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Pricing Drugs Fairly

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Govind Persad, Pricing Drugs Fairly, 62 Wm. & Mary L. Rev. 928 (2021).



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Pricing Drugs Fairly

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PRICING DRUGS FAIRLY

GOVIND PERSAD*

ABSTRACT

Dissatisfaction with drug prices has prompted a flurry of recent legislation and academic research. But while pharmaceutical policy often regards fair pricing as a goal, the concept of fairness itself frequently goes undefined. Legal scholarship—even work ostensibly focused on fairness—has not defined and defended an account of fair pricing. Recent legislative proposals in the House and Senate have similarly avoided a determinate position on fairness. This Article explains and defends an account of what makes a price for a drug fair (identifying fair price with social value), argues for implementing fair pricing through a price ceiling grounded in social value, and examines how the proposed price ceiling could overcome legal and political obstacles. By focusing on fairness, this Article pursues a goal that complements, rather than duplicates, recent legal scholarship on pharmaceutical pricing.

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This Article makes three contributions. First, it identifies, makes explicit, and categorizes the most prominent conceptions of fairness in drug pricing. Second, it advances an account of fair pricing that centers on a drug's value to society. Third, it proposes the implementation of fair pricing via a price ceiling that ensures that the price of a drug does not exceed its value to society and explains how this price-ceiling approach would address a variety of legal and political obstacles.

In Part I, the Article categorizes conceptions of fair pricing. It first considers procedural fairness and critically evaluates the view that any price reached in a procedurally fair negotiation is substantively fair. It then reviews four comparators used for assessing substantive fairness: (a) the cost of developing the drug, (b) the drug's affordability to patients, (c) the drug's customary price, and (d) the drug's social value. Part I concludes that social value should be used to identify when a price is unfair, although the other factors can indicate procedural unfairness or serve to justify other policies, such as subsidized insurance. Part II then takes on the task of defining social value. It explains how cost-effectiveness analysis could be used to define social value and argues that cost-effectiveness analysis should be modified to incorporate factors other than overall costs and health benefits, such as fairness to patients with preexisting disabilities and reduction of health disparities. However, this analysis should not be modified to provide greater incentives to treat rare diseases or diseases lacking other treatments.

Part III turns to implementation, arguing that fair pricing can best be achieved through a price ceiling that tracks social value. It explains how such a price ceiling could incentivize the production of socially valuable treatments and describes the legal, ethical, and political advantages of price ceilings over other options, such as reimbursement ceilings. In particular, the availability of treatments whose price exceeds the reimbursement ceiling will lead to administrators enforcing the reimbursement ceiling taking the blame when patients die or suffer illness. In contrast, while price ceilings may discourage the development of costly drugs, they do not require payers to reject identifiable patients who could benefit from existing treatments or families to refuse those treatments. Price ceilings also

avoid the legal limitations that private and public insurers face when they attempt to deny coverage for expensive treatments.

Part IV identifies potential legal obstacles to the implementation of a price ceiling and explains how to avoid them. Some obstacles, like preemption and the Dormant Commerce Clause, apply only to state-level efforts. Other obstacles, such as the Takings Clause and a potential revival of Lochner-era freedom of contract, also apply to federal initiatives.

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INTRODUCTION

A new gene therapy for spinal muscular atrophy, Zolgensma, was recently priced at over \$2 million per treatment.¹ Insulin prices have tripled between 2002 and 2013, with some patients paying more than \$1000 per month.² Are these prices fair? If not, what should we do about it? While pharmaceutical policy often regards fair pricing as a goal, the concept of fairness itself frequently goes undefined. This Article explains and defends an account of what makes a price for a drug fair that identifies fair price with social value, argues for implementing fair pricing through a price ceiling grounded in social value, and examines how the proposed price ceiling could overcome legal and political obstacles.

By focusing on fairness, this Article pursues a goal that complements, rather than duplicates, recent legal scholarship on pharmaceutical pricing. Since the early 2000s, legal and political obstacles have stymied efforts to regulate drug prices. Washington, D.C.'s regulatory effort to cap the prices of patented drugs was found to be preempted by federal patent law,³ while the recent Maryland drug price regulations were struck down on Dormant Commerce Clause grounds.⁴ Much scholarship on domestic drug pricing has focused on specific legal obstacles to price regulation, such as patent preemption, the Dormant Commerce Clause, takings challenges, or void-for-vagueness challenges.⁵ Other scholarship

1. Peter B. Bach, 'Anchoring' Was at Work in Setting the Price of Novartis' New Gene Therapy, STATNEWS (June 4, 2019), <https://www.statnews.com/2019/06/04/anchoring-price-zolgensma/> [<https://perma.cc/T5EN-TCF2>].

2. Megan Thielking, *Protesters Take Anger over Insulin Prices to Drug Makers, Some Bearing Children's Ashes*, STATNEWS (Nov. 12, 2018), <https://www.statnews.com/2018/11/12/protest-insulin-prices-sanofi-mothers-bring-children-ashes/> [<https://perma.cc/5JWY-KKWX>].

3. *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1365 (Fed. Cir. 2007).

4. *Ass'n for Accessible Meds. v. Frosh*, 887 F.3d 664, 666 (4th Cir. 2018), *cert. denied*, 139 S. Ct. 1168 (2019).

5. See, e.g., Michelle M. Mello & Rebecca E. Wolitz, *Legal Strategies for Reining in "Unconscionable" Prices for Prescription Drugs*, 114 NW. U.L. REV. 859, 863 (2020) (discussing void-for-vagueness challenges); Robin Feldman, Betty Chang Rowe, Rabiah Oral, Amy Y. Gu & Katherine Gudiksen, *The Patent Act and the Constitutionality of State Pharmaceutical Regulation*, 45 RUTGERS COMPUT. & TECH. L.J. 40, 41 (2019) (discussing preemption and takings challenges); AARON BERMAN, THEODORE LEE, ADAM PAN, ZAIN RIZVI & ARIELLE

has searched for innovative legal avenues, such as antitrust or human rights law, to rein in prices.⁶

Despite popular, legislative, and academic dissatisfaction with drug prices, legal scholarship—even when ostensibly focused on fairness—has not defined and defended a specific account of fair pricing.⁷ Recent legislative proposals either pass the buck on defining fairness by indexing the desired price to international drug prices or to inflation or use a catch-all approach that includes almost every plausible criterion for fairness.⁸ Defining a fair price would help to enrich the burgeoning discussion around drug pricing. It could also help forestall the “drunkard’s search” problem, when fundamental policy goals are determined by what seems achievable rather than by what is actually desirable.⁹ And it could also help head off void-for-vagueness challenges.¹⁰

THOMAS, YALE GLOB. HEALTH JUST. P'SHIP, CURBING UNFAIR DRUG PRICES: A PRIMER FOR STATES 12 (2017), https://law.yale.edu/sites/default/files/area/center/ghjp/documents/curbing_unfair_drug_prices-policy_paper-080717.pdf [<https://perma.cc/PRN4-XHW7>] (discussing preemption); Christopher Robertson, *Will Courts Allow States to Regulate Drug Prices?*, 379 NEW ENG. J. MED. 1000, 1000 (2018) (discussing the Dormant Commerce Clause).

6. See, e.g., Harry First, *Excessive Drug Pricing as an Antitrust Violation*, 82 ANTITRUST L.J. 701, 705 (2019); Kwanghyuk Yoo, *Interaction of Human Rights Law and Competition Law: The Right to Access to Medicines and Consumer Welfare in the U.S. Pharmaceutical Sector*, 43 VT. L. REV. 123, 124-26 (2018).

7. See, e.g., Mello & Wolitz, *supra* note 5, at 863 (noting the “deeper normative questions about what constitutes ‘fair’ pricing and how it should be evaluated,” but not attempting to answer those questions); First, *supra* note 6, at 706; BERMAN ET AL., *supra* note 5, at 4 (asserting that “[u]nfair drug pricing represents a particularly egregious problem,” but not defining what constitutes a fair price).

8. See Billy Wynne & Alyssa Llamas, *New Legislation to Control Drug Prices: How Do House and Senate Bills Compare? An Update*, COMMONWEALTH FUND (Jan. 9, 2020), <https://www.commonwealthfund.org/blog/2020/new-legislation-control-drug-prices-how-do-house-and-senate-bills-compare-update> [<https://perma.cc/E9HX-N3FN>] (discussing the House’s Elijah E. Cummings Lower Drug Costs Now Act and the Senate’s Prescription Drug Pricing Reduction Act of 2019); Mello & Wolitz, *supra* note 5, at 870 & n.66 (discussing the Prescription Drug Price Relief Act of 2019, which permits the classification of a drug as “excessively priced” based on its price exceeding the price charged in other developed countries, its price being incommensurate with its cost of development or its health benefits, or “[o]ther factors the Secretary determines appropriate” (quoting Prescription Drug Price Relief Act, S. 102, 116th Cong. § 2(b)(2)(H) (2019) (alteration in original))).

9. See ROBERT JERVIS, *HOW STATESMEN THINK: THE PSYCHOLOGY OF INTERNATIONAL POLITICS* 40-60 (2017) (defining the drunkard’s search problem).

10. Cf. Mello & Wolitz, *supra* note 5, at 905 (asserting that clarifying the standards for “unreasonableness” could help avoid vagueness challenges).

This Article makes three contributions. First, it identifies, makes explicit, and categorizes the most prominent conceptions of fairness in drug pricing. Second, it advances an account of fair pricing that centers on a drug's value to society. Third, it proposes the implementation of fair pricing via a price ceiling that ensures that the price of a drug does not exceed its value to society, and it explains how this price-ceiling approach would address a variety of legal and political obstacles.

While this Article connects its contributions to one another, they are separable. Even those who reject its account of fair pricing should find the taxonomy offered in Part I useful. And Part II.D's proposal to define fair pricing in terms of social value could be implemented in other ways than the price ceiling the Article proposes. Conversely, the price-ceiling approach explained in Part III could be used to implement an account of fair pricing that defines social value differently from the Article's proposal or does not base pricing on social value.

In Part I, the Article categorizes conceptions of fair pricing. It first considers procedural fairness and critically evaluates the view that any price reached in a procedurally fair negotiation is substantively fair. It then reviews four comparators used for assessing substantive fairness: (a) the cost of developing the drug, (b) the drug's affordability to patients, (c) the drug's customary price, and (d) the drug's social value. Part I concludes that social value should be used to identify when a price is unfair, although the other factors can indicate procedural unfairness or serve to justify other policies, such as subsidized insurance.

Part II takes on the task of defining social value. It explains how cost-effectiveness analysis could be used to define social value and considers whether to modify cost-effectiveness analysis to incorporate factors other than cost and health benefits. Part III then defends the use of a price ceiling—a limit on the price that any purchaser can be charged—that tracks social value. It explains how such a price ceiling could incentivize the production of socially valuable treatments, and it describes the legal, ethical, and political advantages of price ceilings over other options such as reimbursement ceilings that limit the price specific purchasers will pay for drugs. In particular, the availability of treatments whose price

exceeds the reimbursement ceiling subject administrators enforcing the reimbursement ceiling to blame when patients die or suffer illnesses. In contrast, while price ceilings may discourage the development of costly drugs, they do not require payers to refuse to reimburse identifiable patients who could benefit from existing treatments.

Part IV identifies potential legal obstacles to a price ceiling and explains how to avoid them. Some obstacles, such as preemption and the Dormant Commerce Clause, apply only to state-level efforts. Other obstacles, such as the Takings Clause and a potential revival of *Lochner*-era freedom of contract, also apply to federal initiatives.

I. WHAT IS A FAIR PRICE FOR A DRUG?

In this Part, I categorize and present a variety of approaches to fair pharmaceutical pricing and defend an approach grounded in social value. While legal scholarship has often raised the question of what a fair price is for a drug, there has not yet been a comprehensive attempt to address it. This Part fills that gap.

I first consider and reject as inadequate the view that a fair price is the price that a drug would command in a competitive market. Even if this approach is normatively compelling, pharmaceutical markets deviate from ideal competition in a way that makes it inapplicable. I then review the four most prominent approaches to defining a fair price for goods in markets that deviate from ideal competition, which I call the *cost*, *affordability*, *custom*, and *social value* approaches.

A. Procedural Fairness

1. *Is Procedural Fairness Sufficient for a Price to Be Fair?*

For most goods and services, modern market societies regard the prevailing price in a competitive market as fair.¹¹ Courts similarly

11. See NAT'L ACADS. SCIS., ENG'G, & MED., MAKING MEDICINES AFFORDABLE: A NATIONAL IMPERATIVE 18 (Norman R. Augustine, Guru Madhavan & Sharyl J. Nass eds., 2018), <https://www.nap.edu/read/24946/chapter/1> [<https://perma.cc/N9G8-AZ5Q>] [hereinafter NAM REPORT] ("In the United States, market forces are generally considered to be the most

often equate fair prices with market prices.¹² This approach makes fair pricing an application of what John Rawls famously called “pure procedural justice,” under which an outcome’s origin in a fair process establishes its fairness.¹³

Unconscionability doctrine is the branch of law that has most closely examined whether fairness is purely procedural. Many legal systems historically regarded nonprocedural factors as relevant to fair pricing: such factors included the seller’s labor investment, the community’s view of reasonableness, and the prices other buyers pay for similar goods.¹⁴ Modern contract law, in contrast, generally restricts itself to procedural considerations.¹⁵ As Ian Ayres observes, “[c]ontracts are almost never struck down for unconscionable price terms,”¹⁶ and the black letter rule is that “courts do not inquire into the adequacy of consideration.”¹⁷

Notwithstanding this black letter rule, modern courts do sometimes question and reform prices in contracts.¹⁸ Often, court intervention is motivated by procedural concerns: while some equate

economically efficient way of determining what goods are provided and at what price.”); Florian Rödl, *Contractual Freedom, Contractual Justice, and Contract Law (Theory)*, 76 LAW & CONTEMP. PROBS. 57, 69 (2013) (“explain[ing] why the fair price is represented as the competitive market price”).

12. See, e.g., *Chattanooga Foundry & Pipe Works v. City of Atlanta*, 203 U.S. 390, 396 (1906) (discussing the “market or fair price” that would have been paid absent sellers’ anticompetitive conduct).

13. JOHN RAWLS, *A THEORY OF JUSTICE* 75 (1999) (“[P]ure procedural justice obtains when there is no independent criterion for the right result: instead there is a correct or fair procedure such that the outcome is likewise correct or fair, whatever it is, provided that the procedure has been properly followed.”).

14. See, e.g., William Boyd, *Just Price, Public Utility, and the Long History of Economic Regulation in America*, 35 YALE J. ON REG. 721, 733-34 (2018) (describing the view that, prior to modern capitalism, “the just price of any particular good or service was tied not to what it could fetch in the market but rather to its cost of production and to the producer’s station in life”).

15. F.H. Buckley, *Three Theories of Substantive Fairness*, 19 HOFSTRA L. REV. 33, 33-34 (1990) (asserting that “contemporary legal scholars” believe that “an unconscionable bargain must be procedurally unfair, in the sense that it was induced through an improper strategy” and that if “the procedural requirements are satisfied, there is no basis for inquiring into the contract’s substantive fairness”).

16. Ian Ayres, *Three Proposals to Harness Private Information in Contract*, 21 HARV. J.L. & PUB. POL’Y 135, 140 (1997).

17. RESTATEMENT (SECOND) OF CONTS. § 79 cmt. c (AM. L. INST. 1981); see, e.g., *De La Torre v. CashCall, Inc.*, 422 P.3d 1004, 1014 (Cal. 2018) (“[U]nconscionability requires oppression or surprise—that is, procedural unconscionability.”).

18. See Mello & Wolitz, *supra* note 5, at 907.

procedural unfairness with seller misbehavior,¹⁹ courts and commentators have also endorsed intervention when sellers have monopoly power over necessary goods or when buyers lack important information.²⁰ And some courts have gone further, striking down or modifying prices even absent procedural unfairness.²¹

2. Procedural Imperfections in Pharmaceutical Markets

The possibility that contractually agreed prices can be unfair absent procedural unfairness would be sufficient to establish the relevance of Part II.B's inquiry into substantive fairness, even in a world where pharmaceutical markets were procedurally impeccable. But, more importantly, intellectual property protection, regulatory exclusivity, barriers to market entry, third-party payment, informational asymmetries, and buyer desperation push pharmaceutical markets far from the theoretical ideal of competition.²² Pharmaceutical patents, of course, involve governmentally created monopolies.²³ But even markets for generic drugs are typically at best oligopolistic, with only a few sellers producing any given drug.²⁴ This reflects both legal restrictions and scientific obstacles. Pharmaceuticals sold in the United States must meet stringent Food and Drug Administration regulations.²⁵ And the expertise needed to produce

19. See, e.g., *Emerald Portfolio, LLC v. Outer Banks/Kinnakeet Assocs., LLC*, 790 S.E.2d 721, 726 (N.C. Ct. App. 2016).

20. See John A. Spanogle, Jr., *Analyzing Unconscionability Problems*, 117 U. PA. L. REV. 931, 948, 955 (1969) (“[A] court may ... interpret ‘oppression’ to mean terms, however obtained, that will create oppressive effects, so that procedural abuses are irrelevant.”).

21. See Mello & Wolitz, *supra* note 5, at 913-15 (collecting cases).

22. See NAM REPORT, *supra* note 11, at 19 (“[D]escribing the biopharmaceutical supply chain in the United States as largely driven by *competitive* market forces would be substantially misleading.”).

23. See Hannah Brennan, Amy Kapczynski, Christine H. Monahan & Zain Rizvi, *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275, 284-85 (2016).

24. See, e.g., Joseph Stiglitz, *The New Era of Monopoly Is Here*, GUARDIAN (May 13, 2016, 9:15 AM), <https://www.theguardian.com/business/2016/may/13/new-era-monopoly-joseph-stiglitz> [<https://perma.cc/AKH5-L54N>] (listing the pharmaceutical industry among several in which “what competition exists is oligopolistic”); Brennan et al., *supra* note 23, at 296 (“[A]s the Federal Trade Commission has shown, the pharmaceutical industry displays oligopolistic dynamics.”).

25. See Andrew Blair-Stanek, *Just Compensation as Transfer Prices*, 58 ARIZ. L. REV. 1077, 1089 n.61 (2016) (explaining that “[v]arious legal and economic hurdles,” such as FDA

even approved drugs is often extensive. Worse, oligopolies often devolve into temporary monopolies when—because of regulatory or manufacturing issues—only one firm can produce a generic drug.²⁶ Opportunistic firms then exploit temporary monopolies to raise prices.²⁷

In addition to limited supplier-side competition, buyers' desire and ability to bargain for lower prices is also weakened in pharmaceutical markets.²⁸ Rather than being purchased and paid for by consumers, prescription drugs are selected by physicians and, for insured patients, paid for wholly or partly by insurers.²⁹ Pharmaceutical markets also involve extensive informational asymmetries, with buyers often understanding little about the properties of the drugs being sold.³⁰ This is true even when buyers have the capacity to make medical decisions, and even more true in situations—such as emergencies—when buyers lack capacity.³¹ These informational asymmetries mean that buyers in pharmaceutical markets often exhibit what has been called “weak agency.”³² While patients can look to physicians for information about the medical effects of prescribed drugs, which helps alleviate informational asymmetries, physicians do not have to bear the financial costs of drugs³³ and often profit from prescribing more expensive drugs.³⁴ Meanwhile,

safety approval, “limit the entry into the market of generic versions of drugs whose patents have lapsed”).

26. See Rachel E. Sachs, *Addressing Pharmaceutical Price Spikes Through Generic Preclearance*, 39 J. LEGAL MED. 169, 171 (2019).

27. See *id.*; Blair-Stanek, *supra* note 25, at 1089 n.61.

28. See Brittany S. Bruns, Note, *The Pharmaceutical Access Act: An Administrative Eminent Domain Solution to High Drug Prices*, 106 CALIF. L. REV. 2023, 2030-31 (2018).

29. See BARUCH A. BRODY, ETHICAL ISSUES IN DRUG TESTING, APPROVAL, AND PRICING 244 (1995); Steven D. Pearson, Len Nichols & Amitabh Chandra, *Policy Strategies for Aligning Price and Value for Brand-Name Pharmaceuticals*, HEALTH AFFS., Mar. 2018, at 1-2.

30. Bruns, *supra* note 28, at 2030 (“[I]nformation asymmetries prevent patients from making educated choices about the costs and benefits of pharmaceutical products.”).

31. See *id.* at 2030-31.

32. See DEBRA SATZ, WHY SOME THINGS SHOULD NOT BE FOR SALE 9 (2010) (defining “weak agency” as arising when “some parties have poor information about the goods they are exchanging, or in which some parties are not direct participants in the exchange but depend on others’ decisions” and arguing that weak agency can support a judgment that a market is noxious).

33. See BRODY, *supra* note 29, at 244; Bruns, *supra* note 28, at 2030.

34. See, e.g., *In re Pharm. Indus. Average Wholesale Price Litig.*, 230 F.R.D. 61, 76 (D. Mass. 2005); Pearson et al., *supra* note 29, at 2 (explaining that Medicare and private insurance often give physicians “incentives to prescribe higher-price drugs”).

insurance reduces patients' incentive to care about price.³⁵ Last, pharmaceutical markets are often characterized by buyer desperation.³⁶ Patients facing the prospect of pain, loss of function, or death often ignore costs as they strive to avoid these outcomes.³⁷ The combination of buyer vulnerability and weak agency further supports concerns about the fairness of pharmaceutical markets.³⁸

Because procedural unfairness in pharmaceutical pricing can result from myriad factors, a uniquely correct strategy for achieving better procedural fairness is unlikely. Various strategies have been proposed for increasing competition, including accelerating regulatory approval for generic drugs when shortages exist, incentivizing firms to enter generic markets when insufficient competition exists, and creating public or nonprofit drug manufacturers to compete with private ones.³⁹ Strategies have also been proposed to incentivize physicians and insured patients to be price-sensitive, including value-based insurance.⁴⁰

But, even if these strategies successfully improve generic competition, a purely procedural approach to fair pricing remains incomplete. Patent protection and regulatory exclusivity, though they preclude fully competitive markets for new drugs such as Zolgensma, are not defects but intentional choices to reduce competition in order to achieve other goals.⁴¹ And the often dire consequences of untreated illness make buyer desperation unavoidable.⁴² These competition-impeding factors make an account of

35. See BRODY, *supra* note 29, at 244; Pearson et al., *supra* note 29, at 1 (observing that subsidized insurance obscures ordinary signals of demand).

36. See Mello & Wolitz, *supra* note 5, at 932 (analogizing the desperation of patients seeking prescription medication to consumers falling victim to predatory lenders).

37. See Bruns, *supra* note 28, at 2030.

38. Cf. SATZ, *supra* note 32, at 9 (describing vulnerability as existing when "some people are so poor or so desperate that they accept any terms of exchange that are offered").

39. See Sachs, *supra* note 26, at 169-70 (summarizing approaches to improving generic competition); see also Mello & Wolitz, *supra* note 5, at 871-72 (describing various initiatives, including a recent proposal to have government manufacture generic medications).

40. See, e.g., Harald Schmidt & Ezekiel J. Emanuel, *Lowering Medical Costs Through the Sharing of Savings by Physicians and Patients: Inclusive Shared Savings*, 174 JAMA INTERNAL MED. 2009, 2012 (2014).

41. See Sachs, *supra* note 26, at 170-71.

42. See Ezekiel J. Emanuel, *When Is the Price of a Drug Unjust? The Average Lifetime Earnings Standard*, 38 HEALTH AFFS. 604, 605 (2019).

substantive fairness for pharmaceutical prices desirable, even within frameworks that regard competitive market prices as fair.

3. *How Procedural Fairness Matters*

Rather than understanding fair pricing as confined to procedural considerations, as a pure procedural justice approach would, procedural fairness is better understood as one among many constraints on the fairness of transactions. Serious procedural defects in a transaction can render that transaction unfair, regardless of price.⁴³ For instance, a transaction in which the seller misrepresents what is sold is unfair, even if the buyer does not pay an unfair price.⁴⁴ But not all procedural defects inevitably generate unfairness. While monopoly power makes substantive unfairness more likely, a price charged by a monopolist can nevertheless be substantively fair.⁴⁵

B. *Substantive Fairness*

The pervasive procedural defects in pharmaceutical markets make an examination of substantive fairness particularly important. Many have noted that justifying fairness determinations is challenging.⁴⁶ In this Section, I will evaluate four prominent approaches, which each rely on a different comparison factor: (a) the *cost* incurred by the seller, (b) the *affordability* of the drug to purchasers, (c) the *customary* prices charged elsewhere for the drug, and (d) the *social value* of the drug.

Scholarly and legislative proposals have recognized these factors and endorsed some or all as relevant.⁴⁷ The Prescription Drug Price

43. See Mello & Wolitz, *supra* note 5, at 911.

44. See U.C.C. § 1-201(b)(20) (AM. L. INST. & NAT'L CONF. OF COMM'RS ON UNIF. STATE LS.) (defining "good faith" as including "honesty in fact").

45. See Mello & Wolitz, *supra* note 5, at 912-13 (discussing "sliding-scale" view); MARK KELMAN, A GUIDE TO CRITICAL LEGAL STUDIES 76 (1987).

46. See, e.g., *Jones v. Star Credit Corp.*, 298 N.Y.S.2d 264, 266 (Sup. Ct. 1969) ("[D]eciding the issue is substantially easier than explaining it."); Steven W. Bender, *Rate Regulation at the Crossroads of Usury and Unconscionability: The Case for Regulating Abusive Commercial and Consumer Interest Rates Under the Unconscionability Standard*, 31 HOUS. L. REV. 721, 754 (1994).

47. See, e.g., Bender, *supra* note 46, at 752-53.

Relief Act of 2019 (PDPRA) permits the classification of a drug as “excessively priced” based on factors including affordability, value, cost of development, and comparison to international prices.⁴⁸ Aaron Kesselheim has similarly suggested that a drug’s clinical value, affordability, and cost of development are all relevant to whether the drug is fairly priced.⁴⁹ Other commentators have identified and described some or all of the four factors I identify without endorsing all as relevant. Michelle Mello and Rebecca Wolitz discuss all four of these factors and endorse the social value approach and (qualifiedly) the cost approach, while rejecting the affordability approach.⁵⁰ Both Frederick Abbott and a team at Yale Law School, conversely, reject the value approach, as well as the customary approach, in favor of the cost approach.⁵¹ Last, the eminent health economist Mark Pauly identifies the cost, value, and custom approaches without explicitly endorsing any.⁵² I will endorse the social value approach and explain the problems with the alternatives.

1. *Cost of Development*

Costs have been regarded as relevant, and sometimes determinative, when assessing the fairness of pharmaceutical prices, as well as prices more generally.⁵³ Historical approaches to substantive fairness often judged a price unfair if it too greatly exceeded the seller’s costs.⁵⁴ Some modern courts also recognize when a “price is

48. Mello & Wolitz, *supra* note 5, at 870; Prescription Drug Price Relief Act of 2019, S. 102, 116th Cong. § 2(b)(2).

49. Aaron Kesselheim, *Ethics Talk: What’s a Fair Price for a Drug You’ll Die Without?*, AMA J. ETHICS (2019), <https://journalofethics.ama-assn.org/podcast/ethics-talk-whats-fair-price-drug-youll-die-without> [<https://perma.cc/HER2-DE4D>].

50. See Mello & Wolitz, *supra* note 5, at 871, 950, 962.

51. See Frederick M. Abbott, *Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health*, 6 U.C. IRVINE L. REV. 281, 303-05 (2016); see also BERMAN ET AL., *supra* note 5, at 13 (discussing the cost of development, customary price, and social value approaches, and praising the cost of development approach as most rigorous).

52. Mark V. Pauly, *The Impact of Health Reform on the Pharmaceutical Industry*, 24 SETON HALL L. REV. 1271, 1279-80 (1994).

53. See Bender, *supra* note 46, at 755 (endorsing the net profit standard as accurately measuring “unfairness of price and related terms such as interest” based on the costs incurred by the seller).

54. See Boyd, *supra* note 14, at 757-58.

grossly excessive in relation to the seller's costs."⁵⁵ Commentators recognize disparity between price and cost as a factor favoring unconscionability, though it is often ambiguous whether the cost encompasses the seller's total costs of operation or only the cost of the good itself.⁵⁶ They have also argued that cost is a normatively appropriate basis for assessing fairness.⁵⁷ More recent case law on unconscionable prices similarly regards a disparity between cost and price as constitutive of unfairness.⁵⁸ Statutes prohibiting price gouging likewise often refer to the seller's acquisition costs.⁵⁹ Some of these cases, however, are ambiguous between the cost approach and other approaches discussed in this Part. This is because the price found unfair is not only disproportionate to cost but also unaffordable or disproportionate or both to customary value or social value.⁶⁰

Psychological research on fair pricing also reveals popular endorsement of a cost-based standard. In a classic study, Daniel Kahneman and co-authors found that "respondents endorsed the fairness of passing on increases in wholesale costs, in operating costs, and in the costs associated with a rental accommodation."⁶¹

55. *Kugler v. Romain*, 279 A.2d 640, 644 (N.J. 1971); *see also* *Perdue v. Crocker Nat'l Bank*, 702 P.2d 503, 512 (Cal. 1985); *Sho-Pro of Ind., Inc. v. Brown*, 585 N.E.2d 1357, 1361 (Ind. Ct. App. 1992); *Toker v. Westerman*, 274 A.2d 78, 80 (N.J. Dist. Ct. 1970) ("[T]he sale was made by a door-to-door salesman for a dealer who therefore would have less overhead expense than a dealer maintaining a store or showroom.").

56. *See* *Bender*, *supra* note 46, at 754 (contrasting "the sales price of the good compared to merchant cost" with "the sales price compared to the merchant's total costs of operation, including the cost of the good sold"); *see also* Harry G. Prince, *Unconscionability in California: A Need for Restraint and Consistency*, 46 HASTINGS L.J. 459, 486 (1995).

57. *Bender*, *supra* note 46, at 755 ("The net profit measure is the most accurate gauge of unfairness of price and related terms such as interest."); Note, *Discriminatory Housing Markets, Racial Unconscionability, and Section 1988: The Contract Buyers League Case*, 80 YALE L.J. 516, 553-54 (1971) (endorsing the "reasonable return" test that permitted a seller to charge its net cost plus a reasonable profit).

58. *Whirlpool Corp. v. Grigoleit Co.*, No. 1:06-CV-0195, 2011 WL 3879486, at *4 (W.D. Mich. Aug. 31, 2011) (finding price unconscionable because it was not moored to "actual cost and labor data"), *aff'd in part, rev'd in part on other grounds*, 713 F.3d 316 (6th Cir. 2013).

59. *See* *Mello & Wolitz*, *supra* note 5, at 872.

60. *See, e.g., Perdue*, 702 P.2d at 512 (observing that courts, in addition to considering the seller's costs, also consider a good's market price and its "true value"); *Kugler*, 279 A.2d at 644; *Toker*, 274 A.2d at 80 (noting that the unconscionably priced goods were sold "for approximately 2½ times their reasonable retail value" and that "during the course of the payments ... [the buyers] were obliged to seek welfare assistance").

61. Daniel Kahneman, Jack L. Knetsch & Richard Thaler, *Fairness as a Constraint on*

For instance, respondents judged it fair for a grocer who paid thirty cents more for lettuce to raise retail prices correspondingly, for a landlord facing increasing costs to raise rents, and for a landlord owning two identical buildings to charge higher rent for an identical room in the building that had been more expensive to construct.⁶² Respondents also judged it fair for an unprofitable employer to cut wages.⁶³ Meanwhile, when costs did not increase, respondents thought it was unfair to raise prices or conduct an auction in response to increased demand for a scarce good,⁶⁴ or to hire the applicant among equally qualified candidates who asks for the lowest salary.⁶⁵ More recent work has replicated many of these results.⁶⁶

Given the use of cost to define fair pricing for other goods, its appearance in pharmaceutical pricing proposals is unsurprising. For instance, the Combatting Unreasonable Rises and Excessively (CURE) High Drug Prices Act defines “price gouging” by reference to a drug’s cost of production,⁶⁷ the PDPRA lists “[t]he costs associated with development of the drug” as a relevant factor,⁶⁸ and the recently invalidated Maryland price-gouging statute used cost of production as part of the determination of when a price increase is unconscionable.⁶⁹ The cost approach is also frequently used abroad. For instance, the Court of Justice of the European Union has evaluated the fairness of a price by looking at “the difference between the costs actually incurred and the price actually charged.”⁷⁰ Many scholars also endorse a cost of development approach, arguing that it is the simplest and most comprehensive way of identifying whether a pharmaceutical price is excessive.⁷¹

Profit Seeking: Entitlements in the Market, 76 AM. ECON. REV. 728, 732 (1986).

62. *Id.* at 732-33.

63. *Id.* at 733.

64. *Id.* at 734-35.

65. *Id.* at 735.

66. *See, e.g.*, Steven J. Kachelmeier, Stephen T. Limberg & Michael S. Schadeewald, *Fairness in Markets: A Laboratory Investigation*, 12 J. ECON. PSYCH. 447, 456 (1991).

67. *See* Mello & Wolitz, *supra* note 5, at 867-68.

68. Prescription Drug Price Relief Act of 2019, S. 102, 116th Cong. § 2(b)(2)(D).

69. *See* MD. CODE ANN., HEALTH-GEN. § 2-802(f) (West 2017), *invalidated by* Ass’n for Accessible Meds. v. Frosh, 887 F.3d 664 (4th Cir. 2018).

70. Abbott, *supra* note 51, at 296 (quoting Case 27/76, United Brands Co. & United Brands Cont’l B.V. v. Comm’n of the European Cmtys., 1978 E.C.R. 1-207) (emphasis omitted).

71. *See, e.g., id.* at 302; Brennan et al., *supra* note 23, at 319 (suggesting limiting drug

One recent white paper asserts that defining “price benchmarks based on the costs of developing a drug” is “[t]he most rigorous approach” to fair pricing.⁷² And Mello and Wolitz have recently endorsed the view that a pharmaceutical pricing regime “must be fair to biopharmaceutical companies,” and that fairness “must permit companies a reasonable return on their overall investment in research, development, and manufacturing.”⁷³

Despite its popularity, the cost approach has three major flaws. The first is practical: determining the cost of producing a drug is very difficult.⁷⁴ Because most research fails to produce a marketable drug, the cost of successful drugs is typically understood as including the research and development costs of their failed siblings.⁷⁵ Firms may also be unwilling to share detailed information about costs in an analyzable form. Additionally, the task of determining what level of profit a seller should receive over and above its costs is also fraught with subjectivity, even for ordinary consumer goods.⁷⁶ For this reason, some courts have rejected the relevance of cost to unconscionability.⁷⁷ Instead, they have concluded that supply and

prices to “risk-adjusted R&D costs plus a reasonable profit”); Evan Ackiron, Note, *Patents for Critical Pharmaceuticals: The AZT Case*, 17 AM. J.L. & MED. 145, 172-73 (1991) (proposing that “the definition of patent misuse ... include[s] pricing which so exceeds that which is cost justified as to be unconscionable”); see also Alexander Walsdorf, Note, *I Get By with a Little Help from My 750-Dollar-Per-Tablet Friends: A Model Act for States to Prevent Dramatic Pharmaceutical Price Increases*, 102 MINN. L. REV. 2497, 2528 (2018) (“The pharmaceutical companies could easily refute the charge of unconscionably high pricing by demonstrating that recovering their expenses and making a reasonable profit justifies the price they set.”).

72. BERMAN ET AL., *supra* note 5, at 13.

73. Mello & Wolitz, *supra* note 5, at 864; see also Walsdorf, *supra* note 71, at 2528 (arguing that price caps “would unfairly harm pharmaceutical companies who rely on pricing certain drugs to a higher-than-desired level—from the prospective [sic] of the consumer, at least—to cover for losses and other operating expenditures”).

74. See Mello & Wolitz, *supra* note 5, at 903-06; LENNART RITTER & W. DAVID BRAUN, EUROPEAN COMPETITION LAW 426 (3d ed. 2004) (“[C]osts can be extraordinarily difficult to determine, especially for multi-product (e.g., pharmaceutical) firms where fixed costs such as capital investment, R&D and administrative and selling costs have to be allocated between many products.”).

75. See RITTER & BRAUN, *supra* note 74, at 426; see also Daniel A. Crane, *Bargaining in the Shadow of Rate-Setting Courts*, 76 ANTITRUST L.J. 307, 313-14 (2009) (arguing that “[r]ate setting for intellectual property must follow a different set of principles than the traditional cost-based approach” because “a cost-based intellectual property rate regulation regime would have to take account of the risk-adjusted investment in the relevant invention”).

76. See Prince, *supra* note 56, at 551 (observing “the absence of any reliable basis for determining when profits become so large as to be unconscionable”).

77. *E.g.*, *Bennett v. Behring Corp.*, 466 F. Supp. 689, 698 (S.D. Fla. 1979) (“The percentage

demand are the appropriate bases for pricing.⁷⁸ And despite asserting that fairness requires that firms receive a reasonable return on investment, Mello and Wolitz ultimately conclude that “definitions of excessive price that involve assessment of a company’s return on its investment are likely to be troublesome.”⁷⁹

The cost approach also creates counterproductive incentives. Pegging prices to costs removes incentives to control costs and in fact creates incentives to raise them—for instance, to pay higher salaries to managers at pharmaceutical firms.⁸⁰ In contrast, defining fair prices in terms of affordability or social value creates socially productive incentives: it encourages sellers to lower their prices or to produce treatments that are more socially valuable.⁸¹

Last, the cost approach lacks compelling normative foundations. There is no obvious normative reason that the seller of a good should be entitled to recoup the cost of developing and producing it.⁸² Modern economic theory understands a good’s price as reflecting supply and demand rather than the cost or burden required to create it.⁸³ Some very expensive goods, such as artworks, are expensive in view of their scarcity, not because they are costly or burdensome to produce.⁸⁴ In contrast, goods viewed as interchangeable

of return on defendants’ capital investment is simply immaterial and irrelevant to the issue of whether or not the contract is unconscionable as between the parties.”); *Hertz Corp. v. Att’y Gen. of State*, 518 N.Y.S.2d 704, 709 (App. Div. 1987) (rejecting the view that “a charge imposed must have a reasonable relationship to actual cost”).

78. *Amoco Prod. Co. v. Kan. Power & Light Co.*, 505 F. Supp. 628, 639 (D. Kan. 1980) (concluding that “[t]he price of deregulated gas will be determined by supply and demand rather than the cost of production,” and that “[c]ost of production is no longer the sole determinative factor in arriving at a fair price”).

79. Mello & Wolitz, *supra* note 5, at 963.

80. For discussions of this phenomenon, known as the Averch-Johnson effect, see *id.* at 942 & n.549; Pauly, *supra* note 52, at 1281. See also Eric Lamm, Comment, *Keeping Consumers Out of the Crossfire: Final-Offer Arbitration in the Pharmaceutical Market*, 65 *UCLAL. REV.* 926, 967 (2018) (“A rate-of-return model encourages inefficient uses of cash and accounting gimmicks to inflate R&D.”).

81. See Emanuel, *supra* note 42, at 610.

82. Before the development of modern capitalism, preventing economic coercion was the primary concern in determining prices. See Boyd, *supra* note 14, at 738.

83. TIMOTHY TAYLOR & STEVEN A. GREENLAW, *PRINCIPLES OF ECONOMICS* ch. 3.1 (2019) (ebook), <https://opentextbc.ca/principlesofeconomics/chapter/3-1-demand-supply-and-equilibrium-in-markets-for-goods-and-services/> [<https://perma.cc/G6F7-GZGL>].

84. *Harrington v. Comm’r*, 48 T.C.M. (CCH) 837, 866 (1984) (observing, as part of an evaluation of a limited run of 250 art prints, that scarcity is “fundamental to the commercial success of a work of art”), *aff’d sub nom.* *Appeal of Harrington*, 774 F.2d 1151 (3d Cir. 1985).

commodities are often priced at, or even below, their cost of production.⁸⁵ Buyers and sellers sometimes receive windfalls that do not reflect cost or burden—a prepaid hotel room in a city that ends up hosting a major sporting event, or a contract for the delivery of goods that precedes a major change in price. But these agreements are not obviously unfair.⁸⁶ Psychological research suggests that ordinary people regard the cost of production as relevant to whether a good has been priced fairly.⁸⁷ But a psychological reaction that something is unfair does not normatively establish unfairness.⁸⁸ Initial psychological responses do not always hold up under systematic reflection.⁸⁹ The burden of substantiating the claim that prices should track the cost of development should be on those defending the claim. They have not met this burden.

The flaws of the cost approach as a *backward-looking* way of assessing fairness do not vitiate the good *forward-looking* reasons that might exist to help firms engaged in socially valuable conduct to offset drug development costs. The risk-adjustment program that the Affordable Care Act (ACA) provides to health insurers represents a useful parallel.⁹⁰ But the protection of risk adjustment is provided as a forward-looking incentive to achieve the socially

85. Economic theory predicts that the price of goods subject to perfect competition, such as agricultural commodities, will equal the marginal cost of production. See TAYLOR & GREENLAW, *supra* note 83, ch. 8.1, <https://opentextbc.ca/principlesofeconomics/chapter/8-1-perfect-competition-and-why-it-matters/> [<https://perma.cc/NJ6E-ZKCW>]. But in the short run, prices can drop below cost of production because firms committed to paying their fixed costs (such as rent) will produce goods even when they are losing money overall. *Id.*; cf. Alison Peck, *The Cost of Cutting Agricultural Output: Interpreting the Capper-Volstead Act*, 80 MO. L. REV. 451, 478, 485 (2015).

86. *E.g.*, Bradford v. Plains Cotton Coop. Ass'n, 539 F.2d 1249, 1255 (10th Cir. 1976) (concluding that “contracts made at or before planting time [that] provided for payment at a price less than half of the market value of the cotton at delivery time” were not unconscionable because “[t]he increase in price ha[d] nothing to do with unconscionability,” and that “[t]he test is the character of the contract at the time of making”).

87. Kahneman et al., *supra* note 61, at 732.

88. *Id.* at 729.

89. Cf. Govind Persad, *Public Preferences About Fairness and the Ethics of Allocating Scarce Medical Interventions*, in INTERDISCIPLINARY PERSPECTIVES ON FAIRNESS, EQUITY, AND JUSTICE 51, 57-58 (Meng Li & David P. Tracer eds., 2017) (discussing potential gaps between survey results and normative conclusions).

90. See N.M. Health Connections v. U.S. Dep't of Health & Hum. Servs., 946 F.3d 1138, 1146 (10th Cir. 2019) (“Congress included the risk adjustment program in the ACA to stabilize health insurance premiums, encourage health insurers to provide plans on the exchanges, and discourage insurers from eluding enrollment of sicker individuals.”).

desirable goal of greater access to affordable health insurance, not a backward-looking reward.⁹¹ It is equally acceptable to try to achieve improved insurance access through regulations, such as requirements to accept enrollees regardless of their health status.⁹² Patent law provides another example of the distinction between backward- and forward-looking justifications. Some have argued that patent protection is justified on backward-looking grounds because it recognizes creators' fundamental moral claim to profit from their creations.⁹³ But the recognized foundation for intellectual property rights, particularly in the United States, is forward-looking: patent protection incentivizes socially valuable creation.⁹⁴ The same is true for pricing. Firms should only be guaranteed benefits that would be unavailable in a competitive market—like guaranteed profits or protection from losses—if these benefits are necessary to achieve socially desirable outcomes.⁹⁵

These arguments against backward-looking conceptions of fair pricing also support rejecting the view that it is unfair to charge different buyers different prices for the same drug. This idea accords with some psychological research finding that buyers object to price

91. The literature on fair pricing often fails to carefully differentiate backward-looking from forward-looking justifications. *See, e.g.*, Thomas F. Cotter, *On Unknown Opportunities and Perils: Reflections on Carrier and Minniti's "Biologics: The New Antitrust Frontier,"* 2018 U. ILL. L. REV. ONLINE 72, 77 (“[W]hat if courts were to condemn any agreements or conduct relating to patented drugs that were not reasonably necessary either to *recoup the cost of past*, or to *induce investment in future*, research and development[?]” (emphasis added)); *see also* William W. Fisher & Talha Syed, *Global Justice in Healthcare: Developing Drugs for the Developing World*, 40 U.C. DAVIS L. REV. 581, 667-68 (2007).

92. *See, e.g.*, JENNIFER TOLBERT, HENRY J. KAISER FAMILY FOUND., *THE COVERAGE PROVISIONS IN THE AFFORDABLE CARE ACT: AN UPDATE 1* (2015), <http://files.kff.org/attachment/issue-brief-the-coverage-provisions-in-the-affordable-care-act-an-update> [<https://perma.cc/3PGR-SVUZ>] (“As enacted, the ACA created a framework for enhancing access to health coverage. It imposed new regulations ... to ensure everyone could purchase coverage regardless of their health status.”).

93. ROBERT P. MERGES, *JUSTIFYING INTELLECTUAL PROPERTY* 156 (2011) (discussing creators' rights); *see also* Fisher & Syed, *supra* note 91, at 669 (endorsing the view that some patent-holders have desert-based claims to benefit financially from their patents).

94. Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 116 & n.215 (1999).

95. *Cf.* Jens David Ohlin, *Is the Concept of the Person Necessary for Human Rights?*, 105 COLUM. L. REV. 209, 227 (2005) (“Corporations themselves have no intrinsic worth. Rather, their worth is extrinsic.... To put the point more directly, the death of a corporation is cause for concern only for its *effects* on individuals.”).

differentiation.⁹⁶ A few scholars also criticize differential pricing as fundamentally unfair, sometimes likening it to racial discrimination.⁹⁷ But this reaction is difficult to defend. Differential pricing often can improve social welfare and is widespread in markets.⁹⁸ For instance, when lots of goods are sold at auction, some buyers may end up paying more than others for an identical good. Though consumers sometimes object to auctions,⁹⁹ auctions are neither immoral nor illegal. Auctions also justify rejecting the “like ought to be treated alike” principle’s conclusion that different prices for the same drug in different high-income countries is unfair.¹⁰⁰ If purchasing countries are willing to pay different prices, this provides evidence that they are *not* alike, even if the differences between them are difficult to observe.¹⁰¹ Some differences, such as race, may be unjust bases for differential pricing, but the wrongness of such differential pricing is not explained by the “like ought to be treated alike” principle, but by the fact that it disadvantages some buyers based on a pervasively significant and historically freighted social category.¹⁰²

Ultimately, disparities between price and cost, especially for generic drugs, are better seen as an indicator of potential procedural unfairness than as constitutive of substantive unfairness. This is because when prices rise and remain high without a corresponding change in input costs, there is reason to suspect market imperfections.

96. Kahneman et al., *supra* note 61, at 735.

97. *E.g.*, Mark Klock, *Unconscionability and Price Discrimination*, 69 TENN. L. REV. 317, 382 (2002).

98. *See* Saul Levmore & Frank Fagan, *The End of Bargaining in the Digital Age*, 103 CORNELL L. REV. 1469, 1512 (2019) (“Discriminatory pricing can ... enable greater output and access, so long as even low-income consumers are willing (and able) to pay a price at least equal to marginal cost.”); *see also* Amy Kapczynski, *The Cost of Price: Why and How to Get Beyond Intellectual Property Internalism*, 59 UCLA L. REV. 970, 983 (2012).

99. Kahneman et al., *supra* note 61, at 735.

100. *See* Rebecca E. Wolitz, *The Pay-Twice Critique, Government Funding, and Reasonable Pricing Clauses*, 39 J. LEGAL MED. 177, 209 (2019) (favorably discussing “[a] non-discrimination standard” for pharmaceutical pricing “that references high-income foreign country prices,” in part on the basis that it “reflects a widely accepted moral principle (‘like ought to be treated alike’)”).

101. *Cf.* Matthew A. Edwards, *Price and Prejudice: The Case Against Consumer Equality in the Information Age*, 10 LEWIS & CLARK L. REV. 559, 592-93 & n.194 (2006).

102. *Id.* at 593 & nn.195-97; *cf.* Peter Westen, *The Empty Idea of Equality*, 95 HARV. L. REV. 537, 568 (1982).

2. *Affordability to Buyers*

Fairness can also be assessed by examining whether a price is affordable to patients in need. The association between fairness and affordability, though not always explicitly articulated, appears in many unconscionability decisions,¹⁰³ and affordability is frequently mentioned in proposals for drug pricing reform.¹⁰⁴ Many cases emphasize that purchasing an unconscionably priced good consumes an excessive amount of a poor buyer's income,¹⁰⁵ and some cases find no unconscionability because of the buyer's capacity to pay the high price charged.¹⁰⁶ Courts have also found unconscionability when a poor seller is induced to accept an overly low price, even without any misconduct on the buyer's part.¹⁰⁷

The affordability approach is persuasively critiqued by Mello and Wolitz, who argue that although “‘excessive’ drug prices may overlap with ‘unaffordable’ drug prices, ... it is important to mark these two terms as conceptually distinct,” and that “an affordable price may not be a fair price.”¹⁰⁸ They reject basing fairness on affordability on the basis that this “could conflict with ... fairness to drug manufacturers,” which they also view as a component of fairness.¹⁰⁹ As explained above, I disagree with Mello and Wolitz's conception of

103. See *Toker v. Westerman*, 274 A.2d 78, 80 (N.J. Dist. Ct. 1970); *Jones v. Star Credit Corp.*, 298 N.Y.S.2d 264, 267 (Sup. Ct. 1969).

104. E.g., NAM REPORT, *supra* note 11, at 126; *Drug Pricing*, DEP'T OF HEALTH & HUM. SERVS., <https://perma.cc/MMY9-QHMF> (arguing that “access is meaningless without affordability”); see Press Release, Bill Cassidy & Mark Warner, Sens., Cassidy, Warner Unveil Draft Legis. to Lower Drug Prices Through Innovative Payment Models (Jan. 29, 2019), <https://www.cassidy.senate.gov/newsroom/press-releases/cassidy-warner-unveil-draft-legislation-to-lower-drug-prices-through-innovative-payment-models> [<https://perma.cc/5CSC-EPC8>] [hereinafter Press Release] (legislation to promote outcomes-based pricing titled “Patient Affordability, Value and Efficiency Act”); Mello & Wolitz, *supra* note 5, at 871 (discussing the “Affordable Drug Manufacturing Act of 2018”).

105. *Toker*, 274 A.2d at 80; *Jones*, 298 N.Y.S.2d at 267.

106. *Guthmann v. La Vida Llena*, 709 P.2d 675, 680 (N.M. 1985), *overruled in part on other grounds by Cordova v. World Fin. Corp. of N.M.*, 208 P.3d 901 (N.M. 2009).

107. See, e.g., *Freeman v. Ow*, No. 16-CV-04817-JST, 2016 WL 6778667, at *4 (N.D. Cal. Nov. 16, 2016).

108. Mello & Wolitz, *supra* note 5, at 864 n.19.

109. *Id.*; see also Michelle M. Mello, *What Makes Ensuring Access to Affordable Prescription Drugs the Hardest Problem in Health Policy?*, 102 MINN. L. REV. 2273, 2286 (2018).

fairness to manufacturers.¹¹⁰ But I agree with them that fair pricing and affordability to individual buyers are separate.

Zeke Emanuel has recently defended an affordability approach to drug pricing.¹¹¹ Emanuel argues that the lifetime cost for all drugs that a person takes over a lifetime should not exceed 11 percent of average lifetime disposable income in their country; in the United States, that means that lifetime drug costs for all drugs should not exceed \$70,715.¹¹² Emanuel's approach laudably attempts to quantify affordability and engages the possibility that price regulation might channel innovation more productively rather than foreclosing it.¹¹³ But defining a combined maximum price for all drugs presents problems. Some drugs, such as antiretrovirals and chemotherapeutics, are typically taken together with others, and people often take many different types of drugs over their lifetimes. This makes it difficult to derive from Emanuel's proposal an answer to the question of whether any given drug's price is too high.

The lifetime cost approach also seems to set the price ceiling simultaneously too low, from a societal perspective, and too high, from an individual perspective. This flaw is not unique to Emanuel's proposal: it is a familiar problem with attempts to use price regulation, rather than subsidies, to achieve affordability for individual buyers.¹¹⁴ Price regulations that achieve affordability for the average patient provide a large windfall to wealthy buyers whose ability to pay exceeds the price ceiling, while leaving poor buyers in a difficult position.¹¹⁵

Because the average lifetime earnings approach considers only individual costs without systematically considering the social value

110. See *supra* notes 73-79 and accompanying text.

111. Emanuel, *supra* note 42, at 607. Emanuel's account requires that a drug meet both an affordability and a social value standard. *Id.* at 606-07.

112. *Id.* at 609.

113. *Id.* at 610 (observing that value- or affordability-based price regulation "might better direct pharmaceutical innovation").

114. Cf. JOSEPH HEATH, *ECONOMICS WITHOUT ILLUSIONS* 155 (2010) (arguing that electricity price caps that aim to improve affordability for poor consumers are often regressive); Russell B. Korobkin & Thomas S. Ulen, *Efficiency and Equity: What Can Be Gained by Combining Coase and Rawls?*, 73 WASH. L. REV. 329, 342 (1998) ("[S]ociety should allow relative prices in competitive housing markets to serve their allocative role of directing resources to their most efficient uses and then ... implement tax-and-transfer policies to redistribute resources in line with society's distributive goals.").

115. See HEATH, *supra* note 114, at 156-57.

of new drugs, it often sets the ceiling too low. From a societal perspective, a new drug is cost-saving if it saves money compared to existing treatments. Typical cost-effectiveness thresholds in the United States are \$50,000-\$150,000 per quality-adjusted life-year saved.¹¹⁶ A drug that extends healthy life by 1.5 quality-adjusted life-years at a cost of \$74,000 is under \$50,000 per quality-adjusted life-year: it is cost-effective even at a \$50,000 threshold, and potentially cost-saving if it replaces a costlier drug for the same condition. Yet this drug on its own would exceed the average lifetime income threshold. This mismatch between value and affordability arises because the price a seller receives need not be, and often is not, the price patients pay. As discussed in Part I.A.2, many patients have their costs partly or wholly paid by public or private insurance. It can be reasonable for insurers—particularly public insurers—to pay for drugs patients would be unable to afford on their own, especially when the drugs save money compared to current treatments.

Meanwhile, even a bill of \$400 is unaffordable for many Americans.¹¹⁷ While lifetime costs are the right place to focus from a societal perspective, a drug that costs \$1,000 or \$2,000 for a one-time dose could meet the average lifetime income standard but be unaffordable, whereas one that costs three dollars per day over a seventy-year span would exceed the average lifetime income standard but would be more affordable.

Concerns about individual affordability have instead motivated some to take the position that some or all medicines should be free to patients.¹¹⁸ Recent surveys of patients in Australia and New Zealand reveal that 45 percent of New Zealanders believe all medicines should be free to all patients,¹¹⁹ and that 60 percent of

116. Emanuel, *supra* note 42, at 607.

117. See Neal Gabler, *The Secret Shame of Middle-Class Americans*, ATLANTIC (2016), <https://www.theatlantic.com/magazine/archive/2016/05/my-secret-shame/476415/> [<https://perma.cc/JB5G-GCMY>].

118. *E.g.*, Matthew Cortland (@mattbc), TWITTER (Feb. 20, 2019, 7:36 PM), <https://twitter.com/mattbc/status/1098380835584180225> [<https://perma.cc/XHC2-2CG7>] (“Insulin should be free. Absolutely, totally, 100% free.”).

119. Charon Lessing, Toni Ashton & Peter Davis, *New Zealand Patients’ Understanding of Brand Substitution and Opinions on Copayment Options for Choice of Medicine Brand*, 40 AUSTRAL. HEALTH REV. 345, 347 (2016).

Australian patients believe essential medicines should be free.¹²⁰ Achieving this goal through the price system by setting drug prices to zero, however, would eliminate incentives to develop or even produce medicines. A more plausible understanding of the view is that medicines should have no out-of-pocket costs at the point of use, which is compatible with permitting sellers to charge a price that is paid for by public or private insurers, or having government purchase their patent rights. In addition, notwithstanding the popularity of the view that drugs should not have out-of-pocket costs, it is not obviously unjust to charge patients for drugs while ensuring affordability through insurance and targeted subsidies, just as many other essentials such as food, housing, and health insurance are made affordable, albeit imperfectly, through targeted subsidies.¹²¹ The use of only nominal drug copayments in publicly subsidized insurance, such as Medicaid, represents an example of such subsidies.¹²²

Ultimately, while affordability is important, *individual* affordability is better achieved through expanding and improving insurance than through the price system. Affordability to *society* is an appropriate basis for pricing, but affordability to society should be based on social value—as discussed in Part I.B.4 below—rather than on patients’ average income.

3. Customary Price

Another way of assessing fairness is a *custom*-based approach, which compares a good’s price to the price other sellers charge for similar goods. This approach is frequently used in unconscionability cases for ordinary consumer goods.¹²³ Courts found unconscionability

120. Evan Doran, Jane Robertson & Glenn Salkeld, *Pharmaceutical Benefits Scheme Cost Sharing, Patient Cost Consciousness and Prescription Affordability*, 35 AUSTL. HEALTH REV. 37, 39 (2011).

121. See Govind Persad, *Choosing Affordable Health Insurance*, 88 GEO. WASH. L. REV. 819, 865 (2020).

122. See, e.g., *Medicaid Benefits: Prescription Drugs*, KFF (2018), <https://www.kff.org/medicaid/state-indicator/prescription-drugs/?currentTimeframe=0&sortModel=%7B%22co1Id%22:%22Location%22,%22sort%22:%22asc%22%7D> [https://perma.cc/7JVH-6GAV]. Thanks to Rachel Sachs for this example.

123. *State v. Strong Oil Co.*, 433 N.Y.S.2d 345, 358 (Sup. Ct. 1980) (“[A] contract will be found unconscionable on the basis of price when there is a great disparity between the selling

in the sale of a refrigerator with a retail value of \$300 for \$900,¹²⁴ of a freezer for two and a half times its reasonable retail value,¹²⁵ and of jade carvings for more than twice their retail value.¹²⁶ In contrast, a price twice the typical retail price was judged acceptable when the buyer received additional benefits unique to the particular sale.¹²⁷ More recently, interest rates that exceed typical rates in the credit market have been found unconscionable.¹²⁸ Prices substantially below, rather than above, market value can also be found unconscionable.¹²⁹ The custom approach is also commonly used in statutes that aim to prevent unfair pricing.¹³⁰

The custom approach has been used to determine fair pricing for pharmaceuticals, most prominently in the use of international reference pricing, in which drug prices are set by reference to the average price that is charged in similar countries.¹³¹ Many complaints about unfair drug pricing have involved objections that American consumers are being charged different prices than consumers abroad for the same drugs, or that drug prices are deviating dramatically upward from what they typically have been.¹³² The recent Prescription Drug Pricing Reduction Act of 2020 also incorporates a limited version of a custom-based approach by requiring pharmaceutical firms to reimburse Medicare if drug prices increase more rapidly than inflation.¹³³

Compared to the cost and affordability approaches, the custom approach has been praised for its greater administrability.¹³⁴ But

price of the goods and its actual market value.”), *affd.*, 451 N.Y.S.2d 437 (App. Div. 1982); *see also* Cal. Grocers Ass’n v. Bank of Am., 27 Cal. Rptr. 2d 396, 402 (Ct. App. 1994).

124. Jones v. Star Credit Corp., 298 N.Y.S.2d 264, 266 (Sup. Ct. 1969).

125. Toker v. Westerman, 274 A.2d 78, 80 (N.J. Dist. Ct. 1970).

126. Vom Lehn v. Astor Art Galleries, Ltd., 380 N.Y.S.2d 532, 541 (Sup. Ct. 1976).

127. Remco Enters., Inc. v. Houston, 677 P.2d 567, 572-73 (Kan. Ct. App. 1984).

128. Carboni v. Arrospide, 2 Cal. Rptr. 2d 845, 849 (Ct. App. 1991) (finding unconscionability in part because “the ‘price’ of the credit was, by at least one objective measure, roughly ten times its value”).

129. Miami Tribe of Okla. v. United States, 281 F.2d 202, 208 (Ct. Cl. 1960) (finding a payment of “only 38% of the value of the land” unconscionable).

130. *See* Bender, *supra* note 46, at 766.

131. *See* Abbott, *supra* note 51, at 303; Pauly, *supra* note 52, at 1280.

132. *See* Mello & Wolitz, *supra* note 5, at 897 (discussing price spike legislation); Wolitz, *supra* note 100, at 209 (“[M]any are deeply dismayed by disparities in what Americans pay for their medications and the prices paid in other high-income countries.”).

133. Prescription Drug Pricing Reduction Act of 2020, S. 4199, 116th Cong. §§ 106, 128.

134. Prince, *supra* note 56, at 487.

the custom approach has a set of disadvantages that are familiar elsewhere in law. Most importantly, as courts have recognized, it cannot identify unfair customary practices.¹³⁵ As Frederick Abbott points out, “It is entirely possible that the lowest baseline price (or the average) among a basket of markets is excessive.”¹³⁶

The problem with relying on custom alone is apparent when considering fair pricing for a new drug like Zolgensma, for which no customary price exists.¹³⁷ The drug could be priced by analogy to other drugs for the same condition, or that provide similar value, but these strategies admit the relevance of factors other than custom—in particular, social value—in setting the price. And an approach like the Prescription Drug Pricing Reduction Act of 2020 would provide no guidance because it applies only to price increases, not to initial pricing.¹³⁸ While custom can be an easily manageable way of setting prices, it relies on the existence of benchmark prices set via some other method, and its normative attractiveness similarly depends on the normative attractiveness of those benchmark prices. Rather than being understood as an independent method, custom-based pricing is better thought of as a way of relying on pricing decisions that are made on some other basis to avoid the political and logistical burdens of making these pricing decisions oneself.¹³⁹

4. Value to Society

Under what I call a *social value* approach, a drug’s price should reflect its value to society, with drugs that greatly extend life or improve health commanding a higher price than drugs with lesser benefits. On this approach, fair pricing is defined in a forward-looking way, in terms of value to patients and society. Several

135. See *Cal. Grocers Ass’n v. Bank of Am.*, 27 Cal. Rptr. 2d 396, 402-03 (Ct. App. 1994).

136. Abbott, *supra* note 51, at 303; cf. Crane, *supra* note 75, at 315 (“[B]enchmarking suffers from the fact that the rest of the market—including the benchmark contracts—may already be the products of the defendant’s monopoly power.”).

137. Cf. Mello & Wolitz, *supra* note 5, at 903.

138. See generally S. 4199.

139. See Persad, *supra* note 121, at 834; see also Mark A. Lemley, Lisa Larrimore Ouellette & Rachel E. Sachs, *The Medicare Innovation Subsidy*, 95 N.Y.U. L. REV. 75, 98 (2020) (“Reference pricing works because it assumes some other country has set the right price.”).

commentators, including Emanuel as well as Mello and Wolitz, regard social value as relevant to fairness, though they do not develop a detailed account of value-based pricing.¹⁴⁰

How should we assess social value? The most common way of measuring social value compares a drug's price to its benefits quantified in terms of quality-adjusted life-years (QALYs) or disability-adjusted life-years (DALYs).¹⁴¹ Social value is typically used to define the boundaries of a fair price rather than to set an exact price to which sellers or buyers are entitled.¹⁴² Medications whose cost of production is low and that are produced by several competing sellers, such as many generics, will typically be priced lower than the maximum price that their social value could justify, meaning that pharmaceutical sellers will not capture the full social value of the products they sell. As an example, manufacturers of generic statins, used to treat excessive cholesterol, are unlikely to be able to price their products at the maximum that their substantial social value would warrant. Instead, generic manufacturers will receive a competitive market price. This recalls the well-known diamond-water problem: water is inexpensive compared to diamonds, even though much more socially valuable, because the comparatively easy availability of water means that it can be obtained for a price lower than the maximum that consumers would be willing to pay if faced with scarcity.¹⁴³

The social value approach uses prices to achieve a goal to which prices are ideally suited—signaling to firms where they should direct investment—while responding to procedural imperfections in pharmaceutical markets that make an unregulated price system undesirable. In competitive markets, price signals allow sellers to identify what quantity of a product buyers value at a given price and to direct their production accordingly.¹⁴⁴ A pharmaceutical

140. See Emanuel, *supra* note 42, at 606-07; Mello & Wolitz, *supra* note 5, at 961; Lamm, *supra* note 80, at 967-68.

141. Mello & Wolitz, *supra* note 5, at 961; Lamm, *supra* note 80, at 967.

142. See Mello & Wolitz, *supra* note 5, at 961.

143. See John Tehranian, *All Rights Reserved? Reassessing Copyright and Patent Enforcement in the Digital Age*, 72 CIN. L. REV. 45, 51 (2003) (explaining that “diamonds have a market value far in excess of water since their availability relative to demand is slight”); see also Uwe Reinhardt, *On the Much Used (and Abused) Word “Value” in Healthcare*, 28 J. HEALTH ADMIN. EDUC. 259, 262 (2011).

144. See Elizabeth Anderson, *How Should Egalitarians Cope with Market Risks?*, 9

market without price regulation, however, produces undesirable results because patients' demand for treatments is price-insensitive.¹⁴⁵ The social value approach addresses this problem by incentivizing the development of socially valuable treatments. Unlike the other approaches discussed in this Part, it requires that a drug's price be justified prospectively by the health benefits it offers to future patients—not retrospectively as compensation for past spending on research or manufacturing. What justifies price regulation in pharmaceutical markets is that, because of limited competition and inelastic buyer demand, unregulated pricing fails to effectively incentivize socially valuable innovation.

The social value approach's strategy of using price to incentivize socially valuable outcomes has some parallels with recent proposals to use prizes, or other forms of regulation, to incentivize the production of socially valuable drugs.¹⁴⁶ What is distinctive about this Article's proposal is that it bases a drug's price, rather than the length of its market exclusivity or the magnitude of a publicly provided prize or enforced penalty, on the drug's value to society. In the next two Parts, I will consider how social value should be defined and how social value criteria should be employed to constrain prices.

II. DEFINING SOCIAL VALUE

Using social value to constrain prices requires a process for assessing social value. In Part II.A, I consider both conventional and extended cost-effectiveness analyses as options for assessing and defining social value. I argue that extended cost-effectiveness

THEORETICAL INQUIRIES L. 239, 242 (2008) ("The efficiency of markets essentially depends on their ability to convey price signals."); David B. Spence, *Can Law Manage Competitive Energy Markets?*, 93 CORNELL L. REV. 765, 802 (2008).

145. See Bruns, *supra* note 28, at 2064 (explaining inelastic demand for pharmaceuticals); Brennan et al., *supra* note 23, at 296 (explaining inelastic demand alternatively as people being "extremely sensitive to even small differences in health outcomes").

146. *E.g.*, Pearson et al., *supra* note 29, at 2-3 (discussing "contingent exclusivity" proposal that would "leave manufacturers free to charge what they wanted but vary the length of their monopoly protection" in proportion to their drug's benefits); Arti K. Rai, *The Ends of Intellectual Property: Health as a Case Study*, 70 L. & CONTEMP. PROBS. 125, 128 (2007) (discussing a government-funded "patent prize system that calibrated rewards" on a social value basis, with prizewinning drugs thereafter "made available at marginal cost").

analysis is the most desirable approach, but should incorporate only normatively justified interests. In Part II.B, I examine and critically evaluate different ways of defining a social value threshold, which differentiates drugs that are socially valuable at a given price from those that are not.

A. *Conventional Cost-Effectiveness Analysis*

Most proposals to incorporate social value into pharmaceutical policy rely on cost-effectiveness analysis (CEA). The National Academies of Medicine (NAM) report on pharmaceutical policy explains how CEA is employed:

Value assessments often involve cost-effectiveness analysis, in which the ratio of the added health gains from a medical intervention to the added costs of treatment is calculated, and a pre-established cutoff value is used to determine which interventions are worthy of support. The use of a quality-adjusted life-year as the health outcome measure in cost-effectiveness analyses has gained wide acceptance in many countries and is used in coverage and reimbursement decisions. The National Institute for Health and Care Excellence in the United Kingdom, for example, uses cost-effectiveness to provide advice about which drugs and treatments should be made available in its National Health Service.¹⁴⁷

As the NAM Report also explains, many national health systems also use CEA either to define a maximum price at which a given drug can be sold or to define the reimbursements that governmental or government-regulated payers provide for specific drugs.¹⁴⁸ England, Scotland, and Sweden use cost per QALY approaches to set prices, and Canada also uses cost-effectiveness considerations in price setting.¹⁴⁹ In addition to the countries that use cost-effective

147. NAM REPORT, *supra* note 11, at 54 (citations omitted).

148. *Id.* at 83-87.

149. Pearson et al., *supra* note 29, at 3; WORLD HEALTH ORG., ACCESS TO NEW MEDICINES IN EUROPE 61 (2015); 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. 6-8, 26-28 (2016) (unpublished manuscript), <https://www.commonwealthfund.org/sites/default/files/2018->

ness for pricing, Australia, Ireland, the Netherlands, Norway, Slovakia, Poland, Switzerland, New Zealand, and the UK use it for determining reimbursement.¹⁵⁰ Other countries such as Belgium, France, Germany, Italy, and Spain use a broader range of criteria, which often include cost-effectiveness as a component.¹⁵¹

Despite the popularity of CEA in other national health systems, it has met resistance stateside. Reasons for this resistance include concerns that conventional CEA is unfair to people with disabilities,¹⁵² and that it ignores other important outcomes, such as protection against financial risk, nonmedical cost savings, or reduction in health disparities.¹⁵³ These concerns have motivated interest in modifications to CEA.

B. Modifying Cost-Effectiveness Analysis

When evaluating proposed modifications to CEA, normatively compelling concerns must be distinguished from exercises of interest group politics. The NAM report asserts that “simply using cost-effectiveness as the outcome measure leaves out other factors such as public perceptions of a disease, political interests, social justice, and other practical considerations, that need to be taken into account when making important societal decisions.”¹⁵⁴ But while these factors are all *practical* considerations, not all have equal *normative* importance. Conflicts between justice and conventional

09/Steven%20Morgan%2C%20PhD_Ten%20Country%20Pharma%20Policy%20Summaries_2016%Vancouver%20Group%20Meeting.pdf [https://perma.cc/3U9K-598L].

150. WORLD HEALTH ORG., *supra* note 149, at 65, 67; Morgan, *supra* note 149, at 2-3, 20, 23-24, 29.

151. WORLD HEALTH ORG., *supra* note 149, at 61; Pearson et al., *supra* note 29, at 3 (observing that countries that benchmark their price guidelines to others that use cost-effectiveness “are, in effect, adopting the same underlying methodology”).

152. See Govind Persad, *Priority Setting, Cost-Effectiveness, and the Affordable Care Act*, 41 AM. J.L. & MED. 119, 132 (2015) [hereinafter Persad, *Priority Setting*]; Govind Persad, *Considering Quality of Life While Repudiating Disability Injustice: A Pathways Approach to Setting Priorities*, 47 J.L. MED. & ETHICS 294, 297 (2019) [hereinafter Persad, *Considering Quality of Life*].

153. Emanuel, *supra* note 42, at 606 (explaining that cost-effectiveness analysis often disregards distributional outcomes, and arguing that pricing should consider a treatment’s nonhealth benefits); Stéphane Verguet, Jane J. Kim & Dean T. Jamison, *Extended Cost-Effectiveness Analysis for Health Policy Assessment: A Tutorial*, 34 PHARMACOECONOMICS 913, 918 (2016).

154. NAM REPORT, *supra* note 11, at 55.

CEA provide a normatively compelling reason to modify CEA even under ideal circumstances.¹⁵⁵ In contrast, conflicts between CEA and mere public perceptions or political interests do not, without more, generate normatively compelling reasons to modify CEA because public perceptions and political interests can be unjust. One example of such publicly endorsed and politically implemented injustice is the ban on travel to the United States by people with HIV, which was supported by members of the public in thousands of letters.¹⁵⁶ This public reaction helps explain why the ban remained, but does not suffice to justify the ban. A modification to CEA that assigned priority to diseases based on their social popularity would similarly be explicable but not obviously justifiable.

In this Section, I will argue that it can be normatively compelling to depart from conventional CEA in order to (1) improve fairness to patients with preexisting disabilities, or (2) achieve other important outcomes such as disparity reduction or realization of important nonhealth goals. In contrast, it is not normatively compelling to depart from traditional CEA in order to permit higher prices for rare disease drugs or “last chance” therapies. Such departures create socially counterproductive incentives to develop drugs that save fewer lives without a countervailing benefit.

1. Fairness to People with Preexisting Disabilities

Much of the controversy over CEA in American health policy has involved claims that CEA unfairly disadvantages patients with preexisting disabilities whose future years of life due to treatment are assigned a lower quality weight.¹⁵⁷ These charges have been marshalled against a variety of policy proposals, including the initial version of Oregon’s Medicaid plan in the 1990s.¹⁵⁸ The

155. See, e.g., A. Zwerling, D. Dowdy, A. von Delft, H. Taylor & M.W. Merritt, *Incorporating Social Justice and Stigma in Cost-Effectiveness Analysis: Drug-Resistant Tuberculosis Treatment*, 21 INT’L J. TUBERCULOSIS & LUNG DISEASE S69, S69 (2017).

156. Michael Vinikoor, *Celebrating the End of the HIV/AIDS Travel Ban*, HEALTH AFFS. BLOG (July 20, 2012), <https://www.healthaffairs.org/doi/10.1377/hblog20120720.021381/full/> [<https://perma.cc/7GG9-3SHL>]. As the political tides shifted, the ban was eventually removed in 2010. *Id.*

157. See Persad, *Priority Setting*, *supra* note 152, at 132.

158. *Id.* (citing Maxwell J. Mehlman, Melvyn R. Durchslag & Duncan Neuhauser, *When Do Health Care Decisions Discriminate Against Persons with Disabilities?*, 22 J. HEALTH POL.

Affordable Care Act limited, though did not proscribe, the use of CEA by Medicare, the Patient-Centered Outcomes Research Institute, and insurers on the ACA's exchanges; its limitations focus on fairness to people with preexisting disabilities.¹⁵⁹ Most recently, proposals to use CEA in private insurers' coverage and reimbursement decisions have raised concerns about fairness to patients with disabilities.¹⁶⁰

These concerns have prompted various modifications to cost-effectiveness approaches. Such modifications do not abandon CEA's goal of getting more value for money but instead modify what counts as a valuable outcome.¹⁶¹ Such a modification is normatively attractive because it avoids compounding preexisting disadvantage, especially when that disadvantage results from injustice.¹⁶² One such approach, the Institute for Clinical and Economic Review's Equal Value of Life Years Gained, does so by excluding quality of life from consideration.¹⁶³ Other approaches modify QALYs to give greater weight to interventions that benefit individuals who are worse off¹⁶⁴ or differentiate cases in which lower quality of life results from disability discrimination.¹⁶⁵ Other recent proposals calculate the value of extended life separately from that of improved quality of life.¹⁶⁶ These new approaches have not yet been employed as extensively as conventional CEA but represent promising strategies for addressing concerns about disability discrimination.

POL'Y & L. 1385, 1396 (1997)).

159. *Id.* at 129-47.

160. Steven D. Pearson, Commentary, *Why the Coming Debate over the QALY and Disability Will Be Different*, 47 J.L. MED. & ETHICS 304, 306 (2019).

161. Persad, *Considering Quality of Life*, *supra* note 152, at 301.

162. *See id.* at 296; *see also* Samuel J. Kerstein, *Dignity, Disability, and Lifespan*, 34 J. APPLIED PHIL. 635, 645 (2017).

163. *See* Pearson, *supra* note 160, at 306.

164. Tyler M. John, Joseph Millum & David Wasserman, *How to Allocate Scarce Health Resources Without Discriminating Against People with Disabilities*, 33 ECON. & PHIL. 161, 170 (2017).

165. Persad, *Considering Quality of Life*, *supra* note 152, at 296.

166. Anirban Basu, Josh Carlson & David Veenstra, *Health Years in Total: A New Health Objective Function for Cost-Effectiveness Analysis*, 23 VALUE HEALTH 96, 98 (2020); Lucio Esposito & Nicole Hassoun, *Measuring Health Burden Without Discriminating Against the Disabled*, 39 J. PUB. HEALTH 633, 634 (2017).

2. Consideration of Other Important Outcomes

Conventional CEA gives no weight to the distribution of QALYs among beneficiaries nor to the realization of nonhealth outcomes.¹⁶⁷ But there are normatively compelling reasons to value nonhealth outcomes, such as environmental protection, and also to narrow health disparities.¹⁶⁸ Including nonhealth outcomes serves to avoid what I have elsewhere called the “Gift of the Magi” problem, when policies in different administrative sectors undermine one another because they do not consider outcomes beyond their sector—for instance, health policies that ignore environmental effects, and environmental policies that ignore health effects.¹⁶⁹ The goal of narrowing health disparities can find further support in an often overlooked part of the ACA that requires consideration of fairness to “diverse segments of the population.”¹⁷⁰ Disparity alleviation and the importance of nonhealth outcomes favor employing cost-effectiveness methodologies that are able to incorporate these aims.¹⁷¹ Such methodologies are often dubbed “extended cost-effectiveness analysis.”¹⁷² Basing a value-based price on extended CEA would incentivize the development of drugs that help achieve important nonhealth and distributional outcomes.¹⁷³

167. See Michael D. Rawlins & Anthony J. Culyer, *National Institute for Clinical Excellence and Its Value Judgments*, 329 BRIT. MED. J. 224, 226 (2004).

168. See Emanuel, *supra* note 42, at 606 (“Life activities other than health matter; in considering the benefits of a treatment, we should also consider how it affects education, employment, and other valuable life activities.”); Emily Whelan Parento, *Health Equity, Healthy People 2020, and Coercive Legal Mechanisms as Necessary for the Achievement of Both*, 58 LOY. L. REV. 655, 670 (2012) (defining health disparities and explaining why they are unjust).

169. Govind Persad, *Beyond Administrative Tunnel Vision: Widening the Lens of Costs and Benefits*, 15 GEO. J.L. & PUB. POL’Y 941, 946 (2017).

170. 42 U.S.C. § 18022(b)(4)(C); see also Persad, *Priority Setting*, *supra* note 152, at 147.

171. See Verguet et al., *supra* note 153, at 913.

172. *Id.*

173. Cf. Lemley et al., *supra* note 139, at 128 (proposing regulatory change to encourage manufacturers to develop “drugs treating diseases that primarily impact low-income populations, including mental health conditions and neglected tropical diseases”).

3. Prioritizing Rare Disease Treatments

The case for modifying cost-effectiveness analysis to incentivize the development of drugs that treat patients with less common diseases is much weaker than the case for the modifications discussed in Parts II.B.1 and II.B.2. To see why, consider the philosopher John Taurek's famous example: six patients are severely ill and only five doses of medicine are available, but five of the patients require only one dose each, while one would require all five doses.¹⁷⁴ Absent any other differences between the patients, both laypeople and normative theorists agree that the five should be saved.¹⁷⁵ Because treatments for rare conditions have smaller potential markets and therefore are only developed if higher prices can be charged, many rare disease patients are in the same position as Taurek's patient who needs all five doses.¹⁷⁶ One recent study found that "median cost per patient is 5.5 times higher for orphan drugs than for non-orphan drugs."¹⁷⁷ Permitting higher prices for rare disease drugs creates an incentive to develop drugs that treat fewer rather than more patients. Creating such an incentive is akin to saving the one person in Taurek's original example.

Some patient advocates have argued that conventional CEA should be modified to encourage the development of rare disease drugs.¹⁷⁸ These arguments have gotten some traction in other countries' national systems.¹⁷⁹ But departing from conventional CEA

174. John M. Taurek, *Should the Numbers Count?*, 6 PHIL. & PUB. AFFS. 293, 294 & n.2 (1977) (citing Philippa Foot, *The Problem of Abortion and the Doctrine of Double Effect*, in MORAL PROBLEMS 28, 35 (James Rachels ed., 1971)).

175. See Mark Kelman, *Intuitions*, 65 STAN. L. REV. 1291, 1307 n.29 (2013) (reporting empirical confirmation of "the predictable finding that far fewer people believe it permissible to save one drowning man rather than ten if one foregoes saving the ten by saving just the one"); Larry Alexander, *Deontology at the Threshold*, 37 SAN DIEGO L. REV. 893, 897 (2000) ("Most philosophers who have considered Taurek's argument have resisted it.").

176. See, e.g., NAM REPORT, *supra* note 11, at 21 ("[P]olicies that are optimal for some patients may not benefit other patients (e.g., the small numbers of people with rare diseases often require the most costly medicines."); *id.* at 114 ("Drugs for rare diseases often have higher prices because of the small size of the eligible patient population.").

177. *Id.* Orphan drugs are drugs that treat rare diseases. *Id.*

178. See, e.g., H.I. Hyry, J.C.P. Roos & T.M. Cox, Commentary, *Orphan Drugs: Expensive yet Necessary*, 108 QJM: INT'L J. MED. 269, 271 (2015).

179. See Emily Harris, *Addressing the Needs of Canadians with Rare Diseases: An Evaluation of Orphan Drug Incentives*, 5 J.L. & BIOSCIENCES 648, 661 (2018).

in order to provide stronger incentives to develop rare disease drugs—while politically unsurprising given the tendency of small, well-organized groups to wield outsized political power¹⁸⁰—is not ethically well founded. Pricing policies should aim to provide equitable incentives and not to value benefits for rare disease patients more highly than benefits for those with more common diseases. The NAM report observes that “previously neglected rare diseases that afflict only small numbers of people (but which have large impacts on individuals and their families) have been benefiting from innovative therapies.”¹⁸¹ While treating rare diseases benefits patients, rarer diseases are not more impactful on a per-patient basis than common diseases.¹⁸² Dying of a common cancer is just as detrimental a loss as dying of an uncommon one. This point also illustrates the non sequitur underlying the claim that rare diseases should receive priority because “the more a disease impairs a person’s capacity to pursue their goals, the more urgent it is that their health need is addressed.”¹⁸³ A patient who dies of a common cancer is no less impeded in pursuing her goals than a patient who dies of a rare cancer. A pricing policy that treats patients equally means that price should reflect the number of patients benefited and the amount of benefit, not whether the disease is rare or common.

That severity and rarity are distinct also means that incorporating the “rule of rescue” into health-system-level decisions (a debatable choice, given that health policymakers, unlike physicians, do not have duties to rescue specific patients)¹⁸⁴ does not support prioritizing rare diseases over other conditions. Emily Largent and Steve Pearson suggest that the rule of rescue might justify paying large sums to treat certain rare diseases—for instance, paying more

180. Cf. John Meadowcroft, *Patients, Politics, and Power: Government Failure and the Politicization of U.K. Health Care*, 33 J. MED. & PHIL. 427, 434, 440 (2008); Karl Claxton, Mark Sculpher, Stephen Palmer & Anthony J. Culyer, *Causes for Concern: Is NICE Failing to Uphold Its Responsibilities to All NHS Patients?*, 24 HEALTH ECON. 1, 2 (2015) (observing that identifiable beneficiaries of programs are able to advance their interests at the expense of “those unidentified NHS patients who bear the true opportunity costs of NICE decisions”).

181. NAM REPORT, *supra* note 11, at 160.

182. *See id.*

183. Hyry et al., *supra* note 178, at 270.

184. *See* BRODY, *supra* note 29, at 212-14.

than \$200,000 per year for a Gaucher disease treatment.¹⁸⁵ But if such expenditures are justifiable, they should be equally justifiable if needed to treat a patient with a comparably severe but more common disease. The rule of rescue responds to identifiable severity, not rarity.¹⁸⁶

Rare disease advocates have also tried to argue that “[c]ost-efficiency calculations cannot be used to prioritize between different patients and patient groups ... because ... one person’s equal opportunities and liberties cannot be sacrificed for another’s.”¹⁸⁷ But this argument overlooks the fact that allowing higher prices for rare disease drugs prioritizes rare disease patients over others without an obvious justification. Pricing policies shape decisions about which research avenues to pursue and which conditions to prioritize treating. Encouraging drugmakers to save more lives by developing treatments that have benefits for a larger patient population is no different from encouraging them to save more lives through investing in greater efficacy or lower toxicity.

All of what I say above is compatible with arguments that cost-effectiveness thresholds should be raised.¹⁸⁸ If some rare diseases deserve investment despite high costs, perhaps spending on health care should increase to fund all treatments that are comparably cost-effective. But patients with common diseases should not be treated less favorably than patients with rare ones.

While some treatments for rare disease patients will score poorly under either conventional or modified CEA,¹⁸⁹ value-based policies need not run contrary to the interests of rare disease patients. Most importantly, a value-based ceiling on prices will—unlike a reimbursement limit—produce major *improvements* in access for rare disease patients in the short term, because the prices of rare disease drugs currently on the market will need to drop in order to align

185. Emily A. Largent & Steven D. Pearson, *Which Orphans Will Find a Home? The Rule of Rescue in Resource Allocation for Rare Diseases*, 42 HASTINGS CTR. REP. 27, 32 (2012).

186. *See id.* at 27.

187. Hyry et al., *supra* note 178, at 270.

188. *See* Peter J. Neumann, Joshua T. Cohen & Milton C. Weinstein, *Updating Cost-Effectiveness—The Curious Resilience of the \$50,000-per-QALY Threshold*, 371 NEW ENG. J. MED. 796, 796-97 (2014).

189. *See* Claxton et al., *supra* note 180, at 5-6.

with their social benefit.¹⁹⁰ Additionally, many treatments for common conditions—for instance, new antibiotics or pain relievers—could improve health outcomes for all patients.

4. *Assisting Patients Without Other Options*

Mello and Wolitz argue that pricing policy should consider the public health importance of specific drugs.¹⁹¹ In defining public health importance, they reference work by the health economist Mariana Social, who argues that, when deciding whether a drug should be a priority for price regulation, “key considerations might include (1) whether the drug saves lives or averts serious harms; (2) the number of people dependent on the drug; and (3) how many alternative therapies are available for the health condition(s) the drug treats.”¹⁹² The first and second criteria are simple and normatively compelling: how many patients benefit, and how much each patient benefits.¹⁹³

However, the third criterion departs from cost-effectiveness principles and equal treatment in a way that is difficult to defend. Basing decisions on the availability of alternatives implicitly regards extending or improving the lives of patients who lack other options as preferable to extending or improving, by the same amount, the lives of patients who have access to some options, even toxic or ineffective ones. Other commentators, including both some patient advocates and a minority appendix to the NAM report, go further to advocate entirely abandoning cost-effectiveness considerations when a drug is the only treatment for a given condition.¹⁹⁴

190. *See infra* Part III.A.

191. Mello & Wolitz, *supra* note 5, at 963.

192. *Id.* at 963-64 (citing Memorandum from Mariana Social et al. on Behalf of the Johns Hopkins Drug Access and Affordability Initiative to Josh Auerbach, Assistant Attorney General, State of Maryland 1-5 (Sept. 21, 2017)).

193. *See id.*

194. Michael Rosenblatt & Henri Termeer, *A Dissenting View*, in NAMREPORT, *supra* note 11, at 159, 174 (“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.”); Hyry et al., *supra* note 178, at 270 (arguing that social value assessments “should not be deployed when the choice is between an only treatment and no treatment ... because failure to provide any treatment would entirely deny an individual the right to pursue their life plan”).

Departing from conventional CEA to give greater weight to saving patients without other options is no more justifiable than modifying it to give greater weight to saving patients with less common conditions. Consider the example of tenofovir for HIV,¹⁹⁵ or the more recent case of hepatitis C antivirals such as sofosbuvir.¹⁹⁶ Tenofovir was not the first treatment for people with HIV,¹⁹⁷ nor were the newer antivirals the first treatment for patients with hepatitis C.¹⁹⁸ But the older treatments for these diseases were less effective and had serious side effects: interferon plus ribavirin for hepatitis had neuropsychiatric effects including depression and suicidal ideation,¹⁹⁹ and stavudine treatment for HIV caused neuropathy and lipodystrophy.²⁰⁰ The development of sofosbuvir almost certainly saved many more lives than the development of a new “last chance” drug for a condition that affects few people. While policy should incentivize the development and production of drugs that have substantial benefits over the status quo—which often are drugs for previously untreated conditions—a modification to CEA that produces a disincentive to invest in drugs like sofosbuvir is difficult to defend.

C. Defining the Social Value Threshold

In pharmaceutical policy, CEA is typically used to define either the maximum price that can be charged for a specific drug²⁰¹ or the maximum price a governmental or regulated payer will pay.²⁰² Certain maximum thresholds, such as \$50,000, \$100,000, or \$150,000 per QALY, are often used but not always carefully

195. See *supra* Part I.B.4.

196. See Neumann et al., *supra* note 188, at 797.

197. See Jay Purcell, *Adverse Clinical and Public Health Consequences of Limited Antiretroviral Licensing*, 25 BERKELEY TECH. L.J. 103, 105 (2010).

198. See NAM REPORT, *supra* note 11, at 78.

199. See Linda S. Good, “The Shadow Epidemic”: *Hepatitis C and the Law*, 35 CLEARINGHOUSE REV. 21, 29-30 (2001).

200. Purcell, *supra* note 197, at 119.

201. See NAM REPORT, *supra* note 11, at 26, 82.

202. See Claxton, *supra* note 180, at 1.

justified.²⁰³ This Section reviews approaches for defining and justifying these maximum thresholds.

1. *Per Capita Income*

The World Health Organization's project on cost-effectiveness advocates the use of per capita income to define a CEA threshold:

[I]nterventions that avert one DALY [disability-adjusted life-year] for less than average per capita income for a given country or region are considered very cost-effective; interventions that cost less than three times average per capita income per DALY averted are still considered cost-effective; and those that exceed this level are considered not cost-effective.²⁰⁴

Some countries, most prominently Poland, explicitly define a maximum threshold using per capita income.²⁰⁵ Others use thresholds roughly consistent with the per capita income approach but express them as a round number that falls within the WHO's recommended range—for instance, Thailand's threshold of one hundred thousand Thai baht.²⁰⁶

Income-based thresholds present the problem that they can permit drugs to be priced or reimbursed at levels that are unaffordable for the health system or that replace spending on other drugs that are more cost-effective.²⁰⁷ For instance, providing sofosbuvir in

203. See Emanuel, *supra* note 42, at 607; Neumann et al., *supra* note 188, at 796 (describing the use of \$50,000/QALY or \$100,000/QALY thresholds as the use of “an arbitrary but convenient round number”).

204. Melanie Y. Bertram, Jeremy A. Lauer, Kees De Joncheere, Tessa Edejer, Raymond Hutubessy, Marie-Paule Kieny & Suzanne R. Hill, *Cost-Effectiveness Thresholds: Pros and Cons*, 94 BULL. WORLD HEALTH ORG. 925, 926 (2016); Raymond Hutubessy, Dan Chisholm & Tessa Tan-Torres Edejer, *Generalized Cost-Effectiveness Analysis for National-Level Priority-Setting in the Health Sector*, COST EFFECTIVE RES. ALLOCATION, Dec. 2013, at 1, 8. QALYs and DALYs are similar and interconvertible measures of health benefit. See Marthe R. Gold, David Stevenson & Dennis G. Fryback, *HALYs and QALYs and DALYs, Oh My: Similarities and Differences in Summary Measures of Population Health*, 23 ANN. REV. PUB. HEALTH 115, 116 (2002).

205. Bertram et al., *supra* note 204, at 927.

206. *Id.*

207. See *id.* at 926 (observing that “GDP-based cost-effectiveness ratios ... do not provide information on affordability, budget impact or the feasibility of implementation”); Emanuel, *supra* note 42, at 607.

publicly funded health insurance in the United States would meet a \$100,000 per QALY threshold but would lead to an increase in national health spending that “is probably unaffordable and more cost-effective interventions would probably be crowded out if sofosbuvir were to be offered on such a large scale.”²⁰⁸ Similarly, recent research suggests that some drugs priced below the United Kingdom’s reimbursement threshold lead to “the displacement of more cost-effective activities by new approvals.”²⁰⁹ The use of an opportunity cost threshold can address this problem, as discussed in Part II.C.3 below.

2. *Explicit or Implicit Valuations*

Instead of being derived from income, thresholds might be determined by looking either at individuals’ explicitly stated preferences for health spending or at the values revealed by their choices. Explicit preferences are typically elicited using surveys, while revealed values are assessed by examining what society or individuals pay to avoid risk.²¹⁰ Research suggests that survey-based thresholds slightly exceed income-based thresholds, while revealed values are more variable, with individual revealed values typically exceeding societal ones.²¹¹

3. *Opportunity Cost*

Thresholds could also be set using opportunity cost: that is, at the point where health improvements from the provision of a new drug at the threshold price outweigh the harms to health that result from diverting resources to pay for that drug. As one group explains,

208. Bertram et al., *supra* note 204, at 926; *see also* Emanuel, *supra* note 42, at 607.

209. Bertram et al., *supra* note 204, at 927.

210. Cf. Richard A. Hirth, Michael E. Chernew, Edward Miller, A. Mark Fendrick & William G. Weissert, *Willingness to Pay for a Quality-Adjusted Life Year: In Search of a Standard*, 20 MED. DECISION MAKING 332, 333-34 (2000).

211. *See id.* at 338; Emanuel, *supra* note 42, at 607 (“Empirical assessments of actual health service trade-offs—that is, what a society’s spending indicates it is willing to pay per QALY in practice—suggest a threshold of about half the per capita GDP, or \$29,000 per QALY for the US.”).

In theory, if all interventions could be measured in similar terms and ranked by the favorability of their incremental cost-effectiveness ratios, decision makers with a fixed budget could maximize health gains by choosing interventions with the lowest (most favorable) ratios and working their way down the list until the available resources were consumed. The cost-effectiveness of the last (least favorable) technology covered would represent society's willingness-to-pay threshold—the highest price society is willing to pay for health gains.²¹²

Other commentators agree that the method of developing a threshold by examining opportunity cost would be theoretically ideal if achievable.²¹³ Opportunity cost thresholds are generally lower than those set using income or explicit valuation.²¹⁴ For instance, a recent study concluded that the United Kingdom's opportunity cost threshold should be closer to £13,000 per QALY given current budgets.²¹⁵ Spending that exceeds the opportunity cost threshold displaces other more beneficial spending, producing additional deaths and worse health.²¹⁶

While an opportunity cost threshold ensures that spending on new drugs will never worsen health outcomes, it could underincentivize the development of treatments whose costs exceed an opportunity cost threshold but that save money compared to currently available alternatives. If the cost-effectiveness threshold is understood in absolute terms (for example, \$100,000 per QALY), cost-saving treatments will sometimes exceed the threshold because some currently available treatments cost far more than that

212. Neumann et al., *supra* note 188, at 796.

213. Hirth et al., *supra* note 210, at 333 n.* (“A theoretically sound cost/QALY standard would reflect the shadow price (opportunity cost) of the resources devoted to obtaining one more QALY.”); *see also* Bertram et al., *supra* note 204, at 925.

214. *See* Praveen Thokala, Jessica Ochalek, Ashley A. Leech & Thaison Tong, *Cost-Effectiveness Thresholds: The Past, the Present and the Future*, 36 PHARMACOECONOMICS 509, 514, 517 (2018).

215. Karl Claxton, Steve Martin, Marta Soares, Nigel Rice, Eldon Spackman, Sebastian Hinde, Nancy Devlin, Peter C. Smith & Mark Sculpher, *Methods for the Estimation of the National Institute for Health and Care Excellence Cost-Effectiveness Threshold*, 19 HEALTH TECH. ASSESSMENT, Feb. 2015, at xxx (“The central or ‘best’ threshold is estimated to be £12,936 per QALY.”); *see also* Andrew Dillon, *Carrying NICE over the Threshold*, NICE (Feb. 19, 2015), <https://www.nice.org.uk/news/blog/carrying-nice-over-the-threshold> [<https://perma.cc/6NT4-PCAF>] (rounding to £13,000).

216. Claxton et al., *supra* note 180, at 3.

threshold.²¹⁷ Replacing these costly treatments could reduce costs or improve health, or both, even if the replacements were priced above \$100,000 per QALY, or whatever that threshold might be. Development of replacements for costly treatments could be encouraged by permitting treatments to be priced above an absolute threshold when they are less costly than presently provided alternatives. While this approach would encourage socially valuable innovation, it would also entrench existing inefficiencies because the cost of the replacement treatments would still greatly exceed the opportunity cost threshold, even though the new treatments would be incrementally cost-saving compared to the status quo. An alternative strategy for incentivizing investment in cost-saving treatments without entrenching inefficiencies would be a fixed “bounty” above the opportunity cost threshold for treatments that replace very costly treatments. This strategy would parallel the prize proposals discussed earlier.²¹⁸

III. IMPLEMENTING THE SOCIAL VALUE THRESHOLD: A PRICE CEILING APPROACH

There are many options for implementing a social value threshold. As described in Part II.A, social value can be used to establish reimbursement thresholds for single-payer or government-regulated insurance or to establish maximum prices at which a drug may be sold. Another option would be to use social value to determine the prices that large governmental insurers, such as Medicare and Medicaid, negotiate with manufacturers.²¹⁹ Still another option would be to impose an excise tax on drug manufacturers who charge prices over the threshold.²²⁰ Each of these options requires deciding which type of threshold discussed in Part I.B (cost, affordability, custom, or social value) to adopt.

In this Part, I propose and defend the implementation of a social value threshold, preferably defined using the opportunity cost

217. See Thokala et al., *supra* note 214, at 510, 519; Ankur Pandya, *Adding Cost-Effectiveness to Define Low-Value Care*, 319 JAMA 1977, 1977 (2018) (identifying currently provided interventions in the United States that cost more than \$150,000 per QALY).

218. See *supra* note 146 and accompanying text.

219. NAM REPORT, *supra* note 11, at 52-53.

220. See, e.g., Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 116th Cong. (2019).

approach, by means of a price ceiling. In Part III.A, I identify the political, practical, and ethical advantages that price ceilings have over other implementation strategies such as reimbursement limits, excise taxes, or negotiation by governmental payers. In the following four Sections, I address four categories of objections to price ceilings, which I call *efficiency-based*, *need-based*, *liberty-based*, and *desert-based* objections. We can think of each category of objection as being offered on behalf of a specific group that the price ceiling affects. Efficiency-based objections are offered on behalf of society, particularly future generations. They raise the concern that price ceilings will lead to underinvestment in the development of socially valuable drugs. Need-based objections are offered on behalf of patients who are unable to pay the maximum price that social value considerations would justify. Conversely, liberty-based objections are offered on behalf of patients who are interested in paying more than the maximum price to access drugs. They contend that it is difficult to justify limiting spending on drugs when spending on other goods is not similarly limited. Last, desert-based objections are offered on behalf of pharmaceutical firms. They argue that the ingenuity required to produce pharmaceuticals merits a price above the ceiling level. In addressing these objections, I further develop the case in support of price ceilings.

A. Political, Practical, and Ethical Advantages

Price regulation—including the setting of maximum prices—has existed throughout history and within a variety of economic systems for goods including food, energy, credit, and medical services.²²¹ While price regulation has faced vigorous criticism from modern economic theory,²²² these criticisms have not undermined its legality

221. See, e.g., Boyd, *supra* note 14, at 735 n.35, 740-41, 756, 770-71; Regulation of Consumer Credit, 28 FED. RES. BULL. 399 (1942).

222. E.g., Hugh Rockoff, *Price Controls*, in THE CONCISE ENCYCLOPEDIA OF ECONOMICS 409, 409 (David R. Henderson ed., 2008) (“Despite the frequent use of price controls ... and despite their appeal, economists are generally opposed to them, except perhaps for very brief periods during emergencies.”); Geoffrey C. Rapp, *Gouging: Terrorist Attacks, Hurricanes, and the Legal and Economic Aspects of Post-Disaster Price Regulation*, 94 KY. L.J. 535, 535 (2005-2006) (“Law and economics loathes price controls.”).

in the United States.²²³ Just as importantly, even economically oriented scholars grant that price regulation can be appropriate in markets, including pharmaceutical markets, in which competition is limited.²²⁴ This Section examines some of the advantages of price ceilings as a regulatory strategy in pharmaceutical markets.

Price ceilings, which limit the price that any buyer can be charged, have advantages over reimbursement ceilings, which limit only the price that certain buyers will pay. A reimbursement ceiling does not guarantee that buyers—even large buyers like Medicare or the Veterans’ Administration—will be able to obtain pharmaceuticals at the ceiling price. In the face of a reimbursement ceiling they judge too low, sellers could demand a higher price while blaming buyers for refusing to pay what it takes to save patients in need.²²⁵ This strategy could be—and indeed has been—especially effective when coupled with pressure from patient advocacy groups, which sellers often support with funding and logistical coordination.²²⁶ Public insurers may capitulate due to political pressure, while private insurers may face public opinion headwinds.²²⁷

In contrast, a price ceiling ensures that, *if* a drug is available, any buyer will be able to purchase it at the ceiling price.²²⁸ Any negative effects of price ceilings will occur at the earlier stage of drug marketing and development decisions, when the patients who might

223. *In re Permian Basin Area Rate Cases*, 390 U.S. 747, 768 (1968) (“It is plain that the Constitution does not forbid the imposition, in appropriate circumstances, of maximum prices upon commercial and other activities.”).

224. *E.g.*, Herbert Hovenkamp, *The First Great Law & Economics Movement*, 42 STAN. L. REV. 993, 1038 & n.230 (1990) (explaining that, even within “neoclassical ... economics,” “[g]overnment intervention to correct market failure might be justified on economic grounds, as in the case of price regulation of a natural monopoly”).

225. Despite Mark Pauly’s criticism of value-based price ceilings, he implicitly recognizes that using value to set a reimbursement ceiling or negotiation target exposes the negotiator to political pressure. *See* Mark V. Pauly, *The Questionable Economic Case for Value-Based Drug Pricing in Market Health Systems*, 20 VALUE HEALTH 278, 281 (2017).

226. *See* Kyle T. Edwards, *Good and Bad Patient Involvement: Implementing the Patient-Involvement Provisions of the 21st Century Cures Act at the FDA*, 128 YALE L.J.F. 1077, 1082-84 (2019) (discussing pharmaceutical firms’ funding of patient advocacy groups).

227. *See* Christopher Robertson, *Essay, The Split Benefit: The Painless Way to Put Skin Back in the Health Care Game*, 98 CORNELL L. REV. 921, 927-28 (2013).

228. Troy Segal, *Price Ceiling*, INVESTOPEDIA (Aug. 7, 2019), <https://www.investopedia.com/terms/p/price-ceiling.asp> [<https://perma.cc/3WZC-LZBN>].

benefit from a future drug are not yet identifiable.²²⁹ Price ceilings therefore have advantages over reimbursement ceilings at addressing the problem of identifiable patients' interests unjustifiably being prioritized over the interests of unidentified patients, leading to worse health outcomes.²³⁰

The use of social value to set a price ceiling, rather than a reimbursement ceiling, has particular advantages with respect to potential objections from patients. Because a price ceiling limits what patients can be charged, rather than what insurers will pay, it makes existing drugs more affordable to patients in the short run,²³¹ while its long-run effects on development incentives are more remote and uncertain. Even if some currently existing expensive drugs would not have been developed had the price ceiling existed at their inception, drugmakers will likely continue manufacturing and selling them at the ceiling price because the marginal cost of producing an already-approved drug is low.²³² Unlike reimbursement limits, price ceilings will not pose the political problem of removing access to existing drugs.²³³

Economic theory predicts that price regulation will reduce long-run investment in drugs whose price will be insufficient to offset their development cost.²³⁴ But this consequence of price regulation

229. See John E. Calfee, Perspective, *Pharmaceutical Price Controls and Patient Welfare*, 134 ANNALS INTERNAL MED. 1060, 1062 (2001).

230. See Claxton et al., *supra* note 180, at 6; cf. Calfee, *supra* note 229, at 1062 (observing that, under price controls, "the beneficiaries of drugs still in development would be unaware of the stakes and thus unable to provide a countervailing force").

231. See Segal, *supra* note 228; cf. Daniel J. Hemel & Lisa Larrimore Ouellette, *Innovation Policy Pluralism*, 128 YALE L.J. 544, 573 (2019) (arguing that better aligning a regulatory proposal with the interests of "a well-resourced interest group" can improve political viability).

232. Cf. Rishi Gupta, *TRIPS Compliance: Dealing with the Consequences of Drug Patents in India*, 26 HOUS. J. INT'L L. 599, 610 (2004) (observing that "it would not make sense for a firm to decide *ex post*, after the research and development investment had been made—a sunk cost, in economic terms—to withdraw from" a market in the face of price controls "unless the controlled price was below the marginal cost of production" (footnote omitted)); Calfee, *supra* note 229, at 1062 ("[D]rugs would continue to be available as long as price ceilings exceeded the costs of manufacturing and distribution, regardless of how much money had been spent on research and development or had been lost by firms that tried and failed to develop similar drugs.").

233. See Marion Haas, Jane Hall, Rosalie Viney & Gisselle Gallego, *Breaking Up Is Hard to Do: Why Disinvestment in Medical Technology Is Harder than Investment*, 36 AUSTL. HEALTH REV. 148, 151 (2012) (observing that "gains from disinvestment are likely to be more diffuse and less readily specified than any losses," which presents political challenges).

234. See Rapp, *supra* note 222, at 550.

is politically acceptable because it reframes lack of access as a conflict between patients and profit-seeking drugmakers rather than as a conflict between patients who need expensive drugs and a government or insurer who is unwilling to pay what it takes to help them. Governmental insurers, even those strongly committed to cost-effectiveness, have frequently capitulated in such conflicts and elected to spend more on treatments than a social value threshold would dictate.²³⁵ Private insurers have similarly come under pressure when attempting to cap reimbursements for costly drugs.²³⁶ A price ceiling relieves this pressure by placing the onus on drugmakers to explain why they have elected not to develop and market rare disease treatments. Patient advocates could also organize charitable investment in drug development,²³⁷ which could enable drugs to be developed and sold at lower cost.

Effectively implementing value-based price ceilings would require a trustworthy source of information about social value. Although the Patient-Centered Outcomes Research Institute created by the ACA only provides information on effectiveness, not cost-effectiveness,²³⁸ effectiveness information could be combined with pricing data to generate reliable information about social value. Alternative sources of information include nonprofits like the Institute for Clinical and Economic Review²³⁹ and cost-effectiveness calculations conducted in countries such as the United Kingdom.²⁴⁰ Price ceilings would have advantages over reimbursement ceilings here as well. They would reduce the pressure on cost-effectiveness assessors by giving patient advocacy groups and pharmaceutical firms opposing

235. See, e.g., John Appleby, *The Cancer Drugs Fund: Inequitable and Inefficient?*, KING'S FUND (Sept. 23, 2014), <https://www.kingsfund.org.uk/blog/2014/09/cancer-drugs-fund-inequitable-and-inefficient> [<https://perma.cc/3VYC-ZQCR>] (describing the UK's decision to give cancer patients publicly subsidized access to drugs that fail to meet the UK's "threshold cost-effectiveness level due to a combination of low effectiveness and high cost," and criticizing the decision for worsening health outcomes and creating "a perverse incentive for drug manufacturers").

236. Pearson, *supra* note 160, at 306.

237. See Anne M. Readle, *Finding a Cure: Incentivizing Partnerships Between Disease Advocacy Groups and Academic Commercial Researchers*, 26 J.L. & HEALTH 285, 287-88 (2013) (describing patient advocacy groups' funding of commercial drug development).

238. See Persad, *Priority Setting*, *supra* note 152, at 132.

239. Pearson, *supra* note 160, at 304-05.

240. See Pearson et al., *supra* note 29, at 3 (discussing countries that "benchmark their prices to UK prices").

incentives: pharmaceutical firms would strive to show that their drugs have large benefits in order to be able to charge higher prices, while patient advocates would have an incentive to challenge these claims in order to secure lower prices.²⁴¹

Price ceilings also have practical advantages over excise taxes on expensive drugs. Because demand is highly inelastic, sellers can simply raise prices to absorb the excise tax, rather than lowering prices to avoid the tax or changing their drug development decisions.²⁴² In fact, the weak negotiating position of tax-funded public insurers such as Medicare²⁴³ means that they may end up absorbing much of an excise tax's burden, which means that the excise tax merely shifts money between governmental agencies.

In addition to these political and practical advantages, price ceilings have two types of ethical advantages. First, as Section B will discuss, price ceilings can incentivize the development of interventions with substantial social value, because high social value is necessary to permit a high price. Second, as Section C will examine, price ceilings protect society and patients from the psychological pressures and ethical burdens that access to extremely expensive treatments can produce.

B. Addressing Efficiency-Based Objections

Outside the pharmaceutical sector, price regulation has often been derided as economically inefficient.²⁴⁴ Even though no real-world market meets the conditions required for the theoretical critique of price ceilings to succeed,²⁴⁵ many of these critiques are

241. Cf. Timothy Flynn, Jr., Note, *On "Borrowed Wits": A Proposed Rule for Attorney Depositions*, 93 COLUM. L. REV. 1956, 1962 (1993) (discussing the argument that an adversarial system's "incentive structure makes it the best system for eliciting truth").

242. See Scott Greenberg, *Five Years Later: ACA's Branded Prescription Drug Fee May Have Contributed to Rising Drug Prices*, TAX FOUND. (June 17, 2015), <https://taxfoundation.org/five-years-later-aca-s-branded-prescription-drug-fee-may-have-contributed-rising-drug-prices/> [<https://perma.cc/M6N7-UB4L>].

243. See Ryan Knox, Note, *More Prices, More Problems: Challenging Indication-Specific Pricing as a Solution to Prescription Drug Spending in the United States*, 18 YALE J. HEALTH POL'Y L. & ETHICS 191, 207-08 (2018).

244. See *supra* note 222.

245. See R.G. Lipsey & Kelvin Lancaster, *The General Theory of Second Best*, 24 REV. ECON. STUD. 11, 12 (1956-1957).

supported by empirical evidence in markets that are reasonably competitive, such as markets for food or housing.²⁴⁶ Price controls for rental housing, for instance, tend to lead to shortages of needed housing and to degradation in housing supply.²⁴⁷

When markets depart from ideal competition, however, price controls can produce good results. In labor markets, for instance, there is empirical support for the view that price floors (that is, minimum wages) can assist disadvantaged workers without substantially increasing unemployment.²⁴⁸ When a pharmaceutical seller enjoys a patent monopoly or market exclusivity due to the difficulty of entry, pharmaceutical price ceilings could improve outcomes for buyers without seriously harming the availability of socially valuable drugs. Most other developed countries employ either price controls or reimbursement limits based on social value.²⁴⁹

Mello and Wolitz, as well as the NAM Report's authors, worry that price controls will reduce beneficial innovation.²⁵⁰ Drugmakers have long highlighted this concern.²⁵¹ But the complexity of innovation in pharmaceutical markets makes it doubtful that unrestricted monopoly pricing—which patents without price controls enable—is either necessary or sufficient for innovation.²⁵² More

246. See HEATH, *supra* note 114, at 161-62.

247. See Edward L. Glaeser & Erzo F.P. Luttmer, *The Misallocation of Housing Under Rent Control*, 93 AM. ECON. REV. 1027, 1027 (2003) (examining the effects of rent control in New York); HEATH, *supra* note 114, at 163-64.

248. See Zachary Liscow, Note, *Reducing Inequality on the Cheap: When Legal Rule Design Should Incorporate Equity As Well As Efficiency*, 123 YALE L.J. 2478, 2498 n.46 (2014) (reviewing evidence supporting the use of minimum wage laws).

249. See NAM REPORT, *supra* note 11, at 132-33 (observing that “enacting direct controls or setting limits on drug prices” is “a strategy adopted by many high-income nations”).

250. *Id.* (“[T]his report does not recommend enacting direct controls or setting limits on drug prices.”); Mello & Wolitz, *supra* note 5, at 933 (asserting that experts believe that “crude price controls,” such as maximum launch prices, “are undesirable from a standpoint of preserving incentives for innovation” and that “given the widely varying investments in research and development and anticipated market sizes for different drugs, imposing a single statutory cap is ill-advised”).

251. See, e.g., Calfee, *supra* note 229, at 1063 (arguing, in an article commissioned by pharmaceutical firms, that pharmaceutical price controls undesirably disincentivize innovative research).

252. Cf. Rachel E. Sachs, *The Uneasy Case for Patent Law*, 117 MICH. L. REV. 499, 544 (2018) (observing that innovation in microbiome technology has proceeded without patent protection).

importantly, not all innovation is socially valuable. A social value price ceiling disincentivizes only the development of drugs unlikely to have sufficient social value to merit a profitable price. While an affordability-based price ceiling is likely to discourage the development of highly beneficial drugs like sofosbuvir,²⁵³ a social value price ceiling is not. Just as minimum wages can encourage competition on quality rather than purely on price,²⁵⁴ maximum drug prices could encourage firms to identify drugs that have large social benefits, enabling them to recoup their costs by charging a high but justified price or reaching a large market.²⁵⁵

One limitation of a price ceiling involves drugs that can be used to treat multiple conditions. For instance, the drug aflibercept can be used to treat both colon cancer and macular degeneration.²⁵⁶ Such drugs have prompted proposals for *indication-specific pricing*, in which the same drug is priced differently depending on the condition it is being used to treat, with lower prices when a drug is used to treat conditions where it produces less benefit.²⁵⁷ Indication-specific pricing could be used to generate multiple ceilings for multiple indications. But indication-specific pricing may be difficult to maintain because of arbitrage: patients with a more serious condition will try to obtain the drug at the lower price charged to patients with the less serious condition, which in turn lowers

253. For an argument against affordability-based pricing, see Mello & Wolitz, *supra* note 5, at 962.

254. See Harry G. Hutchison, *Waging War on "Unemployables"? Race, Low-Wage Work, and Minimum Wages: The New Evidence*, 29 HOFSTRA LAB. & EMP. L.J. 25, 55-56 (2011) ("Minimum wage regulation is ... necessary in order to help create an environment in which firms compete not on the basis of low pay but instead through high labour quality and product and process innovation.") (quoting Simon Deakin & Frank Wilkinson, *Minimum Wage Legislation*, in 2 LABOR AND EMPLOYMENT LAW AND ECONOMICS 158 (Kenneth G. Dau-Schmidt et al. eds., 2d ed. 2009)).

255. Cf. Emanuel, *supra* note 42, at 610 (arguing that value-based pricing "might better direct pharmaceutical innovation" and "would incentivize the development of higher-value drugs such as antibiotics"); Pearson et al., *supra* note 29, at 5 (arguing that "efforts to constrain prices by aligning them with clinical value would not stifle innovation" and that "[t]he innovation that 'wins' when prices align with clinical value is the innovation that demonstrates its ability to improve the lives of patients").

256. STEVEN D. PEARSON, BILL DREITLEIN & CHRIS HENSHALL, INDICATION-SPECIFIC PRICING OF PHARMACEUTICALS IN THE UNITED STATES HEALTH CARE SYSTEM 11 (2016), <https://collections.nlm.nih.gov/catalog/nlm:nlmuid-101704608-pdf> [<https://perma.cc/66DR-7D9P>].

257. *Id.* at 7.

incentives for drug development below their optimal level.²⁵⁸ Another strategy is *outcome-based pricing*, in which buyers pay only if their medical outcomes are favorable.²⁵⁹ An outcome-based approach would allow pricing for different indications and create incentives to produce more effective drugs while preventing arbitrage.

Although both indication-specific and outcome-based pricing might appear to constitute price discrimination, they can both help to align pricing with desirable incentives. Outcome-based pricing is particularly difficult to oppose given its resemblance to established arrangements such as attorney contingency fees, in which clients pay only if they receive a favorable outcome.²⁶⁰

C. Addressing Need-Based Objections

Need-based objections are also offered on behalf of buyers: while efficiency-based objections argue that the social-value-based price ceiling is too *low* to incentivize optimal long-term innovation, need-based objections argue that the ceiling is too *high* to enable short-term access. Frederick Abbott argues that value-based pricing unfairly prioritizes the interests of pharmaceutical firms over those of buyers:

The pharmaceutical industry prefers that discussions about price be based on the “value” to healthcare systems in terms of alternatives. For example, without treatment by a new drug, a patient would develop symptoms, visit doctors, be subject to tests, be admitted to a hospital, become disabled, and potentially die. The cost of hospitalization can be quite high, and the price of hospitalization for an extended period can run into the millions of dollars. Therefore, in “value” terms based on alternatives, even a high-priced medicine may be a “bargain.”²⁶¹

258. *Id.* at 10.

259. See Knox, *supra* note 243, at 227-28; Pearson et al., *supra* note 29, at 5. Recent legislation has been introduced to assist outcome-based pricing. See Press Release, *supra* note 104.

260. See David A. Hyman & Charles Silver, *You Get What You Pay For: Result-Based Compensation for Health Care*, 58 WASH. & LEE L. REV. 1427, 1429 (2001).

261. Abbott, *supra* note 51, at 303-04 (footnote omitted).

Others offer a similar critique, arguing that a social value approach “may not always lead to more affordable prices” because it “compares interventions to the cost of existing interventions.”²⁶²

Abbott also derides the value-based approach as “essentially a ‘hostage’ bargaining model” because

[t]he drug is under the control of the monopoly patent owner, and the price of ransoming the drug is whatever the party seeking to obtain it can pay. If the ransom is not paid, the consequences may be terrible, and in that regard the ransom can be characterized as a bargain. But it is only a bargain because of the threat.²⁶³

Abbott’s ransom analogy goes astray in two ways. First, a value-based price does not permit the drugmaker to charge “whatever the party seeking to obtain [the drug] can pay”²⁶⁴: no drug’s price can exceed a social value maximum. Second, the ransom analogy presupposes an argument that needs to be supplied. Kidnappers are appropriately described as taking “hostages” and charging a “ransom” because their conduct is unquestionably wrongful.²⁶⁵ In contrast, the wrongfulness of the patent-holder’s conduct is the central question at issue.

Abbott also argues that value-based pricing is analogous to permitting a vendor to breach a contract after learning about a specific customer’s willingness to pay:

Imagine a consumer preparing to board an airplane to attend an important business meeting in a faraway city. An airline representative says, “I am sorry but we cannot allow you to board this flight with your current ticket. Our database research shows that you are going to present a proposal that may lead to a very large contract for your employer, and we do not believe that we are being fairly compensated for our side of getting you to your meeting. So, you can only board the aircraft if you agree

262. BERMAN ET AL., *supra* note 5, at 13; *accord* Lamm, *supra* note 80, at 968.

263. Abbott, *supra* note 51, at 304.

264. *Id.*

265. *Cf.* ALAN WERTHEIMER, COERCION 214-15 (1987) (proposing a moralized account of coercion on which A coerces B by threatening to deprive B of something to which B is entitled).

to pay us ten times the current price of your ticket because the value to you of getting to your meeting is much higher than that.”

If your intuition is that this is an abusive pricing practice, what is your intuition about a drug company that says: “You have a fatal illness. If left untreated, you will be hospitalized for a period of months, if not years, attended to by nursing staff and doctors, and prescribed palliative medications. This will cost a great deal of money, which either you or your health insurer will pay. So, we have decided to charge you for this new medicine an amount somewhat lower than the total cost of the treatment you would receive if your disease were allowed to progress to its final stage; at which point you will die. Under these circumstances, do you not think our price fair?”²⁶⁶

The airline in Abbott’s example is proposing to willfully breach an existing contract for economic gain, which could expose it to a disgorgement remedy or other special damages.²⁶⁷ In contrast, there is no contract entitling patients to pharmaceuticals. While the drug company in Abbott’s example is proposing to profit from the patient’s plight, the same is true for trauma surgeons and defense attorneys.²⁶⁸ So it is not obvious that a value-based price becomes abusive or unfair merely because the patient paying it is desperate.

The affordability objection can be further defused through two complementary strategies: competition and publicly subsidized insurance. Remember that social value does not define a specific price to which drugmakers are entitled. Rather, it only sets a maximum.²⁶⁹ When some degree of competition is possible, a lower price than the maximum might be achieved by increasing competition. When competition does not exist, because of patent or regulatory exclusivity, prices could be lowered by reducing the length or stringency of patent protection or of regulatory exclusivity, although

266. Abbott, *supra* note 51, at 304 n.112.

267. See Oren Bar-Gill & Omri Ben-Shahar, *An Information Theory of Willful Breach*, 107 MICH. L. REV. 1479, 1480-81 (2009) (discussing the Third Restatement of Restitution’s proposal that willful breachers should be required to disgorge benefits received from breach, and noting that “within mainstream contract law, there are various ways in which the fault and willfulness of breach matter for the magnitude of damages”).

268. Cf. Mello & Wolitz, *supra* note 5, at 921-22 (discussing the existence of extreme need in nonpharmaceutical medical care contracts).

269. See *supra* Part I.B.4.

these steps are likely to come at some detriment to socially valuable innovation.²⁷⁰ Calculating the trade-off between lower prices and reduced innovation is complex.²⁷¹ This detriment to innovation must be weighed against the improvement to short-term affordability. What price best incentivizes socially valuable innovation is a complex empirical question. But if the prior Section's arguments are correct, that price will always be at or below the social value threshold.

Meanwhile, if a given patient is unable to afford a drug that is socially valuable at its current price, the affordability problem is better addressed through publicly subsidized health insurance than through trying to set a single price that every patient can afford. Pricing based on individual affordability would generate insufficient incentives to produce socially valuable medicines and would create particular disincentives to produce drugs that treat poorer patients.²⁷²

D. Addressing Liberty-Based Objections

Price ceilings apply to all buyers, irrespective of differences in values, preferences, and ability to pay.²⁷³ This Procrustean quality of price ceilings might prompt an objection that they unacceptably restrict the liberty of those who wish to pay more than the ceiling price.²⁷⁴ In line with this reasoning, expert panels in the European

270. See Mello & Wolitz, *supra* note 5, at 957; see also Lamm, *supra* note 80, at 966.

271. Cf. Mello & Wolitz, *supra* note 5, at 961 (explaining the calculation of value-based pricing and the cost-effectiveness ratio); Sachs, *supra* note 252, at 544 (discussing financial reward as a motivator for innovation and identifying the high cost of developing new drugs); Hemel & Ouellette, *supra* note 231, at 569-70 (arguing that exclusive IP rights may not be necessary for some forms of innovation).

272. See Mello & Wolitz, *supra* note 5, at 945; cf. Lemley et al., *supra* note 139, at 121 (discussing the "reason to worry that there is not enough investment in drugs that disproportionately benefit the Medicaid population").

273. Cf. Pauly, *supra* note 225, at 280 ("[B]ecause consumer values vary across the demand curve, there is a distribution of value-based prices.")

274. See, e.g., Michael Jefford, Julian Savulescu, Jacqui Thomson, Penelope Schofield, Linda Mileskin, Emilia Agalianos & John Zalberg, *Medical Paternalism and Expensive Unsubsidised Drugs*, 331 BRIT. MED. J. 1075, 1076 (2005) (arguing that justice "cannot prohibit people accessing treatment they desire using their own funds unless it is unsafe" and that "the decision of how much to spend on healthcare that is not provided by government should be the patient's own"); Robert M. Nelson & Theresa Drought, *Justice and the Moral Acceptability of Rationing Medical Care: The Oregon Experiment*, 17 J. MED. & PHIL. 97, 104

Commission have argued that “authority to regulate prices in the EU should extend only to those medicines purchased by, or reimbursed by, the State,” and not to “medicines not reimbursed by State systems or medicines sold into private markets.”²⁷⁵ This argument is largely accepted with respect to other essential goods: we permit buyers to pay more than most people regard as socially optimal in order to live in a preferred home or buy desired foodstuffs.²⁷⁶

In responding to the liberty objection, I will reject at the outset three common types of responses. First, pure paternalistic arguments that buyers should not be allowed to engage in transactions that make them objectively worse off cannot support a social value price ceiling against the liberty objection because some buyers might in principle be better off—not worse off—if able to purchase drugs at a price that exceeds the social value ceiling.²⁷⁷ Second, while some might wish to prohibit certain harmless transactions, doing so is inconsistent with important commitments of a liberal society.²⁷⁸ Third, “semiotic” arguments that some transactions inappropriately change the meaning of the good being exchanged, whatever their merits elsewhere,²⁷⁹ are inapplicable to pharmaceutical pricing debates because exchanging money for pharmaceuticals is acceptable—the question is whether it is acceptable to limit the *amount* of money exchanged.

This Section’s case against the liberty objection instead focuses on two other arguments. One appeals to negative *externalities*—harmful effects of a private transaction on individuals other than the buyer and seller. The other appeals to what some have called *internalities*, which can justify buyers preferring a regulatory regime that removes certain options from reach.

(1992) (“There is no compelling reason why an individual should not be allowed to use his own private resources to purchase medical care above and beyond the established basic level of benefits.”).

275. See Edurne Navarro Varona, *The EU Pharmaceutical Sector: A Comment on Kyle*, 81 ANTITRUST L.J. 37, 41 n.23 (2016).

276. See Emanuel, *supra* note 42, at 604.

277. See Jefford et al., *supra* note 274, at 1076.

278. See JOHN STUART MILL, ON LIBERTY 68 (Gertrude Himmelfarb ed., Penguin Books 1974) (1859); cf. Alan Wertheimer, *Exploitation and Commercial Surrogacy*, 74 DENV. U. L. REV. 1215, 1227 (1997).

279. See generally Jason Brennan & Peter Martin Jaworski, *Markets Without Symbolic Limits*, 125 ETHICS 1053 (2015).

1. Externalities

As a threshold matter, negative externalities do not automatically make a transaction apt for regulation or prohibition.²⁸⁰ I will focus in this Section on two specific types of externalities that can justify regulation. The first is covered in Part III.A: unregulated prices do not merely permit individual buyers and sellers to freely contract for the provision of treatments that *already* exist, but also create upstream incentives for the development of *new* drugs—incentives that may not be socially optimal. Some have similarly criticized unregulated markets in other areas of health care for incentivizing the misallocation of social resources.²⁸¹

This Section also identifies an additional externality: the availability of expensive drugs that some buyers wish to purchase can generate pressure on others to purchase those drugs. Here, expensive drugs produce a negative externality not by generating socially counterproductive incentives but by functioning as undesired options that expose individuals to pressure.

The possibility of pressure resulting from undesirable options suggests itself as a response to Mark Pauly's complaint about the "nonsensical ... response of pharmacy benefit managers and some insurers to high launch prices for some breakthrough drugs."²⁸² Pauly expresses bewilderment that someone could be forced to pay for a drug they do not value:

They seem to be asserting that the price proposed is higher than the drug's value, and yet they will still be "forced" somehow to purchase the drug at that price and shift the cost to their premium payers in an unsustainable way. The whole point of the notion of value is that it reflects the maximum price above which the buyer's optimal strategy is to walk away (or somehow curtail purchases). If a set of buyers will not walk away at a price higher than the \$100,000 per QALY price, their values must be

280. Neil S. Siegel, *Collective Action Federalism and Its Discontents*, 91 TEX. L. REV. 1937, 1961 (2013) (arguing that many negative psychological externalities do not warrant regulation: for instance, the sale of an erotic novel might produce a negative psychological externality for a prudish third party, but this does not justify prohibiting the sale).

281. See, e.g., Frank Pasquale, *Access to Medicine in an Era of Fractal Inequality*, 19 ANNALS HEALTH L. 269, 287-93 (2010).

282. Pauly, *supra* note 225, at 280.

greater than \$100,000 per QALY, and they are irritated but not charged more than their value.²⁸³

That the existence of an undesired option can nevertheless generate pressure on choosers, however, is a recognized phenomenon that supports regulation in areas ranging from kidney markets to minimum wages.²⁸⁴ And pressure is made more likely by two distinctive aspects of many pharmaceuticals: that they are the *sole means of rescue* for many patients, and that an *equality norm* applies to their distribution.

Consider first how pharmaceuticals' status as the sole means of rescue might lead to choosers coming under pressure to purchase them. People who have the ability to rescue nearby, identifiable individuals are often regarded as morally obliged to do so, even when rescue is costly, even though people are not morally obliged to place themselves where individuals may be in need or to acquire the ability to rescue.²⁸⁵ The development and approval of a new, expensive drug converts private or public funds into a potential means of rescue, and thereby potentially generates new, undesired obligations.²⁸⁶ That access to expensive medical technologies generates a pressure to rescue, sometimes referred to as a "technological

283. *Id.*

284. See, e.g., I. Glenn Cohen, *What (If Anything) Is Wrong with Human Enhancement? What (If Anything) Is Right with It?*, 49 TULSA L. REV. 645, 658-59 (2014) (discussing how the availability of enhancement technologies whose use is nominally voluntary could nonetheless generate coercive pressures); I. Glenn Cohen, *Protecting Patients with Passports: Medical Tourism and the Patient-Protective Argument*, 95 IOWA L. REV. 1467, 1535 (2010) (explaining that allowing workers to waive their entitlement to a minimum wage may generate pressure to waive, which strengthens the case for a nonwaivable entitlement); SATZ, *supra* note 32, at 201 (discussing how, even if "allowing a market in kidneys expands a single individual's set of choices, if adopted in the aggregate it may reduce or change the available choices open to others").

285. See Vanessa Carbonell, *What We Know and What We Owe*, in 3 OXFORD STUDIES IN NORMATIVE ETHICS 235, 245-55 (Mark Timmons ed., 2013) (discussing examples when one is not obliged to acquire knowledge, but when its acquisition generates an obligation to rescue); Thomas Pogge, *Testing Our Drugs on the Poor Abroad*, in EXPLOITATION AND DEVELOPING COUNTRIES 105, 110 (Jennifer S. Hawkins & Ezekiel J. Emanuel eds., 2008) (discussing a situation in which proximity to those in need generates moral obligations, even though there is no duty to come into proximity).

286. Cf. Emanuel, *supra* note 42, at 605 ("High prices exploit citizens' sense of obligation for one another—our unwillingness to let someone suffer or die from the lack of a high-price drug.").

imperative,” has been extensively discussed.²⁸⁷ An appendix to the NAM report illustrates—perhaps unintentionally—the power of the technological imperative, arguing that if “a new drug is created that effectively treats a condition for which there never has been an effective treatment[,] ... 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,” regardless of cost.²⁸⁸ The authors of the appendix regard this scenario as providing an ethical argument against reimbursement limits,²⁸⁹ but it could equally be seen as an argument for price ceilings. Disincentivizing the production of expensive drugs at an early stage, before their potential beneficiaries become organized and identifiable, forestalls the technological imperative.²⁹⁰

In addition to being a means of rescue, pharmaceuticals also are often subject to an *equality* norm: if anyone can access a drug, everyone must be able to.²⁹¹ This equal-access norm produces political difficulties for public and private insurers who attempt to enforce a reimbursement ceiling that denies insurance-dependent patients access to expensive drugs while permitting access for self-pay patients.²⁹² And it can lead to middle-class and poor

287. See, e.g., *In re Doe*, 37 N.Y.S.3d 401, 425 (Sup. Ct. 2016) (endorsing the claim that “[t]he practice of medicine should not be governed by the ‘technological imperative’ [because it exists it must be employed]” (quoting N.Y.C. Health & Hosp. Corp. Bioethics Council, *Ethics and Clinical Practice Guided by the Family Health Care Decisions Act*, 16 NYSBA HEALTH L.J. 79, 80 (2011))); Nancy K. Rhoden, *Litigating Life and Death*, 102 HARV. L. REV. 375, 424 (1988) (discussing “the ‘technological imperative’—the phenomenon whereby the existence of a technology or technique strongly inclines persons toward its use” (footnote omitted)).

288. Rosenblatt & Termeer, *supra* note 194, at 174.

289. See *id.* at 159.

290. See Albert R. Jonsen, *Bentham in a Box: Technology Assessment and Health Care Allocation*, 14 LAW, MED. & HEALTH CARE 172, 174 (1986) (arguing that “explicit evaluations of single technologies” face the technological imperative, but a “general ... allocation policy” does not); BRODY, *supra* note 29, at 212 (discussing the societal adoption of “general policies of withholding costly interventions to save money by not providing physicians with the means to provide those interventions”); Calfee, *supra* note 229, at 1062-63.

291. See, e.g., Dan W. Brock, *Ethical and Value Issues in Insurance Coverage for Cancer Treatment*, 15 ONCOLOGIST 36, 41 (2010) (criticizing tiered prescription drug benefits under which “[p]oorer patients who cannot afford ... copays will be denied ... drugs, while better off patients will still obtain them, [as] an unacceptable form of ability to pay rationing”); Laura Hercher & Anya E.R. Prince, *Gene Therapy’s Field of Dreams: If You Build It, Will We Pay?*, 97 N.C. L. REV. 1463, 1495 (2019) (arguing that “equality of access” is appropriate for novel, expensive gene therapies in order to avoid “creating a world of haves and have-nots”).

292. Cf. Nelson & Drought, *supra* note 274, at 103 (suggesting that a refusal to “restrict an

patients—and especially their families—feeling pressured to spend their limited resources to purchase these drugs.²⁹³ If expensive drugs are not available, equal-access norms will not drive spending on them. Analogously, school uniform requirements limit options in order to relieve equality-based pressure to purchase.²⁹⁴ One ethnographic study suggests that school clothing is also subject to an equality norm: most interviewees “were committed to assuring that their own children would never have less than other children, leading inevitably to ever rising stakes in clothing competition.”²⁹⁵ The existence of this equality norm means that permitting high spending by some parents produces externalities for others. The availability of costly drugs may produce similar externalities.

2. Internalities

The availability of expensive but beneficial drugs may leave some buyers under the psychological pressure to purchase them even when purchasing the drugs would run counter to their long-term interests. Such harms to one’s own long-term interests are

individual’s ability to purchase medical care on the open market” will lead society to “extend the available ‘basic’ minimum of medical care to include all medically necessary procedures” regardless of resource scarcity); Jessica Mantel, *Setting National Coverage Standards for Health Plans Under Healthcare Reform*, 58 UCLAL. REV. 221, 234 (2010) (describing political challenges insurers face in limiting access to treatments).

293. Cf. Robert H. Frank, *Consumption Externalities and the Financing of Social Services*, in *INDIVIDUAL AND SOCIAL RESPONSIBILITY: CHILD CARE, EDUCATION, MEDICAL CARE, AND LONG-TERM CARE IN AMERICA* 175, 182-84 (Victor R. Fuchs ed., 1996), <https://www.nber.org/chapters/c6562.pdf> [<https://perma.cc/7FMU-W7WD>] (arguing that those who “purchase more elaborate” health insurance coverage “reduce the satisfaction of consumers who stick with the basic plan” and that the “perception of unequal access to ‘essential’ medical services ... would translate into irresistible political pressures to upgrade the basic plan”).

294. See Andrew D.M. Miller, *Balancing School Authority and Student Expression*, 54 BAYLOR L. REV. 623, 670 (2002).

295. Ann Bodine, *School Uniforms and Discourses on Childhood*, 10 CHILDHOOD 43, 54 (2003).

sometimes referred to as “internalities.”²⁹⁶ And limiting one’s option set can be an effective way of preventing internalities.²⁹⁷

In medical research, concerns that large financial inducements may lead research participants to take unreasonable medical risks have prompted regulation.²⁹⁸ Expensive drugs present the reverse problem: the promise of large medical benefits could lead patients and families to take unreasonable financial risks.²⁹⁹ A patient may have a long-term preference to choose lower-cost treatments in order to preserve her, or her family’s, resources for other goals.³⁰⁰ But high-cost treatments may be psychologically irresistible for patients, even those who would reflectively prefer not to purchase them, and even more so for family members, who may feel obliged to sacrifice their own well-being for patients’ health.³⁰¹

A final point: concerns about internalities and externalities apply most clearly to drugs that promise—even with great uncertainty—to rescue patients from disaster.³⁰² One patient’s purchase of an expensive “lifestyle drug” is less likely to generate pressure on others to do likewise, because lifestyle drugs do not enable rescue or

296. See Lee Anne Fennell, *Personalizing Precommitment*, 86 U. CHI. L. REV. 433, 433 (2019) (explaining that “internalities’ ... can cause the payoffs for the present self to diverge from what is in an individual’s overall, long-term best interest”); cf. Hemel & Ouellette, *supra* note 231, at 573 (arguing that “the time-inconsistent preferences of policy makers” can justify policymakers’ decisions to constrain their own future options in order to successfully ensure that access to medicines is appropriately regulated).

297. Fennell, *supra* note 296, at 455-56.

298. See Govind Persad, *Paying Patients: Legal and Ethical Dimensions*, 20 YALE J.L. & TECH. 177, 197 (2018).

299. Cf. Adrienne M. Martin, *Hope and Exploitation*, 38 HASTINGS CTR. REP. 49, 54 (2008) (arguing that some pharmaceutical firms exploit patients’ hope in order to charge them unfairly high prices).

300. See Robert H. Frank, *Commitment Problems in the Theory of Rational Choice*, 81 TEX. L. REV. 1789, 1801-02 (2003).

301. See, e.g., Megan A. Stevenson & Daniel E. Abbott, *Societal Responsibility and Moral Hazard: How Much Are We Willing to Pay for Quality-Adjusted Life?*, 114 J. SURGICAL ONCOLOGY 269, 270 (2016) (“[C]ancer patients have been shown to pursue expensive therapies regardless of price, as they often feel pressure to battle cancer ‘at all costs.’”). One scholar has even argued that selling lifesaving drugs at exorbitant prices constitutes tortious infliction of emotional distress. Paul J. Zwier, *High Prices in the U.S. for Life-Saving Drugs: Collective Bargaining Through Tort Law?*, 17 MARQ. BENEFITS & SOC. WELFARE L. REV. 203, 233 (2016).

302. This can help explain the “paradoxical[.]” fact that “people may feel more outrage over high prices for lifesaving therapies ... than over incremental improvements or lifestyle drugs.” Amy C. Madl, Note, *Using Value-Agnostic Incentives to Promote Pharmaceutical Innovation*, 71 STAN. L. REV. 1305, 1310 (2019).

prompt demands for equal access. Patients are likewise unlikely to feel the same degree of psychological pressure to purchase lifestyle drugs. Lifestyle drugs appear more analogous to ordinary consumer goods, for which unrestricted pricing is acceptable.³⁰³

E. Addressing Desert-Based Objections

As Terry Fisher and Talha Syed observe, the incentive-based arguments for rewarding pharmaceutical companies discussed in Part III.B are often supplemented by desert-based arguments that “pharmaceutical firms deserve the financial returns made possible by strong patent protection because they have invested so much effort and money—and run such big risks—in producing their socially valuable products.”³⁰⁴ Fisher and Syed ultimately endorse one version of the desert argument, concluding “that it is only fair that a person who expends labor in a socially valued endeavor should receive a return commensurate with his or her effort” and that therefore “scientists, R & D managers, and others involved in the drug development process do *deserve* a fair reward for the labor they expend in creating medicinal innovations.”³⁰⁵ Fisher and Syed acknowledge that identifying what return is “commensurate” with a given degree of effort is difficult, but they conclude that whatever policies produce optimal innovation incentives will in practice also provide fair rewards.³⁰⁶ Many commentators, including legislators, likewise endorse the relevance of desert, even if they also often believe current pharmaceutical prices exceed what desert can justify.³⁰⁷

303. See Emanuel, *supra* note 42, at 604 (arguing that substantive fair pricing considerations do not apply to restaurant meals, smartphones, or drugs for cosmetic conditions that “are not basic necessities but luxuries”); cf. Hemel & Ouellette, *supra* note 231, at 567 (arguing that “lifestyle drugs or luxury products” are appropriate for “a user-pays principle” rather than publicly subsidized access).

304. Fisher & Syed, *supra* note 91, at 668; see also *id.* (summarizing former PhRMA president Gerald J. Mossinghoff’s argument that “respect for patent rights is essential both to preserve crucial incentives for innovation and to provide the innovators the ‘rewards’ they are due”).

305. *Id.* at 672-73.

306. *Id.*

307. See 152 CONG. REC. 18,941 (2006) (statement of Sen. Jack Reed) (“I believe the pharmaceutical companies deserve a fair return on their investment. They have invested in drug research and development.”); Merck Sharp & Dohme Corp. v. Icelandic Pat. Off., Case

I agree with Fisher and Syed that pharmaceutical companies must be treated fairly, and that adequate incentive payments also suffice for fairness.³⁰⁸ But their argument does not support their conclusion. Current arrangements provide no reward for a small firm whose hard work developing a single drug fails to produce results, which is difficult to justify if fairness takes the form of a “proportion between remuneration and exertion,” as Fisher and Syed seem to believe.³⁰⁹ A better basis for concluding that incentive payments suffice for fairness is the argument I offer in Part I.B.1: that fairness to sellers should not be understood in backward-looking terms, as the provision of a return proportionate to past effort or sacrifice, but instead as fundamentally procedural, encompassing protection from discriminatory legislation and unjustified expropriation. Once these protections are provided, any reward furnished by an appropriately regulated marketplace counts as fair, including rewards whose value is diminished by price regulation.³¹⁰ Firms, including pharmaceutical firms, have no right to reap a return on investments made or to have their commitment to treating harmful diseases recognized with financial rewards.³¹¹ These backward-looking factors should be recognized in other ways,

E-5/17, Judgment, ¶ 35 (EFTA Court Dec. 21, 2017), <http://eplaw.org/wp-content/uploads/2017/12/EFTA-Judgment-negative-term-SPC.pdf> [<https://perma.cc/5F2B-N33X>] (“[P]harmaceutical companies should be rewarded for the efforts they put into research.”); Nancy Black, *Hard to Swallow*, WHITE ROCK LAKE WKLY. (June 7, 2019), <http://whiterocklakeweekly.com/hard-to-swallow/> [<https://perma.cc/5CU6-AD3L>] (criticizing pharmaceutical pricing while conceding that “[p]harmaceutical companies deserve to make money” because “[t]hey spend lots of it researching and developing drugs to help save lives”).

308. Fisher & Syed, *supra* note 91, at 673.

309. *Id.* at 672-73 (quoting JOHN STUART MILL, PRINCIPLES OF POLITICAL ECONOMY 5-24 (William J. Ashley ed., 7th ed. 1909), https://www.econlib.org/library/Mill/mlP.html?chapter_num=2#book-reader [<https://perma.cc/7QKB-K2SJJ>]).

310. *Cf.* *Unity Real Est. Co. v. Hudson*, 178 F.3d 649, 676 (3d Cir. 1999) (concluding that businesses should not be compensated for the effects of, or excused from complying with, a regulation on the basis that it “would be enough to destroy them as profitable enterprises”); *Reliable Wood Prods. Co. v. Fleming*, 160 F.2d 548, 551 (Emer. Ct. App. 1947) (rejecting the claim that an administrator enforcing World War II-era price controls must “establish a maximum price which would return complainant’s costs, plus a profit,” and stating that “[t]he regulation ... is not required to guarantee a profit to every seller”).

311. Here I agree with Anderson, *supra* note 144, at 270 (asserting that “markets cannot operate efficiently unless prices are allowed to vary in response to mere luck,” and arguing that governments should correct market outcomes to respond to need but not to accord with judgments of desert).

such as through prestigious scientific publications or awards, rather than by higher prices.

A different version of the desert argument appeals to comparative desert. The reasoning contends that because actors other than pharmaceutical firms bear responsibility for high prices and limited access to medicines, it is unjust to subject pharmaceutical firms to price regulation without imposing parallel burdens on other actors.³¹² This argument is also normatively unpersuasive. If price regulation can improve health outcomes, it should not be rejected on underinclusiveness grounds.³¹³

IV. SURMOUNTING LEGAL OBSTACLES

In this Part, I discuss potential legal obstacles to the implementation of a price ceiling grounded in social value. The first two obstacles I discuss, patent preemption and the Dormant Commerce Clause, are applicable only to the use of price ceilings at the state level, while the other two challenges would also apply at a federal level. While the implementation of a price ceiling at the federal level would preclude some legal challenges,³¹⁴ it would require surmounting congressional gridlock.

At the outset, price ceilings have an important advantage over reimbursement limits because they can improve access to socially valuable drugs, in both the short term (by lowering prices) and the long term (by changing incentives), without requiring revisions to the rules of large governmental insurers, such as Medicare and Medicaid, or to state laws mandating insurance benefits or constraining private insurers' ability to deny coverage for costly procedures. Medicare is currently constrained from refusing coverage

312. See Govind Persad, *Examining Pharmaceutical Exceptionalism: Intellectual Property, Practical Expediency, and Global Health*, 18 YALE J. HEALTH POL'Y L. & ETHICS 157, 188 & n.127 (2019) (discussing these arguments). Similar arguments have been levied against other price regulations. See, e.g., *Pennell v. City of San Jose*, 485 U.S. 1, 22 (1988) (Scalia, J., concurring in part and dissenting in part) (criticizing defendant for unfairly "using the occasion of rent regulation ... to establish a welfare program privately funded by those landlords who happen to have 'hardship' tenants").

313. See Persad, *supra* note 312, at 188-89; cf. *Williamson v. Lee Optical of Okla., Inc.*, 348 U.S. 483, 489 (1955).

314. See Mello & Wolitz, *supra* note 5, at 953-54.

on cost-effectiveness grounds,³¹⁵ and a recent attempt by Massachusetts's Medicaid program to use cost-effectiveness criteria to exclude coverage for certain drugs was rejected by the federal agency administering the program.³¹⁶ States also constrain the private sector's ability to limit reimbursements by mandating a variety of insurance benefits³¹⁷ and by subjecting insurers' coverage determinations to external review that is often hostile to cost-effectiveness.³¹⁸

A. Patent Preemption

Patent Act preemption could obstruct the use of a price ceiling at the state level. During the early 2000s, the District of Columbia attempted to enforce price controls on certain patented pharmaceuticals; the Federal Circuit eventually struck down these regulations as preempted by federal patent law.³¹⁹ Although the Supreme Court denied certiorari, many have argued that the Federal Circuit's reasoning was dubious because the Patent Act does not entitle patentholders to specific or unregulated profits.³²⁰

Even under the Federal Circuit's reasoning, however, a price ceiling will pass muster if it covers both patented and nonpatented

315. See Pearson et al., *supra* note 29, at 1-2 (explaining that Medicare does not consider prices when making coverage determinations, and that "Medicare's permissiveness sets an implicit standard for all insurers"); Lemley et al., *supra* note 139, at 84-87.

316. See Chris Kukka & Johanna Butler, *Feds Send Mixed Responses on States' Efforts to Control Medicaid Drug Costs*, NAT'L ACAD. FOR STATE HEALTH POL'Y (July 10, 2018), <https://nashp.org/feds-send-mixed-responses-on-states-efforts-to-control-medicaid-drug-costs/> [<https://perma.cc/6FVH-CWBQ>]. Massachusetts's proposal prompted vigorous pushback from pharmaceutical firms and patient advocacy groups. See *Comments Received for MA 1115 June 2017 Amendment Application Demonstration*, MEDICAID.GOV, https://1115publiccomments.medicaid.gov/results/public/bWVkaWNhaWRmZWRyYW1wMTEeXNS1VU184Q2t0WG9QYmhrQkRJVmYtNWU0NDYwYTFiNDQzMDkwMDEeXMDcwMGY5#/pages/Page_21b52233-7087-4437-98e4-0511887cf7d8 [<https://perma.cc/MJ2P-FXJ9>].

317. See Mantel, *supra* note 292, at 236-37; Robertson, *supra* note 227, at 938.

318. See Robertson, *supra* note 227, at 938.

319. *Biotechnology Indus. Org. v. District of Columbia*, 496 F.3d 1362, 1371-74 (Fed. Cir. 2007).

320. See *Biotechnology Indus. Org. v. District of Columbia*, 505 F.3d 1343, 1350-51 (Fed. Cir. 2007) (Dyk, J., dissenting from denial of rehearing); Joshua D. Sarnoff, *BIO v. DC and the New Need to Eliminate Federal Patent Law Preemption of State and Local Price and Product Regulation*, 2007 PATENTLY-O PATENT L.J. 30, 33; see also Mello & Wolitz, *supra* note 5, at 877 ("[M]uch about this ruling invites further inquiry, if not skepticism.").

drugs and does not treat the two differently.³²¹ In this respect, commentators err when they claim that the Federal Circuit’s “decision appears to foreclose state efforts to regulate the prices at which patented medications may be sold,”³²² and that only Congress, not the states, can set a maximum price for drugs.³²³ A price ceiling on all drugs—patented and unpatented alike—would operate analogously to a tax or generally applicable economic regulation, such as a permit requirement or environmental offset fee. Such regulations have never been held to violate the Patent Act, even when they apply to patented as well as unpatented goods.³²⁴

B. The Dormant Commerce Clause

More recently, in *Association for Accessible Medicines v. Frosh*, Maryland’s drug price regulation was struck down for excessively trenching on federal power.³²⁵ In this case, the vehicle for federal supremacy was the Commerce Clause rather than the Patent Act.³²⁶ In an application of the judge-made “Dormant Commerce Clause” doctrine, a panel of the Fourth Circuit ruled that Maryland’s price regulation violated the Commerce Clause because of its effects on out-of-state pharmaceutical transactions.³²⁷ The state statute at issue prohibited pharmaceutical manufacturers and wholesale distributors from engaging in “price gouging,” defined as “an unconscionable increase in the price of a prescription drug,” with respect to certain essential medicines.³²⁸ Unconscionable increases, in turn, are defined as increases that are “excessive and not justified

321. See Feldman et al., *supra* note 5, at 48-49 (explaining that the Federal Circuit’s decision was dependent on the fact that D.C.’s pricing provisions applied only to patented drugs).

322. Mello & Wolitz, *supra* note 5, at 877; cf. Brendan Murphy, Note, *Getting High on Profits: An Analysis of Current State and Federal Proposals to Rein in Soaring Drug Prices*, 12 J. HEALTH & BIOMEDICAL L. 37, 87 (2016) (“[I]f a legislative act diminishes the economic reward to patent holders by setting a maximum allowable price, it will be deemed preempted by the Patent Act.”).

323. Mello & Wolitz, *supra* note 5, at 933 (“Congress (but not the states, given patent preemption issues) could establish a statutory maximum launch price.”).

324. See BERMAN ET AL., *supra* note 5, at 12.

325. 887 F.3d 664, 666 (4th Cir. 2018), *cert. denied*, 139 S. Ct. 1168 (2019).

326. *Id.* at 667.

327. *Id.* at 665, 674.

328. *Id.* at 666 (quoting MD. CODE ANN., HEALTH-GEN. § 2-801(c) (2017)).

by the cost of produc[tion].”³²⁹ The Fourth Circuit invalidated the statute on the basis that it applied to, and dictated prices in, wholesale drug transactions that might occur entirely out of state.³³⁰

The Fourth Circuit’s reasoning is unconvincing in several respects. In particular, its argument that Maryland’s statute “sets prescription drug prices in a way that ‘interfere[s] with the natural function of the interstate market’ by superseding market forces that dictate the price of a good”³³¹ is specious because prescription drug markets deviate substantially from classically competitive markets.³³² The dissenting opinion also criticizes the majority for ignoring the fact that the Maryland statute does not favor in-state over out-of-state economic interests—the core concern animating modern Dormant Commerce Clause jurisprudence—and does not affect transactions that generate no sales of drugs in Maryland.³³³

Even under the framework adopted in the Fourth Circuit’s majority opinion, a social value price ceiling would not violate the Dormant Commerce Clause. A social value price ceiling does not tie maximum prices to the prices charged in other states and need not apply to out-of-state sales.³³⁴ State price regulations that do not tie

329. *Id.* (quoting MD. CODE ANN., HEALTH-GEN. § 2-801(f)).

330. *Id.* at 671-72.

331. *Id.* at 673 (alteration in original) (quoting *McBurney v. Young*, 569 U.S. 221, 235 (2013)).

332. *See supra* Part I.A.2.

333. *Ass’n for Accessible Meds.*, 887 F.3d at 680 (Wynn, J., dissenting). Given the political dimensions of drug pricing, it is noteworthy that the dissent identified an opinion by now-Justice Gorsuch that construed the Dormant Commerce Clause narrowly, *id.* at 681 (citing *Energy & Env’t Legal Inst. v. Epel*, 793 F.3d 1169, 1172 (10th Cir. 2015) (Gorsuch, J.)), and that both Justice Thomas and the late Justice Scalia rejected the Dormant Commerce Clause, *see Comptroller of the Treasury v. Wynne*, 135 S. Ct. 1787, 1811 (2015) (Thomas, J., dissenting) (referring to prior dissents); *id.* at 1808 (Scalia, J., dissenting) (describing the “negative Commerce Clause” as “a judicial fraud”).

334. *See Epel*, 793 F.3d at 1171, 1173 (explaining that the price controls invalidated on Dormant Commerce Clause grounds, in the absence of clearly excessive burdens on interstate commerce or clear discrimination against out-of-staters, have involved three elements: “(1) a price control or price affirmation regulation, (2) linking in-state prices to those charged elsewhere, with (3) the effect of raising costs for out-of-state consumers or rival businesses”); *cf. Timothy Stoltzfus Jost, Pharmaceutical Research and Manufacturers of America v. Walsh: The Supreme Court Allows the States to Proceed with Expanding Access to Drugs*, 4 YALE J. HEALTH POL’Y L. & ETHICS 69, 80, 84 (2004) (observing that a statute upheld against a Dormant Commerce Clause challenge “neither attempted to regulate prices of out-of-state transactions nor favored Maine manufacturers to the disadvantage of out-of-state competitors,” and that the “ruling remove[d] one important drug industry argument in

in-state to out-of-state prices, do not regulate out-of-state conduct, and do not disfavor merchants based on their out-of-state status have typically survived Dormant Commerce Clause challenges.³³⁵

C. Takings

Pharmaceutical vendors contend that price ceilings are regulatory takings of their property that entitle them to compensation. This argument is the legal translation of the desert-based objection discussed in Part III.E: the price ceiling prevents drugmakers from reaping their deserved rewards. Earlier, some argued that price controls on medical services were takings.³³⁶ These arguments were unsuccessful in court.³³⁷ Even courts normatively sympathetic to the desert-based objection to price controls have hesitated to grant it legal bite.³³⁸ Instead, courts concluded that because medical service providers can respond to the disincentivizing effects of price controls, they are not subject to a taking.³³⁹ And even a takings

opposing state drug price regulation programs”).

335. See, e.g., *Quik Payday, Inc. v. Stork*, 549 F.3d 1302, 1308-09 (10th Cir. 2008) (upholding interest rate regulations on payday loans that did not apply to out-of-state transactions and did not tie the regulations to rates charged in other states); *Lotus Bus. Grp. v. Flying J Inc.*, 532 F. Supp. 2d 1011, 1017 (E.D. Wis. 2007) (concluding that price regulation survive[d] Dormant Commerce Clause challenge because of lack of evidence that it “discriminates against out-of-state interests or [was] excessively burdensome on interstate commerce”).

336. See Thomas W. Merrill, *Constitutional Limits on Physician Price Controls*, 21 HASTINGS CONST. L.Q. 635, 639-40 (1994); William S. Brewbaker III, *Health Care Price Controls and the Takings Clause*, 21 HASTINGS CONST. L.Q. 669, 671 (1994).

337. See, e.g., *Garelick v. Sullivan*, 987 F.2d 913, 916-17 (2d Cir. 1993); *Minn. Ass’n of Health Care Facilities, Inc. v. Minn. Dep’t of Pub. Welfare*, 742 F.2d 442, 446-47 (8th Cir. 1984).

338. See *Garelick v. Sullivan*, 784 F. Supp. 108, 112 (S.D.N.Y. 1992) (“If the Court were writing on a clean slate, ... [the providers’] argument might have considerable logical force.”), *aff’d*, 987 F.2d 913 (2d Cir. 1993).

339. See *id.* at 113 (observing that providers “have the option of practicing outside of hospitals, and may even be able to practice in hospitals and still decline to serve Medicare patients”); accord *Minn. Ass’n of Health Care Facilities*, 742 F.2d at 446 (upholding price regulation on nursing homes because “Minnesota nursing homes ... have freedom to decide whether to remain in business and thus subject themselves voluntarily to the limits imposed by Minnesota on the return they obtain from investment of their assets in nursing home operation”).

framework would still require sellers to show that the ceiling price inadequately compensated them.³⁴⁰

D. Freedom of Contract

More speculatively, buyers could bring a due process challenge to price ceilings in the spirit of Eugene Volokh's "medical self-defense" argument—that they have a constitutional due process right to purchase drugs to protect themselves from disease.³⁴¹ This argument is the legal analogue of the liberty argument discussed in Part III.D. Volokh deploys this argument in defense of a right to access various medical interventions without regulatory limits, including unapproved drugs and transplantable organs.³⁴² Although the D.C. Circuit rejected an analogue of Volokh's argument for access to unapproved drugs,³⁴³ economic due process arguments could become more than an academic curiosity. Academic commentators, and even some recently appointed federal judges, have signaled an interest in reviving *Lochner*-era approaches to economic substantive due process.³⁴⁴ An effort to pay an unregulated price to access a potentially lifesaving drug could present an emotionally compelling factual situation that might motivate advocates to seek out a sympathetic judge.

The practical effects of a price ceiling, however, may make it unlikely to raise due process concerns. A price ceiling is unlikely to limit patients' access to existing drugs because most can be produced and distributed at little marginal cost.³⁴⁵ Rather, a price ceiling shifts incentives for future drug development.³⁴⁶ Because a price ceiling is more likely to change future incentives than impede

340. See *Garelick*, 784 F. Supp. at 114.

341. Eugene Volokh, *Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs*, 120 HARV. L. REV. 1813, 1828, 1831-32 (2007).

342. *Id.* at 1828-30, 1835-37.

343. *Abigail All. for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 710-11, 713 (D.C. Cir. 2007).

344. See, e.g., Thomas B. Colby & Peter J. Smith, *The Return of Lochner*, 100 CORNELL L. REV. 527, 531 (2015); Edith Roberts, *Potential Nominee Profile: Don Willett*, SCOTUSBLOG (June 29, 2018, 2:53 PM), <https://www.scotusblog.com/2018/06/potential-nominee-profile-don-willett/> [<https://perma.cc/CJ3Q-EF6E>].

345. See Calfee, *supra* note 229, at 1062.

346. *Id.* at 1062-63.

present access, patients will struggle to show that price ceilings interfere with their right of self-protection against disease. Patient advocacy groups may likewise be uninterested in challenging price ceilings if they can obtain drugs at the ceiling price. A due process challenge could also be avoided by replacing price ceilings with excise taxes or allowing payers to cap reimbursements, while leaving prices themselves unregulated.³⁴⁷ But, as discussed above, a price ceiling has both practical and legal advantages over these alternatives.

CONCLUSION

Pharmaceutical pricing remains among the hardest problems in health law and policy.³⁴⁸ This Article furthers discussion around drug pricing by elucidating and categorizing disparate definitions of fair pricing that are often unexplored or taken for granted in existing debates. It then argues that fair prices should be defined by reference to social value and examines how social value might be defined and a social value threshold established. Last, it describes how a price ceiling could be used to implement a social value threshold, and how such a price ceiling could effectively respond to normative objections and withstand legal challenges. Price ceilings have historically been recognized as politically resilient but criticized for producing bad outcomes,³⁴⁹ while the use of social value criteria in pharmaceutical policy has been praised for improving outcomes but has often proven legally and politically vulnerable.³⁵⁰ A pharmaceutical price ceiling based on social value can combine the best qualities of its parents, successfully improving outcomes while weathering practical challenges.

347. Cf. Mello & Wolitz, *supra* note 5, at 883 (“This approach does not restrict drug prices *per se*, but rather sets an upper limit on the amount that specified drug purchasers in the state will pay.”).

348. See Mello, *supra* note 109, at 2277-78.

349. See *supra* Part III.A.

350. See *supra* Part IV.

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