

2018

What Makes Ensuring Access to Affordable Prescription Drugs the Hardest Problem in Health Policy?

Michelle M. Mello

Follow this and additional works at: <https://scholarship.law.umn.edu/mlr>



Part of the [Law Commons](#)

Recommended Citation

Mello, Michelle M., "What Makes Ensuring Access to Affordable Prescription Drugs the Hardest Problem in Health Policy?" (2018).
Minnesota Law Review. 128.
<https://scholarship.law.umn.edu/mlr/128>

This Article is brought to you for free and open access by the University of Minnesota Law School. It has been accepted for inclusion in Minnesota Law Review collection by an authorized administrator of the Scholarship Repository. For more information, please contact lenzx009@umn.edu.

Article

What Makes Ensuring Access to Affordable Prescription Drugs the Hardest Problem in Health Policy?

Michelle M. Mello[†]

INTRODUCTION

I recently had a front-row seat at a performance of the cacophonous choir that is our nation's prescription drug delivery system. This anecdote of getting an unremarkable drug to a child captures many of the things that make our system the object of international befuddlement.

My seven-year-old son is among the nearly four percent of Americans with a food allergy¹ and needs to have epinephrine available wherever he goes.² For years, we have relied on the

[†] Professor of Law, Stanford Law School, and Professor of Health Research and Policy, Department of Health Research and Policy, Stanford University School of Medicine; Ph.D., University of North Carolina at Chapel Hill; J.D., Yale Law School; M.Phil., University of Oxford; A.B., Stanford University. I have no financial relationships with pharmaceutical or biotechnology companies, but have served as a consultant to CVS/Caremark, whose business includes pharmacy benefit management, on a topic unrelated to prescription drugs. I acknowledge with gratitude the contributions of the chairs, members, fellows, and staff of the National Academies of Sciences, Engineering and Medicine's Committee on Ensuring Patient Access to Affordable Drug Therapies ("the Committee") to generating some of the findings and identifying much of the evidence discussed in this Article. For the Committee's full report, see MAKING MEDICINES AFFORDABLE: A NATIONAL IMPERATIVE (Norman R. Augustine, Guru Madhavan & Sharyl J. Nass eds., 2017), <http://www.nationalacademies.org/hmd/Reports/2017/making-medicines-affordable-a-national-imperative.aspx>. I am also grateful to Chuck Phelps for helpful comments on the draft manuscript and Quinn Walker for research assistance. Copyright © 2018 by Michelle M. Mello.

1. Warren W. Acker et al., *Prevalence of Food Allergies and Intolerances Documented in Electronic Health Records*, 140 J. ALLERGY & CLINICAL IMMUNOLOGY 1587, 1588 (2017) (finding 3.6% of Americans have a food allergy).

2. Epinephrine, another name for the hormone adrenaline, is a rescue medication for allergic anaphylaxis. See Lydia Ramsey, *The Strange History of the EpiPen, the Device Developed by the Military That Turned into a Billion-Dollar Business*, BUS. INSIDER (Aug. 27, 2016), <http://www.businessinsider>

EpiPen Jr., sold by Mylan Pharmaceuticals. It is an indisputably great product: the auto-injector is easy to use, small enough to fit in a purse, and able to deliver a dose in ten seconds.

However, in 2016, public opinion turned against Mylan. The company had been raising the price of the EpiPen for years, and by 2016 the “massive” price increases caught the attention of the media and high-profile members of Congress.³ The price of a two-pack of auto-injectors, containing about \$2 worth of drug,⁴ rose from about \$100 in 2007 to over \$600 in 2016.⁵ The company offered no substantive justification for the price increases. Commentators interpreted them as a last-ditch effort to extract value in the waning days of the EpiPen’s patent.⁶ The public responded with outrage.⁷ Patient advocates stressed that patients were exposed to significant out-of-pocket costs, especially since families

.com/the-history-of-the-epipen-and-epinephrine-2016-8/#when-mylan-acquired-the-epipen-the-drug-was-making-about-200-million-a-year-now-it-makes-more-than-11-billion-a-year-mylan-has-about-90-of-the-market-share-for-epinephrine-devices-9. Produced naturally by the body, epinephrine was isolated as a chemical over a century ago and has been commercially available in the United States for decades. *Id.* The drug itself costs only a few dollars a vial, but most users need it in an easily injectable form, and the surrounding auto-injector device has been where manufacturers have made their money. *Id.* The first auto-injector was developed in the 1970s and used in the military to protect soldiers against possible chemical attacks. *Id.* In 1987, Meridian Medical Technologies obtained FDA approval for the drug/device combination branded the EpiPen, an easy-to-administer, one-dose auto-injector. *Id.* Since 2007, the EpiPen (and its pediatric version, the EpiPen Jr.) has been sold and marketed by Mylan Pharmaceuticals. *Id.* As of 2016, Mylan controlled about ninety percent of the market for epinephrine devices. *Id.*

3. Chris Woodyard & Mary Jo Layton, *Massive Price Increases on EpiPens Raise Alarm*, USA TODAY (Aug. 22, 2016), <https://www.usatoday.com/story/money/business/2016/08/22/two-senators-urge-scrutiny-epipen-price-boost/89129620>.

4. Ben Popken, *Industry Insiders Estimate EpiPen Costs No More Than \$30*, NBC NEWS (Sept. 6, 2016), <https://www.nbcnews.com/business/consumer/industry-insiders-estimate-epipen-costs-no-more-30-n642091>.

5. Sy Mukherjee, *Mylan’s CEO Tells Congress the EpiPen’s Price Hike Was “Fair,”* FORTUNE (Sept. 21, 2016), <http://fortune.com/2016/09/21/mylan-ceo-epipen-price-hike>.

6. Andrew Pollack, *Mylan Raised EpiPen’s Price Before the Expected Arrival of a Generic*, N.Y. TIMES (Aug. 24, 2016), <https://www.nytimes.com/2016/08/25/business/mylan-raised-epipens-price-before-the-expected-arrival-of-a-generic.html>.

7. Tim Chester, *How Social Media Amplified Anger over EpiPen’s Price Gouge*, MASHABLE (Aug. 27, 2016), <http://mashable.com/2016/08/27/epipen-price-hike-social-media>.

with young children may require three or more packs for different caregivers.⁸ Mylan's chief executive, Heather Bresch, drew scorn for her performance defending the price increases in testimony before the House Oversight Committee in October 2016, deflecting questions in a manner that "infuriated lawmakers."⁹

I shared in the outrage, so I was receptive when my son's allergist told us that an alternative product was available. The Auvi-Q auto-injector, manufactured by Kaleo, administers the same drug as the EpiPen, is somewhat easier to use because it has audio instructions, is slightly smaller, and delivers its dose in five seconds. "A lot of my patients like it because it talks the babysitter through the injection," our Harvard-educated physician said. "Of those who have tried it, I'd say about nine out of ten stick with it instead of going back to EpiPen. And the company is offering a zero-cost prescription for patients if you call this number." I was sold.

Weeks later, I would learn that Auvi-Q's list price was a staggering \$4500 per pack.¹⁰ The "no-cost" program, it turned out, was limited to three fills. After that I would have to rely on my insurance coverage and make a copayment with each refill.

I called my insurance company to ask what I would pay for Auvi-Q when the program ran out, as well as what the insurer itself paid. As pharmaceutical companies often point out, the list price of a drug can be considerably higher than what health plans and other bulk purchasers actually pay after discounts and

8. Emily Willingham, *Why Did Mylan Hike EpiPen Prices 400%? Because They Could*, FORBES (Aug. 21, 2016), <https://www.forbes.com/sites/emilywillingham/2016/08/21/why-did-mylan-hike-epipen-prices-400-because-they-could>.

9. Associated Press, *Mylan CEO Minimized EpiPen Profits in Testimony, House Panel Says*, L.A. TIMES (Oct. 3, 2016), <http://www.latimes.com/business/la-fi-mylan-epipen-20161003-snap-story.html>.

10. Meg Tirrell, *EpiPen Competitor Auvi-Q Comes Back Feb. 14 with a Pricing Scheme That Will Blow Your Mind*, CNBC (Jan. 19, 2017), <https://www.cnbc.com/2017/01/19/epipen-competitor-auvi-q-comes-back-feb-14.html>. The list price of a drug is what the manufacturer states as the retail or sticker price, before any discounts and rebates are granted to purchasers. KAISER FAMILY FOUND., FOLLOW THE PILL: UNDERSTANDING THE U.S. COMMERCIAL PHARMACEUTICAL SUPPLY CHAIN 28 (2005), http://avalere.com/research/docs/Follow_the_Pill.pdf.

rebates.¹¹ Indeed, when Mylan came under congressional scrutiny, its CEO emphasized that Mylan gave generous rebates on the drug and very few buyers actually paid list price.¹²

My health insurer, the largest in the United States, was unable to tell me what it paid for the EpiPen. It referred me to its pharmacy benefit manager (PBM), an intermediary organization that procures medicines for the health plan and manages its prescription drug formulary. My third phone call turned up the answer: the discount the PBM had gotten my health plan was a whopping 2.35%. The insurer paid \$4394.10 per pack for Auvi-Q, versus \$554.95 for the EpiPen. And there was more: my insurer didn't cover Auvi-Q at all unless a physician attested that cheaper versions of epinephrine were medically contraindicated. That being unlikely, my projected out-of-pocket cost to refill the Auvi-Q would exceed \$13,000 for the three packs my son needed, compared to \$150 for the EpiPen.

The tale of Auvi-Q and the EpiPen illustrates many of the market failures and perversities of our biopharmaceutical sector.¹³ A company with market dominance seeks to squeeze every last cent out of its government-granted monopoly period. It hikes the product's price although the drug is globally recognized as an essential medication¹⁴ and although the company itself shouldered none of the risk of developing the product. The company is

11. Rebates for drugs sold to Medicare Part D plans have been estimated to average about twenty percent in 2016. THE BDS. OF TRS., FED. HOSP. INS. & FED. SUPPLEMENTARY MED. INS. TR. FUNDS, 2016 ANNUAL REPORT OF THE BOARDS OF TRUSTEES OF THE FEDERAL HOSPITAL INSURANCE AND FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUNDS 147 tbl.IV.B8 (51st ed. 2016), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/downloads/tr2016.pdf>.

12. Stacie B. Dusetzina et al., *Association of Prescription Drug Price Rebates in Medicare Part D with Patient Out-of-Pocket and Federal Spending*, 177 JAMA INTERNAL MED. 1185, 1185 (2017).

13. By biopharmaceutical sector, I mean the entire ecosystem that produces and delivers prescription drugs and biologics, including manufacturers and sellers, payers, prescribers, regulators, and patients. See NAT'L ACAD. OF SCI., ENG'G & MED., MAKING MEDICINES AFFORDABLE: A NATIONAL IMPERATIVE 15 (Norman R. Augustine et al. eds., 2017), <http://www.nationalacademies.org/hmd/Reports/2017/making-medicines-affordable-a-national-imperative.aspx> [hereinafter NASEM REPORT].

14. WORLD HEALTH ORG., WHO MODEL LIST OF ESSENTIAL MEDICINES 17 (19th ed. 2015), http://www.who.int/medicines/publications/essentialmedicines/EML_2015_FINAL_amended_NOV2015.pdf (listing pyrimethamine, which is sold under the brand name Daraprim, as an essential drug).

undeterred by the demonstrable “financial toxicity” that its escalating prices cause.¹⁵ When a public backlash ensues, a market opportunity is created, and a competitor seizes the chance to promote its marginally more attractive product. But rather than waging war on the basis of price, as economic theory would predict, the underdog prices its product more than seven times higher than the market leader.

Yet, the challenger wins market share—not primarily because its product is superior, but because it exploits market failures. The company creates a patient coupon program that (at least temporarily) removes patients’ incentive to choose among comparable drugs based on cost.¹⁶ The program also drives a wedge between patients’ economic interests and those of their insurer.

At the point of prescribing, the patient and physician are both ignorant about the comparative costs of the candidate medications. The physician, who has been the target of marketing messages about the patient coupon program, thinks he is being helpful by recommending a more convenient medication that will cost patients less. He is mistaken. Further, the physician likely has no awareness of the cost of the candidate medications for even the most widely subscribed health plans. If he does, his behavior suggests he does not care. Rather, he is focused on drugs’ immediate costs to patients, not their long-term costs, including the fact that patients’ insurance premiums and cost sharing increase when health plans’ costs rise. On the patient’s part, considerable proactivity and persistence is required to discover what lies ahead in terms of out-of-pocket costs and which choice is more cost-effective for her insurance risk pool.

It is not difficult to understand why such circumstances have permitted prescription drug costs to rise to unsustainable levels in the United States. After all, as the old engineering adage goes, “every system is perfectly designed to get the result it gets.”¹⁷ Medicines now account for nearly seventeen percent of our total national healthcare expenditures.¹⁸ Except for 2016,

15. *Financial Toxicity and Cancer Treatment (PDQ®): Health Professional Version*, NAT’L CANCER INST., <https://www.cancer.gov/about-cancer/managing-care/track-care-costs/financial-toxicity-hp-pdq> (last visited June 17, 2018).

16. For further discussion on patient coupon programs, see *infra* Part II.B.

17. NASEM REPORT, *supra* note 13, at 23.

18. *Id.* at 24–25 (citing U.S. DEP’T OF HEALTH & HUMAN SERVS., OBSERVATIONS ON TRENDS IN PRESCRIPTION DRUG SPENDING 7–8 (2016), <https://aspe.hhs.gov/system/files/pdf/187586/Drugspending.pdf>) (discussing drug expenditures in the United States).

they have been among the fastest-growing segments of healthcare costs.¹⁹ In a recent survey, nearly one in four Americans reported that they or a family member had declined to fill a prescription, skipped doses, or reduced their dose in the past year because of concerns about cost.²⁰ Though it is difficult to find any issue today on which there is bipartisan agreement in Washington, even persons who cannot agree on whether or not the planet is warming agree that the problem of prescription drug costs requires action.²¹

The United States faces a lot of hard problems in health policy, but arguably, reducing prescription drug costs is the hardest. It is more difficult, for example, than figuring out how to get all Americans basic health-insurance coverage, how to improve the quality of care and reduce disparities, or how to focus more resources on preventing disease rather than treating it. As I will show in this Article, there are a number of things about the prescription drug affordability problem that make it distinctively tricky. These problems can be grouped under three rubrics: (1) moral factors; (2) market factors; and (3) political factors.

In Part I, I discuss how empirical and moral ambiguity about the fundamental tradeoff involved in regulating drug prices—affordability versus availability of drugs, or access versus innovation—has plagued policy conversations. I also discuss how our lack of a workable moral framework for assessing pharmaceutical companies' obligations to patients has contributed to

19. *Id.* at 5; *US Drug 2016 Sales, at \$450 Billion, Moderate to Single-Digit Growth*, PHARMACEUTICAL COM. (May 4, 2017), <http://pharmaceuticalcommerce.com/latest-news/us-drug-2016-sales-450-billion-moderate-single-digit-growth>.

20. *Most Say They Can Afford Their Prescription Drugs, But One in Four Say Paying Is Difficult, Including More Than Four in Ten People Who Are Sick*, KAISER FAM. FOUND. (Aug. 20, 2015), <https://www.kff.org/health-costs/press-release/most-say-they-can-afford-their-prescription-drugs-but-one-in-four-say-paying-is-difficult-and-more-than-four-in-ten-for-people-who-are-sick>.

21. *See, e.g.*, Ylan Mui, *Democrats Take Aim at Big Business and Drug Prices in New Economic Campaign*, CNBC (July 24, 2017), <https://www.cnbc.com/2017/07/23/democrats-take-aim-at-big-business-drug-prices-in-economic-campaign.html> (noting that prescription drug costs feature prominently in a new economic platform rolled out by Democrats in 2017); Andrew Siddons, *Don't Force Us to Address High Prices, GOP Tells Drug Industry*, CQ NEWS (Dec. 13, 2017), bit.ly/2CdBDXN (quoting Republican Chairman of the House Energy and Commerce Subcommittee on Health, Representative Michael C. Burgess, as saying the issue had reached a "tipping point" and "there will likely be some type of action" if the pharmaceutical industry did not solve the problem itself); *see also* Drew Altman, *Prescription Drug Costs Break Through the Partisan Logjam*, AXIOS (May 2, 2017), <https://www.axios.com/one-health-care-issue-breaks-through-the-partisan-logjam-2387900255.html> (citing survey data showing that the issue's bipartisan appeal extends to members of the public).

the regulatory dilemma. In Part II, I survey an array of market-related factors that make the pharmaceutical problem especially messy. These include lack of price transparency and many kinds of perverse incentives. In Part III, I discuss the current political environment, in which current policy choices are constrained by ill-advised past choices, and in which an atmosphere of scandal makes cool-headed deliberation difficult.

Much of what I will describe derives from a November 2017 consensus report that I coauthored with other members of a committee of the National Academies of Sciences, Engineering and Medicine (NASEM).²² NASEM is a trio of scientific associations that work together “to provide independent, objective analysis to the nation and conduct other activities to solve complex problems and inform public policy decisions.”²³ Its consensus reports provide evidence-based findings, conclusions, and recommendations on topics of public importance based on information that an ad hoc committee gathers and analyzes.²⁴ Committee members are selected to achieve diverse representation of expertise, experiences, and viewpoints. Recognized professional achievement is a precondition for selection²⁵ and conflicts of interest are closely scrutinized in the appointment process.²⁶

Our committee, which deliberated for more than a year, included seventeen economists, epidemiologists, physicians, legal experts, health-policy experts, and leaders from the public health, healthcare, health insurance, aerospace, finance, and biopharmaceutical sectors.²⁷ Where I draw on our report, I so indicate in the footnotes. On the other hand, statements not attributed to the report represent my own views and not those of the committee or NASEM.

I. MORAL FACTORS

Three moral factors—ambiguity about the tradeoff between drug affordability and availability; lack of consensus about

22. NASEM REPORT, *supra* note 13.

23. *Id.* at iii.

24. *Id.* at iv.

25. NAT'L ACAD. OF SCI., ENG'G & MED., POLICY ON COMMITTEE COMPOSITION AND BALANCE AND CONFLICTS OF INTEREST FOR COMMITTEES USED IN THE DEVELOPMENT OF REPORTS *1 (2003), http://www.nationalacademies.org/coi/bi-coi_form-0.pdf.

26. *Id.* at *3–7.

27. For a summary of Committee members' backgrounds, see NASEM REPORT, *supra* note 13, at 179–88. For a description of the study process, see *id.* at 37–38.

moral principles for assessing drug companies' pricing behavior; and potential effects of U.S. actions to reduce drug prices on pharmaceutical costs for lower-income countries—make drug prices an especially difficult problem to solve, or even talk about coherently.

A. UNCERTAINTY ABOUT THE CORE TRADEOFF: AFFORDABILITY VS. AVAILABILITY

As with other problems in health policy, sorting out how to ensure that prescription drugs are affordable to all who need them raises weighty moral questions. Is healthcare a human right?²⁸ Regardless, does society have a moral obligation to provide it to everyone, at least at a decent basic minimum level?²⁹ How great a disparity in access to care among different groups in the population is ethically tolerable? What mechanism should determine who receives healthcare resources—the market, or some more explicit rationing scheme? How much is a human life worth? Barrels of ink have been spilled over these questions. However, it is worth a closer look at some aspects of the moral debate that have distinctive salience for prescription drugs.

One fundamental problem is that no consensus has emerged in the United States about how to grapple with the core tradeoff involved in the prescription drug market: the tradeoff between *affordability* and *availability* of innovative therapies.³⁰ There is a risk that taking steps to lower what we pay for pharmaceuticals will diminish manufacturers' incentives to invest in research and development (R&D). In other words, it may reduce the amount of innovation—and thus the availability of innovative, safe, effective drugs in the future.³¹ The value of health equity, therefore, sits in tension with other values. While few would disagree that some risk of reduced innovation exists if

28. See *id.* at 6; Julia Lynch & Sarah E. Gollust, *Playing Fair: Fairness Beliefs and Health Policy Preferences in the United States*, 35 J. HEALTH POL. POL'Y L. 849 (2010) (exploring public perceptions of health care policy and how different message framing can lead to different levels of public support).

29. See NORMAN DANIELS, *JUST HEALTH: MEETING HEALTH NEEDS FAIRLY* 17–21 (2008).

30. This section draws on NASEM REPORT, *supra* note 13, at 8–9, 28, 33.

31. NASEM REPORT, *supra* note 13, at 28; Sidney Taurel, *The Campaign Against Innovation*, in *ETHICS AND THE PHARMACEUTICAL INDUSTRY* 326 (Michael A. Santoro & Thomas M. Gorrie eds., 2005) (arguing that market-based pricing is an important precondition to innovation); Rena M. Conti & Meredith B. Rosenthal, *Pharmaceutical Policy Reform—Balancing Affordability with Incentives for Innovation*, 374 NEW ENGL. J. MED. 703, 704–05 (2016); Ian Maitland, *Priceless Goods: How Should Life-Saving Drugs Be Priced?*, 12 BUS. ETHICS Q. 451, 457–58 (2002).

downward pressure on prices is exerted, quantifying it is very difficult. The information needed to understand how companies would respond to reduced drug prices simply is not available.

Companies certainly assert that there is cause for alarm.³² They point to the astronomical cost of new drug development—an estimated \$2.6 billion for each drug that reaches the market, when the costs associated with those that did not make it are rolled in.³³ Only five to ten percent of new drugs entering clinical trials obtain FDA approval,³⁴ so innovator companies and firms that furnish the capital to support their R&D must recoup their investment from the tip of the iceberg. Investors may wait a decade or more to see a return on their investment, given the time required for clinical trials and market approval.³⁵ Companies argue that they must promise supernormal returns in order to attract interest in such a high-risk investment—especially because a great deal of biopharmaceutical innovation today emerges from small companies that rely heavily on private venture capital.³⁶

32. See, e.g., NASEM REPORT, *supra* note 13, at 169 (presenting a dissenting view from the Committee's consensus recommendations that is animated by concerns about discouraging innovation); Michael Rosenblatt & Henri Termeer, *Reframing the Conversation on Drug Pricing*, NEJM CATALYST (Nov. 20, 2017), <https://catalyst.nejm.org/reframing-conversation-drug-pricing> ("For companies to justify risking billions on finding a breakthrough drug, they need to be able to anticipate a corresponding return on their investment.").

33. Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 27 (2016) (estimating the cost of developing a new drug to be in the \$2.3 billion to \$2.8 billion range). The \$2.6 billion figure is controversial. See, e.g., Jay Hancock, *Do Pharma's Claims on Drug Prices Pass the Smell Test? We Found 5 Stinkers*, KAISER HEALTH NEWS (Oct. 2, 2017), <https://khn.org/news/do-pharmas-claims-on-drug-prices-pass-the-smell-test-we-found-5-stinkers> ("Outside authorities criticize the research, saying it comes from untestable data, ignores enormous tax subsidies that reduce costs and inflates results with imaginary expenses, such as profits that could have been earned if drug companies invested research dollars elsewhere."). Competing estimates are lower, ranging from \$161 million to \$1.95 billion, but the DiMasi et al. study has been influential in policy debates. For a summary, see NASEM REPORT, *supra* note 13, at 87–88.

34. NASEM REPORT, *supra* note 13, at 42 (citing Gail A. Van Norman, *Drugs, Devices, and the FDA: Part 1: An Overview of Approval Processes for Drugs*, 1 JACC: BASIC TO TRANSLATIONAL SCI. 170 (2016)).

35. See DiMasi et al., *supra* note 33, at 24 (finding that the average time from the start of clinical testing of a new molecule to FDA approval is approximately eight years).

36. NASEM REPORT, *supra* note 13, at 40 ("[T]he returns on investment for successful drug products may appear to be abnormally high, since the average expected return, from the manufacturer's point of view, must also compensate for many failures. . . . More risk leads to a higher average reward for success, thereby encouraging investments that might not otherwise occur.").

Decrease the rewards for a big hit, they warn, and R&D will suffer.

How credible is that threat? It is hard to say. Some argue that there is plenty of loose money in the pharmaceutical industry to support R&D.³⁷ The industry is among the most profitable in the nation.³⁸ As a group, drug companies spend more money on marketing than they do on R&D, and more on stock repurchases and dividends than on R&D.³⁹ Yet, showing that companies have money to spare does not prove that they would redirect it to R&D if their profit margin were squeezed. In summary, assessing the credibility of claims on both sides of the debate with the information available is challenging.

Even more fundamentally, Americans do not agree about how much innovation we would be willing to forgo, even if we could quantify what the tradeoff would be. In a 2016 poll, seventy-seven percent of Americans said that cost of branded prescription drugs was unreasonable.⁴⁰ Yet Americans have steadfastly resisted attempts to ratchet down healthcare costs that could threaten their access to care.⁴¹ We want it all, at reasonable cost.

37. *Id.* at 9.

38. A number of studies have characterized the drug industry as among the most profitable, though their conclusions as to the precise net profit margins that pharmaceutical companies have experienced have varied somewhat. Those estimates tend to fall in the twenty-five to thirty percent range for manufacturers of branded drugs. For a review, see NASEM REPORT, *supra* note 13, at 9, 65–68. The most recent estimate comes from a November 2017 GAO study, which concluded that the average profit margin in 2015 was 17.1% (20.1% for the largest twenty-five companies) and that 67% of pharmaceutical companies experienced rising profit margins over the 2006 to 2015 period. GAO, GAO-18-40, DRUG INDUSTRY: PROFITS, RESEARCH AND DEVELOPMENT SPENDING, AND MERGER AND ACQUISITION DEALS 17–18 (Nov. 2017). These estimates are disputed by the industry's main trade association, which argues that returns on investment in R&D have been declining. Ed Silverman, *Lawmakers Who Scold Pharma for Price Gouging Get Some New Ammunition*, PHARMALOT (Dec. 19, 2017), <https://www.statnews.com/pharmalot/2017/12/19/drug-prices-rd-pharma>.

39. See NASEM REPORT, *supra* note 13, at 89; William Lazonick et al., *US Pharma's Financialized Business Model* 20 (Inst. for New Econ. Thinking, Working Paper No. 60, 2017).

40. Ashley Kirzinger et al., *Kaiser Health Tracking Poll: September 2016* (Sept. 29, 2016), <https://www.kff.org/health-costs/report/kaiser-health-tracking-poll-september-2016>.

41. See HENRY AARON ET AL., CAN WE SAY NO? THE CHALLENGE OF RATIONING HEALTH CARE 1–10 (2005) (outlining the history of medicine in the United States and concluding that there is a propensity for emphasizing access to care rather than cost); Michelle Mello, Book Review, 44 J. ECON. LIT. 1049, 1053 (2006) (reviewing *id.* and noting that “Americans are steadfastly unwilling

That is probably not possible. Until we confront this problem and agree on the goal we wish to pursue, we will not reach it. In other areas of healthcare, such as physician services, we also hear distress calls from providers when there is talk of reducing reimbursement. However, it is hard to think of another area of health policy where we risk reducing *innovation* if we clamp down on reimbursement. Thus uncertainty about the core tradeoff involved in reducing costs is an especially important, unresolved problem for prescription drugs.

B. FINDING A COHERENT ETHICAL FRAMEWORK

There is no shortage of righteous indignation in discussions of drug prices, but what is lacking is any anchoring of arguments in a coherent ethical framework. Addressing what is wrong in the current system requires that we have some conception of what right and wrong means for a pharmaceutical company. However, it is surprisingly difficult to fix upon an appropriate ethical principle or set of principles for evaluating drug companies' practices relating to pricing and access. Certainly, no consensus has emerged on this issue. Consequently, it is unsurprising that many of these companies feel they have been judged unfairly when they are accused of wrongful behavior, when other industries are subject to no such expectations.

Some instances of pharmaceutical company conduct are so egregious that it is easy to agree that they constitute a moral wrong. As with obscenity, we sometimes have a strong sense that we "know it when [we] see it."⁴² The leading, recent example is Turing Pharmaceuticals' astronomical, overnight hike of the price of the parasitic infection drug, pyrimethamine (sold under the trade name Daraprim).⁴³ Turing did not develop Daraprim, it acquired it. Daraprim was not a new drug, nor had anything in the market changed so as to justify the price increase. Rather, the decision appeared to be "all profit-driven."⁴⁴

to make sacrifices when it comes to the quality and availability of their health care, even when those sacrifices are based on reasoned deliberation about what makes sense for us as a population").

42. *Jacobellis v. Ohio*, 378 U.S. 184, 197 (1964) (Stewart, J., concurring).

43. The company that acquired the drug in August 2015, Turing Pharmaceuticals, immediately raised its price from \$13.50 to \$750 per tablet. A full course for some patients at the increased price could run in the hundreds of thousands of dollars. Andrew Pollack, *Drug Goes from \$13.50 a Tablet to \$750, Overnight*, N.Y. TIMES (Sept. 20, 2015), <https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html>.

44. *Id.*

It is tempting to focus on such scandals in lieu of answering hard moral questions that undergird our intuitions about them. What makes companies' conduct wrongful? What is a fair price? Instances of egregious conduct do not constitute the modal case of high drug costs. More commonly, what we tend to feel in response to high drug costs is not, "This is an outrage!" but something closer to, "I don't like this; I wish it were cheaper." We may find ourselves struggling to articulate exactly *why* drug companies *must* take steps to make their products more affordable.

One line of argumentation proceeds from the fact that patients who depend on life-preserving drugs are highly vulnerable.⁴⁵ Because they have no meaningful choice but to buy the drug at whatever price the seller wishes to charge, the usual presumptions about market exchanges—such as voluntariness, choice, and bargaining power—are disrupted. This arguably creates an ethical obligation on the part of the seller not to extract excessive benefits from those who cannot refuse its offer.⁴⁶ A reply to this argument is that this morally distressing situation may generate an obligation on the part of *society* to ensure that the patient receives the drug, but not on the part of the drug's producer.⁴⁷

Because of pharmaceutical companies' special status as both a for-profit manufacturer of goods and a provider of medical care, it is not clear where to reach for ethical standards to govern their conduct. As for-profit corporations, drug companies compete for capital in the open marketplace and must deliver returns to investors. Yet unlike providers of most products and services, they are delivering lifesaving products to highly vulnerable consumers. Pharmaceutical companies' own statements often acknowledge their special commitment to bringing effective therapies to patients around the world.⁴⁸ Innovator pharmaceu-

45. The remainder of this Section and the next Section draw heavily on a passage of the NASEM report that I drafted in collaboration with Brendan Saloner, Ph.D. I acknowledge his contributions with gratitude. See NASEM REPORT, *supra* note 13, at 31–35. I also thank Rebecca Wolitz for identifying useful literature relating to this discussion.

46. Mikhail Valdman, *A Theory of Wrongful Exploitation*, 9 PHILOSOPHERS' IMPRINT 1 (2009).

47. Richard T. DeGeorge, *Intellectual Property and Pharmaceutical Drugs: An Ethical Analysis*, 15 BUS. ETHICS Q. 549 (2005); Maitland, *supra* note 31.

48. See, e.g., *Mission & Purpose*, PFIZER, <http://www.pfizer.com/careers/en/mission-purpose> ("Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care

tical companies also are populated with, and even led by, physicians and scientists, who entered their field in order to do good in the world.⁴⁹ For these reasons, standard principles of business ethics (for example, honesty, disclosure, and adherence to promises) seem inadequate to conceptualize drug companies' obligations.

Yet alternative frameworks, such as classical liberal principles of medical ethics, are also ill fitting. Those principles—respect for autonomy, beneficence, nonmaleficence, and justice⁵⁰—require absolute fidelity to patients' interests. They are of limited utility in solving population-level problems, balancing competing obligations, and making hard decisions about resource allocation in the face of scarcity. In short, we lack an ethical lodestar to illuminate what ethical obligations to patients, if any, spring from pharmaceutical companies' distinctive role in the market.

Nor are more general ethical arguments about when actors have an obligation to affirmatively aid others very helpful in defining the scope of companies' obligations to make their products accessible. For instance, the rescue principle in moral philosophy posits that one has an obligation to come to the aid of another when one can do so at little personal cost.⁵¹ Such arguments have strong appeal in the context of hypothetical scenarios involving a pair of individuals (for example, introductory philosophy students may be asked, "Do I have a moral obligation to carry an infant off of a railroad track when the train is two hundred yards off?"). However, they are hard to scale. They do not offer clear guidelines about the scope of a company's obligations to a community, a nation, or a world of needy patients.

providers, governments and local communities to support and expand access to reliable, affordable health care around the world.").

49. See, e.g., Nancy A. Nichols, *Medicine, Management, and Mergers: An Interview with Merck's P. Roy Vagelos*, HARV. BUS. REV., Nov.–Dec. 1994, <https://hbr.org/1994/11/medicine-management-and-mergers-an-interview-with-mercks-p-roy-vagelos> (quoting the CEO of Merck: "We got involved in this project because we recognized the seriousness of the health problem, and as a doctor it is very hard for me to turn my back on that. We at Merck try to live by that ethic.").

50. For a general overview of these bedrock principles of medical ethics, see TOM L. BEAUCHAMP & JAMES F. CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* 101–301 (7th ed. 2013).

51. See THOMAS SCANLON, *WHAT WE OWE TO EACH OTHER* 224–28 (1998). For a useful discussion of the duty to rescue in the context of access to pharmaceuticals, see Rebecca E. Wolitz, *A Corporate Duty to Rescue: Biopharmaceutical Companies and Access to Medications* (Dec. 15, 2017) (unpublished manuscript) (on file with author).

Pharmaceutical company leaders may believe that one particular conception of the principle of fairness should drive conclusions about their ethical obligations relating to drug pricing. This conception turns on the notion of just rewards for effort expended and risk incurred. Because innovator companies take on substantial risk and invest considerable time, money, and effort in the development of new products, fairness arguably requires that they be able to reap the returns.⁵² Discussions about restricting price are deeply offensive to this conceptualization of justice.

The upshot is that although critics charge pharmaceutical companies with having committed moral wrongs, little constructive discussion has taken place of what ethic should govern their behavior. In a sense, this is not surprising. It arises from the cognitive dissonance that Americans have—and perhaps *should* have—about wanting companies to innovate at the highest level and make the results available to everyone at a low price. It also reflects our love/hate relationship with pharmaceutical companies. Pharmaceutical companies make products we cherish. Tobacco companies, in contrast, are easy to despise—their products are dangerous vices. A good start toward an honest moral dialogue about fair pricing would be to acknowledge the cognitive dissonance surrounding it.

C. GLOBAL EQUITY CONCERNS

Another perplexing moral problem is that tradeoffs may exist between improving the affordability of prescription drugs for Americans and maintaining their affordability to patients in other countries.⁵³ Branded drug prices in the United States are generally higher than in other countries because most foreign governments have adopted stronger mechanisms than the United States for controlling prices—for example, more consolidated price negotiations or direct price controls.⁵⁴ Because we pay so much, pharmaceutical companies may be more willing or able to grant price concessions elsewhere, including outright donation of critical medications to low-income countries. Actions we take to restrict price, therefore, could have unintended, but real, effects on drug affordability in less wealthy countries.

52. DeGeorge, *supra* note 47, at 549–50.

53. NASEM REPORT, *supra* note 13, at 34–35.

54. For a summary of several countries' approaches, see *id.* at 82–86.

This prospect raises the question of what obligations, if any, Americans have to patients in the rest of the world. Some conceptions of global justice hold that members of relatively wealthy societies have a moral obligation to consider the welfare of individuals in poorer countries in making policy decisions.⁵⁵ Other views challenge the notion that such duties exist.⁵⁶ Some even assert that the status quo is unfair: Americans not only pay more for marketed drugs, they shoulder a disproportionate share of the cost of developing those drugs.⁵⁷ Pharmaceutical R&D is underwritten both by the high prices Americans pay for medicines and the tax dollars we spend on basic-science research to identify promising new molecules.⁵⁸

Americans have not openly confronted these clashing viewpoints as a polity, but strong measures to reduce the cost of prescription drugs here would make the global-justice dilemma hard to ignore. Further, as with the other moral dilemmas discussed above, the problem has greater salience in the context of prescription drugs than in other areas of health policy. It is true that other health policy decisions we make, such as how much of federal agencies' budgets to devote to health system capacity building in low-income countries, also affect the healthcare costs that poor countries must bear. However, because the market for prescription drugs is global but is propped up by high prices in the United States, tamping down drug prices has a zero-sum-game quality that is unique. Squeezing one part of the drug-price balloon may cause it to bulge out in other areas.

In addition to these moral factors, a number of problems in the market for prescription drugs contribute to making drug affordability the hardest problem in health policy. I turn to these issues next.

55. See Charles R. Beitz, *Cosmopolitanism and Global Justice*, in CURRENT DEBATES IN GLOBAL JUSTICE 11–27 (Gillian Brock & Darrel Moellendorf eds., 2005) (discussing how moral cosmopolitanism relates to ideas of global economic and political justice).

56. See Thomas Nagel, *The Problem of Global Justice*, 33 PHIL. & PUB. AFF. 113 (2005) (discussing the limits of equality as a demand on global justice).

57. See, e.g., Rosenblatt & Termeer, *supra* note 32 (“It’s a chronic source of irritation for many in the U.S. that other countries get a relatively free ride, while the U.S. shoulders much of the cost of innovation.”).

58. See *id.*

II. MARKET FACTORS

The prescription drug market in the United States is plagued by numerous market failures and distortions that contribute to high prices.⁵⁹ Two deserve special focus: (1) the lack of transparency about drug prices, and (2) problems of perverse incentives.

A. LACK OF TRANSPARENCY

A profound absence of information makes it almost impossible to follow the money flowing through our drug delivery system from manufacturer to patient.⁶⁰ Where are rents being extracted, and in what amounts? Which actors in the supply chain are the best targets for policy interventions to reduce patients' ultimate costs? The answers to these questions are surprisingly hard to find.

The supply chain that moves prescription drugs from those who make them to those who take them is long and complex. It includes manufacturers, wholesalers, PBMs, health insurers, prescribers, retail pharmacies, and patients.⁶¹ Within this system is a complicated series of rebates and discounts from a drug's list price.⁶² Each player in the supply chain makes its own deal as it passes the drug along to the next.⁶³ The sizes of these rebates and discounts are kept cloaked by those who give and receive them.⁶⁴ Because policymakers know so little about them, it is impossible to say with any certainty how much money each player is pocketing⁶⁵ and where the major opportunities are to squeeze waste or reduce margins without loss to innovation.

59. For a summary of ways in which government intervention in the drug market distorts it, see NASEM REPORT, *supra* note 13, at 29.

60. *Id.* at 16.

61. Useful presentations of the flow of money and prescription drugs from manufacturers to patients are available in NASEM REPORT, *supra* note 13, at 49–50. See also KAISER FAM. FOUND., *supra* note 10 (providing detailed analysis of the pharmaceutical supply chain); Jonathan D. Rockoff, *Behind the Push to Keep Higher-Priced EpiPen in Consumers' Hands*, WALL ST. J. (Aug. 6, 2017), <https://www.wsj.com/articles/behind-the-push-to-keep-higher-priced-epipen-in-consumers-hands-1502036741>.

62. NASEM REPORT, *supra* note 13, at 16.

63. *Id.*

64. *Id.* at 16, 63.

65. *Id.* at 72 (“One cannot know with reasonable clarity how much money is retained at various levels, or how much of that which is retained is due to operational costs and how much is profit.”). For a description of one analyst's attempt to draw conclusions about where money was being retained based on the available data, see *id.* at 69.

What policymakers get instead of information is a great deal of finger pointing among participants in the supply chain.⁶⁶ Manufacturers assert that they give big discounts off the list price to PBMs that PBMs do not fully pass on to health plans and patients.⁶⁷ PBMs complain that the discounts they receive are not as generous as manufacturers portray, but provide little data to explain their claim.⁶⁸ Further, PBMs claim their price negotiations with manufacturers score big savings for their health plan customers but health plans do not fully pass those savings along to consumers.⁶⁹ Health plans object that even at the discounted prices they pay, drug prices are still crippling, and place the lion's share of blame on manufacturers.⁷⁰ In the

66. See Carolyn Y. Johnson, *Pharma, Under Attack for Drug Prices, Started an Industry War*, WASH. POST (Jan. 2, 2018), https://www.washingtonpost.com/business/economy/pharma-under-attack-for-drug-prices-started-an-industry-war/2017/12/29/800a3de8-e5bc-11e7-a65d-1ac0fd7f097e_story.html; see also NASEM REPORT, *supra* note 13, at 10–11, 62 (citing several additional newspaper articles discussing companies' blaming of other companies for keeping drug prices high).

67. NASEM REPORT, *supra* note 13, at 16. For an example of an analysis funded by drug manufacturers blaming intermediary organizations for retaining a hefty share of initial gross drug expenditures, see AARON VANDERVELDE & ELEANOR BLALOCK, BERKELEY RESEARCH GRP., *THE PHARMACEUTICAL SUPPLY CHAIN: GROSS DRUG EXPENDITURES REALIZED BY STAKEHOLDERS 4–6* (2017), https://www.thinkbrg.com/media/publication/863_Vandervelde_PhRMA-January-2017_WEB-FINAL.pdf (finding that manufacturers of branded drugs realized thirty-nine percent of drug expenditures while “non-manufacturer entities” realized forty-two percent).

68. See, e.g., David Dayen, *The Hidden Monopolies That Raise Drug Prices*, AM. PROSPECT (Mar. 28, 2017), <http://prospect.org/article/hidden-monopolies-raise-drug-prices> (discussing the lack of transparency PBMs have in supporting their claims); Michael Hiltzik, *How “Price-Cutting” Middlemen Are Making Crucial Drugs Vastly More Expensive*, L.A. TIMES (June 9, 2017), <http://www.latimes.com/business/hiltzik/la-fi-hiltzik-pbm-drugs-20170611-story.html> (same); Johnson, *supra* note 66 (discussing PBM claims that the majority of the savings they negotiate are passed on to consumers).

69. NASEM REPORT, *supra* note 13, at 62 (citing Jared S. Hopkins & Zachary Tracer, *Blame Game over High Drug Prices Escalates with New Ad*, BLOOMBERG (Apr. 6, 2017), <https://www.bloomberg.com/news/articles/2017-04-06/blame-game-over-high-drug-prices-gets-worse-with-lobby-s-new-ad>).

70. See Lisa Schencker, *Blue Cross Report Blames Pharma Companies for High Drug Prices*, CHI. TRIB. (May 3, 2017), <http://www.chicagotribune.com/business/ct-blue-cross-drug-prices-0504-biz-20170503-story.html>. For examples of analyses funded by the pharmaceutical industry that shift blame to the insurance companies, see Peter J. Pitts, *Rising Drug Prices the Fault of Insurers, Not Drug Companies*, SACRAMENTO BEE (Aug. 29, 2016), <http://www.sacbee.com/opinion/op-ed/soapbox/article98536387.html>; Robert Zirkelbach, *Why Won't the Insurance Industry Tell the Truth About Medicine Costs?*, PHARMA: THE CATALYST (May 10, 2017), <https://catalyst.pharma.org/why-wont-the-insurance-industry-tell-the-truth-about-medicine-costs>.

midst of this, it is difficult for policy makers to get a handle on where their focus ought to be.

Another place where price transparency is strikingly absent is the point of prescribing, as the Auvi-Q story illustrates.⁷¹ Many physicians today are sensitive to the problem of prescription drug costs and would like to take the comparative costs of alternative treatments into consideration when making prescribing decisions and describing options to their patients.⁷² However, they lack information about how much particular drugs will cost health plans or patients—beyond, perhaps, which tier the largest health plans have situated the drug in on their formularies.⁷³ For both prescribers and patients, it takes effort and tenacity to track down these costs. Even more challenging is finding information about how the cost of a drug compares to the long-term cost of treating the condition without the drug. Clinical-decision support tools in electronic health record systems could help by embedding information in patients' medical record about their prescription drug coverage and the costs of different drugs for their health plan; however, such functionalities have been slow to emerge.⁷⁴ As a result, physicians have had difficulty

71. See *supra* note 10 and accompanying text.

72. NASEM REPORT, *supra* note 13, at 110; see William H. Shrank et al., *Physicians' Perceptions of Relevant Prescription Drug Costs: Do Costs to the Individual Patient or to the Population Matter Most?*, 12 AM. J. MANAGED CARE 545 (2006) (concluding that physicians seek to manage out-of-pocket costs for patients).

73. See G. Michael Allan et al., *Physician Awareness of Drug Cost: A Systematic Review*, 4 PLOS MED. 1486 (2007) (analyzing studies showing physicians' lack of knowledge about the true costs of pharmaceuticals); Tim Schutte et al., *Students and Doctors Are Unaware of the Cost of Drugs They Frequently Prescribe*, 120 BASIC & CLINICAL PHARMACOLOGY & TOXICOLOGY 278 (2017) (analyzing survey results regarding physicians' attitudes toward and knowledge of pharmaceutical costs). The challenge of becoming familiar with patients' costs is compounded by the large number of different health insurers and plans in the United States, each of which has its own formulary and cost-sharing requirements. NASEM REPORT, *supra* note 13, at 110.

74. Notably, in November 2017, a consortium of large vendors of electronic health records and PBMs announced a joint effort to deliver drug benefits and price information to prescribers at the point of care. As early as 2018, the functionality may be available to the companies' member providers, which include over half of all United States physicians and nearly two-thirds of patients. Tom Sullivan, *Epic, Cerner, CVS Align with Surescripts to Make Personalized Prescription Benefit, Pricing Info Available in EHRs*, HEALTHCARE IT NEWS (Nov. 7, 2017), <http://www.healthcareitnews.com/news/epic-cerner-cvs-align-surescripts-make-personalized-prescription-benefit-pricing-info-available>.

prescribing with price in mind, even when their patients would appreciate it.⁷⁵

Transparency is increasingly permeating other aspects of healthcare, such as hospital price and quality and physicians' relationships with pharmaceutical companies.⁷⁶ In contrast, opacity reigns in the biopharmaceutical sector.

B. PERVERSE INCENTIVES

A second market factor that is clearly contributing to the drug unaffordability problem is perverse incentives, which are rife throughout the system. I provide a brief tour of several illustrative examples, but there are many others.⁷⁷

The Auvi-Q story captures the problem presented by patient coupon programs. These seemingly well-intentioned programs enable patients to obtain branded drugs without the out-of-pocket costs they would otherwise owe under their health plan's cost-sharing requirements. The manufacturer absorbs the cost of the patient's copayment or other cost-sharing obligation, at least for a limited period of time.

Coupon programs can be a welcome relief for patients, but they burden health plans because their purpose and effect is to get patients onto expensive, branded drugs.⁷⁸ They effectively counteract health plans' efforts to encourage patients to choose less-expensive alternatives by placing them in formulary tiers

75. See NASEM REPORT, *supra* note 13, at 110.

76. *Id.* at 65.

77. One important issue not covered in this discussion is conflicts of interest that arise from pharmaceutical companies' financial relationships with physicians and patient-advocacy organizations, which can contribute to prescribing and advocacy of costly, branded drugs. See COMM. ON CONFLICT OF INTEREST IN MED. RESEARCH, EDUC., & PRACTICE, NAT'L ACADS. OF SCIS., ENG'G AND MED., CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, & PRACTICE 12 (Bernard Lo & Marilyn J. Field eds., 2009), <http://www.nationalacademies.org/hmd/Reports/2009/Conflict-of-Interest-in-Medical-Research-Education-and-Practice.aspx>; NASEM REPORT, *supra* note 13, at 93–94.

78. See Leemore Dafny et al., *When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization*, 9 AM. ECON. J. ECON. POL'Y 91 (2017) (analyzing data on the effect of copay coupons); Joseph S. Ross & Aaron S. Kesselheim, *Prescription-Drug Coupons—No Such Thing as a Free Lunch*, 369 NEW ENG. J. MED. 1188, 1188 (2013) (finding that more than seventy-five percent of coupon programs were for drugs for chronic conditions, which patients will take for an extended period of time, and sixty-two percent were for drugs for which lower-cost treatments were available).

with lower cost sharing.⁷⁹ Payments associated with coupon programs and similar discounts are illegal for Medicare patients under federal antikickback laws,⁸⁰ but have been permitted to operate in the commercial market.⁸¹ They are an increasingly popular strategy among branded-drug manufacturers.⁸²

These programs have driven a wedge between the perceived interests of patients and those of their health plans. They are highly effective in inducing prescriptions for branded drugs: in one study, they increased branded-drug sales by sixty percent, with commensurate reductions in sales of generic drugs.⁸³ Over time, higher health-insurer costs translate into higher premiums, and coupons may expire, leaving the patient on the hook if he or she chooses to continue the drug.⁸⁴ In these ways, coupon programs ultimately may redound to patients' detriment as well.

A similar incentives problem arises from direct-to-consumer advertising. Such advertising has become ubiquitous; pharmaceutical companies spent an estimated \$6.4 billion on it in 2016, representing a sixty-two percent increase since 2012.⁸⁵ Direct-to-consumer advertisements are known to increase the rates at which patients ask their physicians for costly, branded drugs,

79. See NASEM REPORT, *supra* note 13, at 93; Leemore S. Dafny et al., *Undermining Value-Based Purchasing—Lessons from the Pharmaceutical Industry*, 375 NEW ENG. J. MED. 2013, 2013–14 (2016).

80. David Grande, *The Cost of Drug Coupons*, 307 JAMA 2375, 2376 (2012).

81. *Cf.* Ross & Kesselheim, *supra* note 78, at 1189 (discussing litigation against manufacturers offering coupon programs in which plaintiffs argue, with no success to date, that coupons should be disallowed as illegal kickbacks in nonfederal insurance programs).

82. See Dafny et al., *supra* note 79, at 2014 (finding that the proportion of outpatient prescription drug revenue derived from drugs with coupon programs doubled between 2007 and 2010); Grande, *supra* note 80, at 2375 (noting that the number of coupons increased markedly between 2009 and 2011, rising to 340 in 2011).

83. See Dafny et al., *supra* note 79, at 2014. Another analysis estimated that coupon programs will increase drug expenditures for commercially-insured patients by \$32 billion over a decade. Grande, *supra* note 80, at 2376 (citing *How Copay Coupons Could Raise Prescription Drug Costs by \$32 Billion over the Next Decade*, PCMA (Nov. 3, 2011), <https://www.pcmamet.org/how-copay-coupons-could-raise-prescription-drug-costs-by-32-billion-over-the-next-decade>).

84. Grande, *supra* note 80, at 2375.

85. Bruce Horovitz & Julie Appleby, *Prescription Drug Costs Are Up; So Are TV Ads Promoting Them*, USA TODAY (Mar. 16, 2017), <https://www.usatoday.com/story/money/2017/03/16/prescription-drug-costs-up-tv-ads/99203878>.

and physicians frequently are willing to accede to such requests.⁸⁶ A 2016 review of studies concluded that patients' requests relating to advertised drugs "are typically accommodated, promote higher prescribing volume, and have competing effects on treatment quality."⁸⁷

Because insured patients pay only a fraction of the cost of their drug, a negative externality arises when they request advertised drugs.⁸⁸ Patients have insufficient incentives to avoid the resulting, costly insurance claims because others bear the bulk of those costs in the form of higher insurance premiums and Medicare taxes. This incentives problem contributes to the nation's high prescription drug bill.⁸⁹

Patients' and health plans' incentives also splinter because of problems with health-insurance benefit design. In the debate about affordability of prescription drugs, it is often forgotten that affordability is a function of two things: (1) drug prices; and (2) the generosity of a patient's insurance coverage. Many Americans are uninsured or underinsured for drug costs,⁹⁰ and among the insured, incentives problems abound.

Many prescription drug benefits are designed in a way that undercuts incentives for patients to behave as we would like. For example, cost-sharing requirements typically are not reduced or

86. In a 2015 poll, among eighty-two percent of respondents who had seen some form of direct-to-consumer advertising, more than a quarter spoke with their physicians about those ads. Of those, forty-three percent were prescribed the drug they asked about. Bianca DiJulio et al., *Kaiser Health Tracking Poll: October 2015*, KAISER FAM. FOUND. (Oct. 28, 2015), <https://www.kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-october-2015>. A randomized, controlled trial involving patients with depression found that particular branded antidepressants were prescribed far more often when patients requested them than when they did not. Richard L. Kravitz et al., *Influence of Patients' Requests for Direct-to-Consumer Advertised Antidepressants: A Randomized Controlled Trial*, 293 JAMA 1995, 1998–99 (2005).

87. Sara J. Becker & Miriam M. Midoun, *Effects of Direct-to-Consumer Advertising on Patient Prescription Requests and Physician Prescribing: A Systematic Review of Psychiatry-Relevant Studies*, 77 J. CLINICAL PSYCHIATRY e1293, e1293 (2016).

88. An externality occurs when "the well-being of a consumer or the production possibilities of a firm are directly affected by the actions of another agent in the economy." ANDREU MAS-COLELL ET AL., MICROECONOMIC THEORY 351–52 (1995). For a general discussion of externalities in the drug-marketing context, see Ramarao Desiraju & Thanh Van Tran, *Spillovers and Other Externalities in Pharmaceutical Marketing*, in INNOVATION AND MARKETING IN THE PHARMACEUTICAL INDUSTRY 673–700 (Min Ding et al. eds., 2014).

89. NASEM REPORT, *supra* note 13, at 91–92.

90. *See id.* at 98–99.

waived for drugs with large positive externalities, such as infectious disease treatments,⁹¹ even though the association between higher out-of-pocket drug costs and lower medication adherence is well established.⁹² If a patient's employer, health plan, and society have a strong interest in ensuring that the patient receives and takes a prescription drug in order to prevent harm to others, it is not economically rational to impose burdensome cost sharing. Rather, "arguments for eliminating financial barriers to treatment are compelling."⁹³

Benefits design—like direct-to-consumer advertisements—can also create a rift in patients' and insurers' incentive structures. Typically, patients' coinsurance and deductible amounts are pegged to the list price of the drug, not the actual price the health plan paid for the drug.⁹⁴ In other words, even if the health plan has received a big discount on the drug, the patient may nonetheless pay twenty percent of the much higher list price. That design creates situations in which the drug that is most cost-effective for the plan is not the one that costs the patient least. Consider, for instance, two competing drug therapies for hepatitis C with comparable cure rates: a sofosbuvir-ledipasvir combination therapy (sold by Gilead Sciences under the brand name Harvoni); and an elbasvir-grazoprevir combination (sold by Merck under the name Zepatier). Harvoni has a much higher list price (\$94,916) than Zepatier (\$54,841).⁹⁵ A typical Medicare Part D patient⁹⁶ with twenty percent coinsurance will pay \$6995 out of pocket for Harvoni. Cost-conscious patients should prefer Zepatier, which saves them more than \$2000. The manufacturer of Harvoni, however, gives a much bigger rebate to health plans

91. *Id.* at 30, 78.

92. See Victoria Powell et al., *Cost Sharing in Medicaid: Assumptions, Evidence, and Future Directions*, 73 MED. CARE RES. & REV. 383 (2015) (reviewing empirical evidence relating to low-income adults); see also KATHERINE SWARTZ, COST-SHARING: EFFECTS ON SPENDING AND OUTCOMES (2010), https://www.rwjf.org/content/dam/farm/reports/issue_briefs/2010/rwjf402103/subassets/rwjf402103_1 (analyzing literature findings from the 1970s through 2010).

93. NASEM REPORT, *supra* note 13, at 78.

94. *New Data Show More Than Half of Patients' Out-of-Pocket Spending for Brand Medicines Is Based on List Price*, PHRMA (Mar. 29, 2017), <https://www.phrma.org/press-release/new-data-show-more-than-half-of-patients-out-of-pocket-spending-for-brand-medicines-is-based-on-list-price>. Stacie Dusetzina has stressed this point very effectively in public discussions about drug prices. See Dusetzina et al., *supra* note 12, at 1186; NASEM REPORT, *supra* note 13, at 76.

95. Dusetzina et al., *supra* note 12, at 1186.

96. Part D is Medicare's prescription drug-benefit program. For a program summary, see *infra* notes 113–14 and accompanying text.

than the maker of Zepatier,⁹⁷ so health plans' incentive is to have patients on Harvoni.

Very costly, one-time treatments like Zepatier and Harvoni also illuminate another incentives problem in the health insurance system. Some drug therapies avoid the need for a lot of other expensive care, but the bulk of the savings is not seen for many years.⁹⁸ Treating chronic viral-hepatitis patients with medication, for example, can avert cirrhosis, liver transplantation, and cancer.⁹⁹ In such situations, it is cost-effective to provide access to drug therapy, but it is not necessarily economically rational from the current insurer's perspective.¹⁰⁰ Americans change insurance plans frequently, with most eventually moving to Medicare.¹⁰¹ Thus what is medically best for the patient and economically optimal for society is not always where the incentives point for individual insurers.¹⁰² This problem is not unique to prescription drugs. On the contrary, that "the fragmented insurance system creates potential disincentives for coverage of

97. See Cathy Kelly, *Medicaid May Offer Best Opportunity for Merck's Zepatier*, PINK SHEET (Mar. 28, 2016), <https://pink.pharmaintelligence.informa.com/PS057545/Medicaid-May-Offer-Best-Opportunity-For-Mercks-Zepatier>; A Tale of Two New Hepatitis C Drugs (Mar. 10, 2016), <https://www.newswire.com/news/a-tale-of-two-new-hepatitis-c-drugs-9058111> (noting that the rebate for Harvoni can be as high as forty-five percent off the list price and is more generous if the plan agrees to cover Harvoni exclusively).

98. Tomas J. Philipson & Andrew C. von Eschenbach, *Medical Breakthroughs and Credit Markets*, FORBES (Jul. 9, 2014), <https://www.forbes.com/sites/tomasphilipson/2014/07/09/medical-breakthroughs-and-credit-markets> ("The key issue with [the hepatitis C drug] Sovaldi, which is representative of other treatments, is that costs are temporally front-loaded while benefits are delayed. In other words, we face costs now, but the benefits accrue over the course of a lifetime.")

99. Zobair Younossi et al., *Treating Medicaid Patients with Hepatitis C: Clinical and Economic Impact*, 23 AM. J. MANAGED CARE 107, 107 (2017).

100. See Alexis P. Chidi et al., *Economic and Public Health Impacts of Policies Restricting Access to Hepatitis C Treatment for Medicaid Patients*, 19 VALUE IN HEALTH 326, 333 (2016) (finding that paying for hepatitis C drug therapy is cost saving but that "in a multipayer healthcare system, efforts to minimize costs for individual payers can result in cost shifting" and suggesting that, as a result, "collaborative efforts between state and federal payers may be needed to realize the full public health impact of recent advances in hepatitis C therapy"); David Cutler et al., *Insurance Switching and Mismatch Between the Costs and Benefits of New Technologies*, 23 AM. J. MANAGED CARE 750, 754 (2017) (summarizing studies finding that there is a "disincentive for commercial insurer coverage" of hepatitis C drugs because "results [are] borne by Medicare and other downstream payers," with one study estimating that savings would not accrue for a decade and a half).

101. See Cutler et al., *supra* note 100, at 755–56.

102. See *id.*

therapies with up-front costs and long-lived or delayed benefits” is “a widely acknowledged feature of U.S. health care.”¹⁰³ But the discovery of breakthrough drugs, such as the hepatitis C medications, has vaulted this particular perversity into special prominence in that area of healthcare.

Medicare reimbursement rules also create perverse incentives. Most prescription drugs are covered by Medicare Part D, but drugs such as chemotherapy infusions that are administered in hospital-based or standalone outpatient clinics are covered under another component of the program, Part B. The Part B program reimburses providers for these drugs through an arrangement known as buy and bill, in which providers buy the medications at the wholesale acquisition cost and then bill insurers and patients for their use. Currently, these providers are reimbursed at the average sales price of the drug plus six percent plus an administration fee.¹⁰⁴ They derive substantial revenue by retaining the difference between the price they bill and their acquisition cost.¹⁰⁵

Consequently, the reimbursement structure provides an economic incentive to select drugs with the largest difference between the wholesale acquisition cost and the average sales price—which, in practice, means selecting more expensive drugs

103. *Id.* at 750.

104. NASEM REPORT, *supra* note 13, at 51; Blase N. Polite et al., *Payment for Oncolytics in the United States: A History of Buy and Bill and Proposals for Reform*, 10 J. ONCOLOGY PRAC. 357, 357–58 (2014). Recently, the Centers for Medicare and Medicaid Services implemented a partial fix to the Part B reimbursement problem discussed herein. On November 1, 2017, it finalized a rule stating that instead of being reimbursed at the average sales price plus six percent, providers who participate in the federal 340B Drug Pricing Program will now be reimbursed at the average sales price minus 22.5%. *Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs*, 82 Fed. Reg. 52,356, 52,362 (Nov. 13, 2017) (to be codified at 42 C.F.R. pts. 414, 416, 419). This change reflects the fact that under the 340B program, qualified hospitals, clinics, and health centers that serve a large proportion of low-income patients can buy prescription drugs at deeply discounted prices. Walid F. Gellad & A. Everette James, *Discounted Drugs for Needy Patients and Hospitals—Understanding the 340B Debate*, 378 NEW ENG. J. MED. 501, 502 (2018). The average discount is estimated to be at least 22.5% off the average sales price. MEDICARE PAYMENT ADVISORY COMM’N, REPORT TO THE CONGRESS: OVERVIEW OF THE 340B DRUG PROGRAM, <http://medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf>.

105. See NASEM REPORT, *supra* note 13, at 112–13.

over cheaper ones.¹⁰⁶ Studies suggest that oncologists administering chemotherapy respond to this incentive in the predicted fashion.¹⁰⁷ The unfortunate Medicare beneficiary pays twenty percent coinsurance on the drugs they select. This reimbursement system has a complex history,¹⁰⁸ but is hard to defend on economic grounds.

Perverse reimbursement structures also characterize many PBM contracts. PBMs are paid in a variety of ways, but a common arrangement is to make money off the spread, or the difference between the price at which the PBM purchases the drug from the manufacturer, after obtaining a discount or rebate, and the price it charges health plans and other customers for procuring the drug. A hypothetical manufacturer may list a drug at \$1000, for example, but sell it to the PBM at the negotiated price of \$700, and the PBM may then resell it to a health insurer for \$850. Under this arrangement, the PBM's incentive is to sell high—that is, to pass along as little of the \$300 discount as it can. Further, a portion of PBMs' annual fees is based on a given payer's drug expenditures.¹⁰⁹ Other unsavory reimbursement arrangements have also been reported.¹¹⁰ Increasing the prevalence of alternative fee arrangements, such as charging a flat fee for delivering a certain amount of product, would address the

106. Blase Polite et al., *Reform of the Buy-and-Bill System for Outpatient Chemotherapy Care Is Inevitable: Perspectives from an Economist, a Realpolitik, and an Oncologist*, in AMERICAN SOCIETY OF CLINICAL ONCOLOGY EDUCATIONAL BOOK e75, e77 (Don S. Dizon et al. eds., 2015) (“[W]hen wholesale and retail prices for drugs diverge systematically, incentives for dysfunctional behavior may be created. Oncologists and hospitals profit on the spread between the reimbursed price and the wholesale cost.”).

107. See Polite et al., *supra* note 106 (discussing studies that suggest oncologists' drug choices are responsive to this financial incentive); see also Mireille Jacobson et al., *Does Reimbursement Influence Chemotherapy Treatment for Cancer Patients?*, 25 HEALTH AFF. 437, 441–42 (2006); Mireille Jacobson et al., *How Medicare's Payment Cuts for Cancer Chemotherapy Drugs Changed Patterns of Treatment*, 29 HEALTH AFF. 1391, 1393–97 (2010). Some researchers have gone so far as to question whether clinically inappropriate chemotherapy drugs are being selected because of the higher remuneration associated with their use. See, e.g., Polite et al., *supra* note 106.

108. See Polite et al., *supra* note 104, at 357–58.

109. Aaron S. Kesselheim et al., *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 JAMA 858, 862 (2016).

110. *Id.* at 862 (“[W]hen one of the largest pharmacy benefit managers became a publicly traded entity, it was obliged to disclose its business model, much of which depended on payments from drug makers for shifting market share to their products from others in its class.”).

perverse incentives in the current system and better align PBMs' interests with those of their customers.¹¹¹

Incentive problems such as the ones outlined above contribute to the picture of a system that pits players—for example, patients and their health plans—against one another in a zero-sum game that invites strategic behavior. The lack of price transparency and the problem of perverse incentives are two illustrations of how “the complexity of the biopharmaceutical system makes it rife for exploitation.”¹¹²

III. POLITICAL FACTORS

Finally, two political factors have made the problem of prescription drug affordability especially vexing to solve. One relates to political compromises that have hamstrung the federal government's ability to act, and the other to the current political environment.

A. THE LEGACY OF POLITICAL COMPROMISES

Past political compromises have greatly contributed to the situation that we find ourselves in today. Chief among these are the congressional decisions to not allow the federal agency responsible for administering the Medicare and Medicaid Programs, the Centers for Medicare and Medicaid Services (CMS), to take cost or cost-effectiveness into consideration when it makes coverage decisions for the Medicare program and denying CMS the ability to negotiate directly for the price of drugs.

Medicare has offered an outpatient prescription drug benefit, known as Part D, since 2006.¹¹³ The benefit is administered through private plans—CMS contracts with insurance companies and authorizes them to sell Part D insurance policies that adhere to federal rules.¹¹⁴

111. See NASEM REPORT, *supra* note 13, at 55.

112. *Id.* at 11.

113. The Part D program was established by the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified in relevant part at 21 U.S.C. § 355(j), 21 U.S.C. § 355 references in text).

114. For a summary of the Part D benefit and how it is administered, see Susan Alder Channick, *The Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Will It Be Good Medicine for U.S. Health Policy?*, 14 ELDER L.J. 237, 246–56 (2006); see also *Part D / Prescription Drug Benefits*, CTR. MEDICARE ADVOC., <http://www.medicareadvocacy.org/medicare-info/medicare-part-d/#introduction> (last visited June 17, 2018).

Today, Medicare accounts for about twenty-nine percent of all prescription drug spending in the United States¹¹⁵ Ordinarily, massive payers have commensurately strong leverage in negotiating discounts on drugs for their health plans, but CMS does not. By statutory design, each private insurer that provides Part D coverage manages its own benefits, including drug purchasing and drug formularies.¹¹⁶ They may hire PBMs to do this for them to increase their negotiating power. However, the government is prohibited from negotiating prices directly for Medicare patients, leaving negotiations fragmented among numerous buyers.¹¹⁷

Federal law also imposes substantial restrictions on CMS's ability to use information about the cost of treatments in making coverage decisions for Medicare. The Medicare Prescription Drug, Improvement and Modernization Act of 2003, which created the Part D benefit, provides that the program generally will cover outpatient prescription drugs for indications approved by the FDA, except for a few narrow categories of excluded drugs.¹¹⁸ More generally, Medicare coverage is available for treatments that are "reasonable and necessary for the diagnosis or treatment of illness or injury,"¹¹⁹ and historically, CMS has treated FDA approval for a particular indication as establishing that those criteria are met for a drug.¹²⁰ It has not used cost as a component of coverage determinations.¹²¹

115. JULIETTE CUBANSKI & TRICIA NEUMAN, SEARCHING FOR SAVINGS IN MEDICARE DRUG PRICE NEGOTIATIONS 1 (2017), <http://files.kff.org/attachment/issue-brief-searching-for-savings-in-medicare-drug-price-negotiations>.

116. For details, see Haiden A. Huskamp & Nancy L. Keating, *The New Medicare Drug Benefit: Formularies and Their Potential Effects on Access to Medications*, 20 J. GEN. INTERNAL MED. 662 (2005).

117. See 42 U.S.C. § 1395w-111(i) (2012) ("In order to promote competition . . . the Secretary—(1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs."). For a history and summary of this aspect of the legislation, see Thomas R. Oliver et al., *A Political History of Medicare and Prescription Drug Coverage*, 82 MILBANK Q. 283 (2004).

118. For example, drugs for hair growth, prescription vitamins, and drugs used to promote fertility are excluded. See CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE PRESCRIPTION DRUG BENEFIT MANUAL: CHAPTER 6—PART D DRUGS AND FORMULARY REQUIREMENTS § 20.1 (Jan. 15, 2016), <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf>.

119. 42 U.S.C. § 1395y(a)(1)(A).

120. NASEM REPORT, *supra* note 13, at 53.

121. *Id.*; Peter J. Neumann et al., *Medicare's National Coverage Decisions for Technologies, 1999–2007*, 27 HEALTH AFF. 1620 (2008); Peter J. Neumann

CMS cannot decide to exclude other drugs or place them on a restrictive formulary tier; only individual Part D plans can make such decisions.¹²² This is important because even if CMS were given the authority to negotiate on behalf of all Part D plans, it would have little leverage without the power to exclude drugs for which companies refused to grant the sought-after price concessions.¹²³

Also noteworthy are federal statutory provisions relating to the use of comparative-effectiveness research in Medicare coverage decisions. Comparative-effectiveness research is “the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care.”¹²⁴ It examines “the overall value of a strategy . . . by considering costs and benefits together.”¹²⁵ Its aim is not necessarily to promote lower-cost care, but it may identify ways to obtain more favorable clinical outcomes at lower cost.¹²⁶

The Affordable Care Act created an independent research institute to sponsor comparative-effectiveness research, but prohibited findings of such research from being “construed as mandates for practice guidelines, coverage recommendations, payment, or policy recommendations.”¹²⁷ The Secretary of Health and Human Services may not, for instance, adopt a threshold of a certain number of dollars per quality-adjusted life-year saved to decide whether or not Medicare will cover a particular drug.¹²⁸

et al., *Medicare and Cost-Effectiveness Analysis*, 353 NEW ENG. J. MED. 1516 (2005).

122. See MEDICARE PRESCRIPTION DRUG BENEFIT MANUAL, *supra* note 118, at § 10.2.

123. NASEM REPORT, *supra* note 13, at 52 (“For buyers to be able to negotiate on price they must have credible alternatives other than purchasing from the seller.” (quoting OECD, POLICY ROUNDTABLES: MONOPSONY AND BUYER POWER 10 (2009), <https://www.oecd.org/daf/competition/44445750.pdf>)).

124. INST. OF MED., INITIAL NATIONAL PRIORITIES FOR COMPARATIVE EFFECTIVENESS RESEARCH 29 (2009).

125. *Id.* at 34.

126. *Id.*

127. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6301(a), 124 Stat. 119, 734 (codified with some differences in language at 42 U.S.C. § 1320e(d)(8)(a)(iv) (2012)); S. COMM. ON FINANCE, 111th CONG., THE PATIENT PROTECTION AND AFFORDABLE CARE ACT: FACT VS. FICTION ON HEALTH CARE RESEARCH 1 (2009), <https://www.finance.senate.gov/download/2009/11/21/fact-vs-fiction-on-health-care-research-1>.

128. Jane Hyatt Thorpe, *Comparative Effectiveness Research and Health Reform: Implications for Public Health Policy and Practice*, 125 PUB. HEALTH

This provision adopts the approach taken in an earlier statute, the American Recovery and Reinvestment Act of 2009, which also provided federal funding for comparative-effectiveness research.¹²⁹ In order to overcome political objections to the funding, lawmakers made clear that the research could not be used to mandate policies concerning Medicare coverage or reimbursement.¹³⁰

In understanding why these legislative provisions came to exist, it is hard to overlook the enormous lobbying presence of the biopharmaceutical industry.¹³¹ The top-ranking U.S. industry on lobbying spending by far,¹³² the pharmaceutical industry spent \$247 million in 2016.¹³³ It spent more on lobbying the federal government in the first six months of 2017 than it has at any other time during those months over the last decade.¹³⁴ Last year, the industry's main trade association, the Pharmaceutical Research and Manufacturers of America (PhRMA), asked its member companies to contribute another \$100 million annually to strengthen its advocacy efforts and incurred lobbying expenditures of \$57 billion—two-thirds more than its expenditures in 2015.¹³⁵

REP. 909, 911 (2010) (citing Patient Protection and Affordable Care Act Pub. L. No. 111-148, § 6301(c), 124 Stat. 119, 740 (codified at 42 U.S.C. § 1320e-1)).

129. Pub. L. No. 111-5, 123 Stat. 115, 177 (2009).

130. Thorpe, *supra* note 128, at 910.

131. See, e.g., Louise M. Slaughter, *Medicare Part D—The Product of a Broken Process*, 354 NEW ENG. J. MED. 2314, 2314 (2006) (“The final legislation [creating Medicare Part D], heavily influenced by drug-company and health insurance lobbyists, focused mainly on the needs of those industries instead of those of the seniors it should serve.”).

132. See Ctr. for Responsive Pols., *Top Industries*, OPENSECRETS, <https://www.opensecrets.org/lobby/top.php?indexType=i&showYear=2016> (last visited June 17, 2018) (showing that the pharmaceutical industry spent the most money on lobbying in 2016).

133. Ctr. for Responsive Pols., *Pharmaceuticals/Health Products*, OPENSECRETS, <https://opensecrets.org/lobby/indusclient.php?id=h04&year=2016> (last visited June 17, 2018).

134. The industry spent a total of \$145 million in the first half of 2017. Jay Hancock, *Everyone Says We Must Control Exorbitant Drug Prices. So, Why Don't We?*, KAISER HEALTH NEWS (Sept. 25, 2017), <https://khn.org/news/everyone-says-we-must-control-exorbitant-drug-prices-why-dont-we> (discussing drug manufacturers' contributions to congressional campaigns).

135. Jay Hancock, *In Election Year, Drug Industry Spent Big to Temper Talk About High Drug Prices*, NPR (Dec. 18, 2017), <https://www.npr.org/sections/health-shots/2017/12/18/571206699/in-election-year-drug-industry-spent-big-to-temper-talk-about-high-drug-prices>; Dylan Scott, *Readying for Pricing Fight, Drug Lobby to Add \$100 Million to Coffers*, STAT NEWS (Oct. 25, 2016), <https://www.statnews.com/2016/10/25/phrma-drug-lobby-fees>.

The ban on CMS bulk purchasing or price negotiation of drugs arose from congressional attempts to overcome the industry's resistance to adding a prescription drug benefit to Medicare. Companies had long opposed such an addition because they foresaw that they would face a juggernaut at the bargaining table.¹³⁶ The legislative process surrounding the creation of the Part D program has been criticized for its hastiness, partisanship, and rejection of provisions that clearly would have strengthened the long-term economic viability of the program—CMS negotiating power among them.¹³⁷

The influence of Medicare beneficiaries has also played a role in the political deals reflected in current legislation governing Medicare. The large, politically active Medicare population strongly resists attempts to restrict access to benefits—especially those that can be framed as rationing.¹³⁸ Lawmakers' efforts to toe the line between promoting comparative-effectiveness research and reassuring elderly Americans that it would not lead to rationing and discrimination against the aged¹³⁹ reflect their concerns about this pressure.

It would take a great deal of fortitude to resist these political pressures and change the laws that hamstring CMS. Because of these past political compromises, when it comes to arresting prescription drug cost escalation in the Medicare program, we start with a very unclean slate.

136. Lee Drutman, *How Corporate Lobbyists Conquered American Democracy*, ATLANTIC (Apr. 20, 2015), <https://www.theatlantic.com/business/archive/2015/04/how-corporate-lobbyists-conquered-american-democracy/390822>; Stuart Silverstein, *Lobbyists, Campaign Cash Help Drug Industry Stymie Bid to Restrain Medicare Prescription Costs*, OPENSECRETS (Oct. 19, 2016), <https://www.opensecrets.org/news/2016/10/lobbyists-campaign-cash-help-drug-industry-stymie-bid-to-restrain-medicare-prescription-costs>. See generally Oliver et al., *supra* note 117 (describing political factors contributing to the omission of federal negotiating power from the legislation).

137. See, e.g., Slaughter, *supra* note 131, at 2314 (“At the behest of the Republican leadership, however, the House Committee on Rules rejected all but one [proposed amendment], preventing them from being debated by Congress. Many of those amendments—among them, one requiring the administration to use beneficiaries’ collective purchasing power to negotiate lower prices and one allowing Americans to import cheaper drugs from Canada—would have made the legislation far more effective.”).

138. See Jonathan Oberlander & Marisa Morrison, *Failure to Launch? The Independent Payment Advisory Board’s Uncertain Prospects*, 369 NEW ENG. J. MED. 105 (2013).

139. See S. COMM. ON FINANCE, *supra* note 127.

B. THE ATMOSPHERE OF SCANDAL

A crisis atmosphere pervades discussions of pharmaceutical prices in Washington today. A dramatic upsurge in media publicity about the drug-affordability problem has occurred over the past two years, in part due to the availability of new data but perhaps in even larger part driven by highly publicized drug-pricing scandals.¹⁴⁰ Serial instances of culpable conduct by a few companies, such as the Daraprim incident, have contributed to a policy frame in which “price gouging” by bad actors is the problem that needs to be solved.¹⁴¹

Many patient advocates welcome the collision of factors that seems to have opened a “policy window”¹⁴² for taking action on a problem that has long troubled them. However, an atmosphere of crisis and scandal can make it harder to make real progress on a thorny policy dilemma. It can politicize and distort the problem in a way that makes it very hard to coolly deliberate about policy solutions. Under these conditions, public demands to “do something—quick!” may lead to suboptimal policymaking.

Scandals can also lead policymakers and the public to paint an industry with a broad brush when in fact there is substantial variation in business practices among companies. Pharmaceutical companies rightly insist that there are big differences among them. There are big companies and small companies. There are differences in how diversified their portfolios are and how much risk they are shouldering. There are differences in the degree to which they are innovators versus mere acquirers and sellers of fully developed products. There are differences in their sense of mission and corporate social responsibility. For these reasons, it is not hard to understand why some companies may feel that a few bad apples have spoiled the barrel. Such feelings likely explain the recent decision by PhRMA to distance “innovative

140. See *Drug Pricing*, GOOGLE TRENDS, <https://trends.google.com/trends/explore?cat=16&date=today%205-y&q=drug%20pricing> (last visited June 17, 2018) (graphically depicting an upsurge in news stories yielded by a Google search of the term “drug pricing” beginning in 2016).

141. Press Release, H. Comm. on Oversight, Sanders and Cummings Denounce Continued Prescription Drug Price Gouging (Oct. 9, 2015), <https://democrats-oversight.house.gov/news/press-releases/sanders-and-cummings-denounce-continued-prescription-drug-price-gouging>.

142. JOHN W. KINGDON, *AGENDAS, ALTERNATIVES, AND PUBLIC POLICIES* 168–70 (2d ed. 1995). Kingdon posits that a window for policy change opens when three forces align: (1) recognition that a policy problem exists; (2) development of policy proposals to address the problem; and (3) political events that bolster opportunities to take action. *Id.*

pharmaceutical companies” from “platform companies” that merely acquire and sell products,¹⁴³ and, for the first time, restrict membership to companies that make significant expenditures for R&D.¹⁴⁴

The atmosphere of investigation and scandal has not only muddled what the optimal policy responses to the drug-affordability problem are, it has also contributed to the finger pointing going on in Washington. Further, it has helped foster a mentality in which the players in the biopharmaceutical sector keep information that would be helpful in the policy process submerged. There is a sense of hunkering down, rather than being transparent and helping to address problems by providing the information that policy makers need. Finally, there is a palpable sense of victimization on all sides of the debate. Some pharmaceutical companies feel they have been unfairly targeted and misunderstood.¹⁴⁵ Patients’ groups and members of the public point to the high-profile bad actors and the high profitability of the pharmaceutical industry as evidence that they have been hoodwinked.¹⁴⁶ The way forward from here is hard to see.

CONCLUSION

Leo Tolstoy wrote, “All happy families resemble one another, each unhappy family is unhappy in its own way.”¹⁴⁷ Our

143. Robert Zirkelbach, *What Makes Valeant Different Than Innovative Biopharmaceutical Companies?*, PHRMA (Oct. 22, 2015), <http://catalyst.phrma.org/what-makes-valeant-different-than-innovative-biopharmaceutical-companies>.

144. *PhRMA Board of Directors Establishes New Membership Criteria*, PHRMA (May 9, 2017), <http://www.phrma.org/press-release/phrma-board-of-directors-establishes-new-membership-criteria>.

145. See, e.g., Hancock, *supra* note 135 (noting that PhRMA has sought “to distance itself from drug companies earning bad headlines”); Tim McClung, *Biopharma Leads Sustained Economic Growth Driven by IP-intensive Industries*, PHRMA (Sept. 26, 2017), <http://catalyst.phrma.org/biopharma-leads-sustained-economic-growth-driven-by-ip-intensive-industries> (stressing the critical contributions that innovator companies have made in generating novel medicines and sustaining economic growth); Lydia Ramsey, *We Asked Pharma Executives the One Question They Didn’t Want to Hear About Drug Pricing*, BUS. INSIDER (Jan. 23, 2017), <http://www.businessinsider.com/what-if-drug-companies-no-longer-took-routine-price-increases-2017-1> (reporting that some companies have committed to limiting price increases for their products in reaction to pressure caused by “bad apples” that were taking extreme measures to jack up prices).

146. Nancy Yu et al., *R&D Costs for Pharmaceutical Companies Do Not Explain Elevated US Drug Prices*, HEALTH AFFAIRS (Mar. 7, 2017), <https://www.healthaffairs.org/doi/10.1377/hblog20170307.059036/full>.

147. LEO TOLSTOY, ANNA KARENINA 1 (Oxford U. Press 1999) (1877).

drug delivery system is among the unhappy families of American health policy, and its unhappiness is unique. Although some of its problems stem from features shared by other aspects of our healthcare system, it is also plagued by distinctive moral, market, and political problems.

Because of these factors, especially the lack of transparency, policy making in this area is like trying to find one's way out of a dense thicket in dim light. Some progress has been made in responding to some of the worst excesses that have occurred. But as satisfying as it may be to see Turing Pharmaceuticals' former CEO, Martin Shkreli, skewered for hiking the price of Daraprim, attention must be paid to the more fundamental problems contributing to high drug prices. Those problems are systemic, multifaceted, and much more subtle. That makes them exactly the type of problem that Congress is least likely to be able to solve. Finding the right prescription is the hardest problem in health policy today.