The Power of Not Asking: How Do Generic Drug Substitution Laws Affect Patient's Demand for Generic Drugs? [1]

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Abstract

Substituting generic for brand drugs whenever possible has been proposed as an effective way to control prescription drug expenditure growth in the United States. This work investigates whether mandatory switching and presumed consent laws are effective in increasing generic drug use. The analysis uses plausibly exogenous changes in states' drug substitution policies for identification. The Difference-in-Difference regression results indicate that mandatory switching laws have little effect. However, presumed consent laws, whereby the pharmacists could assume patients' consent to switch to generic drugs, reduce consumers' probability of purchasing brand drugs by 4.1 percentage points. We construct and estimate a bounded rationality model to explain why presumed consent laws work. In the model, consumers in states with presumed consent laws incur a cost when asking pharmacists for brand drugs. We find that presumed consent laws' effect in decreasing brand drug use is equivalent to increasing the brand drug price by 3 dollars. The average marginal effect of the policy is to reduce the probability of purchasing brand drugs by 6 and 11 percent. A welfare calculation indicates that consumers' surplus loss exceeds the insurances' gain by 7.5 dollars per person per purchase when states switch from explicit to presumed consent laws.

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1. Introduction

The rising costs of health care expenditures in the United States have captured the attention of academics and policy makers. In 2013, national health expenditures totaled 2.9 trillion dollars, or 17.4 percent of US GDP.[4] Ten percent of this spending went towards prescription drugs. Finding an effective way to control drug expenditure has become a priority for policy makers. A generic drug is usually priced at 10 to 20 percent of the brand name counterpart. One possible way to control the drug expenditures is to dispense generic drugs whenever a multi-source drug is prescribed. For instance, Kelton et al. (2013) estimates that state Medicaid programs could have saved 220 million dollars when generic fluoxetine came to market between 2001 and 2005. [5]

However, it has been well documented that consumers have a high preference for particular brands, even when the alternatives are objectively similar. The majority of consumers typically buy a single brand of beer, cola, or margarine even though relative prices vary significantly over time. Other work finds substantial brand price premium in a wide range of non-consumer package goods, such as automobiles (Sullivan et al. (1994)), index funds (Hortaçsu and Syverson (2003)), and online books (Smith and Brynjolfsson (2001)). In the prescription drug market, Ling et al. (2002) document that a large fraction of consumers buys branded medications, even though generic substitutes are available at the same stores for much lower prices. The preference for brand is also known to be persistent and difficult to change. Beshears et al. (2013) document that short peer testimonials do not increase the impact of a mailed communication on conversion rates to generic drugs, even when the testimonial is presented as coming from socially proximate peers. Carrera and Villas-Boas (2013) find that information on the comparability of generics has no effect on the generic purchase rate relative to the national brand.

Given the potential savings of generic substitution and the well known consumers' prefer-

[4] http://www.cdc.gov/nchs/fastats/health-expenditures.htm. Last accessed Aug 16, 2015.

[5] A multi-source drug is defined as having at least one other drug rated as therapeutically equivalent under the Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations."

ence for brands, it is important to understand what type of policy could effectively increase generic drug substitution rates. In this paper, we evaluate two types of policies employed by states in the United States to increase generic drug use at the retail level. The first type of law regulates whether it is mandatory or permissive for pharmacists to switch to a generic drug. The second type of law mandates whether the patient consent is presumed or has to be explicitly acquired. Presumed consent laws imply pharmacists assume that the patient agrees with the generic substitution unless the patient explicitly rejects the substitution. Explicit consent laws require that pharmacists must ask for patients' permission to switch to a generic drug. A state can choose any combination of the two types of policy tools.

Intuitively, mandatory switching and presumed consent laws should both increase the use of generic drugs. However, there has been no systematic study to quantify the impacts of these laws. The only recent study by Shrank et al. (2010) analyzes the laws' impacts on the generic substitution ratio for Zocor[6]. They find that states implementing policies that require patient consent prior to generic substitution experienced 25 percent lower rates of generic substitution. But more questions remain to be answered. For instance, does the presumed patient consent law have the same level of impact on every type of drug? Why does the presumed patient consent law work? What would happen if all states switch from explicit consent law to presumed consent law?

This paper tries to answer these questions. We provide the first comprehensive analysis of how state generic substitution laws impact the prescription drug market. We collect data on state laws of generic substitution between 2006 and 2012. During the seven year period, eleven states changed their policy on generic drug substitution. For example, Michigan changed from not requiring to requiring consent, while Alabama chose not to require consent in 2009. We exploit these changes to identify the impacts of generic substitution policies on generic drug use.

We merge the law data with the Medical Expenditure Panel Survey (MEPS) data. The

[6]Zocor is used to lower cholesterol and triglycerides (types of fat) in the blood.

MEPS prescribed medicine file provides detailed information on household-reported prescribed medicines for a nationally representative sample of the civilian noninstitutionalized population of the United States. Each record represents one household-reported prescribed medicine that was purchased in that year.

Our analysis includes two parts. In the first part, we empirically establish the impacts of the policies using the difference in differences method. To capture the potential heterogeneity of the laws' effects, we look at nine drugs within three types of drug categories: statins, antidepressants/SSRIs and proton pump inhibitors (PPIs).[7] We find that mandatory switching laws have little impact on the generic drug use compared to permissive switching laws. Mandatory switching laws do not decrease the probability of purchasing brand drugs more than the permissive law for all nine drugs. In comparison, the presumed patient consent law significantly decreases the probability of consumers buying a brand rather than a generic drug for seven out of nine drugs. The magnitude of the impact depends on the molecule under consideration, ranging from a 20 to 70 percent decrease in the probability of buying a brand name prescription drug. To verify the validity of these results, we implement a falsification test. The intuition for the test is that consumers' preference of brand over the counter (OTC) drugs should not be affected by the policies regulating the substitution of prescription drugs. We find that these policies do not affect whether consumers choose brand or generic OTC drugs. We also look at how pharmaceutical firms adjust their pricing strategies in response to these policy changes. We find that the state generic drug substitution laws have no significant impact on consumers' copayment and the total payment for prescription drugs.

After establishing the impacts of the policies on generic substitution, we attempt to understand the mechanisms that drive the effects of the presumed consent policy, and its welfare implications. We model the presumed patient consent law as an extra cost for patients living in states with such policy to buy brand name drugs. We estimate the size

[7]These drugs are used to reduce cholesterol levels, treat depression, and reduce gastric acid production, respectively.

of the cost parameter by modeling the consumer's choice of prescription drug as a discrete choice problem. We find that the effect of the presumed consent law on the patient's decision to buy prescription drugs is equivalent to a three dollar increase in the price of a brand name drug. The average marginal effect of the policy is that the average probability of purchasing brand name drugs decreases by six to eleven percent. A welfare calculation indicates that the consumer's surplus loss exceeds the insurer's gain by 7.5 dollars per person when all states switch from explicit to presumed consent.

The rest of the paper is organized as follows. Section 2 discusses the related literature and this paper's contributions. Section 3 provides background information on the pharmaceutical market and the state laws regulating generic substitution. Section 4 applies the difference in differences method. Section 5 models the presumed consent law in a consumer's discrete choice problem, and Section 6 concludes.

2. Literature Review

With the recent increase in pharmacy spending, pharmacy benefit managers and health plans have adopted benefit changes designed to reduce pharmaceutical use or steer patients to less-expensive alternatives. These cost sharing features of prescription drug benefits include tiered copayments, benefit caps, prior authorization, closed formularies, and reference pricing. Goldman et al. (2007) reviews articles that study the associations between prescription drug cost sharing and medication and medical utilization, spending, and health. These studies show that increased cost sharing is associated with lower rates of drug treatment, worse adherence among existing users, and more frequent discontinuation of therapy. For each ten percent increase in cost sharing, prescription drug spending decreases by two to six percent.

In comparison, much less attention has been paid to the impact of state drug substitution laws on generic drug use. Shrank et al. (2010) evaluate the relationship between different generic substitution policies and generic simvastatin use after patent expiration of Zocor. They find that states implementing policies that require explicit consent prior to generic

substitution experienced 25 percent lower rates of generic substitution. This study suffers from several limitations. By limiting themsevles to one type of drug, they could not capture potential heterogeneous effects of the laws. Further, they do not discuss why the presumed consent law was more effective than the mandatory substitution law. Kelton et al. (2013) examine the movement to generic fluoxetine following patent expiration for Prozac, a widely prescribed antidepressant. They find large differences in states' responses to generic availability. States take between two and ten calendar quarters to reach 90 percent use of generic rather than brand-name fluoxetine. However, they do not explore the potential causes of these variations.

This paper is related to the literature on the choice of prescription drugs. This literature has largely focused on the role of physicians' preferences and learning. Hellerstein (1998) examines the importance of physicians in the process by which patients receive either brand name or generic drugs. Using a data set on physicians, their patients, and the multisource drugs prescribed, she finds that very little of the prescription decision can be explained by observable characteristics of individual patients, but all of the evidence indicates that physicians are indeed an important agent in determining whether patients receive either trade-name or generic drugs. Coscelli (2000) studies the contribution of doctor and patient habits to persistence in market shares in prescription drug markets. He finds significant evidence of time-dependence in prescription choices for both doctors and patients. Other important work includes Coscelli and Shum (2004), Crawford and Shum (2005) and Lundin (2000).

The presumed consent law is widely applied in other scenarios. Abadie and Gay (2006) study the impact of presumed consent legislation on cadaveric organ donation. Under presumed consent legislation, a deceased individual is classified as a potential donor in absence of explicit opposition to donation before death. They construct a data set on organ donation rates and potential factors affecting organ donation for 22 countries over a 10-year period. They find that differences in other determinants of organ donation explain much of the variation in donation rates. Still, even after controlling for those determinants, presumed consent

legislation has a positive and sizable effect on organ donation rates. Another widely known application of presumed consent rules is the default opt-in structure of the 401(k) savings plans in the United States. Madrian and Shea (2000) find that automatic enrollment in 401(k) dramatically changes the savings behavior of employees. Specifically, they find that 401(k) participation is significantly higher under automatic enrollment. Thaler and Benartzi (2004) and Chetty et al. (2012) study similar issues and come to the same conclusions. Carroll et al. (2005) model the 401(k) enrollment and derive conditions under which the optimal enrollment regime is automatic enrollment (i.e., default enrollment), standard enrollment (i.e., default non-enrollment), or active decisions. Thaler (2008) provides various other examples of presumed consent. Most of the existing literature on the presumed consent policy uses a reduced form approach to quantify the effect of presumed consent. An exception is Handel (2013). He investigates consumer inertia in health insurance markets. He leverages a major change to insurance provision that occurred at a firm to identify substantial inertia. He estimates a choice model, and uses these estimates to study the impact of policies that nudge consumers toward better decisions by reducing inertia. Similar to Handel (2013), we view the presumed consent as a policy that nudges consumers towards better decisions by increasing inertia. We model the presumed consent policy as extra costs to buy brand drugs. We contribute to the literature by developing a discrete consumer choice model, and estimate the size of the cost incurred by the presumed consent policy.

3. Background Information of the Pharmaceutical Industry and Generic Substitution Laws

3.1. Background Information of the Pharmaceutical Industry

The pharmaceutical industry is one of the most heavily regulated industries in the United States. A firm has to file a New Drug Application (NDA) for FDA approval to be able to market a new drug. Once approved, this drug is granted market monopoly under the protection of a patent. A patent usually lasts about 20 years. After the drug's patent expires, other firms can apply for FDA approval to produce a generic version of that drug. Before the

passage of the Hatch-Waxman act in 1984, generic producing firms had to go through the same stage of clinical trials as the brand name firm to prove the drug's efficacy and safety. After 1984, generic firms could simply demonstrate bio-equivalence with branded products by showing that the active ingredient in their product diffused into the human bloodstream in a manner similar to the original product. This act dramatically changed the landscape of the pharmaceutical market (Boehm et al. (2013)). Generic drugs now enjoy about 70 percent of the market, compared to about 10 percent in the 1980s.

3.2. Background Information of the Generic Drug Substitution Laws

3.2.1. Generic Drug Substitution Laws in the US

At one time, laws in most states required the pharmacist to fill a prescription as written, precluding generic dispensing when the physician had written the brand name, but the last of these antisubstitution laws was repealed in 1984 (most were repealed in the mid- to late-1970s). They were replaced by two types of laws regulating the substitution of generic drugs. The first type of law can be classified into two categories, permissive or mandatory. An example of the mandatory switching law is the legislation in Florida:

> A pharmacist who receives a prescription for a brand name drug shall, unless requested otherwise by the purchaser, substitute a less expensive, generically equivalent drug product.[8]

An example of the permissive switching law is the Illinois legislation:

> A different brand name or non-brand name drug product of the same generic name may be dispensed by the pharmacist, provided that the selected drug has a unit price less than the drug product specified in the prescription.[9]

The second type of law determines the nature of consent, explicit or presumed, that is

[8] http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0400-0499/0465/Sections/0465.025.html. Last accessed Aug 14, 2015

[9] http://ilga.gov/legislation/ilcs/ilcs3.asp?ActID=1318&ChapAct=225percent26nbsppercent3BILCSpercent26nbsppercent3B85. Last accessed Aug 14, 2015

Table 1: Summary of Generic Drug Substitution Policy Regulating Environment.

	Mandatory	Permissive
Explicit Consent	Pharmacists must switch, and need to acquire explicit patient consent.	Pharmacists can switch, and need to acquire explicit patient consent.
Presumed Consent	Pharmacists must switch, and assume patient consent.	Pharmacists can switch, and assume patient consent.

Note: These are the possible scenarios for the two types of generic drug substitution laws examined in this study, for situations in which a brand name drug is prescribed, and a generic drug that has been rated as bioequivalent by the FDA is available. In all cases, the patient can overrule the substitution and opt for their preferred choice.

required for substitution. An example of the explicit consent law is the regulation in Pennsylvania:

> Any pharmacist who substitutes any drug shall notify the person presenting the prescription of such substitution together with the amount of the retail price difference between the brand name and the drug substituted for it and shall inform the person presenting the prescription that they may refuse the substitution.[10]

Compared to the explicit consent law, the presumed consent law presumes consent from the consumer. It only indicates on the label of the drug that the substitution has taken place. An example is the regulation in Massachusetts:

> The pharmacist shall indicate on the label in the following manner the fact of the interchange: "Interchange (name of exact drug product dispensed)"[11]

States can choose any combination of the two types of laws. Consumers can always refuse the substitution and choose to pay more to get the branded drug. Table 1 summarizes the possible generic drug substitution policy regulating environment.

3.2.2. Generic Drug Substitution Laws in Europe

Similar to the US, Europe has also adopted certain policies to increase the use of generic drugs. Table 2 shows how different countries regulate generic drug substitution. Generic

[10] http://www.health.pa.gov/facilities/Consumers/Healthpercent20Facilities/Homepercent20Healthpercent20Servicespercent20andpercent20Hosp Last accessed Aug 14, 2015

[11] https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVI/Chapter112/Section12D. Last accessed Aug 14, 2015

Table 2: Regulation of How Pharmacists Should Substitute Generic Drugs in Europe

Country	Generic Substitution by Pharmacists	Country	Generic Substitution by Pharmacists
Austria	Disallowed	Italy	Permissive
Belgium	Partly Mandatory*	Lithuania	Permissive
Bulgaria	Disallowed	Latvia	Permissive
Cyprus	Mandatory in public sector	Luxembourg	Disallowed
Czech Republic	Permissive	Malta	Mandatory in public sector
Germany	Mandatory	Netherlands	Permissive
Denmark	Mandatory	Poland	Permissive
Estonia	Permissive	Portugal	Mandatory
Greece	Mandatory	Romania	Mandatory
Spain	Mandatory	Sweden	Mandatory
Finland	Mandatory	France	Permissive
Hungary	Permissive	United Kingdom	Disallowed
Slovenia	Permissive	Slovakia	Mandatory

Notes: * Mandatory substitution for antibiotics and antimycotics only. Sources : Vogler (2012)

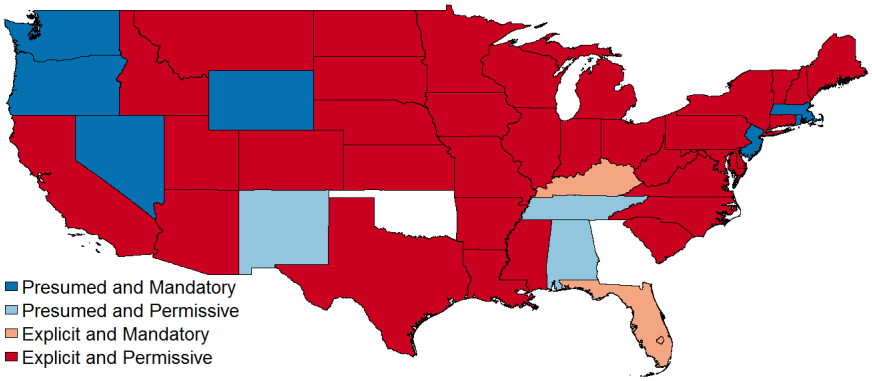
substitution by pharmacists is mandatory in seven, permissive in fifteen, and disallowed in five E.U. member countries. There is less information available on whether patients' consent is required explicitly or can be presumed. In a cross country comparison, the generic drug market share is usually higher in countries with mandatory substitution law. Countries which disallow generic substitution usually have the lowest generic drug market shares.[12] However, since countries in Europe vary significantly in the reimbursement scheme for wholesalers and pharmacies, economic development, and other variables associated with generic drug switch, this evidence does not allow us to identify the effects of the mandatory substitution law.

3.2.3. Evolution of the US Generic Substitution Laws between 2006 and 2012

We take the data from Survey of Pharmacy Laws between 2006 and 2012. Figure 1 plots

[12]See Carone et al. (2012) for a more detailed generic drug market share among EU member countries.

Figure 1: State Generic Drug Substitution Laws Atlas



the distribution of how the US states choose the generic drug substitution laws.

From the figure, we see that the majority of states require explicit patient consent and are permissive towards generic drug substitution, but all four possible combinations of the two laws exist. Table 3 breaks down the distribution of the law types. In 2006, there were three states in the permissive and presumed consent group, and there were also three states in the mandatory and explicit consent group. Seven states belonged to the group that had presumed consent and mandatory substitution. The majority of states were permissive and required explicit patient consent for substitution, with 37 states in this group. During the seven years period between 2006 and 2012, several states changed their generic substitution laws. Panel B in 3 presents the breakdown of the state laws in 2012. In total, eleven states changed these laws. Table 4 shows the details of these policy changes. Changes in both directions exist. For example, Michigan switched from not requiring to requiring consent, while Alabama chose not to require consent in 2009.

4. Empirical Analysis of the Impacts of the State Regulations of Generic Drug Substitution

We exploit exogenous variation from the law changes discussed above to identify the impact of these laws. We merge the law data with the Medical Expenditure Panel Survey (MEPS) data from 2006 to 2012. In this section, we will describe the data used and discuss the empirical results.

Table 3: State Generic Substitution Laws

Panel A : 2006		
	Mandatory	Permissive
Presumed Consent	7	3
Explicit Consent	3	37
Panel B : 2012		
	Mandatory	Permissive
Presumed Consent	5	7
Explicit Consent	6	32

Note : The data of the state regulations of the generic drug substitution is taken from various years of Survey of Pharmaceutical Laws.

Table 4: US State Generic Drug Substitution Policies Changes between 2006 and 2012

Year	Policy Change	State
2008	Mandatory to Permissive Law	Minnesota, Mississippi, New York, Pennsylvania, and West Virginia
2009	Permissive to Mandatory Law	Oregon and Wyoming
2009	Presumed to Explicit Consent	Alabama
2009	Explicit to Presumed Consent	Illinois
2012	Explicit to Presumed Consent	Michigan
2012	Permissive to Mandatory Law	Hawaii

Note: This table is based on Survey of Pharmacy Laws between years 2006 and 2012.

4.1. Data Description

We use two sections of the MEPS data, the household component and the prescribed medicines file. The household component (HC) has a rich set of information on demographic characteristics, health conditions, health status, and use of medical services. The prescribed medicines file provides detailed information on household-reported prescribed medicines. Each record represents one household-reported prescribed medicine that was purchased in that year.

In the empirical work below, we focus on three types of drugs: statins, antidepressants, and PPIs. These drugs are used to lower the level of cholesterol, treat depression, and reduce gastric acid production, respectively. We select statins and antidepressants because heart disease and mental disorder are among the top three most costly conditions according to the MEPS data.[13] We add PPIs to the sample to examine whether the laws impact vary depending on the severity of the disease. Table 5 shows the brand name drugs, their corresponding generic drug name, and the years that the brand and generic drug became available. All nine drugs have generic counterparts between 2006 and 2012.

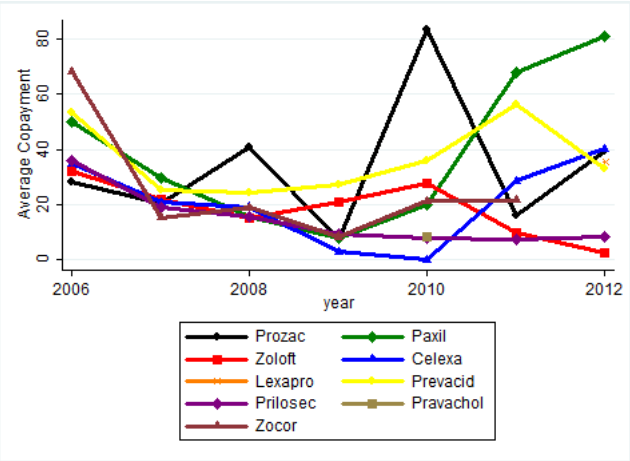
Table 6 breaks down the sample restriction process. The original sample has about two million prescription drug purchase events. The sample shrinks to about eighteen thousand if we keep only selected drugs. In the final sample, we have about sixteen thousand prescription drug purchase events between 2006 and 2012.

In the MEPS prescribed medicines file, each record contains the information about the drug name, quantity of the drug purchased, strength of the drug, copayment amount, and total cost of the drug. We use the information of the quantity and strength of the drug to create a variable indicating the number of months supplied in this purchase. Based on these variables, we obtain the copayment and total cost of purchasing one month's supply of the drug. Table 7 shows the average copayment, average total cost, and average copyament by insurance status[14] calculated from MEPS data between 2006 and 2007. Based on the

[13] MEPS Statistical brief #331

[14] The total payments are defined as the sum of payments for care received, including out-of-pocket payments and payments made by private insurance, Medicaid, Medicare, and other sources.

Figure 2: Evolution of the Average Copayment for One Month's Supply of Selected Brand Drugs



average copayment, the generic drugs are cheaper than the brand name drugs. Consumers pay approximately 13 to 50 percent of the brand drug price to get generic drugs. Not only is the copayment lower for generic drugs compared to brand name drugs, the total cost of generic drugs is also lower. The combined payments from insurance and patient for generic drugs range from 20 to 90 percent of the total costs of brand name drugs. The level of copayment varies depending on the type of insurance the patient has. Patients covered with private insurance always have the lowest out-of-pocket payment and uninsured patients pay the most. This pattern is consistent regardless of the drug purchased. In figure 2 and 3, we plot the copayment change for brand name and generic drugs over time. The copayments for brand and generic drugs declined in this period.

In figure 4, we plot the share of generic drugs within each molecule between 2006 and 2012. The share is calculated based on the months' supplied for each drug in each year. All generic drug market shares have an upward trend between 2006 and 2012, but the level of the share varies depending on the molecule. The generics of Celexa, Zoloft, Paxil, and Prozac have reached about 90 percent share at the end of the period, while other generics have less than 50 percent.

Table 8 presents the demographic information for consumers who purchased antidepressants, statins, or PPIs, grouped according to patient consent law regime. We can see that

Table 5: Drug Information by Disease Type

	Antidepressants/SSRIs				
Generic Name	Fluoxetine	Paroxetine	Citalopram	Sertraline	Escitalopram
Brand Name	Prozac	Paxil	Celexa	Zoloft	Lexapro
Year Brand Available	1989	1982	1982	1982	2002
Year Generic Available	1996	1987	2004	2006	2012
	PPIs				
Generic Name	Lansoprazole	Omeprozole			
Brand Name	Prevacid	Prilosec			
Year Brand Available	1995	1989			
Year Generic Available	2009	2008			
	Statins				
Generic Name	Pravastatin	Simvastatin			
Brand Name	Pravachol	Zocor			
Year Brand Available	1991	1991			
Year Generic Available	2006	2006			

Note : The year of drug availability is obtained from the date of FDA approval.

Table 6: Sample Restrictions of the MEPS data for Difference in Differences Analysis

Selection Criterion	Number of Observations
Original sample	2188898
Keep prescription drug purchase events for antidepressants, PPIs, and statins	181200
Keep if both generic and brand drugs are available in that year	167721
Keep if drug strength variable has valid value	167230
Drop if purchase quantity is less than one week or more than one year supply	164390

Table 7: Average Copayments and Total Payments for One Month's Supply of Selected Drugs

Drug Name	Brand/Generic	Average Copayment	Average Total Payment	Average Copayment with Private Insurance	Average Copayment with Public Insurance	Average Copayment with No Insurance
			Antidepressants			
Prozac	Brand	28.91	121.17	13.01	24.07	98.94
Fluoxetine	Generic	7.08	23.98	3.62	8.26	14.00
Paxil	Brand	30.18	68.28	17.68	36.90	40.60
Paroxetine	Generic	8.34	28.67	5.61	9.01	20.70
Zoloft	Brand	24.50	66.81	19.09	23.83	43.84
Sertraline	Generic	6.64	19.72	4.22	7.54	12.50
Celexa	Brand	18.86	48.25	13.54	17.53	44.47
Citalopram	Generic	5.57	16.37	3.25	6.32	10.93
Lexapro	Brand	29.55	89.91	12.71	36.20	61.57
Escitalopram	Generic	13.81	86.45	10.81	15.32	23.78
			PPI			
Prevacid	Brand	35.72	151.07	19.77	42.09	118.01
Lansoprazole	Generic	13.00	68.33	8.32	14.98	17.54
Prilosec	Brand	18.07	68.11	14.24	21.37	23.89
Omeprozole	Generic	8.91	33.99	5.56	10.94	22.20
			Statin			
Pravachol	Brand	37.31	117.96	25.44	34.96	103.03
Pravastatin	Generic	6.76	21.52	4.61	7.35	12.29
Zocor	Brand	43.59	108.82	41.08	43.02	72.00
Simvastatin	Generic	7.58	26.51	6.03	8.34	12.91

Note : The copay and total payment is calculated for a purchase of one month's supply of each drug with MEPS data. The public insurance includes Medicare, Medicaid, and other public health insurance programs. The time frame is between 2006 and 2012. All copayments and payments are in dollars.

Figure 3: Evolution of the Average Copayment for One Month's Supply of Selected Generic Drugs

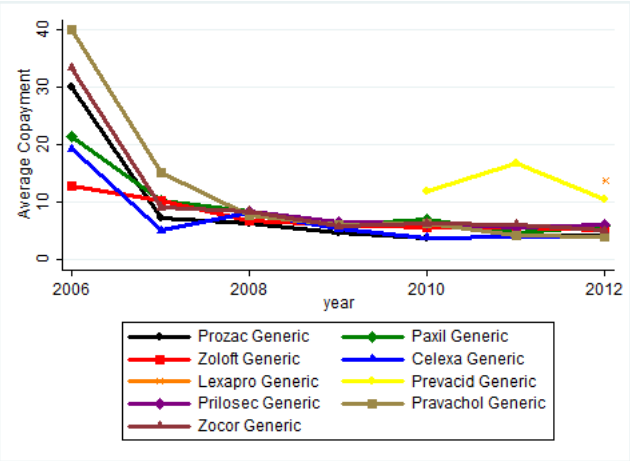


Figure 4: Generic Drug Share Evolution Between 2006 and 2012

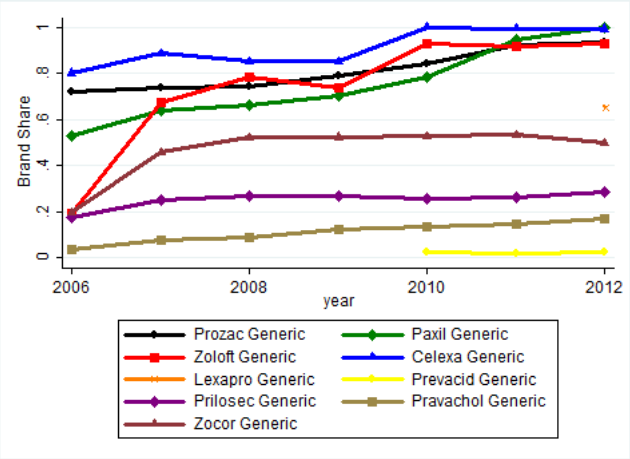


Table 8: Demographic Characteristics of Patients

	States with Explicit Consent	States with Presumed Consent
Male	0.30	0.30
White	0.86	0.84
Black	0.09	0.10
Age	50.69	50.36
Public Insurance	0.57	0.56
Private Insurance	0.37	0.36
	States with Mandatory Substitution Law	States with Permissive Substitution Law
Male	0.39	0.39
White	0.78	0.79
Black	0.15	0.15
Age	57.83	57.12
Public Insurance	0.51	0.55
Private Insurance	0.44	0.38

Note: The data reported in this table is calculated using the sample for difference in differences analysis using MEPS data.

the two types of states are almost identical in terms of the demographic factors considered. Further, we see that people who purchase these drugs are more likely to be female, white, and covered by public health insurance.

4.2. State Regulations on the Probability of Purchasing Brand Drugs

We use the difference in differences method with the MEPS data and estimate the following regression.

$$Brand_{it} = \alpha_0 + \alpha_1 * Presumed\_Consent_{jt} + \alpha_2 * Mandatory_{jt} + \beta * x_{it} + \alpha_3 * Year_t + \alpha_4 * States_j + \epsilon_{ijt} \quad (1)$$

where $Presumed\_Consent_{jt}$ is an indicator for states with a presumed consent policy, and $Mandatory_{jt}$ is an indicator for states with a mandatory substitution law. Consumer characteristics, including age, race, sex, and insurance status, are in x_{it}. State and year fixed

effects are included. The dependent variable is an indicator for whether the purchased drug is brand name or generic.

First, we estimate this equation separately on all nine drugs in the three drug categories. The estimation results are presented in Table 9. In the nine regressions estimated, the coefficients for the presumed consent law are negatively significant in seven regressions. For instance, the presumed consent law reduces the probability of purchasing Pravachol by about nine percentage points. The magnitude of this effect varies, ranging from approximately a one to nine percentage point decrease. In comparison, the coefficients for the mandatory law are almost always not significantly different from zero. The only exception is for the drug Zocor.

Then we run equation 1 with all nine drugs, and include interactions with the disease type and the number of years the generic drug has been available. The results are presented in Table 10. In column 1 of Table 10, α_1 is -0.041. This suggests that the presumed consent law reduces the probability of purchasing a brand drug by 4.1 percentage points on average. Consistent with findings in Table 10, the coefficient for the mandatory law is not significant. This result is robust to clustered standard errors at the state level and block bootstrap procedures suggested by Bertrand et al. (2002). In the second column, we report the results for equation 1 with interactions between law types with the disease type, and how many years the generic drug has been available. The results indicate that the presumed consent law has larger impacts for antidepressants and PPIs than for statins.

4.3. Discussions and Robustness Checks

4.3.1. Interpretation of the Regression Results

At first glance, the regression results might seem counterintuitive. It is surprising that the policy mandating substitution does not increase the sale of generic drugs more than the permissive law. In order to understand this result, we need to explain the pharmacists' incentives. Most insurance payments to pharmacies for prescription drugs are based on a benchmark price called the average wholesale price (AWP). The AWP is reported by generic producers themselves, and until recently has been subject to essentially no independent

Table 9: The Effect of State Regulations on Generic Drug Substitution by Drug

	Antidepressants/SSRIs				
	Prozac	Paxil	Zoloft	Celexa	Lexapro
Presumed Consent	-0.095***	-0.044**	0.052**	-0.038**	-0.026**
	(0.024)	(0.017)	(0.021)	(0.016)	(0.011)
Mandatory	0.127	-0.043	0.036	-0.008	-0.018
	(0.118)	(0.036)	(0.039)	(0.037)	(0.017)
Number of Observations	13782	10109	17574	13951	13288
R Square	0.14	0.22	0.33	0.20	0.30
	PPIs				
	Prevacid	Prilosec			
Presumed Consent	-0.049**	-0.036**			
	(0.022)	(0.015)			
Mandatory	0.013	0.048			
	(0.030)	(0.064)			
Number of Observations	9577	30360			
R Square	0.61	0.13			
	Statins				
	Pravachol	Zocor			
Presumed Consent	-0.088***	-0.006			
	(0.017)	(0.008)			
Mandatory	0.059	0.035**			
	(0.057)	(0.013)			
Number of Observations	14451	55711			
R Square	0.17	0.31			

Note: All regressions include state and year fixed effects. Control variables include patients' race, sex, age, and insurance status. Clustered standard errors are shown in parentheses. *p $<$ 0.1, ** p $<$ 0.05, *** p $<$ 0.01.

Table 10: Difference in Differences Regression Results

Independent Variables	Baseline	Interact Law with Drug Variables	Falsification Test
Presumed Consent	-0.041***	-0.006	0.059
	(0.007)	(0.007)	(0.049)
Mandatory	0.006	0.004	0.096
	(0.005)	(0.005)	(0.095)
Antidepressant		0.055***	
		(0.002)	
PPI		0.204***	
		(0.003)	
Antidepressant*Presumed Consent		-0.013***	
		(0.005)	
PPI*Presumed Consent		-0.037***	
		(0.006)	
Generic Available Years*Presumed Consent		-0.002***	
		(0.000)	
Antidepressant*Mandatory		-0.002	
		(0.004)	
PPI*Mandatory		-0.004	
		(0.005)	
Generic Available Years*Mandatory		-0.000	
		(0.000)	
Number of Observations	162192	162192	5630
R Square	0.20	0.24	

Note : State and year fixed effects are included. Other control variables include age, sex, race, wage in thousands, and insurance status. The omitted group is statins. Standard errors are clustered at state level, and are shown below the coefficient cells. *p < 0.1, ** p < 0.05, *** p < 0.01

verification. As a result, generic producers have an incentive to compete for pharmacy market share by reporting AWPs that exceed actual average wholesale prices. This "spread" leads to larger pharmacy profits and make pharmacies more likely to store their products. In general, gross profit dollars are approximately 50 percent higher for generic drugs than for branded drugs.[15] As a result, even under a permissive, rather than mandatory law, pharmacists already have high incentives to substitute generics for brand name drugs. This is why mandatory substitution laws do not outperform permissive laws in increasing generic drug substitution. A natural follow up question is why pharmacists enjoy a much higher markup for generics compared to brand drugs. The reason is that pharmacists have a much higher bargaining power with generic drug producing firms than the brand name firms. Pharmacists can choose among the same generic drug produced by several firms to store in their pharmacies. However, they can only buy the branded drugs from the single firm who has the patent. This power of choosing with generics leads to a higher markup in generics for pharmacists.

In comparison, the presumed consent law is effective in pushing consumers to buy more generic drugs. This result is surprising given that the literature has documented the difficulty of changing consumers' preference for branded products. We will devote Section 5 to understanding the channels of the presumed consent law's effect.

4.3.2. Endogeneity of the US Generic Drug Substitution Policy Changes

Our estimations about the impacts of the generic drug substitution policies rely on the changes in these laws between 2006 and 2012. As Besley and Case (1994) pointed out, if state policy making is purposeful action, responsive to economic and political conditions within the state, then it may be necessary to identify and control for the forces that lead policies to change if one wishes to obtain unbiased estimates of a policy's effects. This rules applies to our estimates of the generic drug substitution policy effects. The difference in differences estimator is not a panacea for the endogeneity problem. To alleviate concerns of

[15] http://www.forbes.com/sites/greatspeculations/2013/08/07/cvs-strengthens-margins-by-selling-more-generic-drugs/

endogeneity issues, we discuss what might drive states to change the regulation on generic drug substitution.

Due to the scarcity of media discussions of the state policies analyzed in this paper, we look at media discussion of another type of generic drug substitution, substitution between biologics and biosimilars. There are several reasons why the discussion of laws regulating the substitution of biologics and biosimilars are more prevalent in the media. First, the market for biologics and biosimilars are burgeoning. Second, the regulation of biosimilars is still in the very nascent stages. [16]Many of the proposed policies tools are similar to the ones currently used to regulate generic drug substitution. As a result, we will discuss examples of policy changes regulating the substitution of biosimilars for biologics to help understand what might cause generic drug substitution policies to change.

Most of the media discussions about these policy changes show strong presence of lobbying from pharmaceutical firms. For instance, in 2013, the Virginia House of Delegates passed a bill restricting the ability of pharmacists to substitute generic versions of biological drugs for brand name products.[17] The Republican delegate who introduced the bill admitted that Amgen[18] reached out to him beforehand. Another example reveals the same pattern. In North Dakota, a similar bill cleared a committee in the State Senate. The state senator who introduced the bill said that Genentech[19] had brought the bill to him.

From these examples, we can identify a common source of the changes in generic drug substitution policies. Pharmaceutical companies producing brand name drugs often lobby for laws favoring less generic substitution. In comparison, generic drug companies, insurance firms, managed health care companies, and chain pharmacy stores lobby for polices that encourage generic substitution. Though these examples are related to policies regulating

[16]Most biological products are more complex in structure and have larger molecules or mixtures of molecules than conventional drugs (also called small molecule drugs). Conventional drugs are made of pure chemical substances and their structures can be identified. Most biologics, however, are complex mixtures that are more difficult to identify or characterize. Biosimilars are highly similar to the reference product they were compared to, but have allowable differences because they are made from living organisms. (Source: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicAppli

[17]http://www.nytimes.com/2013/01/29/business/battle-in-states-on-generic-copies-of-biotech-drugs.html?_r=0

[18]Amgen is an American multinational biopharmaceutical company headquartered in Thousand Oaks, California.

[19]Genentech Inc., is a biotechnology corporation which became a subsidiary of Roche in 2009.

substitution between biologics and biosimilars, there is no reason to believe that the reasoning would be different for policies regulating generic substitution. The lobbying power of brand name drug firms, generic firms, insurance companies, and other related parties shape how states regulate generic drug substitution.

The important implication for our empirical work is that pharmaceutical firms might also lobby to change other policies that would influence the rate of generic substitution. For example, they might lobby to change how physicians could forbid generic drug substitution, or the way states regulate the drug formulary. Accordingly, we will examine these two policy tools, and whether states changed them between 2006 and 2012.

States vary in how physicians can prevent generic drug substitution. Some states require physician signature on appropriate line of the two line prescription. Others allow use of a "Do not substitute" checkbox. And some states require handwritten "Dispense as written" on the prescription. We checked the Survey of Pharmacy Laws between 2006 and 2012, and found that three states changed this policy. In 2009, Illinois changed from "prescriber must indicate: Dispense as Written in the designated box" to "prescriber must indicate may not substitute in the designated box." Oregon changed from requiring the prescriber to write in own handwriting "Brand Necessary," to the phrase "no substitution" or the notation "N.S." in the practitioner's handwriting or by telephone communication. The last change is by Montana in 2012, which changed the requirement from writing "Brand Necessary" to "Brandname medically necessary."

These changes in state regulations of prescriber control of generic drug substitution should not affect our estimation results, for two reasons. First, these semantic changes are minor, and do not substantially change the way physicians can prevent generic substitution. The effort to write "Dispense as written" is similar for to writing "May not substitute" on the face of a prescription. A switch from handwritten messages to checking a box may have more plausibly affected behavior, but this was not the case. Second, Shrank et al. (2011) documents that physicians request "dispense as written" in only five percent of all prescriptions. Combining the two points, we think the regression estimates should be unbiased by

confounding changes in how prescribers are regulated to prevent generic drug substitution.

Pharmaceutical firms might also lobby to change a state's formulary regulations. There are "positive formulary" states, which identify generics that can be substituted, and there are "negative formulary" states, which list drugs that cannot be substituted. There are also states that do not refer to "Orange Book" standards, have neither a positive nor a negative formulary, and allow pharmacists substitute generics as long as the drugs are pharmaceutically equivalent. In our sample period, two states changed their formulary regulations. In 2009, Delaware changed from a positive formulary to none. And in 2012, Missouri changed from a negative formulary to none. Since all the drugs of this study are in the positive formulary in Delaware, and not in the negative formulary in Missouri, our estimation results should not be affected by these changes.

Another concern about the endogeneity issue is that pharmaceutical companies might adjust their advertising budget in response to the changes in state generic drug substitution laws. However, it is well documented in the literature that prescription drugs without patent protection are rarely advertised by their manufacturers (Sinkinson and Starc (2015)) . This is in contrast to over-the-counter medications, which are often advertised even through an exact molecular substitute is available. Since all our brand name drugs have generic alternatives, we do not think firms' responses in advertising expenditure would bias our estimation results.

4.3.3. Supply Side Pricing Responses to State Regulations of Generic Drugs

If state regulations on generic drug substitution influence consumers' choice of prescription drugs, pharmaceutical firms are likely to adjust their pricing strategies to adapt to different competition environments induced by these regulations. We examine firms' pricing responses by looking at how the copayment and total payment are influenced by the state regulations. We estimate equation 1 with copayment and total payment as dependent variables. The regression results are presented in Table 11.

From this table, we can see that pharmaceutical pricing strategies do not respond to the state law regulations. However, these results should be interpreted with care. Rebates from pharmaceutical firms to insurance and health management companies are known to be an

Table 11: Pharmaceutical Firms' Pricing Response to the State Generic Drug Substitutions

	Copayment	Total Payment
Mandatory	0.251	-0.662
	(0.938)	(1.875)
Presumed Consent	-0.459	1.864
	(0.769)	(1.437)
Brand	15.313***	54.459***
	(1.189)	(2.214)
Brand * Presumed Consent	0.131	-6.250
	(1.895)	(7.899)
Brand * Mandatory	-2.295	4.601
	(1.396)	(7.264)
Number of Observations	162192	162192
R Square	0.174	0.164

Note : The copayment and total payment are for one month's supply of each drug. State and year fixed effects are included. Standard errors are clustered at state level, and are shown below the coefficients. *p < 0.1, ** p < 0.05, *** p < 0.01

important part of prescription drug prices. Since we have no information on the rebates, we can not rule out the possibility that pharmaceutical firms respond to state generic drug substitution laws by changing prescription drug prices.

4.3.4. Falsification Test of the Effect of Prescription Drug Substitution Policies on OTC Drugs

To check the robustness of our results, we implement a falsification test. The test is based on the intuition that these laws apply only to prescription drug purchases. As a result, a consumer's decision to buy brand name or generic OTC drugs should not be affected. We estimate equation 1 with three OTC drugs: Claritin, Zantac, and Zyrtec.[20] The regression results are presented in column 3 of Table 10. The coefficients for both mandatory and presumed consent law are not significantly different from zero.

[20]Claritin, Zantac, and Zyrtec are OTC drugs used to treat allergies, heartburn, and allergies, respectively. To make sure that these drugs are indeed purchased over the counter, we restrict the sample to purchases for the standard OTC dosage, and for which the patient paid 100 percent of the cost of the drug. We considered over 50 types of OTC drugs in ten drug categories. Only the three drugs discussed above have a meaningful number of observations in the MEPS data.

5. A Behavioral Model of the Presumed Consent Law

5.1. Consumer's Discrete Choice Model of Prescription Drugs

Reduced form estimations do not tell us why presumed consent law works and cannot provide counterfactual experiments. To answer these questions, we build a discrete choice model of prescription drug choice. The model is specified below.

We index our specifications by individual (i), product (j), and market (m). The price of a product varies over individuals and markets. The product price we observe in the data is denoted p_{imj}. Other product attributes do not vary over markets. Their interactions with consumer characteristics are denoted as x_{ij}. Some attributes of the products are not observable in the data. The utility of consumer i living in market m from product j is decomposed into observable and unobservable parts:

$$u_{ij} = V(p_{imj}, x_{ij}) + e_{ij} \tag{2}$$

where x_{ij} include product characteristics, and product characteristics interacted with observed individual characteristics. e_{ij} is defined as the difference that makes the equation an identity.

Our specification for $V(.)$ and e_{ij} is given as:

$$U_{ij} = \alpha_0 p_{imj} + \beta x_{ij} + \alpha_1 * Brand_j * Presumed\_Consent_{im} + \epsilon_{ij} \tag{3}$$

There are several elements in this equation worth mentioning. First, the key element of the model is the term $\alpha_1 * Brand_j * Presumed\_Consent_{im}$. It is an extra cost item for consumers who would like to buy a brand name drug in a state with presumed patient consent. The modeling decision is motivated by the intuition that a policy that mandates generic drug substitution can be modeled as a positive infinite cost for patients buying a brand name drug. In this case, a consumer would always choose a generic drug when facing the infinite cost to buy a brand. Similarly a policy with no pharmacist intervention can be modeled as no additional costs for a consumer to buy a brand name drug. The goal of the

model is to identify the cost difference between the presumed and explicit consent policies when buying a brand name drug separately from consumer preferences.

This approach to identify the cost induced by presumed consent is in the spirit of Handel (2013)'s method to document inertia in employer-provided health insurance. The challenge in his work is to separately identify inertia from persistent unobserved preference heterogeneity. He identifies the inertia by observing each family in the sample making both an "active" and a "passive" choice from the same set of health plans over time. Similarly, we observe consumers making decisions under presumed and explicit consent regulations. This allows us to separately identify the cost parameter from unobserved preferences.

Another important issue, as noted by Villas-Boas and Winer (1999) and Petrin and Train (2010), is that not accounting for endogeneity may result in a substantial bias in the parameter estimates of random utility models. In our model, the price p_{imj} variable is endogenous. The econometric problem arises because ϵ_{ij} is not independent of p_{imj}, as maintained by standard estimation techniques. We use the control function approach to deal with the endogeneity problem. The idea behind the control function approach is to derive a proxy variable, which conditions on the portion of p_{imj} that depends on ϵ_{ij}. If this can be done, then the remaining variation in the endogenous variable will be independent of the error term and standard estimation techniques will be consistent. In our context, p_{imj} can be written as a function of all exogenous variables x_{ij}, variables z_{mj} that do not enter consumer's utility function but do impact p_{imj}, and a vector of unobserved terms μ_{mj}. The key to the control function approach is to note that, conditional on μ_{mj}, p_{imj} is independent of ϵ_{ij}.

$$p_{imj} = W(x_{ij}, z_{mj}, \mu_{mj}) \tag{4}$$

Decomposing ϵ_{mj} into the portion that can be explained by a general function of μ_{mj} and the residual yields:

$$\epsilon_{mj} = CF(\mu_{mj}; \lambda) + \widehat{\epsilon_{mj}}$$

where $CF(\mu_{mj}; \lambda)$ is the control function with parameters λ. The simplest choice of the

control function would be a linear function in μ_{mj}. In this case, the utility function is given as

$$U_{ij} = V(p_{imj}, x_{ij}) + \lambda\mu_{mj} + \widehat{\epsilon_{mj}}$$

With this specification, the probability consumer i chooses product j is equal to

$$P_{ij} = \int I(U_{ij} > U_{il} \forall j \neq l) f(\beta_i, \widehat{\epsilon_{mj}}) d\beta_i d\widehat{\epsilon_{mj}} \tag{5}$$

In order to complete the specification, we make a distributional assumption for $f(.)$. We use normal and logit for the distributional assumption for β and $\widehat{\epsilon}$.

The expression of the likelihood for the model is

$$L(\beta, \alpha) = \Pi_{i=1}^{I} \Pi_j (P_{ij})^{y_{ij}} \tag{6}$$

where $y_{ij} = 1$ if person i chooses j, and zero otherwise.

The log-likelihood function is then

$$LL(\beta, \alpha) = \sum_{i=1}^{I} \sum_j y_{ij} ln(P_{ij}) \tag{7}$$

The specification is easily generalized to allow for repeated choices by each sampled decision maker. The simplest specification treats the coefficients that enter utility as varying over people but being constant over choice situations for each person. Utility from alternative j in choice situation t by person i is $U_{ijt} = \beta_i X_{ijt} + \epsilon_{ijt}$, with ϵ_{ijt} being IID extreme value over time, people, and alternatives. Consider a sequence of alternatives, one for each time period, $I = \{i_1, ..., i_T\}$. Conditional on β the probability that the person makes this sequence of choices is the product of logit formulas:

$$P_I(\beta) = \Pi[\frac{e^{\beta x_{itj}}}{\Sigma e^{\beta x_{itk}}}]$$

The unconditional probability is the integral of this product over all values of β:

$$P_I = \int P_I(\beta) f(\beta) d\beta$$

The only difference between mixed logit with repeated choices and with only one choice per decision maker is that the integrand involves a product of logit formulas, one for each time period, rather than just one logit formula. The probability is simulated similarly to the probability with one choice period. A draw of β is taken from its distribution. The logit formula is calculated for each period, and the product of these logits is taken. This process is repeated for many draws, and the results are averaged. In the estimation section below, we show results with and without considering the panel feature of the data.

5.2. Model Estimation

5.2.1. Sample Construction

The estimation of the logit model uses a different sample constructed from the MEPS dataset. There are several reasons for this. First, the multinomial logit model requires price information for all possible product choices of consumers. However, in the dataset, we only observe what the consumer pays out-of-pocket for their consumption choice. Therefore, we need to impute the price they would have paid out-of-pocket for all other products. We use the average price paid by the consumer in the same state, year, and insurance status as the imputed price. Second, the multinomial model requires that consumer chooses the product with the highest utility. However, we observe the same individuals making multiple purchases of different classes of drugs in each interview round. Therefore, we keep only one purchase event, from the highest quantity purchased. The sample restrictions and resulted sample size are reported in Table 12. There are 19135 prescription drug choice scenarios in the final sample.

5.2.2. Consumer Choice Model Estimation Results

The model is estimated in two steps. First, the endogenous variable is regressed on observed choice characteristics and the instruments. The regression residuals are used to

Table 12: Sample Selection of the Prescribed Medicine Events for Logit Model Estimation

Selection Criterion	Number of Observations
Original sample	2208624
Keep the ten antidepressants discussed in Table 5	70368
Keep purchase events for treatment of major depression	56867
Keep purchase events with valid quantity and strength information	56587
Drop multiple purchase events for the same drug in the same interview round	19575
Keep purchase events in the same interview round with the highest quantity	19135

calculate the control function. Second, the choice model is estimated with the control function entering as extra variables.

We use a measure of competition in the market to instrument for price endogeneity. The measure is the number of firms producing the drug in each market. The number of firms producing the same drug would intensify competition and result in price decrease. The MEPS prescribed medicine file reports the NDC code for each purchase[21]. We use the first five digits to infer which company produces that drug. The first stage regression result is shown below. We can see that increasing the number of firms producing a drug in one market would result in the level of copayment in that market decreasing by 1.55 dollars. This number is significant at a one percent level. For robustness checks, we tried the average price of the product in other markets as an instrument, as suggested by Petrin and Train (2010). The exclusion restriction requires that the price of the same product in other markets should not be influenced by the demand side factors in this market. But it should be correlated to the product's price in this market due to common costs of manufacturing. The regression results are presented in the second column of Table 13. The coefficient for the number of firms producing each drug in each market is no longer significant. But the coefficient for the average price in all other markets is 0.98 and highly significant. The estimation results for the choice model shown below are estimated using the number of firms producing each drug

[21]Drug products are identified and reported using a unique, three-segment number, called the National Drug Code (NDC), which serves as a universal product identifier for drugs. Source: http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm.

Table 13: Instrument Regression Results

	Level of Copayment	
The Number of Firms Producing Each Drug in Each Market	-1.55***	0.0588
	(0.0468)	(0.0679)
Average Price in All Other Markets		0.9883***
		(0.0308)
Number of Observations	19152	19152
R Square	0.0541	0.1021

Note: Standard errors are clustered at state level, and are shown below the coefficients. *p < 0.1, ** p < 0.05, *** p < 0.01

in each market as an instrument. The other instruments yield similar results.

The consumer choice model estimation results are presented in Table 14. Columns 1 and 2 give the estimation results with and without instrumenting the endogenous variable. When price is not instrumented, the coefficient for price is positive, which suggests an unreasonable upward sloping demand curve. After instrumenting, the price coefficient changes to a more reasonable estimate, -0.05. This result emphasizes the importance of instrumenting for price when estimating a demand model. The coefficient for brand is 2.01, confirming the large brand premium found in many other works. The estimation results in column 2 also suggest that older and male customers are less likely to buy brand name drugs. The coefficient for the interaction between brand name drug and presumed consent is -0.18. The ratio of this interaction coefficient and the price coefficient indicates that the effect of the presumed consent law on consumer choice of these antidepressants is equivalent to a 3.5 dollar increase in the price of brand name drugs.

In column 3 of Table 14, we allow for repeated choices by each sampled decision maker using otherwise the same specification in column 2. The first thing to notice is that there is an improvement in the model fit, measured by the log-likelihood. The log-likelihood increased from -35808 in column 2 to 33618 in column 3. Second, the standard deviations for the random coefficient of price and brand dummies become highly significant. This suggest that allowing repeated purchases for the same decision maker helps identify the random variation

in consumer preferences. The ratio of the interaction coefficient and the price coefficient increases to about ten.

In column 4 of Table 14, we use a more flexible preference structure while continuing to allow repeated purchases by the same decision maker. We allow consumers to have heterogeneous preferences in each active ingredient. We use this specification because consumers have correlated preference for drugs with the same active ingredient. For instance, when the generic version of Lexapro became available in 2012, it was more likely to draw consumers who previously purchased Lexapro than those who purchased other antidepressants. The flexible preference structure allows us to reproduce these more realistic substitution patterns. The estimation results reveal several interesting points. First, the log-likelihood increased significantly, from -33618 in column 3 to -19685 in column 4. Second, the alternative specific constants are highly significant and the standard deviations for these variables are also significant. This indicates that consumers have different preferences for these antidepressants and there are significant differences in how consumers value these products. Third, the ratio of the coefficient for the interaction between brand and presumed consent is around three, smaller compared to our estimates in column 2 and 3. For these reasons, we choose this specification as our preferred specification. Our discussions below regarding model fit, counterfactuals, and welfare evaluations are based on results estimated with this specification.

Table 14: Consumer Choice Model Estimation Results

Independent Variable	Without Price Correction	Control Function Approach to Instrument Price	Repeated Purchases	Preference Heterogeneity for Each Active Ingredient and Repeated Purchases
Years Available	0.0488***	0.033***	0.00579	0.2750***

Table 14: Consumer Choice Model Estimation Results

Independent Variable	Without Price Correction	Control Function Approach to Instrument Price	Repeated Purchases	Preference Heterogeneity for Each Active Ingredient and Repeated Purchases
	(0.0037)	(0.0039)	(0.0043)	(0.0118)
Brand * Years Available	-0.1628***	-0.1478***	-0.1213***	-.2425***
	(0.0041)	(0.0043)	(0.0049)	(0.0083)
Brand * Age	-0.0078***	-0.0079***	-0.02510***	-0.0099***
	(0.0009)	(0.0009)	(0.0042)	(0.0009)
Brand * Male	-0.1435***	-0.1412***	-0.5165***	-0.243***
	(0.0350)	(0.035)	(0.1737)	(0.0387)
Brand * White	0.0243	0.0311	0.2594	0.0249
	(0.0762)	(0.0765)	(0.4077)	(0.0847)
Brand * Black	-0.1804	-0.1927	-0.4314	-0.2260
	(0.0916)	(0.0920)	(0.4571)	(0.1013)
Brand * Presumed Consent	-0.1807***	-0.1827***	-0.6890***	-0.1381***
	(0.0436)	(0.0439)	(0.2006)	(0.0483)
Average Price	0.0016***	-0.0541***	-0.0665***	-0.0461***
	(0.0003)	(0.0013)	(0.0020)	(0.0032)

Table 14: Consumer Choice Model Estimation Results

Independent Variable	Without Price Correction	Control Function Approach to Instrument Price	Repeated Purchases	Preference Heterogeneity for Each Active Ingredient and Repeated Purchases
Brand Name	1.2508***	2.011***	0.6162	0.4498***
	(0.0993)	(0.1018)	(0.4914)	(0.1481)
Prozac				-31.06***
				(7.04)
Paxil				-6.7820***
				(1.4491)
Zoloft				-2.9010***
				(0.445)
Celexa				-1.9245***
				(0.0751)
SD				
Price Average	0.00002	0.00004	.0330***	0.0019
	(0.00069)	(0.0025)	(0.0017)	(0.0019)
Brand Name	0.0030	0.0033	5.1415***	0.0081
	(0.0632)	(0.0674)	(0.1760)	(0.0865)
Prozac				37.8608***

Table 14: Consumer Choice Model Estimation Results

Independent Variable	Without Price Correction	Control Function Approach to Instrument Price	Repeated Purchases	Preference Heterogeneity for Each Active Ingredient and Repeated Purchases
				(8.9511)
Paxil				6.9039***
				(1.7671)
Zoloft				5.6702***
				(1.2140)
Celexa				0.0571
				(0.1478)
Number of Observations	19002	19002	19002	19002
Log-likelihood	-35895	-35808	-33618	-19685

Note : Standard errors are clustered at state level, and are shown below the coefficient. *p < 0.1, ** p < 0.05, *** p < 0.01. In column 1, the model is estimated without instrumenting for price and without allowance for repeated purchases by the same decision maker. In column 2, the specification uses instruments for price, without allowance for repeated purchases by the same decision maker. Both specifications in column 3 and 4 instrument the price and allow repeated purchases by the same decision maker.

5.2.3. Model Fit

We examine how well the model fits the data by comparing the predicted shares for all

Figure 5: Predicted and Actual Shares for Antidepressants

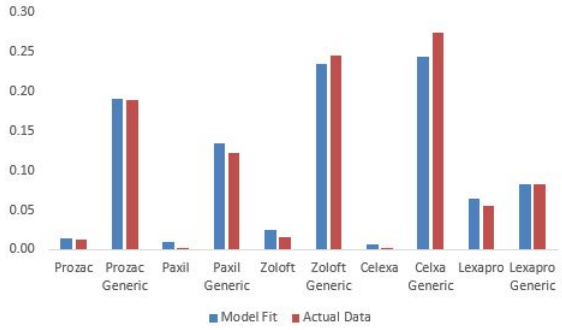
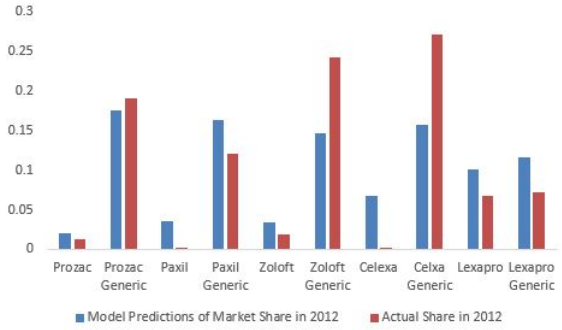


Figure 6: Out-of-Sample Prediction and Actual Shares for Antidepressants



drugs to the actual shares. Figure 5 plots the shares in 2012 predicted by the model and the actual shares in that year. We can see that the model does well in fitting the shares. To further test the model's prediction power, we estimate the model on data between 2006 and 2011 and use the estimates to predict the shares in 2012. Figure 6 compares the out-of-sample predictions to the actual data in 2012. The out-of-sample predictions track the data reasonably well. Another way to measure the effect of the consent laws on consumer choice of prescription drugs is to compare the prediction errors of the model when estimated with and without the consent law variable. Therefore, we estimate the model separately with and without the consent law variable and obtain the predicted share for all drugs. We find that the model estimated with the consent law variable reduces the aggregate absolute prediction error by two percentage points.

5.3. Discussion

5.3.1. Mechanisms of the Model

In the consumer choice model above, the presumed consent law is modeled as an extra

cost to buy brand name drugs. This captures the presumed consent law's impact in a parsimonious way. There could be several behavioral channels underlying this cost parameter. The first possibility is switching costs. The switching costs refer to the effort of the process of asking the pharmacists to switch back to brand drugs.

The second possible channel stems from consumer's inattention. Under presumed consent law, the switching to generic drug is indicated on the label of the prescribed drugs. If consumers did not pay attention, they may not notice the switch. It has been well documented that limited attention affects consumer decisions under various scenarios. DellaVigna and Pollet (2009) compare the response to earnings announcements on Friday, when investor inattention is more likely, to the response on other weekdays. They find that Friday announcements have a 15 percent lower immediate response and a 70 percent higher delayed response. Chetty et al. (2007)show that consumers under-react to taxes that are not salient. They use a field experiment in a grocery store and find that posting tax-inclusive price tags reduces demand by eight percent. And they show that increases in taxes included in posted prices reduce alcohol consumption more than increases in taxes applied at the register.

Other possible sources of the presumed consent law's impact include dynamic preference inconsistency. For instance, a consumer might notice the switch but decide to go to the pharmacist the next day to ask for a brand. The time inconsistency could lead consumers to never make the change. The extra cost parameter in the choice model is meant to capture the aggregate impact of these channels. The data does not allow us to separately identify these models.

5.3.2. Product Substitution Patterns

It's critical that the estimated choice model predicts reasonable product substitution patterns. The percentage change in the probability of choosing alternative j given a percentage change in the price of another alternative k is:

$$E_{ijk} = -\frac{price_k}{P_{ij}} \int \beta_{price} P_{ij}(\beta) P_{ik}(\beta) f(\beta) d\beta$$

Table 15: Substitution Elasticity For Selected Antidepressants

	Prozac	Prozac Generic	Paxil	Paxil Generic	Zoloft	Zoloft Generic	Celexa	Celexa Generic	Lexapro	Lexapro Generic
Prozac	-0.011925	0.003149	0.000105	0.000023	0.000215	0.000014	0.000083	0.000042	0.000617	0.000001
Prozac Generic	0.001526	-0.000903	0.000021	0.000052	0.000069	0.000056	0.000014	0.000081	0.000348	0.000012
Paxil	0.000213	0.000075	-0.009037	0.002353	0.000294	0.000021	0.000102	0.000071	0.001011	0.000000
Paxil Generic	0.000029	0.000091	0.001370	-0.001066	0.000076	0.000075	0.000018	0.000119	0.000577	0.000023
Zoloft	0.000137	0.000082	0.000090	0.000043	-0.004484	0.001185	0.000065	0.000075	0.000692	0.000002
Zoloft Generic	0.000015	0.000077	0.000011	0.000061	0.001940	-0.001026	0.000008	0.000098	0.000382	0.000020
Celexa	0.000202	0.000096	0.000170	0.000046	0.000326	0.000028	-0.005988	0.002131	0.001909	0.000002
Celexa Generic	0.000042	0.000113	0.000035	0.000094	0.000102	0.000096	0.000518	-0.000894	0.001034	0.000040
Lexapro	0.000176	0.000156	0.000156	0.000127	0.000322	0.000098	0.000166	0.000305	-0.003478	0.000085
Lexapro Generic	0.000009	0.000078	0.000005	0.000124	0.000003	0.000137	0.000016	0.000221	0.003809	-0.002611

Note: In each column, we report the percentage change of market share for all drugs responding to a one percent increase in the price of the drug indicated in the column header.

We report the substitution pattern in Table 15. There are two items worth noting. First, the magnitude of the price elasticity is smaller compared to recent estimates found in the literature. For instance, Simonsen et al. (2015) report the price elasticities for prescription drugs in Denmark ranging from -0.09 to -0.25. We think this is caused by the model specification. We are calculating the price elasticity conditional on purchase. Adding an outside option of not purchasing results in higher estimates of the price elasticities. Second, the model exhibits significant within molecule substitution. When the price of a brand name drug increases by one percent, the majority of the consumers who switch choose to buy the generic drug of the same molecule.

5.3.3. Average Marginal Effects of the Presumed Consent Law

Since the model above is non-linear, we cannot directly interpret the impact of the presumed consent law based on the sign and magnitude of the coefficients reported above. To

Table 16: Average Marginal Effect of Change in Consent Law

Drug Type	Predicted Probability of Purchase under Explicit Patient Consent	Predicted Probability of Purchase under Presumed Patient Consent	Percent Change from Explicit to Presumed Consent
Prozac	0.0207	0.0233	-11.02
Fluoxetine	0.1846	0.1818	1.55
Paxil	0.0260	0.0286	-9.32
Paroxetine	0.1215	0.1182	2.76
Zoloft	0.0863	0.0930	-7.28
Sertraline	0.1769	0.1696	4.33
Celexa	0.0245	0.0260	-5.84
Citalopram	0.1878	0.1774	5.85
Lexapro	0.1746	0.1863	-6.30
Escitalopram	0.0794	0.0772	2.84

Note: The predicted probabilities of purchasing drugs are calculated based on the mixed logit model specified in column 4 of Table 14.

ease interpretation, we calculate the average marginal effects of all states switching from an explicit to presumed patient consent law. The results are presented in Table 16. We see that on average, switching to presumed consent reduces the average probability of purchasing the brand name version of a drug by approximately six to eleven percent.

5.3.4. Welfare Evaluations

From a policy maker's perspective, we would like to know the welfare implications of the presumed consent law, in addition to understanding the impact of the policy. There are two parties involved in the welfare calculation, insurance companies and patients. It is clear that insurance companies gain from the presumed consent policy. From column 4 in Table 7, the average insurance payment differs by 41 dollars between a brand and generic antidepressant. Therefore after implementing the presumed consent policy, insurance companies gain by paying less for drugs. Based on the predicted share of drugs in explicit and presumed consent scenarios in Table 16 and the difference in insurance payments between a brand and generic drug, we calculate that the insurance companies pay 0.9 dollars less per person on average.

On the other hand, consumer welfare would decrease because of the extra cost term for buying a brand name drug. Under the logit assumptions, the consumer surplus associated with a set of alternatives takes a closed form that is easy to calculate. By definition, a person's consumer surplus is the utility, in dollar terms, that the person receives in the choice situation. The decision maker chooses the alternative that provides the greatest utility. Consumer surplus is therefore $CS_i = (1/\alpha_0)Max_j(U_{ij})$, where α_0 is the marginal utility of income. The division by α_0 translates utility into dollars. We do not observe U_{ij}. But we observe V_{ij}, and know the distribution of the remaining portion of the utility. Therefore, we can calculate the expected consumer surplus.

$$E(CS_i) = \frac{1}{\alpha_0} E(max_j(V_{ij} + \epsilon_{ij}))$$

Rosen and Small (1979) show that, if each ϵ_{ij} is IID extreme value and utility is linear in income, this expectation becomes:

$$E(CS_i) = \frac{1}{\alpha_0} ln(\sum_{j=1}^{J} e^{V_{ij}}) + C \tag{8}$$

where C is an unknown constant that represents the fact that absolute level of utility can not be measured.[22] The change in consumer surplus that results from a change in the consent law can be calculated from equation 6. In particular, $E(CS_i)$ is calculated twice: first under the conditions before the change, and again under the conditions after the change. The difference between the two results is the change in consumer surplus:

$$\triangle E(CS_i) = \frac{1}{\alpha_0} (ln(\sum_{j=1}^{J} e^{V_{ij}^1} - ln(\sum_{j=1}^{J} e^{V_{ij}^0})) \tag{9}$$

where the superscripts 0 and 1 refer to before and after the change. Since the unknown constant C enters expected consumer surplus both before and after the change, it drops out of the difference and can therefore be ignored when calculating changes in consumer surplus.

[22]We show how to derive equation 6 in the appendix.

Using equation 7, we find that the average consumer loss is about 9.17 dollars.

Combined with the welfare gain for insurance companies, this model suggests that switching from presumed consent to explicit consent would incur 7.48 dollars loss per person per prescription. Some words of caution are necessary. First, this calculation does not consider the supply side response and does not calculate the welfare change for drug suppliers. It is not clear how the suppliers would react and their welfare would change. As a result, the welfare discussion can only be a partial statement. Second, the welfare calculation considers the psychological costs of switching away from default as a real cost. If we ignore this cost and only consider the utility difference of choosing brand and generic drugs, the welfare loss for consumers would be smaller.

6. Conclusions

Prescription drug spending in the US ballooned in 2014 to nearly $374 billion.[23] The ability to promote generic drug use for multi-source drugs will be key to controlling the growth of spending on prescription drugs. State governments and insurance companies have come up with various ways of incentivizing patients to buy generic drugs whenever possible. These strategies include mandatory switching laws for pharmacists, presumed patient consent laws, and tiered pricing in health insurance plans. Consumer's price elasticity for prescription drugs has been widely studied, but there are limited studies of the effects of the state laws on pharmacists' tendencies to switch to generic drugs.

This paper tries to fill that gap in the literature. We use changes in state laws to identify their impacts on generic drug use. We find that the mandatory substitution law has little effect, and the effect of presumed patient law on a patient's decision to buy prescription drugs is equivalent to a 3 dollar increase in the brand name drug price. The average marginal effect of the policy is that the average probability of purchasing brand name drugs decreases between 6 and 11 percent. A welfare calculation indicates that the consumer surplus loss exceeds the insurer's gain by 7.5 dollars per person when all states switch from explicit to presumed consent.

Regarding the estimate of the size of the impact, some words of caution are in order. We do not take supply side responses into account. It is possible that the brand name drug producers decrease the price of their drugs in states with a presumed consent law. Therefore, the impact of the presumed consent law would be smaller compared to our calculations.

[23] http://blogs.wsj.com/pharmalot/2015/04/14/why-did-prescription-drug-spending-hit-374b-in-the-us-last-year-read-this/

Appendix

Derivation of the Welfare Formula

This expected surplus is a very simple expression in the context of the logit model, which is called the log-sum. We will demonstrate this fact in the context of two alternatives. With two alternatives, the values ϵ_1 of ϵ_2 and can be depicted in a plane. This plane contains all the possible combinations of (ϵ_1, ϵ_2). Some of them leads to the choice of alternative 1, and others to the choice of alternative 2. More precisely, alternative 1 is chosen if $\epsilon_2 < V_1 - V_2 + \epsilon_1$, and alternative 2 is chosen if $\epsilon_1 < V_2 - V_1 + \epsilon_2$.

We can rewrite the expected utility as the sum of the two terms $E_1$and E_2, with:

$$E_1 = \int_{\epsilon_1=-\infty}^{\infty} \int_{-\infty}^{V_1-V_2+\epsilon_1} (V_1 + \epsilon_1) f(\epsilon_1) f(\epsilon_2) d\epsilon_1 d\epsilon_2$$

$$E_2 = \int_{\epsilon_2=-\infty}^{\infty} \int_{-\infty}^{V_2-V_1+\epsilon_2} (V_2 + \epsilon_2) f(\epsilon_1) f(\epsilon_2) d\epsilon_1 d\epsilon_2$$

where $f(z) = exp(-e^{-z})$ is the density of the Gumbell distribution.

We derive the expression for E_1, and by symmetry we get the expression for E_2. The expected utility is obtained from summing $E_1$and E_2.

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