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Valuing Medical Innovation

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Abstract. Scholars and policymakers across the ideological spectrum agree that the U.S. drug pricing system is deeply flawed. Most reform proposals focus on one symptom: high prices for existing drugs. But high prices aren't all that ails the U.S. drug pricing system: Current law also provides weak incentives for medical innovation across wide areas, including vaccines, antibiotics, cancer preventives and early-stage cancer treatments, and cardiovascular drugs. Impediments to pharmaceutical innovation not only slow the growth of U.S. life expectancy but also exacerbate racial disparities in health outcomes.

High drug prices and slow pharmaceutical progress are two facets of the same problem: a system that fails to reward medical innovation based on social value. Instead, the United States rewards drugmakers through market exclusivity and federal subsidies that tie reimbursement rates to private-sector prices. The status quo yields two distinct but related consequences. First, rewarding firms based on the profits they can extract over a fixed period of exclusivity provides underpowered incentives for preventives and early-stage treatments, as well as for products that generate positive externalities. Second, linking government reimbursement rates to private-sector prices causes firms to raise prices for nongovernment payers in order to extract larger sums from Medicare and Medicaid. The end result is that the United States pays high prices for drugs of limited efficacy, but those high prices fail to spur the development of more effective drugs in critical areas.

To break out of this bind, the federal government should reward social value directly, using cost-effectiveness analysis to set the prices it pays for medical innovations without

limiting patient access. Models developed by other countries and by the nonprofit Institute for Clinical and Economic Review (ICER) lay the groundwork for value-based pricing, but these models require significant modification to sustain innovation. Of particular concern, ICER and advanced economies other than the United States assign much lower values to human life than U.S. federal agencies typically do. We argue that federal drug pricing should incorporate values for longevity gains that are in line with U.S. cross-agency norms.

Value-based pricing will lower some costs and raise others, with the United States continuing to pay more for pharmaceutical and biotechnology products than do other countries. But the federal government should not forgo opportunities to improve Americans' health just because other countries might receive collateral benefits. Rather, strong federal support for medical innovation should be understood as one way that the United States generates valuable global public goods.

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Introduction

The United States' drug pricing system is "broken."[1] On this point, there is broad, even bipartisan, consensus.[2] But what is less clear is how and why the system is broken, and what to do about it.

One common view—especially but not exclusively on the political left—holds that U.S. drug prices are too high. Per capita pharmaceutical spending in the United States is 42% higher than in Canada, 83% higher than in France, and 89% higher than in Australia.[3] Price disparities for certain individual drugs are even larger. For example, the retail price of a ninety-capsule package of Imbruvica, a treatment for chronic lymphocytic leukemia and other B-cell cancers, is approximately $14,000 in the United States, compared to $7,000 in Canada and $6,000 in Australia and France.[4] These high prices affect not only Americans' pocketbooks but also their health: A recent survey found that 29% of U.S. adults had taken an over-the-counter drug instead of a prescribed drug, not filled a prescription, or cut pills in half or skipped doses "because of the cost."[5]

President Biden, speaking at a community college in February 2022, cited these survey results and the Imbruvica price differential as evidence of the U.S. drug pricing system's ills. "This is the United States of America, for God's sake," an indignant Biden said. "That's just wrong."[6] But high out-of-pocket prices are not all that's wrong with the U.S. drug pricing system. Prices paid by patients and rewards received by drug developers are opposite sides of the drug price equation. And on the developer side, the system fails to provide adequate

1. Matthew Herper, *The Debate over America's Drug-Pricing System Is Built on Myths. It's Time to Face Reality*, STAT (Dec. 23, 2019), https://perma.cc/MF3E-C36P; *see* Annie Sinsabaugh & Meghna Chakrabarti, *Steps to Fix America's Broken Prescription Drug System*, WBUR: ON POINT (Sept. 23, 2021), https://perma.cc/YGJ4-Y4G6.

2. *See* 165 CONG. REC. S6525-26 (daily ed. Nov. 13, 2019) (statement of Sen. Chuck Grassley) (Republican Senator); 164 CONG. REC. S6178 (daily ed. Sept. 17, 2018) (statement of Sen. Mike Lee) (Republican Senator); Press Release, U.S. Senate Comm. on Fin., Grassley, Wyden Release Insulin Investigation, Uncovering Business Practices Between Drug Companies and PBMs that Keep Prices High (Jan. 14, 2021), https://perma.cc/YZU2-SEB6 (describing a joint investigation by Senator Chuck Grassley (R-IA) and Senator Ron Wyden (D-OR) into insulin pricing); Sen. Tammy Baldwin (@SenatorBaldwin), TWITTER (Feb. 8, 2019, 1:00 PM), https://perma.cc/FKL8-KF9F (Democratic Senator).

3. *See* U.S. GOV'T ACCOUNTABILITY OFF., GAO-21-282, PRESCRIPTION DRUGS: U.S. PRICES FOR SELECTED BRAND DRUGS WERE HIGHER ON AVERAGE THAN PRICES IN AUSTRALIA, CANADA, AND FRANCE 8 fig.1 (2021).

4. *See id.* app. IV at 51 tbl.7; *see also* President Joseph R. Biden, Jr., Remarks by President Biden on the Biden-Harris Administration's Work to Lower Healthcare Costs (Feb. 10, 2022), https://perma.cc/A9VE-NPAX.

5. *See* Liz Hamel, Lunna Lopes, Ashley Kirzinger, Grace Sparks, Audrey Kearney, Mellisha Stokes & Mollyann Brodie, *Public Opinion on Prescription Drugs and Their Prices*, KAISER FAM. FOUND. (Oct. 20, 2022), https://perma.cc/9MJP-HZKP.

6. *See* President Joseph R. Biden, Jr., *supra* note 4.

incentives for biotechnology[7] and pharmaceutical firms to invest in the medical innovations that would do the most to improve health. In other words, not only do we pay high prices for existing drugs, but we are also "missing" drugs that likely *would* exist under a more rational reward system.[8] The costs are quantifiable not only in dollars and cents, but also in lost years of life.[9]

Two powerful forces drive rewards for medical innovation in the United States. The first is market exclusivity: the combination of patent rights and other statutory mechanisms that allow firms to block competitors for a fixed period.[10] The second—largely overlooked by legal scholarship until recently[11]—is federally subsidized health insurance: principally Medicare, Medicaid, Veterans Health Administration coverage, and subsidized health insurance plans provided through Affordable Care Act (ACA) marketplaces. In theory, these two forces could combine to produce a healthy "innovation policy pluralism": Market exclusivity could generate powerful incentives for innovation, and federal subsidies could ensure that drugs remain affordable notwithstanding high sticker prices.[12] In practice, the promise of innovation policy pluralism has given way to a system of underpowered incentives across too many fields, resulting in crushing costs for too many patients.[13]

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7. The term "biotechnology" is typically used to refer to medicines derived from living organisms (such as monoclonal antibodies or vaccines), while the term "pharmaceutical" can refer specifically to medicines with a chemical basis (such as most of the drugs in a typical medicine cabinet) or more broadly to all medicinal drugs. The line between biotechnology and pharmaceutical companies is increasingly blurry, with many large firms (such as Johnson & Johnson, Merck, and Pfizer) engaged in both lines of work. We use "pharmaceutical" or "drug" to refer to the entire biotechnology and pharmaceutical industry.

8. *See infra* Part I.A.1.

9. For example, Budish, Roin, and Williams document underinvestment in treatments for early-stage cancers, which take a long time to commercialize. They estimate that if investment in most early-stage cancers had matched investment for the few that do not face this commercialization lag, U.S. cancer patients diagnosed in 2003 would have gained an additional 890,000 life years. *See* Eric Budish, Benjamin N. Roin & Heidi Williams, *Do Firms Underinvest in Long-Term Research? Evidence from Cancer Clinical Trials*, 105 AM. ECON. REV. 2044, 2080-81 (2015).

10. For an overview, see generally Maya Durvasula, C. Scott Hemphill, Lisa Larrimore Ouellette, Bhaven N. Sampat & Heidi L. Williams, *The NBER Orange Book Dataset: A User's Guide* (Nat'l Bureau. of Econ. Rsch., Working Paper No. 30628, 2022).

11. For examples of articles exploring the role of federal health insurance in providing innovation incentives, see generally Rachel E. Sachs, *Prizing Insurance: Prescription Drug Insurance as Innovation Incentive*, 30 HARV. J.L. & TECH. 153 (2016); Mark A. Lemley, Lisa Larrimore Ouellette & Rachel E. Sachs, *The Medicare Innovation Subsidy*, 95 N.Y.U. L. REV. 75 (2020); and Rachel E. Sachs, *The Accidental Innovation Policymakers*, 72 DUKE L.J. (forthcoming 2023).

12. *See generally* Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Policy Pluralism*, 128 YALE L.J. 544 (2019) (describing this theory).

13. *See infra* Part I.

Vaccines are one area where the failures of the U.S. drug pricing system are acute. The lightning-fast development of safe and effective vaccines against Covid-19—accelerated by an $18 billion investment from the federal government's Operation Warp Speed[14]—illustrated the pharmaceutical sector's capabilities given sufficient resources and high-powered incentives.[15] But outside the Covid-19 context, efforts to develop vaccines against common infectious diseases have struggled to attract financial support.[16] According to one pre-Covid estimate, manufacturers spent less than three cents on vaccine research and development (R&D) for every dollar directed at other drugs.[17] Such low levels of investment in vaccine-related R&D are a predictable result of a reward structure based on market exclusivity. Vaccines generate large positive externalities by providing herd immunity, but in a market-based system, vaccine manufacturers can typically charge only the patients who receive their vaccines, not the other members of the population who benefit from herd immunity.[18] Moreover, the benefits of risk-reducing products such as vaccines often vary from person to person, but vaccine manufacturers generally can't tailor their prices to individual risk.[19] So although vaccines are hugely valuable to society, our market-exclusivity-based reward structure allows vaccine makers to capture only a tiny sliver of their products' social

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14. *See* Stephanie Baker & Cynthia Koons, *Inside Operation Warp Speed's $18 Billion Sprint for a Vaccine*, BLOOMBERG BUSINESSWEEK (Oct. 29, 2020, 1:00 AM PDT), https://perma.cc/EF86-BM8R.

15. *See* Helen Branswell, *Why Covid-19 Vaccines Are a Freaking Miracle*, STAT (Feb. 14, 2022), https://perma.cc/39FX-CE2U.

16. *See, e.g.*, BEN LOPMAN, CDC, GLOBAL BURDEN OF NOROVIRUS AND PROSPECTS FOR VACCINE DEVELOPMENT 3-6 (2015), https://perma.cc/JV62-XXRE; Sonya Abraham et al., *Safety and Immunogenicity of the Chlamydia Vaccine Candidate CTH522 Adjuvanted with CAF01 Liposomes or Aluminium Hydroxide: A First-In-Human, Randomised, Double-Blind, Placebo-Controlled, Phase 1 Trial*, 19 LANCET INFECTIOUS DISEASES 1091, 1092 (2019); Kendall Powell, *The Race to Make Vaccines for a Dangerous Respiratory Virus*, NATURE (Dec. 10, 2021), https://perma.cc/X4WM-NU42; Leah R. Vincent & Ann E. Jerse, *Biological Feasibility and Importance of a Gonorrhea Vaccine for Global Public Health*, 37 VACCINE 7419, 7420 (2019); *Vaccine Protection Against Shigella Sonnei Disease*, U.S. FDA, https://perma.cc/5MLJ-ZGZV (last updated Oct. 13, 2020); Ruth Young et al., *Developing New Health Technologies for Neglected Diseases: A Pipeline Portfolio Review and Cost Model [Version 3]*, GATES OPEN RSCH. (Feb. 19, 2020), https://perma.cc/2HDP-9LBW.

17. *See* Stéphane A. Régnier & Jasper Huels, *Drug Versus Vaccine Investment: A Modelled Comparison of Economic Incentives*, 11 COST EFFECTIVENESS & RES. ALLOCATION 23 (2013), at 1, https://perma.cc/2GP6-ACFG.

18. *See* Qiwei Claire Xue & Lisa Larrimore Ouellette, *Innovation Policy and the Market for Vaccines*, 7 J.L. & BIOSCIENCES lsaa026, at 21-23 (2020), https://perma.cc/5BVZ-72QJ.

19. *See* Michael Kremer & Christopher M. Snyder, *Preventives Versus Treatments*, 130 Q.J. ECON. 1167, 1169 (2015).

value—with the consequence that firms invest less in vaccines than in other drugs that yield larger profits but smaller social benefits.

Cancer prevention provides another vivid illustration of the failures of the U.S. drug pricing system. Since the 1970s, drugs designed to prevent cancer have accounted for only around 1% of all cancer-drug clinical trials, and drugs designed to treat cancer before it spreads to surrounding tissues have accounted for an even smaller share.[20] One likely source of this skew is the shorter period of effective market exclusivity for preventives and early-stage treatments. In clinical trials, drugs that seek to prevent cancer entirely, or target cancer at an early stage, typically take longer to demonstrate efficacy. This is because patients in both the treatment and control groups generally will not experience adverse outcomes for several years.[21] Researchers file for drug patents before they begin clinical trials, so clinical trials eat into the fixed twenty-year patent term.[22] Preventives and early-stage treatments thus enjoy fewer years of patent protection following approval by the Food and Drug Administration (FDA), which means fewer years of monopoly profits. In effect, U.S. patent law provides smaller rewards for preventives and early-stage treatments than for late-stage treatments. Unsurprisingly, pharmaceutical-industry investments reflect this incentive structure.[23]

The same pathologies of market exclusivity affect drugs for cardiovascular disease. The number of new cardiovascular-disease drugs starting at all clinical-trial stages declined between 1990 and 2012,[24] even as cardiovascular disease continues to be the leading cause of death in the United States[25] and worldwide.[26] Such quantitative indicators align with the qualitative impressions of professionals in the field. The title of a 2014 meeting of leading scientists from the federal government, academia, and industry captures the sentiment: "Cardiovascular Drug Development: Is it Dead or Just Hibernating?"[27] Researchers point to low return on investment as a key driver

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20. *See* Budish et al., *supra* note 9, at 2047 fig.1 panel B.

21. *See id.* at 2046-47.

22. *See id.* at 2051-52.

23. *See id.* at 2048.

24. *See* Gail A. Van Norman, *Overcoming the Declining Trends in Innovation and Investment in Cardiovascular Therapeutics: Beyond EROOM's Law*, 2 J. AM. COLL. CARDIOLOGY: BASIC TO TRANSLATIONAL SCI. 613, 614 (2017).

25. *See Leading Causes of Death*, CDC, https://perma.cc/Q6UN-U8A5 (last updated Sept. 6, 2022).

26. *See The Top 10 Causes of Death*, WORLD HEALTH ORG. (Dec. 9, 2020), https://perma.cc/CAC2-KQHK.

27. *See* Christopher B. Fordyce et al., *Cardiovascular Drug Development: Is It Dead or Just Hibernating?*, 65 J. AM. COLL. CARDIOLOGY 1567, 1568, 1580 (2015).

of the decline.[28] And again, market exclusivity bears much of the blame. As with cancer preventives and early-stage cancer treatments, cardiovascular-disease drugs typically require long clinical trials that eat into the fixed period of market exclusivity under U.S. law.[29] In the case of cardiovascular-disease drugs, federal health insurance policies further undercut incentives for R&D: The Medicare Act gives pharmaceutical firms less pricing power with respect to cardiovascular drugs than to other common drug classes.[30] In effect, the U.S. drug pricing system has deprioritized drugs that target the number one killer in the country.

The slow pace of progress in areas such as vaccines, cancer prevention and early-stage cancer treatment, and cardiovascular drugs may seem distinct from the scourge of high pharmaceutical prices. Yet these seemingly separate problems are really two different manifestations of the same problem: a U.S. drug pricing system in which rewards for medical innovation bear little relation to the social value of the drugs in question. Instead of rewarding firms based on the health gains generated by their drugs, Medicare's Part B program and Medicaid reimburse firms and providers based on how much they charge other customers for the same drugs—higher prices for other customers mean larger reimbursements from Medicare and Medicaid.[31] The result, from a consumer-welfare perspective, can be even worse than a pure monopoly: Drugmakers in the United States sometimes charge more than the monopolist's profit-maximizing price so they can extract extra federal-reimbursement dollars.[32] Those exorbitant prices may put drugs out of reach for lower- and middle-income patients who aren't covered by Medicare, Medicaid, or other federally subsidized health insurance programs.

The failures of the U.S. system for rewarding medical innovation not only impose harms on the broader population, but also force certain demographic groups to bear disproportionate costs. African Americans experience significantly higher rates of fatal cardiovascular disease than do whites, and the difference in cardiovascular-disease death rates explains a large portion of the Black-white life-expectancy gap.[33] Underinvestment in cardiovascular-disease drugs is thus a racial equity issue as well as a public health issue.

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28. *See id.*

29. *See infra* note 63 and accompanying text.

30. *See infra* notes 118-26 and accompanying text.

31. *See infra* notes 110-16, 135-39 and accompanying text.

32. For evidence that firms raise prices for private patients in order to receive larger Medicaid reimbursements, see Mark Duggan & Fiona M. Scott Morton, *The Distortionary Effects of Government Procurement: Evidence from Medicaid Prescription Drug Purchasing*, 121 Q.J. ECON. 1, 3, 6-8 (2006).

33. *See* Mercedes R. Carnethon et al., *Cardiovascular Health in African Americans: A Scientific Statement from the American Heart Association*, 136 CIRCULATION e393, e394 (2017).

Underinvestment in vaccines also has racially disparate effects because many of the diseases for which we currently lack vaccines—including staph and shigellosis—afflict African Americans at higher rates than whites.[34]

How can policymakers better align pharmaceutical-innovation incentives with social value? If we want pharmaceutical firms to produce drugs that do the most to save lives and improve health, then we ought to reward social value directly, using cost-effectiveness analysis to set the prices that the federal government pays for prescription drugs and vaccines. Importantly, this reward should be based on *comparative* effectiveness: evidence of a drug's value compared with the existing standard of care—a number that could change as new clinical information arrives. To provide an incentive for distribution and administration, the reward should be allocated *per unit administered* rather than as a lump sum for obtaining FDA approval. And it should be *time limited* to reflect the marginal social value generated in the years before someone else would have developed the same drug.[35]

Many other countries have adopted value-based drug pricing schemes—including Australia, Canada, France, Germany, and the United Kingdom[36]—though those countries have assigned much lower values to human life and health than U.S. federal agencies do in regulatory contexts.[37] Scholars and nonprofits have also advocated value-based pricing in the United States.[38] The

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34. *See* Nicole Gualandi et al., *Racial Disparities in Invasive Methicillin-Resistant* Staphylococcus Aureus *Infections, 2005-2014*, 67 CLINICAL INFECTIOUS DISEASES 1175, 1175 (2018); Tanya Libby et al., *Disparities in Shigellosis Incidence by Census Tract Poverty, Crowding, and Race/Ethnicity in the United States, FoodNet, 2004-2014*, 7 OPEN F. INFECTIOUS DISEASES ofaa030, at 1 (2020), https://perma.cc/XD83-52SE.

35. In a separate work, we examine how to balance competing policies in the periods after these time-limited rewards expire. *See* Daniel J. Hemel & Lisa Larrimore Ouellette, *The Generic Drug Trilemma*, in 2 ENTREPRENEURSHIP AND INNOVATION POLICY AND THE ECONOMY (Benjamin F. Jones & Josh Lerner eds., forthcoming Mar. 2023).

36. *See, e.g.*, Adrian Towse, Michael Drummond & Corinna Sorenson, *Measuring Value: Pharmacoeconomics Theory and Practice*, in THE OXFORD HANDBOOK OF THE ECONOMICS OF THE BIOPHARMACEUTICAL INDUSTRY 394, 394-95, 422 (Patricia M. Danzon & Sean Nicholson eds., 2012); VALÉRIE PARIS & ANNALISA BELLONI, OECD, VALUE IN PHARMACEUTICAL PRICING—COUNTRY PROFILE: CANADA 3-6 (2014), https://perma.cc/663F-DXZM.

37. For example, the United Kingdom's National Institute for Health and Care Excellence (NICE) applies a standard cost-effectiveness threshold of £20,000 to £30,000 per quality-adjusted life year (QALY) (approximately $24,000 to $36,000 as of this writing), generally denying coverage to drugs for which prices exceed that range. *See* NAT'L INST. FOR HEALTH & CARE EXCELLENCE, NICE HEALTH TECHNOLOGY EVALUATIONS: THE MANUAL 92 (2022), https://perma.cc/9HBY-U9QP. For a discussion of the values assigned by U.S. federal agenices, see Part II.B.2.a below.

38. *See generally* PETER J. NEUMANN, JOSHUA T. COHEN & DANIEL A. OLLENDORF, THE RIGHT PRICE: A VALUE-BASED PRESCRIPTION FOR DRUG COSTS (2021) (advocating value-based pricing). A committee of the National Academies of Sciences, Engineering, and Medicine recently recommended that "public and private purchasers should adopt
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leading exponent of value-based pricing in the United States is the nonprofit Institute for Clinical and Economic Review (ICER), which already assesses the cost-effectiveness of many drugs and therapies.[39] ICER is right to identify cost-effectiveness analysis as a potential cure (or at least, a highly effective treatment) for the problems plaguing drug pricing in the United States, and it has developed a workable approach that already influences U.S. policy.[40] But ICER's approach suffers from two significant shortcomings that should be corrected before it is adopted more widely. First, ICER's health-benefit price benchmarks of $100,000 to $150,000 per quality-adjusted life year (QALY) are *radically undercompensatory* relative to the values derived from hedonic wage studies and the values used in regulatory cost-benefit analysis.[41] Second, ICER's method for discounting future costs and benefits systematically undervalues one-time interventions with long-lasting effects, such as vaccines that confer lifetime immunity and treatments that target childhood diseases.[42]

Concededly, the transition to value-based pricing will not be easy. A particular challenge—in light of the fragmented structure of the U.S. healthcare market[43]—will be to manage the shift without imposing greater

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value assessment methods" in the United States. COMM. ON ENSURING PATIENT ACCESS TO AFFORDABLE DRUG THERAPIES, NAT'L ACADS. OF SCIS., ENG'G, & MED., MAKING MEDICINES AFFORDABLE: A NATIONAL IMPERATIVE 181 app.B (Norman R. Augustine, Guru Madhavan & Sharyl J. Nass eds., 2018). In an important contribution, Govind Persad has proposed that the federal government set drug price ceilings—but not floors—based on social value. *See* Govind Persad, *Pricing Drugs Fairly*, 62 WM. & MARY L. REV. 929, 936-37 (2021). A price ceiling would reduce costs for public- and private-sector payers but would not address the problem of underpowered incentives in critical areas under current law. In a creative proposal, Christopher Buccafusco and Jonathan Masur have suggested patent-term extensions for welfare-enhancing patents and cancellation of patents that create zero or negative welfare. *See* Christopher Buccafusco & Jonathan S. Masur, *Drugs, Patents, and Well-Being*, 98 WASH. U. L. REV. 1403, 1432-37, 1443-44 (2021). And in another important contribution, Neel Sukhatme and Gregg Bloche have proposed a system of "dynamic value-based" payments and patent terms that would periodically adjust rewards for medical technologies based on new evidence of clinical efficacy. *See* Neel U. Sukhatme & M. Gregg Bloche, *Health Care Costs and the Arc of Innovation*, 104 MINN. L. REV. 955, 1011-16 (2019). These works build on a vast literature discussing how to better align rewards for medical innovation with social value, both within and outside the patent system. *See, e.g.,* AIDAN HOLLIS & THOMAS POGGE, THE HEALTH IMPACT FUND: MAKING NEW MEDICINES ACCESSIBLE FOR ALL 6 (2008); Benjamin N. Roin, *Intellectual Property Versus Prizes: Reframing the Debate*, 81 U. CHI. L. REV. 999, 1001-08 (2014).

39. *See History & Impact*, INST. CLINICAL & ECON. REV., https://perma.cc/NX5W-KJ5S (archived Jan. 21, 2023).

40. *See infra* notes 174-76 and accompanying text.

41. *See infra* Part II.B.2.a.

42. *See infra* Part II.B.2.b.

43. For a more detailed discussion of the structure of the U.S. healthcare market, see Part I below.

costs on low- and middle-income patients for drugs and vaccines that are currently undervalued. To be clear, we are not arguing that U.S. *patients* ought to pay high out-of-pocket prices—the moral case for access to medicines is compelling, as is the economic case for subsidizing goods like vaccines that generate positive externalities. But value-based rewards for developers need not come at the expense of affordability for patients. The most straightforward way to achieve the twin goals of higher-powered incentives for socially valuable vaccines and drugs and lower out-of-pocket costs for patients would be to pursue both objectives through a universal health insurance program. Absent that, we suggest that Congress could begin by mandating value-based rewards for drugs purchased through Medicare Part B and Medicaid. We also emphasize that value-based pricing will *lower* prices paid by the government for some pharmaceuticals purchased through those programs, including overvalued drugs for which high out-of-pocket prices currently impose affordability challenges. Moreover, severing Medicare and Medicaid reimbursements from prices charged to other purchasers should reduce prices for nonfederal purchasers, because firms will no longer have an incentive to raise private-sector prices in order to boost reimbursement rates.

The main purpose of our proposal, though, is not to resolve all the details of a value-based pricing regime, but instead to reorient discussions of prescription drug policy around value promotion rather than (merely) cost containment.[44] Value-based pricing would raise the costs of some drugs and vaccines while lowering the costs of others, with an ambiguous net effect on total spending. Given the bipartisan focus on lowering drug costs, we expect that our argument for *reducing* the prices of drugs that deliver minimal social benefits will draw objections from relatively few readers (except, of course, those drugs' manufacturers). By contrast, we expect greater pushback against our argument that the federal government should pay *more* than it already does for vaccines and certain other prescription drugs. Our Article concludes by addressing concerns about large value-based rewards. High rewards need not limit patient access if those rewards are subsidized by governments—and,

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44. A further note on scope: While we focus on prescription drugs, which have been the primary target of legislative activity focused on cost cutting in recent years, misalignments between private rewards and social value are in no way limited to prescription drugs. As Amy Kapczynski and Talha Syed have illustrated, current law provides underpowered incentives for many nonpharmaceutical medical innovations with lifesaving potential—for example, behavioral strategies that encourage healthy eating, changes to the built environment that promote exercise, and hospital protocols that reduce medical errors, such as the use of checklists. *See* Amy Kapczynski & Talha Syed, Essay, *The Continuum of Excludability and the Limits of Patents*, 122 YALE L.J. 1900, 1928-41 (2013). We set aside the question of nonpharmaceutical medical innovation not because it is insignificant—to the contrary, it is hugely important—but because it is likely to entail a different set of design challenges and policy tradeoffs that merit their own careful analysis. *See id.* at 1955-56.

indeed, a shift to value-based pricing for Medicare and Medicaid would likely lower costs for most patients.[45] Moreover, any potential increase in government-subsidized healthcare spending that could result from a shift to value-based rewards still lies well within the United States' current fiscal capacity.[46] And while value-based pricing would lead to the United States continuing to pay more than other countries for medical innovation, this is not itself a problem—the United States would be generating an important global public good.[47] The United States should not forgo opportunities to improve the health and extend the lives of its own citizens just because individuals in other countries might receive collateral benefits.

Part I of this Article starts with an analysis of the problems with existing pharmaceutical-innovation incentives, focusing on market exclusivity and federally subsidized health insurance programs. Part II sketches the contours of a value-based pricing regime and supplements this sketch with a pair of case studies. Part III considers three alternative approaches to drug pricing reform: (1) the ad hoc price caps mandated by the Medicare drug price "negotiation" provisions in the recently enacted Inflation Reduction Act; (2) proposals that would link prices to drugmakers' costs; and (3) proposals that would replace large ex post rewards for drugmakers with more robust ex ante government support for R&D. We argue that the first two options would fail to align rewards with social value. The third option—greater reliance on value-based direct government funding—is most promising as a complement to, not a substitute for, value-based ex post rewards. Part IV anticipates and responds to arguments against a value-based ex post approach.

I. How We (Mis)Value Medical Innovation

U.S. medical-innovation policy is pluralistic: The federal government mixes and matches a diverse array of mechanisms to incentivize innovation and allocate access to prescription drugs, medical devices, and other health-related products.[48] In theory, a pluralistic approach offers many advantages.[49] But the U.S. version of innovation policy pluralism falls short in several ways. As this Part illustrates, rewards and subsidies for medical innovation do not align with any ethically defensible conception of social value. Worse yet, U.S. policies manage to drive up out-of-pocket prices for consumers while also providing weak incentives for the development of the innovations that are

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45. *See infra* Part IV.A.

46. *See infra* Part IV.B.

47. *See infra* Part IV.C.

48. *See* Hemel & Ouellette, *supra* note 12, at 563-88.

49. *See id.* (emphasizing the potential virtues of a mix-and-match approach).

most likely to save lives. These failures of U.S. innovation policy motivate the search for alternatives in Parts II and III.

A. Market Exclusivity and Its Discontents

Market exclusivity lies at the foundation of the U.S. system for rewarding innovation—medical or otherwise. Patents provide a right to exclude others from making, using, or selling inventions for twenty years.[50] In the medical-innovation context, Congress has enacted other forms of exclusivity, such as FDA-administered regulatory exclusivity that runs concurrently with the patent term, to strengthen and supplement patent protection. For example, the Orphan Drug Act of 1983 provides regulatory exclusivity for a drug that treats a disease that affects less than 200,000 people in the United States for seven years from the date of FDA approval.[51] The Hatch-Waxman Act of 1984 authorizes patent-term extensions of up to five years to offset time lost in the FDA approval process,[52] along with five years of data exclusivity for small-molecule drugs that qualify as a new chemical entity.[53] Most recently, the Biologics Price Competition and Innovation Act of 2009 (BPCIA) provides twelve years of exclusivity for "biologics" (more complex products such as therapeutic proteins and vaccines).[54]

In theory, market exclusivity aligns rewards for medical innovation with consumers' willingness to pay. During the market-exclusivity period, firms can charge up to the amount that consumers are willing to pay without competitors being able to undercut that price. As explained in this Subpart, though, the U.S. system of market exclusivity does a poor job of aggregating information about willingness to pay. Even when it succeeds in this respect, willingness to pay does not necessarily align with social value. The misalignments go in both directions: Reliance on exclusivity can result in underinvestment in R&D under certain circumstances and overinvestment in others.

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50. *See* 35 U.S.C. § 154(a)(1)-(2).

51. *See* 21 U.S.C. §§ 360bb(a)(2), 360cc(a).

52. *See* 35 U.S.C. § 156.

53. *See* 21 U.S.C. § 355(c)(3)(E)(ii), (j)(5)(F)(ii). Unlike market exclusivity under the Orphan Drug Act, this "data exclusivity" merely prevents a generic from relying on the original clinical trial data. *See* JOHN R. THOMAS, CONG. RSCH. SERV., R44951, REGULATORY EXCLUSIVITY REFORM IN THE 115TH CONGRESS 3-4 (2017). But due to the expense of running new trials, data exclusivity effectively excludes most competitors. *See id.* at 4-5.

54. *See* 42 U.S.C. § 262(k)(7)(A); THOMAS, *supra* note 53, at 7-8.

1.   Underinvestment

The problem of underpowered incentives is most acute for medical innovations that: (1) take a long time to commercialize, (2) generate positive externalities, or (3) prevent rather than treat disease.[55]

a.   Long commercialization periods

Clinical trials often consume a large portion of the fixed twenty-year patent term. The actual market-exclusivity period for small-molecule pharmaceuticals is about 13 years on average[56]—significantly less than the statutory 20 years—and exclusivity periods for some drugs are much shorter. For example, if a drug is designed to treat a cancer at stage 0 or 1 (before it has spread), relatively few patients in either the treatment group or the control group are likely to die in the first several years.[57] By the time the trial can show efficacy (when statistically significant differences in mortality rates emerge, which often takes many years), few years may remain on the patent clock. R&D aimed at early-stage interventions thus tends to be relatively unattractive to profit-seeking firms.

The interaction between long commercialization periods and fixed patent terms thus threatens to deter the development of drugs that attack diseases at early stages. The most compelling evidence of this phenomenon comes from Eric Budish, Benjamin Roin, and Heidi Williams, who document private-sector underinvestment in cancer drugs that require longer clinical trials.[58] Using multiple empirical tests, Budish, Roin, and Williams show that decreased investment in drugs with long commercialization times stems from lower monetary incentives rather than differences in scientific opportunity.[59]

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55. A further problem is that market value may be lower than social value when consumers are credit constrained or lack the ability to pay. Market exclusivity also fails to provide incentives for new technologies that cannot be protected with exclusivity. *See* Kapczynski & Syed, *supra* note 44, at 1907.

56. *See* Durvasula et al., *supra* note 10, at 14; Erika Lietzan & Kristina M.L. Acri née Lybecker, *Distorted Drug Patents*, 95 WASH. L. REV. 1317, 1363 (2020).

57. *See* U.S. DEP'T OF HEALTH & HUM. SERVS., CLINICAL TRIAL ENDPOINTS FOR THE APPROVAL OF CANCER DRUGS AND BIOLOGICS: GUIDANCE FOR INDUSTRY 7 (2018), https://perma.cc/48ZW-LCY4 (indicating that overall survival in a randomized study is "the most reliable cancer endpoint").

58. Budish et al., *supra* note 9, at 2045, 2048. In a separate work, Roin argues that patent terms should be adjusted based on commercialization time to help address this deficiency. *See* Benjamin N. Roin, *The Case for Tailoring Patent Awards Based on Time-to-Market*, 61 UCLA L. REV. 672, 684 (2014).

59. First, the correlation between clinical trial time and R&D funding is similar after conditioning on cancer-type fixed effects, cancer-stage fixed effects, or both. Budish et al., *supra* note 9, at 2068-69. Second, when the commercialization period for early-stage cancers is shortened by allowing firms to use different clinical-trial endpoints, there is

They also estimate the social cost of this underinvestment by examining early-stage cancers that are less affected by commercialization lags. For hematologic cancers (leukemia and lymphoma), clinical trials tend to be shorter because developers can establish efficacy using surrogate endpoints—near-term outcomes like blood-cell counts—rather than waiting for the mortality rates in the treatment and placebo groups to diverge.[60] Budish, Roin, and Williams estimate that if drugs for the treatment of nonhematologic cancers could be commercialized as quickly as drugs for the treatment of hematologic cancers, the increased incentive to develop nonhematologic-cancer drugs would have caused U.S. cancer patients diagnosed in 2003 to live an extra 890,000 years combined.[61] In terms of dollars, the authors estimate that the net present value of these extra life-years is a staggering $2.2 trillion.[62]

The problem that Budish, Roin, and Williams identify is not cancer-specific: Vaccines and early-stage treatments for noncancer diseases are also likely to suffer from underinvestment due to commercialization lags. For example, from 1963 to 2015 the average (or, the mean) time from the start of clinical trials to FDA approval for new cardiovascular-disease drugs was 11.3 years,[63] and additional time typically elapses between the patent application and the start of clinical trials.[64] A major reason for these long commercialization lags is that cardiovascular-disease drugs—in order to obtain regulatory approval—generally "need to show clinically significant improvement in [actual] clinical outcomes . . . instead of relying on surrogate markers."[65] Unsurprisingly, pharmaceutical firms appear reluctant to invest in

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no longer a discrepancy. *Id.* at 2070-74. And third, public funding shows a smaller discrepancy, suggesting that the problem is private-sector funding, not a lack of scientific ideas. *Id.* at 2074-77. Budish, Roin, and Williams cannot definitively determine whether the discrepancy stems from shorter effective patent terms or corporate short-termism (or both). *Id.* at 2048. But in either case, it is the lower monetary incentives for drugs with long commercialization periods that drives underinvestment.

60. *See id.* at 2070-71, 2070 n.41.

61. *Id.* at 2078-80.

62. *See id.* at 2080. Note that the authors use a $100,000 value for a lost life-year and a 5% social discount rate. *See id.* In Part II.B.2.a below, we argue that these parameters result in the undervaluation of life-expectancy gains.

63. *See* Jennifer M. Beierlein, Laura M. McNamee, Michael J. Walsh, Kenneth I. Kaitin, Joseph A. DiMasi & Fred D. Ledley, *Landscape of Innovation for Cardiovascular Pharmaceuticals: From Basic Science to New Molecular Entities*, 39 CLINICAL THERAPEUTICS 1409, 1411, 1415 (2017).

64. *See* Budish et al., *supra* note 9, at 2051-52.

65. Aarif Y. Khakoo, Nicole R. Yurgin, Paul R. Eisenberg & Gregg C. Fonarow, *Overcoming Barriers to Development of Novel Therapies for Cardiovascular Disease: Insights from the Oncology Drug Development Experience*, 4 J. AM. COLL. CARDIOLOGY: BASIC TO TRANSLATIONAL SCI. 269, 270 (2019). According to one recent review, "past experience
footnote continued on next page

cardiovascular-disease drugs given the high cost of long clinical trials and the shorter period of patent exclusivity that follows. Thus, phase one clinical trials of cardiovascular-disease drugs account for only around 3% of all clinical trials, even as cardiovascular disease is the cause of roughly one in four deaths in the United States.[66]

Nonpatent forms of market exclusivity—in particular, the Orphan Drug Act's 7-year period, the Hatch-Waxman Act's 5-year data exclusivity period, and the BPCIA's 12-year period—partly offset the distortion identified by Budish, Roin, and Williams because these exclusivity periods start when a drug is approved and thus are not shortened by long commercialization lags. However, these nonpatent forms of market exclusivity also introduce new distortions of their own.[67] Nonpatent exclusivities enhance rewards for slow-to-market technologies, but they also channel R&D efforts in difficult-to-justify ways. For example, because the Orphan Drug Act offers larger rewards for drugs that treat diseases affecting fewer than 200,000 patients, it may push R&D efforts away from areas in which new drugs would save the most lives.[68] Indeed, one study finds that the number of new clinical trials for drugs to treat a given disease *drops* by 30% when that disease's prevalence crosses the 200,000-patient threshold.[69] And the BPCIA's twelve-year exclusivity period likely pushes R&D toward biologics rather than small-molecule drugs even though there is little evidence that biologics cost more to develop or yield larger benefits for society.[70] The upshot is that rewards under these supposedly

strongly suggests that there remains no reliable and proven surrogate end point for phase III [heart failure] trial outcomes." Stephen J. Greene et al., *Reassessing the Role of Surrogate End Points in Drug Development for Heart Failure*, 138 CIRCULATION 1039, 1050 (2018).

66. *See* Van Norman, *supra* note 24, at 614 (referencing clinical trial figures for 2012); NAT'L CTR. FOR HEALTH STAT., DATA BRIEF 427. MORTALITY IN THE UNITED STATES, 2020, at 4 fig.4 (2021), https://perma.cc/52C6-3MTP.

67. Firms may seek to prolong effective patent life through "evergreening," or filing patents on secondary innovations related to their drugs. *See* Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J.L. & BIOSCIENCES 590, 596-97 (2018). However, "evergreening" does not solve the problematic misalignment between rewards and social value. Rather, evergreening often directs resources toward efforts aimed at extending patent life that bring little added value for patients. *See id.* at 597.

68. For a thoughtful critique of prioritizing rare disease treatments, see Persad, *supra* note 38, at 964-66.

69. *See* Wesley Yin, *Market Incentives and Pharmaceutical Innovation*, 27 J. HEALTH ECON. 1060, 1071-73 (2008).

70. *See* Reed F. Beall, Thomas J. Hwang & Aaron S. Kesselheim, Correspondence, *Pre-market Development Times for Biologic Versus Small-Molecule Drugs*, 37 NATURE BIOTECHNOLOGY 708, 708-09 (2019); Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 MANAGERIAL & DECISION ECON. 469, 476-77 (2007); MICHAEL S. WROBLEWSKI, ELIZABETH A. JEX, SUZANNE DRENNON MUNCK, CHRISTOPHER J. GARMON, SUZANNE T. MICHEL, ALISSA WANTMAN & OSSIE L. NEAL, FTC,

market-based incentives often have more to do with arbitrary lines drawn by Congress than with the actual value of the innovations in question.

b. Positive externalities

Second, market exclusivity provides weak incentives for innovations that generate positive externalities, such as vaccines.[71] Readers who have lived through the Covid-19 pandemic will be familiar with this point. Vaccination confers a benefit on the vaccinated individual by lowering the risk and likely severity of disease, but it often confers an even larger benefit on society because each vaccinated individual contributes to a community's herd immunity.[72] Vaccine manufacturers typically contract only with the patients who receive their vaccines (or those patients' insurers), not with the other community members who reap collateral benefits from herd immunity. Since vaccine manufacturers can capture only a small slice of the social value generated by their products, they are unlikely to invest the socially optimal amount in vaccine R&D.[73]

Antibiotics are another area in which new drugs generate positive externalities that drugmakers cannot capture in a market-exclusivity-based system. As with vaccines, antibiotics can reduce the spread of infectious disease. In addition, novel antibiotics can reduce the risk of antimicrobial resistance by facilitating more "diverse prescribing patterns."[74] For example, if most patients use old antibiotic *A*, a patient who instead uses novel antibiotic *B* confers a benefit on future users of antibiotic *A* by reducing the selection pressure for bacterial strains that are resistant to antibiotic *A*. The firm that manufactures

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EMERGING HEALTH CARE ISSUES: FOLLOW-ON BIOLOGIC DRUG COMPETITION, at vi-vii (2009), https://perma.cc/D7DA-DA2S.

71. *See* Xue & Ouellette, *supra* note 18, at 21-22. For another example, consider overdose and addiction treatments. *See* Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Institutions and the Opioid Crisis*, 7 J.L. & BIOSCIENCES lsaa001, at 5, 25 (2020), https://perma.cc/V49K-FVMT.

72. *See* Xue & Ouellette, *supra* note 18, at 22.

73. This problem would be reduced in a single-payer system, where the payer internalizes some of these benefits, but fragmentation in the U.S. healthcare system reduces the incentive of payers to consider social benefits. *See* Rachel E. Sachs, *Integrating Health Innovation Policy*, 34 HARV. J.L. & TECH. 57, 59-60 (2020).

74. *See* SARAH KARLSBERG SCHAFFER, PETER WEST, ADRIAN TOWSE, CHRISTOPHER HENSHALL, JORGE MESTRE-FERRANDIZ, ROBERT MASTERTON & ALASTAIR FISCHER, OFF. OF HEALTH ECON. & ACAD. OF INFECTION MGMT., ASSESSING THE VALUE OF NEW ANTIBIOTICS: ADDITIONAL ELEMENTS OF VALUE FOR HEALTH TECHNOLOGY ASSESSMENT DECISIONS 6 (2017), https://perma.cc/X73D-FYD6; Alec Morton, Abigail Colson, Axel Leporowski, Anna Trett, Taimur Bhatti & Ramanan Laxminarayan, *How Should the Value Attributes of Novel Antibiotics Be Considered in Reimbursement Decision Making?*, MED. DECISION MAKING POL'Y & PRAC., July-Dec. 2019, at 1, 4, 8 tbl.IV.

antibiotic *B* typically cannot capture this benefit because the benefit accrues to future users of antibiotic *A*, who are not direct or indirect customers of antibiotic *B*'s manufacturer.

In recent years, the World Health Organization and other public health authorities have identified the spread of antimicrobial-resistant infections as a growing global health threat.[75] At the same time, private-sector investment in antibiotic development has declined.[76] The 2019 bankruptcy of the U.S. biotechnology company Achaogen—which filed for Chapter 11 protection less than one year after the FDA approved its new antibiotic, plazomicin, for the treatment of urinary tract infections caused by a multidrug-resistant bacterial pathogen—was widely viewed as a sign that even successful efforts to develop novel antibiotics would not be rewarded under the status quo.[77] The senior director of health programs at the Pew Charitable Trusts said at the time that "[t]he antibiotic market is broken and will not fix itself"[78]—a statement that arguably applies more broadly to markets for all medical innovations that generate large positive externalities.

c. Preventives vs. treatments

Third, even apart from the positive-externalities issue, market exclusivity leads to underinvestment in innovations that *prevent* rather than *treat* diseases, particularly when the preventive has a long-term effect, and the treatment must be taken (and thus purchased) repeatedly. Contrary to Benjamin Franklin's famous adage that "an ounce of prevention is worth a pound of cure,"[79] preventives tend to be worth much less to pharmaceutical firms (though likely more to society).

The market bias against preventives arises for at least three reasons. One is durational: Even if a one-time preventive delivers greater lifetime benefit than regular treatments, imperfections in capital and insurance markets may block firms from charging a high price that reflects the preventive's long-term value. Consumers may prefer to make smaller but more frequent payments for each

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75. *See* WORLD HEALTH ORG., 2019 ANTIBACTERIAL AGENTS IN CLINICAL DEVELOPMENT: AN ANALYSIS OF THE ANTIBACTERIAL CLINICAL DEVELOPMENT PIPELINE 1 (2019), https://perma.cc/2ED3-7TCK.

76. *See id.* at 27.

77. *See* Chris Dall, *Achaogen Bankruptcy Raises Worry over Antibiotic Pipeline*, CIDRAP (Apr. 16, 2019), https://perma.cc/8LAL-2N9N.

78. *See id.* (quoting Pew Charitable Trusts' Senior Director of Health Programs Allan Coukell).

79. *See* Benjamin Franklin, *On Protection of Towns from Fire*, PA. GAZETTE, Feb. 4, 1735, *in On Protection of Towns from Fire, 4 February 1735*, NAT'L ARCHIVES: FOUNDERS ONLINE (capitalization altered), https://perma.cc/U9R3-3L7H (archived Jan. 24, 2023).

round of treatment rather than a larger one-time payment because they lack liquid savings and access to low-interest-rate loans. Likewise, private health insurers may have weak incentives to invest in the preventive because much of the benefit will accrue far in the future.[80] By then, currently insured patients may have switched to other private insurers or may be covered by Medicare.[81]

A second problem is behavioral: Whether because of optimism bias or procrastination, individuals may fail to seek out preventives such as vaccines, even when benefits are high and costs are low.[82] For example, during the 2019-2020 influenza season, less than half of U.S. adults received the seasonal influenza vaccine,[83] even though nine in ten had health insurance[84] (which generally covers the full cost of the vaccine).[85] By contrast, individuals are less likely to underestimate their disease risk or delay drug purchases once they actually have the disease.[86]

Third, information asymmetries between consumers and manufacturers present a particular problem in the preventive context, especially when disease risk is heterogeneous.[87] The Lyme disease vaccine LYMErix, approved by the FDA in December 1998, offers a concrete example.[88] Lyme disease risk varies based on geography,[89] pet ownership,[90] occupation,[91] time spent outdoors,[92]

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80. *See* Sachs, *supra* note 73, at 59.

81. *See id.*

82. *See* Xue & Ouellette, *supra* note 18, at 27-29.

83. *Flu Vaccination Coverage, United States, 2019-20 Influenza Season*, CDC (Oct. 1, 2020), https://perma.cc/5D7Q-3Q6T.

84. As of the second half of 2020, 28.6 million American adults lacked health insurance, out of a total of 281.8 million (10.1%). *See* ROBIN A. COHEN, EMILY P. TERLIZZI, AMY E. CHA & MICHAEL E. MARTINEZ, NAT'L CTR. FOR HEALTH STAT., HEALTH INSURANCE COVERAGE: EARLY RELEASE OF ESTIMATES FROM THE NATIONAL HEALTH INTERVIEW SURVEY, 2020, at 11 tbl.II (2021), https://perma.cc/RN57-XG82.

85. *See* 42 U.S.C. § 300gg-13 (requiring coverage of CDC-recommended immunizations without cost sharing).

86. *See* Xue & Ouellette, *supra* note 18, at 28.

87. Kremer & Snyder, *supra* note 19, at 1169.

88. *See* Andrew C. Revkin, *The First Shot Is Fired in the Lyme Disease War*, N.Y. TIMES (Jan. 24, 1999), https://perma.cc/T2ML-DZX5 (to locate, select "View the live page").

89. *See Lyme Disease Map*, CDC, https://perma.cc/3L8W-NEDA (last updated Dec. 2, 2022).

90. *See* E.H. Jones, A.F. Hinckley, S.A. Hook, J.I. Meek, B. Backenson, K.J. Kugeler & K.A. Feldman, *Pet Ownership Increases Human Risk of Encountering Ticks*, 65 ZOONOSES PUB. HEALTH 74, 74, 79 (2018).

91. *See* Nicola Magnavita, Ilaria Capitanelli, Olayinka Ilesanmi & Francesco Chirico, *Occupational Lyme Disease: A Systematic Review and Meta-Analysis*, DIAGNOSTICS, Feb. 2022, at 1, 2, https://perma.cc/KJ95-9PRL.

92. *See* Casey Finch, Mohammed Salim Al-Damluji, Peter J. Krause, Linda Niccolai, Tanner Steeves, Corrine Folsom O'Keefe & Maria A. Diuk-Wasser, *Integrated Assessment of*

and whether individuals wear protective clothing.[93] Even within the Northeast and Midwest, which are high-incidence areas, the value of a Lyme disease vaccine is higher for people who own dogs, work outside, spend their recreational time in wooded areas, and wear shorts than for pet-free, long-pants-wearing individuals who rarely venture outdoors. But GlaxoSmithKline, the manufacturer of LYMErix, could not realistically adjust prices based on individual risk. As a result, it could not capture a large portion of the value of the vaccine—it could either charge a price well below what high-risk individuals were willing to pay (thus sacrificing potential revenue from those individuals), or it could charge a price well above what low-risk individuals were willing to pay (thus sacrificing potential revenue by shrinking the market).[94] Ultimately, GlaxoSmithKline pulled LYMErix from the market because weak sales did not justify the liability risks associated with the vaccine,[95] notwithstanding the fact that—as Mayo Clinic physician and vaccinologist Gregory Poland would later write—"few, if any, scientists believe the evidence points to any substantive safety concerns."[96] Nearly half a million Americans are diagnosed with and treated for Lyme disease each year,[97] even though a safe and highly effective vaccine exists.

The LYMErix saga illustrates a larger phenomenon: As economists Michael Kremer and Christopher Snyder observe, manufacturers face weaker incentives to invest in preventives than in treatments when disease risk is

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Behavioral and Environmental Risk Factors for Lyme Disease Infection on Block Island, Rhode Island, 9 PLOS ONE e84758, at 5 (2014), https://perma.cc/4CYR-NE8X.

93. *See id.*

94. Perhaps concerned about pricing for the high end of the market, a member of the CDC's Advisory Committee on Immunization Practices (ACIP) worried that LYMErix would be a "yuppie vaccine" for people who "will pay a lot of money for their Nikes" and "will have no consideration for cost-effectiveness when they want a vaccine because they're going to travel to Cape Cod." Robert A. Aronowitz, *The Rise and Fall of the Lyme Disease Vaccines: A Cautionary Tale for Risk Interventions in American Medicine and Public Health*, 90 MILBANK Q. 250, 255 (2012). In fact, cost-effectiveness studies found that the benefits of the vaccine substantially outweighed the costs in high-incidence areas. *See* Martin I. Meltzer, David T. Dennis & Kathleen A. Orloski, *The Cost Effectiveness of Vaccinating Against Lyme Disease*, 5 EMERGING INFECTIOUS DISEASES 321, 325-26 (1999); Nancy A. Shadick, Matthew H. Liang, Charlotte B. Phillips, Karin Fossel & Karen Kuntz, *The Cost-Effectiveness of Vaccination Against Lyme Disease*, 161 ARCHIVES INTERNAL MED. 554, 559 (2001).

95. *See* The Associated Press, *Sole Lyme Vaccine Is Pulled Off Market*, N.Y. TIMES (Feb. 28, 2002), https://perma.cc/X89B-WGPW (to locate, select "View the live page").

96. Gregory A. Poland, *Vaccines Against Lyme Disease: What Happened and What Lessons Can We Learn?*, 52 CLINICAL INFECTIOUS DISEASES S253, S257 (2011).

97. *See How Many People Get Lyme Disease?*, CDC, https://perma.cc/MWB3-Y57V (last updated Jan. 13, 2021). This number likely overestimates the number of actual infections. *See id.*

heterogeneous and information about risk is private.[98] Consistent with this theoretical claim, Kremer and Snyder find that although diseases are generally less likely to have a vaccine than a therapeutic drug, the gap is even wider for diseases with substantial and unobservable risk heterogeneity.[99] These effects may help explain why the FDA approved 213 therapeutic drugs, but only 9 vaccines, from 2014 to 2018.[100]

2. Overinvestment

While reliance on market exclusivity often leads to underinvestment, it may simultaneously spur overinvestment in certain R&D projects. By "overinvestment," we mean that marginal R&D expenditures are greater than the expected *social* benefit of those expenditures (including any resulting spillovers), even if they are less than the expected *private* benefit. Just as market value can be less than social value for products with positive externalities, the reverse is true for products with negative externalities—for example, addictive prescription opioids.[101] Patients who pay for opioids do not fully internalize the risk that their drugs will be abused by someone else, and unless drug developers are held accountable for the social costs of their products, they will not fully internalize the cost of those risks either.

Another source of overinvestment stems from "product hopping," when, for example, firms pull drugs with expiring patents from the market in order to transition patients to patent-protected alternatives that provide little added social value.[102] A well-known example is the pharmaceutical firm Indivior's effort to switch patients from the tablet version to a film version of its opioid substitution treatment Suboxone once patent protection on the tablet version expired.[103] Insofar as the film version served only to preserve Indivior's monopoly (and lacked any therapeutic benefit), the R&D and related costs incurred in product hopping were pure social waste. Worse yet, expenditures associated with product hopping may divert resources from the development of more socially valuable (if less profitable) drugs.

Finally, overinvestment can result from duplication of R&D efforts. When two firms are working on the same problem but do not account for the effects of their R&D on other innovators, they can create what is known as "patent

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98. Kremer & Snyder, *supra* note 19, at 1168-71.

99. *Id.* at 1215-17, 1217 tbl.V.

100. *See* Xue & Ouellette, *supra* note 18, at 4 n.26.

101. *See* Hemel & Ouellette, *supra* note 71, at 5, 24.

102. *See* Michael A. Carrier & Steve D. Shadowen, *Product Hopping: A New Framework*, 92 NOTRE DAME L. REV. 167, 168 (2016); Hemel & Ouellette, *supra* note 71, at 9, 11, 13 (providing multiple examples from the opioid context).

103. *See* Hemel & Ouellette, *supra* note 71, at 11-12.

racing" or the "common pool" problem.[104] To illustrate: Imagine that two firms are racing to develop a drug and that the first firm to develop the drug will realize a profit of $100. Firm *A* is on track to complete its work on the drug by next March. Firm *B* can make a $10 investment that will give it an 11% probability of developing the drug by next February. From Firm *B*'s private perspective, the expected benefit of the investment (11% × $100 = $11) is more than worth the cost ($10). But the investment imposes an equal cost on Firm *A* and yields only a small benefit to society—the benefit of getting the drug one month sooner. (We discuss this problem in more detail in Part IV.E.)

In sum, market exclusivity may, in theory, help align innovation rewards with social value. Yet when theory meets reality, misalignments abound. In many cases—for example, early-stage treatments, vaccines, and other preventives—the result is that the private sector invests less than the socially optimal amount in R&D. But the lure of market exclusivity can sometimes result in socially wasteful expenditures too.

B.   Problems with the U.S. Hybrid Model

The status quo for valuing medical innovation in the United States exhibits many of the pathologies of market exclusivity. But it would be a mistake to confuse the status quo *with* market exclusivity. The U.S. status quo is better described as a hybrid model, with a combination of market forces and government interventions determining the price of drugs. In this Subpart, we explain how Medicare and Medicaid, the two major public-payment programs for prescription drugs and vaccines in the United States, value pharmaceutical innovation.[105] We also explain how coverage mandates under the ACA affect the prices paid by private insurers. While Medicare, Medicaid, and ACA coverage mandates all appear to have reduced mortality rates and out-of-pocket costs for beneficiaries,[106] these programs also have affected the allocation of R&D resources in problematic ways.

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104. For an overview of patent racing, see generally Michael Abramowicz, *The Uneasy Case for Patent Races over Auctions*, 60 STAN. L. REV. 803 (2007).

105. Medicare and Medicaid are the most prominent public drug payers, but there are many other smaller programs. For a description of another important public payer, the Department of Veterans Affairs, see Lemley et al., *supra* note 11, at 90-91.

106. *See* Jason Huh & Julian Reif, *Did Medicare Part D Reduce Mortality?*, 53 J. HEALTH ECON. 17, 17 (2017); Andrew Goodman-Bacon, *Public Insurance and Mortality: Evidence from Medicaid Implementation*, 126 J. POL. ECON. 216, 218 (2018); Jacob Goldin, Ithai Z. Lurie & Janet McCubbin, *Health Insurance and Mortality: Experimental Evidence from Taxpayer Outreach*, 136 Q.J. ECON. 1, 3 (2021).

1. Medicare

Medicare is a national health insurance program administered by the Centers for Medicare and Medicaid Services (CMS)—an agency within the U.S. Department of Health and Human Services (HHS)—that covers over 50 million Americans aged 65 and older and over 8 million Americans with long-term disabilities.[107] Medicare's prescription-drug spending is channeled primarily through Part B, which covers professionally administered drugs such as chemotherapy agents, and Part D, which covers prescription drugs dispensed in pharmacies.[108] In 2019, Medicare spent $37.1 billion on drugs under Part B and $183.1 billion on drugs under Part D.[109]

Under Part B, Medicare is required to cover all products "reasonable and necessary for the diagnosis or treatment of illness or injury" or "for the prevention of illness."[110] Once a Medicare administrative contractor or CMS decides to cover a drug under Part B,[111] a statutory reimbursement formula is triggered. Normally, Medicare must reimburse providers for 106% of a drug's average sales price (ASP), though this dropped to 104.3% from July 1, 2022 through September 30, 2031.[112] The ASP is the average price across all the

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107. *See Medicare*, KAISER FAM. FOUND., https://perma.cc/WAJ5-H7QR (archived Jan. 26, 2023); *Medicare Beneficiaries by Type of Entitlement*, KAISER FAM. FOUND., https://perma.cc/48KY-9BLU (archived Jan. 26, 2023).

108. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., U.S. DEP'T OF HEALTH & HUM. SERVS., NO. 11315-P, DRUG COVERAGE UNDER DIFFERENT PARTS OF MEDICARE 1, 4 (2021), https://perma.cc/252U-H4DJ.

109. MEDICARE PAYMENT ADVISORY COMM'N, A DATA BOOK: HEALTH CARE SPENDING AND THE MEDICARE PROGRAM 143 chart 10-2, 168 chart 10-17 (2021). Medicare also paid more than $300 billion in 2020 to cover Part A and Part B services, including drug costs, for Medicare Advantage enrollees. *See id.* at 123.

110. *See* 42 U.S.C. § 1395y(a)(1)(A)-(B); *see also* Kort v. Burwell, 209 F. Supp. 3d 98, 115 (D.D.C. 2016) (holding that CMS's "failure to provide a cogent explanation for the disparate outcomes" of coverage determinations under the reasonable and necessary standard was arbitrary and capricious).

111. *See National and Local Coverage Determinations*, AM. COLL. RADIOLOGY, https://perma.cc/LJY6-6R52 (archived Jan. 26, 2023).

112. *See* 42 U.S.C. § 1395w-3a(b). Under the Budget Control Act of 2011, Medicare benefits are subject to "sequestration" (meaning across-the-board cuts) if Congress fails to meet deficit-reduction targets. For Medicare, the sequester cuts are capped at 2%. Budget Control Act of 2011, Pub. L. No. 112-25, § 302(a), 125 Stat. 240, 256-59 (codified as amended at 2 U.S.C. § 901a). The most recent adjustment to the sequestration schedule occurred in 2021. *See* Protecting Medicare and American Farmers from Sequester Cuts Act, Pub. L. No. 117-71, 135 Stat. 1506 (2021) (codified as amended in scattered sections of 2 and 42 U.S.C.). The 2% reduction applies to the provider payment, not the 20% patient copay. The resulting reimbursement rate is (20% + 98% × 86%) × ASP, which roughly equals 104.3% of ASP. *See* Cole Werble, *Medicare Part B*, HEALTH AFFS. (Aug. 10, 2017), https://perma.cc/G6LY-7PWZ.

manufacturer's sales to U.S. customers in a calendar quarter, excluding sales to certain federal and state purchasers.[113] If providers—for example, physicians' practices and hospital outpatient departments—can purchase drugs for less than the reimbursement amount, they can make a profit based on the margin between the reimbursement amount and the amount they paid.[114] This scheme distorts drug pricing in two important ways. First, manufacturers have an incentive to charge higher prices for drugs administered to non-Medicare patients in order to raise ASP (and thus collect more through Medicare Part B).[115] Second, providers have an incentive to choose higher-priced drugs in order to maximize their profit margins from the add-on to ASP.[116]

Medicare Part D covers self-administered prescription drugs through federally subsidized, privately managed plans.[117] Absent an exemption from CMS, Part D plans must cover every FDA-approved drug in six protected classes: anticonvulsants (antiseizure drugs), antidepressants, antineoplastics (cancer drugs), antipsychotics, antiretrovirals (HIV/AIDS drugs), and "[i]mmunosuppressants for the treatment of transplant rejection."[118] Outside those areas, plans must include at least two FDA-approved drugs per therapeutic category and class.[119] Familiar examples of therapeutic classes

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Part B also covers influenza and pneumococcal vaccines, which are reimbursed at 95% of the average wholesale price (AWP). AWP is a higher benchmark than ASP because it does not include discounts and rebates. *See* Karyn Schwartz, Meredith Freed, Juliette Cubanski, Rachel Dolan, Karen Pollitz, Josh Michaud, Jennifer Kates & Tricia Neuman, *Vaccine Coverage, Pricing, and Reimbursement in the U.S.*, KAISER FAM. FOUND. (Nov. 18, 2020), https://perma.cc/4XP4-5VPP.

113. 42 U.S.C. § 1395w-3a(c).

114. *See* Paul B. Ginsburg, Caitlin Brandt & Steven M. Lieberman, *The Use of Vendors in Medicare Part B Drug Payment*, BROOKINGS (Aug. 2, 2019), https://perma.cc/94QD-BHBE.

115. A similar distortionary incentive is associated with Medicaid. Empirical evidence shows that this incentive does cause firms to raise prices. *See infra* notes 140-41 and accompanying text.

116. *See* STEVEN SHEINGOLD, ELENA MARCHETTI-BOWICK, NGUYEN NGUYEN & K. ROBIN YABROFF, U.S. DEP'T OF HEALTH & HUM. SERVS., MEDICARE PART B DRUGS: PRICING AND INCENTIVES 4-5 (2016), https://perma.cc/8GF9-FA59. Consistent with this hypothesis, the introduction of the 106% of ASP reimbursement scheme in 2005 was associated with a 13%-20% increase in the use of docetaxel, the highest priced among five common cancer chemotherapy agents. *See* Mireille Jacobson, Craig C. Earle, Mary Price & Joseph P. Newhouse, *How Medicare's Payment Cuts for Cancer Chemotherapy Drugs Changed Patterns of Treatment*, 29 HEALTH AFFS. 1391, 1393 exhibit 1, 1396 (2010).

117. *See An Overview of the Medicare Part D Prescription Drug Benefit*, KAISER FAM. FOUND. (Oct. 19, 2022), https://perma.cc/WR5V-WMSR.

118. 42 U.S.C. § 1395w-104(b)(3).

119. 42 C.F.R. § 423.120(b)(2)(i) (2021).

include statins (HMG-CoA reductase inhibitors) and beta blockers (beta-adrenergic blocking agents).[120]

In contrast to Part B, Medicare Part D does not tie prices to ASP. Instead, prices are negotiated between pharmaceutical manufacturers and either the private sponsors of Part D plans or the intermediaries hired for this purpose, known as pharmacy benefit managers (PBMs).[121] In theory, the ability to refuse to cover drugs in therapeutic classes with two or more FDA-approved drugs may allow Part D plans (or their PBMs) to extract price concessions from manufacturers.[122] Consistent with this theory, Mark Duggan and Fiona Scott Morton find that drugs with higher sales to consumers who are eligible for Part D experienced slower price increases after Part D's implementation.[123] Duggan and Scott Morton also find that Part D's downward effect on price does *not* apply to drugs in protected classes or classes with only one or two available treatments.[124] Since Part D requires coverage of all drugs in those classes, PBMs wield significantly less negotiating leverage.[125] Thus, drugs in protected classes or for diseases with no existing treatments receive a larger reward than, for example, a novel and highly effective cardiovascular drug, since cardiovascular drugs are not a protected class and cardiovascular disease already has more than two treatments (though it continues to wreak a devastating toll in the United States and abroad).[126]

Medicare's reward structure affects not only drug pricing but also R&D. Margaret Blume-Kohout and Neeraj Sood find that the rollout of Part D was associated with an increase in preclinical testing and clinical trials for drug classes with larger shares of Medicare-eligible users—reflecting the increase in

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120. Plan D sponsors may use a variety of classification systems. For one example, see Essential Health Benefits Rx Crosswalk Spreadsheet, CTRS. FOR MEDICARE & MEDICAID SERVS., https://perma.cc/2LNN-ARN2 (last updated Jan. 14, 2021) (to locate, select "View/Download File").

121. *See* U.S. GOV'T ACCOUNTABILITY OFF., GAO-19-498, MEDICARE PART D: USE OF PHARMACY BENEFIT MANAGERS AND EFFORTS TO MANAGE DRUG EXPENDITURES AND UTILIZATION 1-2 (2019).

122. *See* Mark Duggan & Fiona Scott Morton, *The Effect of Medicare Part D on Pharmaceutical Prices and Utilization*, 100 AM. ECON. REV. 590, 591-92 (2010).

123. *Id.*

124. *Id.* at 604.

125. Nonetheless, PBMs retain at least some negotiating leverage through "plans' ability to place some (but not all) drugs on less desirable formulary tiers or to require prior authorization or step therapy, which imposes additional regulatory burdens on physicians and patients before providing access to particular drugs within a class." Lemley et al., *supra* note 11, at 87.

126. *See supra* text accompanying notes 24-28. For a critique of favoring drugs that target diseases with no existing treatments, see Persad, *supra* note 38, at 967-68.

market size as a result of the Part D program.[127] This effect was most pronounced for preclinical trials of protected-class drugs, suggesting that firms focused their R&D efforts on the drugs for which they would be able to charge the most.[128]

Two important conclusions emerge from this brief discussion. First, drug prices in the United States are not the product of unadulterated free-market forces. In 2023, Medicare is projected to account for 37% of all U.S. prescription drug spending,[129] and pricing under Medicare is highly structured as a result of statutory and regulatory requirements. Second, Medicare pricing incentives affect the allocation of R&D spending across therapeutic classes and diseases. Which preclinical testing efforts and clinical trials get off the ground reflects not only therapeutic potential but also political economy, as refracted through the Medicare rules.

2. Medicaid

Medicaid is a joint federal-state health insurance program that covers 83.9 million Americans with low incomes or disabilities.[130] Even though Medicaid is administered at the federal level by the same agency as Medicare, its rules regarding drug coverage and pricing look quite different. If a state opts to cover prescription drugs through its Medicaid program (as every state has),[131] then it generally must cover all FDA-approved drugs other than vaccines, with limited exceptions for certain categories (for example, weight-related, fertility, and cosmetic drugs) and for drugs that lack any "significant, clinically meaningful therapeutic advantage" over alternatives.[132] Starting in October

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127. Margaret E. Blume-Kohout & Neeraj Sood, *Market Size and Innovation: Effects of Medicare Part D on Pharmaceutical Research and Development*, 97 J. PUB. ECON. 327, 333-34, 333 tbls.4 & 5 (2013).

128. *Id.* at 333 tbl.4. Blume-Kohout and Sood also find that the introduction of Part D did not have a significant effect on the development of drugs already covered under Part B, for which Medicare reimbursement rules already allowed firms to charge high prices. *Id.* at 333.

129. Table 11 Prescription Drug Expenditures, CTRS. FOR MEDICARE & MEDICAID SERVS., https://perma.cc/823R-PTBB (archived Feb. 20, 2023) (to locate, select "View/Download File," then select "Table 11 Prescription Drug Expenditures.xlsx").

130. *See Medicaid*, MEDICAID.GOV, https://perma.cc/5NTR-STMS (archived Jan. 27, 2023).

131. *See Medicaid Benefits: Prescription Drugs*, KAISER FAM. FOUND., https://perma.cc/NC87-3RQM (archived Jan. 27, 2023).

132. *See* 42 U.S.C. § 1396r-8(d)(2), (d)(4)(C). One state, Tennessee, has obtained a waiver allowing it to exclude a wider range of drugs from coverage. *See* Press Release, Ctrs. for Medicare & Medicaid Servs., CMS Approves Innovative Tennessee Aggregate Cap Demonstration to Prioritize Accountability for Value and Outcomes (Jan. 8, 2021), https://perma.cc/9YYZ-VU7G.

2023, Medicaid will also require states to cover vaccines for all adults,[133] though it has not previously required the coverage of adult vaccines for traditionally eligible beneficiaries.[134]

By statute, Medicaid will not pay more for drugs than other purchasers. To receive Medicaid payments, manufacturers typically enter into agreements with CMS to rebate the government for at least 23.1% of a brand-name drug's average manufacturer price (AMP).[135] If the manufacturer offers a steeper discount to another purchaser (with some exceptions, such as for Medicare Part D or the Department of Veterans Affairs), Medicaid is entitled to this "best price."[136] Most states also negotiate with manufacturers for additional rebates.[137] In 2019, Medicaid spent more than $31 billion on prescription drugs.[138]

Like the Medicare rules discussed above, Medicaid's drug pricing system perversely incentivizes manufacturers to raise prices for nonfederal purchasers. In a typical monopoly, the producer has an incentive to price-discriminate—to offer higher prices to less price-sensitive consumers and prices barely above marginal cost to the most price-sensitive consumers—in order to maximize total profits. In prescription drug markets, by contrast, producers may decline to offer price concessions to the most price-sensitive

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133. Inflation Reduction Act of 2022, Pub. L. No. 117-169, § 11405, 136 Stat. 1818, 1900-01 (codified in scattered sections of 42 U.S.C.).

134. *See* Charleigh J. Granade, Russell F. McCord, Alexandra A. Bhatti & Megan C. Lindley, *State Policies on Access to Vaccination Services for Low-Income Adults*, 3 JAMA NETWORK OPEN e203316, at 2 (2020), https://perma.cc/54X8-ZKPT. As of 2019, only 50% of states provided coverage for all CDC-recommended adult vaccines through their traditional fee-for-service arrangements. *See id.* at 4.

135. *See* 42 U.S.C. § 1396r-8(c)(1)(A)-(B). For generic drugs, the rebate is 13%. *See* 42 U.S.C. § 1396r-8(c)(3)(A)-(B).

136. *See* 42 U.S.C. § 1396r-8(c)(1)(A)-(C). Under a new rule that became effective on January 1, 2022, CMS revised the definition of "best price" to allow manufacturers to enter into "value-based purchasing (VBP)" arrangements—such as only receiving payment for drugs when the patient has a positive clinical outcome—while still ensuring that Medicaid does not pay more than other payers. *See* Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, 85 Fed. Reg. 87,000, 87,002 (Dec. 31, 2020) (to be codified in scattered sections of 42 C.F.R.) (capitalization altered). Several states have also created prescription-drug–pricing boards to lower prices of overvalued drugs, though these boards have limited leverage. *See* Liam Bendicksen, Benjamin N. Rome, Jerry Avorn & Aaron S. Kesselheim, *Pursuing Value-Based Prices for Drugs: A Comprehensive Comparison of State Prescription Drug-Pricing Boards*, 99 MILBANK Q. 1162, 1164, 1190 (2021). These efforts illustrate the government's increasing interest in value-based pricing, although they view value as a one-way ratchet: a tool to reduce spending for overvalued drugs, but not to increase spending for undervalued drugs.

137. *See Medicaid's Prescription Drug Benefit: Key Facts*, KAISER FAM. FOUND. (May 1, 2019), https://perma.cc/T5X8-PL6K.

138. MEDICAID & CHIP PAYMENT & ACCESS COMM'N, MACSTATS: MEDICAID AND CHIP DATA BOOK 9 (2021), https://perma.cc/J9J9-ZS8R.

consumers (for example, low- and middle-income individuals paying out of pocket) because those price concessions will reduce the amount that the producers can charge Medicaid under the best-price rule. Medicaid's best-price rule may thus be part of the reason that pharmaceutical companies rarely offer lower prices to low-income patients who do not qualify for Medicaid, resulting in drugs being even less affordable for uninsured patients than would be the case in a pure monopoly.[139] Consistent with this theory, Duggan and Scott Morton find that a 10% increase in a drug's Medicaid market share is associated with a 7%-10% increase in the drug's average price.[140] This finding suggests that firms are raising prices for private patients in order to extract larger Medicaid reimbursements.[141]

3. ACA coverage mandates

Private insurers have greater flexibility than Medicare, Medicaid, and other public payers in how much they pay for new medical innovations, but they are still constrained by ACA coverage mandates. The ACA mandates that most plans in individual and small-group markets cover essential health benefits (EHBs), including prescription drugs.[142] Under HHS regulations, this means that each plan must cover the greater of (1) one drug in each therapeutic category and class or (2) the number of drugs in each category and class in their state's EHB-benchmark plan.[143]

Just as PBMs negotiating on behalf of Medicare Part D plans have a limited ability to demand price concessions for drugs in classes with only one or two available treatments, PBMs negotiating on behalf of private insurers have little bargaining power when there is only one drug in a class, or when all the drugs in a class are in the applicable EHB-benchmark plan. The effect of coverage mandates can be particularly perverse when the FDA approves drugs based on weak evidence of efficacy. In those cases, the insurer may nonetheless be required to cover the drug. The upshot is that prices paid by ACA individual and small-group plans do not necessarily bear any relation to a drug's health benefits but may have more to do with whether a drug falls into a class that gives its manufacturer unchecked pricing power.

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139. *See* Hemel & Ouellette, *supra* note 71, at 31-33.

140. Duggan & Scott Morton, *supra* note 32, at 3.

141. *See id.* at 23.

142. *See* 42 U.S.C. § 18022.

143. 45 C.F.R. § 156.122(a)(1) (2021).

II. Rewarding Medical Innovation Based on Social Value

In this Part, we shift our focus from the descriptive to the normative. Part I explained how the United States currently rewards medical innovation; this Part presents a vision for a reward system based on social value. We argue that innovators should receive a time-limited, per-unit price based on a drug's or vaccine's demonstrated comparative effectiveness. Firms that want to receive this value-based reward from government purchasers would have to commit to relinquish any right to exclude competitors after the time-limited period (through methods such as patents and other forms of market exclusivity). Once the limited period is over, generic manufacturers would be allowed to compete with the innovator firm.

We begin in Part II.A with the core of the case for value-based rewards. Part II.B then describes the workable framework for comparative-effectiveness analysis developed by the Institute for Clinical and Economic Review (ICER), as well as shortcomings in the ICER approach that should be corrected. Part II.C explores how the United States might transition to a value-based system. Finally, Part II.D applies our proposal to two examples: cystic fibrosis treatments and human papillomavirus (HPV) vaccines.

A. The Core of the Case for Value-Based Rewards

For some readers, the idea that we should reward medical innovation based on its value to society may seem axiomatic.[144] In our view though, proponents of value-based rewards bear a nontrivial justificatory burden. The argument for value-based rewards rests on (at least) three contestable premises:

1. Medical innovation policy should aim to maximize social welfare;
2. Medical innovation responds to innovation incentives; and
3. Methodologies for measuring social welfare have evolved to the point that we can better estimate social value directly than by relying on signals of social value generated by markets and politics.

The first premise is an ethical one. Our argument is welfarist, though in this context welfarism need not imply utilitarianism. A system for valuing medical innovation based on social value could accord greater weight to the interests of the worse off (however defined).[145] The approach we discuss below happens to be utilitarian, but it could be adjusted to accommodate alternative weightings. For example, policymakers could choose to give extra weight to innovations

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144. As noted above, our analysis and proposal contribute to a growing literature on value-based rewards for medical innovation. *See supra* note 38 and accompanying text.

145. *See* Matthew D. Adler & Nils Holtug, *Prioritarianism: A Response to Critics*, 18 POL. PHIL. & ECON. 101, 103-04 (2019).

that address disparities in health outcomes resulting from longstanding structural racism in the United States.[146] Because the relationship between health equity and value-based rewards deserves its own sustained analysis, we set aside this issue for present purposes—though we note that in some cases, a utilitarian approach also will advance important equity objectives.[147]

The second premise—that medical innovation responds to innovation incentives—is empirical, and the evidence in its favor is, we think, compelling. To be sure, the absence of large-scale value-based rewards means that there is not causal evidence that value-based rewards lead to more socially valuable innovation. But there is robust evidence that, broadly, firms produce more of the kinds of innovations that are rewarded financially. Among other studies:

- Pierre Dubois, Olivier de Mouzon, Fiona Scott Morton, and Paul Seabright use cause-specific mortality and GDP data from fourteen countries to estimate the market size for drugs targeting specific diseases.[148] They find that on average a 1% increase in potential revenue results in a 0.23% increase in the number of new chemical entities targeting a disease.[149] Framed another way, a $2.5 billion increase in potential revenue (in 2007 dollars) is associated with one new chemical entity.[150] This estimate is very roughly consistent with estimates that the development of a new drug incurs approximately $800 million to $1 billion in R&D costs, and that

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146. *See generally* DAYNA BOWEN MATTHEW, JUST HEALTH: TREATING STRUCTURAL RACISM TO HEAL AMERICA (2022) (examining racial inequalities in public health). For an approach incorporating equity concerns into cost-effectiveness analysis, see Richard Cookson, Andrew J. Mirelman, Susan Griffin, Miqdad Asaria, Bryony Dawkins, Ole Frithjof Norheim, Stéphane Verguet & Anthony J. Culyer, *Using Cost-Effectiveness Analysis to Address Health Equity Concerns*, 20 VALUE HEALTH 206, 206-07 (2017).

147. *See supra* notes 33-34 and accompanying text. To be sure, the effect of medical innovation on health equity is often nuanced. For example, David Cutler, Ellen Meara, and Seth Richards-Shubik observe that the development of synthetic surfactant, which reduced death rates for infants with respiratory distress syndrome, also increased the Black/white infant mortality ratio. *See* David M. Cutler, Ellen Meara & Seth Richards-Shubik, *Induced Innovation and Social Inequality: Evidence from Infant Medical Care*, 47 J. HUM. RES. 456, 464-66, 465 figs.2 & 3 (2012). This is because the death rate from respiratory distress syndrome was higher for white infants than for Black infants prior to the advent of synthetic surfactant (though the overall infant mortality rate was higher for African Americans). *See id.* at 462 fig.1, 465, 465 fig.3. The innovation therefore had a larger effect on the white infant mortality rate than on the Black infant mortality rate. *See id.* at 462 fig.1, 463-71.

148. Pierre Dubois, Olivier de Mouzon, Fiona Scott-Morton & Paul Seabright, *Market Size and Pharmaceutical Innovation*, 46 RAND J. ECON. 844, 851-54 (2015).

149. *See id.* at 845, 860.

150. *Id.* at 854, 861.

variable costs associated with production, distribution, and marketing consume roughly half of pharmaceutical revenue.[151]

- Daron Acemoglu and Joshua Linn examine the effect of demographic changes on new drug approvals in the United States from 1970 to 2000.[152] They hypothesize that if R&D responds to changes in reward size, firms will focus more on drugs for diseases and conditions that affect larger age groups.[153] Due primarily to the post–World War II baby boom, the age profile of the U.S. population changed meaningfully over the period studied.[154] The authors find that a 1% increase in expected market size is associated with a 4% increase in the number of new drugs targeting that market,[155] suggesting an even stronger link between potential profitability and R&D than do Dubois et al.

- Carmelo Giaccotto, Rexford Santerre, and John Vernon track the relationship between real drug prices and pharmaceutical R&D from 1952 to 2001.[156] They find that "a 10 percent increase in the growth of real drug prices is associated with nearly a 6 percent increase in the growth of R&D intensity" (or, in other words, the share of pharmaceutical revenues devoted to R&D).[157] Their result is consistent with F.M. Scherer's finding that the pharmaceutical industry's gross margins and R&D outlays have moved nearly in lockstep over several decades.[158] These findings strongly suggest that when the pharmaceutical sector generates more revenue, firms invest more in drug R&D.[159]

- Amy Finkelstein examines the effect of three federal vaccine-policy changes on vaccine R&D: a "1991 CDC recommendation that all infants be vaccinated against Hepatitis B"; a 1993 decision for Medicare to make influenza vaccines free for beneficiaries; and a 1986 statutory change that

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151. *See id.* at 861, 864.

152. Daron Acemoglu & Joshua Linn, *Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry*, 119 Q.J. ECON. 1049, 1049, 1067 (2004). For a similar result linking the number of new drugs to demographic changes in market size, see Rodrigo A. Cerda, *Endogenous Innovations in the Pharmaceutical Industry*, 17 J. EVOLUTIONARY ECON. 473, 475 (2007).

153. *See* Acemoglu & Linn, *supra* note 152, at 1054-58.

154. *See id.* at 1062.

155. *Id.* at 1084.

156. Carmelo Giaccotto, Rexford E. Santerre & John A. Vernon, *Drug Prices and Research and Development Investment Behavior in the Pharmaceutical Industry*, 48 J.L. & ECON. 195, 197 (2005).

157. *Id.* at 204-05.

158. F.M. Scherer, *The Link Between Gross Profitability and Pharmaceutical R&D Spending*, HEALTH AFFS., Sept./Oct. 2001, at 216, 219 exhibit 3.

159. *See id.* at 220.

reduced tort-liability exposure for manufacturers of childhood vaccines against polio, diphtheria-tetanus, measles-mumps-rubella, and pertussis (whooping cough).[160] All three policy changes increased the profitability of vaccines targeting the affected diseases.[161] Finkelstein finds that the policy changes were followed by a sharp increase in the number of new vaccine clinical trials for the affected diseases (relative to control groups of unaffected diseases).[162] These findings suggest that disease-specific R&D responds to changes in reward size.

- Wesley Yin examines the effect of the Orphan Drug Act on clinical trials for rare and non-rare diseases.[163] As discussed above, the Orphan Drug Act provides a seven-year period of market exclusivity for drugs that target diseases and conditions affecting fewer than 200,000 people in the United States.[164] In addition, the Act created a tax credit for orphan-drug clinical-trial expenses, and it increased grant funding for orphan-drug development.[165] Yin estimates that the Orphan Drug Act led to a 69% increase in the number of new clinical trials for drugs targeting diseases recognized as rare (relative to the number of clinical trials for non-rare diseases).[166] Yin also finds that when a disease goes from being "rare" to "non-rare" because prevalence surpasses 200,000, the number of new clinical trials drops by 30%.[167]

The evidence described above is just a sampling of the support for the claim that pharmaceutical R&D spending responds to rewards for medical innovation. In addition, as previously noted, Blume-Kohout and Sood find that the passage of Medicare Part D was associated with a higher number of preclinical and clinical trials for drug classes for which the program caused the largest increase in expected market size, again indicating that R&D efforts respond to market incentives.[168] And the finding of Budish, Roin, and Williams that private-sector cancer-drug development flocks toward therapies with shorter commercialization times further demonstrates the relationship between financial incentives and medical innovation.[169]

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160. Amy Finkelstein, *Static and Dynamic Effects of Health Policy: Evidence from the Vaccine Industry*, 119 Q.J. ECON. 527, 534-35 (2004).

161. *See id.*

162. *Id.* at 539-42.

163. Yin, *supra* note 69, at 1060-61.

164. *See supra* note 51 and accompanying text.

165. *See* Hemel & Ouellette, *supra* note 12, at 552 n.12, 558 n.31.

166. *See* Yin, *supra* note 69, at 1068.

167. *See id.* at 1071-73.

168. *See supra* notes 127-28 and accompanying text.

169. *See supra* notes 58-62 and accompanying text.

The hardest part of the case for rewarding medical innovation based on social value lies with the third premise: that policymakers can calculate social value with reasonable accuracy. To a large extent, this premise's proof is in the pudding, and the next Subparts seek to illustrate the mechanics of calculating social value. But before delving into the details, we emphasize two important points.

First, perfection should not be the bar. The alternatives to calculating rewards based on social value are (a) rewarding innovation based on some other measure—for example, profits from time-limited market exclusivity—or (b) not rewarding innovation at all. As emphasized above, the government is already heavily involved in adjusting the rewards for medical innovation. But the way we value medical innovation in the United States today does a poor job of aligning innovation incentives with benefits to society.[170] Our modest claim is that the United States can do at least somewhat better by trying to calculate social value and linking rewards to those calculations than by continuing with the current haphazard approach.

Second, precision need not be the touchstone. Value-based rewards serve to align the allocation of R&D efforts with researchers' expectations regarding social benefit. For example, if a firm is choosing whether to spend its marginal dollar on developing Potential Drug X versus Potential Drug Y, we want that firm's choice to be based on the expected social benefit (accounting for differences in probability of success) rather than on ethically irrelevant factors (for example, whether X or Y would be eligible for orphan-drug designation, be a biologic eligible for twelve-year exclusivity under the BPCIA, fall within a Medicare Part B protected class, and so on). As long as calculations of social value are *unbiased* in the statistical sense (meaning the expected value equals the "true"[171] value), then random errors in either direction are tolerable. Even with random errors in reward sizing, researchers and firms will still have an incentive to choose projects with higher expected social returns.

B. Valuing Health Gains

Fortunately, researchers and policymakers have made considerable headway in developing frameworks for assessing the social value of medical innovation.[172] These approaches—often referred to as "health technology assessment" or "cost-effectiveness analysis"—are used by government healthcare systems to inform coverage choices and/or reimbursement rates in

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170. *See supra* Part I.B.

171. We put "true" in quotation marks because social value is ultimately a normative conclusion, albeit one that is highly dependent on empirical facts.

172. *See* Towse et al., *supra* note 36, at 394.

many other countries, including Australia, Canada, France, Germany, Japan, and the United Kingdom.[173]

The United States does not have a national health-technology-assessment program, but Boston-based ICER, an independent nonprofit founded in 2006, seeks to fill this void by evaluating new therapies based on social value.[174] The two largest PBMs in the United States—CVS Caremark and Express Scripts (now a subsidiary of Cigna)—both have incorporated ICER assessments into rate setting in some contexts.[175] The U.S. Department of Veterans Affairs also regularly consults with ICER when negotiating drug prices.[176]

Because of ICER's influence over health technology assessment in the United States—and because of its admirable transparency in explaining its methodology—we examine ICER's approach in detail here. Although our evaluation is critical in some respects, our critique should not obscure the central point: ICER has devised a practical method for valuing medical innovation that—with several significant modifications—could form the basis of value-based pricing at the federal level. And if pharmaceutical developers knew that receiving a high reward depended on producing rigorous evidence of comparative effectiveness, they would have stronger incentives to generate this evidence in the first place, which would yield the added benefit of providing the FDA with more information for its assessment of whether a new drug should be approved.[177]

1. The ICER value assessment framework

ICER's main measure of social value is the eponymously acronymed "incremental cost-effectiveness ratio" (ICER), or "the cost per unit of health

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173. *See id.* at 394-95, 415, 422 (describing the systems used in Australia, Canada, France, Germany, and the United Kingdom); PARIS & BELLONI, *supra* note 36, at 3-6; Sophie Cairns, *Japan's New CEA-Based Price Adjustments Set to Maintain Pricing Pressure on Innovative Drugs*, PHARM. TECH. (Apr. 22, 2021), https://perma.cc/BGS7-7WVS.

174. *See* KAREN MULLIGAN ET AL., USC SCHAEFFER CTR. FOR HEALTH POL'Y & ECON. & ASPEN INST. HEALTH, MED. & SOC'Y PROGRAM, HEALTH TECHNOLOGY ASSESSMENT FOR THE U.S. HEALTHCARE SYSTEM 2 (2020), https://perma.cc/B9ZC-URP9.

175. *See* Caroline Humer, *CVS Drug Coverage Plan Based on Outside Pricing Review Is Off to a Slow Start*, REUTERS (Oct. 3, 2019, 4:08 PM), https://perma.cc/D6SN-UECQ; Mary Caffrey, *5 Things to Know About the Praluent–Express Scripts Deal*, AM. J. MANAGED CARE (May 4, 2018), https://perma.cc/4DLE-6MLB.

176. *See* Peter Glassman, Steven D. Pearson, Jennifer Zacher, David Rind & Michael Valentino, *VA and ICER at Three Years: Critics' Concerns Answered*, HEALTH AFFS. (June 15, 2020), https://perma.cc/MNV4-QLTR.

177. On the generally low quality of evidence submitted to the FDA, see generally Nicholas S. Downing, Jenerius A. Aminawung, Nilay D. Shah, Harlan M. Krumholz & Joseph S. Ross, *Clinical Trial Evidence Supporting FDA Approval of Novel Therapeutic Agents, 2005-2012*, 311 JAMA 368 (2014).

benefit gained of one treatment over another."[178] When evaluating a new innovation, ICER seeks to identify an alternative treatment that would be used in the absence of the new innovation.[179] It then estimates the additional cost of the new innovation (relative to existing alternatives) and the associated health gains.[180]

In theory, incremental cost-effectiveness ratios can be employed for any health outcome (for example, incremental cost per averted heart attack, or incremental cost per averted hospitalization for Covid-19). In ICER's cost-effectiveness evaluations, the primary measure is typically "the cost per additional quality-adjusted life year (QALY)."[181] The intuition underlying the QALY approach is that health interventions should be assessed based not only on life extension, but also on improvements in wellbeing (for example, reduced pain or increased mobility).[182] The QALY approach allows life extension and wellbeing improvements to be measured in the same units.[183] ICER uses the best available evidence from clinical trials and other sources to estimate the average number of additional QALYs associated with a given intervention.[184]

The Appendix explains in detail how ICER operationalizes QALYs.[185] In short, ICER's experts examine how an intervention changes an individual's health state across five dimensions—mobility, ability to engage in self-care, ability to carry out usual activities, pain/discomfort, and anxiety/depression. Along these dimensions, the levels of disutility associated with different health problems are estimated based on survey data. For example, if a treatment moves a patient from mobility level 5 (unable to walk about) to mobility level 1 (no problems) for one year, then the number of QALYs gained is 0.322. If a treatment allows a patient to live an extra year without the ability to walk (but with full health in the other dimensions), then the number of QALYs gained is $1 - 0.322 = 0.678$.

A common objection to the QALY approach is that it implicitly assigns lower values to the lives of individuals with disabilities.[186] As the previous paragraph illustrates, extending a person's life for one year counts more (in

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178. *See* INST. FOR CLINICAL & ECON. REV., 2020-2023 VALUE ASSESSMENT FRAMEWORK 19 (2022), https://perma.cc/TB39-H7EZ.

179. *Id.* at 12.

180. *Id.* at 12, 19.

181. *Id.* at 19.

182. *See infra* Appendix.

183. *See infra* Appendix.

184. *See* INST. FOR CLINICAL & ECON. REV., *supra* note 178, at 13-18.

185. *See infra* Appendix.

186. *See* Steven D. Pearson, Commentary, *Why the Coming Debate over the QALY and Disability Will Be Different*, 47 J.L. MED. & ETHICS 304, 304 (2019).

QALY terms) if the person is able to walk than if she is not. Because of this concern, the ACA banned the use of QALYs "as a threshold to determine coverage, reimbursement, or incentive programs" under Medicare.[187] In response to concerns over this aspect of the QALY approach, ICER has begun to report incremental cost-effectiveness using a metric called "equal value life years gained" (evLYG) alongside the QALY.[188] The evLYG approach assigns the same weight to all longevity extensions regardless of a patient's health state or disability status.[189] Recent ICER assessments use an evLYG-to-QALY conversion factor of 0.851, reflecting the assumption that the average life year of a person in the United States is equivalent to 0.851 life years of full health.[190]

Our argument does not depend on the particular measure of incremental cost-effectiveness chosen. We generally refer to QALYs to facilitate comparisons with the existing literature. But we think the evLYG approach has intuitive normative appeal. For example, if Person *A* can walk on her own while Person *B* requires a wheelchair to move about, almost everyone would agree that a medical innovation that allows Person *B* to walk on her own should count as a welfare gain. However, we expect that many (probably most) readers will also believe that adding a year to Person *A*'s life has the same social value as adding a year to Person *B*'s life, whether or not Person *B* has the ability to walk.[191] The evLYG approach also addresses legitimate concerns that the QALY approach implicitly discriminates against individuals with disabilities by assigning a lower value to additional life years for individuals with

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187. *See* 42 U.S.C. § 1320e-1(e). Notwithstanding § 1320e-1(e), CMS has continued to use QALYs in cost-benefit analyses of regulations. *See infra* notes 197-98 and accompanying text.

188. *See* INST. FOR CLINICAL & ECON. REV., *supra* note 178, at 22-23.

189. *Id.* at 23.

190. *See, e.g.,* JONATHAN D. CAMPBELL, MELANIE D. WHITTINGTON, DAVID M. RIND & STEVEN D. PEARSON, INST. FOR CLINICAL & ECON. REV., ALTERNATIVE PRICING MODELS FOR REMDESIVIR AND OTHER POTENTIAL TREATMENTS FOR COVID-19, at 7 (2020), https://perma.cc/SR42-WT34.

191. To be sure, one can also devise scenarios in which the evLYG approach leads to results that will strike most readers as strange. For example, imagine that a hypothetical medical innovation will extend Person *B*'s life by a year *and* enable Person *B* to walk. Most of us would think that this innovation is more valuable than an alternative that extends Person *B*'s life *without* enabling Person *B* to walk. However, the evLYG approach appears to assign the same score to both innovations. *See* INST. FOR CLINICAL & ECON. REV., *supra* note 178, at 23 ("The evLYG analysis counts any gains in length of life equally, regardless of the treatment's ability to improve patients' quality of life."). For a discussion of the conceptual challenges facing competitors to the QALY approach, see Nick Beckstead & Toby Ord, *Bubbles Under the Wallpaper: Healthcare Rationing and Discrimination, in* BIOETHICS: AN ANTHOLOGY (Helga Kuhse, Udo Schüklenk & Peter Singer eds., 3d ed. 2016).

disabilities than for individuals without disabilities.[192] To emphasize: Under the evLYG approach, health assessments assign the same value to an extra year of life for all individuals regardless of disability status.

After estimating the QALY and evLYG gains associated with a specific intervention, ICER generates incremental cost-effectiveness ratios measured in "cost per QALY" and "cost per evLYG."[193] ICER then compares these ratios to its health-benefit price-benchmark range of $100,000 to $150,000 per QALY or evLYG.[194] Interventions with incremental cost-effectiveness ratios above the benchmark range are considered to be "not cost-effective."[195] For analyses of Covid-19 vaccines and treatments, ICER has lowered the value of a QALY to $50,000 for "short-term affordability" reasons.[196]

2. Evaluating the ICER framework

The ICER framework lays a foundation for value-based assessments in the United States. ICER's record of assessments (more than ninety since 2007) should bolster confidence in the feasibility of this endeavor. In our view, however, certain aspects of the framework are likely to lead ICER to *undervalue* medical innovation significantly.

a. Undervaluing QALYs and evLYGs

The benchmark range of $100,000 to $150,000 per QALY or evLYG is *extraordinarily* low relative to the values that federal agencies use in other contexts, and lowering the benchmark to $50,000 during a pandemic is even harder to justify. For example, in its November 2021 interim final rule requiring most Medicare- and Medicaid-certified providers and suppliers to ensure that their staff are fully vaccinated against Covid-19, CMS cited a range of $590,000 to $970,000 for the value of a QALY.[197] Thus, the low end of CMS's

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192. On the QALY approach and disability discrimination, see NAT'L COUNCIL ON DISABILITY, QUALITY-ADJUSTED LIFE YEARS AND THE DEVALUATION OF LIFE WITH DISABILITY 40-43 (2019), https://perma.cc/73ZF-9LVR.

193. *See* INST. FOR CLINICAL & ECON. REV., *supra* note 178, at 22-23.

194. *See id.* at 26-27.

195. *Id.* at 31.

196. SARAH K. EMOND & STEVEN D. PEARSON, INST. FOR CLINICAL & ECON. REV., ALTERNATIVE POLICIES FOR PRICING NOVEL VACCINES AND DRUG THERAPIES FOR COVID-19, at 8 (2020), https://perma.cc/BN3K-RJFZ.

197. Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61,555, 61,610 (Nov. 5, 2021); *see also* COVID-19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff, 86 Fed. Reg. 26,306, 26,331-32 (May 13, 2021) (providing a range of $540,000 to $900,000). The agency refers to this value as the "Value of a Statistical Life Year" (VSLY), but then goes on to explain that VSLY is the value that it assigns to a

range is 5.9 times the low end of ICER's range, and the high end of CMS's range is 6.5 times the high end of ICER's range.

  CMS is not an outlier. The value of a statistical life (VSL) used by CMS was $11.5 million in 2021 and $10.6 million in 2020,[198] which is in line with the value placed on human life by other federal agencies, as illustrated in Figure 1. By contrast, ICER's value per QALY or evLYG of $100,000 to $150,000 translates to a VSL of about $2 million to $3 million under ICER's preferred 3% discount rate.[199]


QALY. *See* Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. at 61,610 ("QALYs, when multiplied by a monetary estimate such as the Value of a Statistical Life Year (VSLY), are estimates of the value that people are willing to pay for life-prolonging and life-improving health care interventions of any kind." (citation omitted)). CMS explains that it arrived at the $590,000 figure by converting an $11.5 million value of a statistical life (VSL) to life years at a 3% discount rate, assuming in accordance with HHS guidance that the VSL corresponds to a forty-year-old. The $970,000 figure reflects the same conversion at a 7% discount rate. *See id.* The resulting VSL-to-VSLY ratios match the VSL-to-QALY ratios in OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, U.S. DEP'T OF HEALTH & HUM. SERVS., GUIDELINES FOR REGULATORY IMPACT ANALYSIS 21 tbl.3.2 (2016).

198. *See* Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. at 61,610; COVID-19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff, 86 Fed. Reg. at 26,331.

199. *See* OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, *supra* note 197, at 21 tbl.3.2; INST. FOR CLINICAL & ECON. REV., *supra* note 178, at 25. The implied VSL for ICER is calculated as cost per QALY × 0.851 QALYs per life year × 41 years, for both the high ($150,000) and low ($100,000) ends of the ICER range, using ICER's preferred discount rate of 3%. *See* INST. FOR CLINICAL & ECON. REV., *supra* note 178, at 25.

Figure 1
Value of a Statistical Life by Source[200]
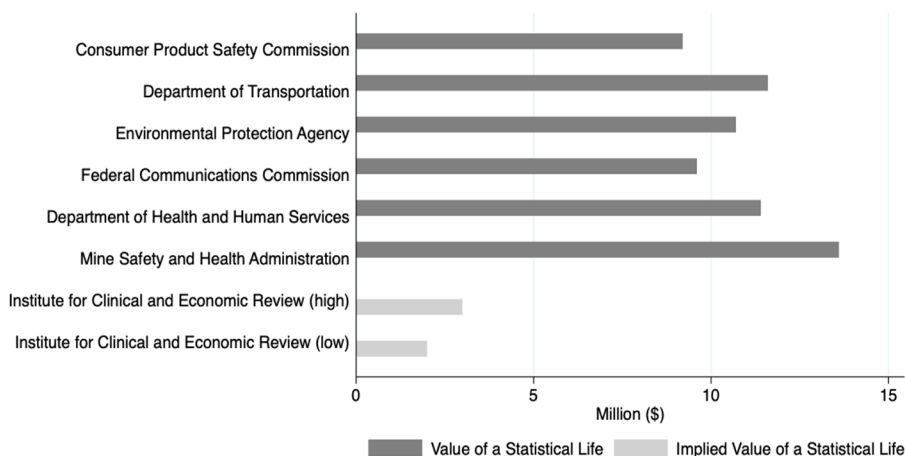
200. HHS states that "analysts should assume that the average individual in [VSL] studies is 40 years of age." OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, *supra* note 197, at 20. Remaining life expectancy at age 40 (for males and females combined) in the United States was 41 years in 2020, the most recent year for which data was available as of this writing. *See The United States of America, Life Tables (Period 1x1), Total*, HUM. MORTALITY DATABASE, https://perma.cc/JG47-QDGK (last updated June 2, 2022) (to locate, select "View the live page"). For sources of the data in the table, see Safety Standard for Operating Cords on Custom Window Coverings, 87 Fed. Reg. 1014, 1044 (Jan. 7, 2022) ($9.2 million in 2019 dollars for the Consumer Product Safety Commission); Medical Certification Standards for Commercial Balloon Operations, 86 Fed. Reg. 64,419, 64,427 & n.54 (Nov. 18, 2021) ($11.6 million in 2020 dollars for the Department of Transportation); OFF. OF AIR QUALITY PLAN. & STANDARDS, U.S. EPA, REGULATORY IMPACT ANALYSIS FOR PROPOSED FEDERAL IMPLEMENTATION PLAN ADDRESSING REGIONAL OZONE TRANSPORT FOR THE 2015 OZONE NATIONAL AMBIENT AIR QUALITY STANDARD 5-14 (2022), https://perma.cc/3NHT-S92M ($10.7 million in 2016 dollars, adjusting for income growth to year 2025, for the Environmental Protection Agency); Implementation of the National Suicide Hotline Improvement Act of 2018, 85 Fed. Reg. 57,767, 57,777 (Sept. 16, 2020) ($9.6 million in 2018 dollars for the Federal Communications Commission); OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, U.S. DEP'T OF HEALTH & HUM. SERVS., APPENDIX D: UPDATING VALUE PER STATISTICAL LIFE (VSL) ESTIMATES FOR INFLATION AND CHANGES IN REAL INCOME, at D-10 (2021), https://perma.cc/LC5G-U6A9 (providing a "central estimate" of $11.4 million in 2020 dollars for the Department of Health and Human Services); and Safety Program for Surface Mobile Equipment, 86 Fed. Reg. 50,496, 50,504 (Sept. 9, 2021) ($13.6 million in 2018 dollars for the Mine Safety and Health Administration).

To be sure, the fact that CMS and other agencies use higher values for life-year extensions in other contexts does not tell us which range—CMS's or ICER's—is "right." Nonetheless, we think there are strong arguments for favoring significantly higher ranges than ICER's benchmarks.

First, ICER's benchmark range is well below the range implied by estimates of the VSL from U.S. wage-risk and stated-preference studies.[201] The gold-standard approach—which forms the basis of the VSLs used by federal agencies in regulatory-impact assessments—relies on meta-analyses of multiple studies.[202] An August 2021 "meta-analysis of meta-analyses" emphasized two studies as being particularly persuasive[203]: a 2018 article by W. Kip Viscusi[204] and a 2016 article by Lisa Robinson and James Hammitt of the Harvard Center for Risk Analysis.[205]

Viscusi's meta-analysis, based on 1,025 different estimates across sixty-eight wage-risk studies,[206] seeks to correct for potential publication bias in the VSL literature.[207] The core publication-bias concern is that researchers may fail to report very low or negative estimates of the VSL (because we *know* the VSL isn't negative), but still will report very high estimates of the VSL.[208] Viscusi addresses this concern by using a weighted regression technique, arriving at an overall mean bias-corrected estimate for U.S. studies of $8.0 million in 2015 dollars (approximately $9.2 million in mid-2021 dollars).[209] This estimate is slightly lower than the figures generally used by U.S. federal agencies, but it is still far above ICER's range. For example, using HHS's

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201. A wage-risk study seeks to estimate the VSL based on wage premiums associated with occupations with higher fatality risks. For example, if an increase in the fatality rate of one death per 10,000 workers per year, or 0.0001, corresponds to a wage increase of $1000 per year (controlling for other job and worker characteristics), then the VSL would be $1000/0.0001 = $10,000,000. Another approach to VSL estimation relies on *stated preferences*—for example, asking survey participants how much they would be willing to pay to avoid a 1-in-10,000 risk of sudden death (or how much they would need to be compensated to accept a 1-in-10,000 risk of sudden death). Again, the VSL is estimated as the monetary amount divided by the change in risk.

202. *See* W. Kip Viscusi, *Best Estimate Selection Bias in the Value of a Statistical Life*, 9 J. BENEFIT-COST ANALYSIS 205, 206 (2018).

203. *See* H. Spencer Banzhaf, *The Value of Statistical Life: A Meta-Analysis of Meta-Analyses* 2, 8 (Nat'l Bureau of Econ. Rsch., Working Paper No. 29185, 2021), https://perma.cc/AXX8-D2N6.

204. Viscusi, *supra* note 202.

205. Lisa A. Robinson & James K. Hammitt, *Valuing Reductions in Fatal Illness Risks: Implications of Recent Research*, 25 HEALTH ECON. 1039 (2016).

206. Viscusi, *supra* note 202, at 209.

207. *See id.* at 217-22.

208. *See id.* at 206-07, 216.

209. *Id.* at 209.

guidance regarding VSL-to-QALY conversions at a 3% discount rate, a $9.2 million VSL corresponds to a value of approximately $470,000 per QALY,[210] far above the $100,000-to-$150,000 range favored by ICER.

Robinson and Hammitt focus on a smaller number of high-quality wage-risk studies that control for nonfatal injury risks, occupation, and industry,[211] along with a small number of well-designed stated-preference studies that elicit "willingness to pay" responses.[212] They arrive at a VSL range of $6.8 million to $12.0 million for the wage-risk studies[213] and a VSL range of $4.2 million to $11.2 million for the stated-preference studies (in 2013 dollars).[214] The low end of Robinson and Hammitt's VSL range, updated to mid-2021 dollars and translated into QALYs based on HHS's ratio, is approximately $250,000 per QALY, still well above the high end of ICER's range.[215]

Second, ICER's reasons for rejecting higher estimates strike us as unpersuasive. In its most recent value-assessment framework, ICER notes "several important limitations" of VSL-based estimates of the value of a QALY: (1) VSL estimates "conflate[]" willingness to pay (WTP) and willingness to accept (WTA) risk, (2) "how to 'spread' the VSL over life years remains unresolved," (3) estimating the VSL from wage-risk studies depends on the assumption that "workers have free choice of employment across jobs with different levels of risk," and (4) "the literature finds a wide range of estimates for VSL across different studies."[216]

In fact, the researchers responsible for the gold-standard VSL meta-analyses pay close attention to the difference between WTP and WTA. (WTP refers to the amount that an individual would be willing to pay to avoid a risk; WTA refers to the amount that an individual would demand in exchange for accepting a risk.[217] ICER views WTP as the "more relevant" measure for estimating the

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210. At a 3% discount rate, HHS recommends a QALY-to-VSL conversion ratio of approximately 19.5-to-1. *See* OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, *supra* note 197, at 21 tbl.3.2.

211. *See* Robinson & Hammitt, *supra* note 205, at 1042.

212. *See id.* at 1042-43. Notably, there is less of a publication-bias risk in the stated-preference context than in the wage-risk context because survey participants rarely say that they value their lives negatively.

213. *Id.* at 1045.

214. *Id.* at 1046.

215. $4.2 million in mid-2013 dollars translates to $4.91 million in mid-2021 dollars. *CPI Inflation Calculator*, U.S. BUREAU LAB. STAT., https://perma.cc/L2R3-GSL2 (archived Jan. 28, 2023) (to locate, select "View the live page"). $4.91 million/19.5 roughly equals $251,795.

216. INST. FOR CLINICAL & ECON. REV., *supra* note 178, at 69-70.

217. *See* Thomas J. Kniesner, W. Kip Viscusi & James P. Ziliak, *Willingness to Accept Equals Willingness to Pay for Labor Market Estimates of the Value of a Statistical Life*, 48 J. RISK & UNCERTAINTY 187, 188 (2014).

VSL.[218]) Kniesner et al. find no statistically significant difference between VSLs for workers who move to safer jobs (thus "paying" for risk reduction through foregone wages) and workers who take more dangerous jobs (thus "accepting" a risk increase in exchange for higher wages).[219] And as noted above, Robinson and Hammitt's compilation of stated-preference studies includes only studies that elicit willingness-to-pay responses.[220]

As for the challenge of converting VSLs into QALYs (and from there into evLYGs): While ICER is right that "how to 'spread' the VSL over life years remains unresolved,"[221] dividing the VSL by remaining life expectancy provides a plausible first cut.[222] Put another way, ICER's benchmark range of $100,000 to $150,000 per QALY—or $85,100 to $127,650 per additional life year with average health[223]—corresponds to a VSL between $3.5 million and $5.2 million for a 40-year-old with 41 years of life remaining,[224] which is still low relative to the bias-corrected wage-risk estimates and stated-preference estimates canvassed above.

As for assumptions about free choice in the labor market: Insofar as workers lack the ability to move across jobs with different risk levels, this should generally bias the VSL in wage-risk studies *downwards*, contrary to ICER's conclusion. The VSL depends upon the elasticity of wages with respect to risk; if wages are inelastic (for example, because workers lack bargaining power), then the estimated VSL would be lower than the "true" value that individuals ascribe to mortality-risk reductions. Finally, with respect to ICER's fourth critique, the wide range of VSL estimates offers little justification for choosing QALY values that imply VSLs near the very low end of that wide range.

Probably the strongest argument in favor of ICER's $100,000-to-$150,000 benchmark range—at least in the private health insurance context—is that a higher range would result in higher healthcare costs. This would, in turn, cause insurers to raise premiums and thus lead some individuals to drop coverage.

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218. *See* INST. FOR CLINICAL & ECON. REV., *supra* note 178, at 70.

219. *See* Kniesner et al., *supra* note 217, at 188.

220. *See* Robinson & Hammitt, *supra* note 205, at 1043.

221. INST. FOR CLINICAL & ECON. REV., *supra* note 178, at 70.

222. *See* OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, *supra* note 197, at 20; Richard A. Hirth, Michael E. Chernew, Edward Miller, A. Mark Fendrick & William G. Weissert, *Willingness to Pay for a Quality-Adjusted Life Year: In Search of a Standard*, 20 MED. DECISION MAKING 332, 335 (2000). For conditions under which this method may yield results that are greater or less than actual willingness to pay per QALY, see generally Daniel Herrera-Araujo, James K. Hammitt & Christoph M. Rheinberger, *Theoretical Bounds on the Value of Improved Health*, 72 J. HEALTH ECON. 102341 (2020), https://perma.cc/KT6H-9DU4 (to locate, select "View the live page").

223. *See supra* notes 190, 194 and accompanying text.

224. *See supra* note 200.

David Vanness, James Lomas, and Hannah Ahn estimate that a $10 million increase (in 2019 dollars) in healthcare expenditures would cause 1,860 people to become uninsured, resulting in ninety-six QALYs lost due to death and illness.[225] This estimate arguably implies that a treatment that costs more than $104,000 per QALY ($10 million/96) would be net QALY-reducing.[226]

Importantly, the Vanness, Lomas, and Ahn estimate is based on one study of mortality and morbidity reductions associated with Medicaid expansions under the ACA,[227] not on mortality and morbidity reductions associated with private health insurance, raising the question of whether the effects of the former can be imputed to the latter. Medicaid provides much more comprehensive coverage—with smaller copays and deductibles—than most private plans.[228] More significantly, though, the Vanness, Lomas, and Ahn threshold assumes that the relevant choice is between foisting the cost of life-saving treatments on lower-income individuals or forgoing those treatments entirely. There is, of course, another option: public provision of life-saving treatments—funded through progressive taxation—that incentivizes medical innovations that are cost-effective according to the standards applied by CMS and other federal agencies, but also shields the most vulnerable members of society from those costs.

Underlying ICER's threshold of $100,000 to $150,000 per QALY or evLYG is a sense—which ICER articulates explicitly—that healthcare in the United States is too expensive. In its value-assessment framework, ICER states its belief that "policymakers are no longer willing to accept cost increases in the US health care system that outpace growth in the overall economy."[229] However, concerns about overpriced medicines would potentially be reduced under a system in which high prices were time limited and depended on manufacturers providing rigorous evidence of comparative effectiveness, including post-marketing evidence. Moreover, standard economic theory suggests that healthcare spending *ought* to outpace overall income growth if

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225. David J. Vanness, James Lomas & Hannah Ahn, *A Health Opportunity Cost Threshold for Cost-Effectiveness Analysis in the United States*, 174 ANNALS INTERNAL MED. 25, 27 (2021).

226. In its value-assessment framework, ICER cites an earlier version of the Vanness research as suggesting that $84,000 per QALY is the break-even threshold. *See* INST. FOR CLINICAL & ECON. REV., *supra* note 178, at 71-72.

227. *See* Vanness et al., *supra* note 225, at 29 (citing Benjamin D. Sommers, *State Medicaid Expansions and Mortality, Revisited: A Cost-Benefit Analysis*, 3 AM. J. HEALTH ECON. 392 (2017)).

228. *See Cost Sharing and Premiums*, MEDICAID & CHIP PAYMENT & ACCESS COMM'N, https://perma.cc/JEG6-KBUD (archived Jan. 28, 2023). For example, Medicaid beneficiaries receive free emergency care and family planning and pregnancy-related services. *See id.* The aggregate amount of cost sharing for all care is capped at 5% of household income, and lower caps apply to a range of other service types. *Id.*

229. INST. FOR CLINICAL & ECON. REV., *supra* note 178, at 72.

the marginal utility of nonhealth consumption declines more quickly than the marginal productivity of healthcare spending, as appears to be the case.[230] It is unclear what the net effect of value-based pricing on government healthcare spending would be, but the United States could afford to spend more on healthcare, and high government healthcare spending need not—and should not—be coupled with lack of access for patients.[231]

Ultimately, the amount that we as a society are willing to pay per QALY is an ethical parameter rather than an empirical one. Our modest ethical claim is that society should be willing to spend the same amount per QALY in the healthcare context as we willingly spend in other contexts, such as clean air and auto safety.[232] Either we are (by ICER's standards) paying "too much" for clean air, auto safety, and so on, or we are (by the standards of federal agencies) paying "too little" for medical innovation. Our inclination is the latter, but our stronger claim is that the federal government should not discount medical innovation *relative* to other public health and safety priorities.

As a final note, it bears mentioning that costs per QALY in the range implied by agencies' VSL estimates do not "scale" to the full population. Gross domestic product (GDP) per capita was approximately $73,000 in the first quarter of 2022;[233] the United States clearly could not afford to bear, for example, a cost per QALY of $590,000 (the low end of the CMS range) to sustain all its citizens' lives. But lack of scalability is not a fatal flaw—the fact that an investment would not be feasible on a massive scale does not render it cost-ineffective at the margins. As discussed below, willingness to pay for health and longevity depends upon income,[234] so a large expense that consumed a significant portion of national income would likewise reduce the value of a QALY. While this dynamic prevents us from extending value-of-a-QALY estimates to scenarios in which national income is significantly greater or less than current levels, it has only limited implications for pharmaceutical spending, which is (and is likely to remain) only a single-percentage-point component of GDP.[235]

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230. *See* Robert E. Hall & Charles I. Jones, *The Value of Life and the Rise in Health Spending*, 122 Q.J. ECON. 39, 48, 68-70 (2007).

231. *See infra* Parts IV.A-.B.

232. *See supra* note 200.

233. *See* Press Release, U.S. Bureau of Econ. Analysis, Gross Domestic Product, First Quarter 2022 (Advance Estimate) (Apr. 28, 2022), https://perma.cc/Z9M4-PCWF (estimating GDP to be $24.38 trillion in the first quarter of 2022); *U.S. and World Population Clock*, U.S. CENSUS BUREAU, https://perma.cc/6K4K-UCLF (archived Jan. 28, 2023) (to locate, select "View the live page") (showing the U.S. population to be roughly 332.7 million).

234. *See infra* Part IV.B.

235. *See infra* note 379 and accompanying text.

b. Discounting future costs and benefits

ICER's approach to time discounting also results in assessments that undervalue medical innovation. The problem is most acute for innovations with temporally distant benefits (for example, preventives and early-stage treatments), which already suffer from underinvestment for reasons discussed above.[236]

ICER discounts all costs and benefits at 3% per year, explaining that "[t]he use of a 3% discount rate in the US as standard for both costs and outcomes is based on estimates of the real consumption rate of interest and data on real economic growth."[237] Thus, a $1 cost is valued at 74.4 cents after ten years and at 22.8 cents after fifty years.[238] Likewise, a QALY ten years from now is worth 74.4% of a QALY today, and a QALY fifty years from now is worth 22.8% of a QALY today.

Discounting costs at a 3% rate is potentially defensible. The underlying idea is that if investments (for example, bonds or stocks) yield 3% per year in real terms, a payer could set aside 74.4 cents today and have approximately $1 in ten years.[239] To be sure, a real return of 3% on bonds is somewhat optimistic in the current climate: The real yield on ten-year U.S. Treasury securities, as of the beginning of August 2022, was 0.09%.[240] But a 3% return is low relative to the historical real return on stocks: For example, the real annualized S&P 500 return (with dividends reinvested) from January 2000 to January 2022 is just below 5%.[241]

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236. *See supra* Part I.A.1.c. For example, one cost-effectiveness study of HPV vaccination finds that the use of a constant 3% discount rate reduces benefits by nearly 80% relative to a scenario with no discounting, since the cervical cancer reduction benefits of HPV vaccination typically accrue decades after the vaccine is administered. *See* Tjalke A. Westra et al., *On Discounting of Health Gains from Human Papillomavirus Vaccination: Effects of Different Approaches*, 15 VALUE HEALTH 562, 566 tbl.3 (2012); *infra* Part II.D.2 (discussing the pricing and cost-effectiveness of HPV vaccines).

237. INST. FOR CLINICAL & ECON. REV., *supra* note 178, at 25.

238. $\$1/1.03^{10} = \$0.744$ and $\$1/1.03^{50} = \$0.228$.

239. On the rationale for discounting future benefits by the rate of return, see generally Dexter Samida & David A. Weisbach, *Paretian Intergenerational Discounting*, 74 U. CHI. L. REV. 145 (2007).

240. *See Daily Treasury Par Real Yield Curve Rates*, U.S. DEP'T OF THE TREASURY, https://perma.cc/3SFY-CU6Q (archived Jan. 28, 2023) (to locate, select "View the live page," then select "Daily Treasury Par Real Yield Curve Rates" from the drop-down menu).

241. *See S&P 500 Return Calculator, with Dividend Reinvestment*, DQYDJ (Jan. 19, 2023), https://perma.cc/UGM5-36L5 (to locate, select "View the live page," then select "2000" from the "Starting Year" drop-down menu and "2022" from the "Ending Year" drop-down menu, then select "Adjust for Inflation").

On the benefit side, the problem with ICER's approach is not the discounting per se, but the fact that there is no corresponding adjustment for income growth. As national income rises, the amount that society should be willing to pay for a QALY ought to rise too (in real terms)—not necessarily because life would become more valuable, but because the marginal utility of an extra $1 of nonhealth consumption would fall. Federal agencies generally recognize this phenomenon and adjust regulatory-benefit estimates accordingly. For example, HHS explains in its guidelines for regulatory impact analysis that it will assume an income elasticity of one,[242] an estimate with theoretical and empirical support.[243] In other words, if a QALY is worth $100,000 today and then national income grows by 10%, the value of a QALY should rise to $110,000.

HHS discounts benefits[244] (which leads to future QALYs being worth less) and adjusts QALYs to reflect income growth (which leads to future QALYs being worth more).[245] If the real discount rate equals the real income growth rate, these effects balance out precisely, and the value of a future QALY is the same as the value of a present QALY. ICER, though, discounts QALYs without adjusting for income growth. The result is a devaluation of future benefits.

This issue is a small one for benefits that manifest within a few years. For benefits that accrue farther in the future though, ICER's asymmetric approach matters hugely. As indicated above, ICER's approach effectively shaves off a quarter of the value of QALYs accruing a decade from now.

ICER could rectify this issue by adopting the approach used by federal agencies: discounting benefits, but also adjusting the dollar value of longevity and health gains for income growth. Again, if the real discount rate equals the real growth rate (and recall that ICER states that its choice of a 3% discount rate is based on real growth data),[246] then with an income elasticity of 1, the two effects wash out. Although reasonable minds may differ on parameter values, the fact that ICER discounts benefits while making *no* adjustment to QALY values for income growth is inconsistent with standard economic theory and the consensus across federal agencies.

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242. *See* OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, *supra* note 197, at 16.

243. *See* Daniel Hemel, *Regulation and Redistribution with Lives in the Balance*, 89 U. CHI. L. REV. 649, 693-95 (2022).

244. OFF. OF THE ASSISTANT SEC'Y FOR PLAN. & EVALUATION, *supra* note 197, at 37.

245. *See id.* at 16.

246. *See supra* note 237 and accompanying text.

C.   Transitioning to Value-Based Pricing

If the United States had a single universal health insurance program, then the transition to value-based pricing would be more straightforward: The federal government could set and pay value-based prices for brand-name drugs and vaccines purchased by the national insurance program, with value calculated by multiplying the expected number of additional QALYs or evLYGs by the selected monetary value per QALY or evLYG. By paying these prices per patient treated, the government would be providing an incentive for the distribution and administration, rather than just the development, of the drug or vaccine. Even in this scenario, though, at least two timing questions would arise, which we will refer to as the "comparison-date" problem and the "end-date" problem. We discuss these timing concerns before turning to institutional considerations.

1.   Timing

The comparison-date problem is as follows: Recall that ICER's approach evaluates health innovations compared with an alternative that would be used in the absence of the new innovation.[247] But from what timeframe should this comparator be selected? If Drug *A* is the first approved treatment for a disease, and a similarly effective Drug *B* is approved second, should Drug *B* be assessed relative to Drug *A* (resulting in little reward), or relative to the earlier baseline of no treatment? ICER's framework does not explicitly address this issue.[248]

One approach to the comparison-date problem would be a strict first-in-time rule, whereby any intervention is compared to the best existing alternative—even if the alternative beat the intervention to market by mere days. This would incentivize firms to bring products to market faster, but it could simultaneously incentivize wasteful "racing" to beat out competitors.[249] It could also disincentivize firms that suspect they might lose the race from bringing their products to market at all. This approach would be particularly problematic when the first manufacturer is not expected to be able to meet full demand rapidly, as in a pandemic.[250]

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247. *See supra* note 179 and accompanying text.

248. Each comparative-effectiveness evaluation has *some* comparator, but ICER does not provide a framework for how comparators should be selected. *See, e.g.*, INST. FOR CLINICAL & ECON. REV., POLY ADP-RIBOSE POLYMERASE (PARP) INHIBITORS FOR OVARIAN CANCER: EFFECTIVENESS & VALUE 4 (2017) ("Relevant comparators were selected based on input from clinical experts and represent appropriate alternative therapies in each of the populations of focus.").

249. *See supra* note 104 and accompanying text.

250. *See, e.g.*, Nicholson Price, Rachel Sachs, Jacob S. Sherkow & Lisa Larrimore Ouellette, *What Are the Innovation Challenges to Scaling Vaccine Manufacturing?*, WRITTEN DESCRIPTION (Sept. 10, 2020, 9:23 PM), https://perma.cc/L44F-8V9K.

Another approach would be to compare a product to the best option at the time the product's clinical trials began—perhaps including comparison drugs in late-stage trials that have publicly announced promising results. This would help firms design clinical trials to provide the most relevant evidence, and it could reduce the disincentive to invest in drugs with long commercialization periods. But it would provide little incentive to conduct clinical trials quickly, unless there is a concern that the market will disappear. The optimal timeframe from which a comparator should be selected likely lies somewhere in between the start of clinical trials and the moment the product reaches the market; for now, we simply identify this timing question as an important policy variable.

As for the end-date problem: Current intellectual property (IP) and non-IP market-exclusivity approaches such as the Orphan Drug Act, the Hatch-Waxman Act, and the BPCIA incentivize innovation through a *time-limited* exclusivity period.[251] Should value-based rewards be time limited as well? Time limits mean that researchers and firms won't capture the full social value of the medical innovations that they develop, and so may underinvest relative to the socially optimal level. On the other hand, we might question whether, for example, Merck still should be receiving a value-based reward for the measles-mumps-rubella vaccine more than a half-century after its approval.[252]

One approach to the end-date problem would be to offer time-limited value-based rewards (for example, seven years), after which the government would no longer be bound by the value-based price and could look for cheaper alternatives from generic manufacturers. A potential justification for this approach is that firms that bring new drugs to market simply *accelerate* the pace of innovation. For example, we might think that if Warner-Lambert hadn't brought atorvastatin (Lipitor) to market in 1996,[253] someone else eventually would have—it just would have taken longer. Thus, the marginal social value generated by Warner-Lambert is not equal to the social value of atorvastatin for eternity; rather, it is equal to the social value generated by atorvastatin in the years before someone else would have invented it.

So when would atorvastatin have reached the market in the absence of Warner-Lambert's investment? We don't really know—either for that drug or for others. Five years? Seven? Twelve? The selection of a time limit for value-

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251. *See supra* notes 51-54 and accompanying text.

252. *See* Dave Roos, *How a New Vaccine Was Developed in Record Time in the 1960s*, HISTORY (updated Oct. 29, 2021), https://perma.cc/2GLS-MVWT; Kevin Dunleavy, *GSK Scores FDA Endorsement for Priorix, Providing Vaccine to Defend Kids Against Measles*, FIERCE PHARMA (June 6, 2022, 9:27 AM), https://perma.cc/WZ2B-QLZ3 (noting that "Merck reported sales of $509 million" for the measles-mumps-rubella vaccine in 2021).

253. Reuters, *Warner-Lambert's Cholesterol Therapy Wins Approval*, N.Y. TIMES, Dec. 19, 1996, at D4.

based rewards is somewhat arbitrary, but an arbitrary choice is probably unavoidable. And note that we make similarly arbitrary choices under the status quo with respect to patent terms and market-exclusivity periods[254]—the use of arbitrary time limits is not a disadvantage distinct to value-based rewards. The seven-year exclusivity period under the Orphan Drug Act[255] might serve as a starting point for policy design, though this too is a variable that remains up for discussion.

2. Institutional dimensions

So far, we have focused on the transition to value-based rewards in the context of a universal national health insurance program. Of course, the United States does not have such a system. Absent a move to Medicare for All, how could value-based rewards be implemented in the United States?

As a first step, the United States could shift to value-based rewards for drugs with prices already mandated by federal law—in particular, drugs procured through Medicare Part B and Medicaid. To receive payment through those programs, pharmaceutical firms would have to agree to accept a value-based price per unit for a fixed period (for example, seven years). Clinical data would be used to set the value-based price for each drug, and this price would be subject to change if and when new data emerged. Firms would have to accept price caps and relinquish the right to exclude generic competition from the U.S. market after the seven-year period.[256] (Policymakers would also have to decide whether to allow new drugs *without* patent protection to benefit from this system.) To ensure that value-based prices do not raise costs for Medicare patients, Congress could lower coinsurance rates for Part B drugs (currently set at 20%).[257] Congress could then transfer money from the federal government's general fund to the Medicare Trust Fund to offset costs.

Value-based pricing could be extended to other programs (for example, Medicare Part D) if and when the federal government takes on a greater role in financing and administering those programs.[258] In the meantime, severing Medicare Part B and Medicaid prices from those charged to nonfederal consumers would remove some of the perverse incentives that the existing

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254. *See supra* notes 50-54 and accompanying text.

255. *See* 21 U.S.C. § 360cc(a).

256. For more on balancing the competing goals of low prices, sufficient quantities, and high quality for generic pharmaceuticals, see Hemel & Ouellette, *supra* note 35.

257. *What Does Medicare Cost?*, MEDICARE.GOV, https://perma.cc/T5HM-PS2P (archived Jan. 29, 2023).

258. Rachel Sachs has examined in more detail how government insurance programs can be reformed to adjust innovation incentives, including in work with one of us. *See* sources cited *supra* note 11.

linkage generates.[259] And even if initially limited to the Medicare Part B and Medicaid contexts, the experiment with value-based pricing would serve to demonstrate that the federal government can accelerate the pace of medical innovation in critical areas while also protecting patients from price increases.[260]

To be sure, moving first toward value-based pricing in the contexts of Medicaid and Medicare Part B could generate new distortions. For one, biotechnology and pharmaceutical firms might be motivated to reorient their R&D portfolios toward those populations (assuming that value-based pricing results in larger rewards). This is less of a concern with respect to Medicaid, which covers a broad cross-section of the age distribution,[261] and more of a concern for Medicare Part B, which primarily serves individuals aged sixty-five and up.[262] In addition, value-based pricing might exacerbate the existing skew of incentives toward biologics relative to small-molecule drugs,[263] since biologics constitute a larger portion of Medicare Part B spending than Part D spending.[264] This, too, is less of a concern with respect to Medicaid, which covers the full range of biologic and small-molecule drugs.[265] Ultimately, policymakers will have to weigh the benefits of a larger demonstration project (which would counsel in favor of including Medicare Part B) against the costs of skewed incentives (which might counsel in favor of limiting value-based pricing to Medicaid only at first).

If policymakers choose to implement value-based pricing through Medicaid and/or Medicare Part B—programs administered by CMS within HHS—they still will be left with numerous questions of institutional design. We doubt that there is a single optimal institutional arrangement, and we expect some amount of trial and error as policymakers seek to construct arrangements that work. While a comprehensive examination of these

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259. *See supra* notes 112-16, 135-41 and accompanying text.

260. On the potential benefits of innovation policy experiments, see generally Lisa Larrimore Ouellette, *Patent Experimentalism*, 101 VA. L. REV. 65 (2015).

261. *See Medicaid Enrollment by Age*, KAISER FAM. FOUND., https://perma.cc/EZ99-HNYM (archived Jan. 29, 2023) (documenting that in 2019, 40% of Medicaid enrollees were in the 0-18 age group; 12% were in the 19-26 group; 22% were in the 27-44 group; 17% were in the 45-64 group; and 10% were 65 or older).

262. *See supra* note 107 and accompanying text. This distortion would present concerns of economic and racial equity. *See* Govind Persad, *Reforming Age Cutoffs*, 56 U. RICH. L. REV. 1007, 1008 (noting that Medicare age cutoffs disadvantage "those facing life-shortening forms of disadvantage, including poverty, geographic disadvantage, health disparities, and structural racism").

263. *See supra* note 70 and accompanying text.

264. *See* SUZANNE MURRIN, U.S. DEP'T OF HEALTH & HUM. SERVS., NO. OEI-05-20-00480, MEDICARE PART D AND BENEFICIARIES COULD REALIZE SIGNIFICANT SPENDING REDUCTIONS WITH INCREASED BIOSIMILAR USE 2 (2022), https://perma.cc/79MU-LB9C.

265. *See supra* note 131-132 and accompanying text.

questions would be an article in itself, we suggest four guiding principles for institutional design.

The first is *political insulation*. Prices should not be determined through the hurly burly of legislative bargaining, which likely would result in the same political pathologies that plague the status quo. A second principle, seemingly in tension with the first, is *political accountability*. Value-based pricing decisions will inevitably depend upon ethical as well as economic judgments. Removing these choices *entirely* from the political realm would raise serious concerns from a democratic-legitimacy perspective. One way to balance the conflicting goals of insulation and accountability would be to vest the ultimate pricing decision in a presidentially appointed, Senate-confirmed official who acts with the advice of independent outside experts but retains decisionmaking authority. For example, HHS could convene advisory committees of outside experts—including physicians, biomedical researchers, health economists, and ethicists—as it already does for issues including drug approval within the FDA, recommended vaccine schedules within the CDC, and Medicare coverage decisions within CMS.[266]

A third principle is *public deliberation*. Data on safety and efficacy should be available to the public; decisionmakers should have to justify their decisions to the public; and interested members of the public (for example, patients and family members) should have opportunities to make their views heard before decisionmakers reach a verdict on price. Advisory committees are statutorily required to follow these practices.[267] Such procedural safeguards would help mitigate the risk that pharmaceutical companies will manipulate the data involved in a value determination. They would also vindicate what Jerry Mashaw has described as the "dignitary values" of administrative law.[268] Without fleshing out a full dignitary theory, our modest claim is that when policymakers make decisions with life-or-death consequences, affected individuals generally should have an opportunity to understand the bases for the decisions and to provide input, even though the decision ultimately lies beyond their control.

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266. *See* Stéphane Lavertu & David L. Weimer, *Federal Advisory Committees, Policy Expertise, and the Approval of Drugs and Medical Devices at the FDA*, 21 J. PUB. ADMIN. RSCH. & THEORY 211, 231 (2011); Susan L. Moffitt, *Promoting Agency Reputation Through Public Advice: Advisory Committee Use in the FDA*, 72 J. POL. 880, 880-81 (2010); Rachel Sachs, Jacob S. Sherkow, Lisa Larrimore Ouellette & Nicholson Price, *How Does the CDC's Advisory Committee on Immunization Practices Impact Innovation and Access to COVID-19 Vaccines?*, WRITTEN DESCRIPTION (Aug. 27, 2021, 3:18 PM), https://perma.cc/R3DD-CBRK; *Medicare Evidence Development & Coverage Advisory Committee*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://perma.cc/7R2Q-8YCX (last updated Mar. 2, 2022).

267. *See* 5 U.S.C. app. § 10.

268. *See* Jerry L. Mashaw, *Administrative Due Process: The Quest for a Dignitary Theory*, 61 B.U. L. REV. 885, 898 (1981).

A fourth principle is *reconsideration*. Further information about safety and efficacy may emerge between the time an initial price is set and the end of the period during which an innovator is entitled to a value-based price. After-the-fact review of all drug pricing decisions may be overkill, but at least for the highest-dollar-value drugs (judged on the basis of price multiplied by volume), reconsideration after several years on the market can serve as a salutary check on potentially excessive rewards. Delaying payment—or providing procedures for a supplementary payment or clawback that depend on longer-term evidence—would also augment the currently weak incentives to complete post-marketing studies.[269]

D. Applying Value-Based Pricing

This Subpart considers how our modified version of ICER's value-based approach might apply to two recent examples from the U.S. pharmaceutical market: cystic fibrosis treatments and HPV vaccines. These innovations are not intended to be representative of the entire pharmaceutical market; rather, they illustrate a few of the phenomena discussed in Part I. They also show that value-based prices are not necessarily higher or lower than current prices—the problem is that current prices often are not aligned with social value, with potential deviations in both directions.

1. Trikafta

About 30,000 Americans have been diagnosed with cystic fibrosis, a genetic condition caused by mutations in the gene that codes for the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) protein, which primarily transports chloride ions across cell membranes.[270] Mutations that disrupt normal CFTR protein functions affect a body's mucus production in ways that can damage the lungs and other organs.[271] This reduces lung function, creating a high risk of severe health events requiring hospitalization and hindering patients' daily activities.[272] Patients often spend hours every day using

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269. *See* Holly Fernandez Lynch & Rachel E. Sachs, *Preapproval Promises to Voluntarily Withdraw FDA-Approved Drugs*, 328 JAMA 2392, 2392-93 (2022).

270. *See* Jeffrey A. Tice, Karen M. Kuntz, Kael Wherry, Rick Chapman, Matt Seidner, Steven D. Pearson & David M. Rind, Inst. for Clinical & Econ. Rev., Modulator Treatments for Cystic Fibrosis: Effectiveness and Value, at ES1 (2020), https://perma.cc/3S6Y-VALT (citing data from 2016).

271. *See id.* at 1.

272. *See id.* at ES1.

treatments to help clear their lungs of mucus.[273] The current life expectancy of people with cystic fibrosis who were born between 2015 and 2019 is 46 years.[274]

The gene responsible for cystic fibrosis was discovered in 1989, but private firms were reluctant to target the disease due to its limited market size.[275] In 2000, the Cystic Fibrosis Foundation (CFF) issued a five-year, $47 million grant (in exchange for future royalties) to a San Diego-based firm, Aurora Biosciences, to attempt to develop a treatment for cystic fibrosis.[276] The goal was to find a drug that would correct the malfunctioning CFTR protein—a CFTR modulator—rather than merely treat the symptoms of the disease.[277]

Aurora was purchased in 2001 by Vertex Pharmaceuticals, and after a decade of work, the cystic fibrosis project produced a line of successful daily-use CFTR modulators: Kalydeco was approved by the FDA in 2012, Orkambi in 2015, Symdeko in 2018, and Trikafta in 2019.[278] Trikafta was touted as a "game-changer" because it is more effective than Orkambi and Symdeko, and it can help about 90% of cystic fibrosis patients—in contrast to the 6% who can use Kalydeco (based on their particular mutations).[279] In a key study of Trikafta, patients in the treatment group experienced substantially improved lung function after 24 weeks—the amount of air they could expel from their lungs in one second increased by 14%.[280] When that study came out, then–National Institutes of Health (NIH) director Francis Collins—who three decades earlier had helped discover the genetic cause of cystic fibrosis—told NPR that he was "overjoyed."[281] Collins predicted that nine in ten cystic fibrosis patients would experience a "substantial and amazing benefit": Trikafta "looks as if it will convert what has been otherwise a very threatening and

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273. *See id.*

274. *Understanding Changes in Life Expectancy*, CYSTIC FIBROSIS FOUND., https://perma.cc/8GLC-3SNB (archived Jan. 29, 2023).

275. *See* Adam Feuerstein & Matthew Herper, *'A Game-Changer': How Vertex Delivered on Cystic Fibrosis*, STAT (Oct. 23, 2019), https://perma.cc/H9V2-XCRB.

276. *See id.* The CFF later sold the royalty rights from its $47 million grant for $3.3 billion in 2014. *See Cystic Fibrosis Foundation Receives $3.3 Billion Royalty Pay Out*, PHILANTHROPY NEWS DIG. (Nov. 24, 2014), https://perma.cc/8LY8-QE87.

277. *See* Feuerstein & Herper, *supra* note 275.

278. *See id.*; TICE ET AL., *supra* note 270, at 4 tbl.1.2.

279. *Id.* (quoting University of Alabama at Birmingham Cystic Fibrosis Research Center director Dr. Steven Rowe).

280. Peter G. Middleton et al., *Elexacaftor-Tezacaftor-Ivacaftor for Cystic Fibrosis with a Single Phe508del Allele*, 381 NEW ENG. J. MED. 1809, 1812 (2019).

281. *New Hope for Patients Living with Cystic Fibrosis After Scientists Unveil Therapy*, NPR (Nov. 1, 2019, 4:09 PM ET), https://perma.cc/Z53Z-AX5Z.

potentially fatal disease into a chronic illness that's going to require treatment but which should allow people to live much more normal lives."[282]

In 2020, ICER conducted a cost-effectiveness assessment of Trikafta and updated its earlier assessment of Vertex's three other CFTR modulators.[283] ICER's review panel found twenty-seven clinical studies testing these drugs in different populations that met the criteria for review, and it concluded that these studies were generally of high quality and demonstrated clinical benefits.[284] But ICER also noted that there was no direct evidence of the long-term impact of Trikafta (the longest study lasted twenty-four weeks), and that the outcome studied (amount of expelled air) is only a surrogate measure of cystic fibrosis's full health impact.[285] Nonetheless, based on current evidence of comparative effectiveness and the EQ-5D approach described in the Appendix, ICER modeled the increase in utility that different CFTR modulators could provide for different populations in order to calculate QALYs.[286]

To evaluate cost-effectiveness, ICER considered not just the wholesale acquisition costs of each drug—which ranged from $272,623 per year for Orkambi to an estimated $311,741 per year for Trikafta—but also the cost savings that CFTR modulators were predicted to provide, such as making patients less likely to need lung transplants and more likely to be employed.[287] Based on these inputs, ICER calculated the cost per QALY gained for each treatment compared with the best supportive care in populations with different genetic mutations causing cystic fibrosis.[288] Estimates ranged from $1,050,000 to $1,480,000 per QALY gained, or $877,000 to $1,360,000 per evLYG gained.[289] Because these values far exceeded ICER's benchmark of $100,000 to

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282. *Id.*

283. *See* TICE ET AL., *supra* note 270, at ES1.

284. *See id.* at 28-49. ICER uses a helpful system of evidence rating, which assesses the quality of evidence in terms of level of certainty and comparative clinical effectiveness. *See* INST. FOR CLINICAL & ECON. REV., *supra* note 178, at 18. ICER used this rating system in its assessment of CFTR modulators to evaluate different combinations of patient population (based on specific genetic mutations) and intervention. For example, based on the study by Middleton et al., *supra* note 280, the evidence for Trikafta versus best supportive care in patients with the particular mutations studied received an "A," indicating a "high certainty" of a substantial net health benefit. *See* TICE ET AL, *supra* note 270, at 53. The evidence for Trikafta versus Symdeko in a different population received a "C++" for a moderate certainty of "a comparable, small, or substantial net health benefit," "with high certainty of at least a comparable net health benefit." *Id.* All other comparisons received an "A," "B+," or "B." *Id.*

285. TICE ET AL., *supra* note 270, at 50-51.

286. *See id.* at 56-77.

287. *Id.* at 67-70, 68 tbl.5.5.

288. *Id.* at 73-77.

289. *Id.* at ES12 tbl.ES6.

$150,000 per QALY, ICER recommended that Vertex lower the price of Trikafta and its other CFTR modulators to better align with their demonstrated benefits.[290]

Trikafta presents a hard case for drug pricing policy. Even using CMS's higher range of $590,000 to $970,000 per QALY,[291] Trikafta does not appear to be cost-effective according to ICER's analysis. Yet patient advocates and ICER critics raise legitimate objections to the organization's approach.[292] In particular, ICER's analysis assumed that Trikafta's price would remain in the $300,000 range even after Vertex's patent terms and market-exclusivity protections expire.[293] That assumption results in a higher estimate of lifetime cost—and a higher cost per QALY—than if ICER had factored in the probability of a price decline after generic manufacturers can enter the market. ICER acknowledged this possibility but added that estimating future price changes "may be especially difficult in the US market, where drug prices are mostly unregulated, and changes in prices occur relatively frequently."[294]

Our proposal would not resolve all of the hard medical, economic, and ethical issues involved in determining the cost-effectiveness of a drug like Trikafta, but it would—at the very least—rationalize the price-setting process. Under our approach, Vertex would be guaranteed a value-based price for a fixed period (for example, seven years), and the company would have to commit to relinquish its right to exclude competitors at the end of the fixed period. Vertex would be rewarded handsomely in the near term—though potentially at a level below the current price of roughly $300,000 per patient per year.[295] The reward would be tied to Trikafta's value to patients rather than Vertex's market power.

Contrast the outcome under our proposal to the status quo, in which Trikafta's high price is largely the function of statutory constraints. ACA-regulated private insurance plans are required to cover at least the number of

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290. *Id.* at 97, 110-11.

291. *See supra* note 197 and accompanying text.

292. *See, e.g.,* Jessica Sagers, *If Trikafta Isn't Good Enough for ICER, What Drug Is?*, TIMMERMAN REP. (May 13, 2020), https://perma.cc/N8ZH-GCTU.

293. TICE ET AL., *supra* note 270, at 68.

294. *Id.*

295. A Vertex-funded study found that even at Trikafta's current price, and before factoring in the possibility of generic entry after Vertex's market exclusivity ends, Trikafta's incremental cost-effectiveness ratio is $482,000 per QALY, which would imply that the current price is cost-justified at CMS's range of $590,000 to $970,000 per QALY. *See* Jaime L. Rubin, Andrea Lopez, Jason Booth, Penilla Gunther & Anupam B. Jena, *Limitations of Standard Cost-Effectiveness Methods for Health Technology Assessment of Treatments for Rare, Chronic Diseases: A Case Study of Treatment for Cystic Fibrosis*, 25 J. MED. ECON. 783, 786, 786 tbl.2 (2022). A head-to-head comparison of the conflicting cost-effectiveness estimates for Trikafta lies beyond this Article's scope.

drugs in each therapeutic class as in their state's EHB-benchmark plan.[296] Vertex's drugs fall into the "Cystic Fibrosis Agents" class, along with only one other drug—Pulmozyme, a Genentech drug approved in 1993 to help clear lung secretions.[297] Many state EHB-benchmark plans appear to cover 3 drugs in this class, which would require coverage of at least 2 of Vertex's drugs. Meanwhile, around 10% of cystic fibrosis patients are Medicare beneficiaries (generally qualifying based on the long-term disability criteria),[298] and Medicare Part D plans are required to cover at least two drugs per therapeutic class.[299]

In theory, the ability to deny coverage for Trikafta in favor of Vertex's other CFTR modulators might give private insurance plans the ability to extract price concessions. But Vertex has a strong incentive to not lower the price for these payers: Over 40% of U.S. cystic fibrosis patients are Medicaid beneficiaries,[300] and if Vertex lowers its price for other purchasers, the Medicaid "best price" rule requires it to sell to Medicaid for this same price.[301] By rewarding Vertex based on how much it charges other purchasers rather than on the value its drug provides, federal law not only allows but encourages Vertex to inflate Trikafta's price.

2. HPV vaccines

HPV is the most prevalent sexually transmitted infection in the United States—with most people who end up experiencing an infection having their first "within a few years of becoming sexually active"—and is a cause of cervical cancer in women and of other cancers and genital warts in women and men.[302] Only one HPV vaccine is currently available in the United States: Merck's Gardasil-9, which protects against nine types of HPV and was licensed in 2014.[303] Gardasil-9 replaced the first HPV vaccine, Gardasil-4, which protects against

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296. *See supra* notes 142-43 and accompanying text.

297. *See* Essential Health Benefits Rx Crosswalk Spreadsheet, *supra* note 120; Lawrence M. Fisher, *Genentech's Drug to Treat Cystic Fibrosis Is Approved*, N.Y. TIMES (Dec. 31, 1993), https://perma.cc/E6LA-94JL (to locate, select "View the live page").

298. *See* CYSTIC FIBROSIS FOUND., PATIENT REGISTRY 2020: ANNUAL DATA REPORT 16 (2021), https://perma.cc/2NMG-ZNUG.

299. *See supra* note 119 and accompanying text.

300. CYSTIC FIBROSIS FOUND., *supra* note 298, at 16.

301. *See supra* note 136 and accompanying text.

302. Lauri E. Markowitz, Eileen F. Dunne, Mona Saraiya, Harrell W. Chesson, C. Robinette Curtis, Julianne Gee, Joseph A. Bocchini, Jr. & Elizabeth R. Unger, *Human Papillomavirus Vaccination: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, MORBIDITY & MORTALITY WKLY. REP.: RECOMMENDATIONS & REPS., Aug. 29, 2014, at 1, 1, 4.

303. Elizabeth Boskey, *What to Know About Human Papillomavirus (HPV) Vaccines*, VERYWELL HEALTH (updated Sept. 20, 2021), https://perma.cc/3L8W-WQTM.

four types of HPV and was licensed in 2006.[304] GlaxoSmithKline (GSK) attempted to enter the U.S. HPV vaccine market with Cervarix, which protects against two types of HPV and was licensed in 2009, but the company withdrew the vaccine from the U.S. market in 2016 due to "very low market demand."[305]

In 2006, the CDC's Advisory Committee on Immunization Practices (ACIP) recommended the use of Gardasil-4 by females aged eleven or twelve (and up to age twenty-six if not previously vaccinated).[306] In support of its recommendation, ACIP cited estimates that at a cost of $300 to $400 per vaccine series, the reduction in cervical cancer in the vaccinated cohort came at a cost per QALY ranging from $3,000 in 2005 dollars to $24,300 in 2002 dollars (about $4,300 to $38,000 today).[307] As additional uses of HPV vaccines were licensed by the FDA, ACIP updated its guidance: In 2009, ACIP determined that Gardasil-4 may be used in boys (who are at risk of genital warts and some cancers, even if not cervical cancer),[308] and in 2015 ACIP recommended Gardasil-9 for both girls and boys.[309]

Merck's decision to roll out Gardasil first in the group that would benefit most—teenage girls—led to political controversy and lower uptake due to concerns about encouraging sexual activity.[310] The company also prices Gardasil-9 higher than any other routine vaccination, with a U.S. list price of $228 per dose (or $684 for a three-dose course), compared with an average price per dose for other routine vaccines of $75.[311] Still, Merck's vaccination campaign has been highly cost-effective: Models of the U.S. HPV vaccination program have concluded that its cost-effectiveness has ranged from cost-

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304. *See id.*

305. *See id.*; Eric Sagonowsky, *GSK Exits U.S. Market with Its HPV Vaccine Cervarix*, FIERCE PHARMA (Oct. 21, 2016, 11:52 AM) (quoting a GlaxoSmithKline spokesperson), https://perma.cc/2BWW-X7R4.

306. Lauri E. Markowitz, Eileen F. Dunne, Mona Saraiya, Herschel W. Lawson, Harrell Chesson & Elizabeth R. Unger, *Quadrivalent Human Papillomavirus Vaccine: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, MORBIDITY & MORTALITY WKLY. REP.: RECOMMENDATIONS & REPS., Mar. 23, 2007, at 1, 16.

307. *See id.* at 15.

308. *FDA Licensure of Quadrivalent Human Papillomavirus Vaccine (HPV4, Gardasil) for Use in Males and Guidance from the Advisory Committee on Immunization Practices (ACIP)*, 59 MORBIDITY & MORTALITY WKLY. REP. 630, 630 (2010).

309. Emiko Petrosky, Joseph A. Bocchini Jr., Susan Hariri, Harrell Chesson, C. Robinette Curtis, Mona Saraiya, Elizabeth R. Unger & Lauri E. Markowitz, *Use of 9-Valent Human Papillomavirus (HPV) Vaccine: Updated HPV Vaccination Recommendations of the Advisory Committee on Immunization Practices*, 64 MORBIDITY & MORTALITY WKLY. REP. 300, 300 (2015).

310. *See* Dan M. Kahan, Perspective, *A Risky Science Communication Environment for Vaccines*, 342 SCIENCE 53, 53-54 (2013).

311. *See* Schwartz et al., *supra* note 112, tbl.3.

saving (meaning it both saved money and increased QALYs) to $35,000 per QALY gained.[312]

Vaccinating teenagers against HPV is cost-effective even according to ICER's low benchmark range of $100,000 to $150,000 per QALY. But the costs of undervaluing health gains are apparent in ACIP's evaluation of HPV vaccines for adults. HPV vaccines are recommended at an early age because they are most effective before exposure to HPV through sexual activity.[313] ACIP also recommends "catch-up" vaccination for young adults through age twenty-six who were not previously vaccinated, but it does not recommend vaccination of older adults because estimates of the cost of vaccinating adults through age thirty or forty-five were over $300,000 per QALY gained in most models.[314] But as explained above, $300,000 per QALY is well below the values used by the federal government in other regulatory contexts.[315] Compared with the $590,000 to $970,000 per QALY benchmark range used by HHS for evaluating regulatory interventions,[316] gaining a QALY at $300,000 is a bargain.

Gardasil is not an anomaly. Vaccines are among the most cost-effective health interventions.[317] So why is the price of Gardasil not even higher? If Vertex can charge over $300,000 per year for a treatment that requires lifetime use, why can Merck receive only $684—or less, since most payers don't pay list price—to save a girl from a lifetime risk of cervical cancer?

One difference between Trikafta and Gardasil relates to the market failures described in Part I.A.1: The private sector underinvests in vaccines because vaccines generate positive externalities and are preventives with long-term effects.[318] All else equal, Merck could receive a higher profit for a repeat-

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312. *See* Elissa Meites, Peter G. Szilagyi, Harrell W. Chesson, Elizabeth R. Unger, José R. Romero & Lauri E. Markowitz, *Human Papillomavirus Vaccination for Adults: Updated Recommendations of the Advisory Committee on Immunization Practices*, 68 MORBIDITY & MORTALITY WKLY. REP. 698, 699 (2019) (reviewing studies).

313. Markowitz et al., *supra* note 302, at 19-20.

314. Meites et al., *supra* note 312, at 699. The cost per QALY of extending vaccination through age forty-five was estimated to be $352,000 to $462,000 using "standardized health economic parameters" and models developed by the National Cancer Institute-sponsored Cancer Intervention and Surveillance Modeling Network (CISNET). *See* HARRELL CHESSON, NAT'L CTR. FOR HIV, VIRAL HEPATITS, STD, AND TB PREVENTION, OVERVIEW OF HEALTH ECONOMIC MODELS FOR HPV VACCINATION OF MID-ADULTS 26 (2019), https://perma.cc/AG2Q-4RA5 (to locate, select "View the live page").

315. *See supra* Part II.B.2.a.

316. *See supra* note 197 and accompanying text.

317. *See generally* Mark A. Miller & Alan R. Hinman, *Economic Analyses of Vaccine Policies*, in VACCINES 1413 (Stanley A. Plotkin, Walter A. Orenstein & Paul A. Offit eds., 6th ed. 2013).

318. *See supra* Part I.A.1.

use treatment for cervical cancer than for a vaccine to prevent the cancer from developing in the first place.

Another difference relates to the way the government sets rewards for vaccines like Gardasil compared with treatments like Trikafta. Vaccines receive lower rewards for at least two reasons. First, unlike for most pharmaceuticals,[319] the government can negotiate vaccine prices. HHS is authorized to negotiate discounted prices for vaccines purchased for the Vaccines for Children (VFC) program, for which over half of young children and a third of adolescents are eligible.[320] The CDC also may negotiate prices for vaccines covered under section 317 of the Public Health Services Act, which provides some vaccines for uninsured adults.[321] Second, for vaccines paid for by private insurance, the ACA requires insurers to cover ACIP-recommended vaccines with no cost-sharing for patients,[322] but ACIP's recommendations reflect relatively low value-per-QALY thresholds. (While ACIP does not state its benchmark range explicitly, recall that ACIP considers a cost above $300,000 per QALY to be not cost-effective.)[323] A Kaiser Family Foundation analysis notes that "the inclusion of economic analysis in the development of ACIP recommendations may help to tamp down on prices for vaccines as compared to other medicines where there is no equivalent federal use of such analysis."[324]

Although it may be tempting to view vaccines' cost-effectiveness as a bargain for society, pricing vaccines so far below their social value likely means that there are socially valuable vaccines being left on the table because manufacturers have little financial incentive to develop them. Low profit margins for vaccines may also affect development speed, increase vaccine shortages,[325] and provide inadequate incentives to invest in new manufacturing techniques.[326] In sum, by paying significantly less than social value for vaccines, we appear to be getting less value in return.

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319. *See infra* notes 328-31 and accompanying text.

320. *See* Schwartz et al., *supra* note 112 (citing 42 U.S.C. § 1396s(d)(3)). The statute also imposes a price cap on vaccines that were available in 1993. *See* 42 U.S.C. § 1396s(d)(3)(B).

321. *See* Schwartz et al., *supra* note 112.

322. *See* 42 U.S.C. § 300gg-13.

323. *See supra* note 314 and accompanying text.

324. *See* Schwartz et al., *supra* note 112.

325. *See* David B. Ridley, Xiaoshu Bei & Eli B. Liebman, *No Shot: US Vaccine Prices and Shortages*, 35 HEALTH AFFS. 235, 240 (2016).

326. *See* Jeffrey B. Ulmer, Ulrich Valley & Rino Rappuoli, *Vaccine Manufacturing: Challenges and Solutions*, 24 NATURE BIOTECHNOLOGY 1377, 1380 (2006).

III. Alternative Drug Pricing Reforms

Policymakers and scholars of law and public health have set forth several alternatives to the drug pricing status quo.[327] Here, we begin by considering two prominent classes of reform proposals: allowing the government to "negotiate" drug prices with pharmaceutical companies (Part III.A) and allowing innovators to recover their costs plus a "reasonable profit" (Part III.B). We argue that these alternatives fall well short of the goal of aligning rewards with social value. In Part III.C, we describe the merits of greater reliance on value-based direct government funding for medical innovation, but we argue that this ex ante funding should be a complement to, not a substitute for, value-based ex post rewards.

A. "Negotiated" Drug Prices

Historically, Congress has barred HHS from negotiating drug prices under Medicare directly with pharmaceutical firms. Medicare Part B pricing is typically based on the ASP formula described above,[328] and the Medicare Modernization Act of 2003 explicitly prohibits HHS from "interfer[ing]" in negotiations between drug manufacturers and Part D plan sponsors.[329] But in August 2022, President Biden signed legislation (informally known as the Inflation Reduction Act of 2022)[330] that—for the first time—provides HHS with a role to play in setting prices for a limited number of drugs under Medicare Parts B and D.[331] The Congressional Budget Office (CBO) estimates that the drug pricing provisions in the August 2022 law will save the federal government approximately $102 billion over the next decade[332]—savings that helped enable Congress to dramatically scale up federal subsidies for clean energy without widening the deficit.[333]

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327. For excellent overviews of legal strategies to address high drug prices, see generally NAT'L ACADS. OF SCIS., ENG'G, & MED., *supra* note 38; and Michelle M. Mello & Rebecca E. Wolitz, *Legal Strategies for Reining in "Unconscionable" Prices for Prescription Drugs*, 114 NW. U. L. REV. 859 (2020).

328. *See supra* note 112 and accompanying text.

329. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 101(a)(2), 117 Stat. 2066, 2098 (codified as amended at 42 U.S.C. § 1395w-111).

330. Pub. L. No 117-169, 136 Stat. 1818 (codified in scattered sections of the U.S. Code).

331. *Id.* § 11001(a), 136 Stat. at 1833-36 (codified at 42 U.S.C. § 1320f).

332. CONG. BUDGET OFF., ESTIMATED BUDGETARY EFFECTS OF H.R. 5376, THE INFLATION REDUCTION ACT OF 2022, at 5 tbl.1 (2022), https://perma.cc/5EXE-TNHR (to locate, select "View the live page," then select "View Document").

333. *See* Press Release, White House, By the Numbers: The Inflation Reduction Act (Aug. 15, 2022), https://perma.cc/QLA9-DNF7.

While the August 2022 legislation provides for meaningful progress in the fight against global warming,[334] it does little to solve the pathologies of U.S. drug pricing. The drug pricing provisions in the Inflation Reduction Act require HHS to select 10 single-source "negotiation-eligible" drugs for in 2026, rising to 15 in 2027 and twenty in 2029.[335] The selected drugs will be the ones for which total Medicare expenditures are highest.[336] For those drugs, the law sets a maximum "fair price" of 40% to 75% (depending on how long the drug has been on the market) of the average manufacturer price in either (a) 2021 (or the drug's first year on the market if later than 2021) or (b) the year before the drug was selected for negotiation, whichever is lower.[337] The manufacturer will have to accept HHS's price or pay an excise tax of 1900% on sales of the drug.[338] (A manufacturer can avoid the tax by pulling all of its drugs from the Medicare and Medicaid programs.)[339] Several categories of drugs will be exempt from negotiation, including small-molecule drugs marketed for fewer than 9 years, biologics marketed for fewer than 13 years, and certain orphan drugs.[340]

The drug pricing provisions in the August 2022 legislation will somewhat offset the preexisting incentive to focus on late-stage treatments rather than early-stage treatments and preventives. By capping prices for certain small-molecule drugs after their ninth year on the market and for biologics after their thirteenth year on the market, the new law lessens the advantage of bringing a drug to market early in its patent life. However, the statute addresses this disparity through a leveling-down rather than a leveling-up approach: Instead of boosting incentives for early-stage treatments and preventives, it dilutes incentives for late-stage treatments. These price cuts will do little to mitigate the

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334. *See* Ben King, John Larsen & Hannah Kolus, *A Congressional Climate Breakthrough*, RHODIUM GRP. (July 28, 2022), https://perma.cc/5YJV-CLG2 (estimating that net U.S. greenhouse gas emissions in 2030 will be 40% below 2005 levels under the legislation, compared to a central estimate of 30% below 2005 levels without the legislation).

335. Inflation Reduction Act § 11001(a), 136 Stat. at 1836-41 (codified at 42 U.S.C. § 1320f-1).

336. *Id.*

337. *Id.* § 11001(a), 136 Stat. at 1843 (codified at 42 U.S.C. § 1320f-3). For drugs selected for negotiation in 2026, the statute links the negotiation price to the average manufacturer price in 2021 (or the drug's first year on the market if later than 2021) only. *Id.*

338. *Id.* § 11003(a), 136 Stat. at 1862-64 (codified at 26 U.S.C. § 5000D). The legislation refers to a "95 percent" excise tax, but this rate is calculated on a tax-inclusive basis. For example, a drug sold for $100 would face a tax of $1900, such that the tax ($1,900) is 95% of the sum of the tax plus the price ($2,000). *See id.*

339. *Id.*

340. *Id.* § 11001(a), 136 Stat. at 1836-41 (codified at 42 U.S.C. § 1320f-1); Rachel Sachs, *Understanding the Democrats' Drug Pricing Package*, HEALTH AFFS. (Aug. 10, 2022), https://perma.cc/C6TB-WHUU. Separate provisions require manufacturers to pay rebates to Medicare if their drug prices rise faster than inflation after mid-2023. Inflation Reduction Act § 11101(a), 136 Stat. at 1865-69 (codified at 42 U.S.C. § 1395w-3a).

human costs of underpowered incentives for early-stage treatments and preventives such as vaccines. And in other respects, the new law could magnify existing innovation distortions—for example, by favoring biologics (exempt from price caps for thirteen years) over small-molecule drugs (exempt for nine), and favoring orphan drugs over all others.[341]

Moreover, the selection of drugs for negotiation will be based on total Medicare expenditures, not on any assessment of whether Medicare is overpaying relative to social value.[342] Highly cost-effective drugs could face price cuts if they end up near the top of the total-expenditure rankings due to widespread use. Efficacy enters the equation only as one factor (technically, a subfactor within a factor) in HHS's decision whether to demand a price below the statutory cap.[343]

Probably the strongest argument in favor of the Medicare drug pricing provisions in the August 2022 law is that whatever ill effects these provisions might have on medical innovation, those ill effects are amply justified by the climate benefits of the legislation as a whole, and the Medicare savings were necessary to offset the cost of the law's climate investments.[344] We have no quarrel with that argument. But the August 2022 law does little to address the problems highlighted in Part I.A.1—specifically, the weak incentives for private-sector investment in important areas of drug development.[345] Tackling that problem will require more than a series of ad hoc price cuts for a handful of drugs each year.

B. Cost-Based Pricing

Scholars of law and public health have set forth numerous proposals to reform the reward systems for new medical technologies beyond negotiating drug prices. Here, we describe the main alternative to value-based pricing: cost-

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341. Inflation Reduction Act § 11001(a), 136 Stat. at 1836-41 (codified at 42 U.S.C. § 1320f-1).

342. *See id.* (adding sec. 1192(b) to Social Security Act, tit. XI).

343. *Id.* § 11001(a), 136 Stat. at 1843-49 (codified at 42 U.S.C. § 1320f-3).

344. *See* Daniel Hemel, *A Complete Breakdown of the Good, the Bad, and the Ugly in the Inflation Reduction Act*, SLATE (Aug. 10, 2022, 5:45 AM), https://perma.cc/36B8-TM3C.

345. Some features of the August 2022 law may have positive effects on medical innovation incentives. The law requires Medicare Part D plans to cover ACIP-recommended adult vaccines for free, *see* Inflation Reduction Act § 11401(a), 136 Stat. at 1896-97 (codified at 42 U.S.C. § 1395w-102), and it also requires state Medicaid plans to provide free access to adult vaccines, *see id.* § 11405, 136 Stat. at 1900-01 (codified in scattered sections of 42 U.S.C.). These changes—by expanding the market for adult vaccines—could potentially encourage vaccine-related R&D.

based pricing.[346] Cost-based pricing seeks to compensate innovators based on the expenditures they incurred and the risk they took—often allowing for a "reasonable profit" (but no more).[347] In the context of the Covid-19 vaccine, advocates for at-cost pricing included two Nobel Peace Prize winners and two Nobel Prize-winning economists.[348]

Cost-based pricing is most easily illustrated by way of example. Consider a firm—we will call it Futura—that is developing a vaccine. In 2022, Futura makes some investment (say, $100 million), which gives it some probability of developing a successful vaccine (say, 10%). How much should Futura be rewarded in 2023 if its vaccine succeeds?[349] The reward cannot simply tally Futura's out-of-pocket expenditures because the investment has a 9-in-10 chance of yielding nothing. No firm would want to innovate if its investments in innovation faced a heads-we-tie, tails-you-lose payoff structure, especially where tails is much more likely than heads. Rather, sophisticated analysts of the subject argue that firms should be compensated not just for their R&D investments, but also for the risk associated with those expenditures.[350]

The general reward formula for this risk-adjusted approach would be $(E/p) \times (1 + r)^t$, where E is the firm's expenditure, p is its ex ante probability of success, r is the positive annual rate of return that represents a "reasonable profit," and t is the time (in years) between expenditure and reward. If we select $r = 10\%$ for arithmetic ease, Futura's reward—if it succeeds in 2023—would be ($100 million / 10%) × 110% = $1.1 billion. Futura would then be investing $100

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346. *See* EMOND & PEARSON, *supra* note 196, at 6-7 (defining cost-based pricing and outlining its advantages and disadvantages).

347. *See, e.g.,* Frederick M. Abbott, *Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health*, 6 U.C. IRVINE L. REV. 281, 302-03 (2016); Frederick M. Abbott & Jerome H. Reichman, *Facilitating Access to Cross-Border Supplies of Patented Pharmaceuticals: The Case of the COVID-19 Pandemic*, 23 J. INT'L ECON. L. 535, 545 nn.48-51 (2020); Hannah Brennan, Amy Kapczynski, Christine H. Monahan & Zain Rizvi, *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275, 283 (2016); Amy Kapczynski & Aaron S. Kesselheim, *'Government Patent Use': A Legal Approach to Reducing Drug Spending*, 35 HEALTH AFFS. 791, 793 (2016); Suerie Moon, Stephanie Mariat, Isao Kamae & Hanne Bak Pedersen, *Defining the Concept of Fair Pricing for Medicines*, 368 BMJ I4726, at 1-2 (2020), https://perma.cc/VKW3-76JG; Rebecca E. Wolitz, *States, Preemption, and Patented Drug Prices*, 52 SETON HALL L. REV. 385, 402-03 (2021).

348. *Uniting Behind a People's Vaccine Against COVID-19*, UNAIDS (May 14, 2020), https://perma.cc/RBC9-4KW3.

349. We use a one-year timeline for ease of explication, but typical drug and vaccine development timelines are significantly longer. *See* Joseph A. DiMasi, Maria I. Florez, Stella Stergiopoulos, Yaritza Peña, Zachary Smith, Michael Wilkinson & Kenneth A. Getz, *Development Times and Approval Success Rates for Drugs to Treat Infectious Diseases*, 107 CLINICAL PHARMACOLOGY & THERAPEUTICS 324, 327 tbls.1 & 2 (2020).

350. *See, e.g.,* Brennan et al., *supra* note 347, at 316; Kapczynski & Kesselheim, *supra* note 347, at 793; Moon et al., *supra* note 347, at 1-2.

million for an *expected* return of $110 million (in other words, the probability of success of 10% multiplied by the $1.1 billion expected return).[351]

On first glance, this risk-adjusted cost-recovery approach may seem sensible. But note that Futura would receive the same expected return no matter what project it invests in. A vaccine for Covid-19 and a vaccine against the Western equine encephalomyelitis virus receive the same reward if they entail the same expenditure and the same ex ante probability of success—notwithstanding the fact that the Covid-19 vaccines likely saved over a million lives in the United States in their first year,[352] while the total death toll from Western equine encephalomyelitis has been in the dozens over the last six decades.[353] A cost-plus-reasonable-profit approach does little to encourage firms to pick the projects that are most beneficial for society.

Cost-plus-reasonable-profit fails to align private incentives with social objectives. Rather, it provides the same incentive, in risk-adjusted terms, for *any* R&D investment, and is thus aimed simply at ensuring that every investment that could be made is made. It is unclear what normative foundation would justify this approach. Whether an investment is made or not would have nothing to do with the factors we think society should ultimately care about: improving health and extending lives. If we want firms to focus on projects with the highest probability of saving the most lives or generating the greatest health improvements, we should reward firms on that basis, and not based on how much money they spent.[354]

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351. Of course, calculating this reward is easier said than done. Errors will be a problem with any reward system, but cost-based rewards have highly asymmetric error costs. If we set rewards a little too high, such that Futura earns a return that pays it slightly more than $(E/p) \times (1 + r)^t$, the consequence is that Futura has a little bit more money and the reward financers (that is, other taxpayers) have a little less. In economic terms, this is a transfer, not a social loss that reduces the total resources available to society. If we set rewards a little too low (such as by overestimating the probability of success), the consequence is that Futura will fail to invest in socially valuable projects that are expected to save lives.

352. *See* Eric C. Schneider, Arnav Shah, Pratha Sah, Seyed M. Moghadas, Thomas Vilches & Alison Galvani, *The U.S. COVID-19 Vaccination Program at One Year: How Many Deaths and Hospitalizations Were Averted?*, COMMONWEALTH FUND (Dec. 14, 2021), https://perma.cc/W947-VNK6.

353. *See* LESLIE V. SIMON, RYAN COFFEY & MICHELLE A. FISCHER, WESTERN EQUINE ENCEPHALITIS (2022), https://perma.cc/P5Y3-7D5S.

354. To be sure, one could partially mitigate this problem by adjusting the cost-based reward based on measures of social value, such as by increasing *r* for high-value projects—but this is just to say that the more cost-based rewards look like value-based rewards, the smaller the problem gets.

C. Why Use Ex Post Rewards?

The problems with status quo rewards, "negotiated" rewards that are not tied to social value, and cost-based rewards do not imply that value-based rewards are without flaws. Although we have argued that any steps to better align the rewards for medical innovation with social value would be steps in the right direction, we acknowledge that calculating valued-based rewards with accuracy will be challenging.[355] Given the array of problems with ex post rewards for medical innovations, one might reasonably wonder why policymakers should bother with ex post rewards at all. Why not just fund biomedical R&D directly, either within the public sector or with grants covering costs at other institutions? Indeed, in prior work we have argued for a much larger government role in drug development and production,[356] and we think these ex ante public-sector investments should also be aligned with social value. But we argue that there are at least three reasons that policymakers should avoid putting *all* their innovation eggs in the public-sector basket.

First, and most obviously, public-sector innovation institutions have problems too. Directly funding R&D projects ex ante based on their expected social value does not eliminate the need to assess value—ideally using something like expected QALYs or evLYGs rather than allocating research dollars to the most effective lobbyists. Direct funding also creates the additional informational burden of assessing which research teams are most likely to generate value. And an advantage of a system of ex post subsidies is that innovators with heterodox ideas—and without strong connections to politicians or elite institutions like the NIH—still can claim government-funded rewards for developing new drugs. One need not be a committed Hayekian to harbor doubts about government actors being the only ones who decide which ideas are worth pursuing.

Second, at present, most infrastructure and human capital related to biomedical R&D is in the private sector, not the government or nonprofit sectors.[357] In 2017, the U.S. pharmaceutical industry funded over $55 billion in

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355. *See supra* Part II.

356. Hemel & Ouellette, *supra* note 12, at 570-71; Hemel & Ouellette, *supra* note 35, at 22-24.

357. Even in the Covid-19 vaccine context, Operation Warp Speed's substantial public-sector funding complemented enormous private-sector investments. From 2016 to 2019, Moderna's private R&D expenses on its novel mRNA platform exceeded $1.6 billion, although the company had yet to bring a successful product to market. *See* Moderna, Inc., Annual Report (Form 10-K), item 6, at 212 (Feb. 27, 2020), https://perma.cc/LF4S-J2CZ. Although Moderna received substantial federal funding after the pandemic struck, it continued to invest private funds as well: In 2020, Moderna's private R&D expenses of nearly $1.4 billion far exceeded all sources of revenue such that the company had a net loss of $0.75 billion—a loss that would have been difficult to recover in the event that their clinical trials failed. *See* Moderna, Inc.,
footnote continued on next page

R&D,[358] more than the $34 billion spent by the NIH on all its operations (only some of which are pharmaceutical-related).[359] And the institutional capacity for late-stage drug development and distribution is almost entirely located in the private sector.[360] Society should want private firms to invest their efforts up to the point that the marginal social benefit from their investments equals the marginal social cost. Although it seems worthwhile to build drug-development capabilities in the public sector, today's medical innovation policy should reflect the reality that at present, the government lacks this ability (and would need years to acquire it).

Finally, ex post rewards are arguably less politically vulnerable than ex ante subsidies. The political hurdles to providing sufficient ex ante funding for medical R&D are both psychological and temporal. When voters underestimate risks, they are unlikely to reward politicians who take action to reduce those risks.[361] Perhaps unsurprisingly, the Flu Vaccine Act—a proposal to spend $1 billion over five years in pursuit of a universal influenza vaccine—has failed in the last three Congresses,[362] even though a universal influenza vaccine could avert around nearly 20,000 deaths from seasonal influenza per year in the United States.[363] Moreover, drug and vaccine development typically takes years—and almost always longer than an electoral cycle.[364] An elected official focused on her own reelection is almost certain to generate greater near-term political dividends through other means. An advantage of using ex post rewards is that the government pays only for success, not for scientific long shots that are more likely than not to result in failure.

Annual Report (Form 10-K), item 1A, at 108, item 7, at 174 (Feb. 26, 2021), https://perma.cc/LC2R-3T8H (to locate, select "View the live page").

358. *See* MARK BOROUSH, NAT'L SCI. FOUND., NSB-2020-3, RESEARCH AND DEVELOPMENT: U.S. TRENDS AND INTERNATIONAL COMPARISONS 33-34 tbl.4-9 (2020).

359. *See* NAT'L INSTS. OF HEALTH, MECHANISM DETAIL: ACTUAL OBLIGATIONS, FY 2000-FY 2009, at 2 (n.d.), https://perma.cc/45UK-GJCR.

360. *See* Hemel & Ouellette, *supra* note 12, at 571.

361. For evidence consistent with this claim from a nonmedical context, see generally Andrew Healy & Neil Malhotra, *Myopic Voters and Natural Disaster Policy*, 103 AM. POL. SCI. REV. 387 (2009).

362. *See* H.R. 6025, 117th Cong. (2021); S. 3258, 117th Cong. (2021); H.R. 1371, 116th Cong. (2019); S. 570, 116th Cong. (2019); H.R. 5092, 115th Cong. (2018); S. 2438, 115th Cong. (2018).

363. *See* Pratha Sah, Jorge A. Alfaro-Murillo, Meagan C. Fitzpatrick, Kathleen M. Neuzil, Lauren A. Meyers, Burton H. Singer & Alison P. Galvani, *Future Epidemiological and Economic Impacts of Universal Influenza Vaccines*, 116 PNAS 20,786, 20,789 (2019).

364. *See* DiMasi et al., *supra* note 349, at 327 tbls.1 & 2.

IV. Objections to Value-Based Rewards

The case for rewarding medical innovation based on social value has several counterarguments, primarily focused on instances where value-based rewards are higher than under the status quo. (As we have emphasized throughout, value-based rewards will lower costs for some drugs, for reasons including that they will be time limited, but we expect few readers will object to these cases of reduced prices.)

Here, we respond to six common objections to increasing prices of undervalued drugs and vaccines: that it will make medical technologies unaffordable for patients (Part IV.A), strain government budgets (Part IV.B), force Americans to pay more than people in other countries (Part IV.C), exacerbate social inequalities (Part IV.D), and generate unnecessary deadweight loss (Part IV.E). While we take these counterarguments seriously, we do not think they defeat the morally compelling and economically sound case for value-based rewards.

A. Cost for Patients

Many of the campaigns to limit "excessive" profits for pharmaceutical developers are motivated by an important and worthy goal: ensuring widespread access to essential medical technologies.[365] Access certainly ought to be a central concern of innovation policy: New technologies won't improve and extend lives if they remain out of patients' reach. And cost is a real barrier to prescription drug access for many Americans.[366]

Fortunately, the tradeoff between incentivizing medical innovation and ensuring access to medical technologies is largely a false choice: We can have both. Governments can reward firms that produce new medical technologies—either through subsidies or direct procurement—and then make those technologies available to patients for free or at low cost. Indeed, this is precisely what we have witnessed over the last year in the context of the Covid-19 vaccines: Approximately 269 million people in the United States have received at least one dose of a Covid-19 vaccine, and none of them have had to pay out of pocket.[367]

The choice between innovation and access is a false one in another sense as well: Rewards based on actual use of a drug (for example, payments from Medicare and Medicaid that depend on the number of units provided to beneficiaries) can motivate drugmakers to invest in getting their products to

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365. *See, e.g.*, Abbott, *supra* note 347, at 282.

366. *See supra* note 5 and accompanying text.

367. *See COVID-19 Vaccinations in the United States*, CDC, https://perma.cc/EJJ8-GCUM (archived Jan. 31, 2023).

patients. Darius Lakdawalla and Tomas Philipson find that in the month after a drug loses patent protection, usage of that drug (including generics) actually *falls* in 40% of cases.[368] Their important (and surprising) finding suggests that marketing efforts—whether in the form of outreach to physicians or direct-to-consumer advertising—have a nontrivial effect on drug utilization. The social consequences of those marketing efforts can be disastrous in some cases (for example, Purdue Pharma's aggressive and misleading marketing of the addictive opioid OxyContin),[369] but they can be salutary in others (for example, Merck's campaigns to promote the HPV vaccine among parents of pre-teens).[370] Reforming the laws governing drug promotion would still be valuable, but reforms should recognize that for socially beneficial products, market exclusivity can spur demand-creation efforts that may reduce intellectual property's allocative inefficiency.

Linking Medicare and Medicaid drug prices to measures of social value also would expand access by severing those prices from the prices charged to nonfederal purchasers. As noted above, drug manufacturers who sell a large share of their output to Medicare Part B providers and Medicaid programs face strong incentives to raise the prices they charge to nonfederal purchasers in order to boost Medicare and Medicaid reimbursements.[371] Even if value-based pricing causes Medicare and Medicaid to pay more for some drugs, it would likely cause other purchasers to pay less for those drugs by eliminating this perverse incentive, thereby motivating firms to offer price concessions to uninsured patients who are currently priced out of the market.[372]

For Medicaid *beneficiaries*, value-based pricing would have no immediate effect on affordability because state Medicaid programs either cover prescription drugs in full or impose very low copay requirements that do not depend on price (for example, $1 per outpatient drug prescription in California).[373] Depending on the allocation of costs between the federal government and the states, value-based pricing might—over time—motivate some states to impose tighter limits on prescription drugs (for example, by enacting new prior authorization requirements) or, at the extreme, drop their Medicaid prescription drug benefits altogether. While we think the latter risk

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368. *See* Darius Lakdawalla & Tomas Philipson, *Does Intellectual Property Restrict Output? An Analysis of Pharmaceutical Markets*, 55 J.L. & ECON. 151, 151-52, 152 fig.1 (2012).

369. *See* Hemel & Ouellette, *supra* note 71, at 16.

370. *See* Laurie McGinley, *Do the New Merck HPV Ads Guilt-Trip Parents or Tell Hard Truths? Both.*, WASH. POST (Aug. 11, 2016, 1:55 PM EDT), https://perma.cc/22DR-DHCZ.

371. *See supra* notes 112-16, 138-41 and accompanying text.

372. *See supra* note 139 and accompanying text.

373. *Medicaid Benefits: Prescription Drugs*, KAISER FAM. FOUND., https://perma.cc/6JBD-Y9NC (archived Jan. 31, 2023).

is remote, Congress could address it by raising the federal medical assistance percentage (FMAP) for prescription drugs—the share of every $1 of state Medicaid spending for which the federal government reimburses the state.[374]

Medicare Part B beneficiaries would be more exposed to higher drug prices because they currently pay 20% coinsurance for covered costs.[375] As noted above, if value-based pricing leads to net price increases, Congress could protect Part B beneficiaries by lowering coinsurance rates or capping out-of-pocket amounts. And even without any adjustment to the coinsurance rate, some Medicare Part B beneficiaries would see their out-of-pocket costs *fall* because the prices of their medications would exceed the cost-effectiveness threshold even at CMS's cost-per-QALY level, or because their medications are past the time limit for value-based rewards.

B. Cost for Government Budgets

A separate concern regarding government-subsidized value-based pricing is that the cost could severely strain the government's budget. Of course, value-based pricing could also be cost-saving overall, in that the government would no longer have to pay high prices where there is no rigorous evidence of comparative effectiveness, and rewards would be time limited. But for some valuable innovations, the rewards would be much higher than under the status quo. Healthcare spending already accounts for more than a quarter of the federal budget,[376] and nearly a fifth of U.S. GDP.[377] One might fairly ask: How much more can we bear?

In short: A lot. By advanced-economy standards, overall U.S. government spending remains quite low relative to gross domestic product. In 2019, the most recent year for which comparative data are available prior to one-time-only Covid-related outlays, government spending (across all levels—federal, state, and local) accounted for 38.2% of GDP in the United States versus 40.3% in the United Kingdom, 45.0% in Germany, and 55.4% in France.[378] We remain a small-government country by international standards. Moreover, prescription

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374. *See Federal Medical Assistance Percentage (FMAP) for Medicaid and Multiplier*, Kaiser Fam. Found., https://perma.cc/KFM7-VLQX (archived Jan. 31, 2023).

375. *See supra* note 257 and accompanying text.

376. Approximately $1.2 trillion out of $4.4 trillion in fiscal year 2019. *See* Urban-Brookings Tax Pol'y Ctr., The Tax Policy Center's Briefing Book: A Citizen's Guide to the Fascinating (Though Often Complex) Elements of the Federal Tax System 7, 346 (n.d.), https://perma.cc/W5WM-B938.

377. *NHE Fact Sheet*, Ctrs. for Medicare & Medicaid Servs., https://perma.cc/8T4T-UGM9 (last updated Dec. 14, 2022, 4:03 PM).

378. *General Government Spending*, OECD, https://perma.cc/RDU9-QN42 (archived Jan. 31, 2023).

drug expenditures account for less than 1.7% of GDP[379]—we could double prescription drug spending with the federal government funding the entire increase and still not catch up to the United Kingdom (much less Germany and France) in terms of government size. The United States is not anywhere near maximum fiscal capacity, and even a massive increase in prescription drug spending would not bring us close.

The upward trend in U.S. healthcare spending is, concededly, real (and rather dramatic), yet it should not necessarily be a cause of great concern. Healthcare spending rose from 5.0% of GDP in 1960 to 19.7% of GDP in 2020,[380] but this is an expected consequence of healthcare being a "superior good" (in economic terms, a good with an income elasticity greater than one).[381] As we get richer, our marginal utility of nonhealth consumption declines: Each additional dollar of nonhealth consumption produces less and less utility (happiness). If the marginal productivity of healthcare spending declines more slowly than the marginal utility of nonhealth consumption, then trading nonhealth consumption for healthcare should become more attractive as income grows.[382] In other words, healthcare should be becoming a larger share of our consumption basket (and thus, of GDP).[383]

Whether the marginal productivity of healthcare spending really does decline more slowly than the marginal utility of nonhealth consumption is impossible to say for sure; economists Robert Hall and Charles Jones review the relevant literature and conclude that the answer is likely "yes."[384] They project that the optimal share of U.S. GDP allocated to healthcare should exceed 30% by 2050 as nonhealth expenditures generate less and less additional utility in a wealthier society.[385] Note that the rate at which the marginal utility of consumption declines is a much-contested parameter and a key input in optimal income tax models—the faster the marginal utility of consumption declines, the greater the benefit of redistributing consumption from the (low marginal utility) rich to the (high marginal utility) poor, and thus the more

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379. NAT'L HEALTH STAT. GRP., U.S. DEP'T OF HEALTH & HUM. SERVS., NATIONAL HEALTH EXPENDITURES BY TYPE OF SERVICE AND SOURCE OF FUNDS: CALENDAR YEARS 1960 TO 2021 (n.d.), https://perma.cc/2JeT-Z378 (to locate, select "View/Download File").

380. U.S. DEP'T OF HEALTH & HUM. SERVS., U.S. DEP'T OF COM. & U.S. BUREAU OF THE CENSUS, NATIONAL HEALTH EXPENDITURES; AGGREGATE AND PER CAPITA AMOUNTS, ANNUAL PERCENT CHANGE AND PERCENT DISTRIBUTION: CALENDAR YEARS 1960-2021 (n.d.), https://perma.cc/83YR-HXNV (to locate, select "View/Download File").

381. *See* Hall & Jones, *supra* note 230, at 40.

382. *See id.* at 47-48.

383. *See id.* at 48.

384. *See id.* at 55-56.

385. *See id.* at 68.

progressive we should want the income tax rate to be.[386] Thus, progressives (in the income-tax sense), who tend to think that the marginal utility of non-tax consumption declines very quickly, should desire to see healthcare spending as a percentage of GDP *rise* over time (unless they are also extreme techno-pessimists regarding medical innovation).

Finally, in the context of pandemic-related innovations, we note that the cost to government budgets of rewarding these innovations may be trivial compared with the cost of the pandemic itself. Consider the federal government's total spending on the Moderna vaccine of $9 billion for 500 million doses.[387] To put that figure in context, CBO analysis indicates that, from the beginning of March 2020 through the end of September 2020, increases in spending and declines in revenue resulting from Covid-19 added approximately $10 billion *per day* to the federal deficit.[388] If the government's contracts with Moderna accelerated the end of these budgetary problems by even one day, they paid for themselves.

C. Paying More than Other Countries

Another potential objection to value-based rewards is that if the United States rewarded medical innovation based on value—with value assessed anywhere close to the cost-per-QALY thresholds that federal agencies use in other contexts—the United States would be paying vastly more than other countries for some prescription drugs and vaccines. Indeed, we already pay vastly more than other countries, with 45% of global pharmaceutical revenue coming from the U.S. market.[389] This disparity is often cited as a source of national shame—as evidence that "Americans massively overpay for drugs" relative to their counterparts in other high-income countries.[390] And yet

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386. *See* Joseph Bankman & Thomas Griffith, *Social Welfare and the Rate Structure: A New Look at Progressive Taxation*, 75 CALIF. L. REV. 1905, 1958 (1987).

387. *See* Moderna, Inc., Current Report (Form 8-K), item 1.01 (Aug. 11, 2020), https://perma.cc/S7AT-XET5 (to locate, select "View the live page"); Moderna, Inc. Annual Report (Form 10-K), item 7, at 165 (Feb. 26, 2021), https://perma.cc/LC2R-3T8H (to locate, select "View the live page").

388. *See* CONG. BUDGET OFF., AN UPDATE TO THE BUDGET OUTLOOK: 2020 TO 2030, at 28 (2020), https://perma.cc/3ZAP-35MJ (estimating that the Covid-19 pandemic added $2.2 trillion to the fiscal year 2020 deficit from March to the end of the fiscal year on September 30—a period of 214 days).

389. ATRADIUS, INDUSTRY TRENDS: PHARMACEUTICALS 16 (2022), https://perma.cc/94M8-YBFM.

390. *Report: For 20 Top-Selling Drugs, Big Pharma Made Far More from U.S. Sales than from the Rest of the World Combined*, PUB. CITIZEN (Sept. 30, 2021), https://perma.cc/5QVC-FRYE; *see* EZEKIEL J. EMANUEL, WHICH COUNTRY HAS THE WORLD'S BEST HEALTH CARE? 354-55 (2020).

paying more than other countries is not inherently problematic—it could just as easily be a source of national pride.

Medical innovation is a global public good—new technologies developed by U.S. firms (or by non-U.S. firms whose most profitable market is the United States) generally benefit patients elsewhere.[391] In that respect, other countries are "free riding" on us. But as long as the benefits to the United States of medical innovation exceed the costs, why should the fact of free riding cause us to stop investing? Perhaps the United States should try to negotiate a deal with other advanced economies to spread biomedical R&D costs more equitably.[392] But until we strike such a deal, it is hard to see why the United States should forgo investments that improve the wellbeing of its own citizens and residents just because those investments also are improving the wellbeing of others. Indeed, we would argue from a global-welfarist perspective that the United States should value its role in dispersing these benefits beyond our borders. We may no longer be "the world's policeman,"[393] yet we remain the world's pharmacopeia.

The debate around U.S. spending on asteroid defense offers a useful analogy. From 2009 to 2019, NASA increased spending on asteroid defense forty-fold.[394] Richard Posner has urged the federal government to increase spending on asteroid defense since the early 2000s, reasoning—we think quite logically—that a large expense would be well worth even a small reduction in the risk of a catastrophic asteroid strike.[395] It would be nonresponsive to this argument to say (for example) "but then we would be paying more than Canada." If an asteroid strikes the Earth, it will bring us little solace to think, in our last moments, "well, at least we did not pay more than the Canadians." Arguments for lower drug prices based on similar cross-country comparisons suffer from the same flaw: We ought not to accept a slower pace of medical innovation just to avoid paying more than our economic peers.

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391. *See* Daniel J. Hemel & Lisa Larrimore Ouellette, *Knowledge Goods and Nation-States*, 101 MINN. L. REV. 167, 192-201 (2016).

392. *See generally id.* (presenting a qualified defense of international IP treaties as a cost-sharing mechanism for investments in knowledge goods).

393. *See* Spencer Bokat-Lindell, Opinion, *Is the United States Done Being the World's Cop?*, N.Y. TIMES (July 20, 2021), https://perma.cc/EXM8-CW82.

394. *See* Casey Dreier, *How NASA's Planetary Defense Budget Grew by More than 4000% in 10 Years*, PLANETARY SOC'Y (Sept. 26, 2019), https://perma.cc/MCK5-UDAR.

395. *See* RICHARD A. POSNER, CATASTROPHE: RISK AND RESPONSE 24-29, 173-74 (2004).

D. Exacerbating Inequality

For some critics of high rewards for medical innovations, inequality is a central concern.[396] There are two dimensions to this concern: (1) that high prices will impede access, and (2) that executives and shareholders of pharmaceutical firms will derive large profits that widen the wealth gap between the rich and the poor. The first dimension parallels the cost-for-patients concern discussed above.[397] Recall again the three responses to that concern: first, that out-of-pocket prices will fall for many drugs; second, that Congress can shield Medicare and Medicaid beneficiaries from price impacts; and third, that the use of value-based pricing by Medicare and Medicaid will actually lower prices for nonfederal purchasers by removing the perverse incentives for price increases. The second dimension is a distinct objection requiring a separate set of responses.

First, to put the inequality concern in perspective, we should keep in mind that executive and shareholder rewards derived from medical innovation are unlikely to have more than a rounding-error effect on the overall wealth distribution. As of the second quarter of 2022, the wealthiest percentile in the United States held an estimated $41.85 trillion in wealth.[398] This is a staggering sum—roughly equal to the wealth of the bottom 90% of households combined.[399] We think the lopsided distribution of wealth in the United States is a blight on the nation, and redistributing resources from the top 1% to poorer households should be at the very front of the policy agenda. That said, adjusting the rewards for pharmaceutical firms will have a negligible effect on this enormous problem. According to Federal Reserve data, corporate equity represents approximately two-fifths (42.3%) of the wealth of the top percentile as of the second quarter of 2022,[400] and biotechnology and pharmaceutical firms represented approximately 8.0% of corporate equities at the end of 2022.[401] Assuming similar sector weights across wealth groups, biotechnology

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396. *See, e.g.*, Robert Silverman & Nicholas Lusiani, *People over Profits: Make COVID-19 Medicines and Vaccines Free and Fair for All*, OXFAM INT'L (June 15, 2020), https://perma.cc/75NM-W2RE (expressing concern that during Covid-19 "Big Pharma's 'business as usual' model" would "exacerbate the inequality crisis" by "funnel[ing] profits to wealthy investors").

397. *See supra* Part IV.A.

398. *See Distribution of Household Wealth in the U.S. Since 1989*, BD. OF GOVERNORS OF THE FED. RSRV. SYS., https://perma.cc/W7QA-ZWYG (last updated Dec. 16, 2022).

399. According to Federal Reserve data, the bottom 90% of the wealth distribution held $43.27 trillion combined in the second quarter of 2022. *See id.*

400. *See id.* (to locate, select "View the live page," then select "Corporate equities and mutual fund shares" from the "Select wealth component" drop-down menu).

401. Authors' calculations based on *Sectors & Industries Overview*, FIDELITY INVS., https://perma.cc/V9NG-KE3W (archived. Feb. 1, 2023) (to locate, select "View the live page," then select "Health Care").

and pharmaceutical stocks would account for around 3% of the total wealth of the top percentile. For most members of the top one percent, huge swings in the value of biotechnology and pharmaceutical firms will show up as little more than a blip on a monthly account statement.

Second, and more importantly, if we think of inequality as the distribution of utilities across persons (rather than the distribution of financial wealth across persons), medical innovation generally *reduces* inequality—and it could be even more egalitarian under a system that weighed all health gains equally, or gave greater weight to the interests of the worse off.[402] If one believes that the marginal utilities of income, consumption, and wealth are rapidly diminishing, then health inequality becomes the primary driver of utility inequality. Innovations that prolong healthy lifespans for individuals who otherwise would have suffered early-onset illness or premature death make us a more equal society, even if a few individuals receive large financial rewards as a result. This is even more apparent in the context of innovations to address pandemic diseases: Covid-19 is itself an important driver of inequality, leading to disparate health outcomes across racial, ethnic, and socioeconomic lines, and much more devastating financial outcomes for low-income Americans than for high-income households.[403]

E.   Deadweight Loss of Taxation or Racing

A final objection to larger rewards for innovation is that these rewards will generate significant "deadweight loss" (defined as a "fall in total surplus that results from a market distortion").[404] The deadweight-loss concern traditionally associated with intellectual property is the familiar loss of efficiency caused by monopoly pricing. Government subsidies largely eliminate this particular source of deadweight loss by ensuring that patients do not pay more than the marginal cost for drugs. But according to the traditional view in public finance, government subsidies merely replace one form of deadweight loss with another—effectively swapping the deadweight loss of monopoly pricing for the deadweight loss of taxation.[405]

A newer view—articulated by Aanund Hylland, Richard Zeckhauser, and Louis Kaplow—posits that taxation does not itself generate deadweight loss

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402. *See supra* notes 145-47 and accompanying text.

403. *See* MATTHEW, *supra* note 146, at 33; Ruqaiijah Yearby & Seema Mohapatra, *Law, Structural Racism, and the COVID-19 Pandemic*, 7 J.L. & BIOSCIENCES lsaa036, at 3-15 (2020), https://perma.cc/XTA8-MU3V.

404. *See* N. GREGORY MANKIW, PRINCIPLES OF ECONOMICS 159 (6th ed. 2012) (defining "deadweight loss").

405. We echoed this traditional view ourselves in Daniel J. Hemel & Lisa Larrimore Ouellette, *Beyond the Patents-Prizes Debate*, 92 TEX. L. REV. 303, 314 (2013).

when tax revenues are used to fund public goods like medical innovation.[406] This new view is increasingly the accepted view in academic public finance,[407] though vestiges of the old view remain. While an in-depth discussion of the new view would take us well beyond the scope of this Article, we will try to summarize the nub of it here.[408]

To start, consider a public good that every taxpayer values at $1.01. Imagine that we could finance it by imposing a $1 charge on every taxpayer. Choosing to fund the public good clearly leaves every taxpayer better off (by one cent). Nobody's choice between labor and leisure would be "distorted," so there would be no deadweight loss.

Now imagine that instead of financing the public good through a $1 charge on everyone, we finance it through a tax that rises with income. In this scenario, low-income taxpayers pay less than $1 but still receive the $1.01 benefit. They are better off than before. High-income taxpayers pay more than $1 (and, indeed, more than the $1.01 benefit), so they are worse off than before. Now, the choice between labor and leisure has been distorted because earning more income means paying a higher tax, which makes labor less attractive than it would be otherwise.

The key insight of the new view is that the labor-leisure distortion—in other words, the deadweight loss caused by taxation—arises from the decision to redistribute wealth from high-income to low-income taxpayers, not from the decision to fund the public good. The government could have financed the public good without any deadweight loss. It generated the deadweight loss because it decided to redistribute. And presumably it decided to redistribute because it thought that financing the public good through a redistributive income tax was at least as desirable, from a social welfare perspective, as financing it through a lump-sum charge (meaning that the equity benefits offset or more than offset the deadweight loss). Under the new view, we ought not count the deadweight loss of redistributive taxation as a "cost" of public provision where financing the public good through a redistributive tax leaves society as a whole at least as well off as in a scenario in which there is no deadweight loss.

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406. *See* Aanund Hylland & Richard Zeckhauser, *Distributional Objectives Should Affect Taxes but Not Program Choice or Design*, 81 SCANDINAVIAN J. ECON. 264, 264-66 (1979); Louis Kaplow, *The Optimal Supply of Public Goods and the Distortionary Cost of Taxation*, 49 NAT'L TAX J. 513, 514 (1996).

407. *See* Alan J. Auerbach & James R. Hines Jr., *Taxation and Economic Efficiency*, in 3 HANDBOOK OF PUBLIC ECONOMICS 1347, 1389-91 (Alan J. Auerbach & Martin Feldstein eds., 2002).

408. For a particularly clear explanation of the new view, see Louis Kaplow, *On the (Ir)Relevance of Distribution and Labor Supply Distortion to Government Policy*, J. ECON. PERSPS., Fall 2004, at 159, 159-60.

Applying this new view to innovation, the choice between market exclusivity and government subsidies as different mechanisms for financing innovation ceases to be a choice between two distortions. Instead, it is a choice between one distortionary mechanism (market exclusivity) and one nondistortionary mechanism (government subsidies). Deadweight loss is a byproduct of taxation only because of a separate policy choice to redistribute from rich to poor—a *good* choice (in our view), but a choice that does not depend on the level of public investment in innovation.

While the new view effectively defuses the argument that value-based rewards will generate deadweight loss through taxation, it does not respond to a separate argument: that value-based rewards will generate deadweight loss through the "racing" problem discussed in Part I.A.2 above—when firms are working on the same problem but do not account for the effects of their R&D on competitors. But how much of a problem is racing? It depends.

In some contexts, whether a drug or vaccine reaches the market one month sooner might not matter much—the costs incurred to win the race are mostly a waste. For example, the first chickenpox vaccine in the United States, developed by Merck, reached the market in May 1995,[409] after a race and a court battle between Merck and SmithKline Beecham.[410] It probably did not matter hugely to the course of history which firm won that race, or whether SmithKline Beecham's vaccine had reached the market a few months sooner. In other cases, though, time is of the essence. For example, having a Covid-19 vaccine just a few months sooner might have saved hundreds of thousands of lives in late 2020 and early 2021.[411] Insofar as high-powered rewards induced a race toward a Covid-19 vaccine, that is a feature, not a bug.

In addition, patent law helps reduce truly duplicative pharmaceutical R&D expenditures. Patent applications are filed early in the drug-development process, and drugs without adequate patent rights are typically dropped from R&D pipelines.[412] Pharmaceutical races are thus more likely to involve nonidentical drugs, which can benefit different patient populations through varied benefits and side effects.[413] And even when the competing drugs are

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409. *Chickenpox Vaccine Debut*, N.Y. TIMES, May 2, 1995, at C11.

410. *See* Smithkline Beecham Pharms. Co. v. Merck & Co., 766 A.2d 442, 444 (Del. 2000).

411. Covid-19 vaccines saved an estimated 20 million lives during their first twelve months on the market. *See* Oliver J. Watson, Gregory Barnsley, Jaspreet Toor, Alexandra B. Hogan, Peter Winskill & Azra C. Ghani, *Global Impact of the First Year of COVID-19 Vaccination: A Mathematical Modelling Study*, 22 LANCET INFECTIOUS DISEASES 1293, 1299 (2022).

412. *See* Benjamin N. Roin, *Unpatentable Drugs and the Standards of Patentability*, 87 TEX. L. REV. 503, 545-47 (2009).

413. *Cf.* Mark A. Lemley, *The Myth of the Sole Inventor*, 110 MICH. L. REV. 709, 753 (2012) ("Inventors racing to solve a problem quite often solve the problem in different ways.").

quite similar, the resulting races are not necessarily winner-take-all. To return to the Covid-19 vaccine example: The fact that the Pfizer-BioNTech vaccine received FDA emergency use authorization one week before Moderna's[414] did not mean that Pfizer-BioNTech captured 100% of U.S. vaccine profits. When drug races can have multiple winners, firms are less likely to undertake socially wasteful expenditures just so that they can cross the finish line first.

As noted in Part II.C, if racing does turn out to be a concern, policymakers can tailor the number of "winners" by adjusting the timeframe for comparisons. Racing will be most acute under a winner-take-all system in which the efficacy of a new drug is compared to the best existing alternative on the date of approval; it will be much less pronounced if efficacy is assessed as of when a drug began clinical trials. Given the lack of current evidence to inform the choice of timeframe, the best approach may be to allow reimbursement programs to experiment by offering different rewards for products tackling different therapeutic classes.

Conclusion

The Covid-19 pandemic has illustrated the value of medical innovation in dramatic fashion. In December 2020, roughly one year after reports of a novel coronavirus first trickled out of China's Hubei province, the first doses of a safe and highly effective vaccine began to enter the arms of high-risk patients.[415] The vaccine, moreover, was free for all Americans[416]: Pfizer and Moderna did not need to charge exorbitant prices to private-sector payers in order to receive large reimbursements from the federal government. Although U.S. vaccination rates remain uneven[417] and the United States has not done nearly enough to address inequitable vaccine distribution globally,[418] the Covid-19 vaccine experience still illustrates how high-powered incentives can be combined with free and widespread access to save over a million lives in the United States, and millions more around the world.

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414. *See* Denise Grady, Abby Goodnough & Noah Weiland, *F.D.A. Authorizes Moderna Vaccine, Adding Millions of Doses to U.S. Supply*, N.Y. TIMES (updated Mar. 16, 2021), https://perma.cc/49AC-HUGD.

415. *See CDC Museum COVID-19 Timeline*, CDC, https://perma.cc/U2HE-AE6U (last updated Aug. 16, 2022).

416. *See Getting Your COVID-19 Vaccine*, CDC, https://perma.cc/JR66-X2PT (last updated Jan. 26, 2023).

417. *See How Vaccinations Are Going in Your County and State*, N.Y. TIMES, https://perma.cc/D892-9C9W (last updated Oct. 20, 2022) (to locate, select "View the live page").

418. Only 25% of the population in low-income countries has received at least one vaccine dose, compared with 82% in high- and upper-middle-income countries. *See* Josh Holder, *Tracking Coronavirus Vaccinations Around the World*, N.Y. TIMES, https://perma.cc/YGM9-UW3K (last updated Oct. 30, 2022) (to locate, select "View the live page").

But it would be a mistake to infer from the success of the Covid-19 vaccine that all is well with American medical innovation. The United States leads the world in new drug discoveries,[419] yet too few of those new drugs are vaccines, too few attack diseases at early stages, too few treat the number-one cause of death (cardiovascular disease),[420] and too many are priced at levels that put them out of reach for lower- and middle-income Americans.[421] The experience of the Covid-19 pandemic presents a challenge to U.S. policymakers: Can we structure a system of subsidies and rewards that produces more innovations like the highly effective Covid-19 vaccines, fewer wasteful innovations, and lower out-of-pocket costs for patients?

In this Article, we have argued that rather than paying high prices for drugs of limited efficacy, the federal government should reward social value directly, and we have illustrated how a value-based pricing regime might work. We have suggested potential institutional mechanisms, but our goal is not to resolve these details. Incremental steps to better align rewards for medical innovation with social value would be movements in the right direction.

To be sure, our push for value-based rewards is a political long shot. The pharmaceutical industry may prefer the status quo in which firms can reap large rewards without delivering significant social value. Meanwhile, political actors on the left and right both have an incentive to stick to the existing narrative: Reducing Medicare and Medicaid drug spending gives the appearance of fiscal responsibility even if, in the long run, that approach is penny-wise and pound-foolish. But like many new drug-development efforts, we would argue that the value-based pricing project—even if it is a political long shot—is well worth the energy and attention of scholars and activists. Medical innovation, after all, occurs only because researchers, firms, and agencies pursue projects that are overwhelmingly likely to fail but will yield huge payoffs for society in the event of a positive outcome. The push for value-based pricing faces a similar risk-reward profile: Success is statistically unlikely, but we think the tremendous social yield justifies the improbability of the enterprise.

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419. *See* Robert Kneller, *The Importance of New Companies for Drug Discovery: Origins of a Decade of New Drugs*, 9 NATURE REVS.: DRUG DISCOVERY 867, 871 fig.1 (2010).

420. *See supra* Part I.A.1.

421. *See supra* note 5 and accompanying text.

Appendix: Calculating QALYs

To operationalize QALYs, ICER generally relies on a measure known as the "EQ-5D."[422] "EQ" refers to the multi-country EuroQol Group of researchers (who developed the tool); "5D" refers to the tool's five dimensions.[423] The five dimensions are: mobility; ability to engage in self-care; ability to carry out usual activities; pain/discomfort; and anxiety/depression.[424] The original version of the EQ-5D includes three levels of severity for each dimension (and is thus known as the EQ-5D-3L).[425] More recently, researchers have migrated toward a five-level version of the instrument (the EQ-5D-5L).[426] Level 1 means that an individual experiences "no problems" on the relevant dimension; level 5 means that an individual experiences "extreme problems" on the relevant dimension.[427] For example, "mobility" level 5 means that an individual is unable to walk; "self-care" level 5 means that an individual is unable to wash or dress.[428]

The five dimensions and five levels within each dimension allow for 3,125 possible health states, ranging from "11111" (meaning a level 1 score on all five dimensions) to "55555" (meaning a level 5 score on all five dimensions).[429] The digits are conventionally arranged in the following order: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.[430] For example, a score of "21231" would represent a level 2 score on mobility, a level 1 score on self-care, a level 2 score on usual activities, a level 3 score on pain/discomfort, and a level 1 score on anxiety/depression.

Health states derived from the EQ-5D-5L are typically translated into measures of health-related quality of life (HRQoL) using a time-tradeoff (TTO) method.[431] In conventional TTO, the respondent is faced with a choice between (A) *x* years of life in a state of full health (level 1 across all dimensions, or 11111), followed by death; or (B) *t* years of life in impaired health state *h*,

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422. *See* INST. FOR CLINICAL & ECON. REV., *supra* note 178, at 22.

423. *See* Mark Oppe, Kim Rand-Hendriksen, Koonal Shah, Juan M. Ramos-Goñi & Nan Luo, *EuroQol Protocols for Time Trade-Off Valuation of Health Outcomes*, 34 PHARMACOECONOMICS 993, 994 (2016).

424. *Id.*

425. *Id.*

426. *See* Mathieu F. Janssen, Gouke J. Bonsel & Nan Luo, *Is EQ-5D-5L Better than EQ-5D-3L? A Head-to-Head Comparison of Descriptive Systems and Value Sets from Seven Countries*, 36 PHARMACOECONOMICS 675, 676 (2018).

427. *See id.* at 677.

428. *See* A. Simon Pickard et al., *United States Valuation of EQ-5D-5L Health States Using an International Protocol*, 22 VALUE HEALTH 931, 936-37 tbl.1 (2019).

429. *Id.* at 932.

430. *See id.*

431. *See* Oppe et al., *supra* note 423, at 994.

followed by death.[432] The value of x is varied until the respondent is indifferent between option A and option B.[433] The HRQoL of the impaired health state $U(h)$ is equal to x/t.[434] To illustrate: Imagine that the respondent is indifferent between (A) 6.3 years of life in a state of full health ($h = 11111$), followed by death; and (B) 10 years of life in a state of slight impairment along all five dimensions ($h = 22222$), followed by death. The HRQoL of the impaired health state 22222 would be equal to 6.3/10, or 0.63.

The conventional TTO approach is best suited to health states that a respondent considers to be better than death. If the conventional TTO approach is applied to a health state that the respondent considers to be worse than death, then x will be equal to zero and the approach will be unable to determine *how much worse than death* the respondent considers the state to be.[435] For health states rated as worse than death, researchers often use a method known as lead-time TTO.[436] In lead-time TTO, the respondent is faced with a choice between (A) $l + x$ years of life in full health, followed by death; and (B) l years of life in full health, followed by t years of life in impaired health state h, followed by death.[437] A health state is worse than death if x is negative (i.e., if the respondent is willing to forgo years of life in full health in order to avoid time in the worse-than-death state).[438]

To illustrate: Consider the worst possible health state (55555). Imagine that the respondent is indifferent between (A) 4.3 years of life in a state of full health, followed by death; and (B) 10 years of life in a state of full health, followed by 10 years of life at $h = 55555$, followed by death. That is, the respondent is willing to sacrifice 5.7 years of healthy life in order to avoid 10 years of life at $h = 55555$, represented by $x = -5.7$. The HRQoL associated with the impaired health state 55555 (meaning, $U(h = 55555)$) would be equal to $-5.7/10$, or -0.57.

The emerging norm in EQ-5D research is to use conventional TTO for health states rated as better than death and lead-time TTO for health states rated as worse than death.[439] This approach is known as "composite TTO."[440] Composite TTO is used to produce HRQoL estimates for all or a subset of

432. *Id.* at 995.

433. *Id.*

434. *See id.*

435. *See id.*

436. *See id.* at 995-96.

437. *See id.*

438. *See id.*

439. *See* Angela Robinson & Anne Spencer, *Exploring Challenges to TTO Utilities: Valuing States Worse than Dead*, 15 HEALTH ECON. 393, 393-95 (2006).

440. *See* Oppe et al., *supra* note 423, at 995-96 (capitalization altered).

possible health states. Researchers then apply regression analysis to derive estimates for the utility effect of each level on each dimension.

Over the past decade, teams across the globe have produced EQ-5D-5L value sets for populations in over twenty countries.[441] Table 1 reports the preferred parameter estimates for the U.S. population, derived by Pickard et al. from a survey of 1,134 U.S. adults performing TTO tasks, and cited by ICER in its value-assessment framework.[442] The left column lists the five dimensions and five levels. The right column reports the estimate of the utility decrement (δ) associated with each level. The HRQoL for a five-dimension health state is equal to 1 plus the sum of all δ's for each level and dimension, ranging from −0.57 for health state 55555 to 1 for health state 11111.

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441. *See EQ-5D-5L: Valuation*, EQ-5D, https://perma.cc/7MJ6-8XJH (last updated Aug. 11, 2022).

442. *See* Pickard et al., *supra* note 428, at 939 tbl.2; INST. FOR CLINICAL & ECON. REV., *supra* note 178, at 58 n.16.

Table 1
U.S. Valuation of EQ-5D-5L Health States[443]

Dimension/Level	"Preferred" Estimates (δ)
Mobility	
Level 1: No problems	0
Level 2: Slight problems	-0.096
Level 3: Some/moderate problems	-0.122
Level 4: Severe problems	-0.237
Level 5: Unable to walk about	-0.322
Self-Care	
Level 1: No problems	0
Level 2: Slight problems	-0.089
Level 3: Some/moderate problems	-0.107
Level 4: Severe problems	-0.220
Level 5: Unable to wash or dress	-0.261
Usual Activities (for example, work, study, housework, family, or leisure activities)	
Level 1: No problems	0
Level 2: Slight problems	-0.068
Level 3: Some/moderate problems	-0.101
Level 4: Severe problems	-0.255
Level 5: Unable to do usual activities	-0.255
Pain/Discomfort	
Level 1: No pain or discomfort	0
Level 2: Slight pain or discomfort	-0.060
Level 3: Moderate pain or discomfort	-0.098
Level 4: Severe pain or discomfort	-0.318
Level 5: Extreme pain or discomfort	-0.414
Anxiety/Depression	
Level 1: Not anxious or depressed	0
Level 2: Slightly anxious or depressed	-0.057
Level 3: Moderately anxious or depressed	-0.123
Level 4: Severely anxious or depressed	-0.299
Level 5: Extremely anxious or depressed	-0.321

443. Pickard et al., *supra* note 428, at 939 tbl.2.

The U.S. study yields logically consistent estimates of δ (meaning, larger decrements for more impaired health states), with one exception: Along the usual-activities dimension, the move from level 4 (severe problems) to level 5 (unable to do usual activities) yields no additional decrement. The estimates also suggest that individuals are especially averse to extreme pain/discomfort—a result that will strike many readers as quite intuitive.

EQ-5D-5L values are inputs into estimates of QALYs gained from medical innovation. For example, if a treatment allows a patient to live an extra year in full health ($h = 11111$), the number of QALYs gained is 1. If a treatment moves a patient from mobility level 5 (unable to walk about) to mobility level 1 (no problems) for one year, then the number of QALYs gained is 0.322. If a treatment allows a patient to live an extra year without the ability to walk (but in full health on other dimensions), then the number of QALYs gained is $1 - 0.322 = 0.678$. And so on.

One potential objection to the EQ-5D-5L-based QALY approach is that EQ-5D-5L values are derived from survey experiments with participants drawn from the general population, rather than experiments involving patients.[444] Arguably, to assess the utility loss associated with (for example) losing the ability to walk, we ought to survey people who actually have lost the ability to walk. One EQ-5D study involving patients with various debilitating conditions found statistically significant smaller decrements associated with mobility and pain/discomfort, but larger decrements associated with anxiety/depression.[445] Note that the effect of using EQ-5D values derived from patients to calculate QALY gains is ambiguous: Smaller decrements mean smaller QALY gains from wellbeing improvements, but larger QALY gains for interventions that extend the lives of patients experiencing less than full health.

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444. *See* Rachel Mann, John Brazier & Aki Tsuchiya, *A Comparison of Patient and General Population Weightings of EQ-5D Dimensions*, 18 HEALTH ECON. 363, 363-64 (2009).

445. *See id.* at 367.