REDUCING THE PRICE OF PRESCRIPTION DRUGS: GAG CLAUSE PROHIBITIONS, GOVERNMENT PATENT USE, AND SHOPPING ABROAD

by

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Dissertation

Submitted to the Faculty of the

Graduate School of Vanderbilt University

in partial fulfillment of the requirements

for the degree of

DOCTOR OF PHILOSOPHY

in

Law and Economics

August 12, 2022

Nashville, Tennessee

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To my unwaveringly supportive family

ACKNOWLEDGEMENTS

This dissertation would not have been possible without the tremendous educational, administrative, and financial support of the Vanderbilt Law and Economics program. I am grateful to have spent the past six years surrounded, supported, and inspired by such remarkable faculty, staff, and peers.

I am particularly thankful for my dissertation committee: Professors Paige Skiba, W. Kip Viscusi, John Graves, and James Blumstein. Each was generous with their time, providing valuable insights and detailed feedback that significantly improved the quality of this dissertation. Special thanks to my advisor and the chair of my committee, Paige Skiba, for her mentorship and guidance throughout the years and through the dissertation process. I am forever grateful for you.

I have been blessed with extraordinary peers in the Law and Economics program. Thank you all for six years of support, encouragement, and—most importantly—friendship. I am particularly indebted to Erin Meyers, Clayton Masterman, and Nick Marquiss, who were always a call away to help think through a thorny issue, celebrate a breakthrough, or mourn a research disappointment.

I would be remiss not to thank the many friends who have supported me from near and far during the last two isolating years. Thank you to Yaneis Autumn, Iesha Mitchell, Mags Manning, Sam Sergent, Liz McElvein, Thomas Cleary, and Connor Jorgensen for your enduring support and understanding when I disappeared into a dissertation pit for long periods of time. Thank you to Blair Prescott for getting me outside, feeding me, and casting a spell or two. Thank you to Adam Karpinski for being a constant source of comfort and laughter during this process.

And thank you to Erin Meyers for each and every hour-long call—I could not have navigated the past years without you.

Last, but certainly not least, an enormous thank you to my family. My parents, Bob and Joan Malone, have been my biggest supporters and source of inspiration. Words are inadequate to express my gratitude for all they have done. And thank you to my brother, Michael, for not only being the best big brother I could ask for, but also the inspiration for much of this dissertation.

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INTRODUCTION

The disproportionately high price of pharmaceutical drugs in the United States has garnered significant attention, particularly in the last several decades. Politicians face substantial public pressure from constituents on both sides of aisle to enact legislation to reduce the price of prescription drugs. And, the high cost of medications have long been the focus of federal, state, and individual efforts to reduce the financial burden. This dissertation examines three approaches to reducing prescription drug costs.

In chapter 1, I examine the effect of a legislative reform that has become popular both at the state and federal levels in the last several years: prohibiting pharmacy benefit managers (PBMs) from including gag clauses in contracts with pharmacies. These clauses prevent pharmacists from telling consumers when they can purchase a prescription more cheaply by paying for it out-of-pocket instead of through their insurance plan. This chapter presents the first empirical study on the effect of prohibiting gag clauses. I find that the common state approach to prohibiting gag clauses modestly reduces out-of-pocket expenditures, while I do not find evidence that the more lenient federal approach does so.

In chapter 2, I consider the viability of systematically using two existing statutory mechanisms for government patent infringement to accelerate generic entry in an effort to reduce prescription drug costs. Bayh-Dole march-in rights and Section 1498 government patent use both provide the government with significant patent infringement discretion. I weigh the potential costs of government patent infringement—namely reduced innovation—against the benefits such a systematic approach may offer. In lieu of federal legislation, these statutes offer an existing, more easily implementable solution to high drug prices.

In chapter 3, I use an experiment to better understand the gap between the portion of Americans struggling to afford their prescriptions and the portion of Americans who purchase from foreign pharmacies to save money. I employ a vignette study to elicit the discount consumers demand before accepting the risks associated with purchasing prescription drugs online from another country and probe risk beliefs about ordering prescription drugs online from foreign countries. I find that respondents demand, on average, a smaller discount to induce purchase from a foreign online pharmacy than the existing discounts available to individuals.

CHAPTER 1: GAG CLAUSE PROHIBITIONS: OUT-OF-POCKET EXPENDITURES AND MEDICATION ADHERENCE

I. Introduction

In the United States, lawmakers face substantial public pressure to reduce the out-of-pocket cost of prescription drugs (Huetteman 2019). Today—and historically—Americans spend dramatically more on prescription drugs than individuals in any other country in the world (Organization for Economic Cooperation and Development 2019). The disproportionately high prescription drug costs in the United States have long been the focus of federal, state, and individual efforts to reduce the financial burden these costs impose. Although state and federal legislative efforts typically do not address the generally-accepted root source of high drug prices—market exclusivity and a lack of government price negotiation common in other countries—recent actions may provide some relief to consumers.

In this chapter of my dissertation, I examine the effect of a legislative reform that has become popular both at the state and federal levels in the last several years: prohibiting pharmacy benefit managers (PBMs) from including gag clauses in contracts with pharmacies. These clauses prevent pharmacists from telling consumers when they can purchase a prescription more cheaply by paying for it out-of-pocket instead of through their insurance plan. Before legislative intervention, close to a quarter of prescriptions involved a copayment in excess of the national average retail price for the drug (Van Nuys et al. 2018). Though the excess copayment amount is relatively small on average, decreasing prescription drug costs has the potential to improve health through increased medication adherence and allow individuals to reallocate savings to other expenditures.

In this chapter, I use a difference-in-differences design to identify the effect of PBM gag clause prohibitions at the federal and state levels on out-of-pocket prescription costs and medication adherence. While the federal government recently took a less stringent legislative approach to prohibiting gag clauses, state legislatures have been implementing more restrictive prohibitions over the last several years. I find that the common state approach of prohibiting gag clauses in contracts and requiring that copayments not exceed the retail price of a drug decreases out-of-pocket prescription drug expenditures between 9 percent and 16 percent. I do not find evidence that the more permissive federal approach to prohibiting gag clauses results in a reduction of out-of-pocket drug expenditures, though this result must be interpreted with some caution.

The chapter proceeds as follows. Part II provides background on the prescription drug cost landscape in the United States and PMBs, gag clauses, and legislative prohibitions of such clauses. Part III discusses related literature on the prevalence of copayments exceeding retail price for prescription drugs and the relationship between prescription drug cost and medication adherence. Part IV presents a simple theoretical model for understanding how pharmacists decide whether to comply with gag clauses. Part V describes my data and empirical approach for analyzing the effect of state and federal gag clause prohibitions. Part VI presents my results. And, part VII discusses the implications of my results.

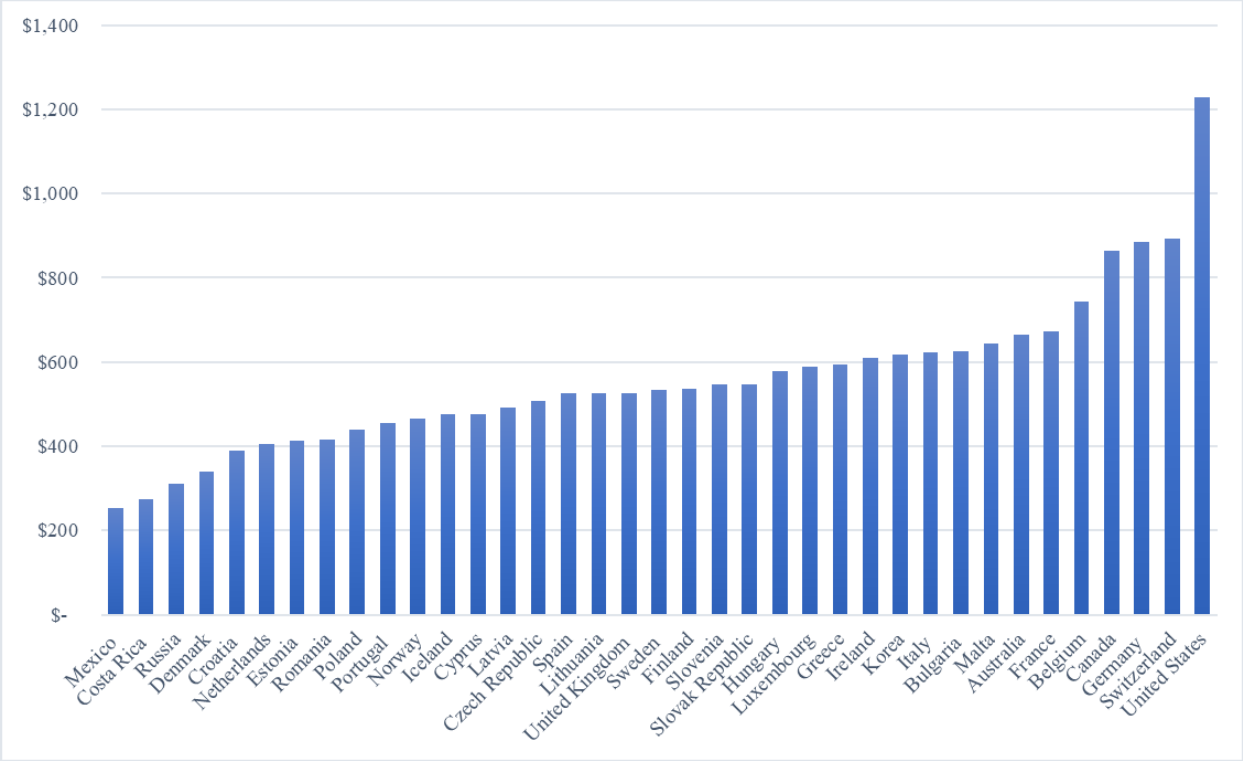
II. Background

This section provides background information on prescription drug costs in the United States and PMBs, gag clauses, and legislative responses to these contractual clauses.

A. Prescription Drug Costs in the United States

On a per capita basis, Americans spend an average of over $1,200 on prescription drugs each year (Organization for Economic Cooperation and Development 2019). This amount exceeds expenditures in any other country in the world; it is almost 40 percent greater than per capita spending in the second-most expensive country, Switzerland, and over 50 percent greater than that in the United Kingdom and other European peer countries (Figure 1). There is one primary reason for the higher expenses Americans face: drug prices. Although drug utilization is similar in the United States and peer countries and generics make up a larger portion of drug utilization in the United States than in most peer countries, Americans spend more largely because pharmaceutical prices are higher (Sarnak et al. 2017).

Figure 1: Per Capita Pharmaceutical Expenditures, 2018



Prescription drug spending in the United States is not only disproportionately high, it is growing and projected to continue to do so. In 2016, net spending for retail prescription drug

coverage—including out-of-pocket expenses, the share of premiums allocated for retail drug benefits, and government spending—totaled $341 billion, an increase of thirty-six percent since 2012 (Urahn et al. 2019). The Centers for Medicare and Medicaid Services estimate that prescription retail spending rose about 27 percent over the same time period, outpacing expenditure growth in any other personal healthcare category. The organization projects that retail prescription spending will continue to outpace growth in other types of healthcare spending through 2026. Unsurprisingly given these spending increases, for the last decade annual increases in drug costs have exceeded general inflation; between 2013 and 2015, costs increased at over six times the rate of general inflation (Hernandez et al. 2019).

Although prescription drug costs are only one element of the high healthcare costs in the United States, they impose a demonstrated burden on Americans' wallets and health. Nearly one-fourth of the U.S. population reported having a hard time affording the cost of prescription drugs in 2019 (Kaiser Family Foundation 2019). The National Center for Health Statistics reported that as of 2017 over 11 percent of adults between the ages of eighteen and sixty-four who were prescribed medication in the past year skipped medication doses, took less medicine, or delayed filling a prescription to reduce prescription drug costs; within the uninsured population, one-third took such measures to reduce prescription drug costs (Cohen et al. 2019). And, in a recent survey, nearly thirty percent of respondents reported not taking their medication as prescribed within the last year due to cost (Kirzinger et al. 2019). Many Americans are forced to seek assistance to afford their prescriptions. Prescription drug charity programs that help individuals with out-of-pocket drug costs constitute a $10 billion industry, with such programs accounting for half of the twenty largest charities in the country (Karlin-Smith 2017). Thousands of

GoFundMe users turn to the online charitable giving platform to seek donations to cover the cost of their prescriptions (Heller 2019).

Unsurprisingly, the inability to afford prescription drug expenses translates into sometimes devastating health consequences. Nonadherence to prescription drugs causes roughly 125 thousand deaths in the United States each year (Peterson et al. 2003). Though nonadherence is not always attributable to drug costs, a strong relationship exists. In addition to the direct cost to individual health resulting from cost-driven nonadherence there are likely secondary effects. Household resource constraints—particularly for low-income households—combined with high out-of-pocket prescription expenses may result in insufficient budget for other needs, such as groceries or rent.

B. Pharmacy Benefit Managers, Gag Clauses, and Prohibitive Legislation

Emerging in the 1970s as fiscal intermediaries that adjudicated prescription drug claims, PBMs originally filled a relatively simple role. When a patient dropped a prescription off at a pharmacy, the pharmacy would contact the PBM to ensure the individual had coverage and determine whether the prescription was covered under the individual's plan, the relevant copayment amount, and whether any additional authorization was required. After the pharmacy filled the prescription, it would contact the PBM to approve the transaction and the PBM would seek payment from the insurer and transfer the payment to the pharmacy.

Today, PBMs are much more than fiscal intermediaries who simply process prescription transactions; they manage the pharmacy benefit for health plans. The companies represent health insurers, self-insured employers, union health plans, and government purchasers in the selection, purchase, and distribution of pharmaceuticals. As the intermediary between payers, drug manufacturers, and dispensers, PBMs play an integral role in determining which drug products

are most frequently used, how they are covered by insurance, and how pharmacies are compensated for their part of the process.

PBMs are involved with the administration of drug benefits for more than 266 million Americans with health insurance (Werble 2017). The market is highly concentrated. In 2018, three PBMs controlled over 75 percent of market: CVS Health, Express Scripts, and OptumRx (Fein 2019). As large, specialized businesses, PBMs have significant negotiating power. PBMs leverage their buying power to negotiate discounts from drug manufacturers who seek to be included in a formulary, or list of drugs that are covered under an insurance plan. Because most Americans are covered by plans with pharmacy benefits managed by PBMs, inclusion on formularies is crucial to market success. Included drugs are cheaper, which increases consumer demand and ultimately drug sales. Drug manufacturers are therefore induced to compete with one another by offering discounts on the wholesale acquisition cost of a drug. Insurers, in turn, are incentivized to contract with PBMs to reap some of the benefits of those discounts.

While the business model has the potential to result in significant price reductions for prescription drugs, it has been heavily criticized in recent years. PBMs make revenue through fees, manufacturer rebates, and pharmacy "spreads"—the difference between what they pay for drugs from a pharmacy what they get paid by the insurer. However, the various negotiated prices are opaque, and a significant criticism has been that PBMs are not passing rebate savings through to insurers and, ultimately, consumers. Another practice that has garnered significant criticism—and legislation—is the companies' inclusion of gag clauses in their contracts with pharmacies.

Gag clauses are contractual terms that constrain a pharmacist's ability to communicate price alternatives to consumers. In particular, they prevent the pharmacist from telling a consumer that they can save money by paying for a prescription out-of-pocket when the retail

price of a drug is lower than their copayment for the drug. Gag clauses are sometimes explicit, stating that pharmacists may not notify consumers that they could save money by paying cash rather than using their insurance. Other times they are captured in broad confidentiality language. If a pharmacist violates the prohibition on communication, the pharmacy risks losing the network contract with the PBM. Generally, the clauses only prohibit a pharmacist from initiating communication about a cheaper alternative; if a consumer asks about a drug's cash price or cheaper alternatives the pharmacist is able to disclose options. Nonetheless, consumers are unlikely to do so because they rationally expect that the cost-sharing nature of their insurance coverage reduces the cost of prescription drugs.

PBMs include such contractual provisions because the companies stand to profit from them. When a consumer pays a copayment amount that exceeds the retail price of a drug, the PBM collects the difference. Despite the financial incentives for including gag clauses in contracts, there is some dispute about the frequency with which they are included in contracts. Representatives from the largest PBMs have publicly stated that they do not impose the restrictions. But many pharmacists report being subject to gag clauses. In a 2016 survey of community pharmacies, 20 percent of respondents reported gag clauses operating in over fifty sales transactions in the last month and an additional 40 percent of respondents reported the restriction operating in between ten and fifty sales transactions in the last month (National Community Pharmacist Association 2016). And the practice of including gag clauses has been prevalent enough to garner significant attention and prompt legislative action at the state and federal level. In 2017 and 2018, news reports about gag clauses appeared in major outlets, such as the New York Times, the Washington Post, and NBC, and states were early movers in legislating to prohibit the practice.

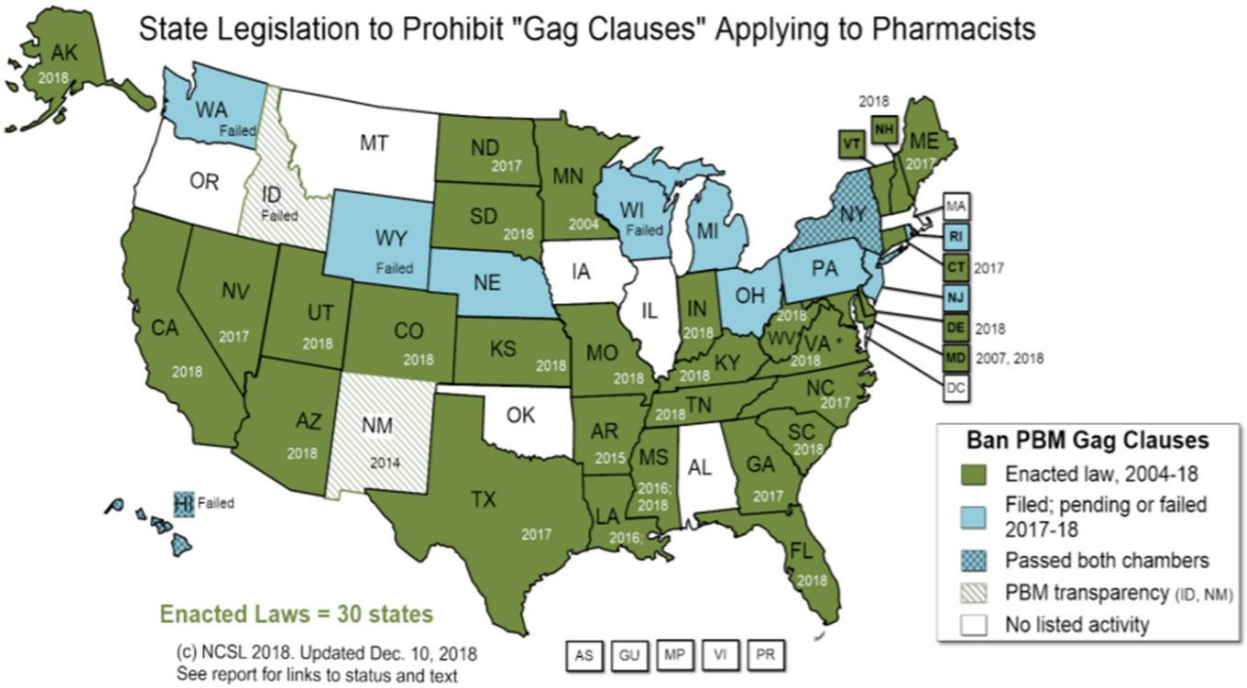
Minnesota enacted the first state-level gag law prohibition in 2004. The legislation required pharmacists to provide patients with both the copayment amount and "the usual and customary price of the prescription." It also explicitly prohibited insurers and PBMs from including contract terms restricting pharmacists from disclosing price information. Maryland followed suit in 2007, with a slightly different approach. The state enacted legislation prohibiting insurers and PBMs from imposing a copayment in excess of the retail price of a prescription drug, effectively mooting the possibility for any gag clause to have an effect. No other state acted until 2015, when Arkansas passed legislation prohibiting gag clause prohibitions. Since that time, state legislation in the area has been swift and widespread. Between 2016 and 2018, thirty states enacted gag clause prohibition laws. Because the federal government also acted in 2018, I restrict my analysis to those states that enacted legislation in 2017 and earlier. This includes twelve states: Arkansas, Connecticut, Georgia, Louisiana, Maine, Maryland, Minnesota, Mississippi, Nevada, North Carolina, North Dakota, and Texas. Figure 2 graphically illustrates state legislative action from 2004-2018.

As illustrated by the differences between the Minnesota and Maryland legislation, states approach prohibitions on gag clauses differently. Most of those which passed legislation before 2018 followed Maryland's approach of prohibiting a copayment amount in excess of the amount a pharmacy is reimbursed for the drug. Several additionally prohibit PBMs from restricting a pharmacist's ability to communicate information about cost or cheaper alternatives to a customer. Minnesota is unique in explicitly requiring pharmacists to disclose both the copayment amount and the usual and customary price of a drug.

The state laws passed during this time did not exempt private sector health plans covered by the Employee Retirement Income Security Act (ERISA), nor did they directly regulate any

health plans. Rather they regulated an intermediary, the PBM. A recent Supreme Court decision confirmed that such regulation is not preempted by ERISA. In *Rutledge v. Pharmaceutical Care Management Association*, the Court ruled 8-0 that ERISA did not preempt an Arkansas law regulating PBMs, explaining, in part, that state regulation of an intermediary contracted by a health plan does not "directly regulate health benefit plans at all."

Figure 2: State Gag Clause Prohibitions, 2004–2018



Source: Cauchi (2018)

In October 2018, the federal government enacted two pieces of legislation prohibiting the use of gag clauses. The Patient Right to Know Drug Prices Act broadly prohibits "a health group plan or a health insurance issuer offering group or individual health insurance coverage" from restricting pharmacies from informing an enrollee of any differential between their out-of-pocket cost for a drug under the plan and the cost for the drug without using health insurance. The legislation specifies that covered entities must ensure that PBMs they contract with do not include any such restrictions either. While the Patient Right to Know Drug Prices Act covers

commercial plans, companion legislation, the Know the Lowest Price Act, prohibits gag clauses in Medicare prescription drug plans. The legislation impacting commercial insurance plans went into effect immediately upon passage, while that impacting Medicare plans went into effect in January 2020.

III. Related literature

To date, there has been no empirical research on the effect of PBM gag clause prohibitions on consumers out-of-pocket expenditures or medication adherence. Researchers at the University of Southern California, however, have documented the frequency and magnitude of prescription drug overpayments. And, my dissertation research intersects with existing research on medication adherence and how individuals respond to income shocks with health enhancing or health detracting investments.

To assess how frequently gag clauses are effective, Van Nuys et al. (2018) compared copayments with the national average reimbursement received by pharmacies for commercially insured patients for the same prescription. Examining copayments from 9.5 million pharmacy claims relative to reimbursement data from the Centers for Medicare and Medicaid Services on national average retail price (NARP), the authors found that 23 percent of claims involved a copayment which exceeded the NARP by more than $2. Overpayment was much more common for generic drugs than brand name drugs. Twenty-eight percent of claims for generic drugs involved overpayment while only about 6 percent of claims for brand name drugs involved overpayment. The authors found an overall mean overpayment of $7.69 and an average overpayment of $13.46 for brand name drugs. Roughly 17 percent of overpayments exceeded $10. Among the twenty most commonly prescribed drugs, twelve involved overpayments of

more than 33 percent. And, in aggregate, overpayments in the sample of pharmacy claims totaled $135 million.

Though the magnitude of the overpayments found by Van Nuys et al. are not immense, the frequency is striking and may have important implications for increased medical services use and negative health outcomes. Medication nonadherence, widespread in the United States, is associated with poor therapeutic outcomes, disease progression, and an estimated burden of billions of dollars in avoidable health care costs each year. Research has consistently shown that 20 percent to 30 percent of medication prescriptions are never filled and that roughly 50 percent of medications for chronic disease are not taken as prescribed (Viswanathan et al. 2012). Nonadherence is estimated to cause about 125 thousand deaths and at least 10 percent of hospitalizations in the United States each year (Peterson et al. 2003). And, nonadherence is estimated to cost the health care system between $100 billion and $289 billion each year (Viswanathan et al. 2012). There are a number of factors contributing to medication nonadherence, including demographic (e.g. age, sex, education, employment, and income), sociocultural (e.g. health literacy and medication beliefs), and behavioral (e.g. cognitive function and mental illness) factors.

Among these factors, cost-related nonadherence has been well documented. Patients themselves often cite cost as the reason for medication nonadherence. In a survey of 10 thousand patients, 17 percent reported the reason for missing medication being high drug costs (Boston Consulting Group 2003). In another survey of about 15 thousand Medicare beneficiaries, over 55 percent who did not fill at least one prescription reported doing so because they thought it would cost too much (Kennedy et al. 2008).

In accord with this self-reporting, several studies have found that reductions in out-of-pocket expenses increase medication adherence. Chernew et al. (2008) estimated the effects of a large employer's intervention that reduced copayments for five chronic medication classes and found a 7-14 percent reduction in nonadherence relative to a control employer. Choudhry et al. (2010) found that a program that eliminated copayments for cholesterol drugs and reduced copayments for a blood clot inhibitor increased adherence for the cholesterol drug about 3 percent and for the blood clot inhibitor about 4 percent. Maciejewski et al. (2010) evaluated an insurance program in North Carolina which eliminated generic medication copayments and reduced copayments for brand-name medications, finding that the program improved adherence to medications for diabetes, hypertension, hyperlipidemia, and congestive heart failure between 1.5 and 3.8 percentage points. Zhang et al. (2011) studied the impact of the introduction of Part D and found that the program increased adherence for individuals without prior drug coverage by between 13.4 and 17.9 percentage points. Choudhry et al. (2011) estimated the effect of randomly assigning patients discharged after myocardial infarction to full prescription coverage or usual prescription coverage for all statins, beta-blockers, angiotensin-converting–enzyme inhibitors, or angiotensin-receptor blockers, finding that adherence was 4 to 6 percentage points higher in the full-coverage group.

IV. Theoretical Model

The effect of gag clause legislation is somewhat theoretically ambiguous for two reasons. First, if PBMs have a difficult time monitoring the behavior of individual pharmacists, there may be significant preexisting noncompliance with the gag clauses. Second, if the cost of communicating the lower retail price to consumers is high for individual pharmacists (e.g. the computer system does not readily display both prices or pharmacists find such communication

onerous), merely removing the gag clause may not increase communications; something stronger, such as an affirmative obligation to provide consumers with price disparity information or match retail price, may be necessary. To formalize a theoretical model of the pharmacist's decision to communicate a lower price option to a customer, I assume that the pharmacist does so when the expected benefit of doing so exceeds the expected cost. My basic model is outlined as follows:

(1) $$u(c) = b + g - p_d(c_d) - c_c$$

Where $u(c)$ is the utility an individual pharmacist derives from communicating a lower cost option, b is the business benefit that accrues from the communication (e.g. customer loyalty or increased patronage), g is the warm glow from contribution to the public good, $p_d(c_d)$ is the expected cost of sanctions for violating a gag clause (the probability of detection times the cost of detection), and c_c is the effort cost of communicating the lower cost option. If $u(c)$ is positive, the pharmacists will communicate the lower price.

If the expected cost of sanctions for violating a gag clause and the effort cost of communicating the lower cost of option were small when gag clauses remained in place, noncompliance with the clauses may have been common and prohibiting such clauses may have little effect. Similarly, if the effort cost of communicating the lower cost option is large and the warm glow from contribution to the public good is small, eliminating gag clauses may have little effect. Conversely, if the expected cost of sanction for violating a gag clause was high and the business benefit, warm glow, and effort cost all relatively small, eliminating gag clauses may induce a pharmacist to communicate the lower cost option.

This model reveals that the federal approach to eliminating gag clause prohibitions—simply disallowing such contractual terms—may be anticipated to have less of an effect on out-

of-pocket drug expenditures than the common state approach of both disallowing such contractual terms and requiring that a copay not exceed retail price. Unless non-compliance with gag clauses was rampant before the prohibition of such clauses, the lower effort cost associated with the state approach should induce a greater price reduction for consumers.

V. Data and Empirical Model

I examine the effect of gag clause prohibitions using both federal and state laws. First, I exploit the different implementation dates of the two pieces of federal legislation to examine the effect of the ban on gag clauses on consumers' out-of-pocket prescription drug costs and cost-related medication adherence. Because the federal law affecting commercial insurers went into effect in late 2018 and the law affecting Medicare Part D insurers did not go into effect until the beginning of 2020, there is a roughly one year period in which Medicare beneficiaries were not protected by the prohibition while their slightly younger counterparts were. In line with previous literature evaluating the impact of Medicare Part D expansion, I use a difference-in-differences design comparing Medicare eligible individuals with the near-elderly who are not Medicare eligible (Engelhardt & Gruber 2011; Liu et al. 2011; Choi et al. 2017).

Second, I exploit the staggered implementation dates of state legislation to examine the effect of the prohibition on gag clauses on consumers' out-of-pocket prescription drug costs. I use a difference-in-differences design comparing expenditures in states that adopted a gag clause prohibition before 2018 to those that did not.

I draw data from several sources. To analyze the effect of the federal gag clause prohibition on out-of-pocket expenditures and medication adherence, I use detailed expenditure data from the Medical Expenditure Panel Survey (MEPS) and cost-related medication adherence data from the National Health Interview Survey (NHIS). To analyze the effect of state gage

clause prohibition on out-of-pocket expenditures I use data from the Consumer Expenditure Survey (CES). In this section, below, I provide detail on the data and my empirical approach.

A. Data

My outcome data for analyzing the effect of the federal gag clause prohibition on out-of-pocket expenditures and medication adherence come from the Medical Expenditure Panel Survey (MEPS) the National Health Interview Survey (NHIS). The MEPS is a set of large surveys of individuals and medical providers that collects data on the utilization of health services for the United States' non-institutionalized population. Each household is surveyed five times over two years and new households enter the survey each year so that each year's data contain responses from two panels. The months that each round of the survey covers differ from household to household.

In addition to other health information, MEPS collects details on the prescription drugs that the respondent used during the survey period. Prescription drug records are collected from pharmacies following written release of records by a survey respondent. The data indicate what drugs (if any) the patient received, dosage, and payment for each filled prescription, including out-of-pocket payments and payments made by private insurance, Medicaid, Medicare, and other sources. Summary statistics for the two groups based on data from 2014-2019 are in Table 1. Relative to the Medicare control group, the near elderly, non-Medicare treatment group is about 8 years younger, has somewhat higher income, uses fewer prescription medications, and spends less on prescription drugs.

Table 1: MEPS Summary Statistics, 2010–2018

	Non-Medicare		Medicare	
	Mean	SD	Mean	SD
Age	60.76	3.156	68.42	2.219
Personal Income ($)	40,686	43,871	36,323	38,166
Family Income ($)	75,396	68,865	66,018	62,062

Total Healthcare ($)	7,897	20,403	11,563	21,698
Total Prescriptions	18.22	27.59	25.96	28.42
Total Prescription ($)	2,219	8,180	3,257	8,844
Out-of-Pocket Prescription ($)	237.1	951.4	350.7	892.0
Male	0.470	0.499	0.438	0.496
White	0.712	0.453	0.749	0.433
Hispanic	0.185	0.388	0.141	0.348
High School or Less	0.487	0.500	0.451	0.498
Some College	0.166	0.372	0.170	0.375
Bachelors	0.162	0.369	0.171	0.376
Masters or Greater	0.102	0.303	0.124	0.330
N	18,437		12,177	

The NHIS is a cross-sectional household interview survey of the United States' non-institutionalized population. The survey includes a number of questions about access to healthcare. Among these are three questions about medication adherence and prescription drug cost: 1) whether the respondent delayed filling a prescription due to cost, 2) whether the respondent took less medication due to cost, and 3) whether the respondent skipped medication doses due to cost. I use data from 2014-2019 in my analysis. Summary statistics for the near-elderly, non-Medicare treatment group and the Medicare control group are in Table 2. Relative to the control group, the treatment group is younger, higher income, and engages in cost-related medication nonadherence more frequently.

Table 2: NHIS Summary Statistics, 2014–2019

	Non-Medicare		Medicare	
	Mean	SD	Mean	SD
Age	61.01	3.146	67.99	1.966
Male	0.454	0.498	0.426	0.494
White	0.799	0.401	0.830	0.376
Hispanic	0.0887	0.284	0.0755	0.264
High School Education or Greater	0.886	0.318	0.881	0.324
Very Good Health	0.443	0.497	0.459	0.498
Delayed Filling Rx	0.0828	0.276	0.0588	0.235
Took Less Medication	0.0714	0.258	0.0501	0.218
Skipped Doses	0.0665	0.249	0.0464	0.210
Family Income > $75K	0.359	0.480	0.258	0.437

N	20,549	15,448

My outcome data for the analysis of the effect of state gag clause prohibitions on out-of-pocket expenditures come from the 2012 to 2018 Consumer Expenditure Survey (CES) microdata files collected by the U.S. Census Bureau on behalf of the Bureau of Labor Statistics. The CES provides comprehensive data on consumer expenditures on a variety of goods and services in the United States. Quarterly expenditures of a rotating panel of roughly 7 thousand households are captured via an interview component. Beginning in 2009, the CES included questions about prescription drug expenditures, which provide the data for my analysis. My data on state laws come primarily from the National Conference of State Legislatures. I confirm the enactment date and the effect of laws by cross-referencing with the text and history of each piece of legislation. State demographic and economic data come from the Bureau of Labor Statistics and the Census Bureau. Summary statistics for the sample are in Table 3.

Table 3: CES and State Characteristic Summary Statistics, 2012–2018

	Mean	SD
Quarterly prescription expenditures ($)	105.76	203.72
Household characteristics		
Family size	2.451	1.388
Household income ($)	72,950	64,078
Age, respondent	56.73	16.27
Female, respondent	0.551	0.497
Married, respondent	0.575	0.494
White, respondent	0.840	0.367
Black, respondent	0.0848	0.279
Asian, respondent	0.0555	0.229
High school or less, respondent	0.300	0.458
Associates degree, respondent	0.0974	0.296
Some college, respondent	0.207	0.405
Bachelors degree or more, respondent	0.395	0.489
State characteristics		
Male	0.493	0.00475
White	0.760	0.0605
Black	0.121	0.0635
Asian	0.0777	0.0515

Hispanic	0.246	0.139
Per capita income ($)	50,696	7,376
Unemployment	0.0615	0.0185
N	61,606	

B. Empirical Model

I use a difference-in-differences design to identify the effect of the federal prohibition on gag clauses on out-of-pocket expenditures and medication adherence. In my primary analysis examining the effect of the gag clause prohibition on expenditures, I run ordinary least squares regressions of the form:

(2) $$Outofpocket_{it} = \beta_0 + \beta_1 Gag_{it} + X_{it}\beta + \delta_t + \varepsilon_{it}$$

where $Outofpocket$ is the out-of-pocket expenditure of individual *i* at time *t*; *Gag* is equal to one for individuals between the ages of 58-63 after the enactment of the Patient Right to know Drug Prices Act in October 2018; *X* is the set of individual controls; and δ is year fixed effects. My coefficient of interest is β_1, which captures the effect of the gag clause prohibition on out-of-pocket expenditures.

In my secondary analysis, examining the effect of the gag clause prohibition on medication adherence, I run ordinary least squares regressions of the form:

(3) $$Adherence_{it} = \beta_0 + \beta_1 Gag_{it} + X_{it}\beta + \delta_t + \varepsilon_{it}$$

where $Adherence$ is a binary variable equal to one if the individual *i* reported delaying filling a prescription due to cost, taking less medication due to cost, or skipping medication doses due to cost in year *t*; *Gag* is equal to one for individuals between the ages of 58-63 after the enactment of the Patient Right to know Drug Prices Act in October 2018; *X* is the set of individual controls; and δ is year fixed effects. My coefficient of interest is β_1, which captures the effect of the gag clause prohibition on each of these three measures of medication adherence.

I also use a difference-in-differences design to identify the effect of state prohibitions on gag clauses on out-of-pocket expenditures. In my analysis examining the effect of gag clause prohibitions on prescription expenditures, I run ordinary least squares regressions of the form:

(4) $$Outofpocket_{ist} = \beta_0 + \beta_1 Gag_{st} + X_{st}\beta + \gamma P_i + \eta_s + \delta_t + \varepsilon_{ist}$$

where $Outofpocket$ is the log quarterly out-of-pocket expenditure of individual *i* in state *s* and year *t*; *Gag* is equal to one for states in years after a gag clause prohibition has been passed; *X* is a set of state demographic and economic controls; *P* is a set of individual controls; and η and δ are state and year fixed effects. My coefficient of interest is β_1, which captures the effect of the gag clause prohibition on out-of-pocket expenditures.

VI. Results

Below I present the results of my research. I do not find evidence that the more permissive approach to prohibiting gag clauses taken by the federal government decreases out-of-pocket prescription expenditures and, correspondingly, do not find evidence that cost-related medication adherence improves. The more restrictive legislative approach commonly used at the state level, however, decreases out-of-pocket prescription drug expenditure between 9 and 16 percent.

A. Federal Gag Clause Prohibition

The critical assumption for identification of a causal effect is that out-of-pocket prescription costs would have evolved in a parallel fashion for the treated and untreated groups but-for the introduction of the gag clause prohibition. Figure 3 plots the mean out-of-pocket prescription expenses for the two groups from 2010-2019, demonstrating similar pre-period trends in my outcome of interest. As an additional test of parallel trends, Figure 4 plots the mean total health care expenses for the treatment and control groups from 2010-2019, and again

demonstrates similar pre-period trends. Figures 5-7 plot the pre-trends for cost-related medication adherence for the two groups from 2014-2019; these, too, demonstrate similar pre-period trends.

Figure 3: Out-of-Pocket Prescription Expenditures, 2010–2018

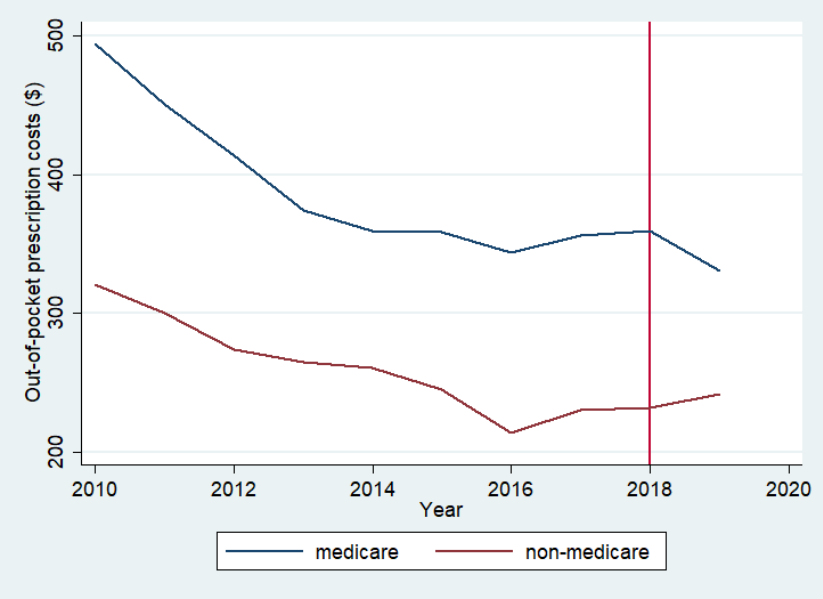


Figure 4: Total Health Costs, 2010–2018

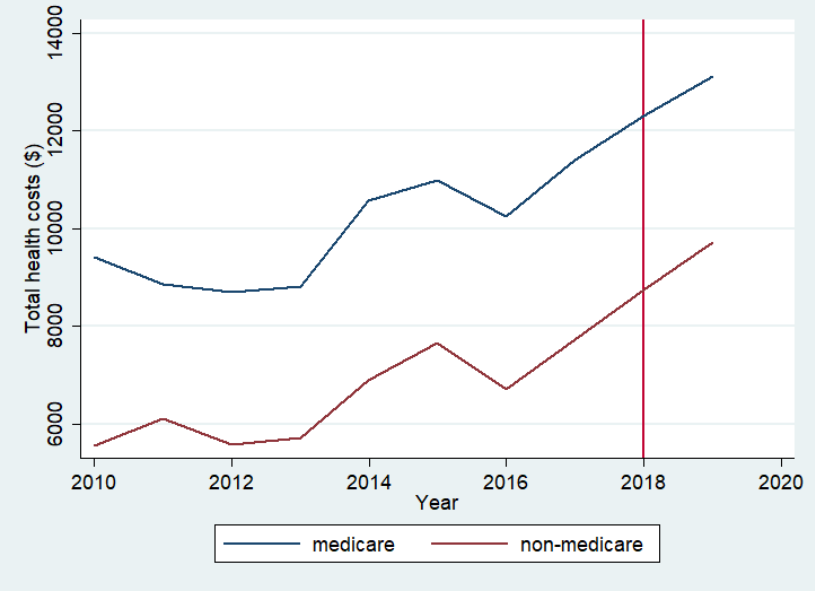


Figure 5: Delayed Purchase, 2014-2019

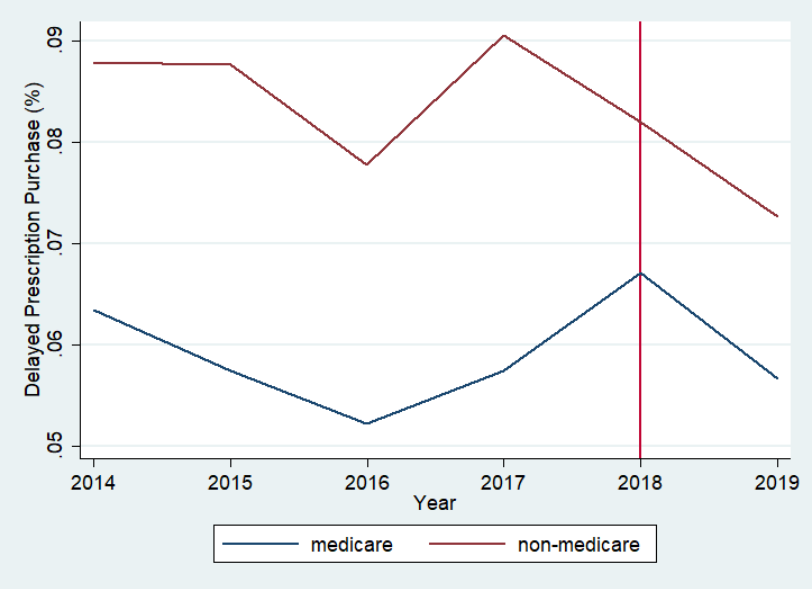


Figure 6: Took Less Medication, 2014-2019

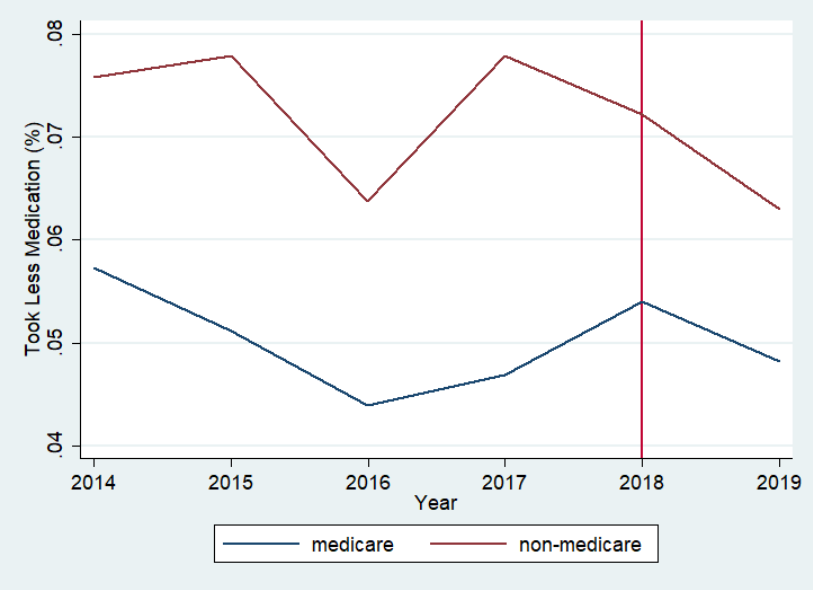
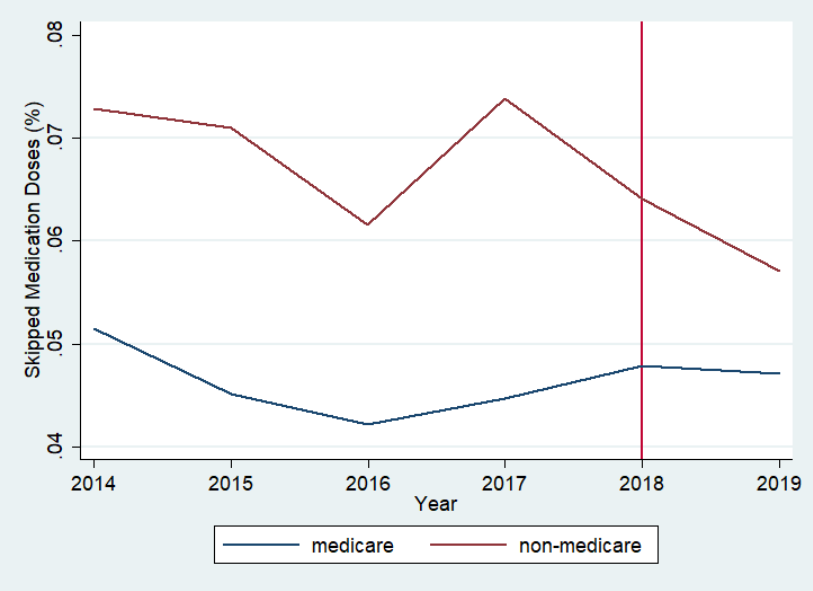


Figure 7: Skipped Doses, 2014-2019



Using equation (2), I estimate the effect of the federal gag clause prohibition on out-of-pocket expenditures on prescription drugs. In the results below, I use an unbalanced panel of data from 2014-2019, though results do not differ meaningfully using a sample from 2010-2019 or 2018-2019. As the results in Table 4 demonstrate, I do not find evidence that the gag clause prohibition has a statistically significant impact on out-of-pocket expenditures. Because the standard errors are quite large, large effects in either direction cannot be ruled out. However, expenditures increase with age and decrease for individuals who are nonwhite.

Table 4: Effect of Gag Clause Prohibition on Out-of-Pocket Expenditure

	Out-of-Pocket Expenditure
Gag clause prohibition	-3.76
	(33.67)
Female	10.98
	(14.35)
Age	7.66***
	(1.49)
Black	-122.15***
	(14.14)
Alaskan Native or American Indian	-89.17**
	(41.24)
Asian	-148.43***

	(21.73)
Pacific Islander	-189.45***
	(97.53)
Hispanic	-118.51***
	(18.54)
Some college or associates	16.87
	(19.72)
Bachelors	26.04
	(22.25)
Masters or greater	38.27*
	(22.93)
Total personal income	-0.00
	(0.00)
Total family income	0.00
	(0.00)
Midwest	69.98***
	(20.53)
South	76.41***
	(18.80)
West	1.28
	(18.45)
Constant	-190.51**
	(95.63)
Observations	29,938
R-squared	0.01

Robust standard errors in parentheses
*** p<0.01, ** p<0.05, * p<0.1

Using equation (3), I estimate the effect of the federal gag clause prohibition on medication adherence. In the results below, I use an unbalanced panel of data from 2014-2019, though results do not differ meaningfully when I restrict the sample to 2018-2019. As the results in Table 5 indicate, the gag clause prohibition does not have an impact on medication adherence. Because I find that the federal gag clause prohibition does not decrease out-of-pocket expenditures, the result that there is no effect on medication adherence should be expected. The results do indicate that there is a positive relationship between age and income and a greater likelihood of medication adherence. They also suggest that individuals with poorer self-reported

health are progressively more likely to suffer from medication nonadherence due to cost (excellent health is the omitted category).

Table 5: Effect of Gag Clause Prohibition on Medication Adherence

	Delayed Filling Prescription	Took Less Medication	Skipped Medication Doses
Gag clause prohibition	-0.0016	-0.0044	-0.0060
	(0.0076)	(0.0071)	(0.0067)
Female	0.0262***	0.0229***	0.0181***
	(0.0033)	(0.0031)	(0.0031)
Age	-0.0042***	-0.0036***	-0.0035***
	(0.0004)	(0.0004)	(0.0004)
Black	-0.0044	-0.0010	-0.0026
	(0.0061)	(0.0056)	(0.0056)
Asian	-0.0268***	-0.0208***	-0.0044
	(0.0076)	(0.0072)	(0.0085)
Hispanic	-0.0089	-0.0115	-0.0049
	(0.0073)	(0.0070)	(0.0071)
High school graduate	-0.0163	0.0417***	0.0234
	(0.0371)	(0.0148)	(0.0219)
Bachelor's degree	-0.0034	0.0532***	0.0336
	(0.0371)	(0.0149)	(0.0220)
Master's degree	0.0031	0.0632***	0.0417*
	(0.0374)	(0.0155)	(0.0223)
Income $0 - $34,999	0.0213	0.0073	0.0029
	(0.0209)	(0.0199)	(0.0206)
Income $35,000 - $49,999	-0.0194	-0.0256	-0.0284
	(0.0213)	(0.0203)	(0.0209)
Income $50,000 - $74,999	-0.0371*	-0.0416**	-0.0361*
	(0.0210)	(0.0200)	(0.0207)
Income $75,000 - $99,999	-0.0579***	-0.0616***	-0.0564***
	(0.0210)	(0.0199)	(0.0207)
Income $100,000 and over	-0.0719***	-0.0704***	-0.0673***
	(0.0207)	(0.0198)	(0.0205)
Very good health	0.0063*	0.0079**	0.0073**
	(0.0037)	(0.0031)	(0.0030)
Good health	0.0249***	0.0245***	0.0237***
	(0.0042)	(0.0037)	(0.0036)
Fair health	0.0768***	0.0680***	0.0709***
	(0.0065)	(0.0059)	(0.0060)

Poor health	0.1161***	0.0995***	0.0967***
	(0.0111)	(0.0100)	(0.0098)
Constant	0.3190***	0.2218***	0.2354***
	(0.0495)	(0.0346)	(0.0385)
Observations	35,997	35,997	35,997
R-squared	0.0616	0.0526	0.0499

Robust standard errors in parentheses
*** p<0.01, ** p<0.05, * p<0.1

B. State Gag Clause Prohibitions

Using equation (4), I estimate the effect of state gag clause prohibitions on quarterly prescription expenditures. Results are presented below in Table 6, where Model 1 reports estimates with no controls, Model 2 adds household-level controls, Model 3 adds state-level controls, and Model 4 adds linear time trends. The results are sensitive to specification, and in the more parsimonious models I do not find evidence that state gag clause prohibitions reduce drug expenditures. In my preferred specifications including household- and state-level controls, I find that state gag clause prohibitions reduce quarterly prescription drug expenses by between 9 and 16 percent, or about $9.50 and $16.80 relative to the mean expenditure.

Table 6: Effect of State Gag Clause Prohibitions on Prescription Expenditures

	Model 1	Model 2	Model 3	Model 4
Gag Clause Prohibition	-0.03	-0.01	-0.09**	-0.16**
	(0.04)	(0.04)	(0.04)	(0.06)
Age		0.02***	0.02***	0.02***
		(0.00)	(0.00)	(0.00)
Female		0.02	0.02	0.02
		(0.01)	(0.01)	(0.01)
Family size		0.03***	0.03***	0.03***
		(0.01)	(0.01)	(0.01)
Less than high school		0.29***	0.30***	0.30***
		(0.11)	(0.11)	(0.11)
High school, no degree		0.52***	0.52***	0.52***
		(0.11)	(0.11)	(0.11)
High school graduate		0.64***	0.65***	0.65***
		(0.10)	(0.10)	(0.10)
Some college, no degree		0.74***	0.74***	0.74***

		(0.10)	(0.10)	(0.10)
Associates degree		0.76***	0.77***	0.77***
		(0.10)	(0.10)	(0.11)
Bachelors degree		0.77***	0.78***	0.78***
		(0.10)	(0.10)	(0.10)
Masters degree		0.79***	0.80***	0.80***
		(0.10)	(0.10)	(0.10)
Doctorate		0.81***	0.81***	0.82***
		(0.14)	(0.14)	(0.14)
Widowed		-0.32***	-0.32***	-0.32***
		(0.02)	(0.02)	(0.02)
Divorced		-0.33***	-0.33***	-0.33***
		(0.02)	(0.02)	(0.02)
Separated		-0.39***	-0.39***	-0.39***
		(0.05)	(0.05)	(0.05)
Never married		-0.19***	-0.19***	-0.19***
		(0.02)	(0.02)	(0.02)
Black		-0.31***	-0.30***	-0.30***
		(0.02)	(0.02)	(0.02)
Native American		0.14	0.14	0.14
		(0.11)	(0.11)	(0.11)
Asian		-0.19***	-0.19***	-0.19***
		(0.03)	(0.03)	(0.03)
Pacific Islander		-0.13	-0.13	-0.12
		(0.09)	(0.09)	(0.09)
Multi-race		-0.21***	-0.21***	-0.21***
		(0.06)	(0.06)	(0.06)
Family income ($10K)		0.01***	0.01***	0.01***
		(0.00)	(0.00)	(0.00)
Male (%)			-19.66	0.86
			(21.18)	(73.30)
White (%)			-17.26	-200.15*
			(20.96)	(106.38)
Black (%)			-18.69	-193.03*
			(22.54)	(115.87)
Asian (%)			-9.32	-271.00**
			(22.56)	(119.90)
Hispanic (%)			1.98	33.30
			(3.17)	(34.54)
Per capita income ($10k)			-0.00*	-0.00
			(0.00)	(0.00)
Unemployment (%)			3.82**	6.48**
			(1.80)	(2.74)
Constant	4.24***	2.63***	29.42	282.39**
	(0.03)	(0.12)	(23.17)	(126.05)

Observations	61,606	60,689	60,689	60,689
R-squared	0.01	0.09	0.09	0.09
State and year FE	YES	YES	YES	YES
Household characteristics	NO	YES	YES	YES
State characteristics	NO	NO	YES	YES
Time trends	NO	NO	NO	YES

Robust standard errors in parentheses
*** p<0.01, ** p<0.05, * p<0.1

Recent work has highlighted the potential pitfalls of using a difference-in-differences specification when there is variation in treatment timing (de Chaisemartin and D'Haultfoeuille 2020; Sun and Abraham 2021; Borusyak et al. 2021; Callaway and Sant'Anna 2021; Goodman-Bacon 2021). In particular, the fact that states treated in period *t* serve as comparison states for those treated in period *t+1* can bias the estimate towards zero if the treatment effect grows over time. For this reason, I perform a stacked difference-in-differences approach that leverages clean comparisons of changes in out-of-pocket expenditures in treated states and the concurrent changes in never treated states for both of my preferred specifications as a robustness check. Results of are presented below, in Table 7. In the specification without linear time trends I no longer find evidence that the gag clause reduces out-of-pocket expenditures, but in the specification with linear time trends I continue to find that gag clause prohibitions reduce quarterly prescription drug expenditures by about 17 percent.

Table 7: Stacked Difference-in-Differences, State Gag Clause Prohibitions

	Model 3	Model 4
Gag Clause Prohibition	-0.06	-0.17***
	(0.05)	(0.06)
Constant	22.19	343.52*
	(46.63)	(197.86)
Observations	207,068	207,068
R-squared	0.09	0.09

Robust standard errors in parentheses
*** p<0.01, ** p<0.05, * p<0.1

VII. Discussion

My empirical results suggest that while the federal approach to gag clause prohibition may not reduce out-of-pocket prescription drug expenditures, the common state approach to gag clause prohibition has succeeded in doing so. These results indicate that the more rigid approach taken by state legislatures of both prohibiting gag clauses in contracts and mandating that copayments not exceed prescription drug retail costs may be the more effective policy approach. Simply allowing pharmacists to communicate a lower cost to consumers may not be as effective. Importantly, however, the limited post-implementation period of the federal intervention and the large standard errors associated with these results temper this conclusion.

From a theoretical perspective, these results suggest that gag clauses may not influence the behavior of a significant number of pharmacists. The federal gag clause ban removes a barrier to information sharing but does not mandate the sharing of information or, like most state legislation, restrict copayment amounts. If gag clauses prevented a significant portion of pharmacists from communicating a lower price option to consumers when they otherwise would have, the federal legislative approach of simply banning such contractual clauses would be expected to translate into consumer savings. Because I find no evidence that the federal approach yields such savings, perhaps because the cost of such communication is too high relative to the benefits for individual pharmacists, the results suggest that the state legislative approach of also capping copayment amounts is the mechanism driving cost reductions for consumers.

In light of existing research, the savings achieved by state legislative efforts may not be significant enough to increase medication adherence and decrease the costly health consequences

of medication nonadherence. While additional state legislation that both prohibits gag clause prohibitions and caps copayments from exceeding the retail price of a prescription medication may be pursued by state lawmakers seeking to reduce prescription drug prices, more drastic legislative measures by the federal government—such as price negotiation—is likely necessary to more dramatically reduce prescription drug costs in the United States.

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CHAPTER 2: GOVERNMENT PATENT INFRINGEMENT FOR ACCELERATED GENERIC ENTRY

I. Introduction

High prescription drug costs in the United States have garnered significant attention in recent years. In a rare showing of bipartisan agreement, a majority of both Democrats and Republicans think that prices are too high (Huetteman 2019). This agreement has placed substantial public pressure on lawmakers to reduce prescription drug prices and, consequently, spawned significant legislative efforts to reduce prescription drug costs at both the state and federal levels. While the efforts at the state level have had success, the failure to pass legislation at the federal level has meaningfully hindered overall price reduction efforts. Recently, the United States House of Representatives included broad measures intended to curb the cost of prescription drugs in the proposed Build Back Better Act.[1] If enacted, the measures have the potential to meaningfully reduce prescription drug costs and generate notable savings for both consumers and the federal government. At this time, however, negotiations on the bill have stalled in the Senate. Nonetheless, the Biden Administration—or future administrations—could potentially exploit existing statutory power to curb the price of prescription drugs.

Two existing statutory mechanisms for government patent infringement—Bayh-Dole march-in rights and Section 1498 government patent use—could be used to accelerate generic drug manufacturer market entry under certain circumstances. Using these statutory provisions in a systematic way has the potential to dramatically reduce the cost of brand-name drugs through both direct and indirect channels years earlier than they would otherwise be reduced. But such an

[1] *See* H.R. 5376 (allowing the federal government to negotiate prices for some high-cost drugs covered under Medicare Part B and D; requiring inflation rebates to limit annual increases in drug prices; capping out-of-pocket drug spending for Medicare Part D enrollees; and limiting cost sharing for insulin to $35 per month.)

approach could also have important negative effects on innovation in the pharmaceutical industry by reducing the incentives associated with innovation.

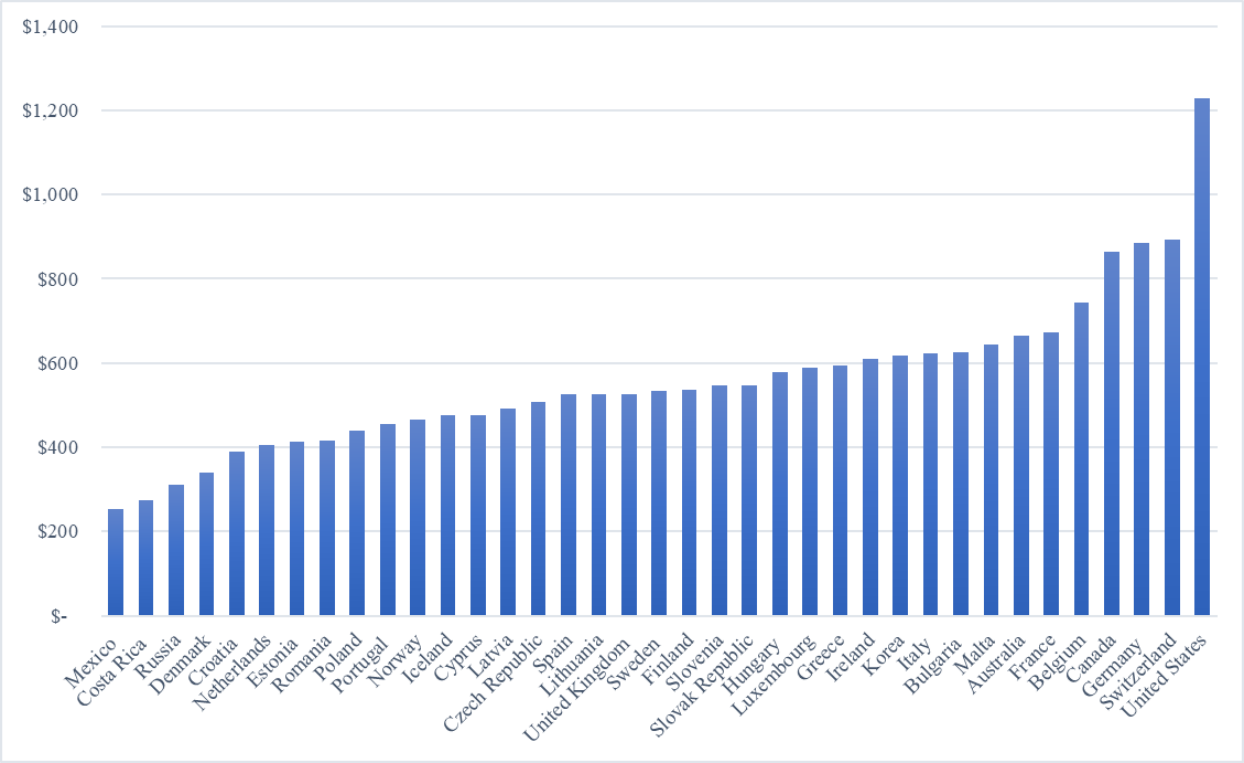
In this chapter of my dissertation, I consider the viability of using these existing statutory mechanisms for government patent infringement to accelerate generic entry in an effort to reduce prescription drug costs. The chapter proceeds as follows. Part II provides background on prescription drug costs in the United States, the factors driving high prescription drug costs in the United States, and the two statutory provisions allowing for government patent infringement. Part III discuses related literature on the economics of innovation. Part IV proposes a systematic approach for use of the statutory provisions for government patent infringement. Finally, Part V considers the costs and benefits of such an approach.

II. Background

A. High Prescription Drug Expenditures in the United States

Americans spend more on prescription drugs than individuals in any other country. While individuals in the United States spend an average of over $1,200 on prescription drugs each year, average expenditures in most European peer countries are roughly half that amount (Organization for Economic Cooperation and Development 2019). Importantly, the primary factor driving this disparity is drug prices. Drug utilization is similar in the United States and peer countries, and generics actually make up a larger portion of drug utilization in the United States than in most peer countries. Americans nonetheless spend more, largely because pharmaceutical prices are higher (Sarnak et al. 2017).

Figure 1: Per Capita Pharmaceutical Expenditures, 2018



In recent years, U.S. prescription drug expenditures have grown significantly and are projected to continue growing. In 2016, net spending for retail prescription drug coverage—including out-of-pocket expenses, the share of premiums allocated for retail drug benefits, and government spending—totaled $341 billion, an increase of thirty-six percent over four years (Urahn et al. 2019). The Centers for Medicare and Medicaid Services (CMS) estimate that, over the same time period, prescription retail spending rose about twenty-seven percent; this growth outpaced expenditure growth in any other personal healthcare category. CMS projects that this trend will continue, with growth in retail prescription spending outpacing growth in other types of healthcare spending through 2026. Notably, for the last decade annual increases in drug costs have exceeded general inflation, and between 2013 and 2015 drug costs increased at over six times the rate of general inflation (Hernandez et al. 2019).

Prevailing prescription drug costs are unaffordable for many Americans, and associated prescription nonadherence threatens their health. In 2019, close to a quarter of the U.S. population reported difficulty affording the cost of prescription drugs (Kaiser Family Foundation 2019). In 2017, the National Center for Health Statistics reported that over eleven percent of adults between the ages of eighteen and sixty-four who were prescribed medication in the previous year failed to take medication as directed—delaying filling prescriptions, skipping doses, or reducing doses—due to cost; within the uninsured population, one-third took such measures (Cohen et al. 2019). And, in a recent survey, nearly thirty percent of respondents reported not taking their medication as prescribed within the last year due to cost (Kirzinger et al. 2019). Another indicator of the financial burden of prescription drugs is the prevalence of prescription drug charity programs and crowdsourcing efforts. Prescription drug charity programs account for half of the twenty largest charities in the country (Karlin-Smith 2017). One-third of money donated to the thousands of GoFundMe users seeking assistance for medical expenses is directed towards covering the cost of prescription drugs (Heller 2019).

The inability to afford prescription drugs can result in devastating health consequences. Nonadherence to prescription drugs causes roughly 125,000 deaths in the United States each year, is responsible for roughly ten percent of hospitalizations annually, and costs the healthcare system between $100-289 billion a year (Brody 2017). Though nonadherence is not always attributable to drug costs, a strong relationship exists: when out-of-pocket expense for a prescription exceeds $50, adherence diminishes, and it does so even more dramatically for particularly expensive drugs (Brody 2017). In contrast, when the cost of medication is covered, individuals are more likely to take the medication as prescribed.

Despite the evidence suggesting drug costs are unaffordable for many Americans, a common rejoinder is that high prices are necessary to fund pharmaceutical companies' high-risk, high-cost research. It is true that pharmaceutical companies invest more in research and development than those in many other industries (Congressional Budget Office 2021).[2] And, there is a body of evidence that demonstrates pharmaceutical companies' investment in research and development is responsive to changes in market size (Dubois et al. 2015; Blume-Kohout & Soodb 2013; Acemoglu & Linn 2004). However, it is not clear that the premiums paid in the United States are tightly linked to investments in research and development. A recent study found that the premiums pharmaceutical companies earn from charging substantially higher prices in the United States compared to other Western countries generate, on average, over 30 percent more revenue than the entirety of the companies' global research and development expenditures (Yu et al. 2017).[3] This suggests that premiums in the United States could be lowered without cutting into the companies' global research and development budget.

Another potential objection to efforts to reduce prescription drug costs in the United States is that drugs are overprescribed and nonadherence could be rational. A recent report demonstrated that the number of prescriptions taken by Americans has increased dramatically in the last twenty years, particularly for older Americans (Lown Institute 2019). Overprescribing can be innocuous at times, but it increases the chance of unnecessary side effects, decreases medication adherence, and can lead to dangerous combinations of drugs that do more harm than good. In some instances, then, nonadherence could be a rational choice. However, the issues of

[2] In 2019, pharmaceutical companies spent $83 billion on R&D, a larger share of revenue than for other knowledge based industries such as semiconductor, technology hardware, and software.
[3] Specifically finding that the premium charged in the U.S. relative to other Western countries generated $116 billion while global R&D costs were only $76 billion. The relationship between premium pricing and global R&D varied by company. While one company spent more than the premium on R&D, several spent roughly the premium, and many earned double their global R&D expenditures from premium pricing.

overprescribing and cost-related nonadherence are largely distinct. Few individuals are equipped with the knowledge requisite to determine which of their prescribed drugs are appropriate for nonadherence, and prescribers are the most appropriate actors in reducing overprescribing. Cost-related nonadherence may be innocuous when it corresponds to overprescribing, but individuals cannot actively and rationally choose not to take a prescription they are unable to afford. Consequently, while overprescribing may reduce the consequences of cost-related nonadherence if an individual is overprescribed, the solution to overprescribing should not be pricing individuals out of receiving necessary prescriptions, but should instead directly target prescribing behavior.

B. Explaining High Drug Prices: Market Exclusivity and Monopoly Pricing

Disproportionately high drug costs in the United States are largely driven by market exclusivity and monopoly pricing. Market exclusivity for pharmaceutical drugs is produced through two legal mechanisms: patent exclusivity and regulatory exclusivity. The United States Patent and Trademark Office grants patents for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[4] The patent then gives the holder "the right to exclude others from making, using, offering for sale, or selling" the invention.[5] Typically, the duration of a new patent is twenty years from the date on which the application was filed.[6] Initial patents protecting the active ingredient are usually obtained when a drug is first synthesized, and the clinical trial and regulatory review process takes an average of six to eight years (Kesselheim et al. 2016). However, under a patent term restoration provision, a patent holder can apply to have this period extended by up to fourteen

[4] 35 U.S.C. § 101 (2012).
[5] 35 U.S.C. § 154.
[6] 35 U.S.C. § 154(a)(2).

years to account for the time spent in regulatory review and clinical trials before the drug can be sold.[7]

Regulatory exclusivity is granted by the Food and Drug Administration (FDA) upon approval of a new drug. In contrast to patent rights, which provide for exclusion, FDA-granted exclusivity rights provide exclusive marketing rights to a manufacturer; the FDA delays or withholds approval of competitor drugs during a set period of time (Food and Drug Administration 2015). The duration of the regulatory exclusivity period varies, with new small-molecule drug products protected from competition for five to seven years and new biologic drugs protected from competition for twelve years.[8]

These two forms of exclusivity often co-occur, with regulatory exclusivity typically expiring before patent exclusivity. The postapproval duration of market exclusivity is often twice the duration of the regulatory exclusivity period; for widely used drugs, the postapproval market exclusivity period has a median length of twelve and a half years and for highly innovative, first-in-class drugs, the postapproval market exclusivity period has a median length of fourteen and a half years (Grabowski et al. 2016; Wang et al. 2015).

Unlike almost every other advanced nation, the United States allows drug manufacturers immense discretion in pricing a given product (Kesselheim et al. 2016; Kavanos et al. 2013). In countries with national health insurance policies, a government body typically negotiates drug prices and declines to cover a drug if it determines that the manufacturer's price is too high relative to the benefit provided by the drug (Stabile et al. 2013). Because the United States grants market exclusivity—monopoly over the production of a given drug—without negotiating drug

[7] 35 U.S.C. § 156.
[8] 21 C.F.R. 314.108, 316.31, 316.34; 42 U.S.C. § 262(k)(7)(A).

prices in a similar manner, manufacturers are able to engage in relatively unimpeded monopoly pricing.

This ability to monopoly price has dramatic implications for overall drug spending in the United States. Although brand-name drugs make up only about ten percent of all dispensed prescriptions in the country, they account for seventy-two percent of drug spending (Kesselheim et al. 2016). Competition between brand-name drugs that act as treatment alternatives may theoretically be expected to exert competitive price pressure and reduce costs, but in practice such price effects are not typically observed. In fact, a review of the literature on brand-brand competition from 1990 to 2019 found no studies demonstrating that brand-brand competition lowers the list prices of existing drugs within a class (Sarpatwari et al. 2019). Rather, the introduction of generic drugs when market exclusivity ends is the only form of competition that reliably and meaningfully decreases prescription drug prices. With two generic drug manufacturers producing a drug, price decreases to about fifty-five percent of the brand-name drug price (Kesselheim et al. 2016). Even more dramatic price reduction occurs as more generic manufacturers enter the market; with five generic manufacturers price decreases to about thirty-three percent of the brand-name price and with fifteen generic manufacturers price decrease to only about thirteen percent of the brand-name price.

Cost savings attributable to generic drugs are immense. In 2019, generic drug savings exceeded $300 billion (Association for Accessible Medicines 2019). Almost fifty percent of these savings accrued under Medicare or Medicaid, $96 billion and $48.5 billion respectively. Over ninety percent of generic prescriptions are filled for less than $20, with an average copay of just under $7. In contrast, the average brand-name copay is roughly eight times as much, about $56. And the effect of generic drug competition on costs can occur relatively quickly. Under

some state drug product selection laws, the generic can be easily substituted for its equivalent brand-name drug; in such states, generic products account for up to ninety percent of a drug's sales within a year of generic market entry (Kesselheim et al. 2016). The cost savings from generic entry do not appear to come at the cost of an inferior product. To obtain approval from the FDA, a generic medication must be bioequivalent to its brand-name counterpart, meaning that chemically the two must be pretty much the same. While the FDA allows from some variation, the observed variation of 4 percent is much lower than what is permissible (Harvard Health Publishing 2021). And, most research demonstrates that generic alternatives perform the same as their brand-name counterparts.

Though market exclusivity and monopoly pricing are the primary reasons for high drug costs in the United States, several other factors contribute to the problem: persistent use of brand-name drugs after generics enter the market, inadequate physician knowledge and consideration of drug prices, restrictive state generic substitution laws, and constrained negotiating power. Many physicians continue to prescribe using brand names after generic drugs become available (Sarpatwari & Kesselheim 2016). One study found that about eighty percent of multisource drug prescriptions were written for brand-name drugs and that there was little change in prescribing behavior even after generics had been on the market for long periods of time (Steinman et al. 2007). This prescribing behavior may be explained by media coverage using brand names, marketing, and the relative complexity of generic drug names (Sarpatwari & Kesselheim 2016). A related though somewhat distinct reason for continued brand-name prescribing is poor physician knowledge of drug prices; doctors tend to underestimate the cost of expensive drugs and overestimate the cost of inexpensive drugs (Allen et al. 2007). Without adequate understanding of medication costs, physicians are less likely to consider treatment alternatives or

prioritize writing generic prescriptions. It is particularly telling that one of the most common cost reduction strategies patients pursue is asking their physician to prescribe a less expensive drug (Kirzinger et al. 2019). State generic substitution laws can help blunt the effect of brand-name prescribing behavior, but many state laws include provisions that hinder generic substitution. As of 2019, substitution was mandatory for some or all pharmacy dispensings in nineteen states but remained permissive in most states and required patient consent and/or notification in most states (Sacks et al. 2021). Finally, because the United States allows manufacturers to set drug prices, negotiations with insurance and prescription benefit providers present the most direct constraint on pricing, but providers' negotiating power is constrained in several ways. Government insurance providers are limited in their negotiating power by broad-based coverage requirements and a rule that prohibits the Centers for Medicare & Medicaid Services from negotiating drug prices or interfering with negotiations between individual Medicare Part D vendors and drug companies.[9] In the private sector there are often insufficient incentives for negotiation because pharmacy benefit managers' annual fees are based on a given payer's spending on drugs.

C. Statutory Provisions for Government Patent Infringement

Two statutes permit government patent infringement: The Bayh-Dole Act of 1980 and 28 U.S.C. § 1498. The Bayh-Dole Act of 1980 was originally designed to enable the commercialization of technology developed by academics, nonprofit organizations, and small businesses using federal funding (Thomas 2016). Many small companies were reluctant to market government-patented discoveries under nonexclusive licenses (Markel 2013). To remedy this, the Act allows a federal contractor to take title to patent rights for an invention it conceives or first reduces to practice during a funding agreement with a federal agency.[10] Although the

[9] *See* 42 U.S.C. § 1395.
[10] 35 U.S.C. § 202(a).

contractor takes title to patent right for an invention, the federal government retains "a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States the subject invention throughout the world."[11] Under the terms of the Act, the government has the authority to "march in" and grant compulsory third-party licenses under certain circumstances.[12] One such circumstance exists if the federal agency under whose funding agreement the invention was made determines that such "action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees."[13] Any compulsory third-party license granted under this provision must be "upon terms that are reasonable under the circumstances," though it remains unclear exactly what satisfies the reasonableness requirement because the federal government has never exercised its authority under the statute (Congressional Research Service 2020).[14] Although the language of the Act only applies to nonprofit organizations and small businesses, a 1983 memorandum issued by President Reagan ordered agencies to treat, as allowable by law, all contractors within the Bayh-Dole Act framework regardless of size and this remains longstanding practice.[15]

The statutory authority in 28 U.S.C. § 1498 applies more broadly to all patented inventions, not only those developed with federal funding.[16] A precursor to the current statute, passed in 1910, was enacted to partially waive the government's sovereign immunity, which previously prevented patent holders from suing the U.S. government for patent infringement.[17] The current version of the statute was codified in 1942 and the pertinent language has remained

[11] *Id.*
[12] *Id.*
[13] § 203(a)(2).
[14] § 203(a).
[15] Memorandum on Government Patent Policy from President Ronald Reagan, to Heads of Executive Departments and Agencies, February 18, 1983, http://www.presidency.ucsb.edu/ws/index.php?pid=40945&st=&st1=.
[16] 28 U.S.C. § 1498(a) (referring to "an invention described in and covered by a patent of the United States").
[17] Act of June 25, 1910, ch. 423, 36 Stat. 851, 851.

unchanged.[18] It allows the federal government to use or manufacture any patented invention "without license of the owner…or lawful right to use or manufacture the [invention]."[19] While permitting the government this broad power to infringe on patent rights, the provision provides the patent holder with a right of action against the government for the "reasonable and entire compensation for such use and manufacture," much like eminent domain.[20] Consequently, a patent holder may not prevent the government from infringing but the government consents to liability for the infringement. Importantly for the purpose of pharmaceutical patents, government use or manufacture includes use or manufacture "by a contractor, subcontractor, or any person, firm, or corporation for…and with the authorization or the consent of the Government."[21] Thus, the government may authorize a generic drug manufacturer to use a pharmaceutical patent for drug production that is intended for government use. Although the government has not employed Section 1498 government patent use for a pharmaceutical drug in many decades, beginning in the 1950s and trailing off in the 1970s, use of the section was common (Brennan et al. 2016). The cases during this time tended to settle, however, so do not provide case law regarding reasonable and entire compensation. Nonetheless, more recent uses in non-pharmaceutical contexts can inform the approach to calculating the cost of reasonable and entire compensation.

D. Incentives to Innovate

This chapter is related to both theoretical and empirical literature on incentives for innovation. A robust theoretical literature beginning with Nordhaus (1969) provides analyses of the optimal design of intellectual property rights and the balance between social gains from greater innovation and losses due to granting monopoly power to innovators. Empirical evidence

[18] 28 U.S.C. § 1498(a) (2012).
[19] *Id.*
[20] *Id.*
[21] *Id.*

on how patent length affects innovation, however, is mixed. Although patent laws are often emphasized as important for creating incentives to innovate, there is also evidence that innovation occurs as a result of knowledge sharing, cultural attitudes that encourage risk taking, and scientific experimentation (Moser 2021). Several surveys have documented evidence on the importance of patents for incentivizing research and development investments in pharmaceuticals (Cohen et al. 2000; Levin et al. 1987; Mansfield 1986). Studies exploiting changes in patent law, however, have found that broader patent protection does not necessarily induce greater investment in research and development. Sakakibara and Branstetter (2001) found that a 1988 patent reform in Japan which broadened patent protection increased the number of claims per patent application but did not increase research and development investments. Similarly, Lerner (2009) examined patent changes in sixty countries over 150 years and found that patent filings were flat after patent laws were strengthened.

Several studies have attempted to identify the relationship between patent strength and pharmaceutical innovation specifically, with similarly mixed conclusions. Qian (2007) studied pharmaceutical patent changes in a cross-section of mostly developed countries between 1978 and 2002 and concluded that domestic research and development did not increase due to a strengthening of patent protection alone. Kyle and McGahan (2012) examined the effect of increased patent protections around the world as a consequence of the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights, finding that patent protection is associated with increases in research and development in high-income countries but not developing countries. Budish et al. (2015) exploit the difference in clinical trial time necessary for different types of cancer drugs to document that patient groups requiring longer clinical trials (which decrease patent terms) are less frequently the target of drug

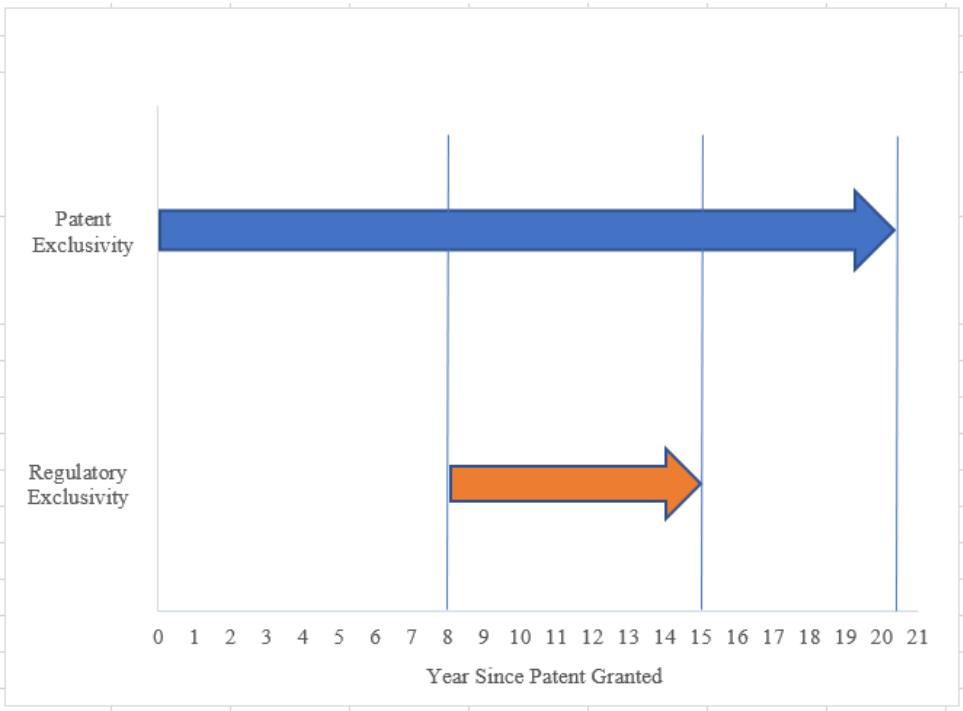
development efforts. Importantly, however, the authors acknowledge that this could be due to complexity and other factors associated with researching drugs that require longer clinical trials.

III. Accelerated Generic Entry Proposal

A. Proposal

Given the primacy of market exclusivity in driving pharmaceutical prices, the following proposal considers using the two existing statutory mechanisms to allow for generic entry during the period of time after which regulatory exclusivity expires but during which patent exclusivity remains in place. Based on generally prevailing market exclusivity duration discussed above, this could permit generic entry about seven years earlier than is typically the case currently (Figure 2).

Figure 2: Patent and Regulatory Exclusivity Duration



Note: Figure 2 demonstrates patent and regulatory exclusivity overlap assuming that the FDA approves a new drug eight years after the patent is granted, that the regulatory exclusivity period is seven years, and that the patent is extended for six months, for a total of twelve and a half years of market exclusivity after FDA approval (which research demonstrates to be the median for certain drugs).

The Agency for Healthcare Research and Quality (AHRQ), housed under the Department of Health and Human Services, could engage in systematic review of drug development costs, drug pricing, and drug sales when regulatory exclusivity expires. Where the agency determines that a manufacturer has recouped research and development costs plus a reasonable profit, the government could use one of two statutory provisions that allow for government patent infringement: Bayh-Dole march-in rights or Section 1498 government patent use.[22]

AHRQ's mission is to "produce evidence to make healthcare safer, higher quality, more accessible, equitable, and affordable, and to work within the U.S. Department of Health and Human Services and with other partners to make sure that evidence is understood and used."[23] As the governmental agency tasked with conducting research related to the "cost-effectiveness of healthcare practices" and "the costs and utilization of, and access to healthcare," it is well positioned to evaluate the cost of drugs and determine whether the price presents an unnecessarily costly threat to the health of Americans.[24] In the past two decades the FDA has approved an average of between twenty and twenty-five new drugs each year, though in the past five years annual approvals have ranged from forty to fifty (Jarvis 2019). If similar rates of approval persist in the future, under this proposal, the agency would be responsible for reviewing somewhere between twenty and fifty drugs each year. To facilitate rigorous review of research and development costs and cost recoupment at the end of the regulatory exclusivity period, the agency might need to engage in rulemaking to require manufacturers to submit data detailing their costs, pricing, and sales.

[22] 35 U.S.C. § 202(a); 28 U.S.C. §1498.
[23] *See Mission and Budget*, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (last visited Dec. 16, 2020), https://www.ahrq.gov/cpi/about/mission/index.html.
[24] 42 U.S.C. §§ 299(b)(1)(B), (D).

If the agency's review revealed that a drug manufacturer had recouped its development costs and earned a reasonable profit after the period of regulatory exclusivity, the government could proceed with either Bayh-Dole march-in rights or Section 1498 government patent use to enable quicker generic entry. Bayh-Dole march-in rights can apply in circumstances where government funding was used in the development of the drug. The more limited Section 1498 government patent use provides a mechanism for facilitating generic drug entry in situations where that is not the case.

If a drug patent resulted from a funding agreement with a federal agency, Bayh-Dole march-in rights present a superior mechanism to Section 1498 government patent use and should be the government's first choice. Because Bayh-Dole march-in rights authorize the government to grant compulsory third-party licenses without restriction on the use of any drug produced under such a license, all drug consumers can benefit from the entry of a cheaper generic when they are used. In contrast, Section 1498 requirements for government use likely limit the beneficiaries of the cheaper drug to those covered by government health programs such as Medicare, Medicaid, and the Veterans Health Administration. Nonetheless, about thirty-five percent of the public is covered by such programs and government patent use could thus still provide meaningful government savings while increasing access to expensive drugs (Keisler-Starkey & Bunch 2020).

B. Establishing Appropriate Damages

Establishing appropriate damages, or royalties, to compensate patent holders upon patent infringement by the government is critical to there being any benefit of such patent infringement and must be weighed against any chilling effect on research and development. If, for example, the patent holder sought and received compensation commensurate with lost profits, the

government is simply subsidizing additional production. On the other hand, if royalties are set too low, the loss experienced by a pharmaceutical company could jeopardize future research and development efforts.

As discussed above, Bayh-Dole march-in-rights have never been exercised, but determinations in Section 1498 cases provide useful guidance about how courts determine reasonable and entire compensation. In modern Section 1498 cases, lost profits have been strongly disfavored and may be entirely unavailable (Chisum 2015).[25] In fact, the Federal Circuit has repeatedly noted that "the proper measure is what the owner has lost, not what the taker has gained" in Section 1498 cases.[26] When an established royalty, licenses, or offers to license exist, they are very influential in determining appropriate compensation. In the pharmaceutical context these are unlikely to exists, however, and for some time courts often relied on the "willing-buyer, willing-seller rule," considering the Georgia-Pacific factors applied in most infringement cases and sometimes using government cost savings as a benchmark (Brennan et al. 2016).

More recently, courts have favored the approach of determining the baseline based on the infringer's profits. To determine the baseline, the court seeks to determine a "residual share" of profits owed to the patentee by deducting the infringer's cost from its price to determine gross profit, allocating the infringer its normal profit, and allocating the remainder to the patentee.[27] From this baseline, courts may make adjustments when the patent holder "took the risks and bore the expense of developing the [infringing products] and creating a market for them" to

[25] *See, e.g.*, Tektronix, Inc. v. United States, 552 F.2d 343, 348 (Ct. Cl. 1977) (explaining that "[i]t is equally a fundamental component of fairness to avoid excessive compensation to the [patent owner] as it is to be sure not to pay him too little."); Decca Ltd. v. United States, 640 F.2d 1156, 1173 (Ct. Cl. 1980) ("The reasonable royalty method is the preferred method of ascertaining the value of patent rights taken by the Government.").
[26] Dow Chem. Co. v. United States, 226 F.3d 1334, 1348 (Fed. Cir. 2000).
[27] *See Tektronix*, 552 F.2d at 350-51 (applying this method to reach a residual share of 4.6%, and increasing this to 10% after considering other factors); *Honeywell*, 107 Fed. Cl. at 693 (applying this method to reach a residual share of 4.2%, and adopting this as the reasonable royalty).

compensate for the cost of development plus a reasonable profit.[28] Though there is no specific guidance in the case law on how exactly a "reasonable profit" should be determined, one possibility is to use industry averages as a guide (Brennan et al. 2016). In the pharmaceutical industry, average profits are estimated to be between 10 and 30 percent, which could act as a useful guide (Ledley et al. 2020; Government Accountability Office 2017; Anderson 2014). In addition to relying on industry averages, reasonable profit can compensate for risk to the extent that a patentee can demonstrate the risk associated with their research and development efforts (Brennan et al. 2016).

IV. Proposal Costs and Benefits

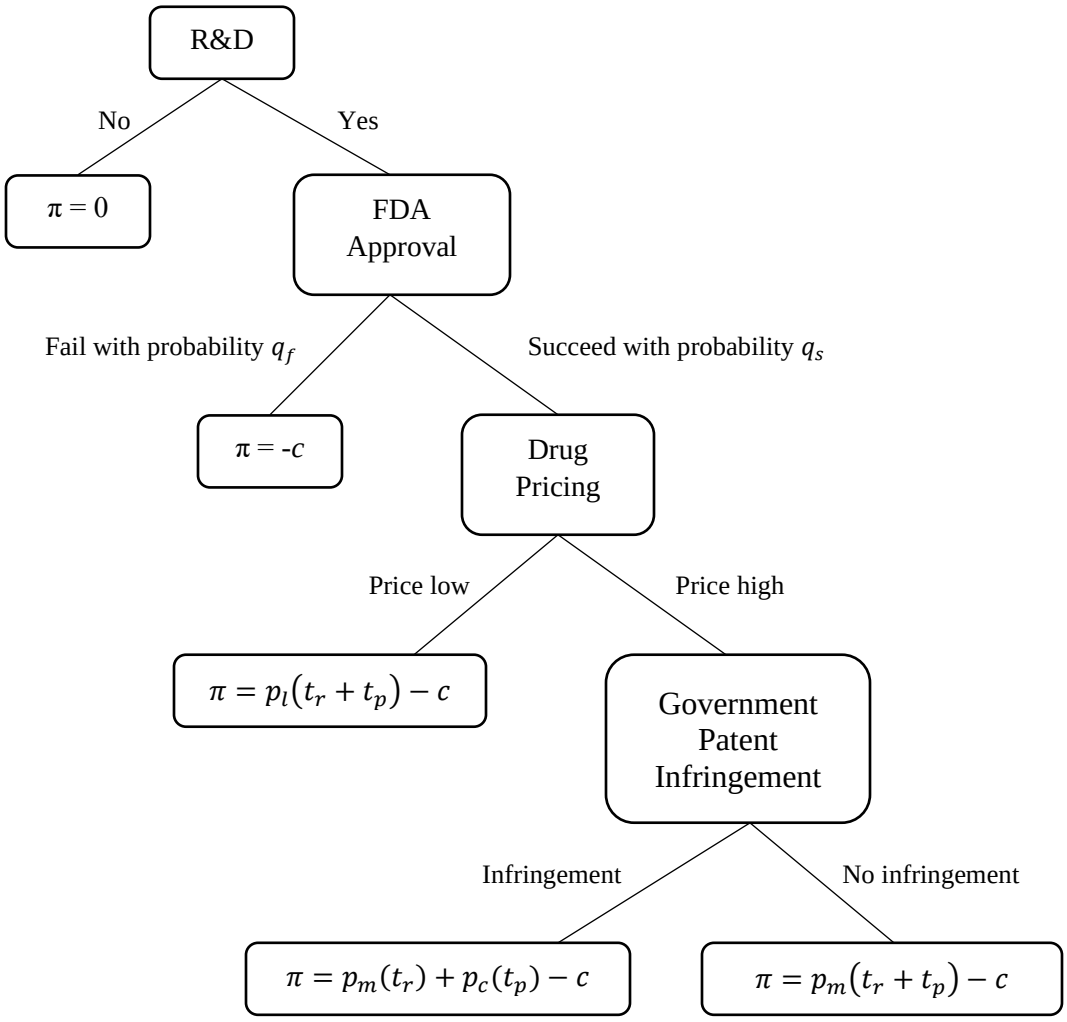
A. Model of the Pharmaceutical Manufacturer's Decision

The impacts of the proposed approach for government patent infringement depend on pharmaceutical manufacturer decision-making under the new policy. The manufacturer's possible decisions and corresponding profit are modeled in Figure 3. In the figure below, π represents profit, q_f represents the probability of failing to obtain FDA approval, q_s represents the probability of successfully obtaining FDA approval, c represents the cost of research and development, p_l represents a below-monopoly price, p_m represents the monopoly price, p_c represents the competitive price after generic entry, t_r represents the term of regulatory exclusivity, and t_p represents the term of patent exclusivity remaining after regulatory exclusivity expires. In step 1, the manufacturer decides whether to engage in research and development. In step 2, the manufacturer applies for FDA approval and succeeds or fails with some probability. In step 3, the manufacturer decides whether to price at the monopoly price or

[28] *Honeywell*, 107 Fed. Cl. at 693 (citing *Tektronix*, 552 F.2d at 350).

some lower price to avoid government infringement. And, in step 4 the government intervenes based on the manufacturers' earnings during the regulatory exclusivity period.

Figure 3: Manufacturer's Decision



Assuming the manufacturer engages in research and development for a given drug and examining the pricing decision alone, there are three possible outcomes. First, the manufacturer may set the price at the monopoly price (p_m) because it is confident that costs and a reasonable profit (c) will not be recouped within the period of regulatory exclusivity (t_r). In this circumstance—essentially the status quo—the manufacturer maintains the monopoly price

during the remaining period of patent exclusivity (t_p) and earns $\pi = p_m(t_r + t_p) - c$. Second, the manufacturer may set the price at the monopoly price knowing that the government will infringe when regulatory exclusivity expires and that it will have to set the price at the competitive price (p_c) for the remaining portion of the patent term. The manufacturer will do so when total profit, $\pi = p_m(t_r) + p_c(t_p) - c$, from doing so is greater than that achievable when pricing lower than the monopoly price and higher than the competitive price for the full potential exclusivity period. Third, and conversely, the manufacturer may set the price lower than the monopoly price but still higher than the competitive price (p_l) to avoid government patent infringement when the profit from doing so, $\pi = p_l(t_r + t_p) - c$, is greater than that achievable under the second option.

The proposal, by impacting the manufacturer's expected profit from a drug, may also influence the manufacturer's decision to engage in research and development at all. The manufacturer will only engage in research and development when the expected profit from any of the three pricing outcomes is greater than zero. The profit maximization problem the manufacturer faces if it monopoly prices for the full exclusivity period is $\max\{ q_s(p_m(t_r + t_p) - c) + q_f(-c), 0 \}$. Similarly, the maximization problem the manufacturer faces if it monopoly prices only during the regulatory exclusivity period is $\max\{ q_s(p_m(t_r) + p_c(t_p) - c) + q_f(-c), 0 \}$. And the maximization problem the manufacturer faces if it prices between the monopoly price and the competitive price during the full period of regulatory exclusivity is $\max\{ q_s(p_l(t_r + t_p) - c) + q_f(-c), 0 \}$.

B. Benefits

The proposal—systematic review of all patented drugs at the point of expiration of regulatory exclusivity and government intervention when a manufacturer has recouped costs and

a reasonable profit—offers several potential benefits, including relatively apparent direct price and supply effects, multiple potential indirect price effects, and a feasible path to implementation.

Direct price and supply effects. The most obvious benefit of the government patent infringement proposal is its potential to directly decrease the cost of particularly expensive pharmaceutical drugs by introducing generic competition. Basic economic theory demonstrates that a market with a single producer—a monopoly—results in higher prices, lower supply, and reduced consumer welfare (Mankiw 2009). As discussed above, the introduction of generic competition results in cost reductions to between about thirteen percent and fifty-five percent of the price of the name-brand drug. Introducing generic competition should not only reduce the price of medications in the documented way but should also do so through the effect of increasing supply. The benefit of generic introduction therefore extends beyond cost savings and improved drug adherence for existing users. It also includes improved access to medication for those in need.

Government intervention using either Bayh-Dole march-in rights or Section 1498 government patent use can be expected to create these benefits, albeit to different degrees. Intervention under Bayh-Dole can be used to grant compulsory third-party licenses to one or more generic drug manufacturers who will introduce supply into the general market for a given drug. In fact, the government may deliberately choose to grant numerous third-party licenses to increase the competitive pressure on price observed where many generic manufacturers participate in production of a drug; if the market for a drug is too small to support as many producers as are granted licenses, less efficient manufacturers should be expected to exit the market under classic economic theory (Mankiw 2009).

Because intervention under Section 1498 government patent use is limited to the subsection of the market for a given drug that is publicly insured, the government is more constrained in its ability to influence the market by authorizing generic manufacturers to use a drug patent. Put differently, the government does not have the ability to authorize patent use by many generic manufacturers in an attempt to facilitate something close to a perfectly competitive market. Nonetheless, because a large portion of the population—close to thirty-five percent—is publicly insured, and a large portion of these individuals are older Americans who tend to use more prescription drugs covered under Medicare, increasing supply via Section 1498 government patent use can reasonably be expected to meaningfully impact the market for some medications (Keisler-Starkey & Bunch 2020).

Indirect price effects during regulatory exclusivity. The government patent infringement proposal has the potential to influence drug pricing during the regulatory exclusivity period, too. As demonstrated in Figure 3, implementing a systematic process for evaluating pharmaceutical companies' cost recoupment and reasonable profit at the close of regulatory exclusivity will force companies to consider pricing decisions during the regulatory exclusivity period if they want to avoid government intervention before the expiration of the full exclusivity period. Rather than simply setting price at the profit-maximizing monopoly price, the credible threat of patent infringement will induce manufacturers to engage in a process of backwards induction, comparing potential profits from a monopoly pricing strategy that may trigger intervention to those possible at a lower supra-competitive price that will allow them to avoid intervention and benefit from the full period of exclusivity. If a manufacturer will not recoup development costs and earn a reasonable profit before the expiration of the regulatory exclusivity period even while engaging in monopoly pricing, there will be no effect. But a manufacturer will price below the

profit-maximizing monopoly price initially if it anticipates that doing otherwise will trigger government intervention that will lower the long-run profit possible under the full exclusivity period. Given the extremely high profit margins on some brand-name drugs, it is likely that the credible threat of patent infringement will induce some price reductions during the period of regulatory exclusivity.

Consider an example. A hypothetical drug manufacturer with ten years remaining on its patent at the time its new medication is approved, with a five-year period of regulatory exclusivity, is deciding how to price the medication. The development cost of the new medication was $200 million and reasonable profit is anticipated to be thirty percent, or $60 million. The manufacturer's market analysis indicates that it can price each course of the medication at $10,000 and sell 7,000 courses each year to maximize monopoly profits. In the first five years the manufacturer will therefore earn $350 million—exceeding its $260 million combined cost and reasonable profit, which could trigger intervention. Alternatively, the company anticipates that it can reduce the price of each course to $5,000 and sell 8,500 courses each year to earn $212.5 million within the first five years and not trigger intervention. Rationally, the manufacturer will choose to price the medication more cheaply—and provide the medication to more individuals—from the start because it can earn $425 million over the full ten-year exclusivity period rather than $350 million within the first five years.

Indirect price effects from infringement threat. There is a second way in which the government patent infringement proposal has the potential to decrease prices without the government actually resorting to patent infringement: negotiation triggered by threatened infringement. There is precedent for such an outcome. In 2001, when the threat of anthrax as a chemical weapon demonstrated a pressing national security concern, the United States sought to

use Section 1498 to stockpile the antibiotic ciprofloxacin for treatment. When the only domestic manufacturer, Bayer, refused to raise production levels and lower the price of the drug for the government, the Health and Human Services Secretary threatened to use the provision to import generic versions. In response, Bayer agreed to provide the desired supply of ciprofloxacin at half the prevailing price for the drug.

The possibility for the government to secure increased supply and lower price without executing on the threat of patent infringement using Bayh-Dole march-in rights or Section 1498 government patent use may offer a distinct benefit. From a government-resource perspective, it is less burdensome to levy a threat than expend the resources necessary to take action under one of the provisions. Such an outcome may therefore remain cost-beneficial, even though the ultimate price reduction may be less dramatic without actual patent infringement.

Intervention does not require congressional action. The government patent infringement proposal has the distinct benefit of being a regulatory, rather than legislative, intervention. Although there is widespread agreement that reducing the cost of prescription drugs should be one of Congress's top priorities and states are engaged in extensive legislative efforts to rein in prescription drug costs (although with uncertain effects and potentially creating inequities across state lines), federal legislative action appears to be a remote possibility in the near term. Legislative solutions are rarely easy to implement, and the current polarization in Congress makes action even less likely (Kane & Willis 2018). If Congress fails to act, they are neglecting a priority for the majority of the American constituency and regulatory action would not seem remiss.

The present proposal provides the opportunity to meaningfully influence particularly high drug prices through regulatory mechanisms when doing so decreases deadweight loss. Though

AHRQ will likely need to engage in time-consuming notice-and-comment rulemaking to require drug manufacturers to provide the necessary information to perform its evaluation, this remains a more feasible path forward than a potential legislative solution.

C. Costs and Objections

Several potential objections may be raised in response the government patent infringement proposal, including the potential for a chilling effect on drug research and development, government competency and resources, unintended private sector price consequences stemming from the use of Section 1498 government patent rights, shortcomings of generic competition as a mechanism to control drug prices, and restrictions in the Medicare drug benefit program. None of these objections fatally undermines pursuit of the proposal, though the potential chilling effects of government patent infringement warrant careful consideration and further study by the government before proceeding with systematic use of these statutory mechanisms

Chilling effects on research and development. High drug prices are most often justified on the grounds that they reflect the risky research and development costs necessary to develop the product and facilitate future research. Under this theory, some may worry that the proposal to infringe on drug patents if a manufacturer has recouped costs and earned a reasonable profit during the regulatory exclusivity period may disincentivize research and development. There are several reasons that this may not particularly concerning. As discussed above, there is little consensus in existing research that weakening or strengthening patent rights influences innovations. The proposal is structured such that both cost recoupment and reasonable profit are necessary prerequisites to intervention; it maintains these incentives for innovation, albeit with less potential for blockbuster profits. Moreover, important innovation is publicly financed to a

large degree, profits in the pharmaceutical industry are significantly higher than in other similarly sized industries, and research suggests that high prescription drug prices are not necessary to spur domestic innovation.

A significant portion of the innovation that produces new drug products is performed in academic institutions and supported by investment from public sources such as the National Institutes of Health (NIH). A recent analysis of the most transformative drugs of the last twenty-five years found that more than half originated in publicly funded basic research in university settings before being further developed through collaboration between public and private entities (Kesselheim et al. 2015). Another recent report found that NIH funding contributed to published research associated with each of the 210 new drugs approved by the FDA from 2010 to 2016 (Cleary et al. 2018). The immense contribution of public funding to new drug development diminishes both the argument that high profits are necessary to fund future research and that high prices are justified to reward risky private investment in research.

Even as the pharmaceutical industry benefits from significant public investment for research and development, it also earns disproportionately high profits. The pharmaceutical industry is one of the most lucrative sectors in business, with drug manufacturer's profits regularly in the billions or tens of billions of dollars (Pagliarulo 2020). A 2017 Government Accountability Office report determined that drug companies had profit margins between fifteen and twenty percent, compared to margins between four and nine percent for companies in other industries. Similarly, a recent academic study found that the median gross profit margin among thirty-five drugmakers studied was seventy-seven percent, compared to about thirty percent across 357 other companies in the S&P 500, and median net income margins were about fourteen and eight percent, respectively (Ledley et al. 2020). Such profits appear divorced from

innovation when one considers that large pharmaceutical companies only invest between ten and twenty percent of revenue in research and development (Kesselheim et al. 2016).

Several studies suggest that the high drug prices in the United States are unnecessary to encourage domestic drug innovation. For example, a 2010 comparative study determined that higher prescription drug spending in the United States does not privilege domestic innovation; in fact, many countries with drug price regulation, such as the United Kingdom and Switzerland, innovated proportionally more than their contribution to GDP or prescription drug spending (Keyhani et al. 2010).

Nonetheless, concerns that government patent infringement will negatively impact pharmaceutical innovation are not unreasonable. Pharmaceutical manufacturers stand to lose immense profits if the government infringes on a blockbuster new drug, eliminating years of market exclusivity. Because the existing empirical evidence is inconclusive about the potential effects of such infringement, there is a risk that pharmaceutical companies will reduce more risky, but important and highly profitable, research efforts despite government funding, larger than typical industry profits, and existing comparative studies suggesting that existing profit margins are not necessary to spur innovation.

Institutional competency and resources. Some may question the choice of AHRQ over the FDA to execute the government patent infringement proposal. Although the FDA has significant institutional competency and interfaces with pharmaceutical manufacturers extensively throughout the drug approval process, the agency's statutory authority makes it less well suited for evaluating cost recoupment and proposing interventions to directly control price. In fact, the FDA itself contends that it has "no legal authority to *investigate* or control the prices

set by manufacturers, distributors and retailers."[29] Rather, the agency's ability to influence price is facilitated through its approval of generic drugs to increase competition. In contrast, AHRQ's mission is squarely aligned with conducting research to make healthcare more accessible, equitable, and affordable and the agency is staffed by experts with the research and data analysis competencies to do so.

With regard to resources constraints, assuming AHRQ pursues rulemaking to require pharmaceutical companies to submit cost, pricing, and sales data for evaluation, the actual process of review should be relatively straightforward. Nonetheless, the agency likely has the resources to hire dedicated staff for the proposed evaluation if necessary. AHRQ has an annual operating budget of about $340 million and authorization for 273 full-time equivalents (FTE). In fiscal year 2019, the agency had eleven unfilled positions, and although the agency has seen a decrease in the number of authorized FTE in recent years it historically has had a number of unfilled positions each fiscal year. Thus, if the work required under the proposal cannot be executed by existing employees, the agency has additional budgeted positions it could use to hire dedicated staff for the review process. And if the burden of implementing the proposal proves to be more burdensome than anticipated, AHRQ could adapt by evaluating drugs losing exclusivity in tranches, prioritizing for review those with the highest cost and those that have been subject to higher-than-average price increases.

Perverse incentives under Section 1498 government patent use. One concern unique to the context of Section 1498 government patent use is that drug manufacturers could theoretically attempt to recoup profits lost on sales to individuals with public health coverage by increasing

[29] *Frequently Asked Questions About CDER*, U.S. FOOD & DRUG ADMIN. (last visited Dec. 16, 2020), https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/frequently-asked-questions-about-cder#:~:text=However%2C%20the%20FDA%20has%20no,of%20competition%20in%20the%20marketplace.

the price of a medication for those with private insurance. Because patent use is restricted to the government under this mechanism, the manufacturer will retain its market exclusivity within the private health market and its ability to engage in monopoly pricing within that market. However, if the pharmaceutical manufacturer was already engaged in monopoly pricing prior to government intervention it is unlikely that it will be able to dramatically increase price once the government engages in Section 1498 government patent use unless demand is uniquely inelastic in the private market relative to the public market.

In addition to purely economic constraints, dramatic price increases may be constrained by two other forces. First, the government intervention and price point will provide a particularly salient price point for private-insurer negotiation; even if such insurers are inadequately incentivized to negotiate rigorously as a general premise, they may balk at a price that is orders of magnitude greater than what the government is paying. In other health services, pricing in private markets tends to follow prices set by the Centers for Medicare and Medicaid Services (Kesselheim et al. 2016). Second, a dramatic price increase may generate public condemnation sufficient to dissuade a manufacturer from attempting to recoup lost profits in this manner due to reputational concerns, though the effect of public outcry will likely vary from company to company.[30]

Generic drug shortcomings. Some may be concerned that the government patent infringement proposal to curb drug prices by accelerating the introduction of generic competition will be inadequate because generic drug approval is often slow and prices for some drugs remain high even after generic availability. One of the reasons for delayed generic entry into the market can be directly addressed by the present proposal. Brand-name drug manufacturers often

[30] *See, e.g.*, Sydney Lupkin, *A Decade Marked by Outrage Over Drug Prices*, SHOTS (Dec. 31, 2019), https://www.npr.org/sections/health-shots/2019/12/31/792617538/a-decade-marked-by-outrage-over-drug-prices

strategically patent small changes in the nontherapeutic aspects of a drug to extend patent exclusivity and forestall generic entry; because this proposal intervenes using patent infringement mechanisms, the government can simply use the same Bayh-Dole march-in rights or Section 1498 government patent rights in such circumstances. A second reason for delayed generic entry is slow approval by the FDA. In the past, generic drug approval could take up to three to four years, but since the passage of the 2012 FDA Safety and Innovation Act approval time has decreased to closer to fifteen months. For first generics, which the FDA prioritizes, the agency successfully reviewed ninety percent of applications within ten months in 2017 (Pew Charitable Trusts 2019). Although lengthy approval processes delay the price effects of generic entry, delays are no longer as worrisome as they once were. It is also important to recognize that delays exist regardless of whether a generic is introduced at the end of regulatory exclusivity or patent exclusivity; intervening at the close of the regulatory exclusivity period will still move generic entry up by many years in most cases.

Concerns driven by persistently high-cost generic drugs are not addressed by the proposal. In markets for drugs with a small number of consumers, entry may simply be unattractive to multiple generic manufacturers. However, the high prices of such generic drugs account for a relatively small portion of the cost of pharmaceutical drugs.

Restricted involvement in the Medicare drug benefit program. When Congress passed the law establishing the Medicare Part D drug benefit program, it included a noninterference clause prohibiting the Centers for Medicare and Medicaid Services from negotiating drug prices or from interfering with negotiations between individual Part D vendors and drug companies. In relevant part, the provision provides that the Health and Human Services 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."[31] There may be some concern that Section 1498 government patent use would be unavailable for Medicare participants because the government's involvement could be deemed interference. Arguably, however, granting a generic manufacturer authorization to produce a drug for government use neither interferes with negotiation nor institutes a price structure, but rather introduces another possible drug manufacturer for pharmacies and PDP sponsors to negotiate with. Nonetheless, if the intervention were deemed to violate the provision, patent infringement under Bayh-Dole would continue to offer benefits throughout the private and public markets and infringement under Section 1498 government patent use would continue to offer benefits for coverage under public insurance other than Medicare.

V. Conclusion

Despite substantial public pressure to reduce the price of pharmaceutical drugs in the United States, meaningful federal legislation to address the problem is unlikely to be forthcoming in the near future. In lieu of federal legislation, the executive could elect to use one of the two existing statutory mechanisms for patent infringement—Bayh-Dole march-in rights and Section 1498 government patent use—to facilitate accelerated generic drug manufacturer market entry under the circumstances detailed above. The proposal is not without risk. Such an approach could impair incentives to innovate in the pharmaceutical industry among other potential drawbacks. Nonetheless, absent congressional action, these two existing mechanisms present a powerful tool for the executive to leverage to reduce the price of pharmaceutical drugs Americans face. However, given the risk that government patent infringement would impair important research and development efforts undertaken by pharmaceutical manufacturers, it

[31] 42 U.S.C. § 1395. Medicare Part D prescription drug plans are commonly referred to as PDPs.

would be prudent for the government to further research and refine the potential costs and benefits of government patent infringement before implementing such a policy.

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CHAPTER 3: RISK PERCEPTIONS OF BUYING PRESCRIPTION DRUGS ONLINE FROM FOREIGN COUNTRIES

I. Introduction

Millions of Americans purchase prescription drugs from outside of the United States each year to save money. The practice of crossing the border into Canada and Mexico to obtain cheaper medication has been an approach taken by individuals seeking a more affordable option for many years, particularly for those living close to the border. More recently, the proliferation of online foreign pharmacies has made access to cheaper prescription drugs more convenient and accessible for individuals living throughout the United States. Purchasing from such retailers often yield over 70 percent savings. Despite the existence of this purchasing option, however, a greater percentage of Americans report having difficulty affording their medications than report purchasing prescription drugs from foreign countries as a cost-saving measure.

Several possible reasons for this inconsistency exist. Individuals may be inexperienced and uncomfortable with online pharmacies. They may be unaware that they can purchase medication from online foreign pharmacies using the prescription written by their doctor or unaware of the magnitude of available savings. They could be—often reasonably—concerned that the prescription they receive will be counterfeit or fail to satisfy Food and Drug Administration (FDA) standards and consequently demand a larger discount than is available to accept that risk.

In this chapter, I use an experiment to better understand the gap between the portion of Americans struggling to afford their prescriptions and the portion of Americans who purchase from foreign pharmacies to save money. I employ a vignette study to elicit the discount consumers demand before accepting the risks associated with purchasing prescription drugs

online from another country and probe risk beliefs about ordering prescription drugs online from foreign countries. Briefly, I find that respondents demand, on average, a smaller discount to induce purchase from a foreign online pharmacy than the existing discounts available to individuals.

The chapter proceeds as follows. Part II provides background on high prescriptions drug costs and purchasing prescription drugs from online foreign pharmacies. Part III explains the experiment design and hypotheses. Part IV presents the results from the experiment. Part V discusses the implications of the results and concludes.

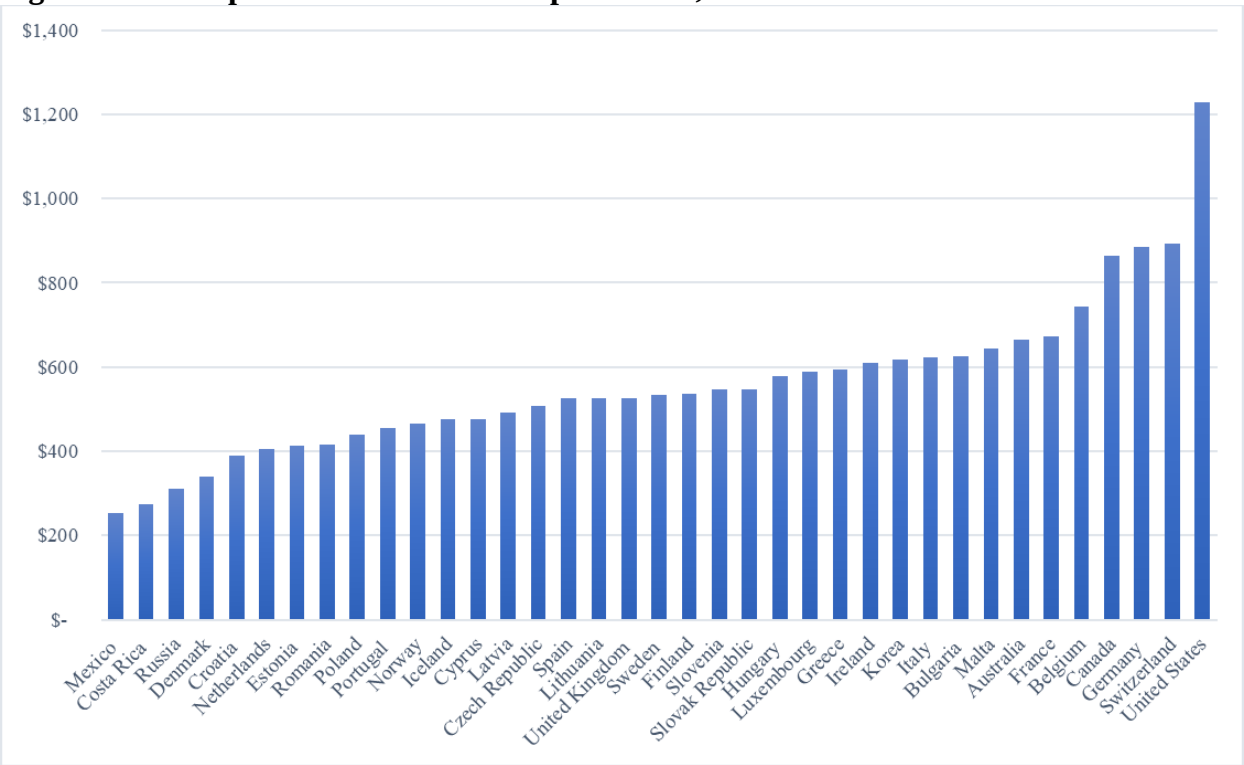
II. Background

A. High Prescription Drug Costs

On a per capita basis, Americans spend more on prescription drugs than individuals in any other country. Per capita prescription drug expenditures are of over $1,200 each year (Organization for Economic Cooperation and Development 2019). This amount exceeds expenditures in any other country by a noteworthy margin; it is almost 40 percent greater than per capita spending in the second-most expensive country, Switzerland, and over 50 percent greater than that in the United Kingdom and other European peer countries (Figure 1). Greater expenditures could be driven by a number of factors, such as higher prices, availability of high-cost drugs not available in other countries, or greater prescription drug utilization. Although there is evidence that the availability of high-cost drugs and over prescribing contribute to pharmaceutical expenditures in the country, there is one primary reason for the higher expenses Americans face: drug prices. Drug utilization is similar in the United States and peer countries and generics make up a larger portion of drug utilization in the United States than in most peer

countries; Americans spend more largely because pharmaceutical prices are higher (Sarnak et al. 2017).

Figure 1: Per Capita Pharmaceutical Expenditures, 2018



Significant portions of Americans report having a difficult time affording their prescription drugs. Nearly one-fourth of the U.S. population reported having a hard time affording the cost of prescription drugs in 2019 (Kaiser Family Foundation 2019). The National Center for Health Statistics reported that as of 2017 over 11 percent of adults between the ages of eighteen and sixty-four who were prescribed medication in the past year skipped medication doses, took less medicine, or delayed filling a prescription to reduce prescription drug costs; within the uninsured population, one-third took such measures to reduce prescription drug costs (Cohen et al. 2019). And, in a recent survey, nearly thirty percent of respondents reported not taking their medication as prescribed within the last year due to cost (Kirzinger et al. 2019). Many Americans are forced to seek assistance to afford their prescriptions. Prescription drug

charity programs that help individuals with out-of-pocket drug costs constitute a $10 billion industry, with such programs accounting for half of the twenty largest charities in the country (Karlin-Smith 2017). Thousands of GoFundMe users turn to the online charitable giving platform to seek donations to cover the cost of their prescriptions (Heller 2019).

The inability to afford prescription drug expenses translates into sometimes devastating health consequences. Nonadherence to prescription drugs causes roughly 125 thousand deaths in the United States each year (Peterson et al. 2003). Though nonadherence is not always attributable to drug costs, a strong relationship exists. And when nonadherence is for a prescription drug that is life-saving, such as insulin, devastating consequences are more likely.

Americans' difficulty affording their prescription drugs is unlikely to abate in the near term. Prescription drug costs in the United States are growing and projected to continue to do so. In 2016, net spending for retail prescription drug coverage—including out-of-pocket expenses, the share of premiums allocated for retail drug benefits, and government spending—totaled $341 billion, an increase of thirty-six percent since 2012 (Urahn et al. 2019). The Centers for Medicare and Medicaid Services estimate that prescription retail spending rose about twenty-seven percent over the same time period, outpacing expenditure growth in any other personal healthcare category. The organization projects that retail prescription spending will continue to outpace growth in other types of healthcare spending through 2026. Unsurprisingly given these dramatic spending increases, for the last decade annual increases in drug costs have exceeded general inflation; between 2013 and 2015, costs increased at over six times the rate of general inflation (Hernandez 2019).

Despite the evidence suggesting drug costs are unaffordable for many Americans, a common rejoinder is that high prices are necessary to fund pharmaceutical companies' high-risk,

high-cost research. It is true that pharmaceutical companies invest more in research and development than those in many other industries (Congressional Budget Office 2021). In 2019 pharmaceutical companies spent $83 billion on R&D, a larger share of revenue than for other knowledge based industries such as semiconductor, technology hardware, and software. And, there is a body of evidence that demonstrates pharmaceutical companies' investment in research and development is responsive to changes in market size (Acemoglu & Linn 2004; Blume-Kohout & Soodb 2013; Dubois et al. 2015). However, it is not clear that the premiums paid in the United States are tightly linked to investments in research and development. A recent study found that the premiums pharmaceutical companies earn from charging substantially higher prices in the United States compared to other Western countries generate, on average, over 30 percent more revenue than the entirety of the companies' global research and development expenditures (Yu et al. 2017). The authors found that the premium charged in the U.S. relative to other Western countries generated $116 billion while global R&D costs were only $76 billion. The relationship between premium pricing and global R&D varied by company. While one company spent more than the premium on R&D, several spent roughly the premium, and many earned double their global R&D expenditures from premium pricing.

Another possible objection to efforts to reduce prescription drug costs in the United States is that drugs are overprescribed and nonadherence could be rational. A recent report found that, over the last several decades, the number of prescriptions taken by Americans has increased dramatically, particularly for older Americans (Lown Institute 2019). Overprescribing is often harmless. Nonetheless, it increases the chance of unnecessary side effects, decreases medication adherence, and can lead to dangerous combinations of drugs that do more harm than good. The problem of overprescribing and Americans' difficulty affording their prescription medication

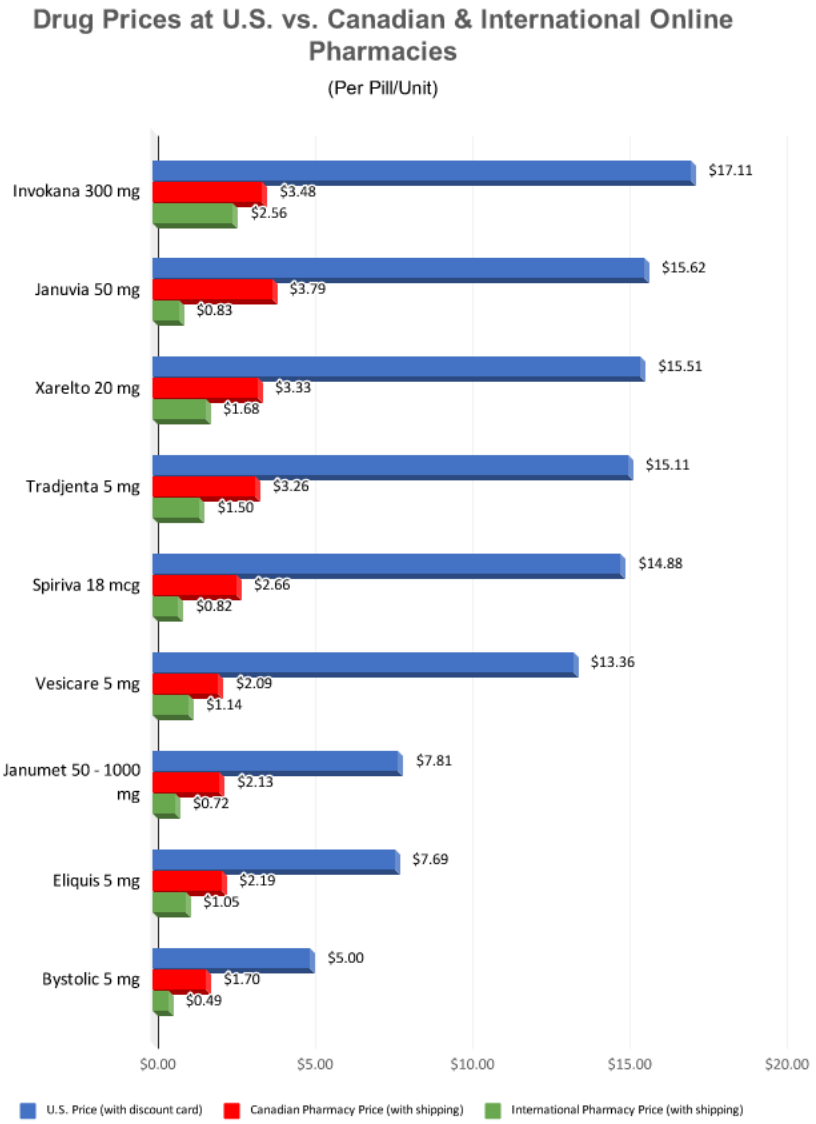
may interact by increasing overall prescription costs. However, the solution to overprescribing should be addressed by prescribers who are equipped to make intentional choices, not by average consumers who are ill-equipped to evaluate which prescription can safely be skipped. Furthermore, individuals who simply cannot afford their medication are not in a position to rationally choose not to take a medication.

B. Prescription Drug Purchases from Foreign Countries

Millions of Americans purchase prescription drugs outside of the country each year to save money. Many purchase the drugs online, while others travel to Canada or Mexico to purchase prescriptions from foreign pharmacies in person. Potential savings are pronounced. Drugs sold in the United States cost an average of 56 percent less in other high-income countries, and savings can be even greater when purchasing from a lower-income country (Miller 2018). For some brand name drugs without generic alternatives in the United States, the savings can be particularly dramatic. For example, a one-month supply of Januvia, a medication used to treat type 2 diabetes, costs about $470 at domestic pharmacies compared to about $115 from a Canadian pharmacy and $25 from a Turkish pharmacy. Similarly, Symbicort, an inhaler, can cost about $330 domestically while being available for $115 in Canada and $27 in Mauritius. Though technically illegal—and not without risk—importing drugs from abroad has long been popular and garnered significant attention due to these cost differences. Research from PharmacyChecker, an online company that helps Americans find low-cost prescription drugs from licensed pharmacies in Canada and other countries, found that consumers could save between 75 percent and 90 percent on ten of the most commonly prescribed, brand-name medications without a generic alternative (Figure 2). And, a recent report from the Committee on Ways and Means found that across 79 brand name drugs without a generic alternative, prices in

the United States were between 70 percent and 4,833 percent higher than in eleven comparator countries.

Figure 2: U.S. vs. International Drug Prices



Source: PharmacyChecker (2019)

Until recently, it was only legal for the manufacturer of a prescription drug to bring it into the country. The Prescription Drug Marketing Act of 1987 limits importation of a prescription drug into the United States to the manufacturer. Although the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 amended Section 804 of the Food, Drug, and

Cosmetics Act to authorize the Secretary of Health and Human Services to issue regulations permitting pharmacists, wholesalers, and individuals to import prescription drugs from Canada, no such regulations were issued for over fifteen years. In October 2020, the FDA issued a final rule allowing pharmacists and wholesalers to import prescription drugs under certain circumstances.

The FDA has not issued regulations related to personal use, and personal importation of prescription drugs remains illegal. However, the FDA has had a longstanding practice of not enforcing importation prohibitions against individuals who are importing small amounts of prescription medicines for personal use. The FDA has expressly recognized an exemption on enforcement for personal importation in its Regulatory Procedures Manual. The general guidance provides, in relevant part, that "FDA personnel may use their discretion to allow entry of shipments of violative FDA regulated products when the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the user." The guidance clarifies that a three-month supply of a drug is generally permissible. And, although the guidance includes a provision about the drug's availability domestically as a consideration in exercising discretion, in practice drugs available in the United States can be imported.

Estimates of how many Americans purchase drugs from outside the country vary dramatically. The Kaiser Family Foundation conducted a poll in 2016 in which 8 percent of respondents said they or someone in their household had imported a drug at some point; extrapolating to the United States population, the organization estimated that about 19 million adults have purchased drugs from another country (Bluth, 2016). Hong et al. (2020) find a much smaller number using data from the 2015-2017 NHIS on self-reported purchase of prescription drugs from other countries. The authors found that among adults taking prescription medications,

roughly 1.5 percent report purchasing prescription drugs outside the U.S. each year, with greater prevalence among older, Hispanic, immigrant, more educated, lower income, and uninsured populations.

While purchasing prescription drugs more cheaply abroad may help alleviate cost-related medication nonadherence, it is not without risk. In the United States and other high-income countries only about 1 percent of prescription drugs in the legitimate drug supply chain (wholesalers, hospitals, and licensed community or mail-order pharmacies) are counterfeit (World Health Organization 2017). Online pharmacies pose greater risk. Reviewing 11,688 online pharmacies, the National Association Boards of Pharmacy (2017) found that almost 96 percent failed to comply with U.S. federal and state laws, about 89 percent dispensed prescription drugs without a prescription, 13 percent dispensed controlled substances, 62 percent did not reveal their physical location, and 17 percent did not have adequate technology to prevent financial or personal data breaches. Online pharmacies such as these are particularly concerning because counterfeit drugs make up approximately a third of the international prescription drug trade to treat chronic diseases in developing countries (World Health Organization 2017). In the last five years, the FDA has issued over seventy warning letters to online pharmacies for offering unapproved prescription drugs of unknown origin, safety, and effectiveness, prescription drugs without a prescription, prescription drugs without adequate directions for safe use, prescription drugs without FDA-required warnings to consumers about the serious health risks associated with the prescription drug. Websites such as PharmacyChecker can help consumers find verified international pharmacies online but are unlikely to remove all of the increased risks associated with purchasing prescription drugs from outside the country online.

III. Experiment Design and Hypotheses

In the absence of instructional observational data, this chapter employs an experimental vignette study designed to elicit the price discount consumers demand before incurring the risks associated with purchasing a prescription drug from abroad. This section describes the vignette design and hypotheses.

A. Vignette Design

The vignette study developed for this chapter asks respondents to choose between different prescription drug purchasing options to obtain medication prescribed to treat migraines. This characterization is desirable because the debilitating effect of a migraine is something a significant portion of the population is familiar with, but it is not a life-threatening condition.

Experimental subjects in the study were recruited via Amazon's Mechanical Turk (mTurk) service. Subjects were compensated $1.00 for about seven minutes of their time, commensurate with prevailing mTurk wages. To ensure that participants were attentive during the experiment, subjects who demonstrated inconsistent choices were dropped from the sample used for analysis.[32] Table 1 presents selected demographics of the final sample of 623 subjects who participated in the study. The sample was 67 percent male and almost 80 percent white. The majority of respondents held a bachelor's degree or higher level of educational attainment and were employed full time. Over 70 percent of the sample had a household income between $20 thousand and $100 thousand. Respondents were more likely to identify as Democrats than either Independent or Republican. On average, respondents use between three and four prescription

[32] A total of 863 subjects completed the experiment, of which 239 were dropped for demonstrating inconsistent preferences. Responses were considered inconsistent when the respondent switched preferences multiple times. In most instances, such inconsistent preferences included numerous changes in response that indicated that the individual was not being attentive to the survey, but rather selecting responses at random.

medications. Over 50 percent of the sample has experience purchasing prescription drugs online, and a surprising 22 percent has experience purchasing prescription drugs online from a foreign pharmacy. And, over 50 percent of respondents were previously aware that they could purchase prescription drugs online from foreign pharmacies. Finally, roughly half the sample has private health insurance and roughly half the sample has government health insurance while only a small portion is uninsured.

Table 1: Sample Summary Statistics

Characteristic	Sample
Mean Age	38.21
Female	33.23%
City or Suburb	82.34%
Race and Ethnicity	
White	79.47%
Black/African American	6.95%
Asian	9.93%
Hispanic/Latino	20.55%
Education	
High School or Less	7.87%
Some College, Technical Degree, or Associate Degree	13.48%
Bachelor's Degree	60.03%
Graduate or Professional Degree	18.62%
Employed Full Time	84.91%
Household Income	
Less than $20,000	11.72%
$20,000 - $50,000	29.69%
$50,000 - $100,000	42.72%
$100,000 - $200,000	9.45%
More than $200,000	1.12%
Political Identity	
Democrat	43.66%
Independent	36.28%
Republican	17.98%
Mean Prescriptions Used	3.52
Purchased Prescription Online	51.04%
Purchased Prescription Online, Foreign Pharmacy	22.47%
Aware of Foreign Online Pharmacies	53.29%
Insurance	
Private	45.43%
Government (Medicare, Medicaid, and Other)	46.71%

None	7.87%
N	623

The study presented all respondents with the same basic underlying vignette. Subjects assumed the role of an individual who has been diagnosed with incapacitating migraines that occur four to five times a week. Their doctor has prescribed Migrx to treat the migraines and the respondent must choose between two purchasing options or indicate that they are indifferent. Each respondent was randomly assigned to one of eight conditions: (1) a low cost prescription to be purchased either at their local brick-and-mortar pharmacy or from a US online pharmacy, (2) a high cost prescription to be purchased either at their local pharmacy or from a US online pharmacy, (3) a low cost prescription to be purchased either at their local pharmacy or from a Canadian online pharmacy, (4) a high cost prescription to be purchased either at their local pharmacy or from a Canadian online pharmacy, (5) a low cost prescription to be purchased either at their local pharmacy or from a Mexican online pharmacy, (6) a high cost prescription to be purchased either at their local pharmacy or from a Mexican online pharmacy, (7) a low cost prescription to be purchased either from a Canadian online pharmacy or a Mexican online pharmacy, and (8) a high cost prescription to be purchased either from a Canadian online pharmacy or a Mexican online pharmacy. To allow for investigation of price sensitivity, high- and low-cost scenarios were identical except for the out-of-pocket cost of the prescription drug. The language used for each low-cost scenario is below; although the language was as similar as possible across the four comparisons some minor changes were necessary. Full text of each version of the survey is included as Appendix 1.

1. US Local Pharmacy v. US Online Pharmacy

> You will be given an option of purchasing a prescription drug in two ways: online or at your local pharmacy. Please make a decision between the two purchasing

options. We are interested in the point at which you are indifferent between the two purchasing options.

You were diagnosed with migraines, which cause you to experience intense headaches 4-5 times a week. These headaches leave you sensitive to light and incapacitate you. No over-the-counter medication alleviates your symptoms. Your primary physician has prescribed Migrx to alleviate your symptoms.

Migrx has been approved by the United States Food and Drug Administration, which has determined that it is safe and effective. The drug is available for purchase at your local pharmacy or from a United States-based online pharmacy. With a valid prescription, you have the option of purchasing a three-month supply of the drug either from your local pharmacy in person or from an online pharmacy.

Over the next slides you will see a choice between purchasing the drug at your local pharmacy in-person or from an online pharmacy. You must choose one of the two purchasing options, or indicate that you are indifferent between the two.

2. US Local Pharmacy v. Canadian Online Pharmacy

You will be given an option of purchasing a prescription drug in two ways: online or at a traditional local pharmacy. Please make a decision between the two purchasing options. We are interested in the point at which you are indifferent between the two purchasing options.

You were diagnosed with migraines, which cause you to experience intense headaches 4-5 times a week. These headaches leave you sensitive to light and incapacitate you. No over-the-counter medication alleviates your symptoms. Your primary physician has prescribed Migrx to alleviate your symptoms.

Migrx has been approved by the United States Food and Drug Administration, which has determined that it is safe and effective, and the drug is available for purchase at your local pharmacy. The drug has also been approved by regulators in Canada, though manufacturers and distributors in the country are held to different standards than in the United States. With a valid prescription, you have the option of purchasing a three-month supply of the drug either in the United States or from a Canadian pharmacy online. You can either submit your prescription to your local pharmacy by your normal method or submit your prescription to the online Canadian pharmacy electronically and have the prescription delivered by mail.

Migrx is often available at a lower out-of-pocket cost from Canada. On the next slide you will see a choice between purchasing the drug in the United States or from Canada. You must choose one of the two purchasing options, or indicate that you are indifferent between the two.

3. US Local Pharmacy v. Mexican Online Pharmacy

You will be given an option of purchasing a prescription drug in two ways: online or at a traditional local pharmacy. Please make a decision between the two purchasing options. We are interested in the point at which you are indifferent between the two purchasing options.

You were diagnosed with migraines, which cause you to experience intense headaches 4-5 times a week. These headaches leave you sensitive to light and incapacitate you. No over-the-counter medication alleviates your symptoms. Your primary physician has prescribed Migrx to alleviate your symptoms.

Migrx has been approved by the United States Food and Drug Administration, which has determined that it is safe and effective, and the drug is available for purchase at your local pharmacy. The drug has also been approved by regulators in Mexico, though manufacturers and distributors in the country are held to different standards than in the United States. With a valid prescription, you have the option of purchasing a three-month supply of the drug either in the United States or from a Mexican pharmacy online. You can either submit your prescription to your local pharmacy by your normal method or submit your prescription to the online Mexican pharmacy electronically and have the prescription delivered by mail.

Migrx is often available at a lower out-of-pocket cost from Mexico. On the next slide you will see a choice between purchasing the drug in the United States or from Mexico. You must choose one of the two purchasing options, or indicate that you are indifferent between the two.

4. Canadian Online Pharmacy v. Mexican Online Pharmacy

You will be given an option of purchasing a prescription drug from two foreign pharmacies online: one in Canada and one in Mexico. Please make a decision between the two purchasing options. We are interested in the point at which you are indifferent between the two purchasing options.

You were diagnosed with migraines, which cause you to experience intense headaches 4-5 times a week. These headaches leave you sensitive to light and incapacitate you. No over-the-counter medication alleviates your symptoms. Your primary physician has prescribed Migrx to alleviate your symptoms.

Migrx has been approved by the United States Food and Drug Administration, which has determined that it is safe and effective, and the drug is available for purchase at your local pharmacy. The drug has also been approved by regulators in Canada and Mexico, though manufacturers and distributors in the countries are held to different standards than in the United States. With a valid prescription, you have the option of purchasing a three-month supply of the drug either from a Canadian or Mexican pharmacy online. We are interested in the point at which you are indifferent between purchasing the drug from the two foreign countries.

> Over the next slides you will see a choice between purchasing the drug from Canada or Mexico. You must choose one of the two purchasing options, or indicate that you are indifferent between the two.

After being presented with the randomized vignette, respondents were asked to choose which purchasing option they would prefer when the out-of-pocket cost is the same for each ($30 in the low-cost scenario and $300 in the high-cost scenario). In the versions comparing purchasing options between the US and Canada and the US and Mexico, participants continue to make a series of pairwise choices between the two purchase options with the price of the online option becoming progressively less expensive until the respondent indicates indifference. In the version comparing US in-person purchase with US online pharmacy purchase and the version comparing online purchase between Canada and Mexico, participants continue to make a series of pairwise choices between the two purchase options with the price of initially disfavored option becoming progressively less expensive. The flexibility in these versions was necessary to allow for the possibility that respondents are willing to pay a premium to purchase from an US online pharmacy for reasons such as convenience or pay a premium to purchase from either an online Canadian or Mexican pharmacy for reasons such as past purchasing experience.

After indicating their preferences for purchasing the prescription, participants were asked to indicate on a five-point scale (did not consider, not very important, somewhat important, important, very important) how important the following factors were in their decision: the ability to speak with their pharmacist about the prescription, the legality of purchasing a prescription drug online, concern that the online prescription will not meet FDA standards, concern that the prescription drug from on online retailer will be counterfeit, the ease of having the prescription delivered by mail, and the delay in receiving their medication associated with ordering from an online pharmacy. Participants were also asked to indicate how likely they believe it is that a

prescription drug purchased online is counterfeit. Finally, participants answered a series of questions about their awareness of online prescription drug purchasing options, experience purchasing prescription drugs online, and demographic information.

B. Hypotheses

The results of my experiment will contribute to understanding individual decision making about online prescription drug purchases from other countries. The hypotheses tested include:

> Hypothesis 1: Respondents will demonstrate risk aversion to purchasing drugs online relative to a brick-and-mortar pharmacy.

I hypothesize that respondents will rationally demonstrate some risk aversion to purchasing the prescription online and demand a price discount to compensate for the risks of doing so.

> Hypothesis 2: Respondents will demonstrate a willingness to purchase drugs online from abroad at a lower discount than the prevailing discount available for many brand-name drugs.

As discussed above, the potential savings from purchasing a prescription drug online from another country are dramatic. I hypothesize that the mean discount at which respondents are willing to purchase the prescription from an online foreign pharmacy will be less than the 75 percent to 90 percent discount available for many brand-name drugs.

> Hypothesis 3: Respondents will demonstrate more risk aversion to purchasing drugs from Mexico, demanding a greater discount to induce purchase.

I hypothesize that individuals demand a larger price discount when purchasing drugs online from Mexico than from Canada because purchasing from Canada is perceived to be safer because of development and regulatory differences between the two countries.

> Hypothesis 4: Respondents will report hesitancy in purchasing drugs abroad because of concerns about legality.

Hypothesis 5: Respondents will report hesitancy in purchasing drugs abroad because of concerns about substandard or counterfeit products.

I hypothesize that respondents are hesitant to purchase prescription drugs online from foreign countries both for legal and safety reasons. I do not have a strong prior on which concern is more prevalent. This experiment will help disentangle the degree to which concern about the two issues dissuades individuals from purchasing prescriptions online from foreign countries.

IV. Experiment Results

Results from the experiment demonstrate that respondents are, in fact, willing to purchase prescription drugs from online foreign pharmacies at a smaller discount than those commonly available for brand-name drugs. Table 2 provides the mean discounts demanded by respondents in each version of the experiment. The baseline discount demanded to purchase a prescription drug from a US online pharmacy instead of in-person at a local pharmacy is relatively small. In the low-cost version, respondents demanded about a $2, or 7.5 percent, discount. In the high-cost version respondents demanded a $7.75, or 4.69 percent, discount. Discounts demanded to purchase the medication from on online foreign pharmacy instead of in-person in the US were significantly larger. Respondents demanded an $11, or roughly 37 percent, discount to purchase the prescription from an online Canadian pharmacy in the low-cost version and a $94, or roughly 41 percent, discount to purchase the prescription from an online Canadian pharmacy in the high-cost version. When deciding whether to purchase the prescription from an online Mexican pharmacy instead of in-person in the US, respondents demanded an even larger discount of almost $13, or over 43 percent, in the low-cost version and $113, or 41 percent, in the high-cost version. When respondents were asked to choose between purchasing their medication from either a Canadian online pharmacy or a Mexican online pharmacy, they demanded an $8.74, or 30 percent, discount to purchase from the Mexican online pharmacy in the low-cost version and

a $43.51, or about 18 percent, discount to purchase from the Mexican online pharmacy in the high-cost version.

Table 2: Mean Discounts Demanded

	Low Cost		High Cost	
	Dollars ($)	Percent (%)	Dollars ($)	Percent (%)
US/US Online	2.06	7.46	7.75	4.69
	(1.12)	(3.74)	(8.20)	(3.64)
US/Canada	11.04	37.17	94	41.37
	(1.31)	(4.32)	(12.32)	(4.54)
US/Mexico	12.88	43.29	113.54	41.07
	(1.37)	(4.52)	(15.09)	(5.11)
Canada/Mexico	8.74	30.00	43.51	17.92
	(1.18)	(3.00)	(9.35)	(3.88)

Note: Standard error in parentheses.

Table 3 presents unpaired t-tests of the median discounts demanded. The mean discount demanded to purchase a prescription drug from a Canadian online pharmacy or a Mexican online pharmacy instead of from a local pharmacy in the United States are both statistically larger, regardless of the cost condition. However, the mean discount demanded to purchase a prescription drug from a Canadian online pharmacy is not statistically different from the mean discount demanded to purchase a prescription drug from a Mexican online pharmacy in either cost condition.

Table 3: Mean Discount T-tests

Alternative hypothesis in t-test	p value	Difference significant at 95% confidence level
Low Cost Discount		
US < Canada	0.0000	Yes
US < Mexico	0.0000	Yes
Canada < Mexico	0.1657	No
High Cost Discount		
US < Canada	0.0000	Yes
US < Mexico	0.0000	Yes
Canada < Mexico	0.1565	No

Mean discount demanded is presented graphically in Figures 3-5. Figure 3 demonstrates the dollar discount demanded by respondents in each of the low-cost versions of the experiment with 95 percent confidence intervals. The discount demanded by respondents to purchase their medication from either a Canadian online pharmacy or a Mexican online pharmacy instead of in-person are statistically different at the 5 percent level from the discount demanded by respondents to purchase their medication at a US online pharmacy instead of in-person. Although the discount demanded by respondents to purchase their prescription from a Mexican online pharmacy instead of a Canadian online pharmacy is larger, the difference is not statistically significantly different.

Figure 3: Mean Dollar Discount Demanded, Low Cost

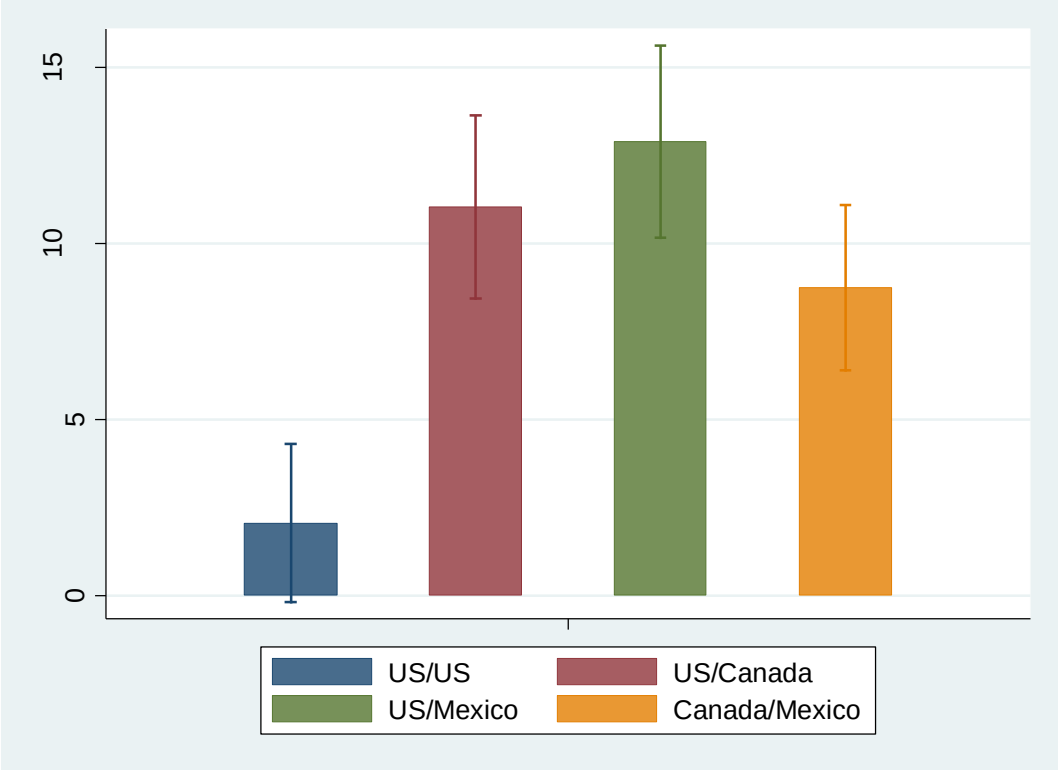


Figure 4 demonstrates the dollar discount demanded by respondents in each of the high-cost versions of the experiment with 95 percent confidence intervals. Again, the discount

demanded by respondents to purchase their medication from either a Canadian online pharmacy or a Mexican online pharmacy instead of in-person are statistically different at the 5 percent level from the discount demanded by respondents to purchase their medication at a US online pharmacy instead of in-person. And, similar to the low-cost version, although the discount demanded by respondents to purchase their prescription from a Mexican online pharmacy instead of a Canadian online pharmacy is larger, the difference is not statistically significantly different.

Figure 4: Mean Dollar Discount Demanded, High Cost

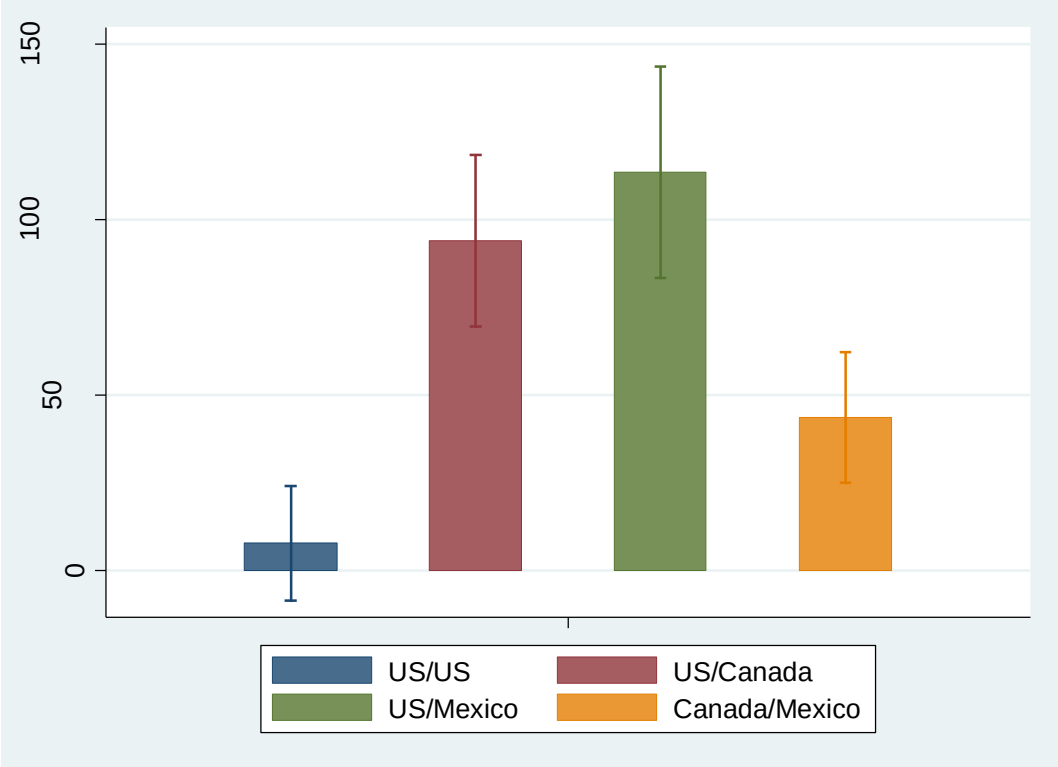
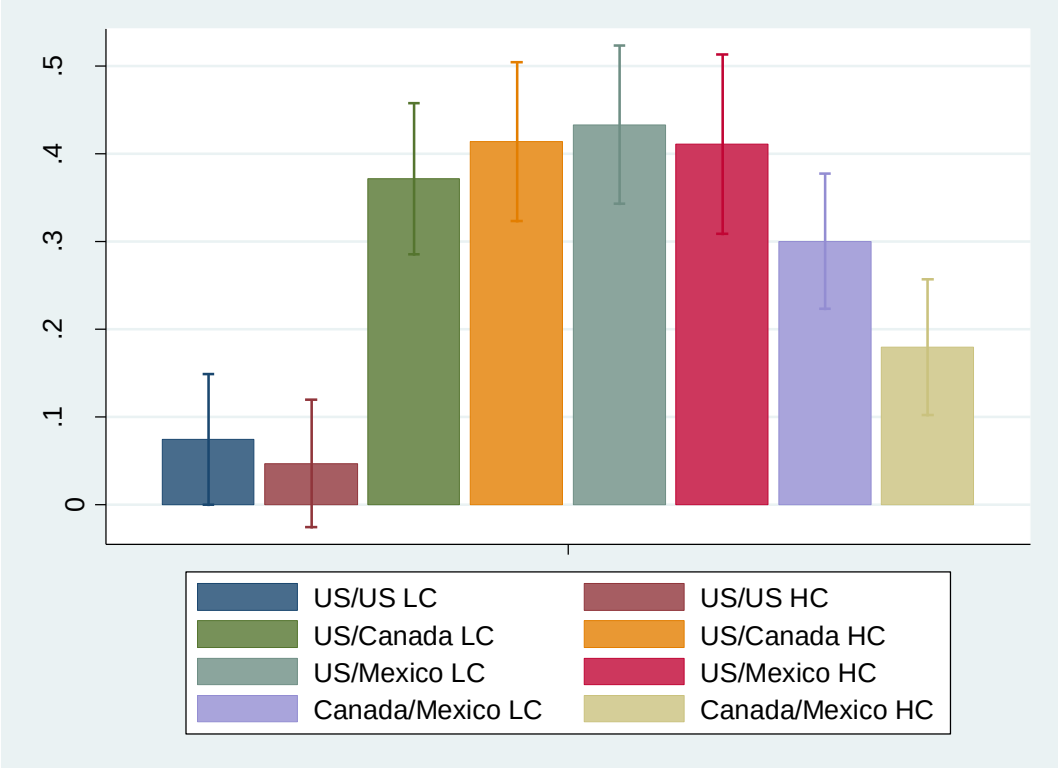


Figure 5 demonstrates the percent discount demanded by respondents in each of the versions of the experiment with 95 percent confidence intervals. Using the percent discount demanded allows comparison across all conditions, which enables price sensitivity analysis. As expected from the previous figures, the discount demanded by respondents to purchase their medication from either a Canadian online pharmacy or a Mexican online pharmacy instead of in-

person are statistically different at the 5 percent level from the discount demanded by respondents to purchase their medication at a US online pharmacy instead of in-person. And, again, although the discount demanded by respondents to purchase their prescription from a Mexican online pharmacy instead of a Canadian online pharmacy is larger, the difference is not statistically significantly different. Although respondents demanded a smaller mean percent discount to purchase the medication online in the US versions, a larger mean percent discount to purchase the medication from a Canadian online pharmacy, a smaller mean percent discount to purchase the medication from a Mexican online pharmacy, and a smaller mean discount to purchase the medication from a Canadian online pharmacy than a Mexican online pharmacy, the differences were not statistically different.

Figure 5: Mean Percent Discount Demanded



These results provide support for hypotheses 1 and 2. Respondents do, in fact, demand a discount when purchasing a prescription drug from an online pharmacy. Although the magnitude of the discount is negligible and not statistically significantly different from zero when making the decision to purchase from a US online pharmacy, the discount demanded when purchasing from a foreign online pharmacy is significant. This suggests that respondents are—often reasonably—concerned that purchasing from a foreign online pharmacy carries much greater risk. The mean percent discounts demanded by respondents to purchase from the foreign online pharmacies instead of the US are clustered around 40 percent, which represents a much smaller discount than those often available.

Regression analysis expands on these basic results. For the purpose of regression analysis, responses to the experiment versions directly comparing purchasing decisions between a Canadian online pharmacy and a Mexican online pharmacy are excluded because the outcome of interest is discount relative to purchasing in-person in the US. Results are presented in tables 4 and 5. Table 4 presents OLS regression results for both the high- and low-cost versions of the experiment from the equation

$$Discount_i = \beta_0 + \beta_1 Foreign + X_i\beta + \varepsilon_i \quad (1)$$

where $Discount_i$ is the discount demanded in dollars by individual i; $Foreign$ is equal to 0 if the individual is making purchasing decisions between US in-person and US online, 1 if the individual is making purchasing decisions between US in-person and Canada online, and 2 if the individual is making purchasing decision between US in-person and Mexico online; and X_i is the set of individual controls. The set of individual controls include sex, age, race, ethnicity, education, employment status, household income, political affiliation, number of prescriptions used, experience purchasing prescriptions online, experience purchasing prescription from

foreign countries, awareness of the ability to purchase prescription drugs online from foreign countries, and insurance type. It also includes responses to the Likert scale questions participants were asked, recoded to a dummy variable equal to 0 if the respondent answered did not consider, not very important, or somewhat important and equal to 1 if the respondent answered important or very important. The results indicate that in the low-cost version, respondents demand a $6.74 greater discount to purchase their medication from a Canadian online pharmacy relative to a US online pharmacy and an $7.57 greater discount to purchase their medication from a Mexican online pharmacy relative to a US online pharmacy. The difference between the discount demanded from a Canadian online pharmacy and the discount demanded from a Mexican online pharmacy is not statistically significant (Prob > F = 0.8717). An increase in the number of prescriptions an individual uses has a small, roughly $0.50 reduction on the discount demanded. Considering the Likert scale questions to be either important or very important does not have any effect on the discount demanded. And, somewhat surprisingly, previous experience purchasing prescription drugs from an online pharmacy, purchasing a prescription drug from a foreign country in-person, and purchasing a prescription drug from a foreign country online do not have any effect on the discount demanded.

In the high-cost version, results demonstrate respondents demand a $80.13 greater discount to purchase their medication from a Canadian online pharmacy relative to a US online pharmacy and $102.77 greater discount to purchase their medication from a Mexican online pharmacy relative to a US online pharmacy. The difference between the discount demanded from a Canadian online pharmacy and the discount demanded from a Mexican online pharmacy is not statistically significant (Prob > F = 0.3433). As in the low-cost version, none of the Likert factors deemed important or very important by the respondent impact the discount demanded. Again,

previous experience purchasing prescriptions online, purchasing prescriptions in-person from a foreign country, and purchasing prescription online from a foreign country have no effect on the discount demanded.

Table 4: Regression Results, High- and Low-Cost Versions

	Low-Cost Discount ($)	High-Cost Discount ($)
Canadian Online Pharmacy	6.74***	80.13***
	(1.98)	(17.95)
Mexican Online Pharmacy	7.57***	102.77***
	(2.25)	(20.52)
Prescriptions	-0.50**	0.50
	(0.23)	(2.53)
Important to Speak with Pharmacist	-0.04	15.64
	(2.01)	(17.90)
Concern that RX Not FDA Standard	-0.17	11.46
	(1.94)	(17.88)
Concern that RX Counterfeit	2.03	19.32
	(1.99)	(19.62)
Ease of Prescription Delivery	-2.28	18.46
	(1.76)	(18.31)
Delay from Online Order	1.15	-6.53
	(5.06)	(18.15)
Previous Foreign Online Pharmacy Purchase	-1.69	-8.04
	(2.44)	(26.44)
Previous Online Pharmacy Purchase	-0.36	-26.53
	(1.90)	(18.69)
Previous Foreign In-Person Purchase	1.65	2.38
	(2.37)	(22.34)
Aware of Foreign Online Pharmacies	-2.02	-1.41
	(1.85)	(17.86)
Constant	10.37	63.62
	(7.15)	(58.38)
R-squared	0.39	0.42
Observations	230	215

Standard errors in parentheses
*** p<0.01, ** p<0.05, * p<0.1

Table 5 presents OLS regression results for both the high- and low-cost versions of the experiment from the equation

$$Pctdiscount_i = \beta_0 + \beta_1 Foreign + X_i\beta + \varepsilon_i \quad (2)$$

where $Pctdiscount_i$ is the percent discount demanded by individual i; $Foreign$ is equal to 0 if the individual is making purchasing decisions between US in-person and US online, 1 if the individual is making purchasing decisions between US in-person and Canada online, and 2 if the individual is making purchasing decision between US in-person and Mexico online; and X_i is the set of individual controls. The results demonstrate that respondents demand a 30 percent greater discount to purchase their medication from a Canadian online pharmacy relative to a US online pharmacy and a 29 percent greater discount to purchase their medication from a Mexican online pharmacy relative to a US online pharmacy. The difference between the discount demanded from a Canadian online pharmacy and the discount demanded from a Mexican online pharmacy is not statistically significant (Prob > F = 0.3075). One Likert question here effects the discount demanded; respondents concerned that prescription from a foreign online pharmacy will be counterfeit increases the discount demanded by 8 percent. Previous experience purchasing prescriptions online decreases the discount demanded by 9 percent. Other factors do not impact the discount demanded.

Table 5: Regression Results, Combined

	Percent Discount
Canadian Online Pharmacy	0.30***
	(0.04)
Mexican Online Pharmacy	0.29***
	(0.05)
High Cost	-0.01
	(0.04)
Prescriptions	-0.01
	(0.01)
Important to Speak with Pharmacist	-0.01
	(0.04)
Concern that RX Not FDA Standard	0.04
	(0.04)
Concern that RX Counterfeit	0.08*
	(0.05)
Ease of Prescription Delivery	-0.01
	(0.04)

Delay from Online Order	0.02
	(0.04)
Previous Foreign Online Pharmacy Purchase	0.04
	(0.06)
Previous Online Pharmacy Purchase	-0.09**
	(0.04)
Previous Foreign In-Person Purchase	0.08
	(0.05)
Aware of Foreign Online Pharmacies	-0.01
	(0.04)
Constant	0.15
	(0.15)
R-squared	0.30
Observations	445

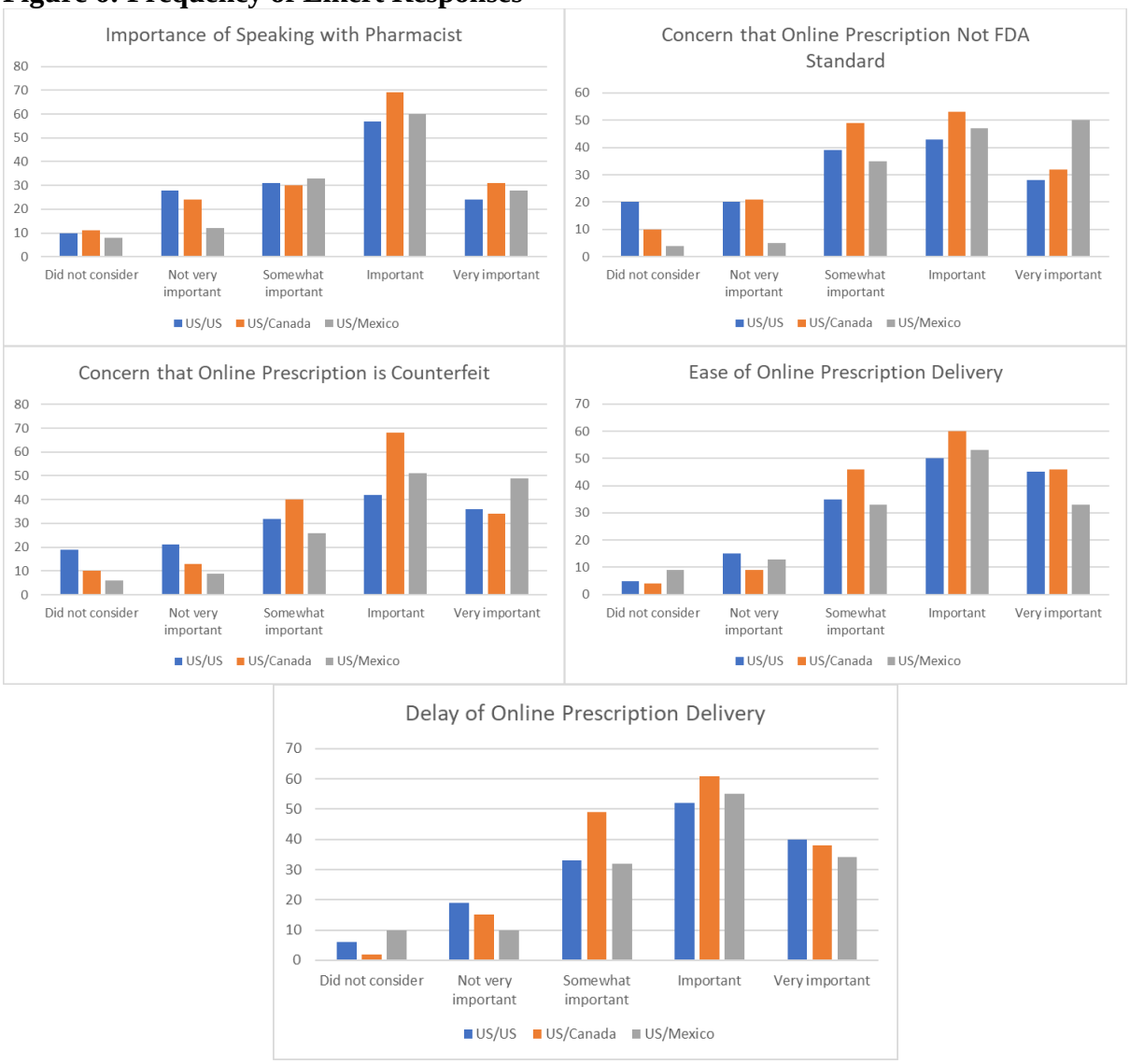
Standard errors in parentheses
*** p<0.01, ** p<0.05, * p<0.1

The regression results again provide support for hypotheses 1 and 2, but little support for the remaining hypotheses. The percent discount demanded is much smaller than discounts available from online foreign pharmacies. In the combined analysis, respondents demand a smaller discount to purchase prescription drugs from a Mexican online pharmacy than from a Canadian online pharmacy relative to a US online pharmacy, but the difference is not significant. Concern about counterfeit medication only impacts the discount demanded in the low-cost version, and other Likert factors do not meaningfully impact the discount demanded.

Though the Likert factors do not, for the most part, have a significant effect on the discount demanded by respondents, visual inspection of the frequency of responses demonstrates some heterogeneity. Frequency, aggregated between the high and low-cost versions of the experiments, of responses are presented in Figure 6. Concern that a prescription drug ordered from an online foreign pharmacy will fail to meet FDA standards was ranked as very important by a noticeably larger portion of respondents in the US/Mexico scenario. Similarly, concern that a prescription drug ordered from an online foreign pharmacy will be counterfeit was ranked as

important by a noticeably larger portion of respondents in the US/Canada scenario and as very important by a much larger portion of respondents in the US/Mexico scenario.

Figure 6: Frequency of Likert Responses



V. Discussion and Conclusion

The results from the experiment suggest that a significant portion of Americans who report having difficulty affording their prescription drugs could benefit from purchasing their medications from online foreign pharmacies. Because individuals only demand a discount well below prevailing available discounts, money is being left on the table and individuals may be

unnecessarily rationing medication or forgoing taking it altogether. Nonetheless, the risks associated with purchasing prescription drugs from online retailers should not be minimized, and consumers must act with care in selecting a vetted foreign online pharmacy option.

The government could act to help ensure that individuals can more easily identify such options. As discussed above, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 amended Section 804 of the Food, Drug, and Cosmetics Act to authorize the Secretary of Health and Human Services to issue regulations permitting pharmacists, wholesalers, and individuals to import prescription drugs from Canada. The current administration could issue regulations permitting individuals to import prescription drugs from Canada, much like the Trump administration did for importation by pharmacists and wholesalers. Doing so would help legitimize the practice, could spread awareness about the option, and could provide government resources to Americans which direct them to online Canadian pharmacies that satisfy any requirements included in the regulations.

In lieu of government action, individuals can use existing online resources such as PharmacyChecker to identify reliable online foreign pharmacies. However, government action has the distinct advantage of making the process of importing prescription drugs for personal use de jure legal rather than de facto legal.

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APPENDIX 1: SURVEY MATERIALS

Version 1 Low Cost—US Brick & Mortar/US Online

You will be given an option of purchasing a prescription drug in two ways: online or at your local pharmacy. Please make a decision between the two purchasing options. We are interested in the point at which you are indifferent between the two purchasing options.

You were diagnosed with migraines, which cause you to experience intense headaches 4-5 times a week. These headaches leave you sensitive to light and incapacitate you. No over-the-counter medication alleviates your symptoms. Your primary physician has prescribed Migrx to alleviate your symptoms.

Migrx has been approved by the United States Food and Drug Administration, which has determined that it is safe and effective. The drug is available for purchase at your local pharmacy or from a United States-based online pharmacy. With a valid prescription, you have the option of purchasing a three-month supply of the drug either from your local pharmacy in person or from an online pharmacy.

Over the next slides you will see a choice between purchasing the drug at your local pharmacy in-person or from an online pharmacy. You must choose one of the two purchasing options, or indicate that you are indifferent between the two.

A. Would you prefer to purchase the drug at your local pharmacy in-person or from an online pharmacy if the out-of-pocket cost is $30 for each purchasing option, or are you indifferent? (*If they choose Local Pharmacy, cost of Online option decreases. If they choose Online, cost of the Local Pharmacy decreases*).
    a. Local Pharmacy
    b. Online
B. Which purchasing option would you choose, or are you indifferent?

Local Pharmacy/Online	Online/Local Pharmacy
$30	$29
$30	$28
$30	$27
$30	$26
$30	$25
$30	Etc.

C. How likely do you believe it is that a prescription drug purchased online will be counterfeit or not meet FDA standards?
    a. Slider indicator
D. Which of the following factors were most important to your above decisions? Please indicate the importance of each according to the following scale:

Did not consider	Not very important	Somewhat important	Important	Very important
1	2	3	4	5

a. The ability to speak with your local pharmacist about the prescription

1	2	3	4	5

b. Concern that the prescription drug from the online retailer will not meet FDA standards

1	2	3	4	5

c. Concern that the prescription drug from the online retailer will be counterfeit

1	2	3	4	5

d. Ease of having prescription delivered by mail

1	2	3	4	5

e. Delayed delivery time with online prescription drug ordering

1	2	3	4	5

E. Now we would like to ask a few questions about you:
   a. Please select your state or territory of residence
      i. Dropdown list of states and territories
   b. How would you describe the area where you live?
      i. City
      ii. Suburb
      iii. Small town
      iv. Country/rural
   c. What sex were you assigned at birth, on your original birth certificate?
      i. Male
      ii. Female
   d. What is your year of birth?
      i. Dropdown list of years
   e. Which of the following best describes your racial background? Select all that apply.
      i. White
      ii. Black or African American

iii. Asian
iv. American Indian or Alaska Native
v. Native Hawaiian or Pacific Islander
vi. Other
vii. I prefer not to answer

f. Which of the following best describes your ethnic background?
    i. Hispanic/Latino
    ii. Not Hispanic/Latino
    iii. I prefer not to answer
g. What is the highest level of education you have completed?
    i. High school or less
    ii. Some college, technical degree, or associate degree
    iii. Bachelor's degree
    iv. Graduate or professional degree
h. Are you currently working for pay or profit?
    i. Yes, full-time
    ii. Yes, part-time
    iii. No
i. What was the total income of your household last year?
    i. Dropdown list with $10,000 bands
j. How many prescription drugs do you use in a typical year?
    i. Dropdown list of choices 1-20+
k. Have you purchased prescription drugs from an online pharmacy?
    i. Yes
    ii. No
l. Have you purchase prescription drugs from a foreign country?
    i. Yes, in person
    ii. Yes, online
    iii. No
m. Are you aware that you can purchase prescription drugs online from foreign pharmacies?
    i. Yes
    ii. No
n. Do you have health insurance?
    i. Yes, private insurance
    ii. Yes, Medicare
    iii. Yes, Medicaid
    iv. Yes, other government insurance
    v. No

Version 2 High Cost—US Brick & Mortar/US Online

You will be given an option of purchasing a prescription drug in two ways: online or at your local pharmacy. Please make a decision between the two purchasing options. We are interested in the point at which you are indifferent between the two purchasing options.

You were diagnosed with migraines, which cause you to experience intense headaches 4-5 times a week. These headaches leave you sensitive to light and incapacitate you. No over-the-counter medication alleviates your symptoms. Your primary physician has prescribed Migrx to alleviate your symptoms.

Migrx has been approved by the United States Food and Drug Administration, which has determined that it is safe and effective. The drug is available for purchase at your local pharmacy or from a United States-based online pharmacy. With a valid prescription, you have the option of purchasing a three-month supply of the drug either from your local pharmacy in person or from an online pharmacy.

Over the next slides you will see a choice between purchasing the drug at your local pharmacy in-person or from an online pharmacy. You must choose one of the two purchasing options, or indicate that you are indifferent between the two.

A. Would you prefer to purchase the drug at your local pharmacy in-person or from an online pharmacy if the out-of-pocket cost is $300 for each purchasing option, or are you indifferent? (*If they choose Local Pharmacy, cost of Online option decreases. If they choose Online, cost of the Local Pharmacy decreases*).
    a. Local Pharmacy
    b. Online
B. Which purchasing option would you choose, or are you indifferent?

Local Pharmacy/Online	Online/Local Pharmacy
$300	$290
$300	$280
$300	$270
$300	$260
$300	$250
$300	Etc.

C. How likely do you believe it is that a prescription drug purchased online will be counterfeit or not meet FDA standards?
    a. Slider indicator
D. Which of the following factors were most important to your above decisions? Please indicate the importance of each according to the following scale:

Did not consider	Not very important	Somewhat important	Important	Very important
1	2	3	4	5

a. The ability to speak with your local pharmacist about the prescription

1	2	3	4	5

b. Concern that the prescription drug from the online retailer will not meet FDA standards

1	2	3	4	5

c. Concern that the prescription drug from the online retailer will be counterfeit

1	2	3	4	5

d. Ease of having prescription delivered by mail

1	2	3	4	5

e. Delayed delivery time with online prescription drug ordering

1	2	3	4	5

E. Now we would like to ask a few questions about you:
   a. Please select your state or territory of residence
      i. Dropdown list of states and territories
   b. How would you describe the area where you live?
      i. City
      ii. Suburb
      iii. Small town
      iv. Country/rural
   c. What sex were you assigned at birth, on your original birth certificate?
      i. Male
      ii. Female
   d. What is your year of birth?
      i. Dropdown list of years
   e. Which of the following best describes your racial background? Select all that apply.
      i. White
      ii. Black or African American
      iii. Asian
      iv. American Indian or Alaska Native
      v. Native Hawaiian or Pacific Islander

vi. Other
vii. I prefer not to answer

f. Which of the following best describes your ethnic background?
    i. Hispanic/Latino
    ii. Not Hispanic/Latino
    iii. I prefer not to answer
g. What is the highest level of education you have completed?
    i. High school or less
    ii. Some college, technical degree, or associate degree
    iii. Bachelor's degree
    iv. Graduate or professional degree
h. Are you currently working for pay or profit?
    i. Yes, full-time
    ii. Yes, part-time
    iii. No
i. What was the total income of your household last year?
    i. Dropdown list with $10,000 bands
j. How many prescription drugs do you use in a typical year?
    i. Dropdown list of choices 1-20+
k. Have you purchased prescription drugs from an online pharmacy?
    i. Yes
    ii. No
l. Have you purchase prescription drugs from a foreign country?
    i. Yes, in person
    ii. Yes, online
    iii. No
m. Are you aware that you can purchase prescription drugs online from foreign pharmacies?
    i. Yes
    ii. No
n. Do you have health insurance?
    i. Yes, private insurance
    ii. Yes, Medicare
    iii. Yes, Medicaid
    iv. Yes, other government insurance
    v. No

Version 3 Low Cost—US/Canada

You will be given an option of purchasing a prescription drug in two ways: online or at a traditional local pharmacy. Please make a decision between the two purchasing options. We are interested in the point at which you are indifferent between the two purchasing options.

You were diagnosed with migraines, which cause you to experience intense headaches 4-5 times a week. These headaches leave you sensitive to light and incapacitate you. No over-the-counter medication alleviates your symptoms. Your primary physician has prescribed Migrx to alleviate your symptoms.

Migrx has been approved by the United States Food and Drug Administration, which has determined that it is safe and effective, and the drug is available for purchase at your local pharmacy. The drug has also been approved by regulators in Canada, though manufacturers and distributors in the country are held to different standards than in the United States. With a valid prescription, you have the option of purchasing a three-month supply of the drug either in the United States or from a Canadian pharmacy online. You can either submit your prescription to your local pharmacy by your normal method or submit your prescription to the online Canadian pharmacy electronically and have the prescription delivered by mail.

Migrx is often available at a lower out-of-pocket cost from Canada. On the next slide you will see a choice between purchasing the drug in the United States or from Canada. You must choose one of the two purchasing options, or indicate that you are indifferent between the two.

A. Which purchasing option would you choose, or are you indifferent?

US	Canada
$30	$30
$30	$29
$30	$28
$30	$27
$30	$26
$30	Etc.

B. How likely do you believe it is that a prescription drug purchased online will be counterfeit?
    a. Slider indicator
C. Which of the following factors were most important to your above decisions? Please indicate the importance of each according to the following scale:

Did not consider	Not very important	Somewhat important	Important	Very important
1	2	3	4	5

a. The ability to speak with your local pharmacist about the prescription

1	2	3	4	5

b. The legality of purchasing a prescription drug online

1	2	3	4	5

c. Concern that the prescription drug from the online retailer will not meet FDA standards

1	2	3	4	5

d. Concern that the prescription drug from the online retailer will be counterfeit

1	2	3	4	5

e. Ease of having prescription delivered by mail

1	2	3	4	5

f. Delayed delivery time with online prescription drug ordering

1	2	3	4	5

D. Now we would like to ask a few questions about you:
   a. Please select your state or territory of residence
      i. Dropdown list of states and territories
   b. How would you describe the area where you live?
      i. City
      ii. Suburb
      iii. Small town
      iv. Country/rural
   c. What sex were you assigned at birth, on your original birth certificate?
      i. Male
      ii. Female
   d. What is your year of birth?
      i. Dropdown list of years
   e. Which of the following best describes your racial background? Select all that apply.
      i. White
      ii. Black or African American
      iii. Asian

iv. American Indian or Alaska Native
v. Native Hawaiian or Pacific Islander
vi. Other
vii. I prefer not to answer

f. Which of the following best describes your ethnic background?
    i. Hispanic/Latino
    ii. Not Hispanic/Latino
    iii. I prefer not to answer
g. What is the highest level of education you have completed?
    i. High school or less
    ii. Some college, technical degree, or associate degree
    iii. Bachelor's degree
    iv. Graduate or professional degree
h. Are you currently working for pay or profit?
    i. Yes, full-time
    ii. Yes, part-time
    iii. No
i. What was the total income of your household last year?
    i. Dropdown list with $10,000 bands
j. How many prescription drugs do you use in a typical year?
    i. Dropdown list of choices 1-20+
k. Have you purchased prescription drugs from an online pharmacy?
    i. Yes
    ii. No
l. Have you purchase prescription drugs from a foreign country?
    i. Yes, in person
    ii. Yes, online
    iii. No
m. Are you aware that you can purchase prescription drugs online from foreign pharmacies?
    i. Yes
    ii. No
n. Do you have health insurance?
    i. Yes, private insurance
    ii. Yes, Medicare
    iii. Yes, Medicaid
    iv. Yes, other government insurance
    v. No

Version 4 High Cost—US/Canada

You will be given an option of purchasing a prescription drug in two ways: online or at a traditional local pharmacy. Please make a decision between the two purchasing options. We are interested in the point at which you are indifferent between the two purchasing options.

You were diagnosed with migraines, which cause you to experience intense headaches 4-5 times a week. These headaches leave you sensitive to light and incapacitate you. No over-the-counter medication alleviates your symptoms. Your primary physician has prescribed Migrx to alleviate your symptoms.

Migrx has been approved by the United States Food and Drug Administration, which has determined that it is safe and effective, and the drug is available for purchase at your local pharmacy. The drug has also been approved by regulators in Canada, though manufacturers and distributors in the country are held to different standards than in the United States. With a valid prescription, you have the option of purchasing a three-month supply of the drug either in the United States or from a Canadian pharmacy online. You can either submit your prescription to your local pharmacy by your normal method or submit your prescription to the online Canadian pharmacy electronically and have the prescription delivered by mail.

Migrx is often available at a lower out-of-pocket cost from Canada. On the next slide you will see a choice between purchasing the drug in the United States or from Canada. You must choose one of the two purchasing options, or indicate that you are indifferent between the two.

A. Which purchasing option would you choose, or are you indifferent?

US	Canada
$300	$300
$300	$290
$300	$280
$300	$270
$300	$260
$300	Etc.

B. How likely do you believe it is that a prescription drug purchased online will be counterfeit or not meet FDA standards?
    a. Slider indicator
C. Which of the following factors were most important to your above decisions? Please indicate the importance of each according to the following scale:

Did not consider	Not very important	Somewhat important	Important	Very important
1	2	3	4	5

    a. The ability to speak with your local pharmacist about the prescription

1	2	3	4	5

b. The legality of purchasing a prescription drug online

1	2	3	4	5

c. Concern that the prescription drug from the online retailer will not meet FDA standards

1	2	3	4	5

d. Concern that the prescription drug from the online retailer will be counterfeit

1	2	3	4	5

e. Ease of having prescription delivered by mail

1	2	3	4	5

f. Delayed delivery time with online prescription drug ordering

1	2	3	4	5

D. Now we would like to ask a few questions about you:
   a. Please select your state or territory of residence
      i. Dropdown list of states and territories
   b. How would you describe the area where you live?
      i. City
      ii. Suburb
      iii. Small town
      iv. Country/rural
   c. What sex were you assigned at birth, on your original birth certificate?
      i. Male
      ii. Female
   d. What is your year of birth?
      i. Dropdown list of years
   e. Which of the following best describes your racial background? Select all that apply.
      i. White
      ii. Black or African American
      iii. Asian
      iv. American Indian or Alaska Native

v. Native Hawaiian or Pacific Islander
vi. Other
vii. I prefer not to answer

f. Which of the following best describes your ethnic background?
    i. Hispanic/Latino
    ii. Not Hispanic/Latino
    iii. I prefer not to answer
g. What is the highest level of education you have completed?
    i. High school or less
    ii. Some college, technical degree, or associate degree
    iii. Bachelor's degree
    iv. Graduate or professional degree
h. Are you currently working for pay or profit?
    i. Yes, full-time
    ii. Yes, part-time
    iii. No
i. What was the total income of your household last year?
    i. Dropdown list with $10,000 bands
j. How many prescription drugs do you use in a typical year?
    i. Dropdown list of choices 1-20+
k. Have you purchased prescription drugs from an online pharmacy?
    i. Yes
    ii. No
l. Have you purchase prescription drugs from a foreign country?
    i. Yes, in person
    ii. Yes, online
    iii. No
m. Are you aware that you can purchase prescription drugs online from foreign pharmacies?
    i. Yes
    ii. No
n. Do you have health insurance?
    i. Yes, private insurance
    ii. Yes, Medicare
    iii. Yes, Medicaid
    iv. Yes, other government insurance
    v. No

Version 5 Low Cost—US/Mexico

You will be given an option of purchasing a prescription drug in two ways: online or at a traditional local pharmacy. Please make a decision between the two purchasing options. We are interested in the point at which you are indifferent between the two purchasing options.

You were diagnosed with migraines, which cause you to experience intense headaches 4-5 times a week. These headaches leave you sensitive to light and incapacitate you. No over-the-counter medication alleviates your symptoms. Your primary physician has prescribed Migrx to alleviate your symptoms.

Migrx has been approved by the United States Food and Drug Administration, which has determined that it is safe and effective, and the drug is available for purchase at your local pharmacy. The drug has also been approved by regulators in Mexico, though manufacturers and distributors in the country are held to different standards than in the United States. With a valid prescription, you have the option of purchasing a three-month supply of the drug either in the United States or from a Mexican pharmacy online. You can either submit your prescription to your local pharmacy by your normal method or submit your prescription to the online Mexican pharmacy electronically and have the prescription delivered by mail.

Migrx is often available at a lower out-of-pocket cost from Mexico. On the next slide you will see a choice between purchasing the drug in the United States or from Mexico. You must choose one of the two purchasing options, or indicate that you are indifferent between the two.

A. Which purchasing option would you choose, or are you indifferent?

US	Mexico
$30	$30
$30	$29
$30	$28
$30	$27
$30	$26
$30	Etc.

B. How likely do you believe it is that a prescription drug purchased online will be counterfeit or not meet FDA standards?
    a. Slider indicator
C. Which of the following factors were most important to your above decisions? Please indicate the importance of each according to the following scale:

Did not consider	Not very important	Somewhat important	Important	Very important
1	2	3	4	5

    a. The ability to speak with your local pharmacist about the prescription

1	2	3	4	5

b. The legality of purchasing a prescription drug online

1	2	3	4	5

c. Concern that the prescription drug from the online retailer will not meet FDA standards

1	2	3	4	5

d. Concern that the prescription drug from the online retailer will be counterfeit

1	2	3	4	5

e. Ease of having prescription delivered by mail

1	2	3	4	5

f. Delayed delivery time with online prescription drug ordering

1	2	3	4	5

D. Now we would like to ask a few questions about you:
   a. Please select your state or territory of residence
      i. Dropdown list of states and territories
   b. How would you describe the area where you live?
      i. City
      ii. Suburb
      iii. Small town
      iv. Country/rural
   c. What sex were you assigned at birth, on your original birth certificate?
      i. Male
      ii. Female
   d. What is your year of birth?
      i. Dropdown list of years
   e. Which of the following best describes your racial background? Select all that apply.
      i. White
      ii. Black or African American
      iii. Asian
      iv. American Indian or Alaska Native

v. Native Hawaiian or Pacific Islander
vi. Other
vii. I prefer not to answer

f. Which of the following best describes your ethnic background?
    i. Hispanic/Latino
    ii. Not Hispanic/Latino
    iii. I prefer not to answer
g. What is the highest level of education you have completed?
    i. High school or less
    ii. Some college, technical degree, or associate degree
    iii. Bachelor's degree
    iv. Graduate or professional degree
h. Are you currently working for pay or profit?
    i. Yes, full-time
    ii. Yes, part-time
    iii. No
i. What was the total income of your household last year?
    i. Dropdown list with $10,000 bands
j. How many prescription drugs do you use in a typical year?
    i. Dropdown list of choices 1-20+
k. Have you purchased prescription drugs from an online pharmacy?
    i. Yes
    ii. No
l. Have you purchase prescription drugs from a foreign country?
    i. Yes, in person
    ii. Yes, online
    iii. No
m. Are you aware that you can purchase prescription drugs online from foreign pharmacies?
    i. Yes
    ii. No
n. Do you have health insurance?
    i. Yes, private insurance
    ii. Yes, Medicare
    iii. Yes, Medicaid
    iv. Yes, other government insurance
    v. No

Version 6 High Cost—US/Mexico

You will be given an option of purchasing a prescription drug in two ways: online or at a traditional local pharmacy. Please make a decision between the two purchasing options. We are interested in the point at which you are indifferent between the two purchasing options.

You were diagnosed with migraines, which cause you to experience intense headaches 4-5 times a week. These headaches leave you sensitive to light and incapacitate you. No over-the-counter medication alleviates your symptoms. Your primary physician has prescribed Migrx to alleviate your symptoms.

Migrx has been approved by the United States Food and Drug Administration, which has determined that it is safe and effective, and the drug is available for purchase at your local pharmacy. The drug has also been approved by regulators in Mexico, though manufacturers and distributors in the country are held to different standards than in the United States. With a valid prescription, you have the option of purchasing a three-month supply of the drug either in the United States or from a Mexican pharmacy online. You can either submit your prescription to your local pharmacy by your normal method or submit your prescription to the online Mexican pharmacy electronically and have the prescription delivered by mail.

Migrx is often available at a lower out-of-pocket cost from Mexico. On the next slide you will see a choice between purchasing the drug in the United States or from Mexico. You must choose one of the two purchasing options, or indicate that you are indifferent between the two.

A. Which purchasing option would you choose, or are you indifferent?

US	Mexico
$300	$300
$300	$290
$300	$280
$300	$270
$300	$260
$300	Etc.

B. How likely do you believe it is that a prescription drug purchased online will be counterfeit or not meet FDA standards?
    b. Slider indicator
C. Which of the following factors were most important to your above decisions? Please indicate the importance of each according to the following scale:

Did not consider	Not very important	Somewhat important	Important	Very important
1	2	3	4	5

a. The ability to speak with your local pharmacist about the prescription

1	2	3	4	5

b. The legality of purchasing a prescription drug online

1	2	3	4	5

c. Concern that the prescription drug from the online retailer will not meet FDA standards

1	2	3	4	5

d. Concern that the prescription drug from the online retailer will be counterfeit

1	2	3	4	5

e. Ease of having prescription delivered by mail

1	2	3	4	5

f. Delayed delivery time with online prescription drug ordering

1	2	3	4	5

D. Now we would like to ask a few questions about you:
   a. Please select your state or territory of residence
      i. Dropdown list of states and territories
   b. How would you describe the area where you live?
      i. City
      ii. Suburb
      iii. Small town
      iv. Country/rural
   c. What sex were you assigned at birth, on your original birth certificate?
      i. Male
      ii. Female
   d. What is your year of birth?
      i. Dropdown list of years
   e. Which of the following best describes your racial background? Select all that apply.
      i. White
      ii. Black or African American
      iii. Asian
      iv. American Indian or Alaska Native

v. Native Hawaiian or Pacific Islander
vi. Other
vii. I prefer not to answer

f. Which of the following best describes your ethnic background?
    i. Hispanic/Latino
    ii. Not Hispanic/Latino
    iii. I prefer not to answer
g. What is the highest level of education you have completed?
    i. High school or less
    ii. Some college, technical degree, or associate degree
    iii. Bachelor's degree
    iv. Graduate or professional degree
h. Are you currently working for pay or profit?
    i. Yes, full-time
    ii. Yes, part-time
    iii. No
i. What was the total income of your household last year?
    i. Dropdown list with $10,000 bands
j. How many prescription drugs do you use in a typical year?
    i. Dropdown list of choices 1-20+
k. Have you purchased prescription drugs from an online pharmacy?
    i. Yes
    ii. No
l. Have you purchase prescription drugs from a foreign country?
    i. Yes, in person
    ii. Yes, online
    iii. No
m. Are you aware that you can purchase prescription drugs online from foreign pharmacies?
    i. Yes
    ii. No
n. Do you have health insurance?
    i. Yes, private insurance
    ii. Yes, Medicare
    iii. Yes, Medicaid
    iv. Yes, other government insurance
    v. No

Version 7 Low Cost—Canada/Mexico

You will be given an option of purchasing a prescription drug from two foreign pharmacies online: one in Canada and one in Mexico. Please make a decision between the two purchasing options. We are interested in the point at which you are indifferent between the two purchasing options.

You were diagnosed with migraines, which cause you to experience intense headaches 4-5 times a week. These headaches leave you sensitive to light and incapacitate you. No over-the-counter medication alleviates your symptoms. Your primary physician has prescribed Migrx to alleviate your symptoms.

Migrx has been approved by the United States Food and Drug Administration, which has determined that it is safe and effective, and the drug is available for purchase at your local pharmacy. The drug has also been approved by regulators in Canada and Mexico, though manufacturers and distributors in the countries are held to different standards than in the United States. With a valid prescription, you have the option of purchasing a three-month supply of the drug either from a Canadian or Mexican pharmacy online. We are interested in the point at which you are indifferent between purchasing the drug from the two foreign countries.

Over the next slides you will see a choice between purchasing the drug from Canada or Mexico. You must choose one of the two purchasing options, or indicate that you are indifferent between the two.

A. Would you prefer to purchase the drug from an online pharmacy in Canada or Mexico if the out-of-pocket cost is $30 for each purchasing option, or are you indifferent? (*If they choose Canada, cost of Mexico option decreases. If they choose Mexico, cost of the Canada decreases*).
    a. Canada
    b. Mexico
B. Which purchasing option would you choose, or are you indifferent?

Canada/Mexico	Mexico/Canada
$30	$29
$30	$28
$30	$27
$30	$26
$30	$25
$30	Etc.

C. How likely do you believe it is that a prescription drug purchased online will be counterfeit or not meet FDA standards?
    a. Slider indicator
D. Which of the following factors were most important to your above decisions? Please indicate the importance of each according to the following scale:

Did not consider	Not very important	Somewhat important	Important	Very important
1	2	3	4	5

a. Concern that the prescription from a Mexican online retailer is less likely to meet FDA standards

1	2	3	4	5

b. Concern that the prescription drug from a Mexican online retailer will be counterfeit

1	2	3	4	5

A. Now we would like to ask a few questions about you:
   a. Please select your state or territory of residence
      i. Dropdown list of states and territories
   b. How would you describe the area where you live?
      i. City
      ii. Suburb
      iii. Small town
      iv. Country/rural
   c. What sex were you assigned at birth, on your original birth certificate?
      i. Male
      ii. Female
   d. What is your year of birth?
      i. Dropdown list of years
   e. Which of the following best describes your racial background? Select all that apply.
      i. White
      ii. Black or African American
      iii. Asian
      iv. American Indian or Alaska Native
      v. Native Hawaiian or Pacific Islander
      vi. Other
      vii. I prefer not to answer
   f. Which of the following best describes your ethnic background?
      i. Hispanic/Latino
      ii. Not Hispanic/Latino
      iii. I prefer not to answer
   g. What is the highest level of education you have completed?
      i. High school or less
      ii. Some college, technical degree, or associate degree

iii. Bachelor's degree
iv. Graduate or professional degree

h. Are you currently working for pay or profit?
    i. Yes, full-time
    ii. Yes, part-time
    iii. No
i. What was the total income of your household last year?
    i. Dropdown list with $10,000 bands
j. How many prescription drugs do you use in a typical year?
    i. Dropdown list of choices 1-20+
k. Have you purchased prescription drugs from an online pharmacy?
    i. Yes
    ii. No
l. Have you purchase prescription drugs from a foreign country?
    i. Yes, in person
    ii. Yes, online
    iii. No
m. Are you aware that you can purchase prescription drugs online from foreign pharmacies?
    i. Yes
    ii. No
n. Do you have health insurance?
    i. Yes, private insurance
    ii. Yes, Medicare
    iii. Yes, Medicaid
    iv. Yes, other government insurance
    v. No

Version 8 High Cost—Canada/Mexico

You will be given an option of purchasing a prescription drug from two foreign pharmacies online: one in Canada and one in Mexico. Please make a decision between the two purchasing options. We are interested in the point at which you are indifferent between the two purchasing options.

You were diagnosed with migraines, which cause you to experience intense headaches 4-5 times a week. These headaches leave you sensitive to light and incapacitate you. No over-the-counter medication alleviates your symptoms. Your primary physician has prescribed Migrx to alleviate your symptoms.

Migrx has been approved by the United States Food and Drug Administration, which has determined that it is safe and effective, and the drug is available for purchase at your local pharmacy. The drug has also been approved by regulators in Canada and Mexico, though manufacturers and distributors in the countries are held to different standards than in the United States. With a valid prescription, you have the option of purchasing a three-month supply of the drug either from a Canadian or Mexican pharmacy online. We are interested in the point at which you are indifferent between purchasing the drug from the two foreign countries.

Over the next slides you will see a choice between purchasing the drug from Canada or Mexico. You must choose one of the two purchasing options, or indicate that you are indifferent between the two.

A. Would you prefer to purchase the drug from an online pharmacy in Canada or Mexico if the out-of-pocket cost is $300 for each purchasing option, or are you indifferent? (*If they choose Canada, cost of Mexico option decreases. If they choose Mexico, cost of the Canada decreases*).
    a. Canada
    b. Mexico
B. Which purchasing option would you choose, or are you indifferent?

Canada/Mexico	Mexico/Canada
$300	$290
$300	$280
$300	$270
$300	$260
$300	$250
$300	Etc.

C. How likely do you believe it is that a prescription drug purchased online will be counterfeit or not meet FDA standards?
    a. Slider indicator
D. Which of the following factors were most important to your above decisions? Please indicate the importance of each according to the following scale:

Did not consider	Not very important	Somewhat important	Important	Very important
1	2	3	4	5

a. Concern that the prescription from a Mexican online retailer is less likely to meet FDA standards

1	2	3	4	5

b. Concern that the prescription drug from a Mexican online retailer will be counterfeit

1	2	3	4	5

A. Now we would like to ask a few questions about you:
   a. Please select your state or territory of residence
      i. Dropdown list of states and territories
   b. How would you describe the area where you live?
      i. City
      ii. Suburb
      iii. Small town
      iv. Country/rural
   c. What sex were you assigned at birth, on your original birth certificate?
      i. Male
      ii. Female
   d. What is your year of birth?
      i. Dropdown list of years
   e. Which of the following best describes your racial background? Select all that apply.
      i. White
      ii. Black or African American
      iii. Asian
      iv. American Indian or Alaska Native
      v. Native Hawaiian or Pacific Islander
      vi. Other
      vii. I prefer not to answer
   f. Which of the following best describes your ethnic background?
      i. Hispanic/Latino
      ii. Not Hispanic/Latino
      iii. I prefer not to answer
   g. What is the highest level of education you have completed?
      i. High school or less
      ii. Some college, technical degree, or associate degree

iii. Bachelor's degree
iv. Graduate or professional degree

h. Are you currently working for pay or profit?
    i. Yes, full-time
    ii. Yes, part-time
    iii. No
i. What was the total income of your household last year?
    i. Dropdown list with $10,000 bands
j. How many prescription drugs do you use in a typical year?
    i. Dropdown list of choices 1-20+
k. Have you purchased prescription drugs from an online pharmacy?
    i. Yes
    ii. No
l. Have you purchase prescription drugs from a foreign country?
    i. Yes, in person
    ii. Yes, online
    iii. No
m. Are you aware that you can purchase prescription drugs online from foreign pharmacies?
    i. Yes
    ii. No
n. Do you have health insurance?
    i. Yes, private insurance
    ii. Yes, Medicare
    iii. Yes, Medicaid
    iv. Yes, other government insurance
    v. No