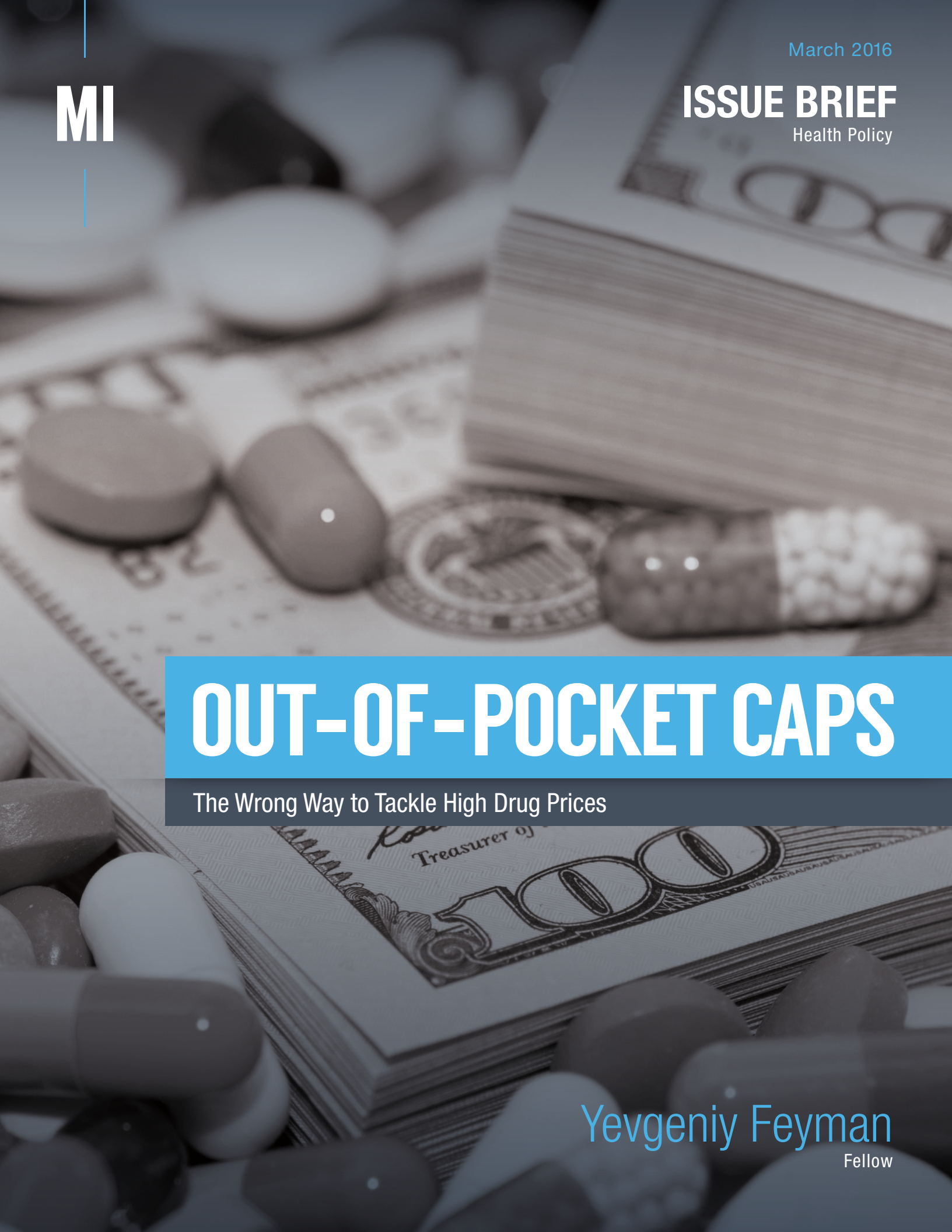

MI

March 2016

ISSUE BRIEF

Health Policy

OUT-OF-POCKET CAPS

The Wrong Way to Tackle High Drug Prices

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Contents

Executive Summary

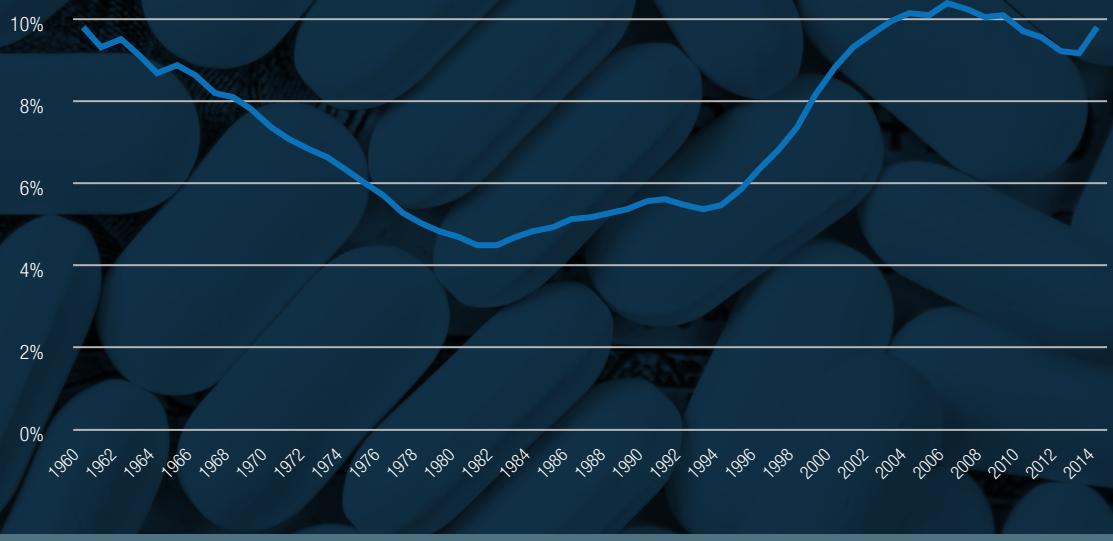
Though the Affordable Care Act remains deeply controversial, drug-pricing debates have largely replaced the ACA as the subject of media headlines and public-policy proposals at the state and federal levels. Although debates about high-priced drugs are not new, recent developments have captured the public imagination, including the launch of hepatitis C medicine Sovaldi in 2013 (list price: $84,000); the 5,000 percent price increase of generic drug Daraprim in 2015; and the high coinsurance (often surpassing 30 percent on ACA exchanges) for certain drugs targeting diseases such as multiple sclerosis and cancer.

Regardless of whether these isolated examples suggest a broad new reality of prohibitively expensive prescription drugs, there is a growing public perception that drug prices are too high. This sentiment is coupled with demands—from insurers, consumer groups, and some political candidates—for government to increase its role in pharmaceutical markets. The 2016 presidential candidates have proposed various reforms to control drug prices, including Medicare directly negotiating prices with drug companies; allowing drug imports from abroad; and accelerating FDA approval of generic versions of expensive biologic drugs whose patents have expired.[1] A number of states have also implemented limits on out-of-pocket (OOP) drug spending for patients.

Would federal OOP drug-spending caps—such as those proposed by Hillary Clinton[2]—make prescription drugs more affordable? This paper finds that adopting federal OOP caps would help a small minority of Americans who face enormous drug costs but would do little for the majority of Americans who fret about high drug prices; OOP caps also risk causing harmful knock-on effects to insurance markets that may result in higher premiums. Rather than intervene in insurance markets with blunt tools, policymakers should take a multipronged approach that harnesses market forces, treats drug spending as investment, and uses targeted tax credits to help the most burdened.

FIGURE 1.

U.S. Drug Spending as Share of Total U.S. Health Care Spending, 1960–2014



Source: Author's analysis of historical National Health Expenditure Accounts

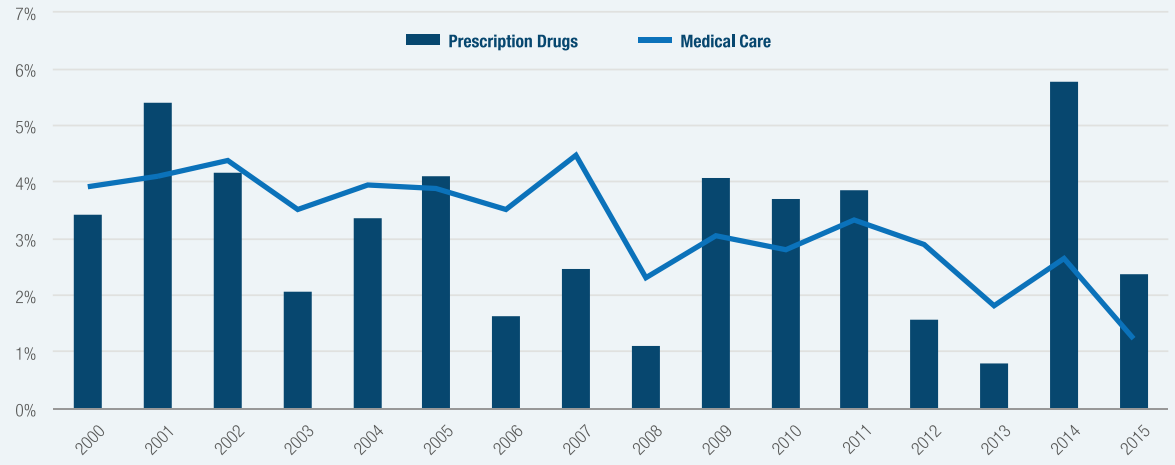
I. Introduction

The recent focus on drug pricing as a major driver of U.S. health care costs belies the realities of prescription drug-spending trends. At only 10 percent of national health expenditures in 2014 (**Figure 1**)[3]—with projections indicating little change in the near future—it is unlikely that prescription drugs are a central cause of the excessive growth in America's health care spending.[4] Not only has U.S. drug spending remained relatively constant as a share of total health spending; aggregate-price increases have also remained mostly in line with the health care system as a whole (**Figure 2**).

Despite the fact that hospital and health care–professional spending equal nearly half of total U.S. health care expenditures[5] and are much less transparent on pricing and provider-level outcomes than drug spending, there has been little momentum to impose OOP caps on inpatient and outpatient services. Why, then, is the public so focused on prescription drug spending?

FIGURE 2.

U.S. Medical Care and Prescription Drug Prices, Percentage Change, 2000–15



Source: Bureau of Labor Statistics

One explanation is due to the fact that a growing share[6] of OOP drug spending involves "specialty drugs"—which may be new, nominally high-priced, and lifesaving.[7] Another, more important, explanation involves the way that U.S. health insurance is structured: some costs are borne by insurance companies, others are borne by the government (or written off as uncompensated care by hospitals), and the remainder is mostly OOP. For drug spending, however, the last method was dominant until the mid-1990s, which made patients more aware of the cost of drugs.[8] (Individuals' OOP share has since fallen sharply, partly because of expanded drug coverage for the elderly, via Medicare Part D.)[9]

Because insurance coverage for pharmacy services lags other health care services, medicines appear to cost patients more, even—as is often the case—when they do not. The OOP share of drug spending—about 15 percent—is significantly higher than the OOP share for hospital services,[10] for instance; because copays, deductibles, and coinsurance are highly visible to patients and because many drugs for chronic illness must be taken for extended periods, even relatively small OOP drug purchases can seem exorbitant compared with OOP costs for, say, doctors' visits.

The cost of a week's stay in a hospital's intensive-care unit or coronary artery bypass surgery can easily run into the hundreds of thousands of dollars; but the patient may pay only a few hundred dollars OOP. On the other hand, copays for specialty drugs are significantly higher, despite the fact that they are far less expensive than similar, hospital-based, lifesaving services. In 2014, American patients spent about $45 billion OOP for prescription drugs, compared with $54 billion for physician services and $31 billion for hospital services.[11]

Drug-price sticker shock will likely grow, too. As more Americans enroll in high-deductible plans, through employers or ACA exchanges, the current fixed-copay structure will begin to disappear. Instead, patients will have to meet a unified deductible before their insurance kicks in, making drug costs still more visible. Further, as a result of the ACA, a large number of plans now offer "closed formularies," where the insurer makes no payments for drugs that are not explicitly covered.[12]

Beyond the issue of how we pay for drugs—and who pays for them—is a more general critique of the pharmaceutical industry: that drugs are simply too expensive for what they deliver. This perception, particularly in specialty areas like cancer, is being driven by the growing focus on the comparative cost-effectiveness of new medicines. One such study[13] found that oncology drugs typically have an incremental cost-effectiveness ratio (ICER) twice that of other drugs (a higher ICER translates to less value).[14]

While price controls—of which OOP caps are an indirect form—hold political appeal, they largely ignore the more important question of value; they do not allow markets to adapt to new information; and they do not take into account the long lag time and high risks that drug manufacturers face to bring new products to market. Economic theory suggests that consumer benefits from price controls—if they accrue at all—are likely to be modest, short-run, and overshadowed by the tremendous long-run costs of lost innovation.[15]

II. OOP Caps

America is the only advanced nation that does not impose direct price controls on pharmaceuticals.[16] Medicaid, the U.S. Department of Veterans Affairs, and the 340b drug-pricing program, among others, impose various sorts of indirect price controls; a number of states have also moved to protect patients from high OOP drug costs by restricting OOP spending on pharmaceuticals (**Figure 3**). This paper focuses its analysis on the potential effects of imposing nationwide OOP caps.

FIGURE 3.

Select States' OOP Caps on Prescription Drug Spending

Delaware	$100 monthly cap for up to a 30-day supply of any single specialty-tier drug; $200 total monthly cap for specialty tier
Maine	$3,500 annual cap
Maryland	$150 monthly cap for up to a 30-day supply of any single specialty-tier drug
Montana	$250 monthly cap per prescription, pre-deductible. Montana's health insurance commissioner will also not approve insurers lacking at least one plan design with pre-deductible copays for all drug tiers.
New York	Bans specialty tiers
Vermont	$1,000 individual ($2,000 family) annual cap (grows with IRS minimum deductible required to be considered a "high-deductible" plan)
California	$250 monthly cap per prescription for Silver plans on the state's exchange

Source: Commonwealth Fund and CapTheCopay.org[17]

States with OOP caps aim to protect insured patients from unreasonable cost-sharing for prescription drugs and to ensure appropriate adherence to medications (i.e., avoiding situations where patients forgo recommended drugs for financial reasons). Advocates of OOP caps often point to a major study, a meta-analysis of patient cost-sharing, which found a negative effect, absent caps, on patients' adherence to recommended drugs—even when copays were modest and drug adherence was associated with improved outcomes.[18] Some polls also indicate that about a quarter of Americans express difficulty paying for prescription drugs and that roughly three-quarters of Americans believe that drugs prices are "unreasonable."[19]

All this suggests that policymakers should focus their efforts on situations where certain drugs are recommended but high OOP costs make such drugs unaffordable. Unfortunately, current copayment insurance policies are not geared to maximizing patients' long-run health; such models also do not reflect varying patient-level responses to drug therapies. For instance, drugs that perform poorly, on average, may, in fact, be highly beneficial for specific patients. In such cases, appropriate cost-sharing should not be determined simply by broad averages.

It is also true that very expensive drugs with large-scale, long-run benefits must be paid for in the present; in a world of imperfect risk-adjustment mechanisms and one-year insurance contracts, insurers may be unwilling to invest in improving patient health when their competitors might reap the benefits many years later. Policies geared toward reducing the current burden of medical spending should therefore target low-income individuals: an affluent family of four earning five times the poverty line does not require the same protection as a single mother earning a poverty-level income.

III. Findings

This paper pools the 2012 and 2013 files from the Medical Expenditure Panel Survey Household Component (MEPS-HC)—which allows for extra precision due to their larger sample size—to project the effect of implementing various OOP caps nationwide: How many people would benefit? By how much? And how would such benefits be distributed? Specifically, it evaluates two possible OOP caps (**Figure 4**): capping OOP drug spending at $1,800 per year ($150 per month); and capping OOP drug spending at $3,000 per year ($250 per month).

Individuals with no health insurance are excluded from the sample (the aforementioned projections affect only the insured; the uninsured are also likely to be unusually price-sensitive and may choose to avoid health spending altogether), as are individuals who report no OOP drug spending (excluded to avoid downwardly biased estimates of mean drug spending). This paper also assumes that all affected spending is within network (under the assumption that legislated caps would not apply to off-formulary drugs) and that spending is even throughout the year (because we are evaluating data on an annual basis). OOP caps do not require insurers to extend universal formulary coverage; if individuals purchase non-formulary drugs, the projected savings, herein, would be upwardly biased. Such adjustments leave a total unweighted sample of 29,737 individuals and a weighted sample of 161 million individuals, using an average of weights during 2012–13.

FIGURE 4.

Distribution of Benefits of Two OOP Caps (Benefits in Millions, $)*

	EFFECTS OF A $3,000 CAP				EFFECTS OF A $1,800 CAP			
	POVERTY LEVEL (%)	SPENDING ($)	LOWER CONFIDENCE INTERVAL ($)	UPPER CONFIDENCE INTERVAL ($)	POVERTY LEVEL (%)	SPENDING ($)	LOWER CONFIDENCE INTERVAL ($)	UPPER CONFIDENCE INTERVAL ($)
Uncapped	0–99	3,450	3,000	3,900	0–99	3,450	3,000	3,900
	100–199	7,800	6,860	8,740	100–199	7,800	6,860	8,740
	200–299	8,440	7,360	9,530	200–299	8,440	7,360	9,530
	300–399	6,040	5,310	6,770	300–399	6,040	5,310	6,770
	400–499	6,330	5,260	7,400	400–499	6,330	5,260	7,400
	500+	15,900	14,100	17,700	500+	15,900	14,100	17,700
	Total	**47,960**	**41,890**	**54,040**	**Total**	**47,960**	**41,890**	**54,040**
Capped	0–99	3,260	2,850	3,670	0–99	3,040	2,700	3,390
	100–199	7,320	6,510	8,120	100–199	6,850	6,160	7,530
	200–299	7,670	6,870	8,470	200–299	7,150	6,440	7,850
	300–399	5,580	4,980	6,180	300–399	5,210	4,690	5,730
	400–499	5,760	4,980	6,530	400–499	5,360	4,690	6,030
	500+	14,900	13,300	16,400	500+	14,000	12,600	15,400
	Total	**44,490**	**39,490**	**49,370**	**Total**	**41,610**	**37,280**	**45,930**
Savings	0–99	184	102	267	0–99	405	259	552
	100–199	482	238	727	100–199	955	585	1,330
	200–299	770	247	1,290	200–299	1,300	661	1,930
	300–399	460	175	744	300–399	831	469	1,190
	400–499	576	57	1,090	400–499	971	387	1,560
	500+	1,020	583	1,450	500+	1,900	1,290	2,510
	Total	**3,492**	**1,402**	**5,568**	**Total**	**6,362**	**3,651**	**9,072**

*95 percent confidence intervals[20]

Source: Author's calculations based on 2012–13 Medical Expenditure Panel Survey Household Component

Figure 4 shows that in the pooled 2012–13 MEPS file, OOP drug spending would total roughly $48 billion—about 17.2 percent of total drug spending for this sample ($279 billion, or slightly greater than the $262 billion average for 2012–13 reported in National Health Expenditure Accounts). Under a $3,000 nationwide OOP cap, total drug spending would fall by about $3.5 billion, affecting 1.5 million people; roughly $1.5 billion (45 percent) of the savings would be captured by households with incomes at, or above, 400 percent of the federal poverty level ($97,000 for a family of four, according to 2015 federal poverty guidelines).[21] Under a nationwide $1,800 OOP cap, total drug spending would fall by $6.4 billion, affecting about 3.8 million people; roughly $2.9 billion (45 percent) of the savings would be captured by households with incomes at, or above, 400 percent of the federal poverty level.

These findings highlight two major drawbacks of imposing OOP caps. First, only a small fraction of the 162 million Americans with OOP drug purchases would be affected by such caps. Second, nearly half of the benefit of such caps would go to households well above the poverty line—households already less likely to be burdened by medical bills. More important, such caps do not link the price of drugs to their value for patients, consumers, and the overall health care system. Indeed, regulating copays and coinsurance threatens to shift patient spending toward more expensive medicines. To the extent that price competition helps hold prices and health care–cost growth for pharmaceuticals in check (the threat to place a drug on a higher, non-preferred tier would achieve this), capping OOP costs would limit market-based competition by making patients less price-sensitive to the benefits of medicines that may be—if at all—only marginally more effective than lower-priced options.

Capping OOP costs below their market rate would also increase costs for insurers and pharmacy-benefit managers (PBMs), which would likely respond by raising insurance premiums or cutting benefits. Milliman, a health care consultancy, modeled the effect of various OOP caps on California's ACA exchange: premium increases were generally held to less than 0.5 percent; but premiums for the most affordable plans, Bronze-tier, rose 1.6 percent–4.8 percent, depending on the cap. To avoid the latter, Milliman noted, OOP maximums or deductibles would have to be raised, while maintaining compliance with actuarial-value requirements would necessitate increasing copays for generic drugs, primary-care visits, or other services.[22]

IV. Better Ways to Tackle High Drug Prices

These findings suggest that OOP caps are untargeted and potentially wasteful. To better tackle high drug prices, policymakers should instead adopt the following reforms:

Let patients benefit from rebates. Take advantage of existing dynamics in the prescription drug supply chain by requiring patient cost-sharing to be based on discounts extended to PBMs. Typically, in exchange for preferred status on a PBM's formulary, a pharmaceutical company will pay a rebate for each prescription written for the company's drug. Consider Harvoni, the second hepatitis C treatment released by Gilead Sciences. At a list price of $94,500 for a 12-week course of therapy, the drug is hugely expensive. But reports indicate that the average discount offered to PBMs is close to 50 percent.[23] Yet patients pay coinsurance on the *full* retail price, not the discounted price.

To the extent that rebates reduce premiums, all enrollees in a PBM's plan will benefit. Still, patients who use the most expensive drugs should benefit directly from such rebates—which is not always the case today. The Department of Health and Human Services and state insurance commissioners should therefore consider requiring prescription drug coinsurance on the individual market to be based on drug prices, net of rebates. This would benefit high-cost patients, as well as, say, individuals who pay coinsurance for less expensive maintenance. Such a rule would harm innovation less than outright price controls on pharmaceuticals. On the other hand, if the details of rebates were made public, this might hurt PBMs' ability to use their market power to demand higher rebates, potentially causing price compression for some of the most heavily discounted drugs. Nevertheless, PBMs with less market power would likely benefit by being able to demand higher rebates. Moreover, absolute rebate transparency is not necessary for this approach, which could be tailored to use average blended rebates if necessary.

Offer tax credits to the most burdened. Make tax credits available to individuals whose drug spending surpasses a particular threshold. The threshold could be a simple dollar value: credits for anyone who spends more than $1,500 OOP on drugs annually, for instance. An even better approach would target credits based on the burden of drug spending (i.e., drug spending's share of an individual's

income): a 5 percent threshold, say, would offer tax credits to individuals whose drug spending surpasses 5 percent of income. A "negative income tax" model, where the credit equals some share of the difference between the threshold and actual spending, would be attractive, too. One way to pay for these credits would involve levying a disease-specific fee on insurers with relatively few patients with specific high-cost diseases.

Encourage credit markets for prescription drugs. Imagine if people only bought homes in the same fashion that they currently buy high-cost drugs—with a lump-sum payment at the time of purchase. Homeownership would tumble and be restricted to the wealthy. Happily, mortgages allow creditworthy buyers to stagger their payments over time. High-priced drugs that save and extend lives are no less valuable investments and would benefit from similar financial innovation. "Amortizing cures" could mirror how hospitals pay for large investments: "The cost of a robotic tool for performing prostate surgery, for example, is typically spread out (or amortized) over the seven years during which the device is presumed to be useful,"[24] note Scott Gottlieb and Tanisha Carino of the American Enterprise Institute. Just as student loans and mortgage interest can be deducted for tax purposes, similar subsidies should be offered for prescription drug "mortgages."

V. Conclusion

High drug costs impose a heavy burden on some patients. This paper finds that adopting federal out-of-pocket drug-spending caps would help a small minority of Americans who face enormous drug costs but would do little for the majority of Americans who say that drugs are unaffordable. Federal caps might also cause insurance premiums to rise, further reducing their efficacy. Rather than artificially reduce OOP burdens, policymakers should take a multipronged approach that harnesses market forces, treats drug spending as investment, and offers tax credits to the most burdened. Such actions would be more targeted, would offer far greater benefits for a larger share of patients, and would avoid harmful distortions to insurance markets.

Endnotes

1 See, e.g., https://berniesanders.com/issues/fighting-to-lower-prescription-drug-prices; and https://www.hillaryclinton.com/briefing/factsheets/2015/09/21/hillary-clinton-plan-for-lowering-prescription-drug-costs.

2 See https://www.hillaryclinton.com/briefing/factsheets/2015/09/21/hillary-clinton-plan-for-lowering-prescription-drug-costs.

3 See https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/index.html?redirect=/NationalHealthExpendData.

4 See https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nationalhealthaccountshistorical.html.

5 See https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/index.html?redirect=/NationalHealthExpendData.

6 Data on the breakdown of OOP drug spending by drug class are difficult to find because the uptake of specialty tiers has grown among insurers and pharmacy-benefit managers.

7 See https://www.healthinsurance.org/glossary/specialty-drug.

8 Author's analysis of National Health Expenditure Account data.

9 Ibid.

10 Ibid.

11 Ibid.

12 See http://www.forbes.com/sites/scottgottlieb/2015/12/09/why-your-drug-coverage-is-an-increasingly-hollow-benefit/#682af881228d25948058228d.

13 See http://www.ncbi.nlm.nih.gov/pubmed/25351969.

14 ICER measures cost-effectiveness based on the cost of an additional year of life in "perfect health."

15 See, e.g., http://www.nber.org/digest/may05/w11114.html.

16 Most OECD countries employ some form of price controls for pharmaceuticals. The U.K.'s National Institute for Health and Clinical Excellence evaluates the cost-effectiveness of new pharmaceuticals; typically, it won't recommend a drug for coverage that does not meet certain cost-effectiveness thresholds. Similarly, French regulators determine a value-metric for soon-to-be-released drugs and then negotiate the price of soon-to-be-marketed drugs based on these metrics. Most European countries also use a form of external reference pricing, which ties reimbursements in one country to prices in another. The Netherlands uses such an approach, as well as reference pricing within drug groups (i.e., reimbursement for a particular class of drug is based on reimbursement of other drugs in the class). See https://ppri.goeg.at/Downloads/Publications/The%20pharmaceutical%20system%20of%20the%20Netherlands_FINAL.pdf.

17 See http://www.commonwealthfund.org/publications/blog/2015/nov/state-efforts-to-reduce-consumers-cost-sharing-for-prescription-drugs; and http://www.capthecopay.org/wp-content/uploads/2014/03/Existing_State_OOP_Laws_Specialty_Tiers_10-2014_ML1.pdf.

18 See http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3278192.

19 See http://kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-august-2015.

20 These represent a range that we expect to include the "true" total of OOP drug spending; more precisely, with infinite sampling of the population, we expect that 95 percent of the time, the range will include the population parameter.

21 See https://aspe.hhs.gov/2015-poverty-guidelines.

22 See http://www.lls.org/sites/default/files/National/USA/Pdf/Milliman%20Report%20on%20Prescription%20Cost%20Sharing%20Limits%20for%20Exchange%20Plans.pdf.

23 See http://www.firstwordpharma.com/node/1262258#axzz3wh4IRASa.

24 Ibid.

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Abstract

There is a growing public perception in the United States that drug prices are too high. This sentiment is coupled with demands—from insurers, consumer groups, and some political candidates—for government to increase its role in pharmaceutical markets.

Key Findings

- The 2016 presidential candidates have proposed various reforms to control drug prices; a number of states have also implemented limits on out-of-pocket (OOP) drug spending for patients.
- Adopting federal OOP caps would help a small minority of Americans who face enormous drug costs but would do little for the majority of Americans who fret about high drug prices; OOP caps also risk causing harmful knock-on effects to insurance markets that may result in higher premiums.
- Rather than intervene in insurance markets with blunt tools, such as OOP caps, policymakers should take a multipronged approach that harnesses market forces, treats drug spending as investment, and uses targeted tax credits to help the most burdened.

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