perhaps most frustrating, the public may uniquely lack this important information. Such information "is likely well known among those in the field" so this "lack of transparency mostly serves to deny the general public, public interest groups, and researchers information that is necessary for evaluating such issues as fair returns on publicly funded innovation."[393]

A default that requires proportional returns provides a streamlined approach to these issues of deciphering whether the public receives a fair return. It puts the onus on those who prefer the status quo—to deviate from a prima facie fair return—to explain why. A flipped default would require policymakers to provide clear, publicly available justifications for deviations from proportionality. Reorienting the default around fairness

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[389] U.S. GOV'T ACCOUNTABILITY OFF., GAO-03-829, TECHNOLOGY TRANSFER: NIH-PRIVATE SECTOR PARTNERSHIP IN THE DEVELOPMENT OF TAXOL 1–4 (2003).

[390] U.S. GOV'T ACCOUNTABILITY OFF., GAO-23-105656, NATIONAL INSTITUTES OF HEALTH: BETTER DATA WILL IMPROVE UNDERSTANDING OF FEDERAL CONTRIBUTIONS TO DRUG DEVELOPMENT 37 (2023).

[391] U.S. GOV'T ACCOUNTABILITY OFF., GAO-21-52, BIOMEDICAL RESEARCH: NIH SHOULD PUBLICLY REPORT MORE INFORMATION ABOUT THE LICENSING OF ITS INTELLECTUAL PROPERTY 41–42 (2020).

[392] *Id.* at 41, 45 n.105, 46 (noting, among other things, that NIH officials cautioned that expanded disclosure would strain resources, while scholars argued that the secrecy involving information is often overbroad and denies the public necessary information to make key assessments).

[393] *Id.* at 45 n.105.

would compel the government to adopt a more skeptical stance toward departures from this principle through well-documented exceptions. This approach facilitates transparency and accountability and enables the public to assess the legitimacy of any deviations from proportionality. Of course, to the extent publicly available justifications for deviations are wanting, government officials will have to contend with increased public scrutiny.

Establishing this new default to achieve these ends would necessitate several key changes and additional policy development. There will be many details to iron out with full treatment reserved for future work. Here, however, I raise four issues. First, resilience to gaming of articulated standards and the granting of exceptions from the default, as noted earlier, will need to be thoughtfully addressed. Second, and furthering that end, a default of proportionality may benefit from companion administrative or legislative efforts to bolster transparency and accountability. Globally, for example, there has been recent activity to improve clinical trial cost transparency given that such trials are "often the biggest part of the overall cost of [the] R&D of health products."[394] A third crucial issue for a default of proportionality will be developing standards for sorting cases. A new, publicly available and understandable standard should be developed to sort cases involving "true" market failures or scenarios close enough to justify deviations from proportional rewards, from those that do not. This sorting mechanism will assist with distinguishing cases where proportionality might undermine innovation incentives. Finally, where in the law should this new default be located and is new legislation required? A principle of proportionality could be deployed under existing agency authority. A default of a principle of proportionality could be embraced as an agency interpretation of 35 U.S.C. § 209. Particularly under the new NIH IRP Access Planning Policy, these access plans could offer a mechanism for experimentation with proportionality and its relationship to drug affordability[395] It could also be utilized under the MDPNP, the Program of this Article's focus, and the vehicle explored below.

F. *The Form Government Rewards Should Take*

To implement a principle of proportionality, policymakers will have to grapple with what *form* an allocation of proportional benefits should take. This question is both complex and critical. A proportional share of benefits can take many forms. Possible forms include royalties, equity stakes, or

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[394] Press Release, Médecins San Frontiéres, MSF Reveals Cost of Landmark TB Clinical Trial in Push for Drug-Development Cost Transparency (Apr. 25, 2024), https://www.msf.org/msf-reveals-cost-landmark-tb-clinical-trial-push-drug-development-cost-transparency.

[395] NAT'L INSTS. OF HEALTH, OFF. OF THE DIR., NOT-OD-25-136 (July 24, 2025), *supra* note 120. The rescinded version of this policy had mentioned "benefit sharing." NAT'L INSTS. OF HEALTH, OFF. OF THE DIR., NOT-OD-25-062, NIH INTRAMURAL RESEARCH PROGRAM ACCESS PLANNING POLICY (Jan. 10, 2025), *supra* note 120.

governance mechanisms that require corporations to reinvest profits into further research.[396] Returns focused on drug accessibility suggest other possibilities, such as pricing clauses or broader access plans.[397] Each option represents a distinct approach to how the government might realize what it is owed based on its proportional return.

It is commonly assumed that the public's return from government support for drug R&D should take the form of reduced or more affordable drug prices. However, it is not immediately clear why fairness demands that benefits to the public ought to be taken "in kind." The reasoning behind this assumption often goes unarticulated.

If one were to construct an argument in support of this intuition, a possible foundation traces back to the idea of an unfulfilled government obligation.[398] As argued above, there may be a background obligation for the government to provide the public with reasonably priced or affordable access to certain medications. If this obligation goes unfulfilled, it could serve as a justification for taking the public's proportional share of benefits in the form of in-kind price reductions or other direct accessibility measures. In this way, the government could use its share to make good on this background obligation.

This line of argument, however, is not without limitations. Even if one accepts that the government has such obligations to the public, it does not necessarily follow that those obligations should dictate the specific form of the government's proportional reward. For instance, the government may have a wide range of obligations to fulfill. Just within health, for example, it may have other background obligations such as funding public health initiatives, supporting underserved populations with access to healthcare, or investing in future innovation. Resources derived from proportional allocations could potentially justifiably be directed toward any of these ends. A compelling argument would therefore be needed to explain why the obligation to provide more reasonably-priced medications should take priority over other governmental responsibilities.

Beyond this, there are practical considerations that suggest the government should have some discretion in deciding how to take its proportional share of benefits. Determining a fair price and translating public contributions directly into in-kind benefits can be particularly complex when government support occurs at early stages of development. For example, most NIH-licensed inventions are licensed at a preclinical stage—often years before any commercial product emerges, with no certainty that the licensed invention will lead to an FDA-approved, let alone commercially

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[396] *See, e.g.*, Silver & Hyman, *supra* note 13, at 878–79; Whitfill & Mazzucato, *supra* note 13; THE PEOPLE'S PRESCRIPTION, *supra* note 13, at 40; *see also* Amy Kapczynski, Christopher Morten & Reshma Ramachandran, *How Not to Do Industrial Policy*, BOSTON REV. (Oct. 2, 2023), https://www.bostonreview.net/articles/how-not-to-do-industrial-policy.

[397] *See, e.g.*, THE PEOPLE'S PRESCRIPTION, *supra* note 13, at 40.

[398] *See supra* Part III.B (discussing the government's obligations).

successful drug.[399] Due to this, "consideration of affordability of the final product that may result from a license is not only difficult but is also irrelevant for the majority of licenses granted by NIH."[400] These uncertainties could make it challenging to impose price-related conditionalities in a meaningful way. Financial metrics, such as royalties or equity stakes, may offer a more concrete and administrable alternative for ensuring that the government receives a proportional share of benefits.

Considerations of governmental fairness to the public in yet another sense also points toward discretion.[401] While everyone contributes to public funding, only those who need a particular medication might benefit directly from in-kind rewards like lower drug prices. Allowing the government to channel its returns into broader programs—such as a fund to offset the costs of prescription medications more generally or to reinvest in future research—might ensure that the benefits are distributed more equitably across society.

In sum, while reduced drug prices are one potential form of return, they are not necessarily the most justifiable or efficient option. The government's proportional share of benefits should be determined with sensitivity to the broader context including fairness, practicality, and the wide array of public obligations it must meet.

G. *Incorporating Considerations of Public Support*

Having explored the principle of proportionality as a moral approach for facilitating a fairer allocation of benefits to the public from their contributions to drug R&D, let us now return to the MDPNP. The MDPNP is a legal vehicle through which a principle of proportionality might be implemented. This Section will briefly consider two sets of issues: (1) To what extent do—or to what extent *could*—CMS's interpretations of the factor of federal support align with this Article's proportionality-based recommendations? (2) Is the MDPNP the appropriate instrumentality for addressing broader concerns for a fair (proportional) return on public contributions to drug R&D?

The MDPNP represents a significant shift in U.S. drug pricing policy. Federal law now explicitly directs policymakers to consider "prior Federal financial support" as a factor in determining a "maximum fair price" for certain drugs. This statutory provision acknowledges the public's role in funding drug R&D and introduces the potential to align pricing decisions with allocational fairness considerations.

Yet, as we have seen, present agency interpretations of this factor lack clarity and may impose limitations that complicate the realization of

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[399] GAO-21-52, *supra* note 391, at 35.

[400] *Id.*

[401] *See* Salbu, *supra* note 303, at 725, 728–29 (observing that the public should weigh in on the form of return it would like and not presume that price concessions would be deemed the most desirable).

proportionality within this framework. Moreover, CMS has avoided adopting proportionality as an overarching guiding principle and instead emphasized the importance of maintaining flexibility.[402] While this posture is understandable given the statute's lack of a proportionality mandate alongside a potential agency desire to maintain broad discretion, it raises important questions.

CMS's guidance defines "prior Federal financial support" broadly, encompassing grants, tax credits, and in-kind support like laboratory space or equipment. This expansive definition aligns with the proportionality-based approach suggested here. It can accommodate recognition of direct government contributions that advance or reduce the risk of the development of specific drugs. However, CMS's implementation may diverge in key respects. For example, CMS's exclusion of federal contributions flowing through intermediaries—such as NIH grants awarded to academic researchers—prioritizes sorting relevant contributions based on the financial flow of funding over the substantive role a contribution plays in advancing or risk reducing a drug's R&D. Its effect would be to potentially discount critical public contributions that may have played a pivotal role in a drug's development. Such exclusions risk undervaluing the public's role in innovation and limiting the scope of public returns that a proportionality-based framework otherwise justifies.

Another divergence lies in CMS's interpretation of "prior" federal financial support. While as noted above the IPAY 2028 Final Guidance removes the specific fifty-two month timeframe, CMS appears to retain its approach of focusing on federal support starting either with "initial research" or the drug's acquisition by a manufacturer.[403] While taking "initial research" as the starting point may align with operationalizing relevant contributions under a proportionality framework, limiting an analysis to the time of a drug's acquisition would seem to depart from the underlying normative considerations counseling which contributions ought to count. In this way, CMS may fail to fully capture the morally relevant extent of the government's investment in drug development, thereby misguidedly diminishing the public's proportional share of benefits.

Finally, CMS's guidance presently lacks articulated normative rationales for line-drawing. Vaguely defined terms and exclusions lacking a robust explanation create uncertainty and raise the risk of unprincipled decision-making.[404] By contrast, a proportionality-based approach (once it reaches its final form) strives to provide both a normatively well-justified approach to analyzing what the public is owed, as well as transparent and consistent criteria for the implementation of its underlying inputs, such as which government contributions ought to be relevant. The absence of an

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[402] *See, e.g.*, IPAY 2027 Guidance, *supra* note 156, at 99.
[403] CMS 2028 ICR, *supra* note 196, at 23; IPAY 2027 Guidance, *supra* note 156, at 309.
[404] *Cf.* Amgen comment *supra* note 201 (observing lack of clarity in approach risks inconsistency)

explicit normative approach, however, is an opportunity. As a legal matter, CMS has the discretion to embrace proportionality as an underlying rationale and modify its interpretations accordingly.

Larger issues, however, remain regarding whether the MDPNP is a suitable instrument for addressing fairness concerns related to public contributions to drug R&D. Three dimensions of this inquiry are especially relevant. First, what role could a principle of proportionality play within the Program's existing statutory framework? Second, to what extent is allocational fairness best pursued through ex ante rather than ex post mechanisms? Third, how might interagency coordination provide an effective institutional foundation for addressing these concerns?

To the first issue, it is important to emphasize that the goal of the MDPNP is to arrive at fair prices for certain Medicare drugs through negotiation with drug manufacturers. This is a distinct, albeit related, task from determining what the public might be fairly owed by way of its underlying contributions to a drug's R&D. While a principle of proportionality might offer an exhaustive normative framework for answering the latter question, it plays only a constituent role in the former. This is because determining a fair price for a drug is often considered a multi-factor inquiry.[405] Even if pricing were to hinge on a single consideration, few would argue that public funding should be the exclusive factor. Public contributions to drug R&D are relevant to fair pricing to the extent that cost is relevant—and cost-plus pricing is widely viewed as an incomplete, if not inadequate, basis for determining a fair price.[406] Implicitly recognizing this, the MDPNP includes "prior Federal financial support" as but one of several statutory factors CMS must consider when determining a drug's "maximum fair price" ("MFP").[407]

As such, the MDPNP cannot be expected to offer a comprehensive solution to the problem of securing fair returns on public investment. Its statutory mandate is focused on drug pricing, and more specifically the pricing of a subset of drugs impacting Medicare. A principle of proportionality holds that benefits should align with contributions. Yet the inclusion of public funding as a single factor *within* the MDPNP does not guarantee that the resulting price concession will reflect the public's proportional share. The lack of transparency about how this factor is weighed and the indeterminate relationship between public funding and the MFP calculation means that any adjustment to the price may bear little resemblance to a proportional allocation of benefits.

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[405] *See, e.g.*, Suerie Moon, Stephanie Mariat, Isao Kamae & Hanne Bak Pederson, *Defining the Concept of Fair Pricing for Medicines*, 368 BMJ 1, 1, 4 (2020) (discussing factors that define their fair pricing framework); Wolitz, Drug Manufacturers, *supra* note 16, at 226.

[406] *See supra* note 266.

[407] 42 U.S.C.A. § 1320f-3(e).

Moreover, the MDPNP's focus on price concessions inherently ties public returns to in-kind benefits—lower prices—rather than other forms of return, such as royalties or equity stakes, which might better reflect a contribution-based share of value. Price reductions may benefit patients and payers, but they do not necessarily track the scope or significance of public investment. This limitation constrains the MDPNP's utility as a mechanism for implementing proportionality in a comprehensive sense.

The MDPNP's ex post orientation poses additional challenges. While it allows CMS to evaluate public funding given a drug's success, allocational fairness, generally, is likely better addressed ex ante. Embedding a proportionality principle, for example, into funding or licensing agreements, tax credits, or other mechanisms ensures that public contributions are accounted for from the outset rather than as an afterthought. Ex ante approaches also provide greater predictability for private-sector actors, allowing them to better anticipate their obligations and adjust their strategies. By contrast, the MDPNP's ex post framework—particularly if its approach lacks transparency—introduces uncertainty.

This raises two questions: First, what role can proportionality meaningfully play within the MDPNP, given its limited, pricing-focused mandate? Second, even if the MDPNP is not designed to solve—and cannot otherwise shoulder—the broader fairness issue, how might it nonetheless advance that goal?

Answering the first question, a proportionality lens will enhance the MDPNP's implementation of the federal funding factor. While proportionality cannot resolve the full fairness question within this pricing-focused structure, it can provide clearer, normatively-justified, consensus-based guidance about which public contributions ought to count and why. It can help CMS articulate a normatively grounded rationale for the inclusion or exclusion of particular inputs and support the development of consistent, transparent decision-making. This would enhance accountability and improve public trust. Even though the statute offers no instruction on how CMS should weigh the statutory factors, the existing explanatory materials provide little further insight. Drawing on a principle of proportionality can offer a step towards increased clarity.

Answering the second question, the MDPNP holds great promise in its institutional role as a site of policy experimentation for implementing a principle of proportionality. While, again, the Program is not designed to tackle the full spectrum of fairness concerns surrounding public R&D contributions, it offers a rare and timely opportunity to surface, validate, and apply new methods for assessing those contributions in line with proportionality. The MDPNP is a testing ground. It allows policymakers to develop administrative practices and evaluative tools for measuring public

investment and considering it in price negotiations. These tools, if successful, could later be used to extend the idea of proportionality to broader ex ante mechanisms or other pricing contexts. Further, to the extent that ex ante mechanisms for ensuring a fair return to the public are absent or underpowered, the MDPNP can provide a backstop for ensuring a fair return to the public.

In this vein, the MDPNP also raises important institutional questions regarding overlapping agential authority. For example, should CMS defer to agreements negotiated by others, such as the NIH, or does it have authority to override such agreements? As part of the MDPNP, CMS collects information on agreements between the federal government and drug manufacturers for selected drugs.[408] If those agreements include pricing concessions or other returns on the government's contributions, it is unclear how CMS assesses or acts based on that information. Nevertheless, if it does not already exist, this underscores the need for a coordinated and integrated approach. To the extent that the MDPNP is grappling with, or its actions will have an impact on, a fair allocation of benefits to the public based on their contributions to drug R&D, there should be interagency collaboration that ensures a systematic approach to this distinct issue of fairness. The NIH and CMS, for example, in light of the MDPNP, could coordinate to establish a unified approach to proportionality, embedding it into both ex ante agreements and ex post evaluations and delineating the agencies' respective roles.

For these reasons, while recognizing its limitations and understanding that it cannot serve as the exclusive instrumentality, the MDPNP should be viewed as a step towards delivering fair returns to the public. The MDPNP represents a significant shift in federal drug pricing policy. It acknowledges the public's role in drug innovation and opens the door to new forms of fairness-based reasoning in regulatory contexts. Policymakers should continue to develop ex ante mechanisms and strengthen interagency collaboration, but the MDPNP provides an institutional space to begin experimenting with and implementing a principle of proportionality. The MDPNP can provide a proof of concept and serve as a backstop. If CMS can integrate a meaningful yet workable proportionality-based principle into its fair pricing framework, this can lay the groundwork for broader application of this principle across funding, licensing, and access policies. If this early experiment succeeds, it may help pave the way for more comprehensive reforms.

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[408] *See e.g.* CMS 2028 ICR, *supra* note 141, at 26 (requiting the Primary Manufacturer to "[l]ist and describe each licensing agreement, pricing agreement, purchasing agreement, and other agreement in place between your company and any federal government agency related to the discovery, research, and/or development of the selected drug.").

CONCLUSION

The public's contributions to biomedical innovation are indispensable. This Article has argued that policymakers should explore, if not adopt, a principle of proportionality as the default approach for ensuring fairness in the allocation of benefits from publicly supported drug R&D. Proportionality is particularly promising not only because it aligns public returns with public contributions but also because it may represent a principle around which broad consensus can be built. Operationalizing this principle requires careful attention to identifying relevant contributions, defining proportional benefits, and determining the appropriate forms of public returns, all while maintaining sensitivity to the goals of biomedical progress.

The MDPNP marks a significant legal shift in how the federal government approaches drug pricing. Its inclusion of "prior Federal financial support" as a fair-pricing factor offers an important opportunity to test, refine, and normalize the kinds of metrics and reasoning that proportionality would require. In this way, though the MDPNP cannot resolve issues of fair returns on public investments in drug R&D writ large, it can hold space for developing more principled frameworks for allocating public and private benefits. It can also serve as a backstop if other possible mechanisms for addressing allocational fairness are unavailable or underpowered.

At a time when allegations of unfairness and public trust in research institutions is fragile, proportionality offers a way to take these concerns seriously—*even if it turns out that no unfairness to the public has occurred*. By committing to a transparent, principled method for assessing what the public is owed, policymakers can help restore confidence in public institutions and demonstrate accountability for the stewardship of public funds. By embracing proportionality and prioritizing collaborative, integrated strategies, policymakers can ensure that public contributions are acknowledged and rewarded in a manner that is equitable, accountable, and reflective of what we—the public—are truly owed.