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THE COST OF HIGH PRICES: EMBEDDING AN ETHIC OF EXPENSE INTO THE STANDARD OF CARE

ISAAC D. BUCK

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THE COST OF HIGH PRICES: EMBEDDING AN ETHIC OF EXPENSE INTO THE STANDARD OF CARE

ISAAC D. BUCK*

Abstract: In the midst of rapid and radical change of America's health care system, the country's crown jewel public health insurance program, Medicare, faces an intensifying cost crisis due to a past of uncontrolled prices and a future of booming enrollment. A cost challenge garnering particular media attention is pharmaceutical drug pricing for Medicare Part B. Historically, congressional action has hamstrung Medicare's ability to limit costs, and as a result, the program is increasingly forced to pass on drug costs—through copays and coinsurance—to its elderly beneficiaries. Public outrage has followed recent stories of pharmaceutical companies seeking to increase their prices, and policymakers have called for increased regulation. Nevertheless, there may be better solutions to Medicare's pharmaceutical drug cost crisis. Recognition of "financial toxicity"—the effect of a pharmaceutical drug's price on the mortality of the patient undergoing treatment—provides a potential new foothold for health care regulation. Like other side effects, if the price of a pharmaceutical drug negatively impacts rates of survival, then the cost of the drug could be an important component of clinical decision making and, presumably, the standard of care. Linking the cost of a drug to its clinical efficacy could dramatically impact which drugs providers choose, giving Medicare a new tool in its efforts to become a better gatekeeper of the public fisc without relying on bureaucratic hard power or legal enforcement. Using the burgeoning field of new governance, this Article focuses on how law and policy could shift to reflect the new understanding of financial toxicity. Arguing that the phenomenon finally provides a connection between cost and quality, this Article examines the instantiation of cost within the ethic of care. This route may provide an opening for a limitation on the ever-increasing price of pharmaceutical drugs and provide a powerful, yet unarticulated, legal signal that drugs that cost too much negatively impact the quality of care that American patients receive.

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INTRODUCTION

More than three years before most Americans had ever heard of Martin Shkreli,¹ three cancer doctors at Memorial Sloan-Kettering Cancer Center (“Sloan-Kettering”) in New York City did something extraordinary.² Trum-peted in a self-authored *New York Times* opinion piece and further publi-cized by the television newsmagazine *60 Minutes*,³ the three doctors, Dr. Peter Bach, Dr. Leonard Saltz, and Dr. Robert Wittes, announced that they were declining to include Zaltrap, a new drug approved by the Food and Drug Administration (“FDA”) to treat colorectal cancer, on Sloan-Kettering’s hospital formulary list of approved drugs.⁴

That they had decided to exclude a drug from the formulary was un-remarkable, but their reason for doing so was astounding.⁵ According to the doctors, Sloan-Kettering would not prescribe Zaltrap for its cancer patients not because it had terrible side effects, nor because it was ineffective, but because it was *too expensive*.⁶ Remarkably, these preeminent providers at one of America’s leading cancer hospitals⁷ had refused to utilize a newly approved FDA drug that reportedly extended survival rates⁸ because of a concern over the threat of “financial toxicity”⁹ it posed to their patients.¹⁰ Particularly, the doctors noted that Zaltrap’s price was more than twice as

¹ Martin Shkreli is the CEO of Turing Pharmaceuticals, which was thrust into the national spot-light during the spring of 2016 after the pharmaceutical company acquired the H.I.V. drug Daraprim and raised its price. See Kelefa Sanneh, *Everyone Hates Martin Shkreli. Everyone Is Missing the Point*, NEW YORKER (Feb. 5, 2016), <http://www.newyorker.com/culture/cultural-comment/everyone-hates-martin-shkreli-everyone-is-missing-the-point> [https://perma.cc/X9YX-Q4GV].

² See Peter B. Bach et al., *In Cancer Care, Cost Matters*, N.Y. TIMES (Oct. 14, 2012), [http://www.nytimes.com/2012/10/15/opinion/a-hospital-says-no-to-an-11000-a-month-cancer-drug.html?_r=1&\[https://perma.cc/RXH4-8DCK\]](http://www.nytimes.com/2012/10/15/opinion/a-hospital-says-no-to-an-11000-a-month-cancer-drug.html?_r=1&[https://perma.cc/RXH4-8DCK]).

³ See Lesley Stahl, *The Cost of Cancer Drugs*, 60 MINUTES, CBS NEWS (Oct. 5, 2014), <http://www.cbsnews.com/news/the-cost-of-cancer-drugs/> [https://perma.cc/9YXW-J6E3].

⁴ See Bach et al., *supra* note 2.

⁵ See *id.*

⁶ *Id.*

⁷ See *Memorial Sloan Kettering Cancer Center*, U.S. NEWS & WORLD REP., <http://health.usnews.com/best-hospitals/area/ny/memorial-sloan-kettering-cancer-center-6213060/cancer> [https://perma.cc/RNN2-E3HG] (noting that Sloan-Kettering is ranked second in the nation for cancer care).

⁸ See Jenny Hope, *New Drug for Advanced Bowel Cancer Can Increase Patients’ Lives by Six Weeks*, DAILY MAIL (Mar. 3, 2013, 7:01 PM), <http://www.dailymail.co.uk/health/article-2287613/New-drug-advanced-bowel-cancer-increase-patients-lives-weeks.html> [https://perma.cc/TS97-99UV].

⁹ Financial Toxicity is a term that references the impact of costly care, particularly costly drugs, on one’s health status or mortality. See Carolyn Y. Johnson, *The Burden of Cancer Isn’t Just Cancer*, WASH. POST (Apr. 8, 2016), <https://www.washingtonpost.com/news/wonk/wp/2016/04/08/cancers-sinister-side-effect-financial-toxicity/> [https://perma.cc/SYG7-BT8R]; see also *infra* notes 213–270 and accompanying text.

¹⁰ See Stahl, *supra* note 3.

much as the clinical alternative drug named Avastin, but Zaltrap offered “no advantage over its competitors.”¹¹

As they did, the doctors encouraged other physicians “to consider the financial strains they may cause alongside the benefits they might deliver”¹² when deciding upon treatment regimens. In an exasperated call, they noted that “if no one else will act, leading cancer centers and other research hospitals should.”¹³ In terms more becoming of health policy bureaucrats than preeminent cancer doctors who make more money by treating more patients with more expensive pharmaceutical drugs,¹⁴ they noted that “[t]he future of our health care system, and of cancer care, depends on our using our limited resources wisely.”¹⁵

The decision garnered attention from all corners of the health policy world. A later *New York Times* editorial commended the doctors on their stand, calling it “unusually bold.”¹⁶ Too long assumed, academics noted that the story highlighted the “importance of purchaser willingness to pay as the basis of manufacturer price setting among cancer drugs in the U.S. market.”¹⁷ Other doctors supported the Sloan-Kettering decision.¹⁸ Patients decried their lack of consumer power in the marketplace but commended the doctors for their advocacy.¹⁹ For its part, the Biotechnology Industry Organization (“BIO”) blamed the insurance industry for the high prices of the

¹¹ See Bach et al., *supra* note 2.

¹² *Id.*

¹³ *Id.*

¹⁴ Under the Medicare program, doctors who administer in-office drugs, which includes many cancer doctors, get reimbursed based upon the price of the drug itself. See *Medicare Part B Drugs Payment Model*, CTRS. FOR MEDICARE & MEDICAID SERVS. (June 14, 2016), <https://innovation.cms.gov/initiatives/part-b-drugs> [<https://perma.cc/3SLJ-AW3U>]. Administering a more expensive drug thus brings a bigger profit for the physician.

¹⁵ See Bach et al., *supra* note 2.

¹⁶ Editorial, *Incredible Prices for Cancer Drugs*, N.Y. TIMES (Nov. 12, 2012), <http://www.nytimes.com/2012/11/13/opinion/incredible-prices-for-cancer-drugs.html> [<https://perma.cc/Q7HP-4H5L>] (“There are few constraints on escalating cancer drug prices in the current health care market. That will need to change. Sloan-Kettering has shown what the medical profession can do to reduce costs if it has a mind to.”).

¹⁷ Rena Conti & Ernst Berndt, *Winners and Losers from the Zaltrap Price Discount: Unintended Consequences?*, HEALTH AFF. BLOG (Feb. 20, 2013), <http://healthaffairs.org/blog/2013/02/20/winners-and-losers-from-the-zaltrap-price-discount-unintended-consequences/> [<https://perma.cc/7M9U-F7Y3>] (“Second, the episode underlines the fact that the threat of formulary coverage exclusion (in this case, by a prominent hospital) appears to have been an effective tool in altering the acquisition price of a branded physician-administered cancer drug in the U.S. It remains to be seen whether oncologists, other physician groups, hospitals and commercial insurers will increasingly exert their newly-found leverage to influence the price setting of other branded specialty pharmaceuticals in the U.S.”).

¹⁸ See *Incredible Prices for Cancer Drugs*, *supra* note 16.

¹⁹ See Jacqueline Dooley, *Dear America, Don't Get Sick*, HUFFINGTON POST: THE BLOG (Sept. 6, 2016), http://www.huffingtonpost.com/jacqueline-dooley/dear-america-dont-get-sic_b_8095440.html [<https://perma.cc/2RYP-X9JU>].

drugs.²⁰ The doctors had started a conversation, and had demonstrated something important.

The only thing more stunning than Sloan-Kettering's decision to exclude Zaltrap from its formulary was the reaction to the doctors' actions by the drug's pharmaceutical manufacturer, Sanofi.²¹ Within one month of *The New York Times* op-ed, Sanofi cut the price of Zaltrap in half.²² Sanofi would lower Zaltrap's price—at least for the first few months after the announcement—through a discount provided to doctors and hospitals but not to patients or to insurance programs.²³

Sloan-Kettering's decision to forcefully push back against the price of Zaltrap demonstrated how instrumental doctors and hospitals can—and, perhaps, must—be in the fight to limit rising expenditures in American health care. Indeed, long the hub in the administration and coordination of health care, physicians have been the target of policy changes that seek to control runaway costs,²⁴ but what occurred at Sloan-Kettering appeared to demonstrate something more powerful. The Zaltrap story seemed to prove, at least in the context of expensive pharmaceutical drugs, that if the expert party can change their belief about the effectiveness of a drug or the value of a procedure—while considering, or even *due to*, the cost of that drug or procedure—then achieving cost effectiveness without hard legal intervention may be a viable pathway in American medicine. If the administrator and deliverer of health care services care about cost, then the American health care system becomes more efficient.

By pushing Sanofi into cutting the price of Zaltrap, the physicians had achieved something no government entity had successfully accomplished. Indeed, left on the sidelines—impotent to control the runaway costs of

²⁰ See Bill Flook, *BIO Pushes Back on '60 Minutes' Report on Cancer Drug Costs, Shifts Blame to Insurers*, WASH. BUS. J. (Oct. 6, 2014, 5:10 PM), <http://www.bizjournals.com/washington/blog/techflash/2014/10/bio-pushes-back-on-60-minutes-report-on-cancer.html>.

²¹ See Stahl, *supra* note 3.

²² See Andrew Pollack, *Sanofi Halves Price of Cancer Drug Zaltrap After Sloan-Kettering Rejection*, N.Y. TIMES (Nov. 8, 2012), <http://www.nytimes.com/2012/11/09/business/sanofi-halves-price-of-drug-after-sloan-kettering-balks-at-paying-it.html> [<https://perma.cc/ZL6V-EJRT>].

²³ *Id.*; see also Conti & Berndt, *supra* note 17 (noting that the discount process that occurred after Sanofi cut the price of Zaltrap caused taxpayers and Medicare to overpay and “suggests another reason for policy makers to shorten the lag”).

²⁴ See, e.g., Jason Millman, *The Obama Administration Wants to Dramatically Change How Doctors Are Paid*, WASH. POST: WONKBLOG (Jan. 26, 2015), <https://www.washingtonpost.com/news/wonk/wp/2015/01/26/the-obama-administration-wants-to-dramatically-change-how-doctors-are-paid/> [<https://perma.cc/3DQS-7R54>] (noting the changes brought about by the Obama administration, most specifically, the “high-profile effort” of “accountable care organizations (ACOs), which are groups of providers who share in the savings—or losses—for managing patients on a budget”). As of early 2015, nearly eight million Medicare beneficiaries were enrolled in plans that were part of the ACO program. *Id.*

drugs²⁵—Medicare, the insurance provider for more than fifty-five million Americans,²⁶ continues to look for a way to limit rising costs. Truly bending the cost curve, the three doctors had accomplished something in one month that Medicare had been attempting for decades. The action seemed to unlock an unknown potential of the physician and the physician *alone*; the legal and regulatory schemas constructed over the last fifty-one years—and even the last eighty-two months²⁷—were of no import.

Through the first six-plus years of the Affordable Care Act (“ACA”) era, a debate has centered on what type and amount of governmental regulation is appropriate and necessary to wring out unnecessary costs and utilization from American health care. Even though the ACA has provoked this debate, it has not answered the question.²⁸ With the ACA’s future in doubt, the future of cost control is even more uncertain. Nevertheless, when it comes to pharmaceutical drugs, the ACA has not ushered in a new era of

²⁵ In its Prescription Drug Benefit Plan of Medicare Part D, Medicare is statutorily prevented from negotiating with drug companies. See Juliette Cubanski & Tricia Neuman, *Searching for Savings in Medicare Drug Price Negotiations*, KAISER FAM. FOUND. (Feb. 9, 2016), <http://kff.org/medicare/issue-brief/searching-for-savings-in-medicare-drug-price-negotiations/> [<https://perma.cc/HH57-MWJG>]. As mentioned:

Notably, Congress added language to the MMA, known as the “noninterference” clause, which stipulates that the HHS Secretary “may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors, and may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.” In effect, this provision means that the government can have no role in negotiating or setting drug prices in Medicare Part D. This is in stark contrast to how drug prices are determined in some other federal programs; for example, the statutory requirement for mandatory drug price rebates in Medicaid, and a requirement that drug manufacturers charge the Department of Veterans Affairs (VA) no more than the lowest price paid by any private-sector purchaser.

Id. Nevertheless, whether or not the Secretary were to receive such ability, it appears that price setting, exclusion, and other techniques may achieve real drug savings. *Id.*; see also Editorial, *Use Medicare’s Muscle to Lower Drug Prices*, N.Y. TIMES (Sept. 21, 2015), http://www.nytimes.com/2015/09/21/opinion/use-medicare-muscle-to-lower-drug-prices.html?_r=0 [<https://perma.cc/V9FM-NNFP>].

²⁶ *Total Number of Medicare Beneficiaries*, KAISER FAM. FOUND. (2015), <http://kff.org/medicare/state-indicator/total-medicare-beneficiaries/> [<https://perma.cc/4J4N-WTQ8>].

²⁷ President Obama signed the ACA into law on March 23, 2010, roughly eighty-two months ago. See Sheryl Gay Stolberg & Robert Pear, *Obama Signs Health Care Overhaul Bill, with a Flourish*, N.Y. TIMES (Mar. 23, 2010), <http://www.nytimes.com/2010/03/24/health/policy/24health.html> [<https://perma.cc/3B28-PKM4>].

²⁸ See Elisabeth Rosenthal, *How the High Costs of Medicare Care Is Affecting Americans*, N.Y. TIMES (Dec. 18, 2014), <http://www.nytimes.com/interactive/2014/12/18/health/cost-of-health-care-poll.html> [<https://perma.cc/BPW8-YR9Z>] (“While the Affordable Care Act has expanded insurance to millions of Americans, including those with existing conditions, it does not directly address cost. And cost is becoming increasingly problematic.”).

tighter governmental regulation and cost control in American health care.²⁹ Many of the pervasive, uniquely American problems regarding excess cost remain, seemingly spurred by a complex relationship between government intervention and medical and corporate autonomy.

Mindful of the nuance that is required to regulate such a complex industry, these tensions make it difficult for a blunt instrument like the law to effectively limit excessive cost and utilization. The tension also tracks the professional and regulatory rivalry between medicine and law; borne out of societal values that view providers as impenetrably independent, citizens hold deep concerns about a medical system that is controlled by a faceless bureaucracy.³⁰ The opposite and pervasive concern, however, features threats from an insular and self-interested medical profession, incentivized to excessively treat and overcharge, with monopolistic control of clinical expertise and medical decision making. In effect, the tension has paralyzed the law in its effort to effectively prevent overtreatment with precision and fairness. As a result, one in three dollars spent every year on American health care may be wasted.³¹

For their part, federal prosecutors have relied on powerful anti-fraud tools available to them in an attempt to crack down on unnecessary utilization and expense. Nevertheless, this has resulted in a haphazardly regulated web of individuals and entities with incentives and penalties pushing providers in opposite directions, draconian statutory anti-fraud penalties that seem to apply unevenly, and aggressive prosecutions that seek to stretch legal tools to, and perhaps, beyond, their limits. The anti-fraud tools are likely to fail in deterring overtreatment because they were never meant to apply to the overtreatment problem in the first place. Indeed, recent scholarship has sought to bring balance to a legal regulatory framework that seems

²⁹ See Caitlin Owens, *Why Prescription Drugs Aren't Part of Obamacare*, MORNING CONSULT (Mar. 24, 2016), <https://morningconsult.com/2016/03/24/why-prescription-drugs-arent-part-of-obamacare/> [<https://perma.cc/SL78-9YRS>].

After six years, the Affordable Care Act has extended health care coverage to millions of people. But affordability problems remain, most prominently in the area of prescription drugs. Obamacare left the pharmaceutical industry largely unregulated while requiring it to pay for some of the law's increased drug coverage . . . [D]rug companies are largely unregulated. They can set their own prices. There are no restrictions on profit margins. And there is very little transparency into the pricing process.

Id.

³⁰ Although the future of the ACA is uncertain, as of the fall of 2016, still only 44% of the American public supported the Affordable Care Act, with 51% opposed to it. See *More Americans Negative Than Positive About ACA*, GALLUP (Sept. 8, 2016), <http://www.gallup.com/poll/195383/americans-negative-positive-aca.aspx> [<https://perma.cc/Y3LW-5K5D>].

³¹ See Nicole Caferella Lallemand, *Reducing Waste in Health Care*, HEALTH POL'Y BRIEF, HEALTH AFF., Dec. 13, 2012, at 1 (noting that "a third or more of what the US spends annually may be wasteful").

to lack it: noting that the federal government should (1) recalibrate its fraud and abuse enforcement mechanism due to the threat of over-enforcement,³² (2) refocus its anti-fraud efforts on excessive utilization instead of care that allegedly lacks medical necessity,³³ (3) empower patients through bolstered informed consent to limit excessive health care,³⁴ and (4) consider moving toward a payer-provider fiduciary model in Medicare.³⁵

Beyond trying to improve an imperfect system, however, the Sloan-Kettering case teaches policy makers and legal academics something even more profound. Instead of fixing a disordered enforcement framework, or exploring new legal theories to attempt to rein in overtreatment, Sloan-Kettering teaches that providers *themselves*—outside of, apart from, and, indeed, truly independent of the anti-fraud context—have access to untapped power in reining in excess spending. It shows that if providers can be pushed to inculcate an ethic of cost into the provision of expensive health care and, subsequently, truly equate expensive care with substandard care, providers themselves can provide a roadmap to a more cost-effective health care marketplace. The lesson from New York may be that to effectively prevent overtreatment and truly bend the cost curve, law's chief goal may be to push doctors into being as mindful about excess cost and utilization as were the doctors at Sloan-Kettering—relying on tools that are located *outside* of the law.

Additionally, there may be an opening here. New thinking on the topic demonstrates the unsurprising but startling conclusion that, after all, expensive care is bad care.³⁶ Recent studies on “financial toxicity”—the stunning phenomenon that patients who are saddled with exorbitant medical costs actually experience *worse* health outcomes as a result of the cost of their care—suggest that treating a patient with an expensive pharmaceutical drug is not just bad for Medicare or the patient's financial wellbeing, but it may be bad for the patient's health as well.³⁷ If one can make the argument that choosing expensive drugs subjects the patient to untenable side effects (based upon the effect of the care on one's financial wellbeing, and therefore, one's physical health), then doctors have a duty to the patient to be

³² See Isaac D. Buck, *Enforcement Overdose: Health Care Fraud Regulation in an Era of Overcriminalization and Overtreatment*, 74 MD. L. REV. 259, 270–71 (2015).

³³ See Isaac D. Buck, *Breaking the Fever: A New Construct for Regulation Overtreatment*, 48 U.C. DAVIS L. REV. 1261, 1297–1307 (2015).

³⁴ See Isaac D. Buck, *Overtreatment and Informed Consent: A Fraud-Based Solution to Unwanted and Unnecessary Care*, 43 FLA. ST. L. REV. 901, 940–56.

³⁵ See Isaac D. Buck, *Furthering the Fiduciary Metaphor: The Duties of Providers to the Payers of Medicare*, 104 CALIF. L. REV. 1043, 1083–93 (2016).

³⁶ Johnson, *supra* note 9 (“[A] growing body of evidence suggests that, far from crass, ignoring cost could be harmful to patients' health.”).

³⁷ See *id.*

aware of, and probably avoid, treatments and drugs for their patients that are not cost effective. Mirroring the traditional medical malpractice regime, physicians who subject their patients to side effects that may harm their health may face common law legal liability. From this perspective, over-treatment regulation could migrate into malpractice regulation, finally spurring the type of legal development and direct focus that rising health care costs surely need.

This Article explores that argument. By pointing to the effects of financial toxicity and relying on the burgeoning scholarly field of new governance for doctrinal guidance, this Article makes the argument that a solution to America's unsustainable overtreatment problem may actually come from outside of the Department of Justice ("DOJ") or even the Centers for Medicare and Medicaid Services ("CMS"). Perhaps, buoyed by the increasing understanding of the negative *health* effects caused by excess cost, the answer to overtreatment relies upon making the argument to providers that overly expensive care is harmful to the patient. This new regime would regulate overtreatment by relying on incentives, pressure, and collaboration, all while moving away from adversarial legalism, as part of a larger effort to push providers into replicating what the three doctors at Sloan-Kettering did.

This Article proceeds in four parts. Part I provides a snapshot of the current state of American health care, particularly focused on the drivers of its cost.³⁸ Part II summarizes the long history of Medicare drug reimbursement policy, with a particular focus on a segment of Medicare reimbursement, Medicare Part B, which has garnered national attention due to recent events.³⁹ Part III presents the phenomenon of financial toxicity.⁴⁰ Finally, Part IV places the effect of financial toxicity on the law with the doctrinal support of new governance, accompanied by an argument that instantiation of the concern of cost—embedded within the clinical standard of care—may be the best way out of America's overtreatment challenge.⁴¹

I. THE COST OF HEALTH

Over six years after the passage of the imperiled ACA bolstered and reconstructed health care delivery, coverage, and access, the health care cost crisis has only grown in intensity.⁴² Millions of Americans face rising drug

³⁸ See *infra* notes 42–88 and accompanying text.

³⁹ See *infra* notes 89–212 and accompanying text.

⁴⁰ See *infra* notes 213–270 and accompanying text.

⁴¹ See *infra* notes 271–293 and accompanying text.

⁴² See Chad Terhune, *U.S. Health Spending Hits \$3 Trillion as Obamacare and Rising Drug Costs Kick in*, L.A. TIMES (Dec. 2, 2015, 1:00 PM), <http://www.latimes.com/business/healthcare/la-fi-health-spending-increase-20151202-story.html> [<https://perma.cc/U6J8-5T33>] (noting that

costs, higher deductibles,⁴³ escalating premiums, and, increasingly, unsustainable copays.⁴⁴ For sure, the ACA pumped people into the insurance marketplace,⁴⁵ expanded access for millions of lower-income Americans through Medicaid,⁴⁶ reformed the character of the insurance plans sold on that health insurance marketplace,⁴⁷ and funded efforts to creatively explore different reimbursement mechanisms,⁴⁸ but did not apply any cost controls to the *price* of health care.⁴⁹ Nor did the ACA's structure that built upon

America spent more than \$9500 per person on health care in 2014, "far higher than what other developed countries pay"). Government officials have noted, however, that the increase in annual health care costs was less than it would have been without the Affordable Care Act. *Id.*

⁴³ See Robert Pear, *Many Say High Deductibles Make Their Health Law Insurance All but Useless*, N.Y. TIMES (Nov. 14, 2015), <http://www.nytimes.com/2015/11/15/us/politics/many-say-high-deductibles-make-their-health-law-insurance-all-but-useless.html> [https://perma.cc/Q2J8-2T9E] (noting the story of individuals who cannot afford to use insurance due to their high deductibles, and finding that "more than half the plans offered for sale through HealthCare.gov . . . have a deductible of \$3,000 or more"); see also Timothy Jost, *Affordability: The Most Urgent Health Reform Issue for Ordinary Americans*, HEALTH AFF. BLOG (Feb. 29, 2016), <http://healthaffairs.org/blog/2016/02/29/affordability-the-most-urgent-health-reform-issue-for-ordinary-americans/> [https://perma.cc/VES7-D9YR] (noting that many Americans living well-above the poverty line "do not have enough to even pay for the deductible of their coverage, much less the out-of-pocket limit"). Further, the "standard silver plan deductibles for individuals without cost-sharing reductions average above \$3,000, a greater amount than many families have available in liquid assets." Jost, *supra*.

⁴⁴ Joseph Walker, *Patients Struggle with High Drug Prices*, WALL STREET J. (Dec. 31, 2015, 10:38 AM), <http://www.wsj.com/articles/patients-struggle-with-high-drug-prices-1451557981> [https://perma.cc/CH7N-FKPH] (noting that "the expense of new cancer drugs is burdensome for growing numbers of patients whose insurance entails substantial copays").

⁴⁵ More than twelve million Americans purchased a health insurance plan on a health insurance exchange during the open enrollment period in 2016. *Health Insurance Marketplace Open Enrollment Snapshot—Week 13*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Feb. 4, 2016), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-02-04.html> [https://perma.cc/E69G-V8VH] (noting that 12.7 million Americans had signed up for insurance plans through the health insurance marketplaces during the open enrollment period that ended at the end of January).

⁴⁶ As of the fall of 2016, thirty-two states and the District of Columbia had expanded their Medicaid programs. *Status of State Action on the Medicaid Expansion Decision*, KAISER FAM. FOUND. (Oct. 14, 2016), <http://kff.org/health-reform/state-indicator/state-activity-around-expanding-medicare-under-the-affordable-care-act/> [https://perma.cc/HA6N-FX5A]. The four states with the largest uninsured population as a percentage of state population in 2016—Texas, Georgia, Oklahoma, and Florida—were all non-expansion states. *Health Insurance Coverage of the Total Population*, KAISER FAM. FOUND. (2014), <http://kff.org/other/state-indicator/total-population/> [https://perma.cc/RF86-4HQW]. In 2014, Texas alone had over four million residents who were uninsured. *See id.*

⁴⁷ See *Health Insurance Market Reforms*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/CIIH/Programs-and-Initiatives/Health-Insurance-Market-Reforms/> [https://perma.cc/73Q3-RMXY] (briefly providing a synopsis of reforms).

⁴⁸ See, e.g., *Pioneer ACO Model*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://innovation.cms.gov/initiatives/Pioneer-aco-model/> [https://perma.cc/8MMQ-4UP9] (providing details of the Pioneer ACO Model).

⁴⁹ In the summer of 2016, President Obama made a compelling case for the creation of the public option within the ACA. See Paul Demko, *Obamacare's Sinking Safety Net*, POLITICO (July

America's private insurance delivery system—unlike, for example, a European single payer regime or even a public option—allow for concerted governmental intervention regarding the price of health care itself.

In some ways, the failure of the United States to adequately address its unsustainable health care finance system may be characterized as a failure of law, but inaction on the cost crisis is due to a number of recognizable societal tensions. In some corners, the cost challenge seems to be borne out of a fear of overregulating and inappropriately constraining a private industry—any private industry, no matter how purportedly “greedy” it is.⁵⁰ Relatedly, perhaps there is concern involved with empowering a government body to seek to cut costs in a country that values personal and corporate freedom. Additional challenges uniquely suited to health care persist: (1) health care is deeply personal and vital to one's identity and self, (2) reimbursement and monetary incentives are not always aligned to limit cost growth, and (3) health care is not easily standardized or reducible to government-enforced standards.

As new research continues to show, America's health care cost crisis can be blamed on two overlapping but general causes: (1) high prices and (2) excess utilization.⁵¹ In an era of dramatic reform, neither of the causes has been adequately addressed by law. Some of the ACA's reforms did seek to incentivize providers to become more cost-conscious of the care they provide. For instance, those who enroll in Accountable Care Organizations (“ACOs”) and in the Medicare Shared Savings Program (“MSSP”) have an incentive to be more aware of cost,⁵² but the reforms are limited, and many

13, 2016, 4:57 AM), <http://www.politico.com/agenda/story/2016/07/obamacare-exchanges-states-north-carolina-000162> [https://perma.cc/LKV8-TA9K] (highlighting the plight of insurance companies that have signed up for the individual exchange, the smaller than expected enrollment numbers, and the reinvigoration of the push toward a public option).

⁵⁰ See Dan Diamond, *Greedy Pharma CEO Cancels 5,000% Price Hike—But He Didn't Fix the Real Problem*, FORBES (Sept. 22, 2015, 11:05 PM), <http://www.forbes.com/sites/dandiamond/2015/09/22/greedy-pharma-executive-cancels-5000-price-hike-but-he-didnt-fix-the-real-problem/#5a061d2d2a26> [http://web.archive.org/web/20160903131414/http://www.forbes.com/sites/dandiamond/2015/09/22/greedy-pharma-executive-cancels-5000-price-hike-but-he-didnt-fix-the-real-problem/#66870301e42b]; Jeffrey Young, *Pharma Bro Emails Reveal Just How Greedy Drug Companies Can Be*, HUFFINGTON POST (Feb. 2, 2016, 6:24 PM), http://www.huffingtonpost.com/entry/martin-shkreli-pharma-bro-drug-prices_us_56b0fac5e4b0655877f75453 [https://perma.cc/9ESR-WEN6].

⁵¹ Atul Gawande, *Health Care's Price Conundrum*, NEW YORKER (Dec. 18, 2015), <http://www.newyorker.com/news/news-desk/health-cares-cost-conundrum-squared> [https://perma.cc/8834-KT76] (noting that Medicare's costs are impacted by utilization, whereas private insurance costs are impacted most by pricing and consolidation).

⁵² Nevertheless, this is a voluntary program, and early results from the MSSP are mixed, to say the least. See Buck, *supra* note 34, at 933.

are voluntary.⁵³ As a result, the new tools put in place by the ACA likely do not go far enough.

Section A discusses the first cause of the increasing price of health care, high prices, including the impact of providers' horizontal and vertical consolidation.⁵⁴ Section B describes the second driving of increasing health care costs, high utilization.⁵⁵ Section C finally discusses the interplay between the two factors.⁵⁶

A. High Prices

First, America's health care cost crisis is largely caused by incomparably high and opaque prices, particularly from hospitals.⁵⁷ Uncapped, health care prices, the costs that hospitals and pharmaceutical companies charge for surgeries, pills, and even paper clips, are just "too damn high."⁵⁸ Americans have known for years that the price of the health care they receive—the sticker price for health care procedures and drugs—far outpaces the costs of health care in other peer countries.⁵⁹ Whereas other countries rely on rate setting or government negotiation to control the cost of health care, America has no such control of its fragmented marketplace.⁶⁰

A central reason U.S. health care spending is so high is that hospitals and doctors charge more for their services and there's little transparency about why The result is a tangled, confusing and largely secretive collection of forces driving health care pric-

⁵³ See, e.g., *Overview of Select Alternative Payment Models*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Mar. 3, 2016), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-03-03.html> [<https://perma.cc/3CUE-DC5X>] (noting that "[p]rovider participation in an ACO is purely voluntary").

⁵⁴ See *infra* notes 57–74 and accompanying text.

⁵⁵ See *infra* notes 75–81 and accompanying text.

⁵⁶ See *infra* notes 82–88 and accompanying text.

⁵⁷ See Erin C. Fuse Brown, *Irrational Hospital Pricing*, 14 HOUS. J. HEALTH L. & POL'Y 11, 15 (2014) ("Despite the enormous administrative costs exacted by this complicated pricing system, hospitals have incentives to inflate the chargemaster to increase bargaining leverage over health plans and maximize profit.").

⁵⁸ David Wolman, *Drug Prices Are Too Damn High. Here's How to Fix Them*, WIRED (Dec. 1, 2015, 6:40 AM), <http://www.wired.com/2015/12/rising-drug-costs/> [<https://perma.cc/5U94-4S98>]; see Matthew Yglesias, *Health Care Is Expensive Because the Prices Are High*, SLATE (Feb. 16, 2012, 10:48 AM), http://www.slate.com/blogs/moneybox/2012/02/16/health_care_is_expensive_because_the_prices_are_high.html [<https://perma.cc/D3NQ-EUZR>].

⁵⁹ See, e.g., Elisabeth Rosenthal, *Paying Till It Hurts* (series), N.Y. TIMES (June 1, 2013–Dec. 18, 2014), <http://www.nytimes.com/interactive/2014/health/paying-till-it-hurts.html> [<https://perma.cc/J5MB-BZ3W>] (detailing high cost of health care in the United States, compared to other countries).

⁶⁰ See Kate Pickert, *Why Our Health Care Lets Prices Run Wild*, TIME (July 1, 2013), <http://swampland.time.com/2013/07/01/why-our-health-care-lets-prices-run-wild/> [<https://perma.cc/7HGE-UDRD>].

es higher and higher. This isn't possible in many other countries either because governments set prices for health care services or broker negotiations between coalitions of insurers and providers. Known as "all-payer rate setting," insurers in these systems band together to negotiate as groups.⁶¹

The American problem is due to more than just regulatory inaction, however; providers, hospitals, and systems are merging and consolidating, and this has likely intensified the price crisis by saturating markets.⁶² Further, largely due to cost pressures, more than fifty rural hospitals have closed since 2010, additionally removing competitors of the large hospital systems, and, of course, dramatically threatening access for rural Americans.⁶³

The staggering connection between consolidation in the marketplace and higher prices in health care has most recently been demonstrated by a compelling 2015 study by the Health Care Pricing Project.⁶⁴ The study concluded "hospital prices in monopoly markets [were] 15.3 percent higher than those in markets with four or more hospitals."⁶⁵ Further, "[m]arkets with two hospitals had prices roughly six percent higher than those with four or more hospitals," and "[t]hree-hospital towns had prices about five percent higher than those with at least four hospitals."⁶⁶ Indeed, according to another 2012 study, when hospitals in concentrated markets merge, "the price increase can be dramatic, often exceeding 20 percent."⁶⁷

⁶¹ *Id.*

⁶² See Melanie Evans, *Data Suggest Hospital Consolidation Drives Higher Prices for Privately Insured*, MOD. HEALTHCARE (Dec. 15, 2015), <http://www.modernhealthcare.com/article/20151215/NEWS/151219906> [<https://perma.cc/43SC-KYLP>] (noting that "[t]he findings are significant as hospitals across the country continue a deal binge that has consolidated markets and created new regional giants").

⁶³ See Paul Demko, *As Rural Hospitals Struggle, Solutions Sought to Preserve Healthcare Access*, MOD. HEALTHCARE (May 16, 2015), <http://www.modernhealthcare.com/article/20150516/MAGAZINE/305169959> [<https://perma.cc/34CW-FLFC>]; see also N. Douthit et al., *Exposing Some Important Barriers to Health Care Access in the Rural USA*, 129 PUB. HEALTH 611, 611 (2015) (finding that rural Americans are reluctant to seek health care "based on cultural and financial constraints, often compounded by a scarcity of services, a lack of trained physicians, insufficient public transport, and poor availability of broadband internet services"); Molly O'Toole, *Rural Americans Face Greater Lack of Healthcare Access*, REUTERS (July 27, 2011, 2:12 PM), <http://www.reuters.com/article/us-rural-idUSTRE76Q0MJ20110727> [<https://perma.cc/CH2U-MRKK>].

⁶⁴ See Zack Cooper et al., *The Price Ain't Right? Hospital Prices and Health Spending on the Privately Insured 6–7* (Dec. 2015) (unpublished manuscript) (on file with Health Care Pricing Project).

⁶⁵ *Id.* at i (alteration in original). This amounts to about \$2000 more per hospital admission. See Evans, *supra* note 62.

⁶⁶ Evans, *supra* note 62.

⁶⁷ Martin Gaynor & Robert Town, *The Impact of Hospital Consolidation—Update*, ROBERT WOOD JOHNSON FOUND., June 2012, at 1, http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2012/rwjf73261 [<https://perma.cc/3PZM-R899>].

Within the American health care industry, consolidation is well underway, and it is accelerating.⁶⁸ Hospitals are consolidating both “vertically” and “horizontally,”⁶⁹ with more than one hundred mergers and deals closed in 2014, which was a substantial increase over 2013.⁷⁰ Stunningly, at the beginning of this millennium, “one in 20 specialists were hospital employees; now the ratio is one in four.”⁷¹ In 2014, Deloitte made the bold prediction that “[i]f horizontal consolidation continues during the coming decade . . . likely only fifty percent of today’s unique health systems are expected to remain.”⁷² This “rapid consolidation” poses risks to the marketplace, most specifically the “effect on rising prices,” largely due to the effect consolidation has on “the increased bargaining power it can give health systems in contract negotiations, which plans assert, may increase consumer prices.”⁷³ When it comes to cost, providers, hospitals, and pharmaceutical companies own an increasing amount of the leverage, whereas insurance companies, government programs, and patients in the fragmented American health care marketplace have increasingly limited options other than simply paying more for health care each year.⁷⁴

⁶⁸ See Melanie Evans, *Consolidation Creating Giant Hospital Systems*, MOD. HEALTHCARE (June 21, 2014), <http://www.modernhealthcare.com/article/20140621/MAGAZINE/306219980> [<https://perma.cc/W5V9-D4WH>] (“Large regional and national healthcare systems are getting bigger and markets are increasingly consolidating, Modern Healthcare’s annual survey of hospital systems shows.”).

⁶⁹ *Hospital Consolidation: Can It Work This Time?*, KNOWLEDGE AT WHARTON (May 11, 2015), <http://knowledge.wharton.upenn.edu/article/hospital-consolidation-can-it-work-this-time/> [<https://perma.cc/K58C-LLHE>]; see also Gaynor & Town, *supra* note 67, at 3 (noting “limited data” demonstrates that vertical consolidation is “increasing”).

⁷⁰ See David Brodwin, *Death by Monopoly*, U.S. NEWS & WORLD REP. (Aug. 17, 2015, 8:30 AM), <http://www.usnews.com/opinion/economic-intelligence/2015/08/17/health-care-consolidation-is-a-disease-not-a-cure> [<https://perma.cc/8T7T-R2JF>].

⁷¹ *Id.*

⁷² *The Great Consolidation: The Potential for Rapid Consolidation of Health Systems*, DELOITTE, 2014, at 9.

⁷³ *Id.* at 1, 13.

⁷⁴ Interestingly, major health insurance companies have announced mergers that have been challenged by the DOJ during the summer of 2016 in court. See Leslie Picker & Reed Abelson, *U.S. Sues to Block Anthem-Cigna and Aetna-Humana Mergers*, N.Y. TIMES (July 21, 2016), <http://www.nytimes.com/2016/07/22/business/dealbook/us-sues-to-block-anthem-cigna-and-aetna-humana-mergers.html> [<https://perma.cc/KD29-RUXM>] (noting Attorney General Lynch as saying, “If these mergers were to take place, the competition among insurers that has pushed them to provide lower premiums, higher-quality care and better benefits would be eliminated . . .”). The increased cost of health coverage, and the fact that the exchanges created under the ACA have been sicker than anticipated, has led the largest health insurance company in the United States to end its participation in a majority of health care exchanges. See Carolyn Y. Johnson, *UnitedHealth Group to Exit Obamacare Exchanges in All but a “Handful” of States*, WASH. POST: WONKBLOG (Apr. 19, 2016), <https://www.washingtonpost.com/news/wonk/wp/2016/04/19/unitedhealth-group-to-exit-obamacare-exchanges-in-all-but-a-handful-of-states/> [<https://perma.cc/VLX4-PA7R>] (noting that this decision was made based on the fact that United was losing money on the exchanges, and has “reported that it expects to lose \$650 million in the exchanges in 2016”).

B. High Utilization

Second, the entities providing health care in America are providing *too much* of it.⁷⁵ This cause largely impacts the rising costs of Medicare each year; indeed, Medicare has the ability to set rates for procedures and health care goods, but, as explored more deeply below, it cannot set, nor negotiate, rates for pharmaceutical drugs in Part D.⁷⁶ Nonetheless, for the regions of the country with the highest Medicare bills, the global cost of health care is due to the amount of health care that is provided in those regions.⁷⁷

Utilization challenges, however, exist outside of Medicare as well.⁷⁸ The total number of scans and tests performed in the United States continues at staggering rates,⁷⁹ and Americans do not experience better health as a result.⁸⁰ The causes of overutilization-based overtreatment are multifacet-

⁷⁵ See Isaac D. Buck, *Caring Too Much: Misapplying the False Claims Act to Target Overtreatment*, 74 OHIO ST. L.J. 463, 473–79 (2013).

⁷⁶ See Philip Moeller, *Column: Why Does Medicare Allow for the Price Gouging of Prescription Drugs?*, PBS (Oct. 7, 2015, 12:19 PM), <http://www.pbs.org/newshour/making-sense/medicare-allow-price-gouging-prescription-drugs/> [https://perma.cc/ZL4Y-CC37].

⁷⁷ See Buck, *supra* note 35, at 1047–49; Atul Gawande, *The Cost Conundrum*, NEW YORKER (June 1, 2009), <http://www.newyorker.com/magazine/2009/06/01/the-cost-conundrum> [https://perma.cc/6ME6-4JCP].

⁷⁸ See Buck, *supra* note 75, at 463 (noting the amount of excess utilization within American health care).

⁷⁹ See Atul Gawande, *Overkill*, NEW YORKER (May 11, 2015), <http://www.newyorker.com/magazine/2015/05/11/overkill-atul-gawande> [https://perma.cc/V8PM-X85Z].

The United States is a country of three hundred million people who annually undergo around fifteen million nuclear medicine scans, a hundred million CT and MRI scans, and almost ten billion laboratory tests. Often, these are fishing expeditions, and since no one is perfectly normal you tend to find a lot of fish. If you look closely and often enough, almost everyone will have a little nodule that can't be completely explained, a lab result that is a bit off, a heart tracing that doesn't look quite right. Excessive testing is a problem for a number of reasons. For one thing, some diagnostic studies are harmful in themselves—we're doing so many CT scans and other forms of imaging that rely on radiation that they are believed to be increasing the population's cancer rates. These direct risks are often greater than we account for. What's more, the value of any test depends on how likely you are to be having a significant problem in the first place. If you have crushing chest pain and shortness of breath, you start with a high likelihood of having a serious heart condition, and an electrocardiogram has significant value. . . . But, if you have no signs or symptoms of heart trouble, an electrocardiogram adds no useful information; a heart tracing that doesn't look quite right is mostly noise. Experts recommend against doing electrocardiograms on healthy people, but millions are done each year, anyway.

Id.

⁸⁰ See Grace Rubenstein, *New Health Rankings: Of 17 Nations, U.S. Is Dead Last*, THE ATLANTIC (Jan. 10, 2013), <http://www.theatlantic.com/health/archive/2013/01/new-health-rankings-of-17-nations-us-is-dead-last/267045/> [https://perma.cc/EN5U-GDB7]; David Squires & Chloe Anderson, *U.S. Health Care from a Global Perspective*, COMMONWEALTH FUND (Oct. 8, 2015), <http://www.commonwealthfund.org/publications/issue-briefs/2015/oct/us-health-care-from-a-global-perspective> [https://perma.cc/ZY5L-ETEZ] (“[D]espite its heavy investment in health care,

ed—from financial inducements, to fragmentation and “siloization” in the health care delivery system, to liability concerns and defensive medicine, to America’s technological arms race.⁸¹ All these causes lead to rampant overutilization of medical services, shepherded by a medical community that seems too infrequently interested in controlling the amount of health care that is provided each year, let alone its cost.

C. Interplay Between Prices and Utilization

Combining both of the causes of rising costs makes for a multifaceted challenge facing health care law and policy experts. A policy meant to solve one of the causes may exacerbate the other. This is particularly true when one examines the ACA-based reforms that are intended to encourage collaboration between providers and entities in ACOs, for instance.⁸²

On one hand, the formation of ACOs may encourage providers and entities to be better stewards of health care resources by being more sensitive to the *amount* of health care they provide; indeed, they are financially incentivized to collaborate and cut down on fragmentation and unnecessary services.⁸³ A potential byproduct of that incentive may push providers into formal collaboration in new networks or mergers, which would instead lead to further consolidation of the market, and may directly result in higher prices.⁸⁴ When and whether a market could be benefitted or harmed by increased consolidation is “not always the same because it depends on the environment in which consolidation occurs.”⁸⁵ Excess utilization and excess price are different species, and the treatment for one may worsen the other.

For its part on both causes, the law has been unable to adequately solve the challenge. Perhaps this is due to the fact that there is no federal

the U.S. sees poorer results on several key health outcome measures such as life expectancy and the prevalence of chronic conditions.”).

⁸¹ See Buck, *supra* note 75, at 473–79.

⁸² See Millman, *supra* note 24.

⁸³ *Id.*

⁸⁴ See David M. Cutler & Fiona Scott Morton, *Hospitals, Market Share, and Consolidation*, 310 J. AM. MED. ASS’N 1964, 1964 (Nov. 2013).

Policy makers both revere and revile these health systems. On the one hand, lack of coordination has long been seen as a key failure of US health care. Integrated health systems have the capacity to address the quality deficiency resulting from lack of coordination. On the other hand, health systems can become so large that they are able to increase prices, harming consumers and taxpayers. Thus, there are increasing calls for greater antitrust scrutiny of hospital systems.

Id.

⁸⁵ *Id.* at 1970.

statutory scheme that is dedicated to capping overly expensive prices,⁸⁶ nor one specifically focused on reining in non-fraudulent unnecessary costs or procedures in American health care.⁸⁷ This is particularly true when it comes to the cost of prescription drugs in America's health care system. An exploration of the regulatory environment for the cost of pharmaceutical drugs, specifically Medicare Part B's history of price regulation, follows.⁸⁸

II. THE PROBLEM OF PRESCRIPTION DRUGS

In late September 2015, newspapers and magazines plastered the face of the thirty-one year-old CEO of Turing Pharmaceuticals ("Turing"), Martin Shkreli, across their pages.⁸⁹ Turing, an infantile pharmaceutical company,⁹⁰ had just acquired the rights to Daraprim, a drug used to treat HIV infections, and had raised its price by 5000% overnight.⁹¹ Immediately, Tu-

⁸⁶ Maryland is currently the only state that requires all parties to pay the same amount for health care. See *Maryland All-Payer Model*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Feb. 6, 2015), <https://innovation.cms.gov/initiatives/Maryland-All-Payer-Model/> [<https://perma.cc/FBR7-9VC9>] ("Maryland operates the nation's only all-payer hospital rate regulation system.").

⁸⁷ See Buck, *supra* note 75, at 479–82 (noting how the anti-fraud statutes are not a substitute for a scheme focused on limiting overutilization).

⁸⁸ See *infra* notes 89–212 and accompanying text.

⁸⁹ See Ariana Eunjung Cha, *CEO Who Raised Price of Old Pill More Than \$700 Calls Journalist a "Moron" for Asking Why*, WASH. POST (Sept. 22, 2015), <https://www.washingtonpost.com/news/to-your-health/wp/2015/09/21/ceo-of-company-that-raised-the-price-of-old-pill-hundreds-of-dollars-overnight-calls-journalist-a-moron-for-asking-why/> [<https://perma.cc/N48H-RVUJ>]; Andrew Pollack, *Drug Goes from \$13.50 a Tablet to \$750, Overnight*, N.Y. TIMES (Sept. 20, 2015), <http://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html> [<https://perma.cc/27BM-HSKR>]; Zoë Schlanger, *Martin Shkreli on Raising Price of AIDS Drug 5,000 Percent: 'I Think Profits Are a Great Thing'*, NEWSWEEK (Sept. 21, 2015, 5:39 PM), <http://www.newsweek.com/martin-shkreli-daraprim-drug-prices-374922> [<https://perma.cc/5B6D-ULEL>].

⁹⁰ See Arlene Weintraub, *Gadfly Pharma Investor Shkreli Starts Anew After Ousting from Retrophin*, FORBES (Feb. 27, 2015, 9:10 AM), <http://www.forbes.com/sites/arnelneweintraub/2015/02/27/gadfly-pharma-investor-shkreli-starts-anew-after-ousting-from-retrophin/#6928a92f359d> [<http://web.archive.org/web/20160516123356/http://www.forbes.com/sites/arnelneweintraub/2015/02/27/gadfly-pharma-investor-shkreli-starts-anew-after-ousting-from-retrophin/#6eed528219f4>] ("Shkreli this week unveiled his new company, Turing Pharmaceuticals, which he's launching with three drugs acquired from Retrophin," described as "a biotech startup he founded").

⁹¹ See John Russell, *After 5,000% Daraprim Hike, Pharma CEO 'Would Have Raised Prices Higher'*, CHI. TRIB. (Dec. 4, 2015), <http://www.chicagotribune.com/business/ct-turing-doubles-down-1205-biz-20151204-story.html> [<https://perma.cc/HJK6-TEVW>] ("I would have raised prices higher," [Shkreli] told an audience at the Forbes Healthcare Summit in New York, according to Forbes.com. "That's my duty." "My shareholders expect me to make the most profit," Shkreli added. "that's the ugly, dirty truth.") (alteration in original); see also Matthew Herper, *Martin Shkreli: 'I Would've Raised Prices Higher'*, FORBES, <http://www.forbes.com/video/4644635141001/> [<http://web.archive.org/web/20160826113913/http://www.forbes.com/video/4644635141001/>].

ring, and more specifically, the “live wire”⁹² and “unapologetic”⁹³ Shkreli, was pushed into the national spotlight.

Not only was the price increase indicative of corporate greed, newspapers, websites, and magazines argued,⁹⁴ but the usage of Daraprim, which treats infections that affect individuals with “compromised immune systems,” made the corporate policy seem even more immoral.⁹⁵ Daraprim is a drug used to treat two infections caused by parasites, malaria and toxoplasma,⁹⁶ and particularly, the drug prevents “a nervous system infection in those with HIV.”⁹⁷ Not only was Turing raising the price to an untenable level, they argued, but it was not doing it for a drug that treated allergies or colds; no, it was changing the price of a drug that Americans—many of whom had faced well-documented discrimination and societal exclusion and, as a result, access challenges—relied on to prevent deadly infections.⁹⁸ Nevertheless, by late November, Shkreli and Turing had offered a discount program for hospitals.⁹⁹

Throughout the fall, however, Shkreli became the bigger story.¹⁰⁰ His combative response to the outrage gave the story immediate cache.¹⁰¹ At

⁹² Weintraub, *supra* note 90.

⁹³ Russell, *supra* note 91.

⁹⁴ See, e.g., Samantha Allen, *Martin Shkreli Is Big Pharma's Biggest A**hole*, DAILY BEAST (Sept. 21, 2015, 5:54 PM), <http://www.thedailybeast.com/articles/2015/09/21/martin-shkreli-is-big-pharma-s-biggest-asshole.html> [<https://perma.cc/U4EC-ETL7>] (filing the article under “despicable” and calling Daraprim’s price increase “reprehensible,” but noting that “there’s no way to stop [Shkreli]”) (alteration in original).

⁹⁵ See Pollack, *supra* note 89 (noting that “Daraprim . . . is used mainly to treat toxoplasmosis, a parasite infection that can cause serious of even life-threatening problems for babies born to women who become infected during pregnancy, and also for people with compromised immune systems, like AIDS patients and certain cancer patients”). Interestingly, Express Scripts offered a treatment to compete with Daraprim and priced its drug at \$1 per pill, compared to \$750 per pill for Daraprim. See *Express Scripts Offers \$1 Alternative to \$750 Daraprim Pill*, CBS NEWS (Dec. 1, 2015, 11:05 AM), <http://www.cbsnews.com/news/express-scripts-will-offer-1-alternative-to-750-daraprim-pill/> [<https://perma.cc/4CGE-7LPQ>].

⁹⁶ Pollack, *supra* note 89.

⁹⁷ Emma Court, *Here's Why Daraprim Still Costs \$750 a Pill*, MARKETWATCH (Feb. 4, 2016, 3:33 PM), <http://www.marketwatch.com/story/heres-why-daraprim-still-costs-750-a-pill-2016-02-03> [<https://perma.cc/Z6YS-NUCW>].

⁹⁸ Individuals with HIV have faced discrimination by medical professionals. See, e.g., *Howe v. Hull*, 874 F. Supp. 779, 782 (N.D. Ohio 1994) (detailing claim of discrimination by doctors against HIV-positive patient).

⁹⁹ See Emily Mullin, *Turing Pharma Says Daraprim Availability Will Be Unaffected by Shkreli Arrest*, FORBES (Dec. 21, 2015, 2:15 PM), <http://www.forbes.com/sites/emilymullin/2015/12/21/turing-pharma-says-daraprim-availability-will-be-unaffected-by-shkreli-arrest/#7258c6cb2e82> [<http://web.archive.org/web/20161110120131/http://www.forbes.com/sites/emilymullin/2015/12/21/turing-pharma-says-daraprim-availability-will-be-unaffected-by-shkreli-arrest/#601342fd1566>].

¹⁰⁰ Interestingly, by November of 2015, Shkreli had also become the CEO of KaloBios, a biotech company. See Arlene Weintraub, *Here's Why Shkreli Is Going to Have His Hands Full Trying to Save KaloBios*, FORBES (Nov. 19, 2015, 12:41 PM), <http://www.forbes.com/sites/arleneweintraub/2015/11/19/heres-why-shkreli-is-going-to-have-his-hands-full-trying-to-save-kalobios/>

times, his testimony on Capitol Hill seemed close to inciting a congressional riot.¹⁰² His backstory, including a past stint as a CEO of a company he started that was not lacking in controversy, added intrigue.¹⁰³ Multiple outlets referred to him repeatedly as “pharma bro,” perhaps in an attempt to cast him as an unconcerned and amoral millennial lacking regard for the greater good.¹⁰⁴ Other outlets called him the “most hated man in Ameri-

#e81c50a2996c [http://web.archive.org/web/20161104071002/http://www.forbes.com/sites/arlene-weintraub/2015/11/19/heres-why-shkreli-is-going-to-have-his-hands-full-trying-to-save-kalobios/#5fe5039a7ce2]. By December of that year, KaloBios had fired him as its CEO and filed for bankruptcy. See *KaloBios Pharmaceuticals Files for Bankruptcy in Wake of Shkreli Arrest*, REUTERS (Dec. 30, 2015, 5:28 PM), <http://www.reuters.com/article/us-kalobios-bankruptcy-idUSKBN0UD0ND20151230> [https://perma.cc/Y6PG-UFYP].

¹⁰¹ Jonathan D. Rockoff, *Martin Shkreli: From Biotech Entrepreneur to Accused Criminal*, WALL STREET J. (Dec. 17, 2015, 5:33 PM), <http://www.wsj.com/articles/martin-shkreli-from-biotech-entrepreneur-to-accused-criminal-1450389335> [https://perma.cc/EUD6-U9JA].

In public, though, Mr. Shkreli is often outspoken and sometimes insulting. At the height of the recent controversy over the more than 50-fold increase in price his company instituted for the parasite drug Daraprim, Mr. Shkreli, on Twitter, dismissed one journalist as a “moron.” . . . Mr. Shkreli was similarly combative on the topic of Daraprim’s price hike. During a recent interview at the Forbes Healthcare Summit, Mr. Shkreli said he had an obligation to “maximize our profit” for his investors.

Id.

¹⁰² See Laura Lorenzetti, *How Martin Shkreli Is ‘Trashing’ the Pharma Industry*, FORTUNE (Feb. 4, 2016), <http://fortune.com/2016/02/04/martin-shkreli-valeant-drug-price-hearing/> [https://perma.cc/AFW8-NPMS] (noting that “the environment in the hearing was heated as lawmakers ranted about the out-of-control drug price increases on a series of off-patent drugs”).

¹⁰³ See Weintraub, *supra* note 90 (noting that Shkreli’s “departure from the company was far from amicable”). Retrophin sued Shkreli for \$65 million. Nate Raymond, *Retrophin to Pay \$3 Million in U.S. Lawsuit Over Shkreli’s Tenure*, REUTERS (Feb. 3, 2016, 2:31 PM), <http://www.reuters.com/article/us-retrophin-lawsuit-shkreli-idUSKCN0VC1K8> [https://perma.cc/3Q98-9KH3]. The company paid \$3 million to settle a lawsuit, which alleged that the company did not disclose transactions that personally benefitted Shkreli during his tenure as CEO. See *id.* In the lawsuit against Shkreli, Retrophin alleged that the former CEO “was the paradigm faithless servant.” Dani Kass, *Drugmaker Retrophin Sues Ex-CEO for \$65M*, LAW360 (Aug. 17, 2015), <http://www.law360.com/articles/691861/drugmaker-retrophin-sues-ex-ceo-for-65m> [https://perma.cc/YKZ2-DNK3].

¹⁰⁴ See Halimah Abdullah, *‘Pharma Bro’ Shkreli Invokes the Fifth Before Congress*, NBC NEWS (Feb. 4, 2016, 7:33 PM), <http://www.nbcnews.com/news/us-news/pharma-bro-martin-shkreli-faces-congress-n511106> [https://perma.cc/H52H-DUHQJ]; Krishnadev Calamur, *The Arrest of the ‘Pharma Bro,’* THE ATLANTIC (Dec. 17, 2015), <http://www.theatlantic.com/national/archive/2015/12/pharma-bro-arrested/420954/> [https://perma.cc/Z8KR-X6AG]; Emily Jane Fox, *Pharma Bro Martin Shkreli Is Even More Terrible Than You Thought*, VANITY FAIR (Feb. 19, 2016, 3:14 PM), <http://www.vanityfair.com/news/2016/02/pharma-bro-martin-shkreli-threat> [https://perma.cc/D7VJ-8EK6]; Dan Mangan, *‘Pharma Bro’ Martin Shkreli Has His Day in Brooklyn Court*, NBC NEWS (Feb. 3, 2016, 11:08 AM), <http://www.nbcnews.com/business/business-news/pharma-bro-martin-shkreli-has-his-day-brooklyn-court-n510446> [https://perma.cc/U9VT-Z2M9]; Dan Mangan, *‘Pharma Bro’ Martin Shkreli Pleads Not Guilty to New Charge*, NBC NEWS (June 6, 2016, 3:47 PM), <http://www.nbcnews.com/business/business-news/pharma-bro-martin-shkreli-pleads-not-guilty-new-charge-n586676> [https://perma.cc/3BH6-2XSM]. The term “bro” has been used in popular culture often to refer to young males who are immature or lacking in seriousness.

ca.”¹⁰⁵ The Shkreli saga had all the hallmarks of a compelling story: innocent patients facing off against a heartless and brash CEO.

Except that is the stuff of Hollywood. Aside from Shkreli’s uncommon personality, the main lesson of the Daraprim story should have been how *ordinary* both Shkreli’s and Turing’s actions were in the early fall of 2015.¹⁰⁶ Once the public got past the personal politics of the antagonist, an unabashed truism—that prices of pharmaceutical drugs are largely unregulated and unlimited—should have made its way into American popular consciousness by late 2015.¹⁰⁷ What was stunning was that this truism also seemed to make its way into the consciousness of various members of Congress at the same time.¹⁰⁸ This, of course, is a Congress that has blocked the Health and Human Services (“HHS”) Secretary from negotiating Medicare’s drug prices¹⁰⁹ and has permitted such a system to take hold without

When supporters of Senator Bernie Sanders lashed out on social media toward supporters of former Secretary of State Hillary Clinton during the Democratic primary campaign for president, a moniker to describe them that stuck was “Bernie Bros.” See Callum Borchers, *The Bernie Bros Are Out in Full Force Harrasing Female Reporters*, WASH. POST (June 7, 2016), <https://washingtonpost.com/news/the-fix/wp/2016/06/07/the-fix/wp/2016/06/07/the-bernie-bros-are-out-in-full-force-harassing-female-reporters/> [https://perma.cc/7ED8-ABR2].

¹⁰⁵ Selim Algar et al., ‘*The Most Hated Man in America*’ Has Been Arrested, N.Y. POST (Dec. 17, 2015, 7:14 AM), <http://nypost.com/2015/12/17/turing-pharma-ceo-martin-shkreli-arrested/> [https://perma.cc/8TDK-YAKG]; Inae Oh, ‘*Most Hated Man in America*’ Martin Shkreli Was Just Arrested for Alleged Securities Fraud, MOTHER JONES (Dec. 17, 2015, 8:46 AM), <http://www.motherjones.com/mojo/2015/12/pharma-ceo-martin-shkreli-was-just-arrested-securities-fraud> [https://perma.cc/3C9G-963G]; Zoe Thomas & Tim Swift, *Who Is Martin Shkreli—‘The Most Hated Man in America?’*, BBC NEWS (Sept. 23, 2015), <http://www.bbc.com/news/world-us-canada-34331761> [https://perma.cc/ATL2-M9V9].

¹⁰⁶ For instance, in 2015, Pfizer raised the prices of 133 of its over 600 drugs. Cynthia Koons, *Pfizer Raised Prices on 133 Drugs This Year, and It’s Not Alone*, BLOOMBERG (Oct. 2, 2015), <http://www.bloomberg.com/news/articles/2015-10-02/pfizer-raised-prices-on-133-drugs-this-year-and-it-s-not-alone> [https://perma.cc/J4ML-S6A2]. Merck & Co. “raised the price of 38 drugs (of more than 200), about a quarter of which resulted in increases of 10 percent or more.” *Id.*

¹⁰⁷ See Allen, *supra* note 94 (noting that there was nothing that could be done to limit or prevent Turing from raising the price of Daraprim).

¹⁰⁸ See, e.g., Michael Hiltzik, *Congress Made Martin Shkreli Look Like a Jerk, but It Bears Responsibility for High Drug Prices*, L.A. TIMES (Feb. 4, 2016, 3:19 PM), <http://www.latimes.com/business/hiltzik/la-fi-mh-shkreli-looked-like-a-jerk-20160204-column.html> [https://perma.cc/8UZ6-93UR].

“You can go down in history as the poster boy for greedy drug company executives or you can change the system,” [Rep.] Cummings told Shkreli. This is absurd. It’s Cummings and his colleagues who can change the system. In truth, people like Shkreli aren’t the real cause of the high drug prices that afflict American consumers.

Id. (alteration in original).

¹⁰⁹ 42 U.S.C. § 1395w-111(i) (2012).

any meaningful cost control of pharmaceutical drugs, acting unlike all other developed countries.¹¹⁰

As a result, the autumnal obsession with Shkreli may have been misguided, and Congressional criticism seemed hollow. As put by the *New Yorker* magazine:

One of the strangest things about the anti-Shkreli argument is that it asks us to be shocked that a medical executive is motivated by profit. . . . A truly greedy executive would keep a much lower profile than Shkreli: there would be no headline-grabbing exponential price hikes, just boring but reliable ticks upward; no interviews, no tweeting, and absolutely no hip-hop feuds. . . . By showing what is legal, he has helped us to think about what we might want to change, and what we might need to learn to live with.¹¹¹

The Shkreli saga ended in mid-December of 2015 when Shkreli was arrested for so-called “small-time hedge fund fraud.”¹¹²

Shkreli was back in the news in February of 2016, when he was called to testify in front of Congress but refused, relying on his Fifth Amendment rights.¹¹³ Instead, he reportedly “smirked several times and appeared on the verge of laughter” in front of Congress.¹¹⁴ After the contentious meeting, Shkreli tweeted that it is “[h]ard to accept that these imbeciles represent the

¹¹⁰ See Nadia Kounang, *Why Pharmaceuticals Are Cheaper Abroad*, CNN (Sept. 28, 2015, 8:46 AM), <http://www.cnn.com/2015/09/28/health/us-pays-more-for-drugs/> [<https://perma.cc/33PE-KAGP>] (“The United Kingdom’s National Health Service . . . purchases drugs for the entire country’s supply, known as a formulary. But in the United States, we have individual insurance groups, hospitals and plans that buy for their individual consumers. Plans and groups negotiate their own prices with the pharmaceuticals, resulting in a [sic] unregulated variety of pricing.”); Jeanne Whalen, *Why the U.S. Pays More Than Other Countries for Drugs*, WALL STREET J. (Dec. 1, 2015, 9:27 PM), <http://www.wsj.com/articles/why-the-u-s-pays-more-than-other-countries-for-drugs-1448939481> [<https://perma.cc/J4WD-TH4D>] (“The state-run health systems in Norway and many other developed countries drive hard bargains with drug companies: setting price caps, demanding proof of new drugs’ value in comparison to existing ones and sometimes refusing to cover medicines they doubt are worth the cost.”).

¹¹¹ See Sanneh, *supra* note 1.

¹¹² Stephanie Clifford & Matthew Goldstein, *Shkreli Indictment Portrays Small-Time Fraud*, N.Y. TIMES (Dec. 17, 2015), <http://www.nytimes.com/2015/12/18/business/dealbook/shkreli-indictment-portrays-small-time-fraud.html> [<https://perma.cc/VHR2-ANUH>]; Julie Creswell et al., *Drug C.E.O. Martin Shkreli Arrested on Fraud Charges*, N.Y. TIMES (Dec. 17, 2015), <http://www.nytimes.com/2015/12/18/business/shkreli-fraud-charges.html> [<https://perma.cc/J7ED-C9PX>].

¹¹³ See Nathan Bomey, *Martin Shkreli Pleads the Fifth, Then Tweets About ‘Imbeciles’ in Congress*, USA TODAY (Feb. 4, 2016, 6:30 PM), <http://www.usatoday.com/story/money/2016/02/04/martin-shkreli-congressional-testimony-turing-pharmaceuticals-valeant-fda-drug-prices/79808004/> [<https://perma.cc/FG8A-GLRE>].

¹¹⁴ *Id.*

people in our government.”¹¹⁵ Even in the wake of this attention, to date, Congress has taken no action to address pharmaceutical drug prices.

Section A discusses the rapid growth and rising prices facing Medicare.¹¹⁶ Section B describes Medicare Part B’s history with prescription drug pricing.¹¹⁷ Section C details the relationship between Part B’s current reimbursement rate and utilization.¹¹⁸ Section D summarizes the lifecycle of an abandoned proposal to alter the Medicare Part B drug reimbursement rate.¹¹⁹

A. *The Uniquely Precarious Position of Medicare*

Nowhere are all of these cost tensions more prominent than in America’s Medicare program. Taxpayer-financed Medicare is facing a fate similar to the individuals on the new health care insurance marketplace: with a blossoming enrollment and rising prices, the program is staring at decades of rapidly increasing costs.¹²⁰ Not only is the Medicare budget growing, but the growth is projected to accelerate over the next decade.¹²¹

Much of this cost crisis is due to enrollment growth. In a period that started in 2010 and will last until 2050, Medicare’s enrollment is projected to move from 47.7 million Americans to 92.4 million Americans.¹²² This is not just a systemic, academic concern; Medicare’s current beneficiaries will face the cost strain. It has already begun; Medicare’s Part B premiums alone rose sixteen percent from 2015 to 2016.¹²³ With beneficiaries on the hook for twenty percent of drug costs, individuals are dedicating an increasing

¹¹⁵ *Id.*

¹¹⁶ See *infra* notes 120–131 and accompanying text.

¹¹⁷ See *infra* notes 132–166 and accompanying text.

¹¹⁸ See *infra* notes 167–178 and accompanying text.

¹¹⁹ See *infra* notes 179–212 and accompanying text.

¹²⁰ See Sean P. Keehan et al., *National Health Expenditure Projections, 2015–25: Economy, Prices, and Aging Expected to Shape Spending and Enrollment*, HEALTH AFF. (July 2016), <http://content.healthaffairs.org/content/early/2016/07/15/hlthaff.2016.0459.full> [<https://perma.cc/UG9R-2726>] (“Influenced largely by the aging of the population, spending growth is expected to be the highest for Medicare among the major payers of health care, as one in five Americans are expected to be covered by the program by 2025.”). Further, Medicare’s spending growth is expected to accelerate from 2015 to 2016, rising from 4.6% to 5.2%. *Id.*

¹²¹ *Id.* Medicare will face a 5.2% expenditure growth in 2016, face an average growth of 6.7% between 2017 and 2019, and average a growth of 7.6% between 2020 and 2025. *Id.*

¹²² *Projected Change in Medicare Enrollment, 2000–2050*, KAISER FAM. FOUND. (July 15, 2013), <http://kff.org/medicare/slide/projected-change-in-medicare-enrollment-2000-2050/> [<https://perma.cc/TY79-YN82>].

¹²³ Juliette Cubanski & Tricia Neuman, *What’s in Store for Medicare’s Part B Premiums and Deductible in 2016, and Why?*, KAISER FAM. FOUND. (Nov. 11, 2015), <http://kff.org/medicare/issue-brief/whats-in-store-for-medicares-part-b-premiums-and-deductible-in-2016-and-why/> [<https://perma.cc/B5MV-W7WL>] (noting that the monthly premium for Medicare Part B would be \$121.80 and the annual deductible would be \$166 for 2016).

percentage of their monthly budgets to prescription drug costs.¹²⁴ To this point, the ACA's reforms have done nothing to impact or slow this intensifying crisis.

Within the Medicare program, a major category of overtreatment results from inefficiently delivered care, excess care, and overpriced pharmaceutical drugs.¹²⁵ Indeed, this seems to suggest that overtreatment is not as much driven by providers bent on defrauding the health care delivery system as it is a result of an environment of non-regulation—a reimbursement methodology and Congress that pays too little attention to incentives, pharmaceutical companies that naturally seek to increase profits,¹²⁶ patients who too often equate cost with quality, and hospitals with a growing amount of market share and control over costs in the health care marketplace (particularly when it comes to excess cost for those with private insurance plans).¹²⁷ It is a system that seems to have resulted due to *inaction*, and the law has not weeded this overgrown lot for decades.

One example of a health policy problem that straddles the two chief causes of the cost crisis mentioned above—that prices are too high and that health care procedures is overused—can be found in the administration of pharmaceutical drugs within Medicare Part B. For example, Part B includes the scenario of a provider choosing an expensive drug instead of a clinically equivalent cheaper drug,¹²⁸ where the excess cost is due to a provider's decision that may or may not be clinically justified. This problem may be compounded where usage of the drug itself may not be clinically required, and also includes the troubling challenge of the cost of pharmaceutical drugs' list prices, which are easily into the tens of thousands per month.¹²⁹ Clinical care that reflects high prices and excess utilization, in addition to

¹²⁴ See Bach et al., *supra* note 2 (noting the 20% co-insurance that Medicare beneficiaries are responsible for under Medicare Part B).

¹²⁵ See Lallemand, *supra* note 31, at 3 (“When two approaches offer identical benefits but have very different costs, the case for steering patients and providers to the less costly alternative may be clear—for example, using generics instead of brand-name drugs.”); see also Buck, *supra* note 75, at 467.

¹²⁶ See Ben Ellman, *Pharmaceutical-Company CEO Has Regrets About Jacking up the Price of Live-Saving Drug—He Wishes He’d Raised It Higher*, N.Y. MAG. (Dec. 4, 2015, 3:19 PM), <http://nymag.com/daily/intelligencer/2015/12/shkreli-i-would-have-raised-prices-higher.html> [<https://perma.cc/4HZV-ERS4>] (“‘I would have raised prices higher,’ Shkreli said, as an answer to a question about how he would redo the last three months. ‘That’s my duty.’ Throughout the 30-minute interview Shkreli returned to his ‘duty’ to shareholders first, likely at the expense any goodwill he may have gotten for almost lowering the price of the drug in late November.”).

¹²⁷ See *supra* notes 57–74 and accompanying text (detailing the relationship between hospital market share, overutilization, and price).

¹²⁸ See Buck, *supra* note 35, at 1053–59 (documenting the story of the two drugs used to treat age-related macular degeneration).

¹²⁹ See, e.g., Pollack, *supra* note 22 (noting that the price of Zaltrap was initially set by Sanofi at \$11,000 per month).

clinically unjustified expense, is a common phenomenon within American health care.

Notably, the ACA reforms do nothing to empower Medicare to negotiate with drug companies, nor have they been successful in changing the calculus facing providers who are choosing between differently priced, but similarly effective, pharmaceutical drugs. Without changing laws, incentives, or norms within the provider's decision-making process, providers have no reason to choose the cheaper drug, let alone to even know which drug is cheaper.

The ACA's silence on addressing increasing pharmaceutical drug costs, particularly within the Medicare program itself, continues a decades-old narrative about Medicare's complicated history with drug pricing. Further, as the cost of health care increases—particularly for Part B drugs—Medicare's beneficiaries are increasingly facing rising costs for prescription drugs.¹³⁰ When patients with fixed incomes face increasing prices for their drugs, the impacts are real and often devastating.¹³¹

B. Medicare Part B's History with Drug Pricing

A cost crisis borne out of how Medicare Part B pays for its drugs is nothing new, but of particular recent interest to policy makers is how Medicare Part B pays for pharmaceutical drugs that are administered on an out-patient, but in-office setting.¹³² Part B is implicated in many of the current cost control efforts, due to the still complex and antiquated reimbursement mechanism that governs it. Unfortunately, the battle to control Medicare's Part B expenditures, and an inability to make headway in addressing the crisis, has been a similar narrative facing CMS for decades.¹³³ This appears to be a narrative that features inattention to detail, powerful interests to protect, and, above all, political inaction. This mix led to the situation that

¹³⁰ See Justin Mack, *Medicare Premiums and Deductibles for 2016*, MEDICARE.COM (July 25, 2016), <https://medicare.com/about-medicare/medicare-premiums-deductibles-2016/> [<https://perma.cc/67G7-93JM>] (noting the 20% co-insurance for which beneficiaries are responsible after the Medicare Part B deductible is met).

¹³¹ *Medicare Patients Struggle with Prescription Drug Prices*, CONSUMER REP. (June 21, 2016), <http://www.consumerreports.org/drugs/medicare-patients-struggle-with-prescription-prices/> [<https://perma.cc/F6ZY-KMZQ>] (“[E]ven with Medicare, many people wind up paying substantial out-of-pocket costs We hear stories about people mortgaging their house just to afford their medications,” according to Joe Baker, the president of the Medicare Right Center).

¹³² See *Medicare Part B Drugs Payment Model*, CTRS. FOR MEDICARE & MEDICAID SERVS. (June 14, 2016), <https://innovation.cms.gov/initiatives/part-b-drugs> [<https://perma.cc/Z2N3-MQ42>] (noting the two phases of “adjustments to the ASP+6 percent formula” and “value-based purchasing”).

¹³³ See *supra* notes 120–131 and accompanying text.

faced the doctors at Sloan-Kettering mentioned above.¹³⁴ Nevertheless, despite the current challenges associated with Medicare Part B reimbursement, it is notable that reimbursement has actually improved over the last two decades.

Specifically, for Medicare's Part B reimbursement, until January 1, 2005, the program paid for drugs under what was known as an average wholesale price ("AWP") system.¹³⁵ Medicare reimbursed physicians who administered drugs covered by Part B based upon what the AWP was for each covered drug. From January 1, 1998 to December 31, 2003, Medicare paid doctors either the lesser of the actual Medicare charge on the claim, or ninety-five percent of the drug's AWP.¹³⁶ From January 1, 2004 to December 31, 2004, Medicare limited its payments to eighty-five percent of the AWP.¹³⁷

The AWP system was ripe for potential abuse, largely because a particular prescription drug's AWP often did not closely reflect its actual sales price.¹³⁸ In effect, the acquisition cost—that is, the price that doctors paid for acquiring the drugs for administration in their offices—was untethered from the reimbursement formula under Medicare Part B.¹³⁹ A settlement

¹³⁴ See *supra* notes 1–27 and accompanying text (explaining how doctors declined to prescribe drugs not because of clinical efficacy, but because of high price).

¹³⁵ See DANIEL R. LEVINSON, OFFICE OF INSPECTOR GEN., DEP'T OF HEALTH & HUMAN SERVS., MEDICARE DRUG PRICE COMPARISON: AVERAGE SALES PRICE TO AVERAGE WHOLESALE PRICE i (June 2005).

¹³⁶ *Historical Part B Drug Pricing Files*, CTRS. FOR MEDICAID & MEDICARE SERVS. (Mar. 23, 2012), <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/HistPartBDrugPricingFiles/Overview.html> [<https://perma.cc/L8RM-65TH>].

¹³⁷ *Id.*

¹³⁸ See Maryan M. Chirayath, Note, *Oh Canada!: Antitrust Geographic Market Definition and the Reimportation of Prescription Drugs*, 46 B.C. L. REV. 1027, 1035 (2005).

At times, the data revealed the drug manufacturer's AWP was thousands of percentage points higher than the DOJ-calculated wholesale price. This difference between the AWP and the actual wholesale price, also known as the "spread," allows drug manufacturers to realize profits in the United States that elude them in other markets, where governmental regulations force drug manufacturers to charge wholesale prices closer to actual cost, thereby decreasing the spread in those markets. As a result, U.S. consumers face higher retail costs for prescription drugs than do foreign consumers whose governments prevent such pricing abuses

Id.; see also Joan H. Krause, *Following the Money in Health Care Fraud: Reflections on a Modern-Day Yellow Brick Road*, 36 AM. J.L. & MED. 343, 359–60 (2010) (noting the "landmark settlement" with TAP Pharmaceutical Product in 2001, which resolved allegations that "TAP knowingly had reported AWP information that was significantly higher than the product's average sales price, thus ensuring a large 'spread' between the actual price and the amount of Medicare reimbursement. The government contended that TAP 'marketed the spread' to physicians, offering its customers a financial inducement to prescribe Lupron in violation of the Anti-Kickback Statute.").

¹³⁹ P.M. Danzon, *Pricing and Reimbursement of Biopharmaceuticals and Medical Devices in the USA*, 3 ENCYCLOPEDIA HEALTH ECON. 127, 127 (2014) ("AWP became increasingly unreliable (usually inflated) measure of the actual average transaction price at which wholesalers sell to

and prominent class action litigated early in the new millennium shined a bright light on the fact that the Medicare reimbursement structure was, at best, woefully inefficient.¹⁴⁰

This AWP reimbursement mechanism, unsurprisingly, provided an opening for tremendous waste, particularly where pharmaceutical companies allegedly “marketed the spread,” a sales technique in which pharmaceutical sales representatives allegedly touted to physicians the steep difference between the drug’s acquisition cost that the physicians would pay and the amount that Medicare would reimburse.¹⁴¹ Allegedly seeking to impress upon them the amount of profit they could pocket for using their drugs, pharmaceutical companies allegedly had a powerful incentive to highlight Medicare’s seemingly broken reimbursement mechanism.¹⁴² Bizarrely, the problems associated with basing Medicare’s Part B reimbursement regime on AWP were well known, even during the AWP era.¹⁴³

There is widespread agreement that the published prices do not reflect the actual price at which many physicians are able to purchase these products, due to volume discounts and other purchasing incentives. Thus, reliance on published AWP may result in

pharmacies. Although AWP and other list prices have remained the basis for payer reimbursement to pharmacies, there is usually a significant discount.”)

¹⁴⁰ See Krause, *supra* note 138, at 359–60 (documenting the TAP Lupron settlement in 2001); Alex T. Paradiso, Note, *Prosecutorial Regulation of Off-Label Promotion: Sidestepping the Courts and Congress to Levy a Tax on Suspect “Big Pharma” Marketing*, 60 SYRACUSE L. REV. 161, 185–86 (2009) (same); see also *In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 178–80 (D. Mass. 2003) (motion to dismiss); Chirayath, *supra* note 138, at 1034–35 (noting the class action complaint in *In re Pharmaceutical Industry*).

¹⁴¹ See Joan H. Krause, *A Conceptual Model of Health Care Fraud Enforcement*, 12 J.L. & POL’Y 55, 125 (2003); see also *In re Pharm. Indus.*, 263 F. Supp. 2d at 178–79 (listing the alleged spreads for pharmaceuticals produced by Abbott Laboratory (“Abbott”), one of the co-defendants in the case). The alleged “spread” in price—between the AWP that was reported and the AWP that was “DOJ determined actual”—ranged from 64% for one of Abbott’s drugs to 20,735% for another (the reported price was allegedly \$670.89 and the “DOJ determined actual” price was listed at \$3.22). *In re Pharm. Indus.*, 263 F. Supp. 2d at 179.

¹⁴² Krause, *supra* note 141, at 125.

¹⁴³ See *id.* at 123–26 (“AWP problems had long been a matter of common knowledge. For the past 30 years, the federal government has been aware that published AWP does not reflect the actual price paid for many prescription drugs.”); Radio Address of President William J. Clinton (Dec. 13, 1997), available at <http://www.presidency.ucsb.edu/ws/index.php?pid=53703> [https://perma.cc/SB5F-JQGA] (“Sometimes the waste and abuses aren’t even illegal; they’re just embedded in the practices of the system. . . . [O]verpayments occur because Medicare reimburses doctors according to the published average wholesale price, the so-called sticker price for drugs. Few doctors, however, actually pay the full sticker price.”); see also *In re Miss. Medicaid Pharm. Average Wholesale Price Litig.*, 190 So. 3d 829, 858 (Miss. 2015) (Lamar, J., dissenting) (noting that “[d]uring the damages period, both President Clinton and Health and Human Services Secretary Donna Shalala publicly referred to AWP as a ‘sticker price’” in an effort to show that the federal government was aware that the reported AWP was not the same as the actual price of the pharmaceutical drugs).

payments that are significantly higher than what many physicians actually pay for the drug, resulting in a nice profit—or “kick-back”—when the physician is reimbursed.¹⁴⁴

Again, the price at which a drug’s AWP was set was largely based on information directly provided by pharmaceutical manufacturers, and Medicare did not have any ability to define what the appropriate AWP for a particular drug was.¹⁴⁵ At the time, Medicare seemed hamstrung by the “wrath of the oncology lobby,” leading it to “turn[] a blind eye to the AWP loophole.”¹⁴⁶ The result, of course, was years of overpayments for Medicare’s Part B drugs.

The move to the average sales price (“ASP”), which was ushered in by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003,¹⁴⁷ featured the adoption of “a far more accurate assessment of the drug’s average market price than the company-reported AWP.”¹⁴⁸ Additionally, studies during the middle of the previous decade proved this point; as part of an effort to align state Medicaid programs’ reimbursement mechanism with the recently adopted ASP-based reimbursement regime in Medicare, the Office of Inspector General (“OIG”) analyzed differences between ASP and AWP in a 2006 report and illuminated fascinating data.¹⁴⁹

Examining pricing from the third quarter of 2004, the report found that replacing AWP with ASP marked a radical shift. ASP was found to be “substantially lower than average wholesale price”¹⁵⁰ for the 2077 national drug codes that OIG reviewed.¹⁵¹ Specifically, the “median percentage difference between ASP and AWP [was] 49 percent.”¹⁵² For single source brand codes, ASP was found to be 26% below the AWP median, with multisource brand codes being 30% below the AWP median.¹⁵³ Stunningly, for generics, the ASP was 68% less than AWP at the median.¹⁵⁴ Further, “the differences between AWP and other prices analyzed [were found to be] similar for both Medicare and Medicaid drugs.”¹⁵⁵

Medicare shifted to the ASP-based regime, in which it reimbursed upon a figure “calculated by the manufacturer every calendar quarter and

¹⁴⁴ See Krause, *supra* note 141, at 124.

¹⁴⁵ *Id.*

¹⁴⁶ *Id.* at 128.

¹⁴⁷ 42 U.S.C. § 1395w-3a (2012).

¹⁴⁸ See Krause, *supra* note 141, at 129.

¹⁴⁹ See Levinson, *supra* note 135, at ii.

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

¹⁵² *Id.* (alteration in original).

¹⁵³ *Id.* at ii–iii.

¹⁵⁴ *Id.* at iii.

¹⁵⁵ *Id.* (alteration in original).

submitted to CMS within 30 days of the close of the quarter.”¹⁵⁶ The calculation is reached after CMS receives the reported prices for sales to every purchasers and “is based on actual transaction price data.”¹⁵⁷ It “includes virtually all discounts and rebates,” and has been called “a near-actual net purchase price.”¹⁵⁸

Indeed, Medicare Part B’s reimbursement regime, the amount that Medicare reimburses doctors for drugs they administer in their offices, is undoubtedly more accurate than the old AWP days, but a familiar narrative continues to permeate the story. Under Medicare’s reimbursement mechanism, the prices of drugs still may influence the physicians who prescribe and administer them. In some regards, it seems stunning that drugs that are more expensive carry a larger potential profit for the doctors who administer them.¹⁵⁹

One example features the substantial price difference between Lucentis and Avastin for treatment of age-related macular degeneration (“AMD”).¹⁶⁰ A condition that affects millions of Americans, AMD is generally treated by these two drugs, both of which are manufactured by the same company.¹⁶¹ Both provide nearly clinically-equivalent benefits, but with Lucentis priced at roughly \$2000 per injection and Avastin at around \$50 per injection, ophthalmologists have a powerful incentive to rely on the more expensive drug due to the “ASP plus six” reimbursement mechanism for Medicare Part

¹⁵⁶ *Medicare Part B Drug Average Sales Price*, CTRS. FOR MEDICARE & MEDICAID SERVS. (May 11, 2016), https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html?redirect=/mcrpartbdrugavgsalesprice/10_vaccinespricing.asp [<https://perma.cc/MH9A-KYA2>]; see 42 U.S.C. § 1395w-3a (establishing and defining use of ASP for Medicare drug payments).

¹⁵⁷ Frederic R. Curtiss et al., *What Is the Price Benchmark to Replace Average Wholesale Price (AWP)?*, 16 J. MANAGED CARE PHARMACY 492, 496 (Sept. 2010).

¹⁵⁸ *Id.*

¹⁵⁹ See Bob Herman, *Latest Physician Data Spotlight How Medicare Pays for Drugs*, MOD. HEALTHCARE (June 6, 2015), <http://www.modernhealthcare.com/article/20150606/MAGAZINE/306069968> [<https://perma.cc/3X3R-L7U3>].

Under Part B, Medicare reimburses physicians for drugs used in their offices and outpatient centers by paying for the drug’s average sales price, plus 6% to cover overhead. That guaranteed additional percentage for physicians has been criticized because it encourages them to buy the highest-cost drugs when cheaper drugs may be just as effective. For instance, studies have shown that Medicare could have saved \$18 billion over 10 years if doctors used the drug Avastin for macular degeneration instead of the more-expensive Lucentis. “The incentives for physicians to use the more expensive drugs are very large,” said Paul Ginsburg, an economist and health policy expert at the University of Southern California. “These data will help show the lack of a system to attempt to contain costs for physician-administered drugs.”

Id.

¹⁶⁰ See Buck, *supra* note 35, at 1054–57.

¹⁶¹ *Id.*

B.¹⁶² For each dose of Lucentis, they stand to profit around \$120, and for Avastin, providers' potential profit is \$3.¹⁶³ As a result, Medicare's system provides an incentive to providers to rely on a more expensive drug.¹⁶⁴

The same is true for drugs that treat advanced cancer. In August of 2012, the doctors at Sloan-Kettering, while determining whether or not to administer Zaltrap to their patients, stood to make a profit of six percent on the price of Zaltrap, which was introduced to the market at \$11,000 per month.¹⁶⁵ In effect, and in a bizarre reality, Medicare Part B is financially incentivizing doctors to choose the more expensive drugs. It is nothing short of stunning when providers, like those at Sloan-Kettering, or even fifty-six percent of ophthalmologists nationwide, reject the more expensive drugs.¹⁶⁶

C. The Relationship Between ASP and Utilization

Even with Medicare Part B's more accurate ASP-based reimbursement mechanism, Part B drug spending has continued to rise without pause; according to CMS, Part B drug costs were estimated to be about \$22 billion in 2015, double what they were in 2007,¹⁶⁷ and about \$3 billion more than what they were in just 2013.¹⁶⁸ Admittedly, whether and how one can be sure that the cost of a specific drug influences the doctors prescribing them, and, if so, to what extent, is a substantial challenge.¹⁶⁹

Nevertheless, recent studies have shown a relationship between an increase in reimbursement and an increase in usage. In a 2015 report, the Medicare Payment Advisory Commission noted that "[t]he six percent add-on to ASP may create incentive to use higher priced drugs."¹⁷⁰ Indeed, the Commission noted that the more expensive drug "has the potential to generate more profit," but also observed that "few studies exist that examine whether the six percent add-on is influencing providers' choice of drugs."¹⁷¹

¹⁶² *Id.*

¹⁶³ *Id.*

¹⁶⁴ *Id.*

¹⁶⁵ See Pollack, *supra* note 22.

¹⁶⁶ *Id.*; see Buck, *supra* note 35, at 1053–59.

¹⁶⁷ See *Hearing on Examining the Proposed Medicare Part B Drug Demonstration Before the S. Comm. on Finance*, 114th Cong. 1 (June 28, 2016) (statement of Patrick Conway, Acting Principal Deputy Administrator, Deputy Administrator for Innovation and Quality, and Chief Medical Officer, Centers for Medicare & Medicaid Services).

¹⁶⁸ See *Report to the Congress: Medicare and the Health Care Delivery System*, MEDICARE PAYMENT ADVISORY COMMISSION 61 (June 2015), [http://www.medpac.gov/documents/reports/chapter-3-part-b-drug-payment-policy-issues-\(june-2015-report\).pdf?sfvrsn=0](http://www.medpac.gov/documents/reports/chapter-3-part-b-drug-payment-policy-issues-(june-2015-report).pdf?sfvrsn=0) [<https://perma.cc/AXH9-VVZY>].

¹⁶⁹ *Id.* at 69.

¹⁷⁰ *Id.* at 68.

¹⁷¹ *Id.*

There have been, however, a handful of studies that seem to demonstrate at least a modest, and some show a substantial, relationship between reimbursement add-ons and utilization, with a 2012 OIG study finding a serious change in physician prescribing behaviors.¹⁷² Indeed, following the removal of a least costly alternative and the reinstatement of the “ASP plus six percent” reimbursement structure for treatments for prostate cancer, this 2012 study found that “utilization patterns shifted dramatically in favor of certain costlier products.”¹⁷³

Other studies have echoed these findings.¹⁷⁴ A 2006 study reviewing chemotherapy drugs found that “[a]lthough reimbursement seems to have little effect on the primary decision to administer palliative chemotherapy to patients with advanced solid tumors, it appears to affect the choice of drugs used.”¹⁷⁵ Overall, the study’s authors found that “physicians receiving more-generous Medicare reimbursements used more-costly treatment regimens.”¹⁷⁶

Further, a 2010 study found that “precipitous drops in reimbursement for [two lung cancer drugs] were associated with a decline in a use of these agents,” and the authors “observed a shift to Docetaxel, the most expensive agent, which provided the largest profit in absolute terms thanks to the fixed six percent margin paid above the ASP.”¹⁷⁷ Nevertheless, the authors noted that straight fee cuts may lead physicians to do more to make up for the lost profit, and noted that “fee cuts cannot reliably or predictably control spending.”¹⁷⁸ The studies seemed to show a relationship between the cost of the drug and potential profit amount for the physician with the usage of the drug.

D. *The Abandoned 2016 CMS Proposal*

In the spring of 2016, CMS put forth a new proposal that envisioned revamping Medicare’s Part B reimbursement mechanism.¹⁷⁹ The proposal,

¹⁷² DANIEL R. LEVINSON, OFFICE OF INSPECTOR GEN., DEPT. OF HEALTH & HUMAN SERVS., LEAST COSTLY ALTERNATIVE POLICIES: IMPACT ON PROSTATE CANCER DRUGS COVERED UNDER MEDICARE PART B 12 (Nov. 2012).

¹⁷³ *Id.* at Executive Summary; see also *Report to the Congress, supra* note 168, at 67.

¹⁷⁴ See MIREILLE JACOBSON & JOSEPH P. NEWHOUSE, NAT’L INST. FOR HEALTH CARE MGMT., EXPECT THE UNEXPECTED? PHYSICIANS’ RESPONSES TO PAYMENT CHANGES 2 (Nov. 2010); Mireille Jacobson et al., *Does Reimbursement Influence Chemotherapy Treatment for Cancer Patients?*, 25 HEALTH AFF. 437, 442 (Mar. 2006), <http://content.healthaffairs.org/content/25/2/437.full> [<https://perma.cc/6U8T-6NJ6>].

¹⁷⁵ Jacobson et al., *supra* note 174, at 442; see also *Report to the Congress, supra* note 168, at 68 (calling it a “modest increase”).

¹⁷⁶ Jacobson et al., *supra* note 174, at 442.

¹⁷⁷ JACOBSON & NEWHOUSE, *supra* note 174, at 2 (alteration in original).

¹⁷⁸ *Id.*

¹⁷⁹ *CMS Proposes to Test New Medicare Part B Prescription Drug Models to Improve Quality of Care and Deliver Better Value for Medicare Beneficiaries*, CTRS. FOR MEDICARE & MEDI-

which sought to “improv[e] incentives” under Medicare Part B,¹⁸⁰ suggested changing the “ASP plus six” formula, and specifically suggested testing “whether changing the add-on payment to 2.5 percent plus a flat fee payment of \$16.80 per drug per day change[d] prescribing incentives and [led] to improved quality and value.”¹⁸¹ Of course, this would have substantially increased the reimbursement for doctors who use inexpensive drugs, and would have substantially decreased reimbursement for physicians who administer expensive ones.¹⁸² The proposal also suggested employing additional “value-based purchasing tools,” including testing reference pricing and indications-based pricing.¹⁸³

Indeed, the proposal would have had an effect on the “add-on” (physician profit) for a drug like Zaltrap.¹⁸⁴ Using the 2012 original price of Zaltrap as an example (roughly \$11,000 per month), under the old formula, physicians would stand to be reimbursed \$11,660 per month under an “ASP plus six” formula, which is an “add-on” totaling \$660.¹⁸⁵ Under the new formula, that doctor would be reimbursed \$11,291.80 per month, an “add-on” total of \$291.80.¹⁸⁶ Medicare Part B would have saved \$368.20 per patient per month on a drug that costs as much as Zaltrap did in 2012.¹⁸⁷

The proposal would have changed the calculus for ophthalmologists treating AMD as well.¹⁸⁸ Using the Lucentis and Avastin example mentioned above, the new proposal would have changed the profit “add-on” a physician makes from administering Lucentis from \$120 to \$66.80, and would have changed the profit “add-on” that physician would pocket for administering Avastin from about \$3 to \$18.05.¹⁸⁹ Although it would not have completely eliminated potential financial incentives that the physician would face, it would have sought to balance them more evenly.¹⁹⁰

CAID SERVS. (Mar. 8, 2016), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-03-08.html> [<https://perma.cc/K8VB-2BDN>].

¹⁸⁰ *Id.* (alteration in original).

¹⁸¹ *Id.*

¹⁸² The CMS website uses the following example: For a drug whose ASP is \$5, the doctor would be reimbursed \$5.30 under the old “ASP plus six” reimbursement scheme, but would be reimbursed \$21.93 under the new “ASP plus 2.5 and \$16.80” scheme (2.5% of ASP is \$0.13, plus the flat fee of \$16.80, plus ASP of \$5). *See id.* Conversely, for a drug whose ASP is \$1000, the current formula would repay the doctor \$1060 (ASP plus 6%), but under the new formula, that doctor would receive \$1041.80. *Id.*

¹⁸³ *Id.*

¹⁸⁴ *See supra* notes 165–166 and accompanying text.

¹⁸⁵ *See CMS Proposes, supra* note 179; *see also* Pollack, *supra* note 22 (noting that Zaltrap was initially set around \$11,000 per month).

¹⁸⁶ *See CMS Proposes, supra* note 179.

¹⁸⁷ *See id.*

¹⁸⁸ *See supra* notes 160–164 and accompanying text.

¹⁸⁹ *See CMS Proposes, supra* note 179.

¹⁹⁰ *See id.*

Reaction to the proposal that suggested revamping the reimbursement scheme for prescription drugs reimbursed under Medicare Part B was as swift as it was loud.¹⁹¹ Within nine days of the new proposal, more than three hundred health care organizations wrote to U.S. Senators Mitch McConnell and Harry Reid, House Speaker Paul Ryan, and House Minority Leader Nancy Pelosi to criticize it.¹⁹² In the letter, the organizations noted that the proposed new payment model would “adversely affect the care and treatment of Medicare patients,” and requested the recipients “ask CMS to withdraw the proposed rule.”¹⁹³

Arguing that the change was “misguided” and that it could “lead to an abrupt halt in [Medicare beneficiaries’] treatment,” the letter specifically targeted CMS’s suggestions regarding restructuring the ASP formula.¹⁹⁴ It condemned the proposal for “fail[ing] to take into account the fact that providers’ prescribing decisions depend on a variety of factors,” and argued a lack of “evidence indicating that the payment changes contemplated by the model will improve the quality of care.”¹⁹⁵ Calling it a “severe reimbursement cut,” and that the drugs covered by Medicare Part B—the target of the proposal—“account for just 3% of total program costs,”¹⁹⁶ the letter followed a separate communication sent to HHS Secretary Burwell two weeks before, which largely made the same argument and request.¹⁹⁷

The New York Times noted that the proposal—“the administration’s first serious attempt to rein in drug spending”—“touched off a tempest.”¹⁹⁸ Senator Orrin Hatch and Representatives Fred Upton and Kevin Brady released a statement, warning that the proposal may “limit access to care” and that it was “another troubling example of unelected bureaucrats making decisions behind closed doors.”¹⁹⁹ In this statement that both seems to prove that changing the financial incentives for physicians will impact patient care and illustrates a shorthanded knowledge of the varying standards of care throughout the country, the Congressmen expressed concern that the pro-

¹⁹¹ See, e.g., Letter from Health Care Organizations to Mitch McConnell, Harry Reid, Paul Ryan, and Nancy Pelosi 1–2 (Mar. 17, 2016), available at <http://freepdfhosting.com/761f486713.pdf> [<https://perma.cc/86EK-5673>] (arguing against proposed rule change).

¹⁹² See *id.* at 2–10.

¹⁹³ *Id.* at 1.

¹⁹⁴ *Id.* at 1–2 (alteration in original).

¹⁹⁵ *Id.* at 2 (alteration in original).

¹⁹⁶ *Id.*

¹⁹⁷ See Letter from Health Care Organizations to The Honorable Sylvia Mathews Burwell and Mr. Andy Slavitt (Mar. 4, 2016), available at http://www.asco.org/sites/www.asco.org/files/asp_all_letter.pdf [<https://perma.cc/7HQ5-X5XX>].

¹⁹⁸ Robert Pear, *Groups Scrutinize White House Plan to Cut Drug Costs in Medicare*, N.Y. TIMES (Mar. 9, 2016), <http://www.nytimes.com/2016/03/10/us/politics/groups-scrutinize-white-house-plan-to-cut-drug-costs-in-medicare.html> [<https://perma.cc/XHA9-47G6>].

¹⁹⁹ *Id.*

posed model may have resulted in Medicare beneficiaries receiving different levels and standards of care based on their geographic area due to the pilot's suggestion that different parts of the country experience the new reimbursement mechanism before others.²⁰⁰

The Pharmaceutical Research and Manufacturers of America ("PhRMA") argued that the existing Medicare Part B drug payment scheme was "effective" and that the new proposal put "Medicare patients who rely on these medicines at risk."²⁰¹ The American Society of Clinical Oncology called the proposal "heavy-handed," noting that it was "inappropriate for CMS to manipulate choice of treatment for cancer patients."²⁰² The American College of Rheumatology argued that the new proposal threatened the viability of small and rural providers, and noted that it had been met with a "huge backlash" by providers.²⁰³

For other entities, it was welcome news: AARP and the Center for American Progress supported the proposal.²⁰⁴ The Obama administration's new policy proposal also signaled what could have been a larger regulatory shift in policing America's ever-growing health care budget, demonstrating the continuation of the Obama's administration's more aggressive policy path than those used by previous administrations.²⁰⁵

It is true that the proposal in question, which featured a plan to test the different prescription drug reimbursement model through Medicare's drug reimbursement policy, was both groundbreaking and non-permanent.²⁰⁶ It was a proposal that could have changed,²⁰⁷ but could have also shifted Med-

²⁰⁰ Virgil Dickson, *Does CMS' Part B Drug Proposal Usurp Clinical Judgment?*, MOD. HEALTHCARE (Mar. 10, 2016), <http://www.modernhealthcare.com/article/20160310/NEWS/160309849> [<https://perma.cc/92J7-VMQ2>].

²⁰¹ *PhRMA Statement on ASPE Issue Brief on Medicare Part B Drugs and Changes*, PHRMA (Mar. 8, 2016), <http://www.phrma.org/media-releases/phrma-statement-on-aspe-issue-brief-on-medicare-part-b-drugs-and-proposed-part-b-changes> [<https://perma.cc/99ZZ-Z8XQ>].

²⁰² Alison Kodjak, *Medicare Looks to Cut Drug Costs by Changing How It Pays Doctors*, NPR (Mar. 9, 2016, 1:38 PM), <http://www.npr.org/sections/health-shots/2016/03/09/469792479/medicare-looks-to-cut-drug-costs-by-changing-how-it-pays-doctors> [<https://perma.cc/EH94-R45A>].

²⁰³ See Sarah Ferris, *Drug Plan Hit with Backlash*, THE HILL (Apr. 12, 2016), <http://thehill.com/policy/healthcare/275918-drug-plan-hit-with-backlash> [<https://perma.cc/E9C4-AJAZ>].

²⁰⁴ See *id.*

²⁰⁵ See, e.g., Millman, *supra* note 24 (noting the new quality-based reimbursement measures, calling the Obama administration's shift "an ambitious goal to overhaul the way doctors are paid" and "the administration's biggest effort yet to shape how doctors are compensated across the health-care system").

²⁰⁶ See Pear, *supra* note 198 ("The announcement is only a proposal for a test, but it has huge implications for the pharmaceutical industry The proposal could, for the first time, link Medicare payments to the effectiveness of a drug and the cost of comparable medications—factors not normally considered in the current reimbursement formula.").

²⁰⁷ See Joyce Frieden, *CMS Open to Changes in Part B Proposal, Official Says*, MEDPAGE TODAY (May 4, 2016), <http://www.medpagetoday.com/publichealthpolicy/medicare/57717> [<https://perma.cc/CB2U-2QKG>] (noting CMS Chief Medical Officer Patrick Conway's remarks that the if

icare's reimbursement scheme for prescription drugs paid for by Medicare Part B quite substantially for decades to come.²⁰⁸ It also is the case that the proposal had differential effects on Medicare providers, depending on specialty and practice. Specifically, the proposal may have "deliver[ed] a blow to those in a handful of specialties, particularly oncologists, ophthalmologists, and rheumatologists, who earn[ed] substantial shares of their revenue from Medicare's longstanding method of paying them a drug's average sales price . . . plus six percent,"²⁰⁹ but it may have benefitted primary care physicians in family practice.²¹⁰

Nonetheless, the negative reaction was too much. Early on, CMS Deputy Administrator for Innovation and Quality and Chief Medical Officer Patrick Conway and HHS Secretary Sylvia Burwell became the targets of an online change.org petition authored by the Coalition of State Rheumatology Organizations.²¹¹ After weeks of "feeling the heat," Conway noted that CMS was open to making changes to the proposal, and, by December of 2016, following the presidential election of Donald Trump, CMS abandoned the Part B proposal.²¹²

III. FINANCIAL TOXICITY

Aside from government reimbursement policy, new work on financial toxicity may provide a foothold for meaningful self-regulation among pro-

the new proposal "doesn't hit [the] point" that financial considerations are removed from "the prescribing of medicine," then the agency would be open to adjusting the proposal) (alteration in original).

²⁰⁸ See Pear, *supra* note 198.

²⁰⁹ Dickson, *supra* note 200.

²¹⁰ *Id.*

²¹¹ Coalition of State Rheumatology Organizations, *Preserve Access to Important Rheumatology Medicines in Medicare*, CHANGE.ORG (Mar. 2016), <https://www.change.org/p/urgent-preserve-access-to-important-rheumatology-medicines-in-medicare> [https://perma.cc/8XX8-DEQE]. Dr. Conway noted that

I was named in a Change.org petition where I got email about every 20 seconds from patients saying their doctor said they wouldn't get their medicine . . . [I]t bothered me personally; it was clear that was not what this proposal is intended to do. It was disappointing they were hearing that from people in the healthcare system.

Frieden, *supra* note 207.

²¹² See Virgil Dickson, *CMS Feels the Heat to Change Medicare Part B Drug Pay Plan*, MOD. HEALTHCARE (May 4, 2016), <http://www.modernhealthcare.com/article/20160504/NEWS/160509979> [https://perma.cc/PBZ3-MHUT] ("Dr. Patrick Conway . . . said the agency is open to making changes, especially ensuring rural providers aren't negatively affected and slowing down the timeline for implementing changes"); Virgil Dickson, *Mandatory Participation Killed the Part B Demo*, MOD. HEALTHCARE (Dec. 16, 2016), <http://www.modernhealthcare.com/article/20161216/NEWS/161219925> [https://perma.cc/N9JR-6FQC].

viders in an industry that must seek to control health care costs.²¹³ Currently recognized within long-term cancer treatment, the phenomenon of financial toxicity likely also exists in other health care contexts, and its policy effects could be wide-ranging.

Roughly defined as “financial difficulties that stem from dealing with cancer [that] can lead people to avoid or delay care or drugs . . . and [that] may also cause stress that can lead to mental and physical health problems,” financial toxicity is drawing increasing attention in health policy circles.²¹⁴ As policymakers and providers learn more about the effects of this new threat in cancer treatment—and as, perhaps, the concern about financial toxicity expands into other corners of American health care largely impacted by cost—the focus may provide the long-awaited impetus for slowing, or even reversing, rising prescription drug costs. What exactly financial toxicity is, followed by what it could mean for policy and legal development in this area, again, a big driver of excess cost in American health care, follows immediately below.

Section A describes financial toxicity as observed in long-term cancer patients.²¹⁵ Section B discusses the potential legal and policy effects of financial toxicity.²¹⁶ Section C examines the potential legal and policy impacts of a linkage between expensive care and poor care.²¹⁷

A. As a Phenomenon

Perhaps a term as dramatic as it is relevant, financial toxicity addresses the long-ignored effect of the cost of very expensive health care—or specifically, pharmaceutical drugs used to treat life-threatening cancer—on the actual health, and mortality rate, of the patients undergoing the treatment or taking

²¹³ A CMS study released in the summer of 2016 estimated that the cost of health care in the United States reached \$3.2 trillion in 2015. *2015–2025 Projections of National Health Expenditures Data Released*, CTRS. FOR MEDICARE & MEDICAID SERVS. (July 13, 2016), https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2016-Press-releases-items/2016-07-13.html?elq_cid=1306202&x_id [<https://perma.cc/EUQ9-PN5R>]; Robert Pear, *National Health Spending to Surpass \$10,000 a Person in 2016*, N.Y. TIMES (July 13, 2016), <http://www.nytimes.com/2016/07/14/us/national-health-spending-to-surpass-10000-per-person-in-2016.html> [<https://perma.cc/28GX-QYXR>]. The report also noted that by 2025, Medicare will cover 20% of the U.S. population and “will spend an average of nearly \$18,000 a year for each beneficiary,” up from \$12,000 in 2015. Pear, *supra*. Important for the instant focus, CMS estimates that prescription drug spending “is projected to grow an average of 6.7 percent per year for 2016 through 2025.” *2015–2025 Projections, supra*.

²¹⁴ Johnson, *supra* note 9 (alteration in original) (“[A] growing body of evidence suggests that, far from crass, ignoring cost could be harmful to patients’ health.”).

²¹⁵ See *infra* notes 218–257 and accompanying text.

²¹⁶ See *infra* notes 258–262 and accompanying text.

²¹⁷ See *infra* notes 263–270 and accompanying text.

the medicine.²¹⁸ Similar to other side effects, “financial toxicity has been linked to differences in health-related quality of life, compliance, and, most recently, survival.”²¹⁹ Recent studies have shown a clear, undeniable connection between patient financial strain and reduced chances of survival.²²⁰ Important for the purposes here, financial toxicity can include multiple negative effects on patients due to the cost of prescription drugs. Indeed, one of these potential negative effects is that “higher co-pays deter patients from filling their prescriptions,” which has been demonstrated by patient study.²²¹

Perhaps more interestingly, as one commenter noted, “cancer’s burden isn’t just high drug costs.”²²² Although a threat of patients skipping out on filling prescriptions due to cost is a problem (mentioned below as “cost-related nonadherence”), recent studies have demonstrated something more profound: that financial stress and personal bankruptcy, particularly due to, or at least precipitated by, health care costs, leads to *worse health outcomes*, at least for cancer patients.²²³ Excessive cost, particularly costs borne by patients who are asked to pay for drugs whose prices are in the thousands of dollars per month, could actually threaten the health of the patient.²²⁴

In one such study that was published in early 2016, the authors compared bankruptcy filing records and cancer registry records in western Washington over fifteen years in an effort “to examine the relationship between bankruptcy filing and survival” for individuals with cancer.²²⁵ Noting that “clinicians are ill prepared to advise patients because they typically have little knowledge of their patients’ health insurance or general financial circumstances,” the study compared those with cancer who file for bankruptcy with those with cancer who do not.²²⁶ In a result likely to start a conversation around whether or not economic hardship and poor health outcomes are related, the authors concluded that “[s]evere financial distress requiring bankruptcy protection after cancer diagnosis appears to be a risk factor for mortality.”²²⁷

Fascinatingly, the authors found that “[m]ortality rates among patients with breast, lung, colorectal, or prostate cancer who filed for bankruptcy

²¹⁸ Johnson, *supra* note 9.

²¹⁹ Jonas A. de Souza, *Discussing Financial Toxicity with Patients Who Have Cancer*, ASCO POST (Oct. 25, 2015), <http://www.ascopost.com/issues/october-25-2015/discussing-financial-toxicity-with-patients-who-have-cancer/> [<https://perma.cc/U93E-2YHE>].

²²⁰ See *infra* notes 223–253 and accompanying notes.

²²¹ See Johnson, *supra* note 9.

²²² *Id.*

²²³ *Id.*

²²⁴ *Id.*

²²⁵ Scott D. Ramsey et al., *Financial Insolvency as a Risk Factor for Early Mortality Among Patients with Cancer*, 34 J. CLINICAL ONCOLOGY 980, 980 (Mar. 20, 2016).

²²⁶ *Id.*

²²⁷ *Id.*

were significantly higher than for patients with those cancers who did not file for bankruptcy.”²²⁸ Further, “[t]he risk of mortality was almost twice as high among patients with prostate cancer who filed for bankruptcy compared with those who did not, and it was 2.5 times as high among patients with colorectal cancer who filed compared with those who did not.”²²⁹

Importantly, the authors completed a propensity score matching process, and focused on patients who received similar initial treatments after diagnosis.²³⁰ The “adjusted hazard ratio” for mortality for those who filed for bankruptcy compared against those who did not was 1.79.²³¹ In order to ensure their comparison was true, the authors “limited to patients diagnosed when the disease was in early stage and who declared bankruptcy within one year of diagnosis so that they would still likely have been in early stage at the time of filing.”²³² The study’s authors “found a consistent, positive association between filing for bankruptcy and earlier mortality, suggesting that those who reach the point of financial insolvency after a cancer diagnosis have significantly poorer outcomes than those who do not.”²³³ Notably, “the impacts of financial insolvency on mortality observed for [the] study [were] similar to or exceed[ed] observed socioeconomic disparities in survival outcomes.”²³⁴ Finally, the authors noted that:

Because financial distress appears to have a significant negative impact on health outcomes, we believe that cancer care facilities and oncology practitioners may need to consider the financial health of their patients as a matter of course simultaneously with the initiation of therapy Our results underscore the importance of considering the recommendation for and use of services that have limited evidence of substantial benefit and potential high out-of-pocket costs.²³⁵

Indeed, those with insurance are surely not immune from the threat posed by financial toxicity. A separate study in March 2016 noted that twenty-nine percent of Medicare’s cancer survivors “reported financial burden of some kind, ranging from bankruptcy to borrowing money to not being able

²²⁸ *Id.* at 983.

²²⁹ *Id.*

²³⁰ *Id.* at 981.

²³¹ *Id.* at 984.

²³² *Id.* at 981.

²³³ *Id.* at 984.

²³⁴ *Id.* at 985 (alteration in original).

²³⁵ *Id.* at 986.

to pay for medical visits.”²³⁶ Of these individuals, eighty-six percent carried health insurance while being treated.²³⁷

The authors of this study found that individuals reporting a financial burden had lower Physical Component Scores (“PCS”) and Mental Component Scores (“MCS”) in a Short-Form Health Survey.²³⁸ Finding that “survivors reporting [more than] three financial problems reported statistically significant and clinically meaningful differences . . . in the mean PCS and MCS compared with survivors without financial problems,”²³⁹ Kale and Carroll concluded that “[c]ancer-related financial burden was associated with lower health-related quality of life, increased risk of depressed mood, and a higher frequency of worrying about cancer recurrence.”²⁴⁰

Specifically, according to Kale, the survivors with “three or more financial problems had clinically meaningful differences in their physical and mental health-related quality of life and were two to three times more likely to report depressed mood and six to eight times more likely to worry about cancer recurrence.”²⁴¹ The survivors most likely to face financial struggles “were younger at diagnosis, female, a member of a racial or ethnic minority, and who had short-survival cancers.”²⁴² Crucially, “[a]s financial problems increased, health-related quality of life decreased.”²⁴³

Finally, “recent research suggesting a link between financial toxicity and greater risk of mortality is compelling.”²⁴⁴ One scholar noted that financial toxicity may lead to increased likelihood of mortality due to three main causes: “(1) poorer subjective well-being, (2) impaired health-related quality of life, and (3) sub-par quality of care.”²⁴⁵ Subjective well-being is characterized by “different valuations that people make regarding their lives, the events happening to them, their bodies and minds, and the circumstances in which they live,” and may “impact health outcomes including

²³⁶ See Johnson, *supra* note 9.

²³⁷ *Id.* On a broader note, Steven Brill has written about how individuals are squeezed under crushing debt due to health care costs, many of whom are insured. See Steven Brill, *Bitter Pill: Why Medical Bills Are Killing Us*, TIME (Mar. 4, 2013), <http://time.com/198/bitter-pill-why-medical-bills-are-killing-us/> [<https://perma.cc/7KTM-HUG5>].

²³⁸ Hrishikesh P. Kale & Norman V. Carroll, *Self-Reported Financial Burden of Cancer Care and Its Effect on Physical and Mental Health-Related Quality of Life Among US Cancer Survivors*, 122 CANCER 1283, 1283 (Apr. 15, 2016).

²³⁹ *Id.* (alteration in original).

²⁴⁰ *Id.*

²⁴¹ Kathryn Doyle, *Financial Burden of Cancer Can Harm Quality of Life*, REUTERS (Mar. 14, 2016, 11:29 AM), <http://www.reuters.com/article/us-health-cancer-finances-idUSKCN0WG1G6> [<https://perma.cc/RJE4-N5BT>].

²⁴² *Id.*

²⁴³ *Id.*

²⁴⁴ S. Yousuf Zafar, *Financial Toxicity of Cancer Care: It's Time to Intervene*, 108 J. NAT'L CANCER INST., no. 5, 2016, at 2.

²⁴⁵ *Id.*

survival.”²⁴⁶ Health-related quality of life includes “aspects of quality of life that relate specifically to a person’s health, including domains of physical, social, and mental functioning.”²⁴⁷ Patients with financial hardship are “more likely to report poor physical health, poor mental health, and less satisfaction with relationships.”²⁴⁸ Indeed, poor health-related quality of life “is an independent negative prognostic marker for cancer patients.”²⁴⁹ Third, financial strain can impact quality of care, implicating cost-related nonadherence to prescription drugs,²⁵⁰ a “significant contributor to avoidable health care costs in this country.”²⁵¹

How providers conceive of financial toxicity informs how they think it should best be addressed. One has advocated for increased disclosure and provider-patient discussion regarding the effects of the costs of drugs so that the doctor can “adjust the treatment if a patient wants.”²⁵² A doctor could choose cheaper drugs for her patients,²⁵³ help the patient seek financial assistance,²⁵⁴ or seek insurance pre-approval for pharmaceutical drugs “before sending the patient to the pharmacy.”²⁵⁵ Others have called for physicians to “focus more on shared decision-making with patients to the extent that’s possible, and spend more time than . . . has been spent in the past to see if you can find equally effective, lower cost treatment.”²⁵⁶ If possible, they argue, perhaps patients should also seek out financial planning assistance.²⁵⁷

The connection between financial toxicity and mortality serves as a profound development in the struggle for cost-effective, high-quality patient care. On some level, however, these studies’ findings do not seem surpris-

²⁴⁶ *Id.* (internal quotation marks and citation omitted).

²⁴⁷ *Id.*

²⁴⁸ *Id.*

²⁴⁹ *Id.*

²⁵⁰ *Id.*

²⁵¹ Aurel O. Iuga & Maura J. McGuire, *Adherence and Health Care Costs*, 7 RISK MGMT. HEALTHCARE POL’Y 35, 42 (2014).

²⁵² Lisa Ward, *The High Cost of Cancer Care May Take Physical and Emotional Toll on Patients*, WALL STREET J. (Feb. 17, 2016, 7:11 AM), <http://www.wsj.com/articles/the-high-cost-of-cancer-care-may-take-physical-and-emotional-toll-on-patients-1455592260> [<https://perma.cc/5J3U-R3CW>]. Dr. Jonas de Souza, an assistant professor of medicine at the University of Chicago Medical Center, is the author of a “questionnaire that physicians can use to assess whether cancer patients are financially distressed.” *Id.*

²⁵³ Lidia Schapira, *Financial Toxicity: Another Hurdle in Cancer Treatment*, CANCER.NET: BLOG, (Apr. 7, 2016), <http://www.cancer.net/blog/2016-04/financial-toxicity-another-hurdle-cancer-treatment> [<https://perma.cc/WRM3-QNZJ>]; Ward, *supra* note 252.

²⁵⁴ See Schapira, *supra* note 253 (noting the process various offices follow to address a patient’s financial concerns).

²⁵⁵ “*Financial Toxicity*” *Can Lower Cancer Patients’ Quality of Life*, DUKE MED. (Dec. 16, 2014), <https://corporate.dukehealth.org/news-listing/%E2%80%98financial-toxicity%E2%80%99-can-lower-cancer-patients-quality-life> [<https://perma.cc/ZFK4-FSSY>].

²⁵⁶ See Johnson, *supra* note 9.

²⁵⁷ See Doyle, *supra* note 241.

ing; as individuals struggle with financial burdens, it would seem natural that their physical health and recoveries may be affected. Nevertheless, the *extent* to which these individuals are affected, and, for the instant focus, the potential impact of financial toxicity on law, quality regulation, health policy, and the nagging problem of overtreatment and excess cost cannot be underestimated. This viewpoint that financial toxicity could serve as a potential legal breakthrough and, at least, a potent policy tool, follows below.

B. As a Legal Breakthrough

Should the understanding of financial toxicity expand beyond cancer care, its teaching could transform the American health care enterprise. After decades of legal and regulatory challenges in this area, an understanding of financial toxicity could radically alter health care delivery. Specifically, if one can show that increased cost leads to worse health outcomes, and that the cost of a procedure or prescription drug can be viewed as providers view other potential bad side effects, then the *legal and policy-based treatment* of the cost issue changes. Once the quality of the care being delivered by the provider is implicated, ethical and legal duties spring forth to protect the patient in her moment of extreme vulnerability.²⁵⁸ Most bluntly, once cost becomes a component factor of quality, as prohibitively expensive health care actually threatens the health of the patient, then the provider is required to begin caring about cost.

Although changing, this is not the current dominant paradigm in American health care. Instead, providers and hospitals too often separate the “quality” question from the “cost” question. Within American health care today, providers seem to treat the cost of care as an issue of secondary importance, and, frequently, policymakers and patients are reminded that the physician’s focus must be solely on the health of the patient. It is this paradigm that leads to the thinking that, if a drug like Zaltrap costs more than \$10,000 per month, but is likely to extend a patient’s life, then the drug should be administered.²⁵⁹ Indeed, it may be one of the chief reasons why drug companies feel emboldened to charge ever-increasing amounts for life-sustaining or life-saving drugs.

Granted, this separation—cost from quality—may have been initially well intentioned. The separation was built to protect the patient against a pro-

²⁵⁸ Richard Dolinar & S. Luke Leininger, *Pay for Performance or Compliance? A Second Opinion on Medicare Reimbursement*, 3 IND. HEALTH L. REV. 397, 413 (2006) (noting the “ethical duty to provide high-quality care”).

²⁵⁹ See *supra* notes 1–10 and accompanying text (summarizing the Sloan-Kettering doctors’ decision to decline to prescribe Zaltrap not because of ineffectiveness, but because of high costs to patients).

vider, hospital, insurance company, or even government-funded Medicare program, bent on limiting cost, from limiting potential treatment options available to the patient.²⁶⁰ Indeed, due to its seeming queasiness about anything that could be viewed as state-sanctioned health care rationing, Congress has even prevented Medicare from imposing a publicly-considered cost-effectiveness requirement for its coverage determinations.²⁶¹ As a result, the American health care system has operated on a nearly cost-blind manner, with too few actors in the enterprise focused on the overall cost of the care that is being delivered. This is particularly true within the Medicare program.

There are at least two major problems with the dominant paradigm. The first, at least based upon the nascent research focused on financial toxicity, is that policymakers cannot separate a patient's financial health, including harm experienced as a result of being administered expensive health care, from her physical health and quality of life. This early research shows that the two influence one another. In effect, it seems, a provider cannot deliver high-quality care until that provider understands all of the potential negative impacts that the treatment may cause the patient. To completely separate "cost" from "quality" seems not only unhelpful, but harmful to the actual quality of care that is being delivered by the provider.

Second, this construction—that cost and quality must be separate—also assumes a belief that is no longer accurate. Specifically, this belief assumes that patients need protection from payers and providers who are bent on not spending enough on or *rationing* their care. By separating cost and quality, the system can be confident that it is free from ulterior motives focused on limitations, and the purity of the health care enterprise—focused solely on patient care—remains intact. Nevertheless, at least in Medicare Part B prescription drug reimbursement, and perhaps in other areas of the federal health care enterprise, this belief seems to be either inapplicable or incorrect.

To an observer of the American health care endeavor, it is clear that providers, hospitals, and particularly, pharmaceutical companies, have very few incentives to limit cost. Granted, the ACA has sought to change some of the twisted incentives that characterized the Medicare program since its inception, and has sought to realign hospital reimbursement to push these centers of care to focus on quality and not just volume.²⁶² Without any rate

²⁶⁰ See Buck, *supra* note 33, at 1270–82 (noting the complicated history of Medicare's relationship with cost).

²⁶¹ See Michael S. Kolber, *Opacity and Cost Effectiveness Analysis in Medicare Coverage Decisions: Health Policy Encounters Administrative Law*, 64 FOOD DRUG L.J. 515, 515 (2009) (noting how Medicare does not take account of cost effectiveness in its coverage determinations).

²⁶² See, e.g., David Muhlestein & Chase Hall, *ACO Quality Results: Good but Not Great*, HEALTH AFF. BLOG (Dec. 18, 2014), <http://healthaffairs.org/blog/2014/12/18/aco-quality-results->

regulation²⁶³ or other serious cost control on the enterprise—and, dependent on a Medicare program that lacks a history of cost effectiveness or efficiency, particularly within Part B reimbursement—it seems as though it may be time to allow cost to be a part of the quality conversation.

The studies on financial toxicity provide the opening. Indeed, they seem to suggest that, at least for patients who are likely to suffer financial burdens as a result of prescription drug costs, administering an expensive drug may not reflect high-quality care. From a legal perspective, forcing the health care enterprise to ignore, or at least not adequately consider, the financial effect of the prescription drug on the health of the patient seems short-sided at best, and counterproductive at worst.

Although this suggestion may seem intuitive, this recognition would constitute a notable change within health law and policy. Indeed, once one can make the argument that, at least for patients who are likely to suffer financial burdens as a result of prescription drug costs, prescribing the most expensive drugs for those patients may be a lower quality option—particularly because of the health effects they may suffer—then the legal, regulatory, and ethical spheres orbiting the provider that govern patient-provider relationship all shift.

C. Finally Linking Cost, Quality, and Harm

The challenge facing American regulators and prosecutors seeking to limit cost growth within the health care enterprise has been complicated by diffuse and disparate legal regimes. For instance, within American health care, patients rely upon state-based medical malpractice doctrines to ensure providers administer health care of a sufficient quality.²⁶⁴ State medical li-

good-but-not-great/ [https://perma.cc/223W-ADAG] (noting that there was “a very low correlation between improved quality and earned savings,” and that the study demonstrated that “improved quality and earned savings only correlate at 8.6 percent, so low that it is statistically insignificant”); *Quality Measures, Reporting and Performance Standards*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Oct. 6, 2016, 7:55 AM), <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Quality-Measures-Standards.html> [https://perma.cc/R42P-ZJKC]; *Readmissions Reduction Program (HRRP)*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Apr. 18, 2016, 5:08 PM), <https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps/readmissions-reduction-program.html> [https://perma.cc/RZ8C-JG77]; Sabriya Rice, *Most Hospitals Face 30-Day Readmissions Penalty in Fiscal 2016*, MOD. HEALTHCARE (Aug. 3, 2015), <http://www.modernhealthcare.com/article/20150803/NEWS/150809981> [https://perma.cc/A3FT-XNP5] (covering the disappointing results of the Hospital Readmissions Reduction Program, noting that “only 799 out of more than 3,400 hospitals . . . performed well enough . . . to face no penalty”).

²⁶³ See *Maryland All-Payer Model*, *supra* note 86 (noting that Maryland is the only U.S. state with an all-payer rate regulation regime).

²⁶⁴ See, e.g., Kristin Madison, *Donabedian’s Legacy: The Future of Health Care Quality Law and Policy*, 10 IND. HEALTH L. REV. 325, 332 (2013) (“Medical malpractice liability and professional licensing continued their roles as quality-control mechanisms, although their effectiveness was widely questioned.”).

censing boards also have the ability to punish providers who fail to meet certain standards.²⁶⁵ For doctors who commit fraud and abuse, America relies upon federal prosecutors at the DOJ to intervene and prosecute. Also, government health care programs like Medicare have the ability to exclude providers, but have never been particularly successful at denying claims in real time.²⁶⁶ Nevertheless, the cost problems facing American health care have their roots in an area within the health care enterprise where none of these legal and regulatory regimes have sufficient reach. The root of America's overtreatment problem seems to be the result of a lack of sufficient action—insufficient incentives, an absence of cost-effectiveness requirements, and no price negotiations, to name a few.

Linking the cost challenge to the concern over quality may transform the regulation of overtreatment, however. Indeed, excessive cost and utilization problems have not typically been seen as a quality problem; patients who may receive excessive health care do not typically rely on medical malpractice lawsuits to sue doctors who allegedly overtreat, nor do state medical licensing boards typically punish providers who aggressively overtreat their patients. Typically, both of those regimes are focused on quality problems—deficient technique, patient harm, and high error rates.

Second, Medicare lacks the resources to adequately address the problem with its regulatory tools. The program performs a delicate dance between increasing staffing for adequate oversight and not overstepping the blurry but ever-present line of “too much” government involvement in American health care. Additionally, federal prosecutors are well-equipped to pursue cases against doctors and hospitals that overtreat their patients as part of fraudulent schemes, but, without evidence of fraudulent intent, these tools are inapplicable as well. Overtreatment, the result of a lack of precise and calibrated regulation, cannot adequately be prevented by fraud actions

²⁶⁵ See *U.S. Medical Regulatory Trends and Actions*, FED’N ST. MEDICAL BOARDS 8 (June 2014) (“Consumers who believe that a physician has engaged in unprofessional conduct or that the quality of medical care they received is substandard should contact their state medical board Because an active license is required to legally practice medicine, and physicians sometimes have more than one license, accurate information about a physician’s credentials and licensure status has always been crucial to state medical boards to enable them to monitor a physician’s practice, protect the public and promote quality health care.”).

²⁶⁶ Medicare is moving away from what is known as “pay and chase.” See T.R. Goldman, *Eliminating Fraud and Abuse*, HEALTH AFF. (July 31, 2012), http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=72 [https://perma.cc/LDY5-SR4Y] (noting the “earlier model,” which noted how the program “paid providers first, then sought to chase down fraud and abuse after the fact”); see also *CMS Cutting-Edge Technology Identifies & Prevents \$820 Million in Improper Medicare Payments in First Three Years*, CTRS. FOR MEDICARE & MEDICAID SERVS. (July 14, 2015), <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2015-Press-releases-items/2015-07-14.html> [https://perma.cc/KF42-WCBN].

that implicate the blunt, draconian, and ever-strengthening²⁶⁷ federal False Claims Act (“FCA”).²⁶⁸

Therefore, if one can make the argument that, contrary to current legal application, when a patient is administered an expensive procedure, or a highly-priced pharmaceutical drug, that patient could face legally compensable harm, the beginnings of a powerful new legal paradigm take shape. For instance, if one is a Medicare beneficiary at high risk of financial duress following a very expensive prescription drug, and nonetheless, her provider prescribes the drug, causing her to suffer personal bankruptcy concomitant with a decline in her quality of life—and perhaps, the loss of her life—it would seem that the care she was provided did not meet the appropriate standard of care. She would definitely have evidence of clear harm.

The advantages of inculcating cost within the ethic of care cannot be underestimated. First, doing so would clearly erect a cost-effectiveness hurdle within the mind of the physician—i.e., pushing the provider to consider whether a given drug, given its cost, would be worthwhile for a particular patient. Second, it would finally appoint a gatekeeper, the physician, between the pharmaceutical company and the patient. A gatekeeper, well versed on the particular advantages of a drug, but also well aware of his patient’s needs, could be an effective advocate for cost-effectiveness. In effect, the law’s recognition of the gatekeeping function would simply be instantiating what some hospitals and doctors nationwide already do.²⁶⁹ It would also jettison Congress’s effort to regulate pricing within the health care and pharmaceutical industry, which, given decades of evidence, either lacks political will or simply does not work.²⁷⁰

Finally, should physicians be explicitly concerned about the financial toxicity threat posed to their patients—indeed, if her patient suffers financial toxicity as a result of care and then is empowered to sue her for a breach of the standard of care—then these cost-effective clinical decisions will be made by the *physician*, as opposed to a government or other third-party. For example, if Medicare tells the doctors at Sloan-Kettering that they

²⁶⁷ See Jeff Overley, *FCA Penalties Set to Double, Raising Fears of Excess Fines*, LAW360 (May 3, 2016, 8:35 PM), <http://www.law360.com/articles/791644/fca-penalties-set-to-double-raising-fears-of-excess-fines> [<https://perma.cc/TEU7-U4AE>] (noting that as of August, the FCA per-claim penalty increased from a \$5500 to \$11,000 range to \$10,781 to \$21,563 range, under a regulation which required updated penalties due to inflation).

²⁶⁸ See 31 U.S.C. § 3729 (2012); Buck, *supra* note 75, at 495–513 (presenting a criticism of the application of the FCA to allegations of overtreatment).

²⁶⁹ See *supra* notes 1–10 and accompanying text (explaining the decision by Sloan-Kettering doctors to not prescribe an expensive drug).

²⁷⁰ See *Report to the Congress*, *supra* note 168, at 61–78 (summarizing and critiquing Congress’s Medicare drug payment policy decisions and exploring policy alternatives to paying providers ASP plus 6%).

are no longer allowed to rely on Zaltrap, or should greatly curtail it because of its cost, one can imagine the lack of perceived legitimacy of such a determination, given the identity of the party making that determination. Indeed, from the perspective of the sick patient, it would appear as though the government is minimizing the expertise of the provider in an effort to cut costs and ration care.

If, however, it is the provider who, after considering the cost of the drug and the needs of her patients, makes the determination that Zaltrap is too expensive for her patients, then this clinical decision is different. In effect, by instantiating the concern of excess prescription drug cost into the standard of care, the Medicare program would be gaining a key gatekeeper who would be focused on cost-effectiveness without any of the negative costs that come with government fiat. Also, the patient would be gaining a key ally who is concerned not just with her *cancer*, but also with her *health*.

As a result, the potential linkage between expensive care and poor care could be legally transformative. At the very least, it would apply pressure on providers to be cognizant of potential financial impacts on their patients, perhaps pushing more providers to seek to emulate the doctors at Sloan-Kettering. If more doctors act like those did at Sloan-Kettering, maybe more prescription drug companies will reduce prices in response, like Sanofi did.

IV. CRUMBLING ADVERSARIAL LEGALISM

The recognition of the potential impact of financial toxicity on the usage, advisability, and cost of prescription drugs comes at a time when a number of the “hard law” tools of litigation and strict regulation—including both legal regimes of Medicare fraud and marketing fraud, two of the premier modern cost control tools within the health law industry—appear to be under assault.²⁷¹ Specifically, a primary way to prevent and punish over-

²⁷¹ See Joan H. Krause, *Truth, Falsity, and Fraud: Off-Label Drug Settlements and the Future of the Civil False Claims Act*, 71 FOOD & DRUG L.J. 401, 402–03 (2016) (presciently documenting the conflicting and confusing relationship between the requirement of falsity in fraud-based FCA litigation and the courts’ new conception of falsity, which requires scientific falsity, in the marketing fraud context). In another sign of the serious limits to Medicare fraud trials, earlier this year, a prominent Medicare fraud case ended in a jury verdict in favor of Abbott Laboratories in Texas. See Lisa Schencker, *Jury Sides with Abbott in \$1 Billion Fraud Case*, MOD. HEALTHCARE (Apr. 8, 2016), <http://www.modernhealthcare.com/article/20160408/NEWS/160409900> [https://perma.cc/YZV7-HRTD] (noting the allegations, in which a whistleblower asserted that Abbott directed him “to educate physicians on the off-label features, benefits and uses of the company’s devices”); see also Tom Korosec & Margaret Cronin Fisk, *Abbott Wins in \$1 Billion Trial Over Marketing of Stents*, BLOOMBERG (Apr. 7, 2016), <http://www.bloomberg.com/news/articles/2016-04-07/abbott-defeats-1-billion-lawsuit-over-stent-marketing> [https://perma.cc/RG2X-UDJQ] (including an allegation that “Abbott . . . [sent] letters on behalf of doctors to potential patients and teaching hospitals and physicians how to code bills to get Medicare reimbursements” and that the whistleblower sold “almost exclusively to physicians who would use them for vascular procedures” (the

treatment caused by the overuse of expensive pharmaceutical drugs, the regulatory regimes of (1) food and drug marketing-based off-label regulation and (2) fraud regulation for off-label marketing, have run into formidable court-made challenges.²⁷² Additionally, medical necessity-based fraud, a potential legal pathway to liability for pharmaceutical companies that allegedly engaged in false marketing, and a powerful tool that could be used to rein in uses of expensive pharmaceutical drugs that may lack cost effectiveness, has also been weakened as a potential pathway to liability.²⁷³

As a result, it is reasonable to believe that whistleblowers and pharmaceutical companies may need to alter their proof calculations for proceeding to trial in these cases. With the state of law in such flux, a solution focused on inculcating cost effectiveness goals within the clinical conception of medical quality and medical standards may be more efficient than more investigations, prosecutions, and lawsuits. Pushing doctors themselves into incorporating and embedding these cost effectiveness concerns seems to be the best, or only, complete solution to America's cost and utilization problem as it relates to prescription drugs.

Section A introduces the framework of new governance to situate the effects of financial toxicity within a larger legal framework.²⁷⁴ Section B then argues that physicians are uniquely suited to effectuate cost savings.²⁷⁵

off-label usage of the stent) (alteration in original). Further, “[a]bout 99 percent of the . . . stents the company sold from 2004 to 2006 . . . were used off-label.” Korosec & Fisk, *supra*. Counsel for Abbott pointedly noted that “[i]f the government believed there was fraud, wouldn’t you think they’d stop paying?” *Id.* (internal quotation marks omitted). “No, they didn’t, year after year.” *Id.* (internal quotation marks omitted). In a related area, but tracking the general trend, a government’s medical necessity-based fraud enforcement action was also dealt a serious setback when a trial court granted summary judgment for a hospice provider in early 2016, concluding that medical disagreement with an expert was not enough to demonstrate falsity under the FCA. *See United States v. AseraCare Inc.*, 176 F. Supp. 3d 1282, 1284 (N.D. Ala. 2016). The case was closely “watched by the hospice industry and False Claims Act experts,” and the verdict could ultimately result in “new standards for false claim lawsuits against hospice providers.” Kent Faulk, *Judge Tosses Out \$200 Million AseraCare Hospice Whistleblower Lawsuit*, AL.COM (Apr. 4, 2016, 9:27 AM), http://www.al.com/news/birmingham/index.ssf/2016/04/judge_tosses_out_aseracare_hos.html [<https://perma.cc/Z8N7-UJSW>].

²⁷² Krause, *supra* note 271, at 404–12.

²⁷³ *In re Plavix Mktg., Sales Practices & Prods. Liab. Litig.*, 123 F. Supp. 3d 584, 609–10 (D.N.J. 2015) (rejecting the allegation that “misrepresentations of the effectiveness of Plavix prevented physicians from making this determination accurately, and that those misrepresentations caused physicians to falsely conclude that Plavix was a medically necessary drug eligible for Medicaid coverage” because medical necessity in a majority of states does not imply a cost-effectiveness requirement).

²⁷⁴ *See infra* notes 276–292 and accompanying text.

²⁷⁵ *See infra* note 293 and accompanying text.

A. Financial Toxicity and New Governance

Although scholars have disagreed on the best way forward to regulate the cost of prescription drugs,²⁷⁶ there are new doctrinal tools that seem to suggest a continued move away from hard law tools and toward collaborative solutions throughout the law. Recently, the theory of new governance, a new doctrinal pathway that seeks more effective regulation, has garnered increased scholarly attention.²⁷⁷ New governance principles occupy an important middle ground between the historically dominant paradigms of command-and-control and market-based solutions within administrative law:

Traditional command-and-control regulation has long been the subject of scholarly critique for its inefficiencies and frequent failures. At the same time, widespread inadequacies of market self-ordering are also well-documented. Given the continuing need for government intervention along with the limits of traditional command-and-control regulation and the growing pressures to liberalize markets, regulators around the world are developing innovative third-way approaches to regulation, collectively referred to as the new governance model.²⁷⁸

New governance provides a doctrinal underpinning of the practical shift advocated here, and supports the notion that old hard law solutions can achieve only a limited amount of regulatory success when attempting to control prescription drug costs. Applying this new doctrine to health law reform has been done before,²⁷⁹ but considering its impact on the price of prescription drugs also seems worthwhile.

²⁷⁶ See Richard G. Frank, *Government Commitment and Regulation of Prescription Drugs*, 22 HEALTH AFF. 46, 47 (May/June 2003) (noting that “Alan Maynard and Karen Bloor argue for a strong set of regulations that override consumer choice and other market mechanisms” and that “Panos Kanavos and Uwe Reinhardt, in contrast, focus on regulations that aim to create market-like incentives to promote greater price competition”).

²⁷⁷ See, e.g., Orly Lobel, *New Governance as Regulatory Governance*, in OXFORD HANDBOOK OF GOVERNANCE 65 (2012) (detailing rise of theory of new governance).

²⁷⁸ *Id.* at 68–69.

²⁷⁹ See Louise G. Trubek, *New Governance and Soft Law in Health Care Reform*, 3 IND. HEALTH L. REV. 137, 139 (2010). Professor Trubek noted that health care

reformers are using new technologies, revising the role of public agencies, expanding the use of information, and creating flexible and participatory tools. These processes are different from previous understandings of health care governance. They are based on an emerging set of practices that can be called “new governance,” “post-regulatory,” or “new proceduralism.” New governance includes devolution, public-private partnerships, new types of regulations and incentives, network creation, coordinated data collection and dissemination, benchmarking, monitoring, and active patient participation.

Particularly, the theory of new governance focuses on public/private collaboration, decentralization, soft law solutions, adaptability, and coordination, among other tenets.²⁸⁰ It purports to be “flexible, revisable, experimental, and/or participatory than traditional legal remedies.”²⁸¹ Among its buzzwords include “cooperative compliance,”²⁸² “collective endeavor,”²⁸³ and “shared problem-solving process.”²⁸⁴ Further, new governance has been hailed for its ability to “blur regulatory lines.”²⁸⁵

Importantly, this includes an increased role for regulated parties. In a new governance regime, the “regulated parties are involved themselves in setting the standards,” as the rule-making authority is decentralized.²⁸⁶ Additionally, these standards and norms are subject to constant change and improvement following near-constant peer review and benchmarking.²⁸⁷ Finally, because of the constant feedback and collaborative solutions, “new governance blurs the boundaries” not only “between law and enforcement,” but also between “policy and implementation.”²⁸⁸ Collaboration means that the regime is seeking to achieve “continuous improvement.”²⁸⁹

New governance is a reaction to failures of the hard law tools in administrative regulation. As Lobel notes,

Since the 1960s, top-down rules and adversarial enforcement—the hallmark of command-and-control—have often failed to achieve their intended goals of increasing compliance and, at times, have been counterproductive in regulating private industry Often, regulatory rules are too complex, markedly vague, needlessly detailed, or simply unsuited to fit the realities of the new economy.²⁹⁰

Indeed, beyond health law, command-and-control regulation seems to have been under attack in other administrative law disciplines as well.²⁹¹

²⁸⁰ See Lobel, *supra* note 277, at 68.

²⁸¹ David M. Trubek & Louise G. Trubek, *New Governance and Legal Regulation: Complementarity, Rivalry, and Transformation*, 13 COLUM. J. EUR. L. 539, 563 (2007).

²⁸² Lobel, *supra* note 277, at 68.

²⁸³ *Id.* at 69.

²⁸⁴ Orly Lobel, *The Renew Deal: The Fall of Regulation and the Rise of Governance in Contemporary Legal Thought*, 89 MINN. L. REV. 342, 377 (2004).

²⁸⁵ See Jason M. Solomon, *New Governance, Preemptive Self-Regulation, and the Blurring of Boundaries in Regulatory Theory and Practice*, 2010 WISC. L. REV. 591, 594.

²⁸⁶ *Id.* at 595.

²⁸⁷ *Id.*; see also Trubek & Trubek, *supra* note 281, at 3.

²⁸⁸ Solomon, *supra* note 285, at 595–96.

²⁸⁹ *Id.* at 596.

²⁹⁰ Lobel, *supra* note 277, at 70.

²⁹¹ See, e.g., Winston Harrington & Richard D. Morgenstern, *Economic Incentives Versus Command and Control*, 2007 RESOURCES FOR FUTURE 13 (detailing how economic incentives are more effective in environmental context than command and control regulations).

Important for the purposes here, new governance outsources the work of regulation to the regulated party. It relies upon private norms and rules, and “asks the regulated private companies to identify problems and risks and to continuously reflect on possible solutions—effectively, to self-regulate.”²⁹² In this way, it seems to fit quite nicely with the policy-based impact that may face American medicine following increased understanding of the dramatic effects of financial toxicity.

B. Role for Physicians

Using the action of the Sloan-Kettering physicians, a new understanding of financial toxicity, and the doctrinal teaching of new governance, this Article contemplates a reconstruction of the health law regulatory structure and a shift in the physician’s standard of care. Indeed, hard law government tools (of which Congress is not likely to provide) and market-based solutions have both failed to rein in prescription drug spending. Furthermore, relying on hard law tools, featuring the FCA and marketing fraud statutes to limit increases in spending appears to be a challenging task.

Using the Sloan-Kettering example as a guide, the party in the best position to effect real change is the prescribing physician.²⁹³ Indeed, with inadequate pressure on the pharmaceutical company, and no rate regulation solution in sight, the best path forward appears to be acting on this decision making of the physician. By linking the cost of the drug to the quality of health care that the provider is administering, Medicare would have a powerful tool that can be used to ensure that cost is finally considered during the provision of care. Doctors already naturally care about their patients’ well-being; including the patient’s financial wellbeing in that sanctified space makes sense, particularly where one’s financial health can so drastically impact one’s physical health, and, indeed, the quality of care one receives. Further, this move would again empower the medical profession, relying upon the physician’s norms and ethics to make cost-constraining decisions without sacrificing quality.

²⁹² Lobel, *supra* note 277, at 71.

²⁹³ Sloan-Kettering is not the only hospital pushing back against the price of prescription drugs. See Jaimy Lee, *Hospitals Take Steps to Control Drug Costs*, MOD. HEALTHCARE (Nov. 29, 2014), <http://www.modernhealthcare.com/article/20141129/MAGAZINE/311299983> [<https://perma.cc/BJ72-VX87>] (“All drugs that cost more than \$10,000 for a course of treatment—about 5% of the medications dispensed through [Christiana Care Health System in Wilmington, Delaware] inpatient and outpatient settings—are now assessed by the medication value subcommittee, which includes 12 physicians, administrators, nurses, pharmacists and finance executives.”) (alteration in original). Further, Harris Health System in Houston, Texas, assists patients in applying for “patient financial assistance programs established by pharmaceutical companies.” *Id.*

CONCLUSION

Pharmaceutical drug costs are rising rapidly, and America, particularly Medicare, has heretofore been unable to find the answer to the deepening crisis. Even well-publicized cases in which pharmaceutical companies seem to brazenly raise the price of their drugs have not been enough to move Congress to act. The DOJ's use of anti-fraud statutes has been strained and stretched, and CMS's proposed new reimbursement mechanism generated so much negative attention, one wonders if it can be successfully implemented. Hard law tactics in this area do not seem promising.

At the same time, researchers are increasingly understanding that a patient's *financial* health following the provision of care greatly impacts that patient's *physical* health. As a result, doctors that provide expensive care to patients may actually be providing poor care. Nowhere does this seem to matter more than in Medicare, with America's elderly facing coinsurance rates that no longer insulate them from feeling the sharp pain of rising pharmaceutical drug costs.

Therefore, following the example of the doctors at Sloan-Kettering, doctors should have a unique and powerful gatekeeping role in the health care enterprise. Indeed, price matters, and as policy makers begin to understand that costs impact health, American medicine must shift to incorporate patient cost concerns into the standard of care. Such a shift gives providers important leverage against, and a backstop to, the harmful prices of pharmaceutical drugs.

REGULATING TAX RETURN PREPARATION

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