The Phenomenon of Financial Toxicity: Healthcare's Insatiable Disease

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ABSTRACT

Ever-increasing pharmaceutical drug costs are garnering greater attention in the United States. Despite pleas for increased regulation of the pharmaceutical market among many policymakers, there have been no concrete legislative proposals to date, and none are in the foreseeable future. This article contemplates the seriousness of this uncontrolled trend and explores how to hinder the growing pharmaceutical drug cost crisis. Recognition of what has become known as "financial toxicity," the negative effect of a pharmaceutical drug's price on the mortality and overall health of a patient undergoing treatment, is only the first step, but an all- important one. Expensive drugs do not guarantee the best treatment. When a patient's health is negatively impacted because of a drug's high cost, that cost must be a critical consideration in determining what treatment is available. Consideration of a drug's cost, unfortunately, is as yet still unconventional. Financial toxicity must be examined in preventing bad care. Too often, expensive care is bad care because too many patients cannot afford the medication available. In applying the concept of financial toxicity, significant progress is made in preventing expensive care from becoming bad care.

INTRODUCTION

Six years ago, three cancer doctors at Memorial Sloan-Kettering Cancer Center (Sloan-Kettering) in New York City did something extraordinary. Dr. Peter Bach, Dr. Leonard Saltz, and Dr. Robert Wittes, refused 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.[1] According to the three doctors, Sloan-Kettering would not prescribe Zaltrap for its cancer patients not because it had terrible side effects or because it was ineffective, but because it was too expensive. Despite reportedly extending the survival rates of cancer patients, Zaltrap offered no advantage over its competitor, Avastin, though it was priced more than twice as much.[2] In light of this difference, the doctors fiercely declined to utilize

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1 Issac Buck, *The Cost of High Prices: Embedding an Ethic of Expense into the Standard of Care.* 58 B.C. L. Rev. 101 (2017), University of Tennessee Legal Studies Research Paper No. 309.

2 *Id.*

Zaltrap because of their concern of the growing threat of "financial toxicity" posed to their patients.

Sloan-Kettering's decision to forcefully push back against the price of Zaltrap demonstrated how instrumental doctors and hospitals can, and must be in the fight to limit rising expenditures in American health care. Within one month of the doctors' decision going public, Zaltrap's manufacturer, Sanofi, cut the price of Zaltrap in half.[3] Sanofi announced it would lower Zaltrap's price, at least for the first few months, through a discount provided to doctors and hospitals only, excluding direct discounts to patients and insurance programs.[4]

In this watershed moment, the Sloan-Kettering doctors sent a message, one that encouraged other physicians to consider the financial strains they may cause patients alongside the benefits they might deliver in providing treatment. In their pioneering moment, the doctors understood that if no one else would act, leading cancer centers and physicians should.

Reflecting upon the Sloan-Kettering example, this article contemplates a novel approach in regulating the cost of health care, particularly pharmaceutical drugs. What has become known as "financial toxicity", a phenomenon born out of the intersection of high prices and the nature of insurance coverage, proposes that expensive care is bad care, and leads to worse health outcomes in patients. Part I of this article provides a snapshot of the current state of American health care, with particular focus on the drivers of its costs. Part II dissects the current public and private payer systems. Part III acknowledges the favorable aspects of a high-priced system. Part IV briefly considers the current approaches in dealing with high costs. Part V presents the phenomenon of financial toxicity and its effect on the pharmaceutical market and health care industry.

I. THE HIGH-COST CHALLENGE

The United States spends more on health care than any other country, and while costs continue to increase dramatically, health status and outcomes are inferior to other competing nations.[5] Although more money is spent on health care, people in the U.S. do not use more health care than people in other countries; Americans go to the doctor less often and get hospitalized less.[6]

Thus far, there have been no legal solutions able to adequately solve the high-cost challenge of health care in the United States. Perhaps this is due to the fact that there is no federal statutory strategy that is dedicated to capping overly expensive prices, nor is there one that is specifically focused on reining in unnecessary costs or procedures in American health care.[7] Nowhere is the issue of uncontrollable costs more pervasive than in the pharmaceutical drug marketplace.

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[3] *Id. at* 105.

[4] *Id.* at 105.

[5] *The U.S. Spends More on Healthcare Than Any Other Country — But Not with Better Health Outcomes*, The LA Times, available at: http://www.latimes.com/nation/la-na-healthcare-comparison-20170715-htmlstory.html), last visited March 19).

[6] *Id.*

[7] *Id.*

The amount spent on pharmaceutical drugs is an important component of overall health care expenditures. In the United States, prescription medications comprise of an estimated 17% of overall personal health care services.[8] Today, there are more and better quality drugs available to prevent and manage acute pain, chronic illnesses and cancer.[9] There are countless prescription drugs that now reduce mortality, prevent complications, and make patients more productive and comfortable.[10] Thus, access to drugs is now a cornerstone of insurance plans and an efficient health care system. With recent increases in pharmaceutical spending, health insurance plans have been forced to adopt benefits designed to reduce pharmaceutical use or steer patients to less expensive alternatives.[11] Even with mandatory generic substitution, coinsurance plans, and multi-tiered formularies, the benefit landscape remains in turmoil for Americans.[12]

a. How Much does the U.S. Spend on Prescription Drugs?

Pharmaceuticals represent a significant and growing share of the United State's health spending, both because new and often costly drugs are emerging from laboratories, and because prices of drugs are rising much faster than prices of other goods and services.[13] The Center for Medicare and Medicaid Services (CMS) estimates prescription drug spending will grow an average of 6.3% per year over the 2016-2025 period.[14] The U.S. government pays more than 40% of the retail prescription drug tab. That works out to $325 billion purchased through pharmacies and mail order alone in 2015 (as opposed to those administered directly by doctors).[15] In turn, this high spending is putting pressure on the federal budget, while also contributing to raising health insurance premiums to unreachable heights for consumers.[16]

Researchers have found that prescription drugs are rising faster than inflation.[17] In a study done by oncologist researchers, 24 patented, injectable Medicare Part B drugs approved by the US Food and Drug Administration (FDA) were examined between 1996 and 2012 for the treatment of cancer.[18] Comparisons were made using the average sales prices published by the Centers for Medicare and Medicaid

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[8] Kesselheim AS, Avorn J, Sarpatwari A., *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*. JAMA. 2016;316(8):858–871. doi:10.1001/jama.2016.11237.

[9] Glen P. Mays, Robert E. Hurley And Joy M. Grossman, *Consumers Face Higher Costs as Health Plans Seek to Control Drug Spending*, available at: Http://Www.Hschange.Org/Content/383/.

[10] *Id.*

[11] *Id.*

[12] *Id.*

[13] *Id.*

[14] *Id.*

[15] CMS.gov, *National Health Expenditures 2016 Highlights*, available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf

[16] *Id.*

[17] Stacy Simon, *Study Shows US Cancer Drug Costs Increasing Despite Competition,* American Cancer Society, available at*:* https://www.cancer.org/latest-news/study-shows-us-cancer-drug-costs-increasing-despite-competition.html.

[18] *Id.*

Services. Costs varied due to discounts or reimbursements, as well as individual copays and deductibles. After an average follow-up period of 8 years, the price of the drugs increased an average 25 percent, or 18 percent after adjusting for inflation.[19] Even when generic versions of drugs became available, the prices still increased. Overall, most of the injectable drug costs in the study continued to rise after launch.[20]

Experts project that the most significant factor that allows manufacturers to set high drug prices is market exclusivity, protected by monopoly rights awarded upon FDA approval and by patents if all statutory requirements are met.[21] The availability of generic drugs after this exclusivity period is the leading method of reducing prices in the U.S., but access to such drugs may be delayed by numerous business and legal strategies.[22] The primary approach to push back against excessive pricing during market exclusivity rests on the negotiating power of the payer, which is currently constrained by several factors, including the requirement that most government drug payment plans cover nearly all products.[23] Another key contributor to high-cost drug spending are physicians' prescribing choices when comparable alternatives are available at different, lower costs.[24] Experts argue that, although high prices are often justified by the high cost of drug development and innovation, there is no actual evidence that associates research and development costs to high prices, but rather, prescription drugs are priced in the United States primarily on the basis of what the market will prop up.[25]

b. Cost-Comparison of Pharmaceutical Spending Among Countries

The U.S. spends substantially more per capita than any other country on prescription drugs.[26] Drug spending exceeds that in all other countries largely because the market is driven by brand-name drugs that have increased in price in recent years at rates far beyond the consumer rate index.[27] The Commonwealth Fund reports that while drug utilization among American patients appears to be similar to citizens in other countries, the prices at which drugs are sold in the U.S. are significantly higher.[28] The U.S. spent $1,112 on retail pharmaceuticals per person in 2014, versus Canada spending $772 per person, followed by Germany at $741, and France at $659.[29]

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[19] *Id.*

[20] *Id.*

[21] Kesselheim, et al. *supra* note 8.

[22] *Id.* at 858.

[23] *Id.*

[24] *Id.*

[25] *Id.*

[26] Peter Olson and Louise Sheiner, *The Hutchins Center Explains: Prescription Drug Spending*, available at: https://www.brookings.edu/blog/up-front/2017/04/26/the-hutchins-center-explains-prescription-drug-spending/.

[27] Kesselheim, et al. *supra* note 8.

[28] Commonwealth Fund, *Paying for Prescription Drugs Around the World: Why Is the U.S. an Outlier?* Available at: http://www.commonwealthfund.org/publications/issue-briefs/2017/oct/prescription-drug-costs-us-outlier. Last visited March 12, 2018.

[29] Peter Olson and Louise Sheiner, *supra* note 20.

Prescription drug spending in the U.S. clearly exceeds that in other high-income countries. This phenomenon appears to be principally explained by the higher prices U.S. purchasers and consumers pay.[30] Americans are more likely than their counterparts to bear this financial burden out-of-pocket; both because the U.S. is the only country among those studied with a large uninsured population, and because even Americans with insurance tend to have less protective benefits than people in other countries.[31]

In a 2016 international survey of adults, 14 percent of insured Americans reported that in the past year, they did not fill a prescription or skipped doses of medicine because of the cost, compared with 2 percent in the U.K. and 10 percent in Canada, the nation with the highest rate after the U.S.[32] Among Americans without continuous insurance coverage over the past year, the rate was twice as high: one-third reported they did not fill a prescription for medicine, or skipped doses of medicine because of the cost.[33] The percentage of insured individuals who skipped doses of medicine due to costs falls just below those uninsured.

As identified above, U.S. prescription drug prices are higher due to the lack of price control strategies. Unlike the U.S., many other countries employ centralized price negotiations, national formularies, and comparative and cost-effectiveness research for determining price ceilings.[34] In the U.S., health care delivery and payment are fragmented, with numerous, separate negotiations between drug manufacturers and payers, and complex arrangements for various federal and state health programs.[35] The U.S. allows wider latitude for monopoly pricing of brand-name drugs than other countries are willing to accept.[36]

II. WHO FOOTS THE BILL?

The significant price differences between the U.S. and other countries appear to at least partly explain current and historical disparities in spending on pharmaceutical drugs.[37] As mentioned above, U.S. consumers face particularly high out-of-pocket costs, both because the U.S. has a large uninsured population and because cost-sharing requirements for those with coverage are more burdensome than in other countries.[38]

In 2015, the U.S. government paid roughly 43 percent of all retail prescription drug costs: 29 percent through Medicare, 10 percent through Medicaid, and the

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[30] Commonwealth Fund, *supra* note 14.

[31] *Id.*

[32] R. Osborn, D. Squires, M. M. Doty, D. O. Sarnak, and E. C. Schneider, *"In New Survey of 11 Countries, U.S. Adults Still Struggle with Access to and Affordability of Health Care,"* Health Affairs First, The Commonwealth Fund, Nov. 16, 2016).

[33] *Id.*

[34] Commonwealth, World Health Organization, *WHO Guideline on Country Pharmaceutical Pricing Policies,* WHO, 2015.

[35] D. Blumenthal and D. Squires, "*Drug Price Control: How Some Government Programs Do It*," To the Point*,* The Commonwealth Fund, May 10, 2016).

[36] *Id.*

[37] Commonwealth Fund, *supra* note 14.

[38] *Id.*

remainder through the Department of Defense (DOD), the Veterans Health Association (VHA), Children's Health Insurance Program (CHIP), and some smaller federal and state programs.[39] Even though the government is such a significant buyer in the prescription drug market, for the most part, it will not negotiate lower drug prices.

a. 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 growing enrollment and rising prices, the program is staring at decades of rapidly increasing costs. Not only is the Medicare budget growing, but the growth is projected to accelerate over the next decade.[40]

Within Medicare, prescription drugs are primarily covered under two different sections of the program: Part B and Part D. Medicare Part B primarily covers physician services in the outpatient setting, however it covers a good portion of prescription drugs that are administered in doctors' offices and outpatient settings.[41] These drugs are typically used for cancer treatment, arthritis, or macular degeneration, costing thousands of dollars per dose, and require multiple doses over a year's time.[42] Part B spending on drugs totaled nearly $25 billion in 2015, and half or more of this total are for anticancer drugs.[43]

Part B coverage of prescription drugs is governed by whatever is "reasonable and necessary for the diagnosis or treatment of illness or injury."[44] However, "reasonable and necessary" is not defined by the statute or regulations already in place, and thus require much intervention from CMS to determine coverage.[45] As a result, Part B drug coverage is quite broad and is restricted to drugs which are not self-administered and are provided in the course of a physician's service.[46] Nevertheless, Part B cannot decline to cover an effective FDA-approved drug simply because it is expensive. In fact, it appears that the Part B payment system is structured to encourage physicians to prescribe more expensive products.[47]

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[39] Peter Olson and Louise Sheiner, *supra* note 8.

[40] 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.

[41] Rachel E. Sachs, *Delinking Reimbursement*, Minnesota Law Review, Forthcoming,

Washington University in St. Louis Legal Studies Research Paper (2018).

[42] *Id.* at 8.

[43] *Id.* at 8, citing MEDPAC, Report to the Congress: Medicare and the Health Care Delivery System 119 (2016)("In 2014, Medicare spending for anticancer drugs accounted for about 55 percent of the nearly $21 billion spent on Part B drugs."). 42 U.S.C. § 1395y(a)(1)(A) (2012).

[44] Sachs, *supra* note 35, see also Exclusions from Coverage and Medicare as Secondary Payer.

42 U.S.C. § 1395y(a)(1)(A) (2012).

[45] *Id.* at 9.

[46] *Id.*

[47] *Id.,* see also MEDPAC, *supra* note 37.

Total expenditures on drugs under the Part D program are much higher than under Part B. In 2015, spending under the program exceeding $135 billion.[48] In creating Medicare Part D, Congress prohibited Medicare from negotiating with drug companies for lower drug prices. The "noninterference" clause, included in the Medicare Modernization Act (MMA), 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."[49] 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, which are discussed below.[50]

More recently, the Affordable Care Act (ACA) reforms have done nothing to empower Medicare to negotiate with drug companies, nor have they been successful in changing the challenge facing providers who are choosing between differently priced, but similarly effective, pharmaceutical drugs.[51] Without changing laws, incentives, or norms within the provider's decision-making process, providers have no reason to choose the less expensive drug, let alone to even research and learn which drug is less expensive. The ACA's silence on addressing increasing pharmaceutical drug costs, particularly within the Medicare program itself, preserves a decades-old narrative about Medicare's complicated history with drug pricing. Further, as the cost of health care increases, Medicare's beneficiaries are increasingly facing devastating rising costs for prescription drugs.

b. Medicaid

The Federal government does not allow for negotiations of Medicaid prices directly. Instead, by law it sets drug prices at the lowest amount others are paying, or sometimes even lower.[52] The situation for Medicaid, the federal-state level health insurance program for low-income Americans is different.

Compared to the Medicare payer system, Medicaid's system of prescription drug coverage is simpler. The federal government does not require that state Medicaid programs cover outpatient prescription drugs, however, even with this flexibility, all states have opted to do so. States must cover all FDA-approved drugs, except cosmetic drugs, and use formulary management tools to steer patients toward less expensive products.[53] Medicaid's coverage requirements come with preferred pricing benefits for the states. By law, pharmaceutical companies must pass on to Medicaid a rebate for each unit of a drug they sell to the program, and these rebates can be quite substantial.[54] For instance, an innovator drug company must remit at least 23.1% of a

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[48] Centers for Medicare & Medicaid Servs., *2015 Medicare Drug Spending Data* (2016), *available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/2015MedicareData.html.

[49] Buck, *supra* note 1 at 106.

[50] Issac Buck, *The Cost of High Prices: Embedding an Ethic of Expense into the Standard of Care.*

58 B.C. L. Rev. 101 (2017), University of Tennessee Legal Studies Research Paper No. 309.

[51] *Id. at 107.*

[52] Peter Olson and Louise Sheiner, *supra* note 8.

[53] Sachs, *supra* note 35.

[54] *Id.* at 11.

drug's Average Manufacturer Price (AMP),[55] and states are urged to seek additional rebates. Medicaid also includes a "best price" rule. If the drug company offers a better discount to another payer, Medicaid is entitled by law to that same "best price" provided to another entity for the drug.[56] Lastly, the Medicaid price model is insulated from price increases of existing drugs that outpace the inflation rate.[57]

c. Veteran Health Association and Department of Defense

The exception to the Federal government's restriction on directly negotiating drug prices with pharmaceutical is the U.S. Department of Veterans Affairs (VA). The VA negotiates prices outright and is able to exclude drugs from coverage, but accounts for only a small share of overall government drug spending. Currently, the VHA and the DOD are the only federal entities allowed to effectively negotiate directly with drug manufacturers; they pay prices that are roughly half of those paid at retail pharmacies.[58]

The VHA pays lower prices for pharmaceutical products than private-sector health care systems do, largely because of federal price controls.[59] Policy and legislation has set two caps on pricing, setting the maximum price that VHA pays for a drug is either the best commercial price net of certain discounts and rebates or the average price paid by pharmacies minus a large statutory discount, whichever is lower.[60] VHA receives additional discounts if drug prices rise faster than general inflation, which they have generally done. The two programs also directly negotiate lower prices with drug manufacturers. They may engage in these negotiations separately, or combine their substantial market share and negotiate together. VHA negotiates further discounts with drug makers for the drugs included on its formulary preferred drug lists, and in return steers its enrollees to use those drugs.[61] These formularies strengthen their negotiating stance. By threatening to offer only limited coverage for a drug, or to leave it off of the formulary entirely, the VHA is able to extract steeper discounts from manufacturers.

d. Private Insurers

Current statutes and regulations governing coverage in the private sector are comparatively complex. Private insurance is regulated at the state level, and providers must adhere to state-level coverage mandates for particular medical conditions. For example, forty-two states require payers to pay for all FDA-approved cancer therapies.[62] Private plans that are regulated under the ACA are jointly

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[55] *Id.* at 11, citing 42 U.S.C. § 1396r-8(c)(1)(B)(i)(VI) (amended by Patient Protection and Affordable Care Act Pub. L. No. 111-148, § 9008(f)(2), 124 Stat.119) (2012)

[56] DEP'T OF HEALTH AND HUMAN SERVS. OFFICE OF INSPECTOR GEN., Medicaid Rebates for Brand-Name Drugs Exceeded Part D Rebates By A Substantial Margin 8 (2015).

[57] *Id.*

[58] Congressional Budget Office, *Comparing the Costs of the Veterans' Health Care System with Private-Sector Costs*. December 2014).

[59] *Id.*

[60] *Id.*

[61] *Id.*

[62] Lee N. Newcomer, *Those Who Pay Have a Say: A View on Oncology Drug Pricing and Reimbursement*, 21 ONCOLOGIST 779, 779 (2016).

regulated at the federal and state level. The Federal regulations currently in place require plans sold in private insurance markets to cover ten essential health benefits, one of which is prescription drug coverage.[63]

Private payers' ability to demand discounts on required prescription drugs is limited by having to conform to Medicaid's "best-price rule". In addition, just because a provider is legally mandated to cover a particular drug does not mean it will be affordable to the patient. In turn, private payers often impose significant out-of-pocket cost-sharing.[64] Privately insured patients enrolled in a high-deductible health plan end up being exposed to thousands of dollars in cost- sharing before their insurance coverage ever kicks in.[65] These costs most likely discourage or prevent patients from accessing even covered products.

i. The Impact of High-Priced Specialty Drugs

Specialty drugs often provide substantially higher health benefits than traditional drugs, but at a significantly higher price. Specialty-tier drugs offer life-saving treatment to some of America's sickest and most vulnerable patients, such as those with hemophilia, hepatitis, multiple sclerosis, HIV/AIDS, and cancer.[66] The price tag for these treatments can be staggering, with consumers owing thousands of dollars each month in coinsurance bills.[67] There is no commonly accepted definition of a specialty drug. What sets the class apart typically is: (1) they often require special handling by pharmacies and physicians; (2) their costs, which can range from $15,000 a year to as much as $750,000 a year; and (3) most have no close substitutes, rendering health plans' traditional efforts to control costs by encouraging generic substitution largely ineffective.[68]

High-priced specialty drugs pose a number of potential dangers. The impact on patient financial solvency and medication adherence is a concern, although those fortunate enough to have health insurance typically have a cap on what they have to pay annually.[69] In the new federal marketplace, ACA policies have a cap of $6,250.[70] Individuals taking drugs on specialty tiers are likely to reach that cap, but drug expenses at that level can pose a hardship even for middle-income people.[71] The uninsured and those with individual policies outside the marketplace have either no

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[63] *Id.* at 11, citing ESSENTIAL HEALTH BENEFITIS REQUIREMENTS, 42 U.S.C. § 18022(b)(1)(F) (2010).

[64] Sachs, *supra* note 35 at 14.

[65] *Id.*

[66] Bradford R. Hirsch, Suresh Balu, and Kevin A. Schulman, *The Impact of Specialty Pharmaceuticals As Drivers Of Health Care Costs,* HEALTH AFFAIRS 33,[11]SEP.NO. 10 (2014): 1714–1720.

[67] Sabrina Corlette , Ashley Williams and Justin Giovannelli, *State Efforts to Reduce Consumers' Cost-Sharing for Prescription Drugs*, To the Point, The Commonwealth Fund. Available at: http://www.commonwealthfund.org/publications/blog/2015/nov/state-efforts-to-reduce-consumers-cost-sharing-for-prescription-drugs. Last visited March 12, 2018.

[68] Stephen Barlas, *Are Specialty Drug Prices Destroying Insurers and Hurting Consumers? A Number of Efforts Are Under Way to Reduce Price Pressure.* Pharmacy and Therapeutics. 2014;39(8):563-566.

[69] *Id.*

[70] *Id.*

[71] *Id.*

caps or higher caps. There is no cap in Medicare Part D; once someone pays $4,550 (in 2014) for drugs, they then become eligible for co-payments and/or co-insurance above that level.[72]

Even what some might assume to be reasonable out-of-pocket costs can be a major disincentive to medication adherence. Those with pharmacy plans are more likely to abandon their new prescriptions as costs rise.[73] The study showed that abandonment rates became significantly higher for both multiple sclerosis (MS) and biologic anti-inflammatory (BAI) drugs when out of pocket costs reached $250.[74] Furthermore, members whose out of pocket costs reached $2,000 or more were 24 times more likely to abandon new MS prescriptions and 19 times more likely to abandon new BAI prescriptions than members whose out of pocket costs were less than $100.[75]

The challenge now posed for the health-care industry is how to guarantee the American people affordable access to these life-saving drugs, without impeding on the drug manufactures financial incentives for research leading to additional innovative cures.

The growth of the specialty pharmaceutical market highlights the need to understand the drivers of demand for health care services and specialty drugs. Given the current state of knowledge, policy makers must balance ensuring that financial incentives within insurance schemes are designed to reduce consumption of low-value products and services and ensuring that benefit designs do not place outsized financial burdens on patients with severe illnesses, such as cancer.[76]

III. IS THERE A POSITIVE TO HIGH-COSTS?

The government is balancing two competing factors: giving pharmaceutical companies a financial incentive to innovate and produce breakthrough drugs, and conversely, keep drug prices as low as possible for patients. These goals are in tension more than ever. If the government allows drug companies to charge hundreds of thousands of dollars to develop a life-saving cancer treatment, more companies will be willing to take the risks inherent in such an uncertain research project. However, in allowing for such flexibility, costs will skyrocket, particularly because some very sick people may be willing to pay arbitrarily high prices for life-saving cures. Finding an appropriate balance is difficult.

America's higher spending on prescription drugs does not necessarily mean the spending is wasteful. A larger, more profitable pharmaceutical sector may attract investments resulting in more innovative and effective drugs in the future.[77] In order to fund and encourage research and treatment, drug companies argue they must recoup investment in other areas. Once one drug treatment is proven effective and

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[72] *Id.*

[73] Starner CI, Bowen K, Yang Qiu Y, et al. *Association of specialty drug prescription abandonment with increasing member out-of-pocket expense.* Prime Therapeutics. 2014 Apr; Available at: http://tinyurl.com/StarnerEtAl.

[74] *Id.*

[75] *Id.*

[76] Bradford, et. al., *supra* note 60.

[77] The Commonwealth Fund, *supra* note 22.

safe, drug companies argue they should be able to charge a commandeered price to allow the company to afford more treatment. Currently, there are highly effective drug treatments being introduced on the market with outrageous, but also arguably cost-effective, prices.[78] For example, sofobuvir-based drugs have been praised as cures for the hepatitis C virus (HCV) infection, with a response rate greater than 95% in most patients.[79] This very treatment is priced out by Gilead Sciences, Inc, at roughly $1000 per pill, or $84,000 for a 12-week course of therapy.[80] Authors Zettler and Fuse Brown explain that drugs such as the HCV medication can have exorbitant price tags precisely because of how effective they are.[81] Without the ability to set the prices of such cost-effective cures high enough, drug therapies could be at risk of being underdeveloped or undersupplied.[82] The authors emphasize that therapies that treat serious conditions and are more effective and safer than existing treatments, similar to sofosbuvir-based products, are exactly the type of novel treatments policymakers encourage, and feel their prices should reflect that.[83]

Further still, there is a business operation consideration. Drug companies argue that it is a high risk, low return proposition for them. Manufacturers spend millions developing a brand-name product, which on average, has a life-span of 13 years or so of sales before a generic competitor enters the market.[84] It is crucial then, for the drug manufactures to have the ability to charge a certain amount for their product in order to recoup and to have additional monies to investigate other products and treatments.

Despite this tug-of-war, some believe that the system is not all that broken. Americans' overall life expectancy has increased over the past few decades in part due to prescription drug innovations, and the costs are worth the benefits.[85] Others believe the government should take radical steps, such as funding all drug research and development and doing away with the patent system all together.[86] Still, others think that the system should be altered, but not completely overhauled. Although it is reasonable to push back on high healthcare prices, there may be limits on how low they should go. For this reason, policymakers who desire to reduce America's prescription drug bill need to weigh the pros and cons of different cost-control policies.[87]

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[78] Patricia J. Zettler and Erin C. Fuse Brown, *The Challenge of Paying for Cost-Effective Cures*, Am J Manag Care**.** 2017;23(1):62-64.

[79] *Id.* at 63 *(*citing Chhatwal J, Kanwal F, Roberts MS, Dunn MA. Cost-effectiveness and budget impact of hepatitis C virus treatment with sofosbuvir and ledipasvir in the United States. *Ann Intern Med.* 2015;162(6):397-406. doi: 10.7326/M14-1336).

[80] *Id.*

[81] *Id.* at 62

[82] *Id.* at 63

[83] *Id.*

[84] Peter Olson and Louise Sheiner, *supra* note 8.

[85] Hutchins, *supra* note 21.

[86] *Id.*

[87] Buck, *supra* note 1.

IV. CURRENT METHODS TO COMBAT HIGH-COSTS

Cost barriers remain far too common, especially for those Americans still without coverage. Ninety-two percent of U.S. adults favor letting the federal government negotiate lower drug prices.[88] Such a reform would mark a significant shift in U.S. policy toward more centralized pricing determinations.

There is much that the federal government could do to lower drug prices by both legislative and executive action. Over the past few years, there has been some discussion about the problem of high drug prices in Congress, but few serious proposals for drug price reform. The only comprehensive proposal to garner significant support at the federal level is a bill spearheaded by Senator Franken (D-MN) and released in March 2017.[89] The bill, titled the "Improving Access to Affordable Prescription Drugs Act," had support of more than a dozen other Senators. Although the bill represented a major step forward, many Republicans in Congress have yet to embrace drug pricing as a legislative priority. While President Trump has expressed support for increasing the affordability of prescription drugs, and has discussed joining forces with Democrats to support giving Medicare the authority to negotiate drug prices,[90] no concrete legislative proposals offered have been successful thus far.

The Trump Administration has outlined a proposal that could significantly lower the prices of pharmaceuticals through Medicare Part B. In his May 11, 2018 statement, FDA Commissioner, Scott Gottlieb, introduced the Trump administration's plan to remove barriers to generic development and market entry as a part of their Drug Competition Action Plan (DCAP), which would result in lower prices and greater access for patients.[91] The plan contains three key parts: substituting private-sector pharmaceutical vendors for the current Part B "buy and bill" practice, changing the Part B Average Sales Price plus 6 percent reimbursement system to a flat fee, and implementing international reference pricing.[92] The administration's role is to ensure that regulatory requirements are efficient, predictable and science-based; which will reduce the time, uncertainty and cost of generic and biosimilar product development.[93] It is critical to note that this proposal is limited to Medicare Part B, and therefore it would not provide benefits for Americans with private insurance or Medicare beneficiaries who have difficulty affording their Part D products.[94]

Many questions remain about the administration's DCAP proposal, including whether and when it would actually move forward because at least a portion of

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[88] *Id.*

[89] S. 771, 115th Cong. (2017); H.R. 1776, 115th Cong. (2017).

[90] Hopkins, Jared, *Trump Sends Pharma Stocks Down With New Tweet on Drug Prices*, *Bloomberg* (March 7, 2017), https://www.bloomberg.com/news/articles/2017-03-07/trump-sends-pharma-stocks-down-with-new-tweet-on-drug-prices.

[91] Statement from FDA Commissioner Scott Gottlieb, M.D., on the Trump Administration's plan to lower drug prices, May 11, 2018, https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm607495.htm.

[92] Rachel Sachs, *Administration Outlines Plan to Lower Pharmaceutical Prices In Medicare Part B*, Health Affairs, available at: https://www.healthaffairs.org/do/10.1377/hblog20181026.360332/full/).

[93] *Id.*

[94] *Id.*

Trump's proposal has been propounded by prior administrations to no avail.[95] Additionally, experts suspect the administration may not be able to withstand the political pressure it will face and surmise, Trump, once again, is offering more than he can deliver.[96] The glaring implication is that the proposal is more about deflecting political pressure than actually doing something about skyrocketing drug costs. Until political leadership decides to be genuine in its efforts, similar proposals are doomed to suffer the same fate.

Over the last several years, states have undertaken a range of legislative efforts to address high drug costs. However, certain remedies for high drug prices can come only from the federal government. For example, as previously mentioned above, only the federal government can authorize Medicare to negotiate drug prices for Part D, plus shorten the time during which drug companies can exclude competitors and enjoy monopoly pricing power.[97] Nevertheless, states do possess significant authority to take a range of measures to regulate drug pricing. Collectively, states can provide direct relief to millions of American citizens and residents through their police power. For example, policymakers have come up with several ways to combat high health care prices. One is an all-payer system, like that seen in Maryland.[98] An all-payer system regulates prices so that all insurers and public programs pay the same amount. A single-payer system could also regulate prices.[99] If attempted nationally or at the state level, either method would be met with resistance from all those who directly benefit from high prices including physicians, hospitals, pharmaceutical companies, and most every other provider of health care in the United States. Despite pushback, this Maryland example demonstrates that states can generate political momentum for a federal response to high drug costs and encourage state laws that allow for transparency about factors influencing drug prices.

Zettler and Fuse Brown share in their article, "The Challenge of Paying for Cost-Effective Cures", an encouraging policy proposal that addresses drug affordability by moving to a "value-based" pricing system. The authors explain, that such a system is based on a drug's cost-effectiveness with the underlying goal to ensure the drug's price is proportional to its health benefits.[100] Simply put, the more effective a drug is, the higher a manufacturer can charge for it, and rightly so. However, the authors confess that even if a value-based system is adopted, highly effective drug treatments could continue to face financing challenges.[101] Value-based prices of highly effective treatments may be unaffordable for a vast majority of Americans without financing mechanisms in place that will help spread the cost amongst the wider population.[102]

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[95] *Id.*

[96] *Id.*

[97] See *As Health Care Debate Shifts, Senator Franken and Senate Colleagues Lead Milestone Effort to Bring Down Prescription Drug Prices*, Press Release (March 29, 2017), available at: https://www.franken.senate.gov/?p=press_release&id=3655.

[98] Austin Frakt and Aaron E. Carroll, *Why the U.S. Spends So Much More Than Other Nations on Health Care*, The New York Times. Available at: https://www.nytimes.com/2018/01/02/upshot/us-health-care-expensive-country-comparison.html.

[99] Buck, *supra* note 1 at 134.

[100] Patricia J. Zettler and Erin C. Fuse Brown, *supra* note 71.

[101] *Id.* at 63.

[102] *Id.*

Zettler and Fuse Brown explain that private health insurers are not built to account for the long-term cost-effectiveness of a given drug treatment because insured patients frequently move between payers.[103] This poses a significant issue for those payers that suffer high short-term costs for highly effective drugs as they will never see the long-term financial benefit.[104] As a result, payers' inability to derive any financial benefit lessens their incentive to pay for the value-based price of effective drugs.[105] An added concern surrounding the value-based system, is that insurers may try to avoid costly patients by structuring their drug formularies to deter patients from choosing their plan all together, resulting in "health-based discrimination."[106]

To make highly effective and affordable drug treatments accessible and possible, the U.S. must explore policy options. Those options will only be discovered and applied when our elected officials are prepared and willing to recognize the very real danger of financial toxicity and how it is impacting the U.S. health care system at large.

V. A NOVEL SOLUTION TO AMERICA'S HIGH-COST PROBLEM: THE PHENOMENON OF FINANCIAL TOXICITY

The cost of pharmaceutical drugs continues to soar to new, unreasonable, and for an ever-increasing number of Americans, unattainable levels. This is a consequence of "financial toxicity". Financial Toxicity is the stunning phenomenon in which patients who are saddled with exorbitant medical costs actually experience worse health care outcomes as a result of the high cost of their care. Simply put, expensive care is bad care.

This concept was first conceived by Isaac Buck, a University of Tennessee health law professor. Buck's studies center mainly on pharmaceutical drugs. He suggests that treating a patient with an expensive pharmaceutical drug is not just bad for Medicare or the patient's financial well-being, but it may be bad for the patient's health as well.[107] Similar to other side effects, financial toxicity has been linked to differences in health-related quality of life, compliance, and, most recently, survival. Recent studies have demonstrated that financial stress and personal bankruptcy are particularly due to, or at least precipitated by, health care costs, which results in worse health outcomes for cancer patients.[108] Excessive costs propped up 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.[109]

Recognition of financial toxicity and its effect on the mortality of the patient undergoing treatment, should provide a potential new foothold for health care regulation. Like other side effects, if the price of a pharmaceutical drug negatively

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[103] *Id.*

[104] *Id.*

[105] *Id.* (Citing: Basu A. Financing cures in the United States. *Expert Rev Pharmacoecon Outcomes Res*. 2015;15(1):1-4. doi: 10.1586/14737167.2015.990887).

[106] *Id.* (Citing: Jacobs DB, Sommers BD. Using drugs to discriminate—adverse selection in the insurance marketplace. *N Engl J Med.* 2015;372(5):399-402. doi: 10.1056/NEJMp1411376).

[107] Buck, *supra* note 1.

[108] *Id.* at 136.

[109] *Id.*

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 prescription drug to its clinical efficacy could dramatically impact which drugs providers choose, giving Medicare, Medicaid and the VHA a new tool in its efforts to become a better gatekeeper of the public's financial wellbeing without relying on legal enforcement.[110]

a. Cancer Patients are Experiencing the Brunt of Financial Toxicity

Patients are facing increasing out-of-pocket costs for cancer care.[111] A study published in the Journal of Clinical Oncology shows that once cancer drugs go on the market, their prices tend to increase over time, sometimes sharply, even in the face of competition.[112] According to the study, prices are rising faster than inflation.[113] Cancer treatment is simply more expensive. This expensive treatment is over utilized, and as a result, the rising costs are passed on to the patient.[114] Those factors together with an aging populace and more patients with access to treatment have prompted a substantial rise in cancer expenses.[115]

i. Objective Burden

High drug prices can have a severe impact on patients' financial well-being as well as their physical well-being. In a national survey sponsored by the American Society of Clinical Oncology, one-fourth of people worried about paying for cancer treatment reported postponing prescriptions, cutting pills in half, or doing something else contrary to doctors' orders to cut costs.[116]

Due to the exorbitant price tag on cancer treatment, third-party payers have shifted a portion of costs to patients in the form of rising premiums, coinsurance, higher prescription drug copayments, and tiered drug formularies.[117] Out-of-pocket cost of oral chemotherapy alone can be over $500 a year, even for patients with private insurance.[118] Evidence suggests that mean out-of-pocket expenses for cancer care, including premiums, can be over $5,000/year.[119] Also important to the overall calculation of the financial burden, is the time patients spend receiving care rather than working or engaging in other activities, known as "patient time costs."[120]

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[110] *Id.* at 102.

[111] Stacy Simon, *Study Shows US Cancer Drug Costs Increasing Despite Competition,* American Cancer Society, available at*:* https://www.cancer.org/latest-news/study-shows-us-cancer-drug-costs-increasing-despite-competition.html.

[112] *Id.*

[113] *Id.*

[114] Zafar SY, Abernethy AP. *Financial Toxicity, Part I: A New Name for a Growing Problem*. Oncology (Williston Park, NY). 2013;27(2):80-149.

[115] *Id.*

[116] Simon, *supra* note 8.

[117] *Id.*

[118] *Id.*

[119] *Id.*

[120] *Id.*

Depending on the type of cancer and phase of care, patient time costs range from hundreds to many thousands of dollars per year.[121]

In addition, other sociodemographic characteristics, including type of insurance, race, marital status, education, geographic location, and comorbidity, all contribute to higher out-of-pocket expenses.[122] Not all patients experience the same objective financial burden; certain subgroups of the population are at higher risk for paying more out-of-pocket. In a study of patients receiving chemotherapy for colorectal cancer, younger patients and those with lower household income were predisposed to experience greater financial burden.[123]

ii. Subjective Burden

Mounting evidence has described the negative implications of cost sharing from the patient's perspective. Research demonstrates that patients receiving cancer treatment experience both an objective financial burden and subjective financial distress. However, compared to objective burden, much less has been published on subjective financial distress and its impact on the cancer experience.

Based on the available evidence regarding subjective financial distress, patients' well-being and quality of care suffer in a number of ways. In order to defray cancer-related out-of-pocket costs, patients are altering their lives and their care. Patients are non-adherent with their medications; they are opting out of expensive treatment; they are spending less on basics like food; and they are spending down their retirement savings.[124] Patients are experiencing financial toxicity as a direct result of their cancer treatment. A large portion of cancer patients (75 percent of whom had applied for copayment assistance), reported either a "significant" or "catastrophic" subjective financial burden[125]. These patients, whom were all insured, cut back on leisure activities and working hours by 68 percent, 46 percent reduced spending on food and clothing, and 46 percent used savings to afford their cancer treatment. In addition to these cutbacks, 20 percent of patients took less than the prescribed amount of medication, 19 percent partially filled prescriptions, and 24 percent avoided filling prescriptions altogether.[126]

b. Understanding Financial Toxicity as a New Approach to Control High Drug Pricing

There is more debate than ever centered on what type and amount of governmental regulation is appropriate and necessary to wring out unnecessary costs and utilization of pharmaceutical drugs. Even though the ACA has provoked this debate, it has not answered the question. When it comes to pharmaceutical drugs, the

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[121] *Id.*

[122] Shankaran V, Jolly S, Blough D, Ramsey SD., *Risk Factors for Financial Hardship in Patients Receiving Adjuvant Chemotherapy for Colon Cancer: A Population-Based Exploratory Analysis*. J. Clin. Oncol. 2012; 30:1608–14. [PubMed: 22412136].

[123] *Id.*

[124] Zafar SY, Peppercorn JM, Schrag D, Taylor DH, Goetzinger AM, et al., *The Financial Toxicity of Cancer Treatment: A Pilot Study Assessing Out-Of-Pocket Expenses and the Insured Cancer Patients Experience*, The Oncologist. 2013 In press.

[125] *Id*. at 382

[126] *Id.*

ACA has not heralded in a new era of tighter governmental regulation and cost control in the American health care system. Many of the pervasive, and uniquely American problems regarding excess costs remain, seemingly prompted by a thorny relationship between government intervention and medical and corporate autonomy.[127] In addition, with the fate of the ACA in doubt, the future of cost control is even more uncertain and troublesome.

Aware of the nuances that are required to regulate our complex health system, a blunt instrument like the law does not effectively limit excessive costs and utilizations of drugs.[128] The tension surrounding government intervention tracks the regulatory and professional feud between the medicine and law, which is the result of society viewing providers as independent.[129] Some Americans hold deep concerns about a medical system that is controlled by government, while others fear a self-interested medical profession, incentivized to excessively treat and overcharge, will gain vast dominance over all medical decision making. As a result, this tension has paralyzed the law in its effort to effectively prevent overtreatment and high costs with precision and fairness.[130]

Current approaches by Federal prosecutors rely on powerful anti-fraud tools available to them in an attempt to keep unnecessary utilization and expense under control. Despite these legal measures, a chaotic web of individuals and entities are either incentivized or penalized, pushing providers in opposite directions. Such statutory anti-fraud penalties and incentives are applied unevenly, with aggressive prosecutions stretching legal resources thin and beyond their limits.[131]

Instead of fixing a haphazard enforcement framework, or exploring new legal theories to attempt to rein in overtreatment, the example of Sloan- Kettering mentioned in this article's opening, teaches that providers themselves, have the power to rein in excess spending and overtreatment. If providers can be pushed to instill an ethic of cost into the provision of expensive health care and, subsequently, truly equate expensive care with substandard care, providers themselves can influence a more cost-effective health care marketplace.[132]

c. Implementing Financial Toxicity Policy

A solution to America's skyrocketing drug cost problem should begin with altering the perspective of the administrator and deliverer of health care themselves by deepening their understanding that expensive pharmaceutical drugs can cause worse health outcomes. This solution to rising drug costs relies upon making the argument to medical providers that overly-expensive, and overly-used care is harmful to patients. With pressure and collaboration, this new regime aims to push medical providers into replicating what the three doctors at Sloan-Kettering did. The goal is to increase awareness of financial toxicity in health policy circles. If policymakers and providers learn more about the effects of this new threat in cancer

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[127] Buck, *supra* note 1 at 107.

[128] *Id.*

[129] *Id.*

[130] *Id.* at 108.

[131] *Id.*

[132] *Id.* at 108.

treatment, the concern about financial toxicity will expand into other corners of American health care largely impacted by cost.

The lesson from New York's Sloan-Kettering may be that to effectively prevent overtreatment and excess costs, we must rely on tools that are located outside of the law. An understanding of financial toxicity could radically alter health care delivery. Specifically, if it is ingrained in the medical profession that increased costs lead 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.[133] Once the quality of the care being delivered by the provider is implicated, ethical and legal duties spring forth to protect patients in their moment of extreme medical and financial vulnerability. Put simply, cost becomes a component factor of quality of care. If attitudes shift to accepting that expensive health care actually threatens the health of the patient, then the provider should be required to begin caring about cost. The same analysis, candidness, and application should be used for all patients and their health concerns.

Transparency is key to limiting future financial distress in patients with cancer. Doctors need to find a way to be more up-front and candid about the true costs of cancer care. As new oral medications and immunotherapy are developed and used effectively, doctors need to discuss with patients and their families the costs of these treatments in terms of benefit versus risks.[134] Medical professionals need to be forthright about costs, and should incorporate this discussion into patients' overall treatment.

CONCLUSION

Pharmaceutical drug costs are rising rapidly in the United States. High drug prices are the result of the approach the U.S. has taken in granting government-protected monopolies to drug manufacturers, combined with coverage requirements imposed on government-funded drug benefits.[135] Even with the most realistic short-term strategies to address high prices, including enforcement of more stringent requirements on exclusivity rights; providing greater opportunities for meaningful price negotiation by governmental payers; generating more evidence about cost-effectiveness of a value-based system[136], government and private payers have been unable to find the answer to the deepening crisis. Even highly-publicized cases in which pharmaceutical companies seem to brazenly raise the price of their drugs have not been enough to move Congress to act.[137] Federal prosecutors use of anti-fraud statutes has been strained and stretched. With the ACA's fate in question, and lack of success from the Trump Administration, one wonders if, and when, a new reimbursement mechanism can be successfully implemented. Tough law tactics do not seem promising in this industry. At the same time, researchers are increasingly understanding that a patient's financial health following the treatment of care greatly impacts that patient's physical health.

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[133] *Id.*

[134] *Id.*

[135] Kesselheim, et al. *supra* note 8 at 858.

[136] *Id.*

[137] Buck, *supra* note 1 at 140.

Policy on the financial toxicity phenomenon may provide a meaningful course of action for regulation among providers in an industry that must seek to control health care costs. Currently associated with long-term cancer treatment, the phenomenon of financial toxicity likely also exists in other health contexts, and its policy effects could reach other corners of the health care market.[138] Price matters, and as policymakers begin to understand that costs impact health, American medicine must shift to incorporate patient cost concerns into the standard of care and more effectively educate patients, prescribers, payers, and policy makers about their choice of treatment.

The Sloan-Kettering doctors started a much needed conversation on the high price of pharmaceutical drugs. If providers can be urged to instill an ethic of cost into the supply of expensive health care and, subsequently, equate expensive care with substandard care, and worse health outcomes, health providers themselves can provide a roadmap to a more cost-effective health care marketplace.[139] The Sloan-Kettering 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 by considering the cost of that drug or procedure, then achieving cost effectiveness without hard legal intervention may be a viable pathway in American medicine. The Sloan-Kettering doctors have shown not only that it can be done, but how.

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[138] *Id.*

[139] *Id.*