Equitably Valuing Medicine

Govind Persad[*]

The federal Inflation Reduction Act and parallel state efforts comprise a paradigm shift in American health law: rather than accepting high prescription drug prices, government now seeks to rein them in through negotiation and affordability reviews. Yet states are still struggling with high drug costs and adopting draconian measures like denying coverage for all anti-obesity drugs. This Article proposes a better and fairer way forward for states and the federal government: evaluate prescription drugs based on equity-informed valuation metrics, such as cost-effectiveness analysis that explicitly values the mitigation of health disparities. Equity-informed, value-based decision-making will improve on presently used but value-oblivious measures, like development costs or government support. Considering equity and value together also helps forestall blanket coverage denials based purely on cost without attention to value. Contrary to some who criticize valuing medicine as inequitable, valuation of medicine is indispensable to achieving health equity.

 Associate Professor, University of Denver Sturm College of Law; JD, PhD, Stanford. Special thanks to Lisa Ouellette, Rachel Sachs, Richard Saver, Megan Wright, Rebecca Wolitz, and Leah Rand for written comments and to Nick Bagley, Ankur Pandya, Sara Gerke, George Horvath, Emily Murphy, Anjali Deshmukh, Anya Prince, Brendan Maher, Christopher Robertson, Jessica Roberts, Carly Zubrzycki, Matthew Lawrence, Wendy Epstein, Nicole Huberfeld, Liz McCuskey, Liza Vertinsky, Rachel Sachs, Joseph Millum, David Simon, Samantha Zyontz, Ameet Sarpatwari, Adam Raymakers, Joseph Daval, Aaron Kesselheim, Carl Coleman, Daniel Hemel, Brett McQueen, Mike DiStefano, Eric Campbell, Kelly Anderson, Kavita Nair, Nancy Leong, Catherine O'Toole, and audiences at the RIBS Workshop at the University of Iowa College of Law; the All-Online Low-Stress Health Law Workshop at Texas A&M; the AALS Health Law Section Virtual Health Law Workshop; and a Works-in-Progress Session at the Program on Regulation, Therapeutics and Law at Harvard Medical School. Dani Fishman, Halli Berrebbi, Liz Ignowski, and Nikki Musco provided valuable research assistance.

After describing various impediments to valuing medicines raised by pharmaceutical firms and influential interest groups, the Article describes the legal constraints governing the valuation of medicine in the United States. It examines responses to the use of value metrics in state Medicaid plan design, restrictions within the Affordable Care Act ("ACA"), and subsequent efforts to restrict the use of value metrics by state Prescription Drug Affordability Boards and in Inflation Reduction Act price negotiations. The analysis reveals that prevailing restrictions primarily aim to prevent the exacerbation of existing disadvantages. Although some efforts to establish restrictions assert the immeasurability of life and health, or question quantitative evaluation of medicine by positing that drug costs present no tradeoffs for government payers, these critiques serve more as rhetorical tools than as explicit legal precepts.

This Article then explains how innovations in health economics can enable integrating equity into the valuation of medicine. To address concerns about disadvantaging patients with preexisting conditions, the paper suggests modifications to cost-effectiveness analysis. These modifications would consider only those improvements or deteriorations in a patient's quality of life that are attributable to treatment, filtering out differences attributable to pre-treatment quality of life. Furthermore, the analysis recommends explicitly valuing the reduction of health inequities as an outcome. The Article concludes with a suite of law and policy reforms to enable equitable valuation of medicine. In particular, it advocates for the ACA's Patient-Centered Outcomes Research Institute to fund research on equitable valuation of medicines, a step it has thus far resisted, and recommends incentives to develop medicines addressing health disparities.

TABLE OF CONTENTS

INTRODUCTION

Americans believe drug prices are too high. To rein prices in, they have sent Medicare to the negotiating table. At the state level, they've authorized leaders to identify unaffordable drugs and to set limits on how much commercial and public entities should fork over to pharmaceutical companies. Negotiation sounds appealing and flexible — and is popular with voters of all political stripes.[1]

Of course, a negotiator needs to know what outcomes to negotiate for. Yet the statutes authorizing negotiation make this difficult.[2] When Medicare's negotiators stride up to the table, their briefcases may be

[1] Ashley Kirzinger, Audrey Kearney, Mellisha Stokes, Liz Hamel & Mollyann Brodie, *The Public Weighs in on Medicare Drug Negotiations*, KFF (Oct. 12, 2021), https://www.kff.org/health-costs/poll-finding/public-weighs-in-on-medicare-drug-negotiations/ [https://perma.cc/Y4PR-VJZ4].

[2] *See* 42 U.S.C. § 1320f-3.

purged of quantitative data on how much value — in terms of longer and healthier lives — a drug will deliver compared to other drugs that might be purchased with the same funds.[3] They may even be prohibited from considering what prices manufacturers are charging in Europe, Canada, and Australia.[4] Instead, they may be limited to a smattering of "manufacturer-specific data" completely unrelated to the drug's potential to help patients, along with limited information about how the drug compares to alternative therapies for the same condition and whether it addresses "unmet medical needs."[5]

Ordinary negotiations do not work this way. An individual — or government — negotiating to buy a car considers how well the car runs, how reliable it has been, and what price the dealer has been charging other customers. The manufacturer's "research and development costs" or "costs of production and distribution," or the "prior federal financial support" they have received, are not pertinent.[6] The government may have bailed carmakers out during the Great Recession,[7] but they don't demand that federal procurement ignore whether a Chrysler is less reliable than a Ford.

Similarly, some states have debarred their prescription drug affordability boards ("PDABs") from considering value when evaluating affordability.[8] Others are simply refusing to pay for new, costly drugs, no matter how well they work. In January 2024, North Carolina refused to cover the anti-obesity drug Wegovy, even though the drug presents good value for money — especially for patients who would otherwise

[3] *See infra* Part II.D.

[4] *See id.*

[5] 42 U.S.C. § 1320f-3.

[6] *See id.* § 1320e-1(a)–(c).

[7] *See* A & D Auto Sales, Inc. v. United States, 748 F.3d 1142, 1147-49 (Fed. Cir. 2014).

[8] *See infra* Part II.C.

need expensive procedures.[9] This is not the first time insurers have refused to pay for expensive but cost-effective drugs.[10]

Who saddled negotiators with these restrictions on considering value? The cynical observer might assume that, once again, pharmaceutical firms' powerful lobbying arms have won the day. They would not be entirely wrong.[11] But drug companies' efforts piggyback on the work of advocacy groups, attorneys, and legislators who have opposed quantifying and comparing the value — net medical benefit compared to financial cost — of different medicines.[12] Often, drugmakers fund these groups' efforts.[13]

Most recently, the Department of Health and Human Services ("HHS") has issued a rule restricting the use of value assessment methods by federal funds recipients — including all health professionals who receive Medicare funds.[14] During 2023, legislation was introduced to ban use of the quality-adjusted life-year ("QALY"), a metric commonly used abroad to assess the value of medicines, in coverage and reimbursement decisions by federal health care programs and federally funded state health programs.[15] These efforts follow a report by the National Council on Disability ("NCD"), an independent federal agency, that recommended banning Medicare and Medicaid from using

[9] Rebecca Robbins, *Buried in Wegovy Costs, North Carolina Will Stop Paying for Obesity Drugs*, N.Y. TIMES (Jan. 26, 2024) https://www.nytimes.com/2024/01/26/business/obesity-drugs-insurance-north-carolina.html (explaining that even though anti-obesity "medications may pay for themselves or even save money in the long run, by preventing heart attacks and strokes that lead to huge hospital bills," state and private insurers are refusing to pay for them due to their high cost).

[10] *See* Michelle M. Mello, *What Makes Ensuring Access to Affordable Prescription Drugs the Hardest Problem in Health Policy?*, 102 MINN. L. REV. 2273, 2295, 2295 n.100 (2018).

[11] *See infra* Part IV.C.

[12] *See infra* Part I.

[13] *See infra* Part IV.C.

[14] Nondiscrimination on the Basis of Disability in Programs or Activities Receiving Federal Financial Assistance, 89 Fed. Reg. 40066 (proposed May 9, 2024) (to be codified at 45 C.F.R. pt. 84) [hereinafter *Final Rule*]; Discrimination on the Basis of Disability in Health and Human Service Programs or Activities, 88 Fed. Reg. 63392 (proposed Sept. 14, 2023) (to be codified at 45 C.F.R. pt. 84).

[15] Protecting Health Care for All Patients Act of 2023, H.R. 485, 118th Cong. § 2.

QALYs.[16] At the state level, patient organizations funded by pharmaceutical firms have denounced efforts by state PDABs to set value-based limits on what state-funded insurance programs will pay for drugs.[17] Instead, they argue, pharmaceutical firms should be entitled to unlimited, taxpayer-funded reimbursement at any price the firm elects to set.[18]

Rather than explicitly rejecting value assessment because it poses a threat to pharmaceutical companies' bottom lines, these proposals decry assessing medicines' value as inequitable or unfairly discriminatory. HHS's background to its proposed rule noted that advocacy organizations have raised "concerns about disability discrimination in value assessment methods."[19] Other organizations — backed by pharmaceutical firms — charge that value assessment tools will exacerbate racial disparities, despite a paucity of evidence to support such claims.[20] The same industry-funded organizations worked to shape NCD's report, despite that report's claims to speak on behalf of patients.[21]

This Article, in contrast, contends that fairness requires valuing medicine equitably, not demurring from value assessment. Pricing and

[16] NAT'L COUNCIL ON DISABILITY, QUALITY-ADJUSTED LIFE YEARS AND THE DEVALUATION OF LIFE WITH DISABILITY 13-15 (2019) [hereinafter NCD REPORT].

[17] *See, e.g.*, *Access and Nondiscrimination in the States Awareness Project*, PATIENT ACCESS PROJECT, https://www.patientaccessproject.org (last visited June 20, 2024) [https://perma.cc/GYX5-24FL]; *PNW Advocates Confab*, CARING AMBASSADORS PROGRAM, https://caringambassadors.org/pnw-advocates-confab/ (last visited June 20, 2024) [https://perma.cc/8L65-6ZMA] [hereinafter PATIENT ACCESS PROJECT].

[18] *See* Lorren Sandt, *Oregon Needs to Listen to Its Patients*, OR. CAP. CHRON. (Mar. 7, 2024, 5:30 AM), https://oregoncapitalchronicle.com/2024/03/07/oregon-needs-to-listen-to-its-patients/ [https://perma.cc/J473-BWXF] ("Every Oregonian deserves unrestricted access to treatments and medicines that can help them live a full life.").

[19] *Id.*

[20] *See* P'SHIP TO IMPROVE PATIENT CARE, NAT'L MINORITY QUALITY F., SICK CELLS & AXIS ADVOC., TRADITIONAL VALUE ASSESSMENT METHODS FAIL COMMUNITIES OF COLOR AND EXACERBATE HEALTH INEQUITIES 1 (2020). The Partnership to Improve Patient Care, which led this report, "includes the lobbying arms of the drug, device and biotechnology industries as well as patient-advocacy groups and medical-professional societies." Alicia Mundy, *U.S. News: Drug Makers Fight Stimulus Provision,* WALL ST. J., Feb. 10, 2009, at A4.

[21] *See* NCD REPORT, *supra* note 16, at 9, 53, 65 (relying on and endorsing perspectives advanced by the Partnership to Improve Patient Care).

reimbursing drugs without regard to value misdirects innovation and leads payers to set limits in unjust and counterproductive ways. When precluded from considering value, payers may set limits purely on the basis of cost, as North Carolina and other payers did when refusing to cover drugs for obesity.[22] Or payers may burden poorer patients by raising premiums and out-of-pocket costs — as Medicare was prepared to do had it been forced to cover the ineffective Alzheimer's drug Aduhelm.[23] Or payers may exclude patients with less time and savvy by requiring them to navigate bureaucratic hurdles. Ignoring value has similarly counterproductive effects on innovation. Focusing on research and development costs rather than value, for instance, channels medical innovation toward interventions that are costlier to develop, regardless of whether they benefit more patients, tackle more severe health problems, or address health inequities.

Although I will critique aspects of HHS's rule and NCD's report, I do so out of concern that their proposed reforms will impede rather than advance the health and well-being of marginalized patients, not out of disagreement with their avowed goals of fairness and equity. Equitably valuing medicine does not mean uncritically accepting the status quo. Marginalized patients often have good reason to seek improvements on "first-generation" valuation methodologies like the QALY — but banning the use of QALYs or cost-effectiveness analysis will not promote equity. Rather than aligning with self-serving drugmakers to support bans on valuing medicine, advocates for health equity should work to promote and support equitable valuation. In doing so, they can draw on "next-generation" approaches to cost-effectiveness that enable incorporating and prioritizing health equity outcomes as part of a medicine's value.

---

[22] *See* Govind Persad & Ezekiel J. Emanuel, *For Obese Patients, Wegovy Is Worth the Cost; North Carolina is Wrong to Deny Coverage. Breakthrough Treatments Curb Additional Health Risks.*, WALL ST. J. (Feb. 23, 2024), https://www.wsj.com/articles/for-obese-patients-wegovy-is-worth-the-cost-insurance-health-north-carolina-2e0edf02.

[23] *See* Allison M. Whelan, *Executive Capture of Agency Decisionmaking*, 75 VAND. L. REV. 1787, 1803 n.67 (2022) (explaining that "about half of the . . . increase in Medicare Part B outpatient premiums for 2022 was in preparation for potential coverage of Aduhelm"); Derek Lowe, *Goodbye to Aduhelm*, SCIENCE (Jan. 31, 2024, 11:36 AM) https://www.science.org/content/blog-post/goodbye-aduhelm [https://perma.cc/5Z4Y-H2SC] (describing Aduhelm's poor efficacy).

In Part I, I delineate three different critiques of valuing. The first and furthest reaching, which I call *rejecting quantitative comparison*, asserts that because life and health are priceless, lifesaving and health-promoting medicines should not be compared to one another or valued in monetary terms.[24] This critique is often buttressed by what I call *tradeoff denialism*, which takes the position that considering value when deciding what to pay for medicines is unnecessary because medical spending does not compete with other spending. The second, which I call *limiting quantitative comparison*, would allow comparisons between medicines based on certain factors, while proscribing others. These limits often seek to constrain consideration of drugs' differential impact on duration or quality of life.[25] Last, a critique based on *questioning informational accuracy* doubts the measurability of health-related quality of life.[26]

Part II connects the critiques raised in Part I with legal restrictions on valuing medicine. Part II.A discusses restrictions on considering value in Medicaid plan design. Part II.B discusses restrictions in the Affordable Care Act ("ACA"). Parts II.C and II.D discuss post-ACA efforts at the state and federal levels to prohibit or restrict efforts to value medicine. I explain that existing restrictions primarily aim to avoid compounding preexisting disadvantage or excluding relevant information. While vitalism and tradeoff denial at times motivated legislators and advocacy groups to seek restrictions, these motives have not been translated into legal text.[27]

Part III begins by explaining why value-based pharmaceutical policies are typically more equitable than other ways of setting limits or creating incentives. It then considers how an innovative "next-generation" approach to cost-effectiveness analysis ("CEA") that I call "baseline-adjusted" CEA can help address concerns that valuing medicine by considering patients' *post-treatment* quality of life will unjustly exacerbate the effects of prior disadvantage. Meanwhile, other innovative approaches like distributional and extended cost-effective analysis can explicitly recognize the additional value of drugs that not

[24] *See infra* Part I.A.

[25] *See infra* Part I.B.

[26] *See infra* Part I.C.

[27] *See infra* Part II.D.

only improve health but counteract health disparities. Important recent legal scholarship discussing cost-effectiveness has not discussed next-generation CEA in detail.[28] Nor has it discussed — at all — distributional or extended CEA.[29]

Part IV considers reforms that would support valuing medicine equitably. Advocates and policymakers should fund and support the use of next-generation CEA to promote health equity, rather than seeking to ban CEA. Regulations on CEA should be clearly worded to promote equitable valuation, rather than chilling all consideration of value. Boards and agencies overseeing or evaluating efforts to value medicines should serve the public interest, avoiding conflicts of interest and interest group capture.

Efforts at pharmaceutical policy reform will founder if they do not consider value: this Article's introduction of innovative health policy and economics methods into the legal literature will help dissolve the illusory conflict between value measurement and health equity.

I. UNDERSTANDING RESISTANCE TO VALUING MEDICINE

This Part reviews three prominent objections to valuing medicine. The first, which I call *rejecting quantitative comparison*, rejects efforts to quantify and compare the benefits of different drugs. This objection encourages decision-makers to believe that paying for medicines presents no tradeoffs, or to resolve tradeoffs without comparing medicines' benefit. The second, which I call *limiting quantitative comparison*, would permit a limited set of comparisons between medicines but would reject many others on the basis that they treat patients differently or compound preexisting disadvantage. The third, which I call *questioning informational accuracy*, objects that prevailing ways of measuring benefit are inaccurate.

[28] *See* Christopher Buccafusco & Jonathan S. Masur, *Drugs, Patents, and Well-Being*, 98 WASH. U. L. REV. 1403, 1419-20 (2021); Carl H. Coleman, *Cost-Effectiveness Comes to America: The Promise and Perils of Cost-Effective Analysis in Medication Coverage Decisions*, 38 GA. ST. U. L. REV. 811, 818-19 (2022); Daniel J. Hemel & Lisa Larrimore Ouellette, *Valuing Medical Innovation*, 75 STAN. L. REV. 517, 545-62 (2023); Govind Persad, *Pricing Drugs Fairly*, 62 WM. & MARY L. REV. 929, 960-61 (2020) [hereinafter Persad, *Pricing Drugs Fairly*].

[29] *See* Persad, *Pricing Drugs Fairly*, *supra* note 28, at 960-61.

A. Rejecting Quantitative Comparison

I begin with the furthest-reaching objection to valuing medicine: that patients must be granted fully subsidized access to any medicine that could benefit them, irrespective of that medicine's cost or cost-effectiveness either in absolute terms or compared to other medical interventions. This approach would make negotiation impossible. A negotiator who cannot walk away cannot effectively negotiate — they must pay whatever price drugmakers ask.[30]

Yet many commentators have rejected value-based limits on access to medicine. A dissenting appendix by pharmaceutical executives Michael Rosenblatt and Henri Termeer to a recent National Academies report elegantly summarizes the rejection of valuing:

> Allowing the government to exclude a drug from its formulary based on cost alone raises serious moral and ethical issues. Imagine that a new drug is created that effectively treats a condition for which there never has been an effective treatment. Under these circumstances, it is hard to imagine the federal government or insurers telling patients or parents of affected children that the drug will not be made available.[31]

While framed around "cost alone," these authors' view would preclude any consideration of cost-effectiveness since cost-effectiveness inevitably considers cost when comparing two beneficial drugs. Others, including the NCD, have similarly claimed that no effective drug should be excluded from coverage based on cost or insufficient cost-effectiveness.[32]

---

[30] *Cf.* James Gibson, *Boilerplate's False Dichotomy*, 106 GEO. L. J. 249, 253 n.5 (2018) ("[E]ven when negotiation is possible, a buyer's ability to walk away from the bargaining table and seek out a competing seller is of paramount importance. One cannot negotiate effectively if the other party knows that it is the only game in town.").

[31] Michael Rosenblatt & Henri Termeer, *Appendix A: A Dissenting View*, *in* NAT'L ACADS. SCIS., ENG'G, & MED., MAKING MEDICINES AFFORDABLE: A NATIONAL IMPERATIVE 159, 174 (Norman R. Augustine, Guru Madhavan & Sharyl J. Nass eds., 2018); *cf.* H.I. Hyry, J.C.P. Roos & T.M. Cox, *Orphan Drugs: Expensive Yet Necessary*, 108 Q.J. MED. 269, 271 (2014) (arguing that social value assessments should not be conducted for drugs that are the only treatment option for a specific disease).

[32] *E.g.*, NCD REPORT, *supra* note 16, at 43 (raising concerns about situations where "the only class of drugs known to be effective for a certain group of patients with

Of course, pharmaceutical firms — who decide what to charge for drugs — cannot credibly claim that life is priceless. Governmental negotiators are never the ones who tell patients that a drug "will not be made available."[33] Drugmakers are the ones who ultimately say no by denying patients access to drugs unless they hand over enough cash. What governments must decide is how much to subsidize patients' purchase of drugs. If firms seek to charge more than the subsidized amount, the dispute is between the firm and the patient. Drugmakers — not governments — are the ones placing a price on life.

Rejecting value-based comparison among effective medicines is often intertwined with an ideological commitment to vitalism, which regards human life as the paramount ethical value.[34] Objective vitalism holds that life is priceless, full stop. Subjective vitalism holds instead that life is priceless whenever the person living that life wishes to continue living.[35] Both forms of vitalism require ignoring a life-prolonging intervention's expense, probability or duration of benefit, and effects on quality of life.[36] The vitalist claim that "life is priceless" sounds high-minded, but it provides no guidance whenever resources are limited and is starkly inconsistent with how actual people live their lives.

disabilities is not covered because the drugs are not considered cost-effective"); *id.* at 62 (rejecting the use of one form of cost-effectiveness analysis because "denial of coverage is possible . . . even where a drug would provide significant clinical benefit, including life extension").

[33] Rosenblatt & Termeer, *supra* note 31, at 174.

[34] *See* JOHN KEOWN, THE LAW AND ETHICS OF MEDICINE: ESSAYS ON THE INVIOLABILITY OF HUMAN LIFE 4 (2012) (explaining that under vitalism, "regardless of the pain, suffering, or expense that life-prolonging treatment entails, it must be administered: human life is to be preserved at all costs").

[35] *E.g.*, Felicia Nimue Ackerman, Commentary, *A Real Enemy of the Old and Disabled*, PROVIDENCE J. (Aug. 25, 2009) (arguing that because "[a]n 85-year-old may value his remaining five years as much as a teenager values his remaining 70," access to treatments should be fully subsidized "so long as conscious life can be preserved or restored").

[36] Objective vitalism is further reaching, since it would require unlimited spending to keep alive humans who cannot value their own continued life, such as anencephalic infants, and those who do not value remaining alive, such as patients with severe dementia who expressed advance wishes not to be kept alive. *See* KEOWN, *supra* note 34, at 5-6.

Turn first to resource limits. Spending on costly medicines must be funded either by increasing revenues — though increased premiums, cost-sharing, or taxes — or by reducing spending on other treatments. Each choice produces what economists call "opportunity costs," which themselves present risks to life and health.[37] Money spent on insurance premiums is money a household cannot spend on healthier foods or safer transportation. Money spent to purchase pharmaceuticals is money a government cannot spend to replace lead pipes or reduce air pollution.

The inevitability of opportunity costs, combined with the health effects of non-health care spending, means that even committed vitalists should reject unlimited medical spending. Medical spending does not merely pit life against filthy lucre. Rather, it presents health-health tradeoffs, which, as Cass Sunstein put it, arise "when the diminution of one health risk simultaneously increases another health risk."[38] Sunstein's classic paper analyzes tradeoffs in risk regulation — like whether a "ban on carcinogens in food additives may lead consumers to use noncarcinogenic products that carry greater risks in terms of diseases other than cancer."[39] But health-health tradeoffs also exist when government shifts spending between programs, changes tax rates, or mandates the content of private insurance coverage.[40] Like risk regulation, spending, taxation, and insurance mandates should avoid increasing net risks to life and health.[41]

Moreover, vitalism is also starkly inconsistent with real people's non-vitalist commitments. People regularly risk their lives to realize other outcomes they value — traveling to see friends, defending their country, hang gliding. Real patients do not value life above all else: they prefer financial flexibility and support for access to the social determinants of

[37] *See, e.g.*, Hemel & Ouellette, *supra* note 28, at 558-59, 559 n.225 (identifying risk that excessive drug prices would lead to higher insurance premiums and rates of uninsurance).

[38] Cass R. Sunstein, *Health-Health Tradeoffs*, 63 U. CHI. L. REV. 1533, 1535 (1996) (italics omitted).

[39] *Id.* at 1536.

[40] *E.g.*, Hemel & Ouellette, *supra* note 28, at 558.

[41] *See id.*

health over unlimited menus of lifesaving treatments.[42] Nor do they ignore side effects or probability of benefit and harm.[43]

Politicians nevertheless often seek to reject limits on spending by invoking promises of unlimited access. In debates over the ACA, Representative Charles Boustany (R-LA) asserted that "doctors should have the ultimate say on how their patients should be treated," and stated that "Congress is not in a position to judge the value of a human life."[44] Likewise, Senator Mitch McConnell (R-KY) claimed that "government bureaucrats shouldn't be able to use [comparative effectiveness] information to determine what treatments Americans can or cannot get," and "[t]hat's a decision we currently leave between a patient and his or her doctor."[45] And patient and pharmaceutical advocacy groups sought "to ensure that the final determination of what treatment option works best for each patient should be made by individuals and their physicians" and rejected the use of "centralized coverage and payment decisions or recommendations."[46]

These criticisms of value-based spending decisions all confuse access with subsidy. Allowing doctors to decide what medicines to prescribe shouldn't mean giving them — or the pharmaceutical industry — a blank check when it comes to payment. As the distinguished health economist Uwe Reinhardt put it, "[W]hy should health care be the only area in an economy in society where I have the right to say spend the limit, spend

[42] *See* Marion Danis, Marjorie Ginsburg & Susan Dorr Goold, *The Coverage Priorities of Disabled Adult Medi-Cal Beneficiaries*, 17 J. HEALTH CARE FOR POOR & UNDERSERVED 592, 595-96 (2006); Donald H. Taylor Jr., Marion Danis, S. Yousuf Zafar, Lynn J. Howie, Gregory P. Samsa, Steven P. Wolf & Amy P. Abernethy, *There Is a Mismatch Between the Medicare Benefit Package and the Preferences of Patients with Cancer and Their Caregivers*, 32 J. CLINICAL ONCOLOGY 3163, 3164-66 (2014).

[43] *See*, *e.g.*, Taylor et al., *supra* note 42, at 3166 (observing that beneficiaries often declined treatment options with substantial side effects).

[44] Jeff Moore, *Reform Worries Escalate,* DAILY ADVERTISER, Aug. 27, 2009.

[45] David Welna, *"Comparative Effectiveness" in Health Debated*, NPR (July 21, 2009, 12:17 AM) https://www.npr.org/templates/story/story.php?storyId=106828530 [https://perma.cc/ZLW7-FJ9P].

[46] Amy Lotven, *New Coalition Aims to Keep Cost Out of Comparative Effectiveness*, 11 INSIDE CMS 24, 24 (2008); *cf.* Sandt, *supra* note 18 ("Physicians should have the resources they need to develop the best treatment plans for their patients — without having to navigate additional complexities created by state pricing schemes.").

$5 million on me and let the taxpayer pick up the tab[?]"[47] Lawyers, architects, and mechanics all get to decide how they want to practice, but they and their clients do not get to send the public the bill.[48]

Other critics of valuing medicine instead deny opportunity costs, arguing that cutting out valueless spending can fund unlimited access to beneficial medicine. After rejecting the use of value-based limits in Medicaid, George H.W. Bush's General Counsel for the Department of Health and Human Services, Michael Astrue, asserted that such limits were unnecessary because states could instead cut "yuppie welfare," restrict medical malpractice suits, and set limits on gender-affirming procedures.[49] During debates over the ACA, opponents of valuing medicine argued that instead of valuing medicine, costs could be effectively contained by removing some mandated insurance benefits, eliminating (unnamed) regulations, permitting insurance purchase across state lines, and providing tax rebates for health savings accounts.[50] Others simply suggest that we should rely on free markets to work things out — sidestepping the fact that Medicare and other insurance programs necessarily involve government spending and regulation rather than market forces alone.[51] Still others have argued

[47] *Making Healthcare Work for American Families: Ensuring Affordable Coverage: Hearing Before the Subcomm. on Health of the H. Comm. on Energy & Com.*, 111th Cong. 67 (2009) (statement of Dr. Uwe Reinhardt, Professor, Princeton University) [hereinafter *Statement of Dr. Reinhardt*]. This point may be particularly persuasive to market-oriented policymakers. *See* Tyler Cowen, *Something's Got to Give in Medicare Spending*, N.Y. TIMES (June 13, 2009) https://www.nytimes.com/2009/06/14/business/economy/14view.html (explaining that "critics who contend that" comparative effectiveness research "amounts to 'rationing' or 'the government telling you which medical treatments you can have' are missing the point," because "[t]he motivating idea is the old conservative chestnut that not every private-sector expenditure deserves a government subsidy").

[48] *Statement of Dr. Reinhardt*, *supra* note 47 (observing that many expenditures are purely private).

[49] Michael J. Astrue, *Pseudoscience and the Law: The Case of the Oregon Medicaid Rationing Experiment*, 9 ISSUES L. & MED. 375, 384-85 (1994).

[50] Steven R. West, *Congress Shouldn't Practice Medicine*, TALLAHASSEE DEMOCRAT, Feb. 8, 2009, at 1B.

[51] *See* Press Release, Sen. John Cornyn, Competition Can Cut the Costs of Health Care (May 6, 2009), https://plus.lexis.com/api/permalink/4fafc1f0-846b-4e95-b659-174166e7b0be/?context=1530671(rejecting comparative effectiveness research on new treatments because "we can get better value for our health care dollars by creating more choices for patients through the free market").

that needed funds could be obtained by eliminating fraud and abuse.[52] Meanwhile, progressive advocates of single-payer health care have argued that "[b]efore we tell people they can't get the care they need," we must first eliminate administrative costs associated with private insurance.[53]

Even if wasteful spending could effectively be identified, agreed upon, and redirected to pay for expensive but beneficial medicine, society would still in short order face tradeoffs between spending on beneficial pharmaceuticals and other beneficial spending.[54] Tradeoffs — including health-health tradeoffs — are an inevitable result of refusing to set value-based limits: invariably, refusing to set value-based limits leads to limits being set in some other way. Sometimes, limits on drug coverage are based on cost alone rather than cost-effectiveness.[55] Or, limits are designed in ways that practically exclude patients who have less time or logistical expertise in navigating insurance denials.[56] At other times, entire groups of patients are categorically excluded from *all* drug coverage in order to control payers' cost exposure, often by the very same decision-makers who piously invoked vitalism to argue against value-based limits.[57] Even when patients are not categorically excluded from eligibility, they are often saddled with high premiums and out-of-pocket costs that degrade the quality of coverage.[58] These exclusions and

[52] *See* THE MILLER CENTER NATIONAL DEBATES: END OF LIFE CARE (2010) (reporting statements of Ken Connor, president of the Center for a Just Society and former attorney for Gov. Jeb Bush in the Terri Schiavo litigation).

[53] Kinsey Wilson, *Nobody Likes The R-Word: Rationing of Care Is Unpopular, But It's Happening Just the Same*, NEWSDAY, Apr. 22, 1993, at 45.

[54] *Id.* at 46 ("Even if we went to a one-payer system and saved $50 billion, which is an enormous political task, you'd offset the rise for only a year.").

[55] *See* Persad & Emanuel, *supra* note 22.

[56] *See* Michael Anne Kyle & Austin B. Frakt, *Patient Administrative Burden in the US Health Care System*, 56 HEALTH SERVS. RSCH. 755, 761 (2021).

[57] *E.g.*, Tom Church & Daniel L. Heil, *Medicare at 60 Would Have Harmful Unintended Consequences*, STAT NEWS (May 3, 2022), https://www.statnews.com/2022/05/03/medicare-at-60-would-have-harmful-unintended-consequences/ [https://perma.cc/5TCK-2AH5]; Nina Owcharenko Schaefer, *Why the Obamacare Medicaid Expansion Is Bad for Taxpayers and Patients*, THE HERITAGE FOUND. (Mar. 5, 2013), https://www.heritage.org/health-care-reform/report/why-the-obamacare-medicaid-expansion-bad-taxpayers-and-patients [https://perma.cc/58N2-BCZ4].

[58] *See infra* notes 260–265 and accompanying text.

high costs are far more prevalent in the United States, which largely does not use valuation of medicines, than in other high-income countries that use cost-effectiveness and other valuation tools more extensively.[59]

Moreover, even if payers genuinely faced no tradeoffs, their spending choices still create powerful incentives for pharmaceutical firms. Even if Medicare spending did not compete with other federal spending, for instance, how Medicare reimburses for drugs would still affect which drugs pharmaceutical companies choose to invest in developing.[60] The power of spending as an innovation incentive is often overlooked in debates over valuing medicine but illustrates that spending priorities affect societal outcomes.

Admirably, HHS's Final Rule on disability discrimination endorses quantitative comparison rather than rejecting it.[61] The Rule explicitly declines to prohibit federal funds recipients from engaging in quantitative assessments of how a treatment's costs compare to its medical benefits.[62] The Rule also recognizes opportunity costs, observing that "nondiscriminatory use of value assessment is an important tool for health care cost containment."[63]

B. Limiting Quantitative Comparison

In contrast to those who reject quantitative comparison among medicines, others are willing to accept value-based constraints but seek to establish guardrails on the consideration of value to avoid disadvantaging some patients or groups. One justification for limiting quantitative comparison among medicines takes the position that equity requires sameness: benefiting one patient should be treated the same as benefiting another, irrespective of magnitude or duration of benefit.[64] Another justification worries that because some disadvantaged patients are less likely to benefit from drugs than others,

[59] *Id.*

[60] *See* Hemel & Ouellette, *supra* note 28, at 521 n.11 and accompanying text.

[61] *Final Rule*, *supra* note 14, at 40103.

[62] *Id.* at 40101.

[63] *Id.* at 40103.

[64] *See infra* Part I.B.1.

valuing medicines in terms of their overall benefit will unfairly compound preexisting disadvantage.[65] It therefore seeks to set limits on which benefits should be considered when assessing value.

When considering concerns that valuing medicine will disadvantage some compared to others, it is crucial to consider both who would be disadvantaged and whether that disadvantage would be unfair. Valuing medicines will disadvantage drugmakers whose products produce less benefit. It may also disadvantage specific groups of patients: those for whom a specific drug or drug class is less cost-effective, or who are less likely to benefit from that drug or class. Neither drugmakers nor these groups of patients should be equated with, or treated as representing, the community of patients who have genuine equity complaints — whose health problems stem from societal inequities such as racism, poverty, or ableism.[66] Efforts to address health shortfalls stemming from societal inequities need not assist either drugmakers who produce drugs with little benefit in comparison to their cost, or patients who are not disadvantaged overall but merely less likely to benefit from certain drugs.

1. Sameness as Equity

Those who advance sameness-based objections often assert that because all lives are equally valuable, efforts to value medicines should not differentiate among treatments by considering the duration or quality of the additional time alive a medicine enables. Law professors Richard Revesz and Michael Livermore have taken this position in a co-authored book.[67] (Revesz's views are notable because, as of December 2024, he directs the federal government's Office of Information and Regulatory Affairs, a position Cass Sunstein — who endorses

[65] *See infra* Part I.B.2.

[66] *See* Dayna Bowen Matthew, *Structural Inequality: The Real Covid-19 Threat to America's Health and How Strengthening the Affordable Care Act Can Help*, 108 GEO. L.J. 1679, 1679 (2020) (describing "health equity" as "eliminating health disparities that grow out of persistently systemic inequality").

[67] RICHARD L. REVESZ & MICHAEL A. LIVERMORE, RETAKING RATIONALITY: HOW COST-BENEFIT ANALYSIS CAN BETTER PROTECT THE ENVIRONMENT AND OUR HEALTH 2 (2008).

considering duration and quality of life — previously held.[68]) Revesz and Livermore's focus is on risk regulation rather than pharmaceutical spending.[69] But their arguments are equally applicable to spending decisions, and critics of valuing medicine have essayed virtually identical defenses.[70]

Revesz and Livermore reject considering duration of benefit and quality of life in valuation decisions. They present their view as a disagreement with Michael Moore and Kip Viscusi, who argue that "the duration of life" should be considered when valuing the benefit of interventions, because "lives are extended, not permanently saved."[71] In Viscusi and Moore's view, interventions that extend life for longer are more valuable.[72] Viscusi and Moore's approach coheres with both common sense and medical practice — chemotherapies, for instance, are frequently assessed by their efficacy in extending survival.[73] Revesz and Livermore, by contrast, claim that considering duration of life is "inconsistent with economic theory and flatly contradicted by empirical data on how people value risk."[74] Revesz and Livermore adopt the premise that an intervention's value should reflect individuals' willingness to pay for it.[75] Accordingly, because some study respondents are equally willing to pay to preserve their future lifespan irrespective

[68] *See* Jonathan S. Gould, *Cost-Benefit Analysis in Polarized Times*, 75 ADMIN. L. REV. 695, 709-10 (2023).

[69] *See id.* at 726.

[70] *See* Ackerman, *supra* note 35; NCD REPORT, *supra* note 16, at 43.

[71] Michael J. Moore & W. Kip Viscusi, *The Quantity-Adjusted Value of Life*, 26 ECON. INQUIRY 369, 369-70 (1988); *cf.* Cass R. Sunstein, *Lives, Life-Years, and Willingness to Pay*, 104 COLUM. L. REV. 205, 208 (2004) ("No program literally 'saves' lives; life extension is always what is at issue. If the goal is to promote people's welfare by lengthening their lives, a regulation that saves five hundred life-years . . . is, other things being equal, better than a regulation that saves fifty life-years.").

[72] *See* Moore & Viscusi, *supra* note 71, at 370.

[73] FOOD & DRUG ADMIN., CLINICAL TRIAL ENDPOINTS FOR THE APPROVAL OF CANCER DRUGS AND BIOLOGICS: GUIDANCE FOR INDUSTRY 8 (2018), https://www.fda.gov/media/71195/download [https://perma.cc/4NRU-H75A] [hereinafter FDA].

[74] REVESZ & LIVERMORE, *supra* note 67, at 77.

[75] *Id.*

of its length, they conclude that we should value all lifesaving interventions identically, irrespective of duration of benefit.[76]

Revesz and Livermore's denial that duration of benefit matters has several major problems. First, it ignores how people comparatively value a shorter versus longer extension of their own lives. Even if seventy-year-olds are just as willing to pay to avoid death as thirty-five-year-olds are, we should also ask whether thirty-five-year-olds are willing to pay more to avoid dying at forty versus seventy, or indeed whether seventy-year-olds are willing to pay more to avoid dying at seventy-five versus ninety.[77]

Second, the societal importance of preventing a harm can be distinct from its subjective importance to potential victims.[78] For instance, psychological studies demonstrate the prevalence of hyperbolic discounting — choosing a dollar tomorrow over ten dollars next year.[79] But human vulnerability to hyperbolic discounting does not entail that society should hyperbolically discount.[80] Similarly, society need not prioritize extending the life expectancy of eighty-year-olds over extending the life expectancy of eighteen-year-olds merely because the former think more about impending death while the latter cavalierly discount risk.

Third, Revesz and Livermore's approach would convert measures of value into measures of wealth since older adults tend to be wealthier, and payments present a less intense tradeoff with basic needs as wealth

---

[76] *See id.* at 77-78; *accord* NCD REPORT, *supra* note 16, at 34 (asserting that "patients with a limited number of years left to live typically value a year much more highly").

[77] *See* Sunstein, *supra* note 71, at 214 ("[I]t would be astonishing if the welfare gain, to each of us, of ten more years of life were generally equivalent to the welfare gain of forty more years of life.").

[78] *See* T.M. Scanlon, *Preference and Urgency*, 72 J. PHIL. 655, 659-60 (1975).

[79] *See* Arden Rowell, *The Cost of Time: Haphazard Discounting and the Undervaluation of Regulatory Benefits*, 85 NOTRE DAME L. REV. 1505, 1508 n.6 (2010) ("[P]eople in fact exhibit what is called 'hyperbolic discounting,' meaning that they place a very high premium on goods they get immediately, and apply a steeply declining discount rate thereafter.").

[80] *Cf.* Cass R. Sunstein & Arden Rowell, *On Discounting Regulatory Benefits: Risk, Money, and Intergenerational Equity*, 74 U. CHI. L. REV. 171, 184 (2007) (explaining that if "people display hyperbolic discounting, treating the future as if it were worth very little, we might not want to use the resulting judgments for purposes of policy").

increases.[81] Ultimately, as Douglas Ginsburg (of the D.C. Circuit) and Christopher DeMuth put it when reviewing Revesz and Livermore's book, "Lives saved is not a gold standard; insisting that regulators ignore the years of life saved by their rules is not a rational high ground . . . and taking account of years saved is not 'antiregulation.'"[82] Rather, as DeMuth and Ginsburg suggest, lives and years saved should both be considered.[83]

Revesz and Livermore castigate consideration of duration of benefit as wrongly holding that "older people are less valuable than younger people."[84] But they are silent regarding what proper respect for the equal value of older and younger beneficiaries would require instead. One understanding of equal value might view extending a beneficiary's life for a year as equally important regardless of their age. But this understanding is fully compatible with considering duration of benefit.[85] Revesz and Livermore's conception of equal value therefore appears to require treating differently situated people identically. For instance, Revesz and Livermore's approach would regard averting the loss of an older adult's ten-year remaining lifespan as just as important as averting the loss of a young adult's fifty-year lifespan — even though losing fifty years of life is much worse than losing ten.[86] Valuing different-sized *benefits* differently is clearly distinct from valuing different *people* differently.

Professors Lisa Heinzerling and Frank Ackerman make a different argument: since murderers who deprive their victims of more life are not punished more, public policy should not consider duration of benefit.[87] This misses the mark. Murder is criminal because it involves

[81] *See* Sunstein, *supra* note 71, at 229.

[82] Christopher C. DeMuth & Douglas H. Ginsburg, *Rationalism in Regulation*, 108 MICH. L. REV. 877, 892 (2010).

[83] *See id.*; *see also* Sunstein, *supra* note 71, at 240-41.

[84] REVESZ & LIVERMORE, *supra* note 67, at 77.

[85] Moreover, there is an ethical case for prioritizing younger people even when expected duration of benefit is the same, because dying earlier in life is worse. *Cf.* Sunstein, *supra* note 71, at 220 n.56 ("[W]ho counts as the least well-off? In an important sense, young people fall in that category, because they have not yet had the opportunity to accumulate welfare . . . .").

[86] *See id.* at 215.

[87] *See id.* at 224.

intentional offense against another's fundamental rights. Punishing murder expresses moral disapproval of the murderer's violation of the social order.[88] By contrast, when murderers are sued civilly for wrongful death, compensation differs across victims based on their losses.[89]

Elsewhere, we recognize that sameness is not equity.[90] Health law is no different. We should reject the facile argument that fairness requires assigning the same value to every treatment that forestalls someone's death, and instead recognize that the value of treatments varies depending on how much benefit they produce and how much harm they risk.

Of course, that the size of benefits and harms matters does not mean that *only* size matters.[91] How badly off a patient or group would be without a drug can matter too. So could a drug's prospects of mitigating health inequities. Part III will discuss how valuing medicine can incorporate these and other factors.[92]

2. Not Compounding Disadvantage

In addition to the dubious claim that considering duration of benefit wrongly values people differently, Revesz and Livermore advance a subtly but importantly different critique: that considering duration of benefit will further disadvantage those who are already vulnerable.[93] To understand the basis for this concern, imagine an intervention that prevents immediate death for people whose remaining life expectancy, due to ill health, is only five years. Considering duration of benefit would regard providing this intervention as less valuable than delivering a lifesaving intervention to a population with a longer future life

[88] *See id.*

[89] *See id.* at 224-25.

[90] *E.g.*, U.S. DEP'T OF AGRIC. FARM SERVS. AGENCY, AO-1825, ADVANCING EQUITY AT FSA (2022), https://www.fsa.usda.gov/Internet/FSA_Notice/ao_1825.pdf [https://perma.cc/Q38V-Q643].

[91] *Cf.* Sunstein, *supra* note 71, at 213 (noting importance of distribution).

[92] *See infra* Part III.

[93] REVESZ & LIVERMORE, *supra* note 67, at 79 ("Adopting a life-years methodology would prevent some of the most vulnerable people in our society from being counted the same as everyone else . . . .").

expectancy. This may compound the existing disadvantage of people with short future life expectancies.

Revesz and Livermore also charge that if quality of life is measured using quality-adjusted life-years, "the lives of people with disabilities or chronic ailments will be systematically undervalued."[94] As with duration, Revesz and Livermore do not make clear what properly valuing — as opposed to "undervaluing" — outcomes for individuals would involve. One dimension of proper valuation, discussed in the next Subsection, may involve improving the accuracy of quality-of-life estimation.[95] But Revesz and Livermore may instead be pressing a more fundamental concern. When a patient genuinely has a lower baseline quality of life, QALY-based cost-effectiveness analysis assigns lower value to extending their life at that quality level: an extra decade at a quality of life of 0.7 produces only 7 QALYs of health benefit, whereas an extra decade in full health produces 10.[96] Yet, just as considering duration of benefit may appear unfair to those who face life-shortening disadvantage, considering quality of life may appear to unfairly render someone who already experiences poorer quality of life even worse off if their poorer quality of life is counted against them when considering the expected results of providing them a treatment.[97]

Properly assessing the charge that considering duration of benefit or quality of life will exacerbate disadvantage requires disentangling various factors that might diminish expected benefit. First, expected benefit might be diminished for patients further along in a finite human lifespan. Recognizing that someone's expected benefit is diminished because they have already lived longer neither compounds disadvantage nor injustice, because having lived longer is not a disadvantage and the finitude of human lifespan is not an injustice.[98] Second, expected benefit might be diminished by "bad luck in the 'natural lottery,'" rather than

---

[94] *Id.* at 146; *accord* NCD REPORT, *supra* note 16, at 66.

[95] *See infra* Part I.C.

[96] Arti Kaur Rai, *Rationing Through Choice: A New Approach to Cost-Effectiveness Analysis in Health Care*, 72 IND. L.J. 1015, 1050 (1997).

[97] *See id.*; Sunstein, *supra* note 71, at 219.

[98] *Cf.* Sunstein, *supra* note 71, at 220 ("Under the life-years approach, older people are treated worse for only one reason: They are older. This is not an injustice.").

social injustice.[99] Recognizing that bad luck may diminish expected benefit would compound disadvantage, but not injustice. Third, expected benefit might be diminished by the effects of social injustices a patient previously suffered.[100] Considering such a reduction in benefit would compound not merely disadvantage but injustice.[101]

This analysis illustrates differences between objections to valuing medicine raised on behalf of older adults, patients with rare diseases, people with disabilities, and marginalized minority communities. The association between having lived longer and diminished future benefit reflects neither disadvantage nor injustice: we would all prefer to live longer, even if the flip side is diminished future benefit. By contrast, associations between rare disease and diminished benefit reflect bad luck but not social injustice. Associations between identity-based marginalization and diminished benefit, meanwhile, reflect social injustice. Associations between disabilities and diminished benefit are ambiguous: some such associations involve the effects of structural ableism, whereas others are more like bad luck in the natural lottery.

Experts have recognized and grappled in different ways with concerns that value metrics compound injustice and disadvantage. Sunstein asserts that "[w]here demographic disparities in the welfare effects of regulatory policies are a product of background injustice, government is properly blocked from taking those disparities into account in formulating policy."[102] By this, Sunstein means that if injustice has limited someone's expected benefit from a regulation, government should ignore this fact and treat them as if they could fully benefit. By contrast, where people "have been dealt an unfortunate blow by fate" but not by social injustice, Sunstein argues that "government should take reasonable steps to ameliorate such blows" — but does not say that

[99] *Id.* at 223.

[100] *See id.* at 218; *see also* Govind Persad, *Considering Quality of Life While Repudiating Disability Injustice: A Pathways Approach to Setting Priorities*, 47 J.L., MED. & ETHICS 294, 302 (2019) [hereinafter Persad, *Considering Quality of Life*].

[101] Sunstein, *supra* note 71, at 218 (noting that unlike some other factors that produce differential benefit, racial "inequality reflects injustice"); *see also* Deborah Hellman, *Sex, Causation, and Algorithms: How Equal Protection Prohibits Compounding Prior Injustice*, 98 WASH. U.L. REV. 481, 513 (2020) (proposing a "moral obligation to avoid compounding injustice").

[102] Sunstein, *supra* note 71, at 218 (italics omitted).

such reasonable steps require ignoring all differences in expected benefit.[103]

One way to formalize Sunstein's effort to avoid compounding disadvantage resulting from injustice would substitute Standard Expected Years of Life Lost ("SEYLL") or Potential Years of Life Lost ("PYLL") for the actual years of life lost a medicine is expected to avert.[104] SEYLL uses the global highest average life expectancy at the age when the patient was treated, whereas PYLL could use the highest recorded human life expectancy.[105] So, for example, even though life expectancy is lower in poorer U.S. counties,[106] SEYLL and PYLL would not disadvantage patients from poorer counties based on their shorter post-treatment life expectancy when calculating the benefits of providing them an intervention. Post-treatment life expectancy is already typically calculated using population-level data that have similar effects to using SEYLL or PYLL: for instance, cost-effectiveness analyses of medical interventions do not generally differentiate post-treatment life expectancy by patients' income, even though income is a determinant of life expectancy.[107]

Meanwhile, Arti Rai suggests modifying cost-effectiveness analysis to exclude the effects of a candidate's "unrelated disability" that limits their overall post-treatment quality of life compared to a "person without that disability."[108] For instance, if a life-extending operation is equally likely to succeed for a newborn with Down Syndrome as for one

[103] *Id.* at 223.

[104] Dietrich Plass, Patsy Yuen Kwan Chau, Thuan Quoc Thach, Heiko J. Jahn, Poh Chin Lai, Chit Ming Wong & Alexander Kraemer, *Quantifying the Burden of Disease Due to Premature Mortality in Hong Kong Using Standard Expected Years of Life Lost*, 13 BMC PUB. HEALTH 1, 5 (2013).

[105] *Id.* at 2.

[106] Wendy Netter Epstein, *The Healthcare System Misnome*r, 82 OHIO ST. L.J. 779, 783 (2021) ("Between the richest and poorest counties in America, life expectancy can vary by as much as 30 years.").

[107] *Cf.* Sunstein, *supra* note 71, at 220 n.54 (considering the claim that valuing duration of benefit discriminates against groups that suffer life-shortening disadvantage, but concluding that "in practice, regulatory policies that focus on statistical life-years do not run into that problem, because they are too coarse-grained to discriminate in this fashion").

[108] Rai, *supra* note 96, at 1080.

without, Rai's approach would exclude any continuing quality of life impacts of Down Syndrome when valuing the operation's benefit.[109] In contrast, if chemotherapy would be less effective against one type of cancer, Rai's approach would include the harmful effects of uncured cancer when valuing the benefit of chemotherapy, because cancer is the very medical condition chemotherapy aims to treat.[110] Rai's approach separates an intervention's ability to extend life or improve quality of life from the effects of an unrelated disability on both baseline and post-treatment quality of life.[111] Part III will discuss an approach to valuing medicine — baseline-neutral CEA — that operationalizes Rai's suggested modification.[112]

When seeking a method of valuing medicines that best mitigates concerns about compounding disadvantage, it is important to remember that Revesz and Livermore's preferred valuation metric — the "value of a statistical life" ("VSL") — also risks compounding disadvantage. This is because disadvantage and subjection to injustice may also affect a patient's probability of survival, not just their expected duration of survival or their quality of life.[113] Eschewing consideration of duration or quality of life accordingly does not eliminate the possibility of disadvantaging those who are less likely to benefit.[114] Indeed, assigning the same value to "lifesaving" interventions irrespective of how much life is saved — as duration-insensitive methods like the VSL do — tends to systematically value extending the lives of older adults more than extending the lives of younger adults by the same amount.[115]

Moreover, while modifications to cost-effectiveness analysis like those discussed above can help avoid compounding disadvantage or injustice, completely avoiding such compounding is not an absolute

[109] *See id.* at 1080-81.

[110] *See id.* at 1082.

[111] *See id.* at 1082-83.

[112] *See infra* Part III.

[113] Rai, *supra* note 96, at 1082 (observing that the use of "survival rates" can disadvantage individuals who are less likely to survive).

[114] *Cf. id.* ("No matter what measure of health benefit is used . . . maximizing that benefit discriminates against individuals who lack the capacity to achieve that health benefit measure.").

[115] *See* Sunstein, *supra* note 71, at 219.

constraint ethically or legally.[116] Many legally permissible and ethically acceptable policies unavoidably compound the harmful effects of prior disadvantage and injustice. For instance, enforcing educational or experience requirements for jobs can disparately exclude disadvantaged candidates.[117] But these requirements can nonetheless be justified because better outcomes also matter — particularly when health and safety are at stake.[118] Similarly, recognizing that some people are less likely to benefit from treatments or interventions can be justifiable, even if their lower likelihood of benefit stems from prior disadvantage or injustice.[119]

Fairly valuing cure as opposed to palliation represents a scenario when compounding preexisting disadvantage can be justifiable. NCD's report criticizes cost-effectiveness analysis for "undervaluing" treatments that are purely palliative, rather than curative.[120] Yet curative treatments and those that enable long-term management can often be enormously more valuable than palliative ones: antiretroviral medications that forestalled the onset of AIDS following HIV infection, for instance, were enormously more valuable than earlier palliative approaches.[121] In order to incentivize manufacturers to cure or prevent painful and burdensome conditions like AIDS, not merely to palliate the

[116] *Cf.* Frances M. Kamm, *Deciding Whom to Help, Health-Adjusted Life Years and Disabilities*, *in* PUBLIC HEALTH, ETHICS, & EQUITY 225, 240 (Sudhir Anand, Fabienne Peter & Amartya Sen eds., 2005) (stating that it can sometimes be permissible to assign someone lower priority for a scarce resource on the basis that they are less likely to benefit, even when the lower likelihood reflects undeserved disadvantage).

[117] *E.g.*, Johnson v. City of Memphis, 770 F.3d 464, 478 (6th Cir. 2014).

[118] *E.g.*, *id.* (discussing the need for trained vehicle operators in order to ensure passenger safety).

[119] *See* DeMuth & Ginsburg, *supra* note 82, at 894; *cf.* Rai, *supra* note 96, at 1082 (rejecting an outcome under which "society would spend all its resources on a few individuals, produce relatively minimal benefit for those individuals, and ignore the claims of those individuals whose conditions could have been improved significantly"). *But see* Sunstein, *supra* note 71, at 218 (rejecting "a kind of vicious circle, in which disparities in welfare justify increased disparities in welfare, which in turn justify ever-increasing disparities in welfare").

[120] NCD REPORT, *supra* note 16, at 33.

[121] Steven R. Salbu, *The FDA and Public Access to New Drugs: Appropriate Levels of Scrutiny in the Wake of HIV, AIDS, and the Diet Drug Debacle*, 79 B.U. L. REV. 93, 102-11 (1999).

suffering they cause, we must value cure more highly than palliation alone — even if a cure will do little for those patients who are beyond cure and can only benefit from palliation.

C. Questioning Informational Accuracy

While Revesz and Livermore, the NCD, and others raise concerns that considering quality of life will compound disadvantage, many of these criticisms also hinge on concerns that quality of life assessments are inaccurate. Their criticisms primarily question the surveys used to develop quality of life assessments.

1. Survey Designs

Health-related quality of life is most often assessed using surveys.[122] These surveys ask respondents what burdens are associated with specific health conditions or infer their beliefs about burdens from answers to questions about tradeoffs.[123] These answers are then used to calculate the benefit of medical interventions that treat or prevent these conditions.[124]

One way to assess health-related quality of life is a "ratings scale approach, which asks interviewees to rate a particular state of health on a scale of 0 to 1, where being dead is valued at 0 and perfect health is valued at 1."[125] The most common such approach is the EQ-5D, which asks respondents to rate a condition along five different dimensions: mobility, usual activities, self-care, pain and discomfort, and anxiety and depression.[126] The most recent version of the EQ-5D, the EQ-5D-5L, provides five levels for each dimension: no, mild, moderate, severe, and extreme.[127] A respondent assessing how painful a condition is, for instance, could report "no," "mild," "moderate," "severe," or "extreme"

[122] See NANCY DEVLIN, DAVID PARKIN & BAS JANSSEN, METHODS FOR ANALYSING AND REPORTING EQ-5D DATA, at v (2020).

[123] See *id.* at vii.

[124] *Id.*

[125] Rai, *supra* note 96, at 1050.

[126] DEVLIN ET AL., *supra* note 122, at 2-6.

[127] *Id.* at 2.

pain.[128] EQ-5D results are then translated into health-related quality of life values ranging between 0 (death) and 1 (perfect health) by considering respondents', or the public's, relative preferences among health states.[129] These preferences can be elicited via the EQ-5D-VAS, which asks individuals to rate their own health on a visual analogue scale between 0 (worst imaginable health) and 100 (best imaginable health), or can be based on prespecified assessments of preferences among health states.[130]

Critiques of the EQ-5D and similar survey methods have charged that they do not clearly specify the meaning of each level; that respondents' answers are insufficiently reflective; that their answers are inconsistent over time; and that they overlook that the relative value of health states varies across environments.[131] Advocates of these surveys, by contrast, have argued that appropriately designed surveys are also tested for validity and designed to be insensitive to arbitrary factors.[132]

Alternatives to ratings scale approaches include the "[s]tandard gamble (what chance of death would the interviewee risk to avoid living in a particular diminished state of health)" and the "time trade-off (how many years of life would the interviewee give up to avoid living in that diminished health state)."[133] Tradeoffs could also be assessed using revealed preferences. If people select risky or costly medical procedures to address a medical condition, this indicates how much the condition worsens quality of life.

Though the EQ-5D and other approaches to measuring quality of life are imperfect, critiques that reject all such approaches miss the mark. For instance, neither the EQ-5D nor other methods of assessing health-related quality of life assess people's "life's worth" or compare the fundamental importance of different people.[134] Rather, these methods

[128] *Id.*

[129] *Id.* at 6.

[130] *See* DANIEL M. HAUSMAN, HOW HEALTH CARE CAN BE COST-EFFECTIVE AND FAIR 19 (2023).

[131] *See id.* at 19-21; *see also* NCD REPORT, *supra* note 16, at 67.

[132] *See* Anna Alexandrova, *Is Well-Being Measurable After All*, 10 PUB. HEALTH ETHICS 129, 133-35 (2017).

[133] Rai, *supra* note 96, at 1050.

[134] *Contra* NCD REPORT, *supra* note 16, at 25.

assess the value of interventions that help people attain or avoid certain health states.[135] For instance, if the health-related quality of life associated with severe chronic pain is 0.71, as chronic pain patients themselves report,[136] then an intervention that extends life by a year but causes severe chronic pain would have a value of only 0.71, whereas one that provides a chronic pain patient with an additional pain-free year would have a value of 1.

Likewise, metrics for assessing quality of life do not and need not presume that life with a disability is inherently worse than life without one.[137] Survey methods like the EQ-5D merely presume that if people in a given setting *report* that one health state is worse for them than another, then that health state is *in fact* worse for them.[138] A worse health state, however, need not be inherently worse. For instance, the genetic variation underlying sickle-cell trait is protective against malaria, potentially advantaging people in environments where malaria is prevalent, but occasionally causing painful complications during low-oxygen activities like mountain climbing.[139] Whether sickle-cell trait is worse for someone depends on their environment. In recognition of the fact that health states' effect on health-related quality of life can differ across settings, some have developed country-specific or setting-specific assessments of how health states translate into quality-of-life outcomes.[140]

---

[135] *See* DEVLIN ET AL., *supra* note 122, at 6, 61-86.

[136] Pekka Vartiainen, Tarja Heiskanen, Harri Sintonen, Risto P. Roine & Eija Kalso, *Health-Related Quality of Life and Burden of Disease in Chronic Pain Measured with the 15D Instrument*, 157 PAIN 2269, 2272 (2016).

[137] *See* NCD REPORT, *supra* note 16, at 39.

[138] DEVLIN ET AL., *supra* note 122, at 6.

[139] *See* Kimani Paul-Emile, *The Regulation of Race in Science*, 80 GEO. WASH. L. REV. 1115, 1139-40 (2012).

[140] *See, e.g.*, Romina A. Tejada, Luz Gibbons, María Belizán, Ericson L. Gutierrez, Nora Reyes & Federico Ariel Augustovski, *Comparison of EQ-5D Values Sets Among South American Countries*, 26 VALUE HEALTH REG'L ISSUES 56, 59 (2021), https://doi.org/10.1016/j.vhri.2021.02.001 [https://perma.cc/K344-N7HU] (describing the use of "local value sets" that reflect local population preferences regarding health states).

Similarly unconvincing is the claim that "disability's impact on quality of life being reduced to a series of five numbers" is "dehumanizing."[141] The EQ-5D does not assess how disability affects quality of life; it addresses the narrower question of how *health states* affect *health-related* quality of life.[142] While translating qualitative experience into numbers is necessarily imperfect, it is no more dehumanizing than asking an injured patient to rate their pain on a numerical scale, or calculating pain and suffering damages for an injured plaintiff.

In sum, merely using a survey design like the EQ-5D does not inherently disregard disability or other discrimination considerations. While surveys like the EQ-5D should be regularly evaluated for their validity, ease of use, and other desirable characteristics, assessing whether people value or wish to avoid a certain health state is a legitimate form of information elicitation.

2. Participant Selection

Whether surveys, revealed preferences, or other methods are used to measure the value of health states, we must also determine *whose* responses count. Some have argued that valuing health states should proceed via representative surveys of the general public.[143] Because the public comprises individuals with different backgrounds, perspectives, and health conditions, combining their perspectives may provide a better sense of a health state's average value.[144] Additionally, considering public preferences can align policies with societal values.[145] In this view, decisions about the societal value of medicines are fundamentally public decisions, akin to determining minimum wage levels or the scope of publicly funded insurance programs.

Others have argued, however, that assessments of the value of health states are more akin to expertise-based judgments — like making a

---

[141] *Contra* NCD Report, *supra* note 16, at 28.

[142] DEVLIN ET AL., *supra* note 122, at 1-22.

[143] *See* Gert Helgesson, Olivia Ernstsson, Mimmi Åström & Kristina Burström, *Whom Should We Ask? A Systematic Literature Review of the Arguments Regarding the Most Accurate Source of Information for Valuation of Health States*, 29 QUALITY LIFE RSCH., 1465, 1466 (2020).

[144] *See id.* at 1479-80.

[145] *See id.* at 1479.

medical diagnosis — than political judgments.[146] Viewing value assessments this way requires determining who counts as an expert about the value of a health state. Potential experts include: (1) patients currently in that health state; (2) people who have experienced that health state; (3) medical professionals; and (4) caregivers.

Advocacy groups sometimes contend that people who currently have a medical condition have the most — or even *only* — accurate perspectives on the quality of life associated with that condition. HHS, for instance, asserted that "persons without disabilities systematically undervalue the quality of life of those with disabilities."[147] On this view, lived experience of a condition provides unique access to the health-related quality of life associated with being in that condition. Asking the general public to assess health-related quality of life associated with a condition would be like asking them to describe someone's experience of seeing their child take their first steps — it would overlook the special access I have to that information.

Using *only* reports by current patients, however, sweeps too broadly.[148] A patient's situation provides them a distinctive perspective on that situation, but it does not make them its exclusive arbiter. Analogously, Americans have a distinctive experience of quality of life in the United States but are not the only qualified arbiters. Their experience gives them a particular vantage point, producing both privileged access to information and vulnerability to bias. Cross-country comparisons accordingly typically consider multiple factors, including ones that may diverge from the subjective experience of people within a country: someone considering relocation might assess quality of life in a candidate destination by considering whether rights or opportunities

[146] *See id.* at 1467.

[147] DEP'T OF HEALTH AND HUM. SERVS., HHS NEWS RELEASE ¶ 31,778 (1992) [hereinafter HHS NEWS RELEASE]; *cf.* REVESZ & LIVERMORE, *supra* note 67, at 90 ("QALY surveys underestimate the quality of life of people with disabilities and health problems."); Buccafusco & Masur, *supra* note 28, at 1425 ("Because healthy people focus on becoming unhealthy rather than being unhealthy . . . they tend to overestimate both the magnitude and duration of negative experiences." (italics omitted)).

[148] *Cf.* Samuel R. Bagenstos & Margo Schlanger, *Hedonic Damages, Hedonic Adaptation, and Disability*, 60 VAND. L. REV. 745, 776 (2007) ("Neither people with nor those without disabilities have epistemic access to the 'true' enjoyment of life with a disability.").

they greatly value would be more, less, or equally available.[149] Additionally, it is challenging to separate claims about policy from factual descriptions of health states. People who live near a park may have the most relevant lived experience of that park. But their estimates of the park's value are likely also skewed upward by their personal stake in ensuring that the park is preserved. The same may be true when value estimates are known to be relevant to health policy.[150]

Innovations in psychology could improve assessment of how treatments affect health-related quality of life. Christopher Buccafusco and Jonathan Masur argue that "the best way to measure a drug's effect on well-being is to follow the practices of hedonic psychology by surveying people who are taking the drug and asking them how they are feeling."[151] They propose using experience sampling methods to track individual responses to questions about the positive and negative emotions people taking the drug are experiencing.[152] They also observe that similar approaches have been used to "explore patients' experiences with different treatments for breast cancer, kidney transplants, and ADHD."[153]

Another compelling source of expertise is people who previously had a medical condition but now no longer have it.[154] These respondents can draw on a broader set of experiences, since they have knowledge of life both with and after the condition. However, even this group is fallible. Consider someone who previously lived in one country and has moved to another. People forget what life was like in their old country, and their experiences in their new country shape their assessment of their former life.[155]

---

[149] *Cf.* AGNES CALLARD, ASPIRATION: THE AGENCY OF BECOMING 58-59 (2018) (describing how someone might come to understand what it is like to have an experience through reading texts about that experience).

[150] *See* Helgesson et al., *supra* note 143, at 1479.

[151] Buccafusco & Masur, *supra* note 28, at 1421-22.

[152] *Id.*

[153] *Id.* at 1423.

[154] Nir Eyal, *Measuring Health-State Utility via Cured Patients*, *in* DISABILITY, HEALTH, LAW, AND BIOETHICS 266, 269 (I. Glenn Cohen, Carmel Shachar, Anita Silvers & Michael Ashley Stein eds., 2020).

[155] CALLARD, *supra* note 149, at 149-56.

Medical professionals and caregivers are another source of information. Medical professionals have distinctive knowledge about how their patients' conditions evolve over time.[156] If health states are valued in terms of their effect on capabilities or opportunities rather than how they affect subjective well-being, professionals may have particularly relevant insight.[157] Caregivers, who typically spend far more time with patients than medical professionals do,[158] are another potential source of expertise. Professionals, however, have their own biases,[159] while non-professional caregivers lack physicians' professional expertise. And both lack current and prior patients' introspective access to the felt experience of life in the condition itself.

Subject selection is more legally constrained than survey design. If surveys unreasonably fail to accommodate, or disproportionately exclude, specific legally protected groups, such as patients with certain disabilities or racial and ethnic minority communities, this can violate antidiscrimination law.[160] But because disabilities and chronic conditions are highly prevalent in the general population,[161] a well-designed survey of the general public or of patients will comprise many people with disabilities. The broad prevalence of disability illustrates the error in claims that when public preferences are used, "the utility values used to describe the extent to which a disability impacts quality

[156] *See* HAUSMAN, *supra* note 130, at 20.

[157] *Id.* ("Members of the population at large know much less than sociologists and health professionals about how health states bear on opportunities and on well-being.").

[158] *Cf.* Martin McElligott, *A Balanced Approach to A Growing Problem: How Congress Can Keep Roads Safe and the Elderly Population Happy*, 23 ELDER L.J. 191, 207 (2015) (observing that family caregivers "are able to observe behavior all day, and may notice things that a doctor does not in their short visits").

[159] Lisa I. Iezzoni, Sowmya R. Rao, Julie Ressalam, Dragana Bolcic-Jankovic, Nicole D. Agaronnik, Karen Donelan, Tara Lagu & Eric G. Campbell, *Physicians' Perceptions of People with Disability and Their Health Care*, 40 HEALTH AFFS. 297, 298 (2021).

[160] *See, e.g.*, Jennifer S. Bard, *Lifting the Barriers Excluding People Living with Disabilities from the Benefits of Inclusion in Research Studies*, 6 U. PA. J.L. & PUB. AFFS. 489, 528 n.177, 559 (2021) (discussing the possibility of lawsuits seeking inclusion in surveys); David C. Hadorn, *The Problem of Discrimination in Health Care Priority Setting*, 268 JAMA 1454, 1455-56 (1992) (raising concerns that disabled respondents were disproportionately excluded from Oregon's survey of health condition priority).

[161] *See* Bard, *supra* note 160, at 498.

of life are derived from people without disabilities."[162] Over half of American adults have at least one chronic condition, and around a quarter identify as disabled.[163] To be sure, public values are derived from people who may not have the *exact same* health condition. But every patient's experience of disease is unique, making it unworkable to limit respondents to those with the "exact same" condition.

Even when law requires reasonable inclusion, it does not require *only* surveying patients who currently have a specific medical condition. Indeed, doing so would disproportionately exclude other groups who have a legitimate claim to be heard. A legally preferable approach would be to consider both the views of a representative sample of the public and the views of groups with distinctive expertise, including current patients, former patients, medical professionals, and caregivers.

3. Non-Survey Methods

Surveying patients can sometimes be impractical. Some pediatric conditions affect infants who cannot complete surveys.[164] Other conditions may preclude survey completion in adults.[165] One alternative to surveying patients is to have proxies complete surveys like the EQ-5D.[166] Another approach, however, could also be used, both in these situations and more generally. Rather than seeking to measure patients' actual or predicted subjective well-being, assessment could seek to understand how health conditions affect patients' capabilities and opportunities. Experts are working to create lists of health capabilities and understand how different conditions affect health capabilities.[167]

[162] NCD REPORT, *supra* note 16, at 33.

[163] Peter Boersma, Lindsey I. Black & Brian W. Ward, *Prevalence of Multiple Chronic Conditions Among US Adults, 2018*, 17 PREVENTING CHRONIC DISEASE 1, 2 (2020); *Prevalence of Disability and Disability Types by Urban-Rural County Classification — United States, 2016*, CTRS. FOR DISEASE CONTROL & PREVENTION (Oct. 27, 2021), https://www.cdc.gov/ncbddd/disabilityandhealth/features/disability-prevalence-rural-urban.html [https://perma.cc/GHV2-74TE].

[164] Researchers, have, however, created a version of the EQ-5D adapted for youth respondents, the EQ-5D-Y. *See* DEVLIN ET AL., *supra* note 122, at 100.

[165] *Id.* at 2-3.

[166] *Id.*

[167] Jennifer Prah Ruger, *Health Capability: Conceptualization and Operationalization*, 100 AM. J. PUB. HEALTH 41, 46-47 (2010); *see* Marion Coste, Mouhamed Ahmed Badji,

Survey approaches and capability approaches map onto the established theoretical categories of *preference-based* and *objective list* definitions of well-being.[168] Surveys elicit preferences, whereas capability approaches assess how health states affect a predefined capability list. Some have suggested that future neuroscience may allow for direct assessments of pleasure and pain, operationalizing the third commonly proposed definition of well-being: hedonism.[169]

Non-survey methods are also crucial to quantifying medicines' life-extending benefits. Patients have no special knowledge of their future lifespan: how long someone is expected to live can more readily be assessed from the outside than can their health-related quality of life. [170] Comparisons of the life-extending outcomes of medical interventions accordingly rely on clinical trials or observational studies, rather than surveys.[171]

II. LEGAL CONSTRAINTS ON VALUING MEDICINE

Legal limitations on the use of cost-effectiveness analysis in American health policy have targeted the quality-adjusted life-year ("QALY"). The QALY seeks to quantify medical interventions' contribution to two core goals: helping people to live longer lives and helping them live healthier lives.

Medicine's ability to lengthen lives can be expressed in terms of life-years ("LY") gained.[172] But living longer is not all that matters. We also

Aldiouma Diallo, Marion Mora, Sylvie Boyer & Jennifer J. Prah, *Applying the Health Capability Profile to Empirically Study Chronic Hepatitis B in Rural Senegal: A Social Justice Mixed-Methods Study Protocol*, 12 BMJ OPEN 1, 4 (2022).

[168] *See* Matthew D. Adler, *Expressive Theories of Law: A Skeptical Overview*, 148 U. PA. L. REV. 1363, 1464 (2000) ("Views of well-being can be divided into the following categories: (a) preference-based views; (b) hedonic views; (c) objective-list views; and (d) mixed views.").

[169] *See* Adam J. Kolber, *The Experiential Future of the Law*, 60 EMORY L.J. 585, 608-09 (2010).

[170] *Cf.* DeMuth & Ginsburg, *supra* note 82, at 894 ("To measure regulatory benefits by lives saved or life years saved is to deal with, in principle, objective facts," whereas "valuing benefits by the quality of years saved . . . is to introduce an irreducible element of subjectivity.").

[171] *E.g.*, FDA, *supra* note 73, at 7.

[172] *See* DeMuth & Ginsburg, *supra* note 82, at 891, 894.

prefer medicines that better counteract the painful or restrictive effects of disease, and that have fewer burdensome side effects.[173] These outcomes can be described as improved post-treatment quality of life ("QoL").

The QALY summarizes an intervention's overall benefit by multiplying its lifespan-extending benefits by recipients' average quality of life during their post-treatment lifespan.[174] Imagine two treatments that each extend life for a decade. Patients who receive the first treatment experience only eighty percent of full health during that additional decade, due to drug side effects or incomplete treatment efficacy against the underlying condition. The first treatment thus adds ten LYs but only eight QALYs. In contrast, the second treatment has fewer side effects or more effectively treats the underlying condition and so enables the additional decade to be lived in full health, adding ten QALYs.

QALYs can be used to assess the comparative effectiveness of two medications without regard to cost: a treatment is comparatively more effective when it delivers more benefit in QALY terms. Commonly, however, QALYs are used in cost-effectiveness calculations.[175] If a course of the first treatment costs $80,000, it will have a cost-effectiveness of $10,000/QALY. In contrast, at the same price, the second treatment's cost-effectiveness will be better at $8,000/QALY.

QALYs are commonly considered in other national health systems.[176] By contrast, their use in American health policy has been more controversial, yet not categorically foreclosed. This Part discuss four areas where restrictions on QALYs' use, sometimes spilling over to

[173] *See, e.g.*, Rosado v. Semple, No. 3:20-CV-1908 (JAM), 2022 WL 673275, at *1 (D. Conn. Mar. 6, 2022) (explaining that newer medications for treating Hepatitis C virus "work more quickly, cause fewer side effects, and treat chronic HCV more effectively").

[174] *See* Rai, *supra* note 96, at 1050.

[175] *See id.* at 1052.

[176] *See id.* at 1051 n.149; Steven Morgan, *Summaries of National Drug Coverage and Pharmaceutical Pricing Policies in 10 Countries: Australia, Canada, France, Germany, the Netherlands, New Zealand, Norway, Sweden, Switzerland and the U.K.* at 2 (The Commonwealth Fund, Working Paper, 2016), https://www.commonwealthfund.org/sites/default/files/2018-09/Steven%20Morgan%2C%20PhD_Ten%20Country%20Pharma%20Policy%20Summaries_2016%20Vancouver%20Group%20Meeting.pdf [https://perma.cc/NH6C-9FU2].

other forms of cost-effectiveness analysis, currently exist or have been proposed: in Medicaid programs; as part of the Affordable Care Act; and in post-ACA federal and state laws. Rather than categorically prohibiting cost-effectiveness analysis, present policies have emphasized concerns that QALY-based cost-effectiveness analysis could exacerbate unfair disadvantage under certain circumstances.[177] Some proposals not yet adopted, however, would prohibit the use of QALYs and other forms of cost-effectiveness analysis more broadly.[178]

A. Medicaid

In 1987, Oregon proposed using cost-effectiveness analysis in its Medicaid program. Oregon's efforts sought to deploy limited Medicaid funds to cover uninsured patients and realize more population health benefits.[179] In order to rank interventions for inclusion, Oregon collected information about clinical effectiveness and cost from professionals.[180] In addition, Oregon collected public input on the effects of various health conditions via hearings and a telephone survey and conducted focus groups around the state to identify health values.[181] Based on this input, Oregon then created a prioritized list of seventeen general categories of treatment.[182]

HHS rejected Oregon's initial plan, claiming that its ranking of treatments unacceptably took the position that "the value of the life of a person with a disability is less than the value of the life of a person without a disability."[183] HHS insisted that "the rankings of

[177] *See infra* Parts II.B, II.C.

[178] *See infra* Part II.D.

[179] BOB DIPRETE & DARREN COFFMAN, A BRIEF HISTORY OF HEALTH SERVICES PRIORITIZATION IN OREGON 1 (2007), https://www.oregon.gov/oha/HPA/DSI-HERC/Documents/Brief-History-Health-Services-Prioritization-Oregon.pdf [https://perma.cc/KYY2-LYMQ].

[180] *Id.* at 2.

[181] *Id.*

[182] *Id.* at 3-4.

[183] Timothy B. Flanagan, *ADA Analyses of the Oregon Health Care Plan*, 9 ISSUES L. & MED. 397, 410 (1994) [hereinafter *HHS Analysis*].

condition/treatment pairs should be redone without using rankings derived from the telephone survey as a starting point."[184]

As Part I.C.2 discussed, surveys of public values and preferences should not unfairly exclude specific groups, including people with disabilities.[185] Ethically, Oregon's survey should have better included respondents with disabilities. But categorically excluding public input due to potential bias — as HHS's response proposes — would be both ethically mistaken and unsupported by law. For instance, it would prohibit benefit designs based on deliberative engagement with Medicaid or Medicare beneficiaries regarding their preferred benefit package.[186] Such a prohibition would not serve the interests of patients with disabilities and would likely disserve the interests of other marginalized patients. Antidiscrimination law, meanwhile, ensures that the process of participation does not discriminatorily exclude participants and that laws adopted after public participation do not unjustly discriminate.[187] But it does not foreclose the use of public deliberation as an input into the development of laws, or exclude deliberators on the basis that their beliefs and values may reflect bias.[188]

HHS also raised what Part I called concerns about *compounding disadvantage*: that the use of QALYs would unjustly disadvantage people with preexisting disabilities.[189] HHS argued that the way that Oregon's Medicaid program considered "quality of life" and "ability to function" would unacceptably "place importance on 'restored' health and functional 'independence' and thus expressly value a person without a

[184] *Id.* at 411.

[185] *See infra* Part I.C.2.

[186] *E.g.*, Danis et al., *supra* note 42, at 595-96; Taylor et al., *supra* note 42, at 3164-66.

[187] *Cf.* Schuette v. Coal. to Def. Affirm. Action, Integration & Immigrant Rights & Fight for Equal. by Any Means Necessary, 572 U.S. 291, 313 (2014) (plurality opinion) (explaining that "when hurt or injury is inflicted on racial minorities by the encouragement or command of laws or other state action, the Constitution requires redress by the courts").

[188] *Cf. id.* at 312 (rejecting the proposition that "a difficult question of public policy must be taken from the reach of the voters, and thus removed from the realm of public discussion, dialogue, and debate"); *id.* at 334 (Breyer, J., concurring) ("[T]he Constitution foresees the ballot box, not the courts, as the normal instrument for resolving differences and debates . . . .").

[189] *See infra* Part I.

disability more highly than a person with a disability in the allocation of medical treatment."[190]

While HHS raised concerns about valuation approaches that would disadvantage people with preexisting disabilities, it did not reject consideration of treatment efficacy. Rather, HHS conceded that Medicaid programs may consider factors including, but not limited to, "cost of medical procedures, the length of hospital stays, prevention of death, and prevention of contagious diseases."[191] In addition, HHS's comments permitted consideration of treatments' success more generally. What HHS viewed as unacceptable was deciding not to "cover a treatment based entirely on the existence of a disabling condition, where similarly situated individuals without that condition would receive treatment."[192] In contrast, if a Medicaid program could identify a difference in success among treatments or conditions, candidates would not have been similarly situated, so prioritization based on success would have been allowed. For instance, coverage prioritization decisions for liver transplants could "be made based on an appropriate record," such as "the principles followed by Medicare for the coverage of liver transplants, namely, that coverage in the case of alcoholic cirrhosis is conditioned on evidence of sufficient social support to assure assistance in alcohol rehabilitation."[193] This evidence-based prioritization would be acceptable even if the social support requirement compounded disadvantage for individuals with alcoholism.[194]

In permitting differential treatment of individuals based on expected treatment effectiveness, HHS rejected more limiting interpretations of disability law that would categorically prohibit consideration of treatment outcomes.[195] Max Mehlman, for instance, asserts that "[i]f the

[190] Flanagan, *supra* note 183, at 411.

[191] *Id.*

[192] *Id.* at 411-12.

[193] *Id.* at 412.

[194] *See* Kelsey N. Berry, Norman Daniels & Keren Ladin, *Should Lack of Social Support Prevent Access to Organ Transplantation?*, 19 AM. J. BIOETHICS 13, 21 (2019).

[195] *Cf.* Rai, *supra* note 96, at 1092 ("Capacity to benefit hardly seems an unreasonable qualification for obtaining medical care. . . . Medical practice has recognized this reality — the routine medical use of such outcomes measures as survival rates depends on the assessment of capacity to benefit according to that measure. Moreover, there is no

anti-disability discrimination laws mean anything, they mean that a treatment that is provided to someone who will not be disabled after treatment cannot be denied to someone who will be disabled."[196] Mehlman's interpretation implies that if a serious health condition (e.g., cancer) constitutes a legal disability, then a treatment expected to cure that condition in some patients must also be offered to other patients for whom it will have limited or no efficacy.[197] Likewise troubling, Mehlman's interpretation implies that a treatment must be offered irrespective of whether it will cause patients to develop a new, undesired health condition that constitutes a disability. HHS's approach, in contrast, permitted considering whether a treatment will cause or treat a medical condition that constitutes a disability, while excluding consideration of a patient's preexisting disability that does not affect treatment success.[198]

Notably, HHS never formalized its position via rulemaking, nor was its position tested in court. Rather, Oregon chose to revise its plan, removing the public input component and relying solely on expert judgments to determine priorities.[199] The list was then updated via legislative negotiations.[200]

Oregon's plan secured enough support to ultimately be adopted, commanding allegiance from many who believed it served the public interest even if it might be worse for certain groups.[201] And the Oregon

evidence that Congress, in enacting the disability laws, intended to invalidate the routine medical use of such outcomes measures.").

[196] Maxwell J. Mehlman, Melvyn R. Durchslag & Duncan Neuhauser, *When Do Health Care Decisions Discriminate Against Persons with Disabilities?*, 22 J. HEALTH POL., POL'Y & L. 1385, 1396 (1997).

[197] *Contra* Rai, *supra* note 96, at 1082 (advocating for permitting policy to consider the differences "between a type of cancer that is more amenable to treatment and a type that is less amenable").

[198] *Cf. id.* at 1083 (explaining that "disabled persons would have the same access to lifesaving measures as nondisabled people *so long as* the disability did not affect the medical efficacy of the intervention" (emphasis in original)).

[199] DIPRETE & COFFMAN, *supra* note 179, at 4.

[200] *Id.*

[201] *E.g.*, Timothy Egan, *Oregon Seeks to Revive Health Care "Rationing" Plan*, N.Y. TIMES, Aug. 14, 1992, at A17 (explaining that "some groups representing the disabled in Oregon strongly support the health plan, saying it will ultimately benefit more people with disabilities than it will harm" and reporting statements from two such groups);

plan, in modified form, is still in use today.[202] The regulatory roadblocks and interest group opposition Oregon's plan faced, however, may have had a broader chilling effect. No other state has attempted an overall design of its Medicaid coverage based on value to patients.[203]

B. The Affordable Care Act

The Affordable Care Act returned debates over cost-effectiveness to the fore. Political critics of the ACA raised the specter of cost-effectiveness considerations leading to "rationed" health care.[204] As with Oregon's plan, influential interest groups lobbied against the use of quality-adjusted life-years.[205]

Some distinguished commentators have overread the ACA to categorically bar consideration of cost-effectiveness.[206] This misreading

Editorial, *Give Oregon Health Plan a Chance*, N.Y. TIMES, Aug. 22, 1992, § 1, at 20 (questioning HHS's allegations of discrimination and concluding that "Oregon, faced with tight budgets and no national health reform in sight, made a hard, honorable choice"); Editorial, *Oregon's Plan Deserved Waiver*, SEATTLE POST-INTELLIGENCER, Aug. 5, 1992, at A14 ("Denying the waiver was a mistake and a failure of leadership.").

[202] *See* DIPRETE & COFFMAN, *supra* note 179, at 6-7.

[203] *See* Teresa A. Coughlin & Stephen Zuckerman, *State Responses to New Flexibility in Medicaid*, 86 MILBANK Q. 209, 221 (2008).

[204] *See* Elizabeth Weeks Leonard, *Death Panels and the Rhetoric of Rationing*, 13 NEV. L.J. 872, 872-87 (2012).

[205] Leah Z. Rand & Aaron S. Kesselheim, *Controversy Over Using Quality-Adjusted Life-Years in Cost-Effectiveness Analyses: A Systematic Literature Review*, 40 HEALTH AFFS. 1402, 1403 (2021) ("[I]n the face of intense lobbying, the Affordable Care Act was amended to include language that prohibited the use of QALYs to set thresholds for determining coverage or reimbursement of health care."); *see also* Kavita Patel, *Health Reform's Tortuous Route to the Patient-Centered Outcomes Research Institute*, 29 HEALTH AFFS. 1777, 1777-81 (2010).

[206] *E.g.*, Amitabh Chandra, Anupam B. Jena & Jonathan S. Skinner, *The Pragmatist's Guide to Comparative Effectiveness Research*, 25 J. ECON. PERSPS. 27, 28 (2011) ("Congress explicitly forbade the use of cost-effectiveness analysis in government programs."); Barry R. Furrow, *Cost Control and the Affordable Care Act: CRAMPing Our Health Care Appetite*, 13 NEV. L.J. 822, 853 (2013) (claiming that the ACA "appears to explicitly block study of a treatment's cost-effectiveness"); Neel U. Sukhatme & Maxwell Gregg Bloche, *Health Care Costs and the Arc of Innovation*, 104 MINN. L. REV. 955, 989 (2019) (discussing "[t]he ACA's proscription against developing cost-effectiveness measures that take life-expectancy and quality-of-life gains into account").

made its way into the background to HHS's recent proposed rule.[207] The reality is more nuanced. As this Section will explain, the ACA restricts certain uses of cost-effectiveness while permitting many others — including the use of QALYs. It aimed to ensure that people with disabilities *unrelated* to the treatments they sought were not disadvantaged in accessing treatments on the basis of those unrelated disabilities.[208] The ACA explicitly permits consideration of whether health conditions affect treatment effectiveness and whether a treatment might cause new health conditions, including when those conditions constitute disabilities.[209]

More generally, the ACA and other federal health statutes repeatedly recognize cost-effectiveness and quality of life as legitimate health policy aims. Community health teams, for instance, have the delivery of cost-effective medical care as one of their objectives,[210] as do health centers.[211] Likewise, the Preventive Services Task Force is directed to consider cost-effectiveness when making recommendations for preventive services.[212] The Agency for Health Research and Quality is empowered to fund cost-effectiveness research.[213] Other federal funding programs are similarly directed to consider cost-effectiveness as a

[207] Discrimination on the Basis of Disability in Health and Human Service Programs or Activities, 88 Fed. Reg. 63392, 63409 (Sept. 14, 2023) (to be codified at 45 C.F.R. pt. 84).

[208] *Cf.* Rai, *supra* note 96, at 1081 (discussing relatedness requirement).

[209] *See infra* notes 210–211 and accompanying text; *see also* Govind Persad, *Priority Setting, Cost-Effectiveness, and the Affordable Care Act*, 41 AM. J.L. & MED. 119, 132 (2015).

[210] 42 U.S.C. § 256a-1(c)(6)(D).

[211] *Id.* § 254b(c)(1)(E).

[212] *Id.* § 299b-4(a)(1); *see also id.* § 280g-10(a) (describing cost-effectiveness mission of the Community Preventive Services Task Force).

[213] *Id.* § 299 ("The Agency shall promote health care quality improvement by conducting and supporting research that develops and presents scientific evidence regarding all aspects of health care, including . . . the outcomes, effectiveness, and cost-effectiveness of health care practices."); *id.* § 299b-1 (explaining that AHRQ is to support "[t]he conduct of research on the comparative effectiveness, cost-effectiveness, and safety of drugs, biological products, and devices"); *id.* § 299b-4 (stating that the Preventive Services Task Force "shall review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations"); *id.* § 299b-5 (directing the AHRQ Director to consider "costs, benefits, and cost-effectiveness").

relevant objective.[214] Patient well-being and quality of life are likewise relevant objectives for various health law programs, including programs created by the ACA.[215]

The ACA created the Patient-Centered Outcomes Research Institute ("PCORI"), a government-funded nonprofit organization intended to research the effectiveness of treatments.[216] In a section titled "Limitations on Certain Uses of Comparative Clinical Effectiveness Research," the ACA establishes guardrails on how HHS can draw on information generated by PCORI, including cost-effectiveness information.[217] It prohibits the Secretary from using "evidence or findings from comparative clinical effectiveness research" conducted by PCORI in determining "coverage, reimbursement, or incentive programs" under the Medicare statute, "in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill."[218] Put in simpler terms, when

[214] *E.g.*, *id.* § 285b-7a (directing National Heart, Lung, and Blood Institute to evaluate "the development of safe, efficient, and cost-effective diagnostic approaches"); *id.* § 285c-5 (directing National Institute of Diabetes and Digestive Kidney Diseases to evaluate "model programs for cost effective and preventive patient care"); *id.* § 290bb-7 (prioritizing the use of "evidence-based and cost-effective methods" by grant applicants); *id.* § 300x-1 (explaining that states receiving mental health grants must explain how "cost-effectiveness" will be realized); *id.* §§ 300ff-12–300ff-23 (requiring assessment of cost-effectiveness to receive HIV response grants and HIV care consortium grants); *id.* § 1395y (authorizing grantmaking to support certain original research if, inter alia, "such procedure has the potential to be more cost-effective in the treatment of a condition than procedures currently in use with respect to such condition").

[215] *E.g.*, 21 U.S.C. § 360e-3 (directing FDA to expedite development of medical devices that "improve patient quality of life"); 42 U.S.C. § 247b-4 (collecting recommendations for "improving the . . . quality of life" of individuals with developmental disabilities); *id.* § 280b-1f (authorizing programs "designed to maximize independence and quality of life for older adults"); *id.* § 280g-9 (directing HHS to "carry out projects and interventions to improve the quality of life and long-term health status of persons with paralysis and other physical disabilities"); *id.* § 3032k (requesting that grant recipients identify strategies to provide "comprehensive and coordinated health and social services to sustain the quality of life of older individuals").

[216] 42 U.S.C. § 1320e(b)(1).

[217] *See id.* § 1320e-1.

[218] *Id.* § 1320e-1(c)(1).

quantifying the benefits of life-extending medicines in order to make coverage, reimbursement, or treatment decisions, the effects of treatment-unrelated disabilities on quality of life during the period of life extension must be excluded.

In contrast, the ACA explicitly authorizes decision-makers to use "evidence or findings from such comparative clinical effectiveness research in determining coverage, reimbursement, or incentive programs" under the Medicare statute "based upon a comparison of the difference in the effectiveness of alternative treatments in extending an individual's life due to the individual's age, disability, or terminal illness."[219] Again, put more simply, the Secretary is allowed to consider how a preexisting disability or illness may limit treatment effectiveness. Additionally, the Secretary and other decision-makers may also consider "the likelihood that a health care treatment will result in disability"[220] — that is, the likelihood that a health care treatment will either cause a new disability or remove an existing disability. Under the ACA's approach, decisions about access to medical interventions may treat individuals differently based on disability when the disability is treated or caused by the intervention being provided.

In the same section, the ACA provides that PCORI "shall not develop or employ a dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual's disability) as a threshold to establish what type of health care is cost effective or recommended."[221] In addition to restricting PCORI's use of a cost-per-QALY threshold, this section also disallows the use of a cost-per-QALY threshold to determine which interventions Medicare will cover. Such thresholds are used in the United Kingdom's health system.[222] That the use of QALYs is only prohibited as a threshold suggests that they may be usable in other ways.

Last, the ACA restricts HHS from using PCORI findings to design Medicare coverage "in a manner that precludes, or with the intent to discourage, an individual from choosing a health care treatment based on how the individual values the tradeoff between extending the length

[219] *Id.* § 1320e-1(c)(2).

[220] *Id.* § 1320e-1(d)(3).

[221] *Id.* § 1320e-1(e).

[222] *See* Hemel & Ouellette, *supra* note 28, at 525, 549-50.

of their life and the risk of disability."[223] This language is puzzling, perhaps reflecting known challenges in the ACA's drafting process.[224] Choices among treatments often depend on how one values extended life versus avoiding a specific medical condition that may constitute a disability. For instance, whether to seek a prophylactic mastectomy to avoid breast cancer depends in part on one's concern about specific impairments (e.g., being unable to breastfeed).[225] Providers should dissuade patients from making medical decisions misaligned with those patients' values. Yet this statutory language threatens to preclude designing or covering a decision aid that helps patients align decisions with their values.

In addition to creating PCORI, the ACA directs HHS to define a package of "essential health benefits" various health plans must cover.[226] In defining these benefits, the Secretary may not "make coverage decisions, determine reimbursement rates, establish incentive programs, or design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life."[227] This provision does not define what constitutes impermissible discrimination, making it difficult to interpret. In the same section, the ACA also directs HHS to ensure "that health benefits established as essential not be subject to denial to individuals against their wishes on the basis of the individuals' age or expected length of life or of the individuals' present or predicted disability, degree of medical dependency, or quality of life."[228] This reference to "predicted disability" could be read as prohibiting consideration of predicted treatment outcomes such as effectiveness or toxicity. A better reading, however, is that while essential health benefits should not be denied based on patients' predicted health trajectory (including disability) *independent* of treatment, whether particular interventions are covered may depend on their expected effectiveness. This includes expected effectiveness in addressing life-shortening or quality-of-life-worsening

[223] 42 U.S.C. § 1320e-1(d)(1).

[224] *See* King v. Burwell, 576 U.S. 473, 491-92 (2015).

[225] *See* Meghan Boone, *Lactation Law*, 106 CALIF. L. REV. 1827, 1871 (2018).

[226] 42 U.S.C. § 18022(b)(1).

[227] *Id.* § 18022(b)(4)(B).

[228] *Id.* § 18022(b)(4)(D).

medical conditions. This reading would harmonize the rules applicable to essential health benefits with the clearer rules applicable to Medicare benefits.

The ACA also requires that the essential health benefits package be designed to consider the health care needs of "diverse segments of the population, including women, children, persons with disabilities, and other groups."[229] This language has not been enforced or operationalized, but creates an important beachhead to consider health equity when valuing medicine, as Part III will discuss.

In sum, the ACA's focus is ensuring that cost-effectiveness is not used to disadvantage patients with preexisting disabilities. Its text permits considering QALYs, so long as they are not used in conjunction with a cost-per-QALY threshold or to disadvantage people based on preexisting conditions unrelated to the treatment being evaluated. For instance, the ACA permits Medicare to design formularies by comparing interventions based on cost-effectiveness so long as a fixed threshold is not set.[230] Moreover, the ACA permits the use of next-generation CEA approaches, discussed in Part III, that consider whether an intervention improves (or worsens) quality of life irrespective of patients' baseline quality of life. Similarly, it permits the use of CEA approaches that evaluate interventions by considering only life-years saved rather than differentiating patients by quality of life.[231]

C. State-Level Restrictions on Valuing Medicine

Following the ACA's passage, a few states enacted restrictions on valuing medicines. Oklahoma, for instance, passed the "Nondiscrimination in Health Care Coverage Act," which imposed provisions identical to the ACA's on its state agencies, prohibiting them from defining a uniform cost-per-QALY threshold to establish cost-effective or recommended care and from using such a threshold to make

[229] *Id.* § 18022(b)(4)(C).

[230] *See id.* § 1320e-1(e).

[231] *Cf.* Coleman, *supra* note 28, at 842 ("Medicare could still base coverage determinations for life-extending treatment on other forms of CEA that do not incorporate quality-of-life considerations, such as the evLYG.").

coverage, reimbursement, incentive program, or utilization management decisions.[232]

Notably, Oklahoma explicitly identifies only three protected identities as suffering from medical discrimination: disability, advanced age, and chronic illness.[233] According to the statute, "historically, persons with disabilities, advanced age or chronic illness have faced discrimination in the health care system, including the denial of access to life-sustaining care," and "[l]ack of access to appropriate health care can result in significant adverse health consequences" for these groups.[234] Racial and ethnic minorities, women, gender and sexual minorities, children, and poorer people, by contrast, are not recognized as subject to discrimination. Likewise, when the statute directs "[a]ny agency making decisions on utilization management measures, coverage, reimbursement or incentive programs" to consult with patient groups, disability self-advocacy groups, and "representatives of organizations that advocate for the rights of older persons to receive health care,"[235] it contains no parallel requirement that agencies consult with advocates for children, women, minorities, or the poor. This is so even though categories like race and sex also give rise to health disparities and have stronger federal constitutional and statutory antidiscrimination protections than do age or disability status.[236]

Oklahoma's guidelines do regard "loss of function" and "reduced quality of life or even death" as genuine health setbacks rather than illusory or discriminatory concepts.[237] Yet they also direct agencies to consult with organizations that "advocate for the rights of patients to obtain treatment without regard to the patients' quality of life."[238] A charitable assumption is that such organizations support treatment

[232] OKLA. STAT. tit. 63, § 2563 (2020).

[233] *Id.* § 2561.

[234] *Id.*

[235] *Id.* § 2565.

[236] *See, e.g.*, Wax v. Sec'y of Health & Hum. Servs., No. 03–2830V, 2012 WL 3867161, at *7 n.10 (Fed. Cl. Aug. 7, 2012) (explaining that greater scrutiny is applied to classifications based on race, national origin, or gender than to classifications based on age, disability, or wealth).

[237] OKLA. STAT. tit. 63, § 2561 (2020).

[238] *Id.* § 2565.

access for patients whose quality of life is limited by incurable medical conditions. But pharmaceutical firms hawking treatments that fail to effectively prevent loss of function or improve quality of life would also have a stake in supporting patients' publicly subsidized access to those firms' ineffective treatments "without regard to the patients' quality of life."[239]

Oklahoma is the only state to have adopted restrictions on CEA across state agencies. Massachusetts and other states, however, have considered similar rules.[240]

More recently, states creating prescription drug affordability boards ("PDABs"), which seek to improve prescription drug affordability for states and residents by improving states and their resident insurers' capacity to negotiate drug prices,[241] have restricted these boards' ability to consider QALYs. Rather than banning QALYs categorically, however, such restrictions typically seek only to avoid exacerbating disadvantage for people with preexisting disabilities. Oregon, for instance, only prohibits its PDAB from using "quality-adjusted life-years, or similar formulas that take into account a patient's age or severity of illness or disability, to identify subpopulations for which a prescription drug would be less cost-effective."[242] It also provides that "[f]or any prescription drug that extends life, the board's analysis of cost-effectiveness must weigh the value of the quality of life equally for all patients, regardless of the patients' age or severity of illness or disability."[243] Minnesota likewise provides that QALYs and similar measures may not be used to "identify subpopulations for which a treatment would be less cost-effective due to severity of illness, age, or pre-existing disability."[244]

---

[239] *Id.*

[240] Joshua P. Cohen, *Massachusetts Legislature Proposes Banning Use of Cost-Effectiveness Analysis to Inform Healthcare Coverage Decisions*, FORBES (Dec. 3, 2021, 6:17 AM), https://www.forbes.com/sites/joshuacohen/2021/12/03/massachusetts-legislature-proposes-banning-use-of-cost-effectiveness-analysis-to-inform-healthcare-coverage-decisions/ [https://perma.cc/KEE9-T54S].

[241] *See* Govind Persad, *Defining Health Affordability*, 109 IOWA L. REV. 241, 260-62 (2023) (explaining and describing PDABs).

[242] OR. REV. STAT. § 646A.694(4)(a) (2023).

[243] *Id.*

[244] MINN. STAT. § 62J.92 (2023).

Even carefully designed provisions like these still produce surprising results. In particular, *younger* age or *lesser* severity of illness or disability can also reduce the cost-effectiveness of prescription medications. For instance, COVID-19 vaccines are much more cost-effective for older adults than for children.[245] There is no evidence that the Oregon statute has been enforced to bar consideration of differential cost-effectiveness for children, but its text might be read to do so. It could also bar consideration of whether older age diminishes the cost-effectiveness of some types of treatment, as is true for fertility treatment and some types of cancer screening.[246] Most likely, these statutory provisions aimed to ensure — like the ACA — that patients were not disadvantaged in accessing a treatment on the basis of disabilities that worsen quality of life but are unrelated to the effectiveness of that treatment. If so, more precise wording would have avoided overbroad results.

Washington State's statute is better worded.[247] It provides that its board "must not use quality-adjusted life years that take into account a patient's age or severity of illness or disability to identify subpopulations for which a prescription drug would be less cost-effective," and that "[f]or any prescription drug that extends life, the board's analysis of cost-effectiveness may not employ a measure or metric which assigns a reduced value to the life extension provided by a treatment based on a preexisting disability or chronic health condition of the individuals whom the treatment would benefit."[248] By specifically tailoring its policy to ensure that individuals with *preexisting* disabilities are not disadvantaged, the Washington statute avoids interfering with

[245] Joanna J. Regan, Danielle L. Moulia, Ruth Link-Gelles, Monica Godfrey, Josephine Mak, Morgan Najdowski, Hannah G. Rosenblum, Melisa M. Shah, Evelyn Twentyman, Sarah Meyer, Georgina Peacock, Natalie Thornburg, Fiona P. Havers, Sharon Saydah, Oliver Brooks, H. Keipp Talbot, Grace M. Lee, Beth P. Bell, Barbara E. Mahon, Matthew F. Daley, Katherine Fleming-Dutra & Megan Wallace, *Use of Updated COVID-19 Vaccines 2023–2024 Formula for Persons Aged ≥6 Months: Recommendations of the Advisory Committee on Immunization Practices — United States, September 2023*, 72 MORBIDITY & MORTALITY WKLY. REP. 1140, 1142 (2023).

[246] *See, e.g.*, Govind Persad, *Evaluating the Legality of Age-Based Criteria in Health Care: From Nondiscrimination and Discretion to Distributive Justice*, 60 B.C. L. REV. 889, 891-92 (2019).

[247] *See infra* Part III.

[248] WASH. REV. CODE § 70.405.050(3) (2022).

consideration of whether a medication might relieve or cure illness. Minnesota similarly provides that if its PDAB "uses cost-effectiveness results, it must use results that weigh the value of all additional lifetime gained equally for all patients no matter their severity of illness, age, or *pre-existing* disability."[249]

In contrast to more nuanced state approaches that focus on preventing discrimination based on preexisting disability, Colorado adopts an approach that is closer to the ACA's. It directs its PDAB to "not consider research or methods that employ a dollars-per-quality adjusted life year, or similar measure, that discounts the value of a life because of an individual's disability or age,"[250] even when QALYs are merely being used to compare treatments rather than to identify subpopulations. This restriction risks impeding value-based pricing and is broader than needed to prevent discrimination against patients with preexisting disabilities. However, Colorado's implementing regulations appear better designed. Under the regulations, the board "may use information that uses a quality-adjusted life year analysis to evaluate relative financial effects, but will not use quality adjusted life year analysis to determine an upper payment limit or other appropriate costs of a prescription drug."[251] In addition, the Board is required to consider "health equity impacts to priority populations" when using QALY analysis.[252] This approach aligns with suggestions to incorporate equity into the valuation of medicines that will be discussed in Part III.

PDABs are likely to be a continuing area for advocacy and litigation. Some of the same drugmaker-funded organizations that previously challenged other attempts to value medicines have redirected their efforts toward PDABs, seeking to discourage states from adopting them and to attenuate PDABs' capacity to consider value. The drugmakers Biogen, Gilead, Genentech, Merck, and Pfizer have partnered to fund the "Access and Nondiscrimination in the States Awareness Project," which claims that "reliance on third-party cost-effectiveness analyses to determine the 'value' of prescription drugs" is "detrimental to patient

[249] MINN. STAT. § 62J.92 (2023) (emphasis added).

[250] COLO. REV. STAT. § 10-16-1407 (2023).

[251] COLO. CODE REGS. § 702-9:3.1 (2023).

[252] *Id.*

access."[253] Their advocacy appears to reject not only QALYs, but even "similar metrics that treat patients as averages"[254] — seemingly denying the legitimacy of using population-level data when deciding which drugs should be prioritized for taxpayer-funded reimbursement. A recent report from a drugmaker-funded advocacy group, the Partnership to Improve Patient Care ("PIPC") details a variety of efforts to challenge PDABs' use of value metrics — including, but not limited to, QALYs.[255] It also directs readers to an op-ed claiming that "[p]rescription drug affordability boards do more harm than good" and that public insurers should not be able to set limits on the quantity of taxpayer funds that must be directed to drug reimbursements.[256]

D. Recent Federal Initiatives

The Inflation Reduction Act's provisions concerning drug price negotiation restate some of the ACA's language that prohibits assigning a different value to life extension based on a preexisting disability.[257] More recent initiatives have gone further. In February 2024, the House passed, along party lines, a bill to prohibit use of QALYs or "similar measures" across a variety of programs.[258] In contrast to the specific

[253] PATIENT ACCESS PROJECT, *supra* note 17.

[254] *Id.*

[255] *PIPC Weekly Update: April 22, 2024*, P'SHIP TO IMPROVE PATIENT CARE (Apr. 22, 2024), https://www.pipcpatients.org/blog/pipc-weekly-update-april-22-2024 [https://perma.cc/YK5A-LF3Y].

[256] Jen Laws, *Prescription Drug Affordability Boards Do More Harm Than Good*, CHI. SUN-TIMES (Apr. 2, 2024, 4:00 AM), https://chicago.suntimes.com/other-views/2024/04/01/prescription-drug-affordability-boards-do-more-harm-than-good-illinois-legislation-jen-laws [https://perma.cc/KM2D-SHMX].

[257] 42 U.S.C. 1320e-1(c)(1) (directing that the "Secretary shall not use evidence or findings from comparative clinical effectiveness research . . . in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill").

[258] Joshua P. Cohen, *House of Representatives Passes Bill to Ban Use of QALYs in Federally Funded Healthcare Programs*, FORBES (Feb. 9, 2024, 3:07 PM), https://www.forbes.com/sites/joshuacohen/2024/02/09/house-of-representatives-passes-bill-to-ban-use-of-qalys-in-federally-funded-healthcare-programs/ [https://perma.cc/CLW9-HJW3]; *see* Leah Z. Rand, Adam Raymakers & Benjamin N. Rome, *Congress' Misguided Plan to Ban QALYs*, 329 JAMA 2125, 2125 (2023).

focus of the ACA on avoiding discrimination based on preexisting disability, the newer legislation appeared motivated by sweeping rhetoric that the use of cost-effectiveness analysis in any form is fundamentally contrary to fairness and human dignity.[259] Notably, an amendment proposed that would have "explicitly protected the use of unweighted life-extension measures," as the ACA does, was rejected.[260]

While this legislation's future is uncertain, the Department of Health and Human Services appears poised to take more immediate action. HHS has adopted a rule on the applicability of Section 504 of the Rehabilitation Act to value assessment methods.[261] This rule, like the proposed legislative ban on QALYs, applies to all federal funding recipients. It prohibits the use of any value assessment method that "discounts the value of life extension on the basis of disability"[262] to deny aid, benefits, or services to qualified individuals with disabilities.

The language in HHS's rule could conceivably be read to broadly prohibit the consideration of treatment effectiveness. Under the latter possibility, the "on the basis of disability" language would be read to exclude consideration of whether an aid, benefit, or service *causes* or *fails to cure* a medical condition defined by the relevant statute as a disability.[263] For instance, a manufacturer might develop a cancer drug that prolongs overall survival as well as alternatives, but is much less effective at mitigating cancer progression and pain, or causes painful side effects such as neuropathy that alternative drugs do not. When a recipient of federal funds declines to include this less effective or more toxic drug in a formulary, imposes value-based price caps on this drug, or seeks to consider its poorer effectiveness in price negotiations, the manufacturer could then reply that the extension of life with a disability (cancer, in the case of the less effective drug, or neuropathy, in the case

[259] *See* Press Release, House Energy & Com. Comm. Chair, Chairs Rodgers, Smith and Reps. Burgess, Wenstrup Introduce Legislation to Ban QALYs (Jan. 31, 2023), https://energycommerce.house.gov/posts/chairs-rodgers-smith-and-reps-burgess-wenstrup-introduce-legislation-to-ban-qal-ys [https://perma.cc/6HFP-D9KY].

[260] Rand et al., *supra* note 258, at 2125.

[261] *Final Rule*, *supra* note 14.

[262] Discrimination on the Basis of Disability in Health and Human Service Programs or Activities, 88 Fed. Reg. 63392, 63410 (proposed Sept. 14, 2023) (to be codified at 45 C.F.R. pt. 84).

[263] Mehlman, *supra* note 196, at 181.

of the more toxic drug) must not be considered less valuable than the extension of life without that disability.

The better reading of the Final Rule, however, would protect people with preexisting disabilities without ignoring treatment effectiveness. In the background to the Final Rule, HHS asserts that rather than rejecting value assessment methods broadly, it elected to limit its restrictions to "measures that discount the value of life extension on the basis of disability when used to deny or provide an unequal opportunity for a qualified person with a disability to participate in or benefit from an aid, benefit, or service."[264] Preferring a treatment that does not cause neuropathy, unlike discounting life extension on the basis of preexisting neuropathy, does not limit opportunities for a qualified person with a disability.

Unlike the background to the Final Rule, the background material to HHS's proposed rule conflated two very different situations: (1) legitimate consideration of treatment effectiveness, and (2) troubling situations where a preexisting disability forms the basis for denying treatment that a similarly situated individual without that disability would receive. For instance, the preamble raised the concern that ICER's analysis rates the quality of life of "a person with multiple sclerosis with a score of eight on the Expanded Disability Status Scale" as very poor.[265] But the quality-of-life information in the ICER analysis was being used to assess the value of a treatment *for multiple sclerosis*, not to determine whether people with multiple sclerosis should be excluded from treatments *for other conditions*.[266] In context, the quality-of-life data indicates that an effective treatment that slows multiple sclerosis progression would be very valuable to many with that condition. Furthermore, the quality-of-life data was collected by directly surveying individual *patients with multiple sclerosis themselves* and

[264] *Final Rule*, *supra* note 14, at 40101.

[265] Discrimination on the Basis of Disability in Health and Human Service Programs or Activities, 88 Fed. Reg. 63410 (proposed Sept. 14, 2023) (to be codified at 45 C.F.R. pt. 84).

[266] *See* INST. FOR CLINICAL AND ECON. REV., SIPONIMOD FOR THE TREATMENT OF SECONDARY PROGRESSIVE MULTIPLE SCLEROSIS: EFFECTIVENESS AND VALUE: FINAL EVIDENCE REPORT ES2 (2019).

contextualized alongside statements from patients with that disability. For instance, one patient stated:

> I lost the ability to stand, transfer, or walk a few steps (with a walker) in 2010, which had a huge impact on my life. My cognitive function has continued to become gradually more impaired. By far the most valuable breakthroughs for me would be treatments [or] therapies that would address either or both of these challenges.[267]

It would be perverse to read disability law to prohibit incentivizing the development of treatments that meet that patient's stated needs, or reimbursing for treatments based on their efficacy at meeting those needs. Antidiscrimination law protects disabled people; it neither does nor should protect ineffective or toxic treatments.

Likewise, HHS criticized an ICER report that "valued a year of life with cystic fibrosis with a ppFEV1 (percent predicted forced expiratory volume in one second, an established measure of lung function for cystic fibrosis) between 20–29% at 0.653," less than the value of a year of life with improved lung function.[268] Yet this data was derived from the experience of living with greatly reduced forced expiratory volume, offered by people with cystic fibrosis themselves.[269] And the data was used to assess the potential value of a treatment that mitigates undesired symptoms,[270] not to deny cystic fibrosis patients access to treatments for other conditions.

Both the cystic fibrosis and multiple sclerosis contexts involve patients with a disability reporting that specific medical symptoms are burdensome and seeking effective treatment for those symptoms.

---

[267] *Id.* at 12.

[268] Discrimination on the Basis of Disability in Health and Human Service Programs or Activities, 88 Fed. Reg. 63410 (proposed Sept. 14, 2023) (to be codified at 45 C.F.R. pt. 84).

[269] Judy M. Bradley, Steven W. Blume, Maria-Magdalena Balp, David Honeybourne & J. Stuart Elborn, *Quality of Life and Healthcare Utilisation in Cystic Fibrosis: A Multicentre Study*, 41 EUR. RESPIRATORY J. 571, 574 (2013).

[270] INST. FOR CLINICAL AND ECON. REV., MODULATOR TREATMENTS FOR CYSTIC FIBROSIS: EFFECTIVENESS AND VALUE: FINAL EVIDENCE REPORT AND MEETING SUMMARY 66 (2020), https://icer.org/wp-content/uploads/2020/08/ICER_CF_Final_Report_092320.pdf [https://perma.cc/AVN4-A9WW].

Measures should value *treatments* unequally when they are less effective at treating a medical condition or are more toxic, so long as they do so without providing "an unequal opportunity for a qualified person with a disability to participate in or benefit from an aid, benefit, or service."[271] Basing access to or reimbursement for a treatment on facts *about the treatment* — how well it works to achieve its intended and desired medical outcome — should be recognized as different from basing access or reimbursement on facts about the patient's disability that are not relevant to treatment effectiveness or toxicity.

Last, the background to the proposed rule criticized "a $150,000 per QALY threshold for valuing a treatment for cystic fibrosis, calculated based on an analysis that assigned a lower value to extending the lives of persons with cystic fibrosis than persons without cystic fibrosis."[272] This analysis missed the mark in two ways. First, the cost-per-QALY threshold was not calculated based on the analysis or applied only to cystic fibrosis patients — it was selected by the agency based on budget constraints.[273] Second, the preamble implausibly claims that *even when valuing treatments for cystic fibrosis*, decision-makers may not attach lower value to extending life with more severe cystic fibrosis compared to extending life with less severe cystic fibrosis. When evaluating the effectiveness of a treatment that patients seek in order to treat a condition, decision-makers should be permitted to assign lower value to a treatment that extends life but does not effectively treat that condition's burdensome symptoms.

In contrast, other parts of the background to the proposed rule laudably recognized that it is permissible to consider treatment effectiveness and toxicity, noting that "[w]here an underlying disability would interfere with the efficacy of a particular treatment, a recipient could provide a person with that disability a different treatment than it

---

[271] Discrimination on the Basis of Disability in Health and Human Service Programs or Activities, 88 Fed. Reg. 63410 (proposed Sept. 14, 2023) (to be codified at 45 C.F.R. pt. 84).

[272] *Id.*

[273] *See* N.Y. DEP'T OF HEALTH, N.Y. STATE MEDICAID DRUG UTILIZATION REVIEW (DUR) BOARD MEETING SUMMARY FOR APRIL 26, 2018, at 7 (Apr. 26, 2018), https://www.health.ny.gov/health_care/medicaid/program/dur/meetings/2018/04/summary_durb.pdf [https://perma.cc/CS85-YV9F].

would provide to similarly situated nondisabled individuals."[274] The Final Rule itself also recognizes that medical treatment decisions can consider the "effectiveness, or ease of administration"[275] of treatments even when doing so may involve consideration of disability.

Most importantly, the Final Rule explicitly permits the use of value assessment methods that do not discount the value of life extension on the basis of disability. In doing so, it explicitly rejects a proposal, advanced by the drugmaker Genentech, to "prohibit the use of certain value assessment methods that rely on 'cost per generic health metric' analyses or thresholds,"[276] explaining that such a broad prohibition would inappropriately "encompass alternative methods of value assessment that do not discriminate on the basis of disability."[277] Moreover, the Final Rule explicitly does not "outright ban the use of specific measures such as QALYs," nor does it endorse any measure as best.[278] Ultimately, "the specific context and purpose for which a value assessment method is utilized" is most important.[279] The Final Rule by its own lights is a "carefully targeted approach to addressing disability discrimination in value assessment," not a categorical prohibition, and reaffirms that the "nondiscriminatory use of value assessment is an important tool for health care cost containment."[280]

Notably, the preamble to the proposed HHS rule relied heavily on the testimony of specific advocacy groups such as the Autistic Self-Advocacy Network ("ASAN") and advocacy groups for people with Down Syndrome.[281] These groups may see the disabilities around which their advocacy is centered as diverse identities rather than medical

[274] Discrimination on the Basis of Disability in Health and Human Service Programs or Activities, 88 Fed. Reg. 63406 (proposed Sept. 14, 2023) (to be codified at 45 C.F.R. pt. 84).

[275] *Id.* at 63405.

[276] Letter from David Burt, Exec. Dir., Genentech, Inc., to Melanie Fontes Rainer, Dir., Off. for C.R., Dep't of Health & Hum. Servs. (Nov. 13, 2023).

[277] *Final Report*, *supra* note 14, at 40101.

[278] *Id.* at 40102.

[279] *Id.*

[280] *Id.* at 40103-04.

[281] Discrimination on the Basis of Disability in Health and Human Service Programs or Activities, 88 Fed. Reg. 63392, 63400 (proposed Sept. 14, 2023) (to be codified at 45 C.F.R. pt. 84).

conditions, and so may not seek treatments related to their disability. As such, ASAN's interests may diverge from those of advocacy groups for patients with disabilities like cancer, multiple sclerosis, or cystic fibrosis, who may highly value affordable, effective treatments that alleviate symptoms of those disabilities. Groups like ASAN may instead fear that considering cost-effectiveness will disadvantage them in access to treatments for conditions unrelated to their disability — although improving the efficacy of such treatments or lowering their price would benefit both them and other patient groups. Individual patients' interests will also inevitably differ from the interests of advocacy groups who seek to represent people with their condition, particularly because advocacy groups are informal, rather than democratically selected, representatives.[282]

Proposals to ban or restrict the use of QALYs also align with the National Council on Disability's report that harshly criticizes the use of QALYs and calls for their prohibition in the Medicare and Medicaid programs. NCD claims that "[d]isability rights advocates and people with disabilities oppose the use of QALYs,"[283] eliding the wide diversity of views held by people with disabilities and their advocates,[284] and calls the QALY "simplistic and potentially discriminatory."[285] Illustrative of the mismatch between the backgrounds of advocacy group leadership and of many ordinary patients and individuals with disabilities, the NCD chair overseeing this report was Neil Romano. Romano is a longtime Republican staffer involved in developing the Reagan Administration's "Just Say No" campaign and its response to AIDS, who was nominated to the NCD by Senator Mitch McConnell and subsequently as NCD chair by President Trump.[286] ASAN, whose founder also advises the

[282] *See* WENDY SALKIN, SPEAKING FOR OTHERS: THE ETHICS OF INFORMAL POLITICAL REPRESENTATION 180-201 (2024).

[283] *See* NCD REPORT, *supra* note 16, at 41 (citing only two objections to QALYs, by ASAN co-founder and PIPC advisor Ari Ne'eman and PIPC founder Tony Coelho).

[284] *Cf.* SAMUEL R. BAGENSTOS, LAW AND THE CONTRADICTIONS OF THE DISABILITY RIGHTS MOVEMENT 5-8 (2009) (explaining the multiple and often divergent views held by different disability communities); Egan, *supra* note 196, at A17 (describing disability advocacy groups who support value-based policies).

[285] NCD REPORT, *supra* note 16, at 20.

[286] *Neil Romano*, VOICEAMERICA, https://www.voiceamerica.com/guest/53023/neil-romano (last visited Feb. 5, 2024) [https://perma.cc/EH79-3SP4].

pharmaceutical-industry funded Partnership to Improve Patient Care and whose staff has collaborated with PIPC,[287] worked closely with NCD in developing the report.[288]

III. INNOVATIONS IN VALUING MEDICINE

Recent action around valuing medicine has sought to prohibit the use of ostensibly discriminatory value metrics.[289] But without well-designed policies to actively promote the equitable valuation of medicines, merely prohibiting the use of QALYs and similar value metrics will make things worse, not better.[290] Governmental and private payers will still need to decide which treatments to include in formularies and how generously to reimburse for treatments. Often, limits are set by ability to pay: "limitless" formularies generate high deductibles and coinsurance.[291] At other times, limits are set through "rationing by inconvenience": patients can receive drugs only after navigating prior authorization requirements, appeal processes, or other mechanisms that delay or stymie many patients.[292] To secure subsidized access,

[287] Ari Ne'eman, *Formulary Restrictions Devalue and Endanger the Lives of Disabled People*, HEALTH AFFS. (Oct. 29, 2018), https://www.healthaffairs.org/content/forefront/formulary-restrictions-devalue-and-endanger-lives-disabled-people (identifying Ne'eman as an advisor to PIPC); *see* Kelly Israel & Sara van Geertruyden, *It Is Time to Let Go of the QALY's Legacy of Discrimination*, P'SHIP TO IMPROVE PATIENT CARE (July 20, 2021), https://www.pipcpatients.org/blog/pipc-patient-blog-it-is-time-to-let-go-of-the-qalys-legacy-of-discrimination [https://perma.cc/FK7Z-24S4] (co-authored blog post by ASAN's policy director, who helped lead the development of the NCD report, and PIPC's executive director).

[288] NCD REPORT, *supra* note 16, at 9 (describing central role of ASAN's policy analyst and director of public policy in developing NCD's report); Israel & van Geertruyden, *supra* note 287, at 49 (basing claims about QALYs on interview of ASAN's former director by ASAN's policy analyst).

[289] *See supra* Parts II.B, II.D.

[290] *Cf.* Buccafusco & Masur, *supra* note 28, at 1457 ("[W]e agree that QALYs are flawed . . . . At the same time, we are confident that using QALYs to estimate patient value is far superior to the current alternative: the United States' deeply imperfect market for healthcare.").

[291] *See infra* notes 294–298 and accompanying text.

[292] Gerald W. Grumet, *Health Care Rationing Through Inconvenience: The Third Party's Secret Weapon*, 321 NEW ENG. J. MED. 607, 608 (1989); *see* Rachel E. Sachs, *Administering Health Innovation*, 39 CARDOZO L. REV. 1991, 2020-21 (2018).

patients are reduced to targeting the sentimental motivations of specific politicians[293] — a scenario more feudal than democratic.

Manufacturers, likewise, must still choose among promising candidates for research and development.[294] Removing their incentives to consider expected benefits will lead to more extensive reliance on other factors, such as a treatment's cost of development, the political popularity of the patients who benefit, or the idiosyncratic preferences and hunches of specific lawmakers or corporate directors.[295] There is good reason to fear that these alternatives will be worse at advancing health equity.

This Part will explain how, rather than seeking to ban the use of QALYs or similar measures, advocates for health equity can and should draw on innovative health economic measures that seek to avoid exacerbating disadvantage or that prioritize achieving health benefits for those who have faced disadvantage or injustice.

A. Comparing First-Generation CEA to Alternatives

Some advocacy organizations have painted QALY-based cost-effectiveness analysis ("CEA") as inevitably discriminatory.[296] This is a mistake. As HHS's rule recognizes, whether first-generation CEA will compound disadvantage depends on where it is used and what alternative would be used instead.[297]

The fairness of using first-generation CEA — or CEA more generally — must not be compared to a fantasy world in which all medicines are fully subsidized for anyone who can benefit. Instead, fairness should be

---

[293] *See* Sally L. Satel & Benjamin E. Hippen, *When Altruism Is Not Enough: The Worsening Organ Shortage and What It Means for the Elderly*, 15 ELDER L.J. 153, 173 (2007) (discussing how "the drama of so-called identified lives — specific patient-constituents who personally appealed to their politicians to save them" led to Medicaid funding for dialysis patients).

[294] *See* Hemel & Ouellette, *supra* note 28, at 598.

[295] *Cf. id.* at 581-82 (discussing the role of lobbying and other factors).

[296] *E.g.*, *Americans Agree: QALYs Have No Place in U.S. Health Care*, VALUE OUR HEALTH (2020), https://valueourhealth.org/wp-content/uploads/2020/04/QALYS-Have-No-Place-in-U.S.-Health-Care.pdf [https://perma.cc/342H-LQQT].

[297] *Final Rule*, *supra* note 14, at 40102 ("[W]e reiterate that the discriminatory use of a measure by a recipient violates this provision, but other uses may not. Nor does the rule outright ban the use of specific measures such as QALYs.").

considered in comparison to the cost control measures payers will take if barred from using CEA to assess value.[298] Recall, for instance, HHS's stance that a state Medicaid program may allowably consider "the cost of medical procedures" without regard to value.[299] As the example of categorical refusal to cover obesity drugs indicates, making decisions based on cost alone without regard to value can often lead to less equitable results than would result if value were considered.[300] Disadvantaged patients, or patients with disabilities, are not less likely *in general* to obtain value from medicines, even if some such patients are less likely to obtain value from *specific* medicines. The example of obesity medications, which have disparately *greater* expected benefits in disadvantaged populations, illustrates this point.[301] Moreover, because considering value enables the same amount of spending to produce greater overall health gains, considering value may improve absolute health outcomes even for those patients who are genuinely less likely to obtain value relative to others. A system that leaves disadvantaged patients sicker and poorer than alternatives, even if it narrows differences in outcome, is neither equitable nor desirable.

NCD's report repeatedly criticizes QALYs and health systems that use them without comparing them to alternatives in actual use. It charges that the use of QALYs "may have a negative impact on the health and welfare of people with disabilities,"[302] and that "[d]isability rights advocates are concerned that the widespread use of QALYs by health insurance companies and healthcare agencies will deny people with disabilities access to the care that they need."[303] But denials of beneficial interventions are inevitable: the question should not be whether using QALYs permits coverage denials but whether doing so has a *more* negative impact than the strategies payers would otherwise use. The

[298] *Cf.* Michelle M. Mello & C. Jason Wang, *Ethics and Governance for Digital Disease Surveillance*, 368 SCIENCE 951, 953 (2020) ("[T]he wisdom of adopting a digital surveillance measure should be evaluated not in the abstract but by reference to the counterfactual. What would be used instead of the technology, and is that more or less desirable?").

[299] HHS NEWS RELEASE, *supra* note 147, at 31,779.

[300] Persad & Emanuel, *supra* note 22.

[301] *Id.*

[302] NCD REPORT, *supra* note 16, at 11.

[303] *Id.* at 41.

report claims that "the use of QALYs to help allocate healthcare funding means that new palliative care treatments are always competing with alternative uses of the same money."[304] But the finitude of healthcare funding means that new palliative care treatments *always* involve potential opportunity costs, regardless of whether QALYs or other methods of assessing cost-effectiveness are considered. Competition among treatments arises due to limited funding, not due to any specific metric for allocating that funding.

Fairly evaluating the United Kingdom's health care system, which considers QALYs, likewise requires systematic comparisons rather than cherry-picking. Consider, for instance, the claim that in the United Kingdom, "[t]he coverage denials and loss of access to care faced by people with disabilities . . . illustrate what might happen if the United States made a similar choice."[305] No country provides every medicine that could potentially benefit some patient.[306] The relevant question is how access to health care overall differs across countries, and — more importantly — how health *outcomes* differ, since the point of health care is to improve health. Although patients with certain specific health conditions may have poorer outcomes in the United Kingdom or be unable to obtain taxpayer-funded subsidies for specific drugs, overall health care outcomes are nonetheless much better in the United Kingdom than the United States.[307] Many specific health outcomes

[304] *Id.* at 34.

[305] *Id.* at 13.

[306] Dana O. Sarnak, David Squires & Shawn Bishop, *Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier?*, THE COMMONWEALTH FUND (Oct. 5, 2017), https://www.commonwealthfund.org/publications/issue-briefs/2017/oct/paying-prescription-drugs-around-world-why-us-outlier [https://perma.cc/58Z5-NCKJ].

[307] *See* Munira Z. Gunja, Evan D. Gumas & Reginald D. Williams II, *U.S. Health Care from a Global Perspective, 2022: Accelerating Spending, Worsening Outcomes*, THE COMMONWEALTH FUND (Jan. 31, 2023), https://www.commonwealthfund.org/publications/issue-briefs/2023/jan/us-health-care-global-perspective-2022 [https://perma.cc/Z5F5-KLUZ] (showing life expectancy is over three years longer in the United Kingdom than the United States); Eric C. Schneider, Arnav Shah, Michelle M. Doty, Roosa Tikkanen, Katharine Fields & Reginald D. Williams II, *Mirror, Mirror 2021: Reflecting Poorly: Health Care in the U.S. Compared to Other High-Income Countries*, THE COMMONWEALTH FUND (Aug. 4, 2021), https://www.commonwealthfund.org/publications/fund-reports/2021/aug/mirror-mirror-2021-reflecting-poorly [https://perma.cc/3MEZ-XK7S].

connected to disparities, such as maternal mortality and post-operative complications, are markedly worse stateside.[308] And the United Kingdom performs better even though the United States "spends three times as much per person on healthcare."[309] While British patients cannot receive taxpayer subsidies for certain specific drugs judged to provide insufficient value for money, many more American patients cannot obtain drugs — even those that provide good value for money — because of excessive out-of-pocket costs stemming from high prices.[310] NCD also entirely ignores the many other developed countries that consider QALYs, all of which outperform the United States on health care outcomes despite spending less, and many of which also substantially outperform the United Kingdom.[311]

NCD's report recognizes that "some consideration of cost-effectiveness is reasonable in national health insurance programs," but claims that "strict prioritization that is overly reliant on QALYs, similar to the kind utilized in the United Kingdom, is contrary to U.S. civil rights law and disability policy."[312] Yet they do not explain why the use of QALYs would be worse than alternative approaches for people with disabilities. Any way of setting priorities will benefit some patients

[308] Imani Telesford, Emma Wager, Krutika Amin & Cynthia Cox, *How Does the Quality of the U.S. Health System Compare to Other Countries?*, PETERSON-KFF HEALTH SYS. TRACKER (Oct. 23, 2023), https://www.healthsystemtracker.org/chart-collection/quality-u-s-healthcare-system-compare-countries/ [https://perma.cc/B4YB-XVJY].

[309] Monica Desai, Bernard Rachet, Michel P. Coleman & Martin McKee, *Two Countries Divided by a Common Language: Health Systems in the UK and USA*, 103 J. ROYAL SOC'Y MED. 283, 286 (2010).

[310] Sarnak et al., *supra* note 306 ("In a 2016 international survey of adults, 14 percent of insured Americans reported that, in the past year, they did not fill a prescription or skipped doses of medicine because of the cost, compared with 2 percent in the U.K. and 10 percent in Canada, the nation with the highest rate after the U.S. . . . Among Americans without continuous insurance coverage over the past year, the rate was twice as high: one-third reported they did not fill a prescription for medicine, or skipped doses of medicine, because of the cost.").

[311] *See* Morgan, *supra* note 176, at 3, 8, 15, 20, 23, 28, 30, 32 (explaining that Australia, Canada, Germany, New Zealand, Norway, Sweden, Switzerland, and the United Kingdom all formally consider cost-effectiveness); Schneider et al., *supra* note 307 (explaining that the United States ranks last in health care outcomes compared to Australia, Canada, France, Germany, the Netherlands, New Zealand, Norway, Sweden, Switzerland, and the United Kingdom).

[312] NCD REPORT, *supra* note 16, at 53.

compared to others, leaving it unclear why QALYs should be thought to violate disability law.

Broader criticisms of cost-effectiveness analysis often shade into tradeoff denial. Consider, for instance, requirements that taxpayer-funded programs "cover only the most cost-effective drugs and treatments, or . . . impose restrictions on less cost-effective treatments."[313] Because taxpayer funds are finite, coverage decisions must always be made. If coverage is not targeted toward cost-effective interventions or narrowed for less cost-effective ones, coverage will be broadened or narrowed in other ways — as happened when North Carolina categorically excluded anti-obesity drugs from coverage while including other less cost-effective drugs.[314] Likewise, NCD calls for funding "cost-effectiveness research that facilitates greater access to care, and does not reduce access to care for people with chronic health conditions and disabilities."[315] But facilitating greater access to care for some people with chronic conditions and disabilities will often affect access to treatments for others. For instance, the Orphan Drug Act creates a greater incentive to treat orphan conditions than common conditions that affect many disadvantaged patients.[316] Equitable policy must facilitate access to care for people with chronic conditions and disabilities considered as a community, not create a one-way ratchet that prohibits reducing any individual patient's access to specific treatments even if doing so would enable helping more people or people with more severe conditions.

Like any other approach to setting priorities, considering cost-effectiveness will have differential effects across patient populations. For instance, there is currently no highly effective treatment for Alzheimer's disease.[317] In contrast, there are effective treatments for

[313] *Id.* at 69.

[314] *See* Persad & Emanuel, *supra* note 22, at 1; Robbins, *supra* note 9, at 1.

[315] NCD REPORT, *supra* note 16, at 14.

[316] *See* Buccafusco & Masur, *supra* note 28, at 1435; Mark A. Lemley, Lisa Larrimore Oullette & Rachel E. Sachs, *The Medicare Innovation Subsidy*, 95 N.Y.U. L. REV. 75, 120 n.218 (2020).

[317] *See* Whelan, *supra* note 23, at 1803.

many cancers.[318] Cost-effectiveness favors devoting limited funds to more effective cancer drugs rather than less effective Alzheimer's drugs. Importantly, however, which patient populations gain when cost-effectiveness is considered can shift over time. The arrival of new, cost-effective hepatitis C drugs, for instance, means that hepatitis C patients now stand to gain if cost-effectiveness is considered.[319]

Although effects will vary across subpopulations, the overall population of patients does better when cost-effectiveness is considered because considering cost-effectiveness promotes the development of treatments that produce more benefit for a given cost. This pattern of overall benefit with differential impact echoes other population-scale policy efforts: for instance, reducing carbon emissions will improve overall outcomes in the United States, even though some specific locations will benefit more than others.[320]

Rather than allowing comparisons between drugs for different conditions, the NCD report proposes that patients with a condition should be allowed to define which treatments are the highest value, and what constitutes value.[321] This is certainly appropriate for patients' own spending. But it is unworkable as a standard for public spending.

Meanwhile, others suggest that cancer drugs should only be compared to other cancer drugs.[322] This approach lacks justification and provides no guidance in resolving important tradeoffs, creating room for bias and fertile ground for lobbyists. There is no obvious reason why drugs for lung cancer should be compared to drugs for prostate cancer, but not drugs for other lung diseases.

---

[318] Ambinintsoa H. Ralaidovy, Chaitra Gopalappa, André Ilbawi, Carel Pretorius & Jeremy A. Lauer, *Cost-Effective Interventions for Breast Cancer, Cervical Cancer, and Colorectal Cancer: New Results from WHO-CHOICE*, 16 COST EFFECTIVENESS & RES. ALLOCATION 1, 1 (2018).

[319] *See* Rosado v. Semple, No. 3:20-CV-1908 (JAM), 2022 WL 673275, at *1 (D. Conn. Mar. 6, 2022) (explaining that new hepatitis C drugs are much more effective than older drugs, are now the standard of care, and are provided in the Medicaid program).

[320] *See* Solomon Hsiang, Robert Kopp, Amir Jina, James Rising, Michael Delgado, Shashank Mohan, D.J. Rasmussen, Robert Muir-Wood, Paul Wilson, Michael Oppenheimer, Kate Larsen & Trevor Houser, *Estimating Economic Damage from Climate Change in the United States*, 356 SCIENCE 1362, 1363-64 (2017).

[321] NCD REPORT, *supra* note 16, at 64.

[322] *Id.* at 68 (citing Interview by Ana Torres Davis with Ari Ne'eman (Jan. 9, 2019)).

Moreover, payers and manufacturers must frequently make comparisons across categories.[323] Because funds to develop or reimburse for cancer drugs and other drugs come from the same pool, these drug classes must be compared when deciding which to prioritize. Refusing to compare drugs across categories based on their value might appeal to interest groups confident they can successfully lobby for spending on their illness, but it will inevitably shortchange patients who are ill-placed to lobby the public, like low-income pregnant women and infants. Not accidentally, these very groups fare the worst in the United States compared to other developed countries like the United Kingdom.[324]

In sum, first-generation CEA — despite its flaws — is typically more equitable than alternatives that ignore value. Comparisons between the United States and other developed countries underscore this point and illustrate that banning the use of QALYs will hamper rather than advance equity. But first-generation CEA could nonetheless be improved further from an equity standpoint, and HHS's Final Rule — though not categorically prohibiting the use of QALYs — endorses a shift toward more equitable methodologies for value assessment. As Parts III.B and III.D will explain, CEA can and should be modified to better advance equity and avoid compounding disadvantage.[325]

B. Changing How Quality of Life Is Incorporated

Most uses of CEA compare different *interventions* across a similar population of patients.[326] These comparisons are unlikely to compound disadvantage because the differences in outcomes are attributable to differences between the treatments rather than differences between patients. Concerns about compounding disadvantage can therefore often be addressed through modifications, like those adopted by many

[323] Hemel & Ouellette, *supra* note 28, at 530-37 (explaining that drugmakers often face incentives to underinvest in developing certain categories of drugs compared to others).

[324] *See* Telesford et al., *supra* note 308.

[325] *See infra* Parts III.B, III.D.

[326] *See* Rand & Kesselheim, *supra* note 205, at 1408.

prescription drug affordability boards, that avoid comparisons across subpopulations.[327]

CEA presents the most risk of compounding disadvantage when used to compare *different patients* seeking the *same intervention*. When different patients seek the same intervention, one patient's poorer expected outcome may reflect their poorer baseline health status rather than differences in efficacy between interventions.[328] This Section will discuss modifications to CEA that mitigate the risk of compounding disadvantage when comparing different groups of patients. Such modifications further the Final Rule's goal of promoting the development of value assessment methods.

1. Quality-Free CEA

Removing all consideration of quality of life by evaluating interventions solely in terms of life-years gained avoids compounding disadvantage for patients with poorer baseline quality of life. Call this approach "quality-free CEA."

But quality-free CEA overlooks important differences between interventions, such as side effects. Imagine a drug that extends life for ten years but causes paraplegia during the additional years. An approach that ignores quality of life would implausibly regard this side effect as irrelevant. Many actual drugs have painful, dangerous, or activity-limiting side-effects, and most agree that reducing or eliminating these side effects is valuable.[329] Even advocacy communities that regard some health conditions as "mere differences" rather than disadvantages still often view the imposition of new health conditions as disadvantaging due to the time and effort needed to adapt.[330] As Part II.B explained, the

[327] *Id.* at 1408 ("Health technology assessment organizations limit the scope of QALY-based analyses to prevent discriminatory decisions, such as separating out people with disabilities into a subgroup for cost-effectiveness evaluations.").

[328] *Cf. id.* (noting that "[s]uch a situation is rare").

[329] *See, e.g.*, Jill Elaine Hasday, *Mitigation and the Americans with Disabilities Act*, 103 MICH. L. REV. 217, 242 (2004) (explaining that many medications have "undesirable or dangerous side effects"); David G. Owen, *Dangers in Prescription Drugs: Filling A Private Law Gap in the Healthcare Debate*, 42 CONN. L. REV. 733, 740 (2010) (similar).

[330] *See* David Wasserman, *Assessing Health-State Utility: Is There a Uniquely Privileged Perspective?*, 7 J.L. & BIOSCIENCES 1, 3 (2020).

ACA does not prohibit agencies from recognizing and quantifying the prospect that an intervention may "result in disability."[331] Other drugs both extend life and cure preexisting illness, such as recently developed antivirals for hepatitis C.[332] An approach that ignores quality of life would overlook the curative value of these interventions. Perhaps for this reason, the Final Rule does not require that value assessment methods ignore quality of life.[333]

2. Baseline-Adjusted CEA

Rather than ignoring quality of life entirely, another strategy for avoiding the exacerbation of preexisting disadvantage considers how much a treatment improves quality of life. This can be done by assessing post-treatment quality of life but adjusting for the effects of baseline quality of life prior to treatment. This subsection explains the strengths and weaknesses of two recent approaches that seek to incorporate consideration of a treatment's effects on quality of life: the Equal Value of Life Years Gained ("evLYG") and the Health Years in Total ("HYT") approaches. It then sketches a third, preferable approach for assessing treatment effects, which it calls the Treatment Incremental Life Extension Plus Quality ("TILEPQ").

The evLYG is designed for use when comparing two interventions rather than assessing an intervention's benefit across any potential comparisons. Whenever a treatment — such as a new drug for migraine or cardiovascular disease — is compared to the current standard of care, the evLYG assigns the average population quality of life to any additional years lived during the period of extended survival enabled by the new drug.[334] By contrast, years that would be lived under either the

[331] *See* 42 U.S.C. § 1320e-1(d)(3); *supra* Part II.B.

[332] *See* Rosado v. Semple, No. 3:20-CV-1908 (JAM), 2022 WL 673275, at *1 (D. Conn. Mar. 6, 2022).

[333] *Final Rule*, *supra* note 14, at 40103 (noting that compliance with the Final Rule "does not require the use of a cost-per-life-year valuation, an approach that is relatively uncommon when evaluating interventions that improve patient quality of life").

[334] *See* Ken O'Day & Dylan J. Mezzio, *Demystifying ICER's Equal Value of Life Years Gained Metric*, INT'L SOC'Y FOR PHARMACOECONOMICS & OUTCOMES RSCH., https://www.ispor.org/publications/journals/value-outcomes-spotlight/vos-archives/issue/view/overcoming-vaccine-hesitancy-injecting-trust-in-the-community/demystifying-

status quo treatment or the new treatment are valued at the health-related quality of life associated with each treatment, including the effects of baseline quality of life.[335]

Compared to QALYs, evLYGs better address concerns about compounding disadvantage because they filter out the effect of baseline quality of life on the years lived during the extended survival period. And compared to quality-free CEA, they better recognize the value of a treatment that improves quality of life during the period that would be lived no matter what.

While potentially preferable to quality-free CEA for these reasons, evLYGs still fail to recognize that the intervention that extends life the longest could be further improved by reducing ongoing side effects during the period of extended survival that only this intervention achieves. Because the additional time alive is stipulated to be lived at the average population quality of life irrespective of side effects, the burdens of side effects during this time are ignored. Moreover, evLYGs have two problems not shared by quality-free CEA. First, evLYGs do not filter out the effects of baseline quality of life during the time that would be lived under either treatment, exposing evLYGs to concerns that they compound disadvantage.

Second, unlike either quality-free CEA or QALYs, evLYGs' approach to comparing interventions can generate decision instability.[336] Compare Treatment Y, which extends survival for two years at an average health-related quality of life ("HRQoL") of 0.6, and Treatment Z, which extends survival for four years at an average HRQoL of 0.2. If Treatment Y is the current standard of care, Treatment Z is preferable in evLYG terms since the two additional evLYs it generates outweigh the higher average quality of life Treatment Y produces during the first two years. By contrast, if Treatment Z is the current standard of care, then Treatment Y is preferable because it generates more QALYs during

icer-s-equal-value-of-life-years-gained-metric (last visited Jan. 17, 2024) [https://perma.cc/CDN2-DA5Y]; *see also* Hemel & Ouellette, *supra* note 28, at 552 (favorably discussing the evLYG methodology).

335 O'Day & Mezzio, *supra* note 334.

336 *See* Mike Paulden, Chris Sampson, James F. O'Mahony, Eldon Spackman, Christopher McCabe, Jeff Round & Tristan Snowsill, *Logical Inconsistencies in the Health Years in Total and Equal Value of Life-Years Gained*, 27 VALUE HEALTH 356, 362 (2024).

the first two years — which would be lived under either treatment — than Treatment Z does over four years. Because Treatment Z is the current standard of care, the additional two years it provides are assessed in QALY rather than evLYG terms.

The Health Years in Total ("HYT") metric seeks to improve on the evLYG by considering a treatment's effect on quality of life during the *entire* period of post-treatment survival. To see how HYT operates, compare Treatment X, which extends survival for one year at an average HRQoL of 1, to Treatment Y, which extends survival for two years but only at an average HRQoL of 0.6. Rather than multiplying years of life gained by health-related quality of life, as the QALY does, HYTs are calculated by *adding* years of life gained to a modified version of quality-adjusted life-years gained. The modification stipulates that treatments that do not maximize length of survival can generate "counterfactual" quality-adjusted life-years during the period between the actual survival expected with *that* treatment and the maximum survival possible under *any* treatment. The additional counterfactual years during this period are imagined to be lived at whatever quality of life the patient experienced during their actual lifespan. So, Treatment X would produce 3 HYT (1 LYG plus 2 modified QALYs, with 1 modified QALY accruing during a survival period that only Treatment Y produces in reality). Treatment Y produces 3.2 HYT (2 LYGs plus 1.2 QALYs).[337]

HYTs generate an intuitively plausible result when comparing Treatments X and Y, though they do not factor out baseline quality of life and so appear vulnerable to concerns that they could exacerbate disadvantage. Other comparisons, however, generate more substantial problems for the HYT approach.[338] Introduce Treatment Z, previously discussed when comparing treatments in evLYG terms. Treatment Z extends life for 4 years at an average HRQoL of 0.2. It thus generates 4.8 HYT (4 LY plus 0.8 QALY). But because the presence of Treatment Z extends the maximum survival possible under any treatment, it also alters the quantity of HYT generated by Treatments X and Y. Treatment Y now produces 4.4 HYT (2 LY plus 1.2 QALY plus 1.2 modified QALY

[337] *See* Anirban Basu, Josh Carlson & David Veenstra, *Health Years in Total: A New Health Objective Function for Cost-Effectiveness Analysis*, 23 VALUE HEALTH 96, 102 (2020) ("HYT are the sum of life expectancy plus modified QALYs.").

[338] *See* Paulden et al., *supra* note 336, at 363.

during the stipulated additional 2 years at a HRQoL of 0.6). Treatment X, by contrast, produces 5 HYT (1 LY plus 1 QALY plus 3 modified QALYs during the additional 3 years at a HRQoL of 1). This comparison suggests that HYT will at least sometimes favor a treatment that extends survival much less, compared to one that extends survival much more but at a lower quality of life. More seriously, the comparison shows that the presence of a third intervention will sometimes reverse the preferability of two interventions relative to one another.

A better approach, which would address these problems with the HYT and evLYG metrics, would factor out all effects of baseline quality of life while continuing to consider both how a treatment affects length of life and how it affects quality of life. Building on Rai's proposal discussed in Part I, I suggest a novel metric, TILEPQ, which builds on the HYT approach's core advance — separation of length from quality of life-- while avoiding its problems.

The TILEPQ recognizes how a treatment improves or worsens quality of life while filtering out differences in baseline quality of life. It does so by adding years gained to *incremental* quality of life improvements during each year. For instance, a cardiovascular disease treatment that extends length of life by 10 years without affecting quality of life adds 10 TILEPQ. In contrast, a similar treatment that extends length of life by 10 years while improving quality of life each year by 0.2 adds 12 TILEPQ. Conversely, extending life by ten years but worsening quality of life by 0.2, for instance due to side effects, would add only 8 TILEPQ. Because TILEPQ considers only *changes* in patients' quality of life, not patients' *absolute* quality of life, it avoids compounding disadvantage for patients with a preexisting lower quality of life, while recognizing the value of medicines that improve quality of life and the disvalue of those that lower it.

Applied to the examples above, TILEPQ would judge Treatments X, Y, and Z differently depending on the patient's pre-treatment quality of life, as exemplified in Table 1. For Patient A, whose pre-treatment quality of life is 1, Treatment X would produce 1 TILEPQ (1 LY plus 0 incremental QALYs), Treatment Y would produce 1.2 TILEPQ (2 LY plus -0.8 incremental QALYs), and Treatment Z would produce 0.8 TILEPQ (4 LY plus -3.2 incremental QALYs). By contrast, for Patient B, whose pre-treatment quality of life is 0.6, Treatment X would produce

1.4 TILEPQ (1 LY plus 0.4 incremental QALYs), Treatment Y would produce 2 TILEPQ (2 LY plus 0 incremental QALYs), and Treatment Z would produce 2.4 TILEPQ (4 LY plus -1.6 incremental QALYs).

TILEPQ ensures that the value of life extension is never discounted based on a qualified individual's preexisting disability. Indeed, it has the important consequence of *advantaging*, rather than disadvantaging, patients with a lower pre-treatment quality of life. In the examples above, Treatments X, Y, and Z produce more TILEPQ for Patient B than Patient A because they produce more incremental QALYs or decrease quality of life by less. TILEPQ also avoids the decision instability of HYT and evLYG because TILEPQ values treatments irrespective of which treatment is assigned as the current standard of care.

However, because TILEPQ focuses on a treatment's effects rather than on overall outcomes, it — like evLYG and HYT— sometimes evaluates a treatment as better even when it leads to equally or less good overall outcomes in QALY terms. For instance, imagine that we are deciding whether to provide the last dose of Treatment X to Patient A or Patient B. Providing it to Patient A will produce only 1 TILEPQ, whereas providing it to Patient B will produce 1.4 TILEPQ. Yet, regardless of who receives Treatment X, the outcome is the same: one person will live for an additional year at a quality of life of 1. Dan Hausman claims that this consequence is an "implausible implication," arguing that we should be indifferent about whether to provide a life-extending treatment to Patient A, whose quality of life will remain the same, or to Patient B, whose quality of life will improve from a lower baseline.[339] But this consequence can instead be seen as appropriately recognizing the special importance of helping someone whose baseline health status was worse. It hardly seems implausible to treat the severity of someone's pre-treatment health condition as a tiebreaker in the above example. This implication of TILEPQ seems preferable to ignoring quality of life, as quality-free CEA does; accepting decision instability along with residual exacerbation of disadvantage, as evLYGs and HYT risk doing; or accepting substantial exacerbation of disadvantage, as QALYs can.

[339] HAUSMAN, *supra* note 130, at 188-89.

While valuing treatments in QALY terms risks the exacerbation of disadvantage, it does not always exacerbate *unfair* preexisting disadvantage, or indeed exacerbate preexisting disadvantage at all. For instance, if a previously advantaged patient ultimately develops a condition, like irreversible coma, that would make it impossible for them to be a "subject of quality of life" irrespective of societal injustice, considering baseline quality of life may seem appropriate.[340] Alternatively, a metric akin to TILEPQ could be devised that only filters out aspects of baseline quality of life that are due to injustice, rather than all effects of baseline quality of life.[341]

People may also reasonably disagree about the weight of not exacerbating preexisting disadvantage. In some situations, preexisting disadvantage may so substantially limit the prospect of benefit that considering it appears warranted.[342] The mitigation of preexisting disadvantage could accordingly be balanced against consideration of post-treatment outcomes.[343]

C. Considering Who Receives Benefits

Baseline-adjusted CEA can effectively avoid compounding unfair disadvantage. However, going further to mitigate health inequities, rather than merely not compounding the status quo, requires building the mitigation of inequity either into the metrics themselves or their application.

Traditional CEA is indifferent to the distribution of medical benefits across recipients. For instance, it evaluates a medicine that has large, highly concentrated benefits the same as one that has smaller benefits

[340] *See* Ryan H. Nelson & Leslie P. Francis, *Justice and Intellectual Disability in a Pandemic*, 30 KENNEDY INST. ETHICS J. 319, 325 (2020).

[341] Persad, *Considering Quality of Life*, *supra* note 100, at 301.

[342] *See* Rai, *supra* note 96, at 1092-94.

[343] *See* Tyler M. John, Joseph Millum & David Wasserman, *How to Allocate Scarce Health Resources Without Discriminating Against People with Disabilities*, 33 ECON. & PHIL. 161, 163 (2017).

for a larger number of patients.[344] CEA's traditional credo is that "a QALY is a QALY is a QALY"[345] — *whose* QALY it is does not matter.

In contrast, distributional CEA ("DCEA") assigns greater importance to benefiting specific patient groups.[346] For instance, DCEA might attach greater importance to benefiting patients who are poorer, socially marginalized, less healthy right now, or expected to have the poorest lifetime health.[347] An intervention that successfully does so — for instance, by treating diseases more common among marginalized patients and doing so in a way that those patients can access — can help mitigate health inequities or disparities.[348] DCEA does this by identifying relevant population subgroups and defining distributional weights for each subgroup.[349] It then adjusts outcomes to reflect distributional weights.[350]

Other types of distributional CEA, though not usually described as such, prioritize certain diseases over others. An example is the United Kingdom's Cancer Drugs Fund, which subsidizes cancer therapies more generously than therapies for other diseases.[351] Some studies have concluded that this higher threshold "caused roughly five times more quality-adjusted life-years (QALYs) to be lost elsewhere in the NHS than were generated by the fund's activities . . . ."[352] The Fund's defenders argued, however, that "public attitudes and reactions support

[344] Sarah J. Whitehead & Shehzad Ali, *Health Outcomes in Economic Evaluation: The QALY and Utilities*, 96 BRIT. MED. BULL. 5, 5-21 (2010).

[345] *Id.* at 14.

[346] *See* Richard Cookson, Susan Griffin, Ole F. Norheim, Anthony J. Culyer, & Kalipso Chalkidou, *Distributional Cost-Effectiveness Analysis Comes of Age*, 24 VALUE HEALTH 118, 119 (2021).

[347] *See id.*

[348] *See id.*

[349] *See id.*

[350] *See id.*

[351] *See* Padraig Dixon, Charlotte Chamberlain & William Hollingworth, *Did It Matter That the Cancer Drugs Fund Was Not NICE? A Retrospective Review*, 19 VALUE HEALTH 879, 882 (2016); Andrew Jack, *Which Way Now for the Cancer Drugs Fund?*, 349 BMJ 14, 15 (2014).

[352] Dixon et al., *supra* note 351, at 879.

a more favourable assessment for treatments for cancer relative to other conditions."[353]

Similar approaches to the Cancer Drugs Fund have been advocated for other conditions. In particular, patients who have rare diseases or diseases for which there is currently no effective treatment have argued that cost-effectiveness thresholds should be relaxed for their conditions.[354] But this approach is also challenging to justify: experiencing harm from a rare disease is not worse than experiencing the same severity of harm due to common disease. Similarly, having a condition that can only be treated with toxic or sub-optimally effective drugs is not better than having an equally severe condition for which no drugs are available. Severity can be an appropriate consideration for DCEA, but the relevant consideration should be how severe the disease is after any available drugs are tried, considering the harm of side-effects as well as direct harm from disease.

Determining what distributional weights DCEA should use — that is, how much more it matters to improve health for certain groups — is an ethical rather than scientific question. At the extreme, benefiting disadvantaged patients could be treated as categorically more important than achieving greater population benefit, but this consequence — which might prioritize a small benefit for very disadvantaged groups over a large benefit for the population — is generally rejected.[355] Ethical analyses, public deliberation, or even surveys can help provide reasonable answers when assigning distributional weights.

D. Incorporating Non-Medical Benefit

Traditional CEA only considers medical benefit as an outcome.[356] In contrast, extended CEA ("ECEA") considers outcomes other than

[353] Jack, *supra* note 351, at 14.

[354] *See* Hyry et al., *supra* note 31, at 269.

[355] *Cf.* Rai, *supra* note 96, at 1082 (rejecting health policies under which "society would spend all its resources on a few individuals, produce relatively minimal benefit for those individuals, and ignore the claims of those individuals whose conditions could have been improved significantly").

[356] *See* Stéphane Verguet, Jane J. Kim & Dean T. Jamison, *Extended Cost-Effectiveness Analysis for Health Policy Assessment: A Tutorial*, 34 PHARMACOECONOMICS 913, 913-23 (2016).

medical benefit. The most used form of ECEA considers financial protection alongside medical benefit.[357] Such an ECEA expresses the outcome in terms of cost both per QALY gained (medical benefit) and per case of poverty averted (financial protection). ECEA can be combined with DCEA to both consider multiple outcomes and evaluate how they are distributed.

ECEA could also consider outcomes beyond financial protection. For instance, justice-enhanced cost-effectiveness analysis considers the dignitary benefits of a given medical intervention.[358] ECEA could likewise consider whether an intervention narrows racial or disability health disparities, which could in turn support greater reimbursement for such interventions.[359]

Precedent for such a program can be found in Congress's creation of incentives to encourage the development of medicines treating conditions, such as malaria or onchocerciasis, "for which there is no significant market in developed nations and that disproportionately affect[] poor and marginalized populations . . . ."[360] Some have suggested using similar incentives to encourage racial diversity in clinical trials.[361] Dropping or adjusting the "no significant market in developed nations"[362] language would create an incentive for drugmakers to address disparities affecting the poor and marginalized stateside, rather than only those elsewhere.

---

[357] *See id.*

[358] *See* Maria W. Merritt, C. Simone Sutherland & Fabrizio Tediosi, *Ethical Considerations for Global Health Decision-Making: Justice-Enhanced Cost-Effectiveness Analysis of New Technologies for* Trypanosoma brucei gambiense, 11 PUB. HEALTH ETHICS 275, 275-92 (2018).

[359] For racial disparities, ensuring that payment incentives focus on the intervention rather than the recipient would help to avoid reverse discrimination challenges. *See* Govind Persad, *Allocating Medicine Fairly in an Unfair Pandemic*, 2021 U. ILL. L. REV. 1085, 1120 [hereinafter Persad, *Allocating Medicine Fairly*]; *cf.* Lemley et al., *supra* note 316, at 128 (suggesting the use of more generous payment for "diseases that primarily impact low-income populations").

[360] 21 U.S.C. § 360n; *see* Sachs, *supra* note 293, at 2009 (explaining the program).

[361] *See* Sarah Thompson Schick & Kirsten Axelsen, *Considering Modifications to Existing FDA Regulatory Incentives to Achieve Greater Racial and Ethnic Diversity in Pivotal Clinical Trials for Drug Approvals*, 77 FOOD & DRUG L.J. 246, 259 (2022).

[362] 21 U.S.C. § 360n.

Ultimately, ECEA and DCEA could be combined with baseline-neutral metrics like HYT to provide a policy suite for valuing medicine that both produces more benefit *and* better reduces disparities than proposals to ignore value. Compared to ignoring value, such policies should be preferred by everyone except drugmakers producing costly, ineffective drugs and advocates fundamentally committed to the irrelevance of benefit.

E. Alternatives to Cost-Effectiveness Analysis

Outside health care, policymakers commonly use cost-benefit analysis ("CBA") to value interventions or policies.[363] NCD's report advocates CBA as preferable to CEA.[364] Unlike cost-effectiveness analysis, CBA assigns a monetary value to a medicine's benefits as well as its costs.[365] If the medicine's financial cost is the same as its monetized benefit, the CBA will produce a value of zero. If the cost of the medicine is less than its monetized benefit, then provision creates a net gain. Distributional weights can also be attached to cost-benefit analyses, enabling them to prioritize health equity as a goal.[366] But assigning a monetary value to health benefits is challenging.[367] Moreover, willingness to pay for health benefits, which is used to determine the monetized value of health, reflects income.[368] For this reason, cost-benefit analyses are infrequently used in health policy.[369]

Moving in the opposite direction from cost-benefit analysis, other approaches attempt to evaluate a broader range of costs and benefits without the use of a single summary measure like HYT or QALY. The

[363] *See* Matthew D. Adler & Eric A. Posner, *Rethinking Cost-Benefit Analysis*, 109 YALE L.J. 165, 169 (1999).

[364] *See* NCD REPORT, *supra* note 16, at 62.

[365] *Cost-Benefit Analysis*, YORK HEALTH ECON. CONSORTIUM, https://yhec.co.uk/glossary/cost-benefit-analysis/ (last visited Oct. 24, 2024) [https://perma.cc/4D6L-SYVV].

[366] *See* Matthew D. Adler, *Benefit-Cost Analysis and Distributional Weights: An Overview*, 10 REV. ENV'T ECON. & POL'Y 264, 264 (2016).

[367] *Cost-Benefit Analysis*, *supra* note 365.

[368] *See* SWEDISH AGENCY FOR HEALTH TECH. ASSESSMENT AND ASSESSMENT OF SOC. SERVS., ASSESSMENT OF METHODS IN HEALTH CARE: A HANDBOOK 109 (2016).

[369] *See id.*

NCD report expresses a preference for various non-summary measures, such as cases of disease prevented, deaths prevented, years of life saved, or other outcomes such as remissions.[370] The problem with these other metrics is that they obscure comparisons of the "true benefit patients gain from treatment."[371] For instance, for a drug that puts a given disease into remission, it matters how long the remission lasts, how burdensome the disease was prior to remission, and whether the drug has any undesirable side effects. Summary measures can enable comparisons that consider these outcomes, whereas merely counting remissions would not.

Non-summary approaches are typically forms of multicriteria decision analysis ("MCDA").[372] The simplest form of MCDA would treat length and quality of life improvements as separate dimensions of value without combining them into a summary measure.[373] On this approach, interventions could still be easily compared if one is better with respect to both length and quality. But if one intervention performs better on length and another on quality, comparison would require a more holistic balancing of factors.

Rather than using only two vectors, however, most MCDA methods consider numerous health dimensions.[374] This makes comparisons more difficult and creates more room for lobbying and arbitrary discretion. Manufacturers often favor MCDA in the hope of arguing that because their treatments perform well along one dimension, they should be viewed as effective overall.[375] If MCDA is used, the number of vectors

[370] NCD REPORT, *supra* note 16, at 35 (complaining that QALYs "aggregate quantity and quality of life").

[371] NCD REPORT, *supra* note 16, at 62.

[372] *See generally* Coleman, *supra* note 28, at 874 (explaining the design of multicriteria decision analysis and how it differs from traditional CEA).

[373] *See* John Mullahy, *Live Long, Live Well: Quantifying the Health of Heterogeneous Populations*, 10 HEALTH ECON. 429, 435 (2001) (explaining that a QALY is the product of a vector representing length of life and one representing quality of life).

[374] *E.g.*, Ivett Jakab, Melanie D. Whittington, Elizabeth Franklin, Susan Raiola, Jonathan D. Campbell, Zoltán Kaló & R. Brett McQueen, *Patient and Payer Preferences for Additional Value Criteria*, 12 FRONTIERS PHARMACOLOGY 1, 3 (2021) (proposing a list of fifteen criteria to be used in MCDA).

[375] *See* Carlos Campillo-Artero, Jaume Puig-Junoy & Anthony J. Culyer, *Does MCDA Trump CEA?*, 16 APPLIED HEALTH ECON. HEALTH POL'Y 147, 148 (2018).

considered should be limited and double counting of benefits or costs avoided.[376]

IV. PROMOTING EQUITABLE VALUATION

Health economists and researchers have, as Part III explained,[377] proposed multiple frameworks that value the equity outcomes of medicines as well as their net benefits and that seek to avoid exacerbating disadvantage. They have also identified contexts where use of "first-generation" frameworks like the QALY are more and less likely to compound disadvantage. This Part considers how equitable frameworks can go from paper to policy.

A. Replacing Chilling with Warming Effects

"[R]egulated parties should know what is required of them so they may act accordingly . . . ."[378] Yet current and proposed limits on valuing medicine fail to provide agencies and private payers clear guidance.[379] Unclearly worded prohibitions on valuing medicine, like Congress's proposed ban on using QALYs or "similar measures," are likely to chill interest in equitable modifications like the use of Health Years in Total or of distributional or extended cost-effectiveness analysis.[380] While pharmaceutical firms uninterested in competing on value may support vague prohibitions, organizations sincerely interested in avoiding

[376] *See id.*

[377] *See supra* Part III.

[378] FCC v. Fox Television Stations, Inc., 567 U.S. 239, 253 (2012).

[379] *Cf.* Richard S. Saver, *The New Era of Comparative Effectiveness: Will Public Health End Up Left Behind?*, 39 J.L., MED. & ETHICS 437, 442 (2011) (explaining that the ACA set "confusing boundaries" around the use of cost-effectiveness, and that the "quality of . . . governmentally funded research would improve greatly if there were consistent, thoughtful regulatory guidance as to optimal cost-evaluation methodologies or when cost comparisons are appropriate, rather than the current approach of cautiously avoiding the subject altogether").

[380] *See* Rand et al., *supra* note 258, at 2125.

unjust discrimination should reject ambiguous legislative language that impedes equitable valuation.[381]

Health decision-makers should instead be given clear guidance about which approaches are encouraged. For instance, PCORI or other funders could be explicitly empowered to fund research using baseline-adjusted approaches, ECEA, or DCEA, and decision-makers like Medicare and state Medicaid programs could be empowered to make coverage decisions using these formulas. A safe harbor approach akin to that used in the health care fraud and abuse laws could help further these goals.[382]

More generally, legislation should make clear the goal of any restrictions on cost-effectiveness analysis. If the goal of legislation is to avoid further disadvantaging patients who are already disadvantaged, for instance, this goal should be expressed in the preamble. The use of illustrative examples would additionally help clarify what types of valuation are acceptable and unacceptable.[383] Agencies using equitable methodologies could also receive formalized safe harbors.[384]

B. Funding Equitable Valuation

In addition to permission, funding can help advance equitable valuation. One funding priority should be the creation of best practices for converting first-generation CEA findings to alternative metrics. Another should be conducting surveys of diverse and representative populations to understand their views on the quality of life associated with different health conditions and treatments.[385]

---

[381] *Cf.* Gregory E. Maggs, *Reducing the Costs of Statutory Ambiguity: Alternative Approaches and the Federal Courts Study Committee*, 29 HARV. J. ON LEGIS. 123, 128 (1992) (extolling the value of legislative clarity).

[382] *See* Susan C. Morse, *Safe Harbors, Sure Shipwrecks*, 49 UC DAVIS L. REV. 1385, 1391 (2016).

[383] *Cf.* 29 C.F.R. § 2520.102-2 (2024) (explaining that "the use of clarifying examples and illustrations" can make the restrictions in an employee benefits plan easier to understand); Susan C. Morse & Leigh Osofsky, *Regulating by Example*, 35 YALE J. ON REGUL. 127, 142 (2018) (detailing how examples can help in "decoding" regulations and "can make the law more relatable and understandable").

[384] *See* Morse, *supra* note 382, at 1391.

[385] *See* NCD REPORT, *supra* note 16, at 37.

The Final Rule's drafters believed that the Rule "may spur an expansion in research making use of nondiscriminatory methods of value assessment and research further developing and refining such alternative measures."[386] Yet PCORI has obstructed the development of equitable methodologies of value assessment by flatly refusing to fund grant proposals that assess cost-effectiveness or compare costs.[387] PCORI even rejects proposals using non-QALY approaches such as the evLYG or cost-benefit analysis,[388] despite clear legislative permission to consider cost.[389] PCORI's refusal to fund research that considers costs

[386] *Final Rule*, *supra* note 14, at 40104.

[387] Joe Selby, *Straight Talk with . . . Joe Selby*, 18 NATURE MED. 1164, 1164 (2012) ("We're very clear in our funding announcements that we do not fund — in fact, we don't even review — proposals that have cost-effectiveness analyses in them or projects that propose to compare the cost of care for two different treatments."); *What You Need to Know to Apply*, PATIENT-CENTERED OUTCOMES RSCH. INST., https://www.pcori.org/funding-opportunities/what-you-need-know-apply (last visited Oct. 24, 2024) [https://perma.cc/GB2J-MHK2] (explaining PCORI won't fund "[c]ost-effectiveness analysis measuring dollar-cost per quality-adjusted life-year" or "[c]omparisons that focus on the relative costs of care as the primary criterion for choosing between alternatives").

[388] *See* PATIENT-CENTERED OUTCOMES RSCH. INST., APPLICANT TOWN HALL AUGUST 2013 CYCLE 8, (2013), https://www.pcori.org/assets/2013/06/PCORI_Addressing-Disparities_0813.pdf [https://perma.cc/3LZH-W43V] (stating that studies that evaluate interventions' benefit in terms of non-adjusted life-years, like the evLYG, will not be funded); *2023 Supplemental Funding for Existing PCORI-Funded Comparative Clinical Effectiveness Research to Improve Understanding of Patient-Centered Economic Outcomes FAQ*, PATIENT-CENTERED OUTCOMES RSCH. INST., https://www.pcori.org/funding-opportunities/applicant-and-awardee-resources/frequently-asked-questions-faqs/2023-supplemental-funding-existing-pcori-funded-comparative-clinical-effectiveness-research-improve-understanding-patient-centered-economic-outcomes-faq (last visited Aug. 22, 2024) [https://perma.cc/R8NC-X9L6] ("PCORI will not fund research that compares and contrasts interventions on the basis of comparative costs or cost-effectiveness. This includes methods known as cost-effectiveness, cost-benefit, cost-minimization, cost-consequences, cost-feasibility and cost-utility analyses.").

[389] David H. Howard & Cary P. Gross, *Producing Evidence to Reduce Low-Value Care*, 175 JAMA INTERNAL MED. 1893, 1894 (2015) ("The Patient Protection and Affordable Care Act (ACA) prohibits PCORI from establishing a threshold to determine whether a service is cost-effective but does not prohibit it from funding studies in which cost is an outcome."); Sean D. Sullivan, Josh J. Carlson & Ryan N. Hansen, *Comparative Effectiveness Research in the United States: A Progress Report*, 16 J. MED. ECON. 295, 297 (2013) ("The PPACA does not preclude PCORI from either conducting or funding cost-effectiveness research.").

left open a gap that was filled by nonprofit organizations like the Institute for Clinical and Economic Review ("ICER").[390]

PCORI should fund studies using any value assessment method compatible with the Final Rule. Its refusal to do so represents an unwarranted departure from its statutory mandate, though one that is more difficult to challenge because of PCORI's status as a nonprofit rather than a federal agency.[391] Nothing in PCORI's authorization indicates that it cannot use these approaches. In fact, the specificity of the restrictions on PCORI's use of cost effectiveness methods indicates that uses that fall outside the restrictions would be permitted. Increasing the availability of research using equitable valuation metrics, which PCORI could do by matching its funding priorities to its statutory scope, could enable a pivot away from an unappealing binary decision between decision-making grounded only in first-generation CEA (such as QALYs) and decision-making that is indifferent to value and considers cost alone.

Why has PCORI taken such a restrictive approach to value considerations, including equitable value metrics? The answer lies not in the text of its statutory mandate, but in interest group politics. Organizations like the Partnership to Improve Patient Care strove to ensure that pharmaceutical firms and advocacy groups funded by those firms were well-represented on PCORI's board, though the board also includes representatives of other groups as well.[392] When PCORI was reauthorized, these organizations rejected the idea that PCORI could consider cost-effectiveness or the societal cost of interventions.[393] If even some interest groups and pharmaceutical companies showed a

[390] *See* Rand & Kesselheim, *supra* note 205, at 1403.

[391] *See* Saver, *supra* note 379, at 438-39, 443-44.

[392] *See* Mundy, *supra* note 20, at A4.

[393] *See, e.g.*, Letter from the P'ship to Improve Patient Care, to Nakela Cook, Exec. Dir., Patient-Centered Outcomes Rsch. Inst. (Nov. 13, 2020), https://www.pcori.org/sites/default/files/PCORI-Proposed-Principles-Outcomes-Data-2020-Public-Comment-Submission-PIPC.pdf [https://perma.cc/7UNJ-Y7QN] (rejecting the consideration of societal cost or cost-effectiveness); *cf.* Victoria Colliver, *Stimulus Prompts Talk of Health Care Rationing*, S.F. CHRON. (Feb. 12, 2009), https://www.sfgate.com/news/article/stimulus-prompts-talk-of-health-care-rationing-3251484.php [https://perma.cc/FW2S-WYPH] (explaining that PIPC "supports comparative effectiveness research — as long as the information is not used to make decisions about cost").

willingness to support rather than impede equitable valuation — as HHS has now done as part of the Final Rule — PCORI's unwillingness to fund it may change. If PCORI, for political reasons, maintains a ban on considering cost, states could also step in to fund equitable valuation.[394]

C. Combating Conflicts of Interest

The restrictive approach to value PCORI has taken exemplifies pharmaceutical firms' efforts to influence governmental efforts to value the very medicines they sell to governments. This influence also manifests in the form of financial and positional conflicts of interest that arise when drugmakers pay or partner with organizations that ostensibly serve the interests of patients or marginalized communities.[395]

The NCD report's uncritical attitude toward pharmaceutical companies' price-setting decisions illustrates the risk that conflicts of interest present. They report that Vertex Pharmaceuticals refused to lower prices to cost-effective levels for a cystic fibrosis drug in the UK, claiming that doing so would set a precedent that makes research and development impossible.[396] There is no evidence that lower prices would have rendered research impossible: Vertex's CEO was paid nearly $19 million the same year, evidencing the company's financial flexibility to absorb price changes.[397] Yet NCD's report strikingly refuses to question

394 *Cf.* Myrisha S. Lewis, *Halted Innovation: The Expansion of Federal Jurisdiction over Medicine and the Human Body*, 2018 UTAH L. REV. 1073, 1115 (discussing California's funding of stem cell research).

395 *See, e.g.*, Mello, *supra* note 10, at 2291 n.77 (critiquing "pharmaceutical companies' financial relationships with physicians and patient-advocacy organizations, which can contribute to prescribing and advocacy of costly, branded drugs"); Susannah L. Rose, *Patient Advocacy Organizations: Institutional Conflicts of Interest, Trust, and Trustworthiness*, 41 J.L., MED. & ETHICS 680, 682 (2013) (detailing drugmakers' extensive funding of patient advocacy organizations and explaining that such organizations "might also be more likely to advocate for insurance coverage of drugs that yield minimal or no benefits").

396 NCD REPORT, *supra* note 16, at 53.

397 Andrew Dunn & Ned Pagliarulo, *Follow the Money: How Biopharma CEOs and Workers Got Paid in 2018*, BIOPHARMA DIVE (May 28, 2019), https://www.biopharmadive.com/news/biotech-pharma-ceo-employee-pay/554283/ [https://perma.cc/2NMC-E82M].

Vertex's claims.[398] And Vertex is hardly the only beneficiary of this solicitude: nowhere in NCD's report are drugmakers' pricing decisions recognized as hampering patients' access to medicine, despite ample evidence that prices are a major barrier to Americans' access to medicine. NCD's silence on excessive pricing may assist industry-funded organizations like PIPC, but it does not serve the interests of patients with disabilities and chronic conditions. Moreover, the NCD report's refusal to criticize Vertex and other drugmakers contrasts with its sustained criticism of pharmacy benefits managers who decline to pay for drugs that provide insufficient value for money.[399]

Likewise, NCD's report does not discuss approaches to valuing medicine, like DCEA or ECEA, that intentionally aim to mitigate health disparities that disabled patients face. DCEA and ECEA might well be more effective at addressing these disparities than ignoring value would be.[400] But they would also create a mechanism for governments and other payers to hold pharmaceutical companies to account when their drugs neither improve overall health nor mitigate disparities. Such accountability would advance both health and equity but might be unappealing to drugmakers.

The NCD's members, the organizations with whom they partnered in developing the report, and the experts they interviewed should also be required to disclose their conflicts of interest.[401] The public should understand the extent to which NCD's ostensibly equity-driven recommendations are influenced by drugmakers' interests. When regulatory agencies rely on representations by NCD or advocacy organizations like PIPC in formulating regulations, any conflicts of interest should be publicly visible. Medical and public health journals require that contributors disclose conflicts of interest.[402] More effective

[398] NCD REPORT, *supra* note 16, at 53.

[399] NCD REPORT, *supra* note 16, at 62.

[400] *See supra* Parts IV.C, IV.D.

[401] *See* Israel & van Geertruyden, *supra* note 287; *see generally* NCD REPORT, *supra* note 16 (not listing potential conficts of interest).

[402] *See* Cynthia M. Ho, *A Dangerous Concoction: Pharmaceutical Marketing, Cognitive Biases, and First Amendment Overprotection*, 94 IND. L.J. 773, 823 (2019).

than disclosure, but more challenging to obtain, would be constraints on conflicted individuals' participation in decision-making.[403]

Oversight agency officials can play an important role in preventing conflicts of interest. PCORI's board members, for instance, are selected by the Comptroller General,[404] who could work to ensure that these members do not have conflicts of interest. NCD's board members are selected by the President and the majority and minority leaders in Congress,[405] who could likewise commit to avoiding conflicts. NCD's report criticizing cost-effectiveness analysis, however, was developed through a partnership with external organizations, circumventing public accountability that would otherwise exist.

Courts, notwithstanding their imperfections, can also serve as a counterweight to conflicts of interest. When agencies promulgate interpretations of statutes that are inconsistent with legislative purpose or reflect industry influence, courts can step in to reject them. The demise of *Chevron* deference further empowers courts to overrule agencies.[406] While this expansion of judicial power may threaten health in other contexts, it has the silver lining of further empowering courts to check captured agencies' regulatory interpretations of statutes.[407] For instance, the text and history of the ADA evinced no intent to prohibit consideration of patients' benefit from a drug.[408] If HHS were to nevertheless interpret the ADA to prohibit such consideration, that

[403] Daniel S. Goldberg, *The Shadows of Sunlight: Why Disclosure Should Not Be a Priority in Addressing Conflicts of Interest*, 12 PUB. HEALTH ETHICS 202, 209 (2019).

[404] *Governance*, PATIENT-CENTERED OUTCOMES RSCH. INST., https://www.pcori.org/about/governance (last updated Dec. 27, 2022) [https://perma.cc/6YXN-X8AU].

[405] 29 U.S.C. § 780.

[406] *See* Loper Bright Enters. v. Raimondo, 144 S. Ct. 2244, 2273 (2024).

[407] Some argued that courts should serve as a stronger check even before *Chevron*'s demise. *E.g.*, Kimberly N. Brown, *Public Laws and Private Lawmakers*, 93 WASH. U. L. REV. 615, 669 (2016) (arguing that "agency policymaking should not receive *Chevron* deference to the extent that it derives from substantial private sector influence"); Brie D. Sherwin, *The Upside Down: A New Reality for Science at the EPA and Its Impact on Environmental Justice*, 27 N.Y.U. ENV'T. L.J. 57, 96 (2019) (suggesting that courts should "provide less deference than what was dictated in *Chevron* to agencies that are clearly subject to agency capture").

[408] *See* Rai, *supra* note 96, at 1092 n.329, 1092-93.

interpretation should be invalidated, and would be easier to invalidate under less agency-deferential approaches.[409]

D. Rewarding Equitable Outcomes

Banning the use of first-generation approaches to valuation, like QALYs, allows interest groups and organizations to appear equitable without spending money or effort creating better alternatives. But bans without alternatives leave payers without affirmative incentives to mitigate health disadvantages. Pharmaceutical companies are likewise left without incentives to develop drugs that mitigate inequities.

Rather than banning first generation CEA, innovation policy should strive to align rewards with equitable valuation. Consider one example. The Orphan Drug Act gives drug companies a stronger incentive to treat a rare disease than an equally severe common disease. But patients with rare diseases are hardly the only group that should benefit from such incentives. As Buccafusco and Masur observe, "the Orphan Drug Act is an imperfect fit for the goal of increasing human welfare"[410] — it is also an imperfect fit from an equity standpoint. Instead, it would be preferable to incentivize the development of interventions that address health disparities.[411] This could be done via an exclusivity scheme akin to the Orphan Drug Act, though doing so might raise the short-term price payers pay for these drugs. Alternatively, it could be achieved by offering a prize incentive for drugs that address these problems.[412]

Similarly, the more generous reimbursements in the Medicare program, compared to Medicaid, give drug companies a stronger

[409] *Cf.* Mark Seidenfeld, *A Syncopated* Chevron*: Emphasizing Reasoned Decisionmaking in Reviewing Agency Interpretations of Statutes*, 73 TEX. L. REV. 83, 129 (1994) (proposing a modification to *Chevron* deference under which "the agency should explain why its interpretation is good policy in light of the purposes and concerns underlying the statutory scheme").

[410] Buccafusco & Masur, *supra* note 28, at 1436 ("If a disease afflicts fewer than 200,000 people, that is — if anything — an indication that a drug that treats that disease *may not* have a substantial aggregate effect on welfare." (emphasis in original)).

[411] *See* Lemley et al., *supra* note 316, at 106-07.

[412] *Cf.* Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Policy Pluralism*, 128 YALE L.J. 544, 557 (2019) (discussing prizes as innovation incentives and asserting that "prizes are preferable to patents when willingness to pay is a poor proxy for social value (such as for vaccines aimed at contagious diseases primarily afflicting the very poor)").

incentive to develop treatments for the diseases of Medicare beneficiaries.[413] Medicare beneficiaries tend to be older and whiter than the general U.S. population,[414] whereas the Medicaid population is poorer and more racially diverse than the general population.[415]

State prescription drug affordability initiatives, as well as the Inflation Reduction Act's drug price negotiation efforts, are another place where equitable valuing approaches could effectively be used. The ACA's language about fairness to diverse segments of the population indicates the importance of achieving health equity, as do many states' endorsement of efforts to mitigate health disparities.[416] Moreover, recognizing health equity as a relevant goal need not contravene legal constraints on the consideration of characteristics like individual patients' race, so long as health equity is pursued without treating individual beneficiaries differently based on their race.[417] Identifying the mitigation of health inequities and disparities as a relevant factor in negotiation and reimbursement could narrow gaps for current patients and create desirable incentives for future equity-promoting innovation.

CONCLUSION

Some argue that fairness to people who are disadvantaged requires ignoring the efficacy of the medicines they take. This Article disagrees. The way to be fair to people who are unfairly disadvantaged is to increase access, now and in the future, to interventions that benefit people and reduce health disparities.

In seeking support for these equity-oriented reforms, it will be crucial to enlist multiple constituencies and interest groups, including some of

---

[413] *See id.*

[414] *Medicare Beneficiary Enrollment Trends and Demographic Characteristics*, ASSISTANT SEC'Y FOR PLAN. & EVALUATION 5 (Mar. 2, 2022), https://aspe.hhs.gov/sites/default/files/documents/f81aafbba0b331c71c6e8bc66512e25d/medicare-beneficiary-enrollment-ib.pdf [https://perma.cc/9QRD-CRHL].

[415] ROBIN RUDOWITZ, JENNIFER TOLBERT, ALICE BURNS, ELIZABETH HINTON & ANNA MUDUMALA, KFF, MEDICAID 101, at 9 (2024), https://www.kff.org/health-policy-101-medicaid/ [https://perma.cc/M4CS-P7YJ].

[416] *See* Persad, *Allocating Medicine Fairly*, *supra* note 359, at 1128-29.

[417] Govind Persad, *Antiracist Medicine in Colorblind Courts*, 123 MICH. L. REV. 145, 200-02 (2024).

the same groups who have criticized QALY-based CEA. This Article's proposal to equitably value medicine aims to address two core constituencies. First, it strives to show advocates sincerely interested in fairness that valuing medicine need not further disadvantage those who are unfairly marginalized and can in fact narrow health disparities. By emphasizing the incremental benefit of medicines rather than patients' overall post-treatment health outcomes, equitable approaches to valuation reduce the risk that patients' preexisting disadvantage will lead to their being assigned lower priority for access to medicines. Additionally, equitable approaches can assign special importance to providing medicines that help address health disparities. While some strands in religious traditions may seem to reject valuation, others, like the "preferential option for the poor" in Catholic theology,[418] support equitable valuation. Despite NCD's criticisms of QALYs, it has called for more investment in next-generation CEA.[419]

Second, pharmaceutical firms in fact have good reason to support equitable valuation, particularly when compared to alternative ways that prices or reimbursements might be limited. Given that the Inflation Reduction Act has authorized the government to leverage its buying power to obtain better purchasing terms, pharmaceutical companies need not fare worse if the government negotiates based on value than if it negotiates based on companies' past research and development costs or receipt of government support.[420] Firms that are confident that they can deliver high-benefit interventions that advance equity should prefer a value-based approach to negotiation over one based on research and development costs.[421]

---

[418] Benjamin Pietro Marcus, *Base Constitutional Communities: Lessons from Liberation Theology for Democratic Constitutionalism*, 133 YALE L.J. 272, 298-99 (2023).

[419] NCD REPORT, *supra* note 16, at 63-64, 71 (cost benefit analysis and MCDA; calling for more investment in MCDA).

[420] *See* Hemel & Ouellette, *supra* note 28, at 585 (observing that considering cost-effectiveness could support more generous reimbursements than are currently offered for effective medications).

[421] *See* Jennifer C. Chen & Anna Kaltenboeck, *Who is Sowing Seeds of Confusion About the QALY?*, HEALTH AFFS. FOREFRONT (July 24, 2020), https://www.healthaffairs.org/content/forefront/sowing-seeds-confusion-qaly [https://perma.cc/JRJ8-W4NN] (explaining that firms who see profit opportunities in valuing medicine have been happy to conduct and disseminate cost-effectiveness analyses).

Critics of valuing medicine have asserted that they "just don't think the government should be in the business of determining what people can and can't have for health care options."[422] This Article has argued that because subsidizing some patients' health care options inevitably affects access for others, the question is *how*, not *whether*, such determinations should be made. Any decision by governments and insurers about which medicines to pay for, and how much to pay for them, affects access for patients and generates incentives for drugmakers. Equitably valuing medicines — not refusing to value them — is the best path to improving access for marginalized patients and incentivizing drugmakers to promote health equity.

TABLE 1: ILLUSTRATING THE TREATMENT INCREMENTAL LIFE EXTENSION PLUS QUALITY (TILEPQ) METRIC

	Baseline HRQoL	**Treatment X (+1 yr @ HRQoL 1)**		**Treatment Y (+2 yrs @ HRQoL 0.6)**		**Treatment Z (+4 yrs @ HRQoL 0.2)**	
		ΔLY	**ΔHRQOL**	**ΔLY**	**ΔHRQOL**	**ΔLY**	**ΔHRQOL**
Patient A	1	1	0	2	-0.8	4	-3.2
TILEPQ (ΔLY+ ΔHRQOL)		1		1.2		0.8	
Patient B	0.6	1	0.4	2	0	4	-1.6
TILEPQ (ΔLY+ ΔHRQOL)		1.4		2		2.4	

HRQoL: health-related quality of life
LY: years of life
Δ: change in health-related quality of life or years of life
Patients A and B are hypothetical patients with different baseline HRQoL, receiving the same treatment

[422] Colliver, *supra* note 393.