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FOR THE DEGREE

OF

DOCTOR OF PHILOSOPHY

BY

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Abstract

In this dissertation, I study the topics in generic drugs. My dissertation includes three chapters. The first chapter studies the impact of authorized generic drugs. This chapter models and empirically examines whether the introduction of authorized generic drugs changes the independent generic firms' decisions on entering the market. I use an instrumental variable approach to evaluate the effect of authorized generic drugs on the responses of generic manufacturers. The results show that the entry of authorized generic drugs deters and delays the entry of generic drugs. My second chapter studies the effect of price shocks and health behavior. In this paper, using data from Medical Expenditure Panel Survey, I investigate the extent to which consumers' health behaviors respond to price shock. Estimates from the event study indicate that the reduction of drug price negatively correlates with physical activity and diet. My third essay studies the effect of state generic substitution laws on the generic utilization and market competition. I use a difference-in-differences approach and state Medicaid prescription drug data to investigate the effects of these laws. My results show an increase in generic drug utilization with mandatory generic substitution laws, and provide some evidence brand name drug use declined.

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Chapter 1

Strategic Behavior and Entry Deterrence by Branded Drug Firms: The Case of Authorized Generic Drugs

1.1 Introduction

Standard economic theory implies that with the entry of rival firms selling similar products, the incumbent firm's profits will fall. Pharmaceutical firms that market brand name drugs lose substantial market share after patent expiration as price-sensitive consumers substitute to cheaper generic drugs (Chen (2007)).. Furthermore, the US government encourages consumers to use generic drugs to minimize prescription expenditures. Some states have implemented policies requiring pharmacists to substitute a generic for a brand name medication unless the prescriber specifies otherwise (Song & Barthold (2016)). As a consequence, branded manufacturers have, at times, introduced their own version of generic medications known as "authorized generics" (Appelt (2015)). The critical question this paper asks is whether the introduction of an authorized generic drug deters or delays the entry of independent generic manufacturers.

Authorized generic drugs can affect the entry decisions of generic manufacturers since some consumers are more willing to buy the authorized generic drugs instead of the standard generic drugs. Authorized generic drugs carry the names of trusted brand name drug makers stamped on the packages, which could be viewed as a sign of authenticity and quality control. While generic drugs are therapeutically equivalent to brand name drugs, some patients and healthcare providers remain uncertain about whether they produce identical outcomes(Chen (2007); Colgan et al. (2015); J. A. Greene & Kesselheim (2011)).. Thus, some consumers are willing to pay a premium for generics from branded manufacturers (Hansen et al. (2016)).. As a result, the launch of authorized generic drugs will attract consumers from the standard generic drug markets (Bairoliya et al. (2017)).

Authorized generics may be profitable because they allow branded manufacturers to use their existing commercial distribution systems and marketing infrastructure to sell premium-priced generics as if they were brand name drugs. However, the authorized generic drugs

are cheaper versions of their originator drugs and they are produced by the same branded manufacturers. Given that authorized generic drug competes with its originator drug, not all branded manufacturers choose to produce authorized generic drugs.

The debate surrounding authorized generics and market competition has largely centered on the impact of these drugs on average drug prices, but empirical evidence yields mixed conclusions. Some studies suggest that the entry of authorized generic drugs benefits consumers by offering a cheaper price substitute for the brand and by promoting competition with other generics (Berndt, Mortimer, Bhattacharjya, et al.(2007); Reiffen & Ward (2007); Cheng et al. (2017)). Others argue that the launch of authorized generic drugs may in fact lead to increased drug prices (Hollis & Liang(2007); Hollis (2005)), since the entry of authorized generic drugs could discourage the entry of other generic drugs, and hence reduce future competition from generics. As a result, a market with authorized generics will be more concentrated leading to increased drug prices. However, there has been little empirical evidence to inform this debate. Moreover, although prescription drugs constitute a large and growing share of government expenditure, the previous literature has not empirically studied how authorized generics affect government spending on generic drugs. Evidence about the effects of authorized generic drugs on government spending will help policymakers better understand the possible welfare effects of this strategy on competition in the generic drug markets.

Previous literature reports that the launch of authorized generics will not deter or delay the entry of other generic drugs. Some studies found that authorized generic drugs undermine the generic exclusivity period that Congress created to encourage generic manufacturers to challenge the patents that prohibit competition (Hollis & Liang (2007), Chen (2007)). Other studies have focused on the impact of authorized generics on the entry of other generic drugs. Berndt, Mortimer, & Parece (2007) reported that, in spite of increased authorized generic entry, the intensity of entry by generic manufacturers remained high. Hassett & Shapiro

(2007) found that competition from authorized generics did not reduce the entry of generic drugs. However, one limitation of these studies is that they do not directly measure generic drug entry and instead use R&D investment as a proxy for such entry. No studies directly examine the effect of authorized generic drugs on the likelihood and extent of generic drug entry in the U.S. market.

Empirical study of this issue has proven challenging for three reasons. First, previous research on authorized generic drugs has relied upon simple linear regression models or reviewing descriptive statistics to reach conclusions. However, the one-stage linear regression models without the instrumental variables can only reflect the correlations between the authorized generic entries and the generic entries. Such methods cannot show the causal relationship between authorized generics and generic entries. Second, the simple linear regression models cannot address the issue of endogeneity. Brand and generic manufacturers are making entry decisions simultaneously, causing a problem of endogeneity. Most of the previous literature ignored this problem and found no evidence of entry deterrence. One exception is Appelt (2015), who instrumented for the entry of authorized generic drug and found that the entry of authorized generic drugs would deter the entry of generic drugs in the German market. Third, prior literature considers only a subset of the possible generic drug entrants for patent challengers, and this will cause the issue of selection bias. My research will address these challenges by developing an instrument for authorized generic entry and by examining the full set of potential generic drug entrants.

In this paper, I will use data from the U.S. Food and Drug Administration (FDA) and an instrumental variable approach to examine the effect of authorized generic drugs on the entry decisions made by generic manufacturers and the timing of generic entry in the U.S. market. My approach takes account of the fact that many originators will expand not only into generic drugs but also into medical devices. The instrumental variable "share of the introduction of the medical device for the branded manufacturers" can capture the

originators' willingness to issue authorized generic drugs. After instrumenting for authorized generic entry, my study uses data on state level Medicaid drug sales from the Centers for Medicare & Medicaid Services (CMS) to examine the effect of authorized generic entry on drug utilization and expenditure in the Medicaid program.

My results indicate that both the likelihood of generic entry and the entry time of standard generic drugs are significantly negatively affected by the entry of authorized generic drugs. Results also show that the amount reimbursed for branded manufacturers (including sales of both brand name drugs and authorized generic drugs) increases if they are producing the authorized generic drug, indicating that branded manufacturers are making profits by using this strategy. The launch of authorized generic drugs also causes a reduction in the the utilization and sales of generic drugs. These results suggest that generic manufacturers are losing profits in the markets with authorized generics.

This study contributes to the broader economics literature that has examined the consequences of deterrence strategies and strategic behaviors of branded pharmaceutical firms[1]. Previous literature found little evidence that the defensive strategies detered the entry of generic drugs (Danzon & Furukawa (2011); Ellison & Ellison (2011); Berndt, Mortimer, & Parece (2007); Hollis & Liang (2007)). Danzon & Furukawa (2011)examined the impact of co-branding and new formulations on the probability of generic entry and the number of generic entrants in ten countries, but they found little effect of the defensive strategy. Ellison & Ellison (2011) showed that entry-deterring behavior was important in mid-sized markets. Prior studies on how authorized generic drugs may affect the drug market provide mixed results. Some showed that the entries of authorized generic drugs could raise drug prices because the authorized generic drugs might deter the entry of other generic drugs (Hollis (2005); Hollis (2003) ; Reiffen & Ward (2007); Kong & Seldon (2004)). How-

[1]The introduction of second-generic products, the reformulation of drugs for sale over the counter rather than by prescriptions (Rx-to-OTC switch), and the introduction of authorized generic drugs are among the best-known strategies.

ever, other studies indicated that the entry of authorized generic drugs could lower drug prices because the authorized generic drugs would not have a delaying or deterring effect on generic entry(Berndt, Mortimer, Bhattacharjya, et al. (2007); Cheng et al. (2017); Hassett & Shapiro (2007);Berndt, Mortimer, & Parece (2007)). My study provides new evidence that the launch of authorized generic drugs will significantly deter and delay the entry of other generic drugs using an empirical approach that accounts for both endogeneity and selection issues.

This study also has important policy implications. By analyzing the effect of authorized generic drugs on Medicaid reimbursement, this study shows how the defensive strategy of branded manufacturers affects government spending and competition in drug markets. The results indicate that government will pay more to the generic drugs in the market with authorized generic drugs than in the markets without authorized generic drugs. As a consequence, with the increasing number of authorized generic drugs, government expenditure on drugs will increase. Moreover, drug markets may be more concentrated given the entry deterrence. Consequently, drug prices may be relatively higher in market with authorized generic drugs than in markets without authorized generic drugs.

Furthermore, this study contributes to the literature that has examined the determinants of generic drug entry (Morton (1997); Saha et al. (2006); Hurwitz & Caves (1988); Hudson (2000)). Prior studies showed that pre-entry revenues, firm and drug characteristics, and the brand drug's goodwill stock were important determinants of generic entry. My study also provides additional evidence about the determinant of generic drug entry. The results indicate that the pre-entry revenue, monopoly duration years, brand and generic competitors and field experience are associated with an increase in the likelihood of generic entry.

The paper proceeds as follows: Section 2 discusses the background and previous literature on authorized generic drugs. Section 3 describes a theoretical model of generic entry. Section 4 discusses the data I use in the study. In section 5, I describe the methodologies

and assumptions. Section 6 discusses the results, and section 7 is the conclusion.

1.2 Background and Literature Review

1.2.1 Background

A brand name drug is the innovator drug produced by the branded manufacturer and approved under a New Drug Application (NDA) by FDA. Brand name drugs have patent protection, which ensures that it will not face generic competition until after its patent expires. Competition in prescriptive drug markets is regulated by the Hatch-Waxman Act. To foster competition, the Hatch-Waxman Act allowed generic manufacturers to file an Abbreviated New Drug Application (ANDA) to demonstrate the bioequivalence to an innovator drug, which could be filed before the innovator's patents expired. The drugs that are marketed under an ANDA are called generic drugs. Generic drugs are cheaper than their brand name counterparts, and they typically capture a substantial market share of the brand name drugs once they enter the market (Chen (2007)). Paragraph IV of the Hatch-Waxman Act accelerates generic market entry: Under Paragraph IV, generic firms are incentivized to challenge branded firms' patents, since the first generic manufacturer to file an ANDA with a successful Paragraph IV certification (a patent challenge or claim of noninfringement) is allowed a 180-day marketing "exclusivity" period during which no other ANDA filers can market their version of the drug (Berndt, Mortimer, & Parece (2007)). This six month period allows the first ANDA firm to reap the economics benefits of being the first generic drug in the market.

Authorized generics refer to pharmaceutical products that are produced by innovator (brand) companies under a New Drug Application (NDA), and marketed and distributed with a generic product label. According to the Food and Drug Administration (FDA), an authorized generic is a brand name prescription drug already approved by the FDA but

marketed as a generic under a private label. It has the identical size, shape, color, taste, smell, mouthfeel, and active ingredients as the brand. Unlike a standard generic, the authorized generic has the identical inactive ingredients as well. Since 2006, 689 authorized generics have been launched, and 505 of these products are still being marketed today [2]. Authorized generics compete with standard generic products approved by the FDA as substitutes for specific branded products, and the prices of authorized generic drugs are often higher than the prices of standard generic drugs (Chen (2007)).. Moreover, authorized generics may be marketed to consumers during and after the 180-day exclusivity period. Although the first generic drug has the 180-day marketing "exclusivity" period, in practice this period has never truly been "exclusive" as the NDA holders and its distributors and licensees have always been authorized to continue to sell the originally approved drug product throughout this 180-day period and beyond. Figure 3.1 shows the timeline of authorized generic entries and generic entries relative to the patent expiration year. The x axis represents the difference between the initial marketing year and the patent expiration year. The y axis is the percentage of drugs. This figure indicates that most authorized generic drugs enter the market between two years before and one year after patent expiration. Moreover, most traditional generic drugs enter the market between one and two years after the patent expiration.

On one hand, the launch of authorized generic drugs not only captures a share of branded drug sales, but it also erodes incentives for future generic entry. The anticipation of authorized generic entry can lower the incentives for generic entry because their expected profits may be lower. Consequently, the launch of authorized generics may deter the entry of other generic drugs, allowing authorized generics to dominate the market. The introduction of authorized generic drugs is one of the best-known strategies of branded manufacturers when it competes with generic manufacturers. It has been estimated that for a branded product with $110 million in US domestic annual sales in the early 1990s, postponing the entry of generic drugs by one year would increase the branded manufacturer's after-tax

[2]Publicly Available Data 2006 to 2016. Symphony Health Solutions; First Databank NDC data.

profits by about $12 million (in 1990 dollars) (Cook (1998); Grabowski & Vernon (1994)). As a result, it is not surprising that branded manufacturers are developing strategies to delay the entry of generic drugs. In recent years, although there are many drug approvals for generic drugs, relatively few generics were launched into the market. The U.S. Food and Drug Administration has approved more than 1,600 generic drug applications since January 2017, but more than 700 of those generics were not yet on the market as of January 2019. Moreover, 36 percent of generics that would be the first to compete against a brand drug are not yet for sale.

On the other hand, an authorized-generic mid-priced medicines is in direct competition with its respective brand name drug, which may cause a loss of profits for the branded manufacturer. As a result, not all branded manufacturers choose to produce authorized generic drugs.

An example of an authorized generic drug is Tekturna, a blood-pressure medication produced by PDL BioPharma whose its patent expired in 2018. PDL launched its own authorized generic Tekturna in March 2019 before the first generic Tekturna was on the market. The price of brand name Tekturna is $208 per month and the authorized generic Tekturna costs $187 per month. Generic Tekturna produced by Anchen is cheaper than the other two versions of Tekturna produced by the branded manufacturer at $166 per month. From 2018, authorized generics appeared at the rate of about once a week (Hancock & Lupkin (2019)).. High profile examples in recent years include Mylan's generic version of the EpiPenanti (anti-allergy injector) and Eli Lilly's generic Humalog.

The introduction of authorized generic drugs has raised policy concerns(Federal Trade Commission et al. (2010, 2011); The European Commission (2008)). Authorized generic drugs could decrease the generic firm's first-mover advantage and reduce expected generic revenues. This could reduce competition following patent expiration and lower the incentive for future generic entry. The European Commission (2008) notes that "the possibility to

obtain a first-mover advantage is important from a competition policy perspective because it stimulates companies to enter the market as quickly as possible, thereby creating competition and bringing down prices for consumers." Reducing this advantage could limit competition by reducing the prospect for generic entry.

1.2.2 Literature Review

Prior research has examined how authorized generic drugs may affect the average price in a drug market, but the empirical results have been mixed. Hollis (2005) has studied pseudo-generics, the equivalent of authorized generics in the Canadian pharmaceutical market, and found that pseudo-generics likely increase the prices of both generic and brand name drugs. Reiffen & Ward (2007) showed that the anticipated entry of an authorized generic drug could raise long-run prices by roughly 1-2% in small to medium-size drug markets. However, other studies indicated that the entry of authorized generic drugs lowered drug prices in the short run. An IMS consulting study, supported by Pharmaceutical Research and Manufacturers of America (PhRMA), reported that drugs experiencing authorized generic entry during an exclusivity period had generic discounts to the brand price that were sixteen percentage points higher than those with no authorized generic entry. A study by Hollis & Liang (2007) found that brand name prices in markets with authorized generic drugs increased more than those in markets without authorized generic drugs. Berndt, Mortimer, Bhattacharjya, et al. (2007), who reviewed descriptive statistics from 1999 to 2003, argued that the entry of authorized generics benefits consumers through lower short-run prices. Cheng et al. (2017) showed that the availability of an authorized generic was associated with reduced average generic and brand price in the antidepressant market from year 2000 to 2011.

The question of whether the launch of authorized generic drugs will deter or delay the entry of other generic drugs has been hotly debated, but there has been little empirical

evidence to inform this debate. Hollis (2003) andKong & Seldon (2004) suggested that authorized generic drugs would deter the entry of other generic drugs. The reasoning is that with lower expected gains, generic manufacturers may be reluctant to enter the market, or choose to enter the market later. Prior theoretical research by Hollis (2003) predicted that the strategy of authorized generic drugs detered generic entry into smaller drug markets and slowed the process of entry. Kong & Seldon (2004) modeled the effects of authorized generic entry in the context of a market in which the authorized generic drug replaced what would have been a single independent generic firm, and they found similar results. Others argued that the entry of authorized generic drugs would not have a delaying or deterring effect on generic entry. However, evidence of such an effect is limited. Hassett & Shapiro (2007) found that competition from authorized generics did not reduce the investments of other generic firms and argued that authorized generic drugs would not deter the entry of other generic drugs. Berndt, Mortimer, & Parece (2007) argued that even when authorized generic entry reduced the expected gains of other generic firms, sufficient incentives remained so that in spite of increased authorized generic entry, the probability of entering remained high.

However, these studies did not specifically estimate generic entry decisions. Three major factors contribute to the scarcity of convincing and significant evidence. First, previous studies have ignored the endogeneity of authorized generics and lack a rigorous identification strategy. As a consequence, the evidence about the effects of authorized generic entry on generic drug entry may be limited. Second, most studies consider the firms who have entered the market but not the potential generic firms. Third, some studies reach their conclusions by inference rather than by directly analyzing the impact of authorized generic drugs. As a result, most of the previous literature cannot find significant empirical evidence that authorized generic drugs will deter or delay the entry of generic drugs.

1.3 Theoretical Model

I use a two stage game to model the competitive decisions made by branded manufacturer (B) and generic manufacturer (G). I assume there are two players - branded manufacturer (B) and generic manufacturer (G), and each player plays optimally at every decision node.

In the first stage of the game, I assume that a branded manufacturer chooses to either Launch or not Launch an authorized generic drug prior to patent expiration. In the second stage of the game, generic manufacturer makes a decisions to either Enter or Not Enter the market following a branded drug's patent expiration.

As a consequence, there are four situations with different payoffs, and Figure 3.2 depicts the sequence of actions and the corresponding payoffs. In the first scenario, the branded manufacturer will not launch an authorized generic drug and the generic manufacturer will not enter into the market. Thus, the branded manufacturer will only receive profits from selling the brand-name drug and the expected profits following patent expiration in the absence of generic entry is π_b. The generic manufacturer will not enter into the market, so the payoff for the generic manufacturer is 0. In the second scenario, the branded manufacturer will not launch an authorized generic drug, but the generic manufacturer will enter into the market upon patent expiration. Since there is a competition between the brand-name drug and the generic drug, the branded manufacturer will receive a smaller payoff $\pi_b'(\pi_b' < \pi_b)$. The generic manufacturer will receive the payoff π_g in this case. I assume the profit for the generic manufacturer $\pi_g > 0$, so the generic manufacturer will be certain to enter the market if the branded manufacturer chooses not to launch the authorized generic drug. In the third scenario, the branded manufacturer will launch an authorized generic drug, but the generic manufacturer will not enter the market. The branded manufacturer will receive profits from selling both its brand name drug and its authorized drug, so the payoff for

branded manufacturer is π_{b+ag}. Since the generic manufacturer will not enter the market, the payoff is 0 for generic manufacturer. In the fourth scenario, the branded manufacturer will launch an authorized generic drug and the generic manufacturer will enter the market. In this case, the branded manufacturer will receive payoff π'_{b+ag} and the generic manufacturer will receive payoff π'_g. Since the authorized generic drug competes against the generic drug, π'_{b+ag} is smaller than π_{b+ag} and π'_g is smaller than π_g.

I assume the branded manufacturer produces X_b units of brand-name drug and X_{ag}units of authorized generic drug [3]. The generic manufacturer will produce one generic substitute at the output level X_g. I assume there are constant marginal costs for the brand-name drug, the authorized generic drug and the generic drug. Moreover, I assume there exists a cost of entry for the generic manufacturer if it decides to enter. To successfully file an ANDA, the generic manufacturer has to implement some experiments to get the identical effect as the brand-name drug. Moreover, the generic manufacturer may need to buy a new system to produce the generic drug. Since the authorized generic drug is produced by the branded manufacturer and it uses the NDA as the brand-name drug, I assume there is no entry cost for the authorized generic drug. The entry cost is different for different drug market and different generic manufacturer. For example, longer monopoly duration years may represent that the brand-name drug is hard to copy, so the entry cost may be higher. Moreover, if the generic manufacturer has experience in producing a similar product, the entry cost may be lower since the generic manufacturer can use the existing producing system. As a consequence, I assume the entry cost is a function of the brand-name drug's monopoly duration years and generic manufacturer's field experience. Thus, the cost functions are:

$$\begin{aligned} C_b &= cX_B \\ C_{ag} &= cX_{ag} \\ C_g &= f_g(MD, FE) + cX_g \end{aligned} \tag{1.1}$$

[3]The brand-name firm will produce the authorized generic drug when it is profitable to do so.

Where f_g is the start-up cost for generic manufacturer. MD is the monopoly duration year of the brand-name drug, it represents the characteristic of the drug markets. FE is the field experience of the generic manufacturer, it represents the characteristic of the generic manufacturer.

Thus the profit functions for branded and generic manufacturers are:

$$\begin{aligned} \pi_b &= (P_b - c)X_b \\ \pi_{b+ag} &= (P_b - c)X_b + (P_{ag} - c)X_{ag} \\ \pi_g &= (P_g - c)X_g - f_g \end{aligned} \tag{1.2}$$

Solving the game shows that a brand firm will launch an authorized generic if $\pi'_{b+ag} \geq \pi'_b$. The generic firm will be certain to enter if there is no authorized generic drug in the market.

In the case with an authorized generic drug, the generic manufacturer will enter the market if $\pi'_g \geq 0$, that is $(P_g - c_g)X_g \geq f_g$. If the entry cost is high, the expected profit of entering the drug market will be lower and the generic manufacturer will be less likely to enter the market. Moreover, some other variables could affect the expected profits of entering the market and then affect the probability of entering. For example, if the market size of the brand-name drug is large prior to patent expiration, the generic manufacturer may expect to earn more profits in this market, and then they will be more willing to enter the market.

1.4 Data

The data sets for this study come from three sources. The FDA's National Drug Code (NDC) dataset includes patent information (expiration date and patent holder), market ap-

proval dates, nonproprietary names, proprietary names, available strength, drug forms, and therapeutic fields. Then, by merging FDA's NDC files with the dataset of the Anatomical Therapeutic Chemical (ATC) Classification System using the INN (International Nonproprietary Name), I get the therapeutic field of each drug [4]. The Medicaid Utilization dataset contains the number of prescriptions, total amount reimbursed, Medicaid amount reimbursed, utilization type and the National Drug Codes (NDC) at the state level. The Medicaid utilization dataset is a large and nationally representative sample; it is far larger than any of the government surveys that examine healthcare utilization (Ghosh et al. (2019)) and provides quarterly information in addition to annual state level data. One of the key advantages of the Medicaid dataset is that it contains rich drug information such as National Drug Codes, brand names and nonproprietary names, which allows me to merge this dataset with the FDA's NDC files.

Table 3.1 shows the summary statistics for generic drug entrants from 1999 to 2018. In total, 180 drug markets [5] lost patent protections between 1999 and 2018. Of those, 141 markets experienced generic entry, whereas the other 39 markets did not have any generic drugs on the market until 2018. Of the 141 drug markets with generics in the market, 55 have authorized generic drugs and 86 do not. From 1999 to 2018, 2,084 generic products were launched in the 180 drug markets that lost patent protection during that time; 1,281 of them are authorized generic drugs. The average monopoly duration for all drug markets is 11 years; the average is 9.6 years in the drug markets with authorized generic drugs. Substitute brands refer to the brand name competitors with the same ingredient. On average, there are 2.2 substitute brands in each drug market. Substitute generics refer to the generic competitors with the same ingredient, and the average number of competitors is 40 in each drug market.

Figure 3.3 shows the average number of prescriptions at the state level from 2010 to

[4] ATC3 and ATC5 are used in the analysis

[5] Drug market is defined as ingredient. Different ingredient is defined as different drug market.

2017 using the Medicaid dataset. It shows that generic utilization is much higher than brand utilization and it has increased rapidly, particularly after 2013, which coincides with Medicaid expansion under the Patient Protection and Affordable Care Act (PPACA). Unlike the trends in generic utilization, brand utilization decreased from 2010 to 2017. The number of prescriptions of authorized generic drugs increased from 2010 to 2012, and then began to decline beginning in 2013. Figure 3.4 shows the average Medicaid amount reimbursed at the state level. The amount reimbursed by Medicaid is the total reimbursement in each year for each different drug market. Consistent with the trends in Figure 3.3, the Medicaid amount reimbursed for brand name drugs decreased rapidly from 2011 ($ 952.52 million dollars) to 2017 ($378.21 million dollars). However, the amount reimbursed for generic drugs increased incrementally, from $185.78 million dollars in 2010 to $582.92 million dollars in 2017. While the amount reimbursed for brand name drugs was much higher than generic drugs before 2015, it decreased incrementally from 2011 and became lower than the generic drug amount starting in 2016. The amount reimbursed for authorized generic drugs is historically much lower than that of brand name drugs and generic drugs, but it increased slightly from 2010 to 2015 (from $18.22 million dollars to $37.28 million dollars).

Figure 3.5 shows the accumulated number of authorized generic drugs by year in my sample. A total of 16 drug markets had authorized generic drugs enter the market between 2010 and 2018. From 2012 to 2014, ten authorized generic drugs emerged in the market. However, from 2015 to 2017, two authorized generic drugs were discontinued by the branded manufacturer. Figure 3.6 shows the number of drugs that entered the market after the patent expiration. Most authorized generic drugs enter prior to standard generics, and this allows them to potentially deter entry. Moreover, most authorized generic drugs and first-entered generic drugs [6] entered the market within a year of the patent expiration date of the brand name drug.

[6]First-entered generic drugs refer to the standard generic drugs who first entered into the market.

These figures jointly indicate that both authorized generic drugs and generic drugs were becoming more prevalent from 2010 to 2018, while the amount reimbursed for brand name drugs are decreasing during this period. As a result, some authorized generic drugs are launched into drug markets before the patent expiration to compete with standard generic drugs and these authorized generic drugs create another source of revenue for the brand manufacturers.

1.5 Methodology

1.5.1 The effect of authorized generic drugs on the likelihood of generic entry

To examine whether the entry of an authorized generic drug deters the entry of standard generic drugs and overcome any issues with endogeneity, I use an instrumental variable approach. I first use an instrumental variable to estimate the likelihood of authorized generic entry, then use this predicted variable to estimate the probability of generic entry.

An important consideration in the analysis is the determination of the potential generic competitors. Prior research has neglected this issue and they only considered the generic manufacturers who eventually entered the market. However, by considering only a subset of the possible generic drug entrants for patent challengers would cause the issue of selection bias. I follow the selection rules of Morton (1997) and Appelt (2015) to select potential generic manufacturers. I construct two sets of potential generic manufacturers for each drug market and identify generic manufacturers that never enter into the market. I first define the generic manufacturer as a firm with at least half of its retail form portfolio classified as generic drugs; after applying this selection rule, the FDA's dataset lists 695 generic drug manufacturers. I then select the active generic manufacturers as the generic firms with at

least 50 retail forms, giving me 207 active generic manufacturers in my dataset [7]. These active generic manufacturers produced 96% of all generic drugs available in the U.S. market between 1999 and 2018.

Table 3.2 shows the summary statistics of the two constructed data samples. The first data sample contains all active generic manufacturers (the manufacturers with a generic product share larger than 50% and supply at least 50 retail forms). The second data sample of potential generic manufacturers is a subset of the first group of entry candidates, which contains the active generic manufacturers that have experience in operating in a given therapeutic drug class [8]. In total, there are 207 active generic manufacturers in data sample 1, and the average number of potential generic manufacturers is 142 by drug market. The number of market-firm-year observations with no generic entry is 23,530, and the number of observations with generic entry is 2,084, so the total number of observations in data sample 1 is 25,614. Data sample 2 was constructed by taking account of firms' therapeutic experiences. In data sample 2, the average number of potential generic manufacturers is 44.7. There are 5,564 observations in which we observe no entry by a generic firm, and 2,084 observations in which generic entry occurred before November of 2018. The total number of observations in data sample 2 is 7,648.

I assume that authorized generic entry decisions are made independent of generic manufactures' decisions. Furthermore, generic companies and brand companies make entry decisions simultaneously. Based on these assumptions, the probit model is:

$$\begin{aligned} GenericEntry_{df} &= 1[GenericEntry^*_{df} > 0] \qquad where \\ GenericEntry^*_{df} &= \beta AG_f + \theta X_{df} + \varepsilon_{df} \end{aligned} \tag{1.3}$$

[7] Drug manufacturers with at least half of the retail form portfolio classified as generic drugs and with at least fifty retail form.

[8] Drug class is broadly defined by the Anatomical Therapeutic Chemical Classification System at the third level (ATC3)

where the $GenericEntry_{df}$ is the market entry decision for firm f in drug market d. AG_f equals to 1 if the authorized generic drugs are introduced into the market, and zero otherwise. X_{df} is a set of control variables. I control for pre-entry market revenue, monopoly duration years, the number of generic substitutes, the number of brand name substitutes, field experiences, therapeutic fields and drug forms (Hurwitz & Caves (1988); Morton (1997); Hudson (2000); Saha et al. (2006); Regan (2008); Moreno-Torres et al. (2009))..The variable "pre-entry revenue" is lagged three calendar years to remove possible endogeneity problems. The variable "monopoly duration years" measures the years from the start marketing date until the loss of patent. "Substitute brand" and "substitute generics" are the numbers of substitutive active ingredients of brand name drugs and generic drugs listed in the same therapeutic field of indication (ATC5 classification). The variable "field experience" measures the potential entrants' therapeutic capabilities, which is the number of products launched in relevant therapeutic field of indication (ATC3 classification) prior to the loss of patent. Furthermore, this model is estimated with standard errors that are clustered by firms because the entry decisions of a single firm across different drug markets are likely to be dependent (Appelt (2015)).

The drug markets that authorized generic drugs enter are not likely to be chosen at random (Hollis & Liang (2007); Federal Trade Commission et al. (2010); Federal Trade Commission et al. (2011); Appelt (2015)). Many unobserved factors could potentially affect the entry decisions of originators, thus it is crucial to account for this endogeneity problem when assessing the effects of authorized generic entry. I use the "share of medical devices" as an instrumental variable for the entry of authorized generic drug:

$$\begin{aligned} AG_f &= 1[AG_f^* > 0] \qquad where \\ AG_f^* &= \gamma SMD_f + \theta X_{df} + \varepsilon_{df} \end{aligned} \tag{1.4}$$

This instrumental variable measures the number of medical device introductions of the brand

in the year prior to the loss of patent relative to the size of the drug portfolio at that time. After a patent expires, branded manufacturers may expand not only into generic drugs but also into medical devices or other fields. Appelt (2015) uses the "share of non-core products" as the instrumental variable to predict the entry of authorized generic drugs in the German market. The introduction of medical devices, as the important component of non-core products, can provide a proxy for the branded manufacturers' willingness to introduce authorized generic drugs. Appelt (2015) suggests that a branded firm is more likely to launch authorized generic drug if they have more financial distress. The entry decision of authorized generic drugs is arguably motivated by the branded firm's financial distress, and the financial distress is expected to have a positive effect on the likelihood of authorized generic drug entry Appelt (2010). After a patent expires, branded firm who introduce new medical devices in the year prior to the patent loss may have less financial distress since they can get profits from selling medical devices, and thus they may be less likely to launch the authorized generic drug. As a result, the introduction of medical devices can indirectly measure the originators' willingness to launch authorized generic drugs. Moreover, scaling by firm size (drug portfolio size) introduces an important weighting of medical device introductions. The exclusion restriction of instrumental variable requires "the share of medical devices" to be unrelated to the entry of generic drugs. The introduction of medical devices is not expected to provide a source of competition in generic drug markets, hence it is reasonable to expect that the introduction of medical devices is not correlated with generic entry decisions.

Given the endogeneity of authorized generic entry, I use the predicted variable $\hat{AG}_f$ to examine the effect on the likelihood of generic entry. The specifics of the model are given below:

$$\begin{aligned} GenericEntry_{df} &= 1[GenericEntry^*_{df} > 0] \qquad where \\ GenericEntry^*_{df} &= \beta \hat{AG}_f + \theta X_{df} + \varepsilon_{df} \end{aligned} \tag{1.5}$$

where SMD_f is the share of the introduction of medical devices in the year prior to the loss of patent of the originator relative to the size of drug portfolio. X_{df} is a set of control variables, and the variables included in the X vector are as previously defined. The standard errors are robust to heteroscedasticity and clustered at firm level.

This recursive bivariate probit model captures the simultaneity of authorized generic and generic entry decisions as well as the unidirectional effect of authorized independent generic entry decisions. Exclusion restrictions are not required for the recursive probit model, while the identification in the bivariate probit model relies on the model of sequential entry and the assumption of normality (Wilde (2000); W. H. Greene (2003); Norton (2011)).

1.5.2 The effect of authorized generic drugs on the timing of generic entry

In this section, I use a two-stage proportional hazard model to analyze whether authorized generic drugs delay the entry of generic drugs in the market. The primary identification strategy compares the year of generic drug entry of generic drugs between markets with and without authorized generic drugs. I use the same instrumental variable mentioned above to predict the probability of introducing authorized generic drugs, and then I use a Cox regression to analyze the effect of authorized generic drugs on the timing of standard generic entry. The estimating equation is given below:

$$EntryTime(t) = EntryTime_0(t) \times exp(\beta \hat{AG}_f + \theta X_{df}) \tag{1.6}$$

where $EntryTime(t)$ is the difference between the year of patent expiration and the year of generic entry. If there is no generic entry, the observation is treated as censored. $\hat{AG}_f$ equals 1 if an authorized generic drug is introduced into the market, and zero otherwise. X_{df} is the

set of control variables.

1.5.3 The effect on Medicaid utilization and amount reimbursed

To analyze the effect of authorized generic drugs on Medicaid utilization and amount reimbursed, I exploit difference in the timing of patent expiration across drug markets to identify the effects of authorized generic drugs on all drugs and on brand name drugs. There are two groups in this analysis: the drug markets with authorized generic drugs, and those without. As before, I first use the instrumental variable "share of new medical devices " to predict the entry probability of authorized generic drugs, then I use a series of dummy variables to indicate the years relative to the patent expiration to estimate the dynamic effects of authorized generic drugs. I study three different outcomes: the total number of prescriptions, total amount reimbursed, and total Medicaid amount reimbursed. The estimating equation is defined below.

$$Outcome_{dts} = \alpha + \sum_{k=-4}^{2} \beta_k \cdot \hat{AG}_d \cdot YEAR_{dt}^k + \gamma AG_d^* + F_t + F_s + X_{dts} + \varepsilon_{dts} \tag{1.7}$$

where the $Outcome_{dts}$ is the outcome variable. $\hat{AG}_d$ is the predicted variable using the instrumental variable "share of new medical devices ". $YEAR_{dt}^k$ equals to 1 if time t is k years before or after the patent expiration, and zero otherwise. k is equal to 0 in the year of patent expiration. F_t is the year-quarter fixed effect. F_s is the state fixed effect. X_{dts} is a set of control variables [9] and ε_{dts} is the residual term. Outcome variables are calculated as population rates (per 100) by dividing the outcome variables by Census Bureau estimates of the non-elderly adult population.

I estimate Equation (1.7) for a balanced panel with data available for four years prior

[9]The control variables are: utilization type; seasonal effect; start marketing year; atc3; originator's monopoly year; brand competitors; time trends; years after the launch of authorized generic drugs. All the descriptions of control variables are presented in the appendix table A1

to patent expiration up to two years after, instead of the whole unbalanced panel, to remove the bias caused by unbalanced panel. [10]. Thus, the time-after-expiration dummy variables ($YEAR_{dt}^{k}$) are capped at -4 years and 2 years. The comparison year is the last year prior to the patent expiration ($k = -1$). The reason of using a balanced panel is that not all drug markets have data available for each year relative to the patent expiration. Drug markets in which the patent expired early in the period have fewer years of data before the patent expiration, and drug markets whose patent expired later have fewer years of data after the patent expiration. Thus, the composition of drug markets identifying the coefficients β_k varies with k [11].

The event study model used in this study allows for a partial test to determine whether the outcome variables of interest would have similar trends without the patent expiration, in drug markets with different patent expiration years. If the timing of patent expiration is unrelated to the underlying trends and individuals do not respond before the patent expiration, there should be no trend in the β_k for $k < 0$.

The launch of authorized generic drugs may affect the utilization and amount reimbursed of standard generic drugs. With the competition from authorized generic drugs, standard generic drugs may have lower utilization and lower Medicaid reimbursement compared to the standard generic drugs without authorized generic competition. I Equation (1.7) with the outcome variables "the number of prescriptions of generic drugs," "the total amount reimbursement of generic drugs, " and "the Medicaid amount reimbursement of generic

[10]The event window is balanced from $k = -4$ to $k = 3$ if I do not divide the outcome variables by Census Bureau estimates of the non-elderly adult population. Because the Census Bureau estimates are from 2010 to 2017, while the Medicaid data is from 2010 to 2018.

[11]For example, assume that after the patent expiration, the total utilization decreases in the drug markets with authorized generic drugs, but the treatment effect is larger for drug markets whose patents expired later. Drug markets with later patent expiration dates have less data available after the patent expiration, so a panel including all drug markets will be unbalanced with respect to the time relative to the patent expiration. Estimating equation 1.7 on this sample indicates that the treatment effect diminished over time, since the coefficients β_k in later years relative to the patent expiration are identified mostly from the early patents expired drug markets that had smaller treatment effects. The estimates of the trend in the years before patent expiration may also be affected by such compositional changes.

drugs" to analyze the effect of authorized generic drugs on the standard generic drugs. Since there are no generic drugs before the patent expiration, the event window is from $k = 0$ to $k = 2$.

1.6 Results and Discussion

1.6.1 The effect of authorized generic drugs on the likelihood of generic entry

Table 3.3 shows the results from effects of authorized generic drugs on generic drug entry. The first column reports the results from the IV estimation, it shows that the instrumental variable "share of new medical devices" is significantly correlated with the entry of authorized generic drugs, but has no effect on generic entry in the single-equation probit model[12]. This suggests that the instrumental variable is strong and can provide a good predication.

The second column of table 3.3 reports the second stage results, and the outcome variable is the probability of generic drug entry. The negative coefficient indicates that authorized generic entry decreases the probability of entry for generic manufacturers. The table presents results for each of the two datasets. Although the composition of the two datasets is different, the relative size of coefficients is similar, reflecting the robustness across the two different samples. To gauge the magnitude of this effect, I calculate the average marginal effects (AME). Table 3.4 presents the average marginal effects computed for the two data samples. The average marginal effect in column 1 indicates that the authorized generic entry leads to a 7.54 % (data sample 1) decrease in the probability of generic entry

[12]The F statistics is 296.94. Table A2 shows the preliminary results by using the single-equation probit model. The results show that the launch of authorized generic drugs is positively correlated with the entry of generic drugs, which suggest that the authorized generic drugs will increase the probability of generic entries. One important result in this table is that the instrumental variable "share of new medical devices" does not have a statistically significant impact on generic entry.

on average.

This result suggests that the entry of authorized generic drugs deters standard generic drug entry. In other words, the launch of authorized generic drugs will decrease the number of generic drugs on the market after the patent expires. As a consequence, markets with authorized generic drugs may be expected to have higher average prices and be associated with increased Medicaid expenditures.

Tables 3.3 and table 3.4 also show other determinants of generic entry. Pre-entry revenues have a significant and positive effect on the likelihood of generic entry. A one-unit increase in the log-transformed variable "Pre-entry Revenue" induces a 0.56% increase in the likelihood of generic entry. Monopoly duration years have a small and positive effect on the entering decisions of generic manufacturers, so generic manufacturers are more likely to enter a market whose innovator has a longer monopoly duration. The magnitude of the effect of monopoly duration year is small, but the length of monopoly duration may no longer be a good proxy for branded firms' accumulated goodwill [13]. This table also shows that the number of brand name competitors (substitute brand) and generic competitors (substitute generics) have significant and positive effects on generic entries. A one-unit increase in the number of brand and generic substitutes increases the probability of generic entry by 1.57% and 0.1%, respectively. Furthermore, a firm's field experience encourages entrance, and the coefficients are significant in both data samples. The probability of generic entry increases by 0.56% with each additional generic drug that the firm launched in other markets prior to the loss of patent.

[13]Since recent generic drug use initiatives in industrialized nations eliminated the scope for reputational gains ((?, ?)))

1.6.2 The effect of authorized generic drugs on the timing of generic entry

Figure 3.7 shows the resulting effects of authorized generic entry on the timing of standard generic entry, and they provide non-parametric, unconditional estimates of generic entry time. The Kaplan-Meier survival curves plot the share of markets with and without authorized generic drugs. The x-axis represents the relative years after the patent expires. The solid and dashed lines represent the survival curve of generic drug markets with and without authorized generics on the market, respectively. Fail equals 1 if the generic drug enters the market. On average, generic drugs in markets without authorized generic drugs come into the market a half-year earlier than generic drugs in markets with authorized generic drugs. This figure shows that the solid line is always above the dashed line, meaning that that generic manufacturers in markets with authorized generic drugs enter the market later than those in markets without authorized generic drugs. Figure A1 is the Kaplan-Meier Survival Estimates by drug markets using data sample 2; results are similar to figure 3.7.

Table 3.5 presents the regression results for the proportional hazard model with the instrumental variable. Coefficients are reported instead of hazard ratios. The coefficients for the variable "AG Entry" are negative and statistically significant at the 0.01 or 0.05 level in both columns. This suggests that the entry of authorized generic drugs significantly delays the timing of standard generic drug entry. For interpretability, I compute hazard ratios by exponentiating the parameter estimates [14]. The hazard ratio suggests that there is an additional delay of 4.8 months of in the markets with authorized generic drugs compared to those without since the average generic entry time in the market without authorized generic drugs is six months after the loss of patent. Using data sample 2 to test this effect, I find that the magnitude indicates longer delay. My results suggest that standard generic drug

[14]Specifically, the coefficient of "AG Entry" is -1.6375, so I exponentiate this coefficient and get the hazard ratio, which equals 0.194

firms are more cautious about entering authorized generic drug markets, perhaps because they are less certain about expected profits. Authorized generic drugs will attract many consumers after they enter the market, so they may occupy large shares in the market. On the other hand, authorized generic drugs have higher prices than standard generic drugs. Thus, consumers may be less willing to pay the higher prices.

The results also suggest that in markets with higher pre-entry revenue and more brand competitors, generic manufacturers tend to enter the market earlier. Moreover, generic manufacturers with more field experience are more likely to enter the market earlier. However, if the monopoly duration years is large, generic manufacturers tend to enter the markets later.

1.6.3 The effect on Medicaid utilization and amount reimbursed

The effect on Medicaid utilization

Table 3.6 presents the 2SLS regression results for the effects of authorized generic drugs on utilization. Column (1) shows the effect on total drug utilization (includes brand name drugs, authorized generic drugs and generic drugs). Column (2) shows the effect on brand name drugs' utilization only, Column (3) shows the effect on brand name drugs' and authorized generic drugs' utilization, and Column (4) shows the effect on standard generic drug utilization (excluding AG utilization).

The results in Column (1) show that total Medicaid drug utilization is greater in markets with authorized generic drugs relative to markets without authorized generic drugs. The magnitude of this effect is not trivial. Table 3.6 Column (1) shows that the number of prescriptions increases by 22.2 percentage points after the patent loss in markets with authorized generic drugs compared to markets without authorized generic drugs. The dynamic effects in Column (1) indicate that the number of prescriptions increases by 15 percentage

points in the year of the patent loss in markets with authorized generic drugs compared to markets without authorized generic drugs. Moreover, the coefficients become smaller incrementally from the year of patent loss to the second year after the patent loss, which suggests that the effects of authorized generic drugs diminished over time.

While authorized generic drugs may attract some consumers to switch from generic drugs, they also compete with their own companies' brand name drugs. Column (2) in Table 3.6 shows the coefficients of estimating Equation (1.7) on the brand name drugs only. It provides evidence that with the entry of authorized generic drugs, the number of prescriptions of brand name drugs decreases. Dynamic effects in Column (2) shows that in markets with authorized generic drugs, the total number of prescriptions of brand name drugs declines incrementally after the patent loss, compared to markets without authorized generic drugs. In the year of patent loss, the number of prescriptions decreased by 1.9 percentage points, and decreased by 21 percentage points in the second year after the patent loss. This result is consistent with the idea that the launch of authorized generic drugs will attract some consumers from a company's own brand name drugs, and this may cause a decline in the number of brand name drug consumers.

Table 3.6 Column (3) shows the average treatment effects when I consider the effects of authorized generic drugs on the sales of both authorized generic drugs and the brand name drugs [15]. The results show that the number of prescriptions increases in markets with authorized generic drugs compared to markets without authorized generic drugs. The dynamic effects indicate that in the year of the patent loss, the utilization of the sum of brand name drugs and authorized generic drugs increases by 3 percentage points in markets with authorized generic drugs, compared to markets without authorized generic drugs, and this coefficient increases to 12 percentage points in the first year after the patent expiration and 15.4 percentage points in the second year after patent loss.

[15]Before the patent expires, the observations refer to the brand name drugs. After the patent expiration, the observations refer to the sum of brand name drugs and authorized generic drugs.

Table 3.6 Column (4) shows the effects of authorized generic drugs on the utilization of standard generic drugs by estimating the equation (1.7). The average treatment effect is negative, which indicates that the utilization of standard generic drugs is lower in markets with authorized generic drugs. Moreover, the magnitude of coefficients become smaller from the year of patent loss to the second year after patent loss. From the year of patent expiration to the year after, the number of prescriptions decreased by 36.9 percentage points in markets with authorized generic drugs, and this coefficient increases to 2 percentage points in the second year after the patent expiration. As a result, it is reasonable to infer that the launch of authorized generic drugs attracts some consumers from the standard generic drug markets.

The effect on Medicaid amount reimbursed

Table 3.7 presents the 2SLS regression results of the effects of authorized generic drugs on total Medicaid amount reimbursement for an ingredient. Column (1) shows the effect on overall drugs (includes brand name drugs, authorized generic drugs and generic drugs). Column (2) shows the effect of authorized generic drugs on branded firm reimbursement (from both brand and authorized generic drug), Column (3) shows the effect on brand name drugs and authorized generic drugs, and Column (4) shows the effect on generic drugs.

Consistent with the results of Table 3.6, results in Column (1) show that the Medicaid reimbursement increases after a patent expires in markets with authorized generic drugs, compared to markets without authorized generic drugs. Moreover, the amount reimbursed by Medicaid in markets with authorized generic drugs is 34.8 percentage points higher than in markets without authorized generic drugs. Consistent with the increasing number of prescriptions, the Medicaid amount reimbursed increases in markets with authorized generic drugs. In the year of patent loss, the amount reimbursed by Medicaid in markets with authorized generic drugs is 36.5 percentage points higher than in markets without authorized generic drugs. These results suggest that the Medicaid spends more in markets with

authorized generic drugs.

Column (2) in Table 3.7 shows that with the entry of authorized generic drugs, the Medicaid amount reimbursed of brand name drugs decreased. In the year of patent loss, the Medicaid amount reimbursed decreased by 1.8 percentage points, and decreased by 33 percentage points in the second year after the patent loss. This suggests that the authorized generic drug is competing with the brand name drug and may cause a decline in the profit of brand name drugs.

While the effects of authorized generic drugs on the brand name drugs' reimbursement are negative, the coefficients are positive if I consider the overall reimbursement for the branded firm from its brand name drug and authorized generic drug. Table 3.7 Column (3) shows the average treatment effects when I consider both the reimbursement of authorized generic drugs and the brand name drugs. Dynamic effects in Column (3) show that the coefficients diminish from the year of patent loss to the second year after the patent loss. In the year of the patent loss, the Medicaid amount reimbursed for brand name drugs and authorized generic drugs increased by 17.9 percentage points in markets with authorized generic drugs, compared to the markets without authorized generic drugs. This coefficient decreases to 15.1 percentage points in the first year after the patent expiration and 14.2 percentage points in the second year.

Results of Column (3) in both Table 3.6 and Table 3.7 suggest that launching authorized generic drugs increases the total profits of branded manufacturers. Although authorized generic drugs compete with their own companies' brand name drugs, overall they earn higher reimbursement as a consequent of the authorized generic strategy.

The effects of authorized generic drugs on the generic drugs' Medicaid reimbursement are similar to the effects on the number of prescriptions. The Medicaid amount reimbursed for generic drugs decreases after the patent loss in markets with authorized generic drugs,

compared to the markets without authorized generic drugs. In the second year after patent loss, the Medicaid amount reimbursed for generic drugs decrease by 61.5 percentage points in markets with authorized generic drugs. Thus, I can infer that generic manufacturers are losing profits if there is an authorized generic drug on the market. Moreover, the expected profits are lower in markets with authorized generic drugs.

1.7 Conclusion

This study examines the impact of the entry of authorized generic drugs on the likelihood and timing of standard generic drug entry. Specifically, it explores the extent to which authorized generic drugs deter or delay the entry of standard generic drugs. I also examine the effect of authorized generic drugs on Medicaid utilization and Medicaid reimbursement. I test this analysis by using the instrumental variable approach together with the probit model and the proportional hazard model. This analysis provides a better understanding of the strategy used by branded manufacturers when deciding whether to introduce authorized generic drugs. At the same time, it explains why generic manufacturers may choose not to enter the market.

My results show that the launch of authorized generic drugs deters and delays the entry of standard generic drugs. Moreover, I find that the launch of authorized generic drugs increases the net profit of branded manufacturers, while the expected profits of generic manufacturers decrease. The fixed effect model with instrumental variable provides two notable results. First, the launch of authorized generic drugs decreases the utilization of the brand name drug and the amount of government (Medicaid) reimbursement. On the other hand, selling authorized generic drugs and brand name drugs at the same time increases the firm's net profits. Second, compared to markets without authorized generic drugs, in markets with authorized generic drugs, both the utilization and reimbursement of generic

drugs decline incrementally. This indicates that authorized generic drugs are attracting some generic consumers. It is reasonable to infer that with the introduction of authorized generic drugs, the expected profits of brand name manufacturers will increase and the expected profits of generic manufacturers will decrease.

There are some limitations in this paper. First, my analysis does not control for other strategies used by branded manufacturers, such as advertisement, the introduction of second-generic products, and the reformulation of drugs for sale over the counter rather than by prescriptions (Rx-to-OTC switch) after a patent expires. If branded manufacturers employ a mixed strategy, the effect of authorized generic drugs may be overstated. Second, the analyses on utilization and reimbursement amounts are based only on drugs covered by Medicaid which may present a selection bias. Third, this analysis only considers data within two years after the patent of a given drug expires.

There are two key implications of this paper. First, this strategy is effective in discouraging standard generic drug entry. Second, government bears the burden of this strategy in that they end of paying higher Medicaid reimbursement in the markets with authorized generic drugs. My results suggest that authorized generic drugs may decrease the incentive of generic manufacturers to enter the market. Consequently, there will be less competition in these drug markets, and perhaps will cause higher market concentration and ultimately raising the prices of both authorized and standard generic drugs and increasing government spending.

Chapter 2

Price Shocks and Health Behavior

2.1 Introduction

Over the past 20 years, drug prices have increased rapidly, making treatment for chronic diseases very costly. Summary statistics provided by the Medical Expenditure Panel Survey show that the average expenditure of prescription drugs in the year 2000 was $594 per year per person. By 2014, it had nearly tripled to $1792. The effects of drug prices have drawn a considerable amount of attention in the last 20 years. For example, using data from the National Health and Nutrition Examination Survey, Kahn (1999) shows that the cost reduction of diabetes treatment, induced by technological advancement, increases the probability of dieting, engaging in physical activity, and smoking fewer cigarettes. In this paper, I will examine the effects of drug price reduction induced by the entry of generic drugs on health behaviors such as physical activity, diet, and smoking.

The substantial savings from using generic drugs may cause a modification of health behavior. People influenced by price shock from medications for diabetes can be divided into two groups: those who had never taken any diabetes drugs, and those who took brand-name

diabetes drugs previously. Low-income patients who cannot afford brand-name drugs may be able to afford cheaper generic drugs. Drugs are more effective when coupled with good health behavior, so price shock may lead to positive effects on health. On the other hand, drug therapy may also reduce good health practices, since patients may see it as a substitute for good health behaviors and thus reduce physical activity. Another possible scenario is that for people who were taking brand-name drugs previously, using more affordable generic drugs instead of brand-name drugs will increase their real wealth and hence increase their ability to invest in good health behavior. Thus, price reduction may lead to a positive effect on health behavior.

In 2012, Huang et al. analyzed the effect of drug price adjustments on utilization and expenditures. Lexchin's paper in 2004 examined the effect of generic competition on the price of brand-name drugs. The entry of generic drugs expands access to health care because more people can afford drug therapy. Previous literature on this expansion always focused on the effects of new drugs or changes in insurance policies. For example, using information from the Framingham Heart Study, Kaestner et al. (2014) showed that the introduction of statins encouraged physical exercise but discouraged dieting. Klepser et al. (2007) analyzed the effect of switching from a copayment insurance plan to a coinsurance plan, and Joyce et al. (2002) examined the effect of changing drug benefit plans of employers. Although there are many studies to determine the effect of cost changes or expansion of healthcare on health behavior, papers directly addressing the effect of price reduction on health behavior are rare.

The increasing cost of drugs makes treatment for chronic disease, particularly diabetes, very costly. In this paper, I will investigate the effect of a drug price shock on health behavior in the context of diabetes care. According to the American Diabetes Association, in 2012, 29.1 million Americans (9.3% of the population) had diabetes, and 86 million Americans had pre-diabetes. In 2010, there were 234,051 deaths listing diabetes as an underlying

or contributing cause of death; in fact, diabetes is the 7th leading cause of death in the United States. Diabetes can cause many complications, such as hypoglycemia, hypertension, dyslipidemia, cardiovascular disease, hearth attack, stroke, eye problems, and kidney disease. These complications increase both the cost of treatment and the risk of death.

There are two major factors leading to the scarcity of papers that directly examine the effect of price shock on health behavior. First, drug prices change frequently, and small changes are unlikely to lead to a meaningful change in behavior. In this paper, I use the entry of generic drugs as the price shock in the brand-name drug market. Since generic drugs have the same formulation as the brand names but are much cheaper, the entry of generic drugs can be treated as price shock. The entry of generic drugs is also exogenous, because such entry depends only on the expiration date of brand-name drug patents and the size of the market.

Second, there are many factors that may affect health behavior, especially for people with chronic diseases, so choosing control variables is important. For example, physical exercise can help to increase the efficiency of insulin, so people with diabetes are usually encouraged to exercise more. However, patients with both diabetes and asthma are incapable of much physical exercise, so they may put more attention on their diets. MEPS data contains useful information I can use as control variables.

In this research, I use event study as my estimation strategy to investigate the effect of price shock on health behavior. Since different generic drugs enter the market at different times, I will use a set of dummy variables to indicate the relative year of the generic drug launch to examine the dynamic effect of the price shock.

Data for this study is drawn from full-year consolidated files and prescribed medicine files in the Medical Expenditure Panel Survey (MEPS). The full-year consolidated files contain

multiple variables: geographic, demographic, income and tax filing, employment, health insurance, disability, and health status. The prescribed medicine files contain drug names, types (generic or brand-name), and expenditures. The outcome variables I examine in this paper are physical exercise, diet, body mass index (BMI) and smoking. Physical activity is recommended to patients with non-insulin-dependent diabetes mellitus (NIDDM), because it increases sensitivity to insulin. A study by Helmrich et al. in 1991 provides evidence that physical activity is inversely related to the development of NIDDM, and the incidence rates decline as energy expenditure increases from less than 500kcal to 3500kcal. Diet is also very important to diabetes patients since the foods they eat are directly related to their blood sugar levels. When patients pay less for diabetes drugs, they may spend more on healthier food to further control their blood sugar levels. Smoking has been shown to increase the risk of type 2 diabetes (Eliasson, 2003). Drugs included in this study are from the article "A complete list of diabetes medications." From 2000 to 2014, seven brand-name diabetes drugs had generic versions in the market. I use the launch dates of generic drugs as the dates of price reduction.

The results show that price shock is negatively correlated with physical activity and diet. The effects on physical exercise are statistically significant from the first year after launch until the eighth year after launch. While the effects of price shock on physical activity is statistically significant, the effects on smoking and BMI are not. Lower drug prices lead patients to substitute this benefit for positive health behavior by decreasing the probability of physical exercise and diet control.

The rest of my paper is structured as follows: Section 2 discusses previous literature. Methodology and data are presented in Section 3 and 4. Section 5 shows the results and Section 6 discusses my findings and future studies.

2.2 Literature Review

Previous literature on the effects of price shock on health behavior has focused mainly on the expansion of access to insurance plans, which can reduce costs and change health behavior. Asfaw (2017) empirically examined whether the availability of Medicare Part D causes older patients with chronic diseases to complement or substitute this benefit by changing their health behaviors. The author found that the availability of Medicare Part D reduces the probability of engaging in physical exercise but did not find any evidence of an effect on diet and smoking, suggesting that access to Part D led patients to substitute coverage for good health practices.

For people who cannot afford to buy expensive brand-name drugs, the entry of generic versions provides access to medications they would not otherwise take. Kaestner et al. (2014) examined the effect of statin use on health behaviors. Using the data from the Framingham Heart Study and person fixed effect model, they empirically show that statin use is associated with a small increase in BMI and a significant increase in alcohol use. Statin use was also associated with an increase in physical activity among males and a decrease among females.

To examine the dynamic effect of this price shock, I followed the event study model by Reber (2005). Instead of the standard after-treatment indicator variable, she uses a set of dummy variables that indicate the relative year to the implementation year. This method can not only provide the dynamic coefficients, but also allows for a partial test of identifying assumptions by plotting the coefficients both before and after treatment.

2.3 Methodology

1. Event Study

In this section, I discuss the main regression I use in this research. When patents of brand-name drugs expire, generic drugs come on to the market very quickly, with the same formulations as the brand-name drugs at much lower prices. From 2001 to 2014, seven patents of seven brand-name drugs expired. Thus, seven generic drugs came on to the market at different dates. Instead of using an after-treatment indicator variable, I use a set of dummy variables that indicate the year relative to the launch year of a generic drug to examine the dynamic effect of the price shock.

The specification form of my estimation strategy is:

$$y_{it} = \alpha + \sum_{k=-5}^{k=13} \beta_k HAD_{k,it} + \delta GENERIC_{it} + X_{it} + F_t + F_{drug} + \epsilon_{it}$$

where y_{it} is the health behavior variable for person i in year t ($phyexe = 1$ if individual i currently spends half an hour or more in moderate to vigorous physical activity at least five times a week, $nofat = 1$ if individual i currently restricts to no fat food, $smoke = 1$ if individual i currently smokes). α is a constant. $GENERIC_{it}$ equals to 1 if person i is taking a generic drug in year t, and 0 otherwise. Note that $GENERIC_{it}$ will only be equal to 1 for some people after the launch of a generic drug. So the coefficient of $GENERIC_{it}$ captures the average treatment effect of using generic drugs. F_t is the year fixed effect. F_{drug} is the medication fixed effect and it controls for the same drug formulation. For example, for brand-name drug GLUCOPHAGE and its generic form metformin, they are both metformin, so $F(drug = GLUCOPHAGE) = F(drug =$ metformin). ϵ_{it} is the residual. $HAD_{k,it}$ is an indicator variable equals to 1 if year t is k years relative to the year of launch year. All years less than -5 are included in the -5 category.

Table 3.11 shows the descriptions of the health behavior variables and control variables used in my study. X_{it} is a set of control variables. I have controlled for family size, region, age, sex, race and ethnicity, marital status, education, income, poverty category,

employment status, insurance status, and the presence of other chronic diseases. I controlled for demographic variables because age, sex, race, education level, income and employment status all influence health behavior. Insurance status also impacts an individual's health behavior. For example, an individual without health insurance may engage in more physical exercise because he/she does not want to spend money on medications. The presence of additional chronic diseases may also influence health behavior and therefore is also controlled in my regression. For example, diabetes patient who also has asthma may not be able to engage in vigorous physical activity.

The inclusion of β_{-5} to β_{-1} allows me to do a partial test of identifying assumptions. Before the entry of generic drugs, health behavior variables should trend similarly across years, and the timing of implementation should be unrelated to trends. Thus prior to the entry of generic drugs, I expect to see a set of random coefficients insignificantly around zero with no trend. The trend of β_k describes changes in the trend in the health behavior variables associated with the entry of generic drugs. For example, $\beta_1 - \beta_0$ is the expected change in the outcome variable associated with moving from time zero to time one.

The availability and affordability of generic drugs could lead patients to substitute the drug for positive health behaviors, so the price benefit may lead to a negative effect on positive health behavior. In the case of substitution effect, I expect to see a set of negative β_k, indicating that price shock is negatively correlated with health behavior. Alternatively, the availability of generic drugs could lead people to engage in more positive health behavior if generic drugs are complements to health behavior. So in the case of complement effect, I expect to see a set of positive coefficients which means that price shock is positively correlated with health behavior.

2. Sub-analysis

To test whether the generic drug users engage in different health behavior after generic launch, I regress an interaction term $HAD_{k,it} \times GENERIC_{it}$ in addition to the variable $HAD_{k,it}$. People who are taking generic drugs can be divided into two groups - those who did not take brand-name drugs previously and those who did take brand-name drugs previously. People who are taking generic drugs are supposed to be affected by the launch of generic drugs, no matter whether they took brand-name drugs previously or not. Thus people who are taking generic drugs may act differently than people who continue taking brand-name drugs.

Thus, I add the following sub-analysis to my study:

$$y_{it} = \alpha + \sum_{k=-5}^{k=13} \lambda_k HAD_{k,it} \times GENERIC_{it} + HAD_{k,it} + X_{it} + F_t + F_{drug} + \epsilon_{it}$$

where the interaction term $\sum_{k=-5}^{k=13} \lambda_k HAD_{k,it} \times GENERIC_{it}$ allows me to identify the coefficients of generic users. Before the launch date of generic drugs, no one used generic drugs. Thus coefficients $\lambda_k = 0$ for all $k < 0$.

With the launch of generic drugs, I expect to see a negative coefficients of λ on *phyexe* and *diet*, which means generic users are less likely to take physical exercise than brand-name users, control their diets after the launch of generic drugs. And I expect to see a positive coefficients of λ on smoking, which means generic users are more likely to smoke cigarettes than brand-name drug users after the launch of generic drugs.

People in different age groups may have different health behavior and different levels of understanding of diabetes. Thus I grouped individuals into 9 groups. They are $age < 30$, $30 \leq age < 40$, $40 \leq age < 50$, $50 \leq age < 60$, $60 \leq age < 65$, $65 \leq age < 70$, $70 \leq age < 75$, $75 \leq age < 80$,and $80 \leq age < 90$. Because most individuals with diabetes are 60 to 80 years old, I grouped people under 60 years old by 5 years, and others by 10 years.

The specification form of the age sub-analysis is:

$$y_{it} = \alpha + \sum_{k=0}^{k=9} \gamma_k AGE_{k,it} \times GENERIC_{it} + HAD_{k,it} + X_{it} + F_t + F_{drug} + \epsilon_{it}$$

where the variable $AGE_{k,it}$ is a set of dummy variables for the nine age groups. The interaction term $AGE_{k,it} \times GENERIC_{it}$ allows me to analyze the effect of taking generic drugs on health behaviors for different age groups.

Since individuals in different age groups understand diabetes to different degrees, they may respond differently to the entry of generics. For example, young people may be careless about their disease, and they may need more money to live, thus taking generic drugs may substitute for their good health behavior. Older adults may prioritize treatment of chronic disease, and thus taking generic drugs may complement for their good health behavior.

2.4 Data

1. MEPS Data

   There are four datasets used in my study. Full year consolidated data files and prescribed medicine files are from the Medical Expenditure Panel Survey (MEPS). Four health behavior outcome variables are drawn from the full year consolidated data files. MEPS asks each respondent whether or not they currently spend a half hour or more in moderate to vigorous physical activity at least five times a week, restrict high cholesterol food, or smoke. As a combination of physical activity and diet, I also include BMI as one of the outcome variables. So the outcome variable $phyexe = 1$ if individual

i currently spends half an hour or more in moderate to vigorous physical activity at least five times a week, and zero otherwise. $nofat = 1$ if individual i currently restricts to no fat food, and zero otherwise. $smoke = 1$ if individual i currently smokes, and zero otherwise. The full year consolidated data files also include information about whether individual have diabetes or not. In this study, I include only individuals who have diagnosed diabetes. The prescribed medicines files contain information about drug expenditures such as out-of-pocket payment and total cost. It includes generic name, trade name, and amount paid by self or insurance. I can link the full year consolidated data files and prescribed medicines files using the unique person IDs assigned by MEPS to each respondent. FDA's NDC data file contains information of national drug codes and the marketing category name (generic drugs or brand-name drugs). I use the FDA's NDC file to merge with the MEPS data files, and thus I can identify the generic drugs or the brand-name drugs by the national drug codes.

MEPS tracks an individual over the course of one year, and has five rounds in a panel year. For variables *phyexe* and $nofat$, survey questions are asked in round 3 and 5, so I keep only the purchasing data from purchase round 3 and round 5 when I analyze the effect on physical activity and diet. For variable *smoking*, questions are asked in round 2 and 4, so I use data from round 2 and 4 to examine the effect on smoking. BMI is based on body weight and is therefore an indicator of health behavior. I grouped people with BMI ranges between 18.5 and 25 as "normal," 25-30 as "overweight" and above 30 as "obese."

Table 3.8 presents the summary statistics for my variables in selected years. The average age of my sample is about 60, their total income is around $20,000 per year and most of them are from low- to middle-income households. Since the average age is around 60, most of the respondents in my sample are unemployed and insured.

Table 3.9 shows some summary statistics of outcome variables. $phyexe = 1$ if the

subject currently spends half an hour or more in moderate to vigorous physical activity at least five times a week; on average the figure is 35%. $nofat = 1$ if the subject currently restricts high cholesterol food; the average is 70.24%. On average, 7.94% of my sample are in the normal BMI range, 88.35% are overweight, and 14.41% currently smoke.

2. Drugs Data

Drugs included in this study are from an article "A complete list of diabetes medications." In this article, diabetes medications are separated into two large categories: medications for type 1 diabetes and medications for type 2 diabetes. They are also categorized by their effects; for example, under the category of insulin, there are five different branches: short-acting insulins, rapid-acting insulins, intermediate-acting insulins, long-acting insulins, and combination insulins. For each drug in this article, I used the FDA website to determine its submission classification and approval date. In this study, I only include medications classified as type 1, "New Molecular Entity." Other diabetes medications are type 3 (new dosage form), type 4 (new combination) or type 5 (new formulation or new manufacturer). The price differences between generic forms of type 3, type 4 and type 5 medications compared with their brand-name drugs are not as extreme, so I will not consider these. From 2001 to 2014, seven brand-name drugs had generic forms launched in the market.

Table 3.10 is a summary table of drugs that have generic forms launched in the market from 2001 to 2014. Drugs with uppercase names are brand-name drugs and lowercase names are their generic forms. "# of purchases" is the total number of purchases in the year before or after the launch date of its generic version. "Average total cost" and "average self-payment" were calculated using data from one year before or after the launch date. From this table, we can see that GLUCOPHAGE is the most commonly used brand-name drug in the sample: There were 8,055 purchases in 2001,

one year before the launch date of its generic version, metformin, which appeared on the market on January 24, 2002. In 2003, there were 30,512 purchases of metformin. This suggests that many people used generic metformin rather than GLUCOPHAGE when it is available, or more people began to take medicine. The average total cost per month of GLUCOPHAGE in 2001 was $77.96, while the total cost of metformin in 2003 was $21.05, 72% lower than GLUCOPHAGE. The average self-payment per month of GLUCOPHAGE was $29.58 in 2001; for metformin in 2003 it was $6.42 (78% lower). For other drugs listed in the table 3.10, we can clearly see a lower cost of using generic drugs compared with using brand-name drugs.

2.5 Result

1. Physical Activity

   The effects of price reduction (induced by the appearance of generic alternatives) on physical activity are shown in table 3.12 and figure 3.8. "Years" indicates the year of purchase relative to the launch year of the generic drug.

   The average treatment effect is the coefficient of variable $GENERIC_{it}$ from the main equation. $GENERIC_{it}$ equals to 1 if individual i takes generic drug at time t, and zero otherwise. Note that $GENERIC_{it}$ can only equal to 1 for time after the launch of generic drug. Thus, the coefficient of variable $GENERIC_{it}$ captures the average treatment effect of all generic users.

   Table 3.12 column 1 shows the results of all observations. The average treatment effect shows that the price reduction is negatively correlated with physical activity. In

the year of the launch of generic drugs, the price reduction is significantly negatively correlated with physical activity, suggesting that people cut their exercise hours when they are able to acquire affordable generic versions of expensive drugs. There is no significant effect of price reduction on physical activity in the first and second year after the launch of generic drugs. From the third year, the price reduction starts to become statistically significant correlated with physical activity again. This result suggests that people are substituting the benefit of price reduction for regular physical exercise in both the short term and the long term. Figure 3.8 plots the coefficients on all individuals in the sample. The y axis is the coefficients and the x axis is the relative years to the launch year of generic drugs. Coefficients of $k = -3, -2$ are all negative and statistically insignificant, but coefficients of $k = -5, -4$ are positive and statistically significant. If the identification assumption is perfect satisfied, I expect to find that coefficients of $k < 0$ are statistically insignificant and around zero. Thus, the identification assumption is not perfectly satisfied in the case of physical exercise.

Table 3.12 column 2 shows the results of my sub-analysis. Coefficients for generic users are positive and significant for the second year and eighth year after the launch of generic drugs. This suggests that people who use generic drugs respond differently to the price reduction than people who use brand-name drugs, and people who use generic drugs are more likely to take physical exercise than brand-name drug users in the short term and long term. However, this positive effect only occurred in the two years. In the fourth and fifth year after the launch of generic drugs, coefficients of generic users become negative, suggesting that generic users are less likely to take physical exercise than brand-name users. Figure 3.9 plots coefficients of generic users from $k = 0$.

Analysis from the different age groups provides an interesting result. Individuals who are from 40 and 50 years old are more likely to engage in physical exercise after generic

drugs become available. This suggests that this age group is complementing the price benefit for physical exercise. However, individuals who are from 75 to 80 years old are less likely to exercise after the launch of generic drugs, and this suggests that old people are substituting this price benefit for physical exercise.

The results are reasonable. With the decrease in drug price, generic users can save money on medication and spend more on physical activity than brand-name drug users, so there are positive effects for generic users in the second year after generic drugs become available. Then, from the third year after the launch year, generic drug users are less likely to do physical exercise than brand-name drug users. For all individuals in the sample, the price reduction is negatively correlated with physical exercise, indicating that people do substitute the benefit of price reduction by reducing their physical activity.

2. Diet

The effect of price shock on diet is shown in table 3.14 and figure 3.10. Table 3.14 column 1 shows the coefficients for all individuals. The average treatment effect is negative and statistically significant, it means that the price reduction is associated with a lower probability of controlling diet. In the launch year of generic drugs, price reduction is negatively significantly correlated with diet. This suggests that people are less likely to control their diet after the launch of generic drugs. Figure 3.10 plots the coefficients of all observations. All the coefficients of $k < 0$ are statistically significant, suggesting that behavior was trending in a particular direction prior to the launch of the generic drug. Therefore, the identification assumption is not satisfied in the case of diet. Moreover, while some coefficients are negative, others are positive. As a result, there is no trend for diet after the launch of generic drugs.

Table 3.14 column 2 shows the results of my sub-analysis. For generic drug users,

the price reduction is negatively significantly correlated with diet. This indicates that generic drug users respond differently than brand-name drug users, and are less likely to control their diet after the launch of generic drugs. Figure 3.11 plots the coefficients of generic users.

Analysis for different age groups suggest that different age groups act similarly after the launch of generic drugs. Patients from all age groups are less likely to control their diet after the entry of generic drugs.

3. BMI

Table 3.16 shows the coefficients of the effect of price reduction on BMI. Column 1 and 2 show the coefficients for all observations. All the coefficients are negative when I use raw BMI and grouped BMI as the outcome variables, but the average treatment effects are statistically significant. In the fourth, seventh and eighth years after the launch of generic drugs. BMI is an indicator of healthy behavior, so a negative effect suggests that people are complementing the benefit of price reduction for positive health behavior. However, before the launch of generic drugs, some coefficients are statistically significant, indicating that the identification assumption is not satisfied in the case of BMI.

Although the price reduction does not alter consumers' BMI much, I do observe a set of statistically significant coefficients of price reduction on BMI for generic users. Column 2 of table 3.16 shows that generic drug users act differently than brand-name drug users. For generic users, BMI increases after the launch of generic drugs. Price reduction leads to an increase in BMI for patients who use generic drugs relative to those who use brand-name drugs. This suggests that price reduction leads generic users to substitute medication for good health behavior, thus affecting BMI. However, in the

long-run, the price reduction is negatively correlated with the BMI. This suggests that generic users are complementing the price benefit for good health behavior.

Analysis for different age groups provide an interesting result. For all age groups, generic entry is positively correlated with BMI, suggesting that people are less healthy after the launch of generic drugs. The positive coefficient is largest for people are less than 30 years old. From the results of BMI, we can infer that both young and old people substitute the price benefit for good health behavior.

4. Smoking

The effects of price shock on smoking are shown in table 3.19 and figure 3.14. The average treatment effect is positive but not statistically significant. Column 1 shows a negative significant correlation between price reduction and smoking in the third year and eighth after launch, indicating that subjects are less likely to smoke in this period. Figure 3.14 plots the coefficients of all observations. Before the launch of generic drugs, some of the coefficients are statistically significant and most of the coefficients are below zero. Trends in smoking were downward prior to the price shock, so the identification assumption is not perfectly satisfied in the case of smoking.

Table 3.19 column 2 shows the coefficients of generic users. For the year of launch and the first year after the launch of generic drugs, generic users are more likely to smoke than brand-name drug users. From the second year after the launch, generic users start to be less likely to smoke than brand-name users. However, in the seventh year after the launch of generic drugs, generic users are more likely to smoke than brand-name users. Figure 3.15 plots all the coefficients of generic users.

Analysis for different age groups reveals an interesting result. For people from 40 to 50 years old and 65 to 70 years old, the generic entry has a positive effect on smoking. This

indicates that individuals in those two age groups are more likely to smoke after the launch of generic drugs and tend to substitute the price benefit for smoking. However, people in the 60 to 65 group are less likely to smoke after the entry of generic drugs.

2.6 Conclusion and Discussion

1. Conclusion

   This paper analyzes the effect of price shock on physical exercise, diet, BMI and smoking. Using information from the Medication Expenditure Panel Survey and a drug list, the results show that the price shock is negatively correlated with physical exercise and diet. These results suggest that people are less likely to engage in physical exercise and control their diet after the price reduction. After the launch of a cheaper generic version of a drug, people substitute the price benefit for positive health behavior by reducing the probability of physical exercise and diet control. While the effects on physical exercise and diet are statistically significant, effects of price shocks on smoking and BMI are not statistically significantly different from zero.

   The results are consistent with some previous literature. For example, Asfaw (2017) finds that the expansion of health care reduces the probability of engaging in physical exercise, which is consistent with my results on physical exercise. The results of my study not only reveal the effect of price shock on health behavior, but also reveal this effect dynamically. In the context of diabetes drugs, I find the price shock, induced by the launch of generic drug, substitutes for positive health behaviors.

2. Further research

(a) Data

One important limitation of this study is that MEPS data is not panel data. Since health behavior is affected by many unobservable personal factors including family members, it will be much better to use a person-fixed effect model instead of an event study model with control variables. Another issue is that with the MEPS data, I cannot observe the behavior of those who used brand-name drugs previously and switched to generic drugs, and thus it is impossible to use a difference-in-difference strategy. There are some panel datasets that may allow me to do the person fixed effect model and use difference-in-difference strategy, such as the Framingham Heart Study data. In the next stage of my research, I will use panel data and a difference-in-difference strategy to analyze the effect of price shock.

The other concern of this study is the outcome variable. The MEPS questions regarding health behaviors were not very detailed, so the measure may not reveal some changes in health behaviors such as exercise. For example, MEPS asks each respondent whether they currently spend half an hour or more in moderate to vigorous physical activity at least five times a week. Consider the case of an individual who spent half an hour or more in moderate to vigorous physical activity three times a week previously, and after the launch of generic drugs, he/she spent a half hour or more in moderate to vigorous physical activity four times a week. He/she changed his/her behavior, but the answer of physical activity questions are "no" both before and after the launch of generic drugs. Thus, we cannot observe any difference using the rough questions.

(b) Time

Data used in this paper are from the Medical Expenditure Panel Survey from 2001 to 2014. At the end of 2016, a bio-similar insulin came on to the market.

For diabetes patients, insulin is often necessary but expensive; the existence of a bio-similar insulin will likely reduce the expenditure of insulin. Thus, including data from 2017 will increase the precision of the effect of price shock on health behavior.

Chapter 3

The Effect of State Generic Substitution Laws on the Generic Utilization and Market Competition

3.1 Introduction

Healthcare expenditures have risen drastically in the United States over the past several decades. In 2017, U.S. health care costs reached $3.5 trillion, equal to 17.9% of the gross domestic product, and 9.5% of this spending went towards prescription drugs [1]. Moreover, the cost of brand-name oral prescription drugs rose more than 9% per year from 2008 and 2016, while the annual cost of injectable brand-name drugs rose more than 15% (Hernandez et al., 2019). Generic drugs are required to be clinically equivalent to brand-name drugs, but are much less expensive (Corrao et al, 2014; Kesselheim et al,. 2008; Richard Frank, 2007). As a result, prescribing generic drugs instead of brand-name drugs is an effective way to control prescription drug expenditure. However, state governments have few tools to influence Medicaid enrollees' prescription drug use. By adopting a generic substitution law that encourages the substitution of generic drugs after patents expire, states may greatly reduce the amount spent on prescription drugs. Different states have different generic drug substitution laws to encourage the use of generic drugs. Shrank et al. (2010) note that some states use mandatory generic substitution policies, which require pharmacists to substitute a generic for a brand-name medication if the prescriber does not specify that the latter drug should be used. More permissive generic substitution laws enacted in other states give pharmacists more discretion by allowing, but not requiring, pharmacists to substitute generics. The goal of the mandatory policies is to increase the use of generics and decrease the use of brand-name drugs, however, there is little empirical evidence about these effects. It is also possible that these policies may lower the market advantage of brand-name drugs and thus may affect market competition. The key research question in this study is whether mandatory generic substitution laws effectively increase the use of generic drugs, lower the use of brand-name drugs, and consequently lead to a reduction in overall spending on drugs.

Generic substitution laws do not affect the behavior of physicians; they merely regulate

[1] https://www.cdc.gov/nchs/fastats/health-expenditures.htm

dispensing procedures used by pharmacists. Previous literature shows that consumer preference for brand names is difficult to change (Ling, Berndt, and Kyle 2002, Beshears et al. 2013, Carrera and Villas-Boas 2013, Bronnenberg et al. 2015). As a result, it is important to examine which type of policy could effectively increase generic utilization. Intuitively, the switch to a mandatory policy or any less discretionary policy could increase the utilization of generic drugs. Under the permissive generic substitution laws, the brand-name drugs may retain their market advantage, whereas generic drugs may gain a market advantage under the mandatory laws. As a consequence, switching to a mandatory policy may increase the prescription drug market share of generic drugs, lower the prescription drug market share of brands, and thereby reduce the overall expenditure on drugs.

Some studies indicate that generic substitution laws increase the use of generic drugs, but evidence is limited. Goldberg et al. examined the effect of law change between 1974 to 1977, and Carroll et al. found generic substitution rate was higher in states with less discretionary laws based on the data from 1981 to 1984. However, generic drugs represented only a tiny proportion of filled prescriptions before 2003, and the drug market has changed dramatically since then (Aitken et al. 2008). A more recent study is conducted in 2007 by Anderson et al., but their study examined law changes in Sweden, which has a very different health care delivery system than the United States has.

Only two recent studies have analyzed the effect of generic substitution laws on the utilization of generic drugs in the U.S. drug market. Shrank et al. (2010) found that states implementing permissive policies experienced 25% lower rates of generic substitution relative to states with the mandatory policies. They also found that prices per prescription are much lower in states that do not require patient consent for generic substitution than in other states. However, their study focused on only one drug, and they did not have a strong identification strategy to determine a causal effect of the laws.

Song and Bathold (2018) found less discretionary policy reduced the probability of

purchasing brand drugs by 4.1%. However, their study only considered a limited number of drugs. Also, they did not distinguish between generic drugs and authorized generic drugs (the generic drugs produced by brand-name drug firms). Authorized generic drugs have higher prices than traditional generic drugs. So a shift to authorized generics instead of traditional generics may result in less savings. Among the nine drugs they examined, five had authorized generic alternatives enter the market during their analysis period. If a brand-name drug has both an authorized generic drug and a standard generic drug on the market, pharmacists may be more willing to dispense the authorized generic version instead of generic version even under the permissive laws, since the authorized generic drug is identical to the brand-name drug. As a result, the change from permissive to mandatory laws may not be effective in reducing spending for drugs that have authorized generic versions on the market. Third, the study used data from the Medical Expenditure Panel Survey (MEPS) and only included individuals who bought brand-name drugs before the law change; they did not consider individuals who did not buy the brand-name drugs before the law change but started to buy generic drugs after the law change. Thus, they could only show whether the change of laws affected people already using brand-name drugs. Fourth, they did not test whether the assumption of difference-in-differences research design is valid. Finally, they found that a switch to a mandatory law would not increase generic utilization. However, mandatory laws are likely to have some impact since they require pharmacists to default to generic drugs.

My analysis uses prescription drug sales data from Medicaid and a difference in differences approach to analyze the effect of generic substitution laws on drug utilization and Medicaid reimbursement. I exploit differences in the timing of law changes across states to examine these effects. I also conduct an event study model to determine whether there are pre-trends, add joint tests for the pre-period coefficients, and add state-specific year trends for different states to test the validity of my empirical model.

My results show that mandatory laws do lead to an increase in the use of generic

drugs, and less discretionary laws will lead to a decrease in amount of reimbursement of brand-name drugs. However, contrary to expectation, I find the less discretionary laws will lead to an increase in overall reimbursement for all drugs. I also find the prescription drug market share of authorized generic drugs increased after the passage of less discretionary laws. Moreover, I find that although average prices for generic drugs declined, the average prices for brand-name drugs and authorized generic increased, which may help explain why overall reimbursement went up.

My results provide evidence about the effectiveness of generic drug substitution laws and show that while some objectives are accomplished, some unanticipated effects are revealed. First, it tests whether the generic substitution laws are effective in increasing the generic utilization by using an improved methodology and a broader set of drugs in the study. The results of this study indicate that switching to a mandatory policy will increase generic utilization and decrease brand name utilization.

Second, this is the first study to examine the effect of generic substitution laws on prescription drug market shares and average reimbursed prices. While the literature focuses on the effect of substitution laws on the utilization of generic drugs, previous research has not examined on the impact of those laws on market concentration. However, by switching to less discretionary generic substitution laws, generic drugs may gain a market advantage. Thus, prescription drug market shares and average reimbursed prices may change. I find that a switch to a less discretionary law will result in an increase in prescription drug market shares of authorized generic drugs. These law changes will also cause a lower average price for generic drugs, and a higher average price for brand-name drugs and authorized generic drugs.

Third, my results have important policy implications. Since the generic substitution laws are effective in increasing the utilization of generic drugs, generic manufacturers may expect to see more profits after entering the market. As a consequence, more generic manu-

facturers may choose to enter the market when there are mandatory substitution laws or less discretionary laws, which could increase competition and put downward pressure on generic drug prices. However, my results also show that the average prices for brand-name drugs and authorized generic drugs increase with the mandatory substitution laws. Such price changes may not have been anticipated by policymakers and may serve to increase overall drug spending.

The paper proceeds as follows: Section 2 contains the background and literature review. Section 3 discusses data I use in the study. In section 3, I describe the methodology and assumptions. Section 4 discusses the results, and section 5 offers some conclusion.

3.2 Background and Literature Review

3.2.1 Background

There are two types of generic substitution policies that have been used by the states. The first type regulates whether it is mandatory or permissive for pharmacists to substitute a generic drug for its brand-name equivalent. It regulates pharmacists' options when they are filling a prescription for a brand-name drug. Under mandatory substitution laws, pharmacists must default to the generic drug. However, under permissive substitution laws, pharmacists can prescribe the generic drug for consumers, but it is not required. One example of a mandatory substitution law is this 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, generally equivalent drug product." (Florida Legislature, 2016) One example of a permissive substitution law is from Illinois: "A 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."

(Illinois Legislature, 2016)

The second type of law regulates whether the patient's consent is presumed or has to be explicitly acquired. Under the presumed consent laws, pharmacists assume that the patient agrees with the generic substitution unless the patient explicitly rejects the substitution. The consent laws require that pharmacists ask for patients' permission to switch to a generic drug. One example of a presumed consent law from Massachusetts merely requires notification of the substitution on the label: "The pharmacist shall indicate on the label in the following manner the fact of the interchange: 'Interchange: (name of exact drug product dispensed'." (Massachusetts Legislature, 2016). One example of an explicit consent law is the legislation of 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." (Pennsylvania Legislature, 2016).

Note that a state can choose any combination of the two types of policies. Table 3.20 shows the summary statistics of the state laws in 2016. At that time, ten states were using mandatory policies, while the other 38 states in the dataset were using permissive policies. Nine states are using presumed consent laws and 39 states are using explicit consent laws.

Table **??** shows the changes of laws from 2006 to 2012. In total, 13 states have changed their generic substitution laws: Seven changed from permissive to mandatory policies, and two changed from mandatory to permissive policies. Moreover, two states changed from explicit consent laws to presumed consent laws, while two states changed from presumed consent laws to explicit laws.

3.2.2 Literature Review

Previous studies provide evidence that the preference for brand-name drugs is hard to change. Beshears et al. (2013) show 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. Ling et al. (2002) showed that a large fraction of consumers indicate a preference for brand-name drugs, even though generic substitutes are available for much lower prices. Moreover, Carrera and Villas-Boas (2013) found that even when consumers have full knowledge of the comparability of generics and brand-name drugs, the information has no effect on their utilization of generic drugs.

State generic substitution laws are used to increase generic substitution rates. They are proven to be effective, but evidence is limited and not convincing. Goldberg et al. examined the change of Michigan generic substitution law on generic substitution between 1974 and 1977. In 1974, Michigan started to allow pharmacists to exercise their judgment in selecting the product to be dispensed. Their results indicated that this law change effectively decreased government expenditure on prescription drugs. Carroll et al. found that generic substitution rate was higher in states that did require patient consent prior to substitution. However, their study is based on drug utilization data from 1981 to 1984. A more recent study of generic substitution laws was conducted by using Sweden's drug data. The authors found that the Sweden's generic substitution laws would increase generic use (Anderson et al. 2007).

Shrank et al. (2010) and Song and Barthold (2018) are the only two recent studies that have analyzed the effect of state generic substitution laws in the U.S. drug market. Shrank et al. (2010) analyze the laws' impacts on the generic substitution ratio for the cholesterol-lowering drug Zocor (simvastatin). They find that states implementing permissive policies experienced 25% lower rates of generic substitution. By using data from the Medical

Expenditure Panel Survey and a difference-in-differences methodology, Song and Barthold (2008) showed that mandatory laws did not have any effect on generic utilization, while permissive laws reduced the probability of purchasing brand drugs by 4.1%.

Previous literature about generic substitution laws are either too old or not in the context of U.S. drug market. Two recent studies did not consider all prescription drug markets, and they did not investigate the effect of less discretionary laws on prescription drug market shares and average drug prices. As a consequence, a study that uses recent data from U.S. drug market and considers all drug markets is needed.

3.3 Data

I use quarterly Medicaid drug utilization data in each state from the Centers for Medicare and Medicaid Services. These state-level data include the total number of prescriptions filled, total units of drugs reimbursed, and Medicaid reimbursement for each drug. To get the detailed information of each drug, I use the National Drug Codes(NDC) to merge the Medicaid utilization data file with FDA's NDC data file. The FDA's NDC dataset includes marketing category name[2], patent information (expiration date and patent holder), market approval dates, nonproprietary names, proprietary names, available strength, drug forms, and therapeutic fields. I also use drug classification data from the Anatomical Therapeutic Chemical Classification System using the INN (International Nonproprietary Name) to get the therapeutic field of each drug (ATC3 is used in the analysis).

I use population data from the American Community Survey (ACS) to calculate the per-capita utilization of generic drugs. The ACS collects information on approximately three million people each year covering over 92% of the U.S. population. The survey is conducted on a monthly basis with estimated populations for each state and different age groups. I

[2]It is an identification of brand-name drug, standard generic drug and authorized generic drug

limit the sample to non-disabled adults between the ages of 18 and 64.

To characterize state generic substitution laws, I reviewed policies and years of implementation used in previous studies with particular attention to information in Song and Barthold (2018) and Shrank et al. (2010). Shrank et al. (2010) listed the state generic substitution laws for 44 states in 2006. Song and Barthold (2018) listed all the states that changed their generic substitution laws from mandatory to permissive and from permissive to mandatory from 2006 to 2012.

Figure 3.16 shows the average units reimbursed by Medicaid from 2006 to 2012. On average, 3,932 million units of brand-name drugs were reimbursed by the Medicaid program each year, and 9,269 units generic drugs were reimbursed. Figure 3.17 shows the average amount reimbursed by Medicaid from 2006 to 2012. On average, $6,613 million was reimbursed by Medicaid for brand-name drugs, and $2,616 million were reimbursed for generic drugs.

3.4 Methodology

To examine the effect of generic substitution laws, I exploit differences in the timing of law changes across states. Since the generic substitution laws will only affect drug markets with generic drugs, I limit the sample to drug markets whose patents have expired and have generics available. To test the effect of switching from permissive to mandatory laws, I use states who changed their substitution laws from permissive to mandatory between 2006 and 2012 as my treatment group. I also test the effect of switching to a less discretionary law, meaning the state changed from a permissive to a mandatory law or from an explicit consent to a presumed consent law.

The treatment group in this analysis includes states who changed their substitution

law from permissive to mandatory or from explicit consent to presumed consent from 2006 to 2012. The control group includes states who used permissive laws and explicit consent laws in 2006 and did not change their substitution laws during my sample period. I use the information about state generic substitution laws in Shrank et al. (2010), they listed the state generic substitution laws for 44 states in 2006. 33 states were using permissive generic substitution laws and explicit consent laws in 2006, so they are included in my data sample. In total, I have 8 treatment states, and 25 control states in my sample [3]. Moreover, there are 1,385,789 observations in my data sample. Among them, 264,886 observations are brand-name drugs, 1,072,316 observations are standard generic drugs, and 48,587 observations are authorized generic drugs.

Drug utilization in a state is measured in terms of log units reimbursed by Medicaid, log number of prescriptions, and log amount reimbursed by Medicaid. The estimating equation is defined below, and standard errors are clustered at the state level.

$$Outcome_{dst} = \alpha + \beta \cdot Treat_s POST_{st} + F_s + F_t + X_{dst} + \epsilon_{dst} \tag{3.1}$$

In equation 1, the dependent variable is "log units reimbursed", "log number of prescriptions", and "log amount reimbursed by Medicaid" for drug d in state s and year t. The unit of observation is the state-year-quarter-drug. $Treat_s$ is a policy indicator for whether the state has changed its law from permissive to mandatory (or to a less discretionary law). It equals to one if state s changed its generic substitution law from permissive to mandatory (or to a less discretionary law), and zero if there were no changes to the state's generic substitution law. $POST_{st} = 1$ if time t is after the change of state law, and zero otherwise. F_s is the state fixed effect. F_t is the time (year-quarter) fixed effect.

[3] I excluded 11 states. Nine of them were using mandatory laws from 2006 to 2012, two of them were using mandatory laws in 2006 and switched to permissive laws during my sample period.

X_{dst} is a set of control variables. I controlled for drug classification by using ATC3, since different drug classes may be affected differently under the law changes [4]. I also controlled for drug age [5], since there may be differences between generic drugs that have been on the market for years compared to those launched recently. For example, suppose there are two drugs, one launched over five years ago, the other one just launched one year ago. After states change their generic substitution laws, the recently launched drug may be affected more than the older generic drug. Older generic drugs may be more familiar to patients and healthcare providers than newer ones, so they will use generic drugs even under the permissive laws. Since consumers may not know the newer generic drugs, under the explicit consent laws, consumers may refuse to substitute to a newer generic drug that they are not familiar with. Thus, a mandatory switch may have a larger effect on new generic drugs. I also controlled for drug markets with or without authorized generic drugs. Authorized generic drugs are the generic drugs produced by brand-name manufacturers and are identical to the brand-name drug. As a result, pharmacists may be more willing to dispense those to consumers over standard generic drugs. Because price of authorized generic drug is higher than price of generic drug, as more consumers are using authorized generic drugs instead of generic drugs, generic substitution laws will be less effective in cost reduction. Although the total number of prescriptions of authorized generic drugs is only about 5% of all drugs, omitting the category is likely to cause biased results in expenditure of all generic drugs.

The main goal of generic substitution laws is to decrease government spending on prescription drugs, so I estimate whether mandatory switching and less discretionary switching will lead to a decrease in government spending on all prescription drugs [6]. I use the same specification as equation (1) with the outcome variable "Medicaid amount reimbursed of all drugs" to identify the effect of law changes on total Medicaid reimbursement on prescription drugs.

[4] I also tried to have the drug specific fixed effect, and all estimates are similar with the control of ATC3.
[5] Drug age is a drug's time on the market.
[6] All prescription drugs include brand-name drugs, generic drugs, and authorized generic drugs.

Although mandatory switching and the presumed consent switching may increase generic use, they may also reduce the use of brand-name drugs and limit a brand's market advantage. Moreover, generic manufacturers will expect to see more profits with the increasing number of states using mandatory laws or presumed consent laws instead of permissive laws or explicit consent laws. Thus, more generic manufacturers may be willing to enter into the market, thereby increasing the generic competition in the market. As a consequence, mandatory switching and less discretionary switching may be expected to lower the average reimbursed prices for generic drugs.

I test whether the law change will affect prescription drug market shares, market concentration and average reimbursed prices. Prescription drug market share is defined as the number of prescriptions of drug d in state s in time t divided by the total number of prescriptions of drug market j in state s and time t. To calculate market concentration, I use the Herfindahl-Hirschman index (HHI) as the measurement. The HHI is calculated by taking the prescription drug market share of each drug j in each drug market d, squaring them and then summarizing the results. HHI ranges from 0 to 10,000: The higher the HHI, the more concentrated the market is. The average reimbursed price is calculated by taking Medicaid amount reimbursed and dividing by number of prescriptions, so the average reimbursed price in my analysis is the amount reimbursed per prescription.

The difference-in-differences research design represented by equation 1 assumes that under the assumption that, in the absence of a law change, outcomes would be the same. To test the validity of this assumption, I follow the approach of Autor(2003) to test the parallel trends assumption.

First, I estimate a model that examines whether there are differences in trends in outcomes in periods prior to the change of state policies. This model tracks the difference in outcomes in periods up to and following the event, which in this case is the change of state generic substitution law. I added a series of dummy variables for each year and interact them

with the treatment variable. I then examine the β coefficient for these interaction terms in the years prior to the law change and test to see if the coefficients prior to the law change are jointly different than zero. The p values for those tests are reported in each table of results. The estimating equation is straightforward in this case:

$$Outcome_{dst} = \alpha + \sum_{k=-4}^{12} \beta_k \cdot Treat_s \cdot POST_{st}^k + F_s + F_t + X_{dst} + \epsilon_{dst} \tag{3.2}$$

The specification is similar to equation 1 with the exception of the new interaction terms and β_k. $POST_{st}^k$ equals to 1 if time t is k years relative to the law change year, and zero otherwise. The pattern of β_k describes the change in the trend in the left-hand-side variable associated with the law changes. For example, $\beta_1 - \beta_0$ is the expected change in the dependent variable associated with moving from year 0 to year 1 (from law change year to one year after law change), controlling for the calendar year. I also balanced the panel to 4 quarters before the law change and 12 quarters after the law change [7].

Evidence for a valid design is that there is no divergence between the trends in outcomes (number of prescriptions, units reimbursed, and Medicaid amount reimbursed) in periods prior to the change of state laws. Thus, if the timing of law change is unrelated to the underlying trends and individuals do not respond before the law change, there should be no trend in the for $k < 0$. I test this by conducting the joint test of pre-policy coefficients and I report the p-value in each table. The coefficients of βs in the difference-in-differences model are valid if I fail to reject the joint significant of the pre-policy coefficients β_k.

[7] Same balanced data sample for equation 1

3.5 Results and Discussion

3.5.1 Effect of Law Change on Generic and Brand Utilization

This section describes the effect of law changes on generic drug use (generics and authorized generics) and brand-name drug use. I estimated difference-in-differences model for three dependent variables: log units reimbursed by Medicaid, log number of prescriptions, and log amount reimbursed by Medicaid. Coefficients of estimating equation 1 are presented in Table 3.23 and Table 3.24, the p values reflect whether or not there is a pre trend from the estimation of equation 2.

I first examined whether changing from permissive to mandatory law or changing to a less discretionary law (from permissive to mandatory or from explicit consent to presumed consent) will increase generic drug utilization. Figures 3, 4, and 5 show the coefficients from the interaction terms from the pre trends test, and p-values in Table 3.23 shows the results of joint tests of pre-policy coefficients. Figure 3.18 shows results for all generic drugs when generic utilization is measured as log units reimbursed by Medicaid. Figure 3.19 shows results for all generic drugs when generic utilization is measured as number of prescriptions. Figure 3.20 shows results for all generic drugs when generic utilization is measured as log amount reimbursed by Medicaid. As can be seen from Figures 3, 4, and 5, most of the coefficient estimates on the pre-policy variables are statistically insignificant in the models with state linear trend. In addition, when estimating the effects of mandatory switching on log of number of prescriptions and units reimbursed, results from F-tests of the joint significance of the pre-policy coefficient estimates in column (1) and (2) do not reject the null hypothesis that estimates are jointly equal to zero. As shown in columns (1) and (2), switching from permissive to mandatory laws will increase the number of prescriptions of generic drugs, and the coefficients are statistically significant in both models with and without state linear trend. As a result, I can conclude that the mandatory switching caused an increase in

number of prescriptions of generic drugs.

The magnitude of the effect of mandatory switching on the number of prescriptions is not trivial. Specifically, the average treatment effect in column (2) shows that with the switch to mandatory laws, the number of prescriptions will increase by 5.6%. The mean number of prescription is 1,061 per drug per state per quarter. Evaluated at the mean, this represent an increase of 59 prescriptions per generic drug per quarter on average in the states.

Similar to the effect on number of prescriptions, the mandatory switching is associated with an increase in units reimbursed. On average, there is a 4.3% increase in states who changed their laws from permissive to mandatory. The average units reimbursed for each drug in a state is 30,856 units per quarter. A 4.3% increase in the states with mandatory switching represents an increase of 1,326 units of reimbursement per drug per quarter.

Although the effect of mandatory switching is statistically significant on the amount of reimbursement of generics, the common trends assumption does not hold. The estimation of the effects of less discretionary switching on three outcomes do not pass the F-tests of the joint significance of the pre-policy coefficient estimates.

The effects of law change on the use of brand-name drugs are presented in Table 3.23. The plot of the coefficients from the pre-trends test are shown in Figures 3.21-3.23. As can be seen Table 3.23 column (2), the p-value of the F-test of the joint significance of the pre-policy coefficient estimates does not reject the null hypothesis that pre-policy estimates are jointly equal to zero when the outcome variable is the log of units. The coefficient estimate shows that mandatory switching is significantly negatively correlated with units reimbursed. This means that with the mandatory switching, the units reimbursed of brand-name drugs will decrease by 8.4 %. Evaluated at the mean, this effect translates into a decrease of 5,281 brand-name drug units per state per quarter.

The p-value of the joint test of pre-policy coefficient estimates does not reject the null hypothesis when analyzing the effect of less discretionary switching on log of amount of reimbursement. The coefficient estimate is reported in column (4). I find that the less discretionary law will lead to a decrease in amount of reimbursement of brand-name drugs by 86.8%. Evaluated at the mean, this represent a decrease of $69,227 on average in the states.

Overall, my results provide evidence that the mandatory generic substitution laws did lead to an increase in the number of generics dispensed and a reduction in brands dispensed among Medicaid recipients. There is also evidence that Medicaid brand reimbursement in the states with less discretionary generic substitution laws declined. The results for brand-name drugs are consistent with the objectives of the policy. This shows the mandatory switching will decrease the units and amount reimbursed of brand-name drugs. As a result, I can infer that the generic substitution rate is higher after mandatory switching.

3.5.2 Effect of Law Change on Medicaid Reimbursement

In this section, I present the effect of law changes on Medicaid expenditure for all prescription drugs. All results are shown in Table 3.25. Specifically, columns (1) and (2) are the results of changing from permissive to mandatory laws, while columns (3) and (4) are the results of changing from permissive to mandatory laws or from explicit consent to presumed consent laws. As can be seen in Table 3.25 columns (2) and (4), the p-values suggest that there is not a pre-trend. Coefficients of average treatment effects are positive and statistically significant, indicating that switching to a less discretionary law will increase Medicaid expenditure on all prescription drugs.

Moreover, the effects on amount reimbursed are large. As can be seen in column (2), mandatory switching is associated with a 119.5% increase in reimbursement for Medicaid

prescription drugs. Results in column (4) suggest an 84.3% increase in Medicaid expenditure for states who changed to less discretionary laws.

The positive impact of the laws on overall reimbursement presents a puzzle. However, the law change may affect the market competition in each drug market. As a result, the average reimbursed prices may change and the total reimbursement may increase[8]. I test the effect of law change on the prescription drug market share and average reimbursed price, and report the results in the next subsection.

3.5.3 Effect of Law Change on Prescription Drug Market Share and Market Concentration

In this section, I show the effect of law changes on prescription drug market share, market concentration, and average reimbursed prices.

Table 3.26 presents the results of the effect of switching on prescription drug market share and market concentration. Figure 3.25 shows the plot of coefficients from the pre-trend test. Table 3.26 column (1) shows the effect on the prescription drug market share of brand-name drugs, column (2) shows the effect on standard generic drugs (without authorized generic drugs), column (3) shows the effect on authorized generic drugs, and column (4) shows the effect on market concentration (calculated using HHI).

The coefficient estimate on authorized generic drugs is positive and statistically significant, and it also passes the F-test of joint significance for pre-policy coefficients. This means that the prescription drug market share of authorized generic drugs increased after states changed to less discretionary laws. With a less discretionary law enacted in a state,

[8]Two states changed from mandatory laws to permissive laws and two states changed from presumed consent laws to explicit consent laws between 2006 and 2012. The increasing expenditure on Medicaid prescription drugs may be the reason for the switch back to a discretionary law.

pharmacists will not only dispense more standard generic drugs, but also more authorized generic drugs. Thus, the use of authorized generic drugs is expected to increase and the prescription drug market share of authorized generic drug will increase.

The coefficient of average treatment effect on brand-name drugs is positive and statistically significant. However, it does not pass the F-test of joint significance for pre-policy coefficients. Although we can reject a pre trend for the analysis on standard generic drugs, the coefficient of average treatment effect is not statistically significant. As a result, there is no clear evidence that the mandatory laws or the less discretionary laws affect the prescription drug market share of brand-name drugs and standard generic drugs.

I did not find any evidence that the law change affects the market concentration measure, HHI.

Table 3.27 shows the effect of law changes on average Medicaid reimbursements for brands, generics, and authorized generics. Figure 3.26 shows the plot of coefficients from the pre-trend test.

From column (1), the coefficient of the average reimbursed price of brand-name drugs is positive and statistically significant, indicating that the mandatory switching cause an increase in brand-name drugs' reimbursed prices. Moreover, the magnitude of this effect is not trivial. With mandatory switching, the average reimbursed price of brand-name drug increased by $35.62. While the average reimbursed price of brand-name drugs is $225.08, the mandatory switching increased reimbursed prices of brand-name drugs by more than 15%.

In column (2), the coefficient of average reimbursed prices for standard generic drugs is negative and statistically significant, which means that mandatory switching leads to a decrease in the prices of standard generic drugs. On average, mandatory switching is associated with a $2.14 decrease in average reimbursed prices of standard generic drugs. This effect represents 7.3% of the average generic drug reimbursement. Moreover, less discre-

tionary switching will lead to a $1.59 decrease in average reimbursed prices of standard generic drugs.

Since the laws encourage more use of generic drugs, they may also lead to more entry and competition among generic drug manufacturers. As a result, more generic drugs may come into the market. The stronger competition in standard generic drug markets will lead to a decrease in generic drug prices.

In contrast, the coefficient estimate on the average reimbursed price of authorized generic drugs is positive and statistically significant, which means that mandatory switching is positively associated with an increase in the reimbursed price of authorized generic drugs. On average, mandatory switching will cause an increase of $3.45 for authorized generic drug reimbursed prices, a difference of 9.3%.

While brand manufacturers are losing profits under the mandatory laws, some may choose to compete by selling an authorized generic drug. The results for reimbursement prices of brand-name drugs compared to authorized generic prices are consistent with previous literature on prices of brand-name drugs after generic entry. Most previous studies provide evidence that with the generic entry, brand name firms will increase drug prices. Frank and Salkever (1997) studied a sample of 32 drugs that lost patent protection during the early to mid 1980s and found that brand-name prices increase after generic entry. Lexchin (2004) found evidence that with an increasing number of generic drugs available in the market, the brand-name drug's price will increase. Consistent with previous studies, my study shows that with the law change, the brand manufacturer will increase both the brand-name drug's price and the authorized generic drug's price to maximize their profits. This may help to explain why overall drug reimbursement goes up with the law changes. Policymakers may not have anticipated the strategic response of the brand name industry to the law changes.

3.6 Conclusion

This study examines the effect of state generic substitution laws on the use of generic and brand-name drugs, drug market concentration, and average reimbursed prices. Specifically, it explores the effect on the drug market after changing a state's policy from permissive to a mandatory substitution policy, and the combined effect of changing from permissive to mandatory policy or from explicit consent to presumed consent policy. My analysis examines these effects using Medicaid prescription drug data from the states and a difference-in-differences methodology. This analysis provides a better understanding of the effects of these laws on the pattern of drug use and Medicaid expenditures in the states. At the same time, it explores the impact of state generic substitution laws on prescription drug market share and average reimbursements.

My results show that the mandatory switching will increase generic drug use and decrease brand-name drug use. Number of prescriptions and units reimbursed for generic drugs both increase when a state changes to a mandatory law, while units reimbursed for brand-name drugs decreases after a state changes to a mandatory law. The prescription drug market shares of authorized generic drugs also increase in states with less discretionary policies. However, contrary to expectations, overall Medicaid expenditure on all drugs increased following the laws. The effect of law changes on drug prices provides evidence that both mandatory switching and less discretionary switching lead to reductions in the average reimbursed prices of standard generic drugs. I also find that mandatory switching leads to increased average reimbursements for authorized generic drugs and brand-name drugs. The increasing average reimbursements of brand-name drugs and authorized generic drugs may help explain the greater total spending by the states on drugs.

There are three key implications of this paper. First, the less discretionary laws are effective in increasing the use of standard generic drugs and decreasing the use of brand-name

drugs. As a result, the less discretionary generic substitution laws are effective in increasing the generic substitution rate. Second, both mandatory switching and less discretionary switching will decrease the average prices of generic drugs. This might be the result of a more competitive generic drug market. Third, contrary to expectation, the less discretionary laws increased Medicaid expenditure on all prescription drugs, and increased average reimbursement of authorized generic drugs and brand-name drugs. Consequently, these results suggest that the policy led to some unanticipated effects, which may have contributed to greater drug spending.

There are two limitations of this study. First, I only have the year of the law, but not the month.This may lead to some bias if exact timing of the law change in a given year in not precisely estimated. Second, I am unable to observe changes in the drug formularies used by different state Medicaid programs over time. Thus, I am not able to fully determine the extent to which a drug formulary also affected physician prescribing and drug utilization over time. I did control for two states that changed their formularies in 2006 and 2012 in my analysis. In addition, my state fixed effects and state year effects provide added control for unobserved changes in state formularies. This, however, remains an important topic for future research.

Appendices

Table 3.1: Generic Entry (1999 - 2018)

	Drug Markets	Market Entries	Monopoly Duration (years)		Substitute Brands		Substitute Generics	
	Number	Number	Mean	Median	Mean	Median	Mean	Median
Generic Entry	141	2,084	10.6	10	2.6	2	65.1	24
AG Entry	55	1,281	9.6	8.4	2.8	2	63.4	29
No AG Entry	86	803	11.9	13	2.5	2	66.1	22
No Generic Entry	39	0	12.2	12.6	1.5	1	1	1
Total	180	2,084	11	10.3	2.2	1	40.1	15

Notes: Monopoly duration measures the number of years from the approval of a brand name drug to the loss of patent. Substitute drugs are drugs under the same indication. Therapeutic areas are classified by the ATC system at the fifth level of aggregation (ATC5).

Table 3.2: Data Set Descriptions

	Data Sample 1	Data Sample 2
	Active generic drug manufacturers (generic retail form share >50%) supplying at least 50 retail forms	All companies in data set 1, operating in given indication areas (ATC3)
Potential Entrants		
Total	207	207
Mean	142.3	44.7
Median	145	40
Zero Entries		
Total	23,530	5,564
Drug markets with generic entry (141)	17,930	4,598
Drug markets with no generic entry (39)	5,600	969
Mean		
Drug markets with generic entry (141)	127.2	33.3
Drug markets with no generic entry (39)	143.6	31.2
Median		
Drug markets with generic entry (141)	130	27
Drug markets with no generic entry (39)	145	32
Generic Entries		
Total	2,084	2,084
Mean	14.8	17.1
Median	9	12
Sample Size (N)	25,614	7,648

Notes: Potential entrants in data sample 1 are defined as active generic manufacturers supplying at least 50 retail forms before the loss of patent of a brand name drug. Potential entrants in data sample 2 are defined as all companies in data sample 1 operating in the same ATC3 as the brand name drug before the loss of patent.

Table 3.3: The Effects of Authorized Generics on Standard Generic Entry Decisions

	Data Sample 1 (N = 25,614)		Data Sample 2 (N = 7,648)	
	First Stage	Second Stage	First Stage	Second Stage
AG Entry	- -	-1.1323*** (0.3143)	- -	-1.2109*** (0.04263)
Share of New Medical Devices (IV)	-7.5211*** (1.5947)	- -	-0.8537** (0.0425)	- -
Pre-entry Revenue (log)	0.1288*** (0.0306)	0.0393** (0.0152)	0.0365** (0.0160)	0.0496*** (0.0137)
Monopoly Duration (years)	0.0633*** (0.0095)	0.0102* (0.0061)	0.0053 (0.0088)	0.0184** (0.0070)
Substitutes Brands	1.0681*** (0.0863)	0.2314*** (0.0450)	0.5111*** (0.0337)	0.2697*** (0.0574)
Substitutes Generics	-0.0868*** (0.0078)	0.0073* (0.0042)	-0.0184** (0.0029)	0.0183*** (0.0040)
Field Experience	0.0134 (0.0046)	0.0393*** (0.0083)	0.0045 (0.0038)	0.0369*** (0.0063)
Therapeutic Field (0/1)	YES	YES	YES	YES
Dosage Form (0/1)	YES	YES	YES	YES
Year Expiry (0/1)	YES	YES	YES	YES

Notes:
The outcome variable in this analysis is the likelihood of generic entry.
Robust standard errors in parentheses.
*** p¡0.01, ** p¡0.05, * p¡0.1

Table 3.4: Average Marginal Effects

	Data Sample 1 N = 25,614	Data Sample 2 N = 7,648
AG Entry (0/1)	-0.0754** (0.0320)	-0.3116*** (0.0765)
Pre-entry Revenue (log)	0.0056*** (0.0015)	0.0101*** (0.0027)
Monopoly Duration (years)	0.0003 (0.0006)	0.0008 (0.0014)
Substitutes Brands	0.0157*** (0.0045)	0.0682*** (0.0104)
Substitutes Generics	0.0010*** (0.0004)	0.0045*** (0.0007)
Field Experience	0.0056*** (0.0015)	0.0072*** (0.0012)

Notes:
The outcome variable in this analysis is the likelihood of generic entry. This table shows average marginal effects (AME) calculated for two data samples. Average marginal effects indicate average changes in the likelihood of authorized generic entry.
Robust standard errors in parentheses.
*** p¡0.01, ** p¡0.05, * p¡0.1

Table 3.5: The Effects of Authorized Generics on Standard Generic Entry Time

	Data Sample 1 (N = 25,614)		Data Sample 2 (N = 7,648)	
	First Stage (coefficients)	Second Stage (coefficients)	First Stage (coefficients)	Second Stage (coefficients)
AG Entry	- -	-1.6375** (0.8217)	- -	-2.2366*** (0.4857)
Share of New Medical Devices (IV)	-11.5327*** (1.0385)	- -	-0.5278*** (0.0775)	- -
Pre-entry Revenue (log)	0.0703** (0.0278)	0.0604* (0.0792)	0.0137* (0.0118)	0.1046** (0.0357)
Monopoly Duration (years)	0.0927*** (0.0086)	-0.0797** (0.0339)	0.0137* (0.0091)	-0.0587** (0.0262)
Substitutes Brands	1.4439*** (0.0806)	0.2728** (0.1217)	0.6841*** (0.0219)	0.3104*** (0.0776)
Substitutes Generics	-0.1176*** (0.0069)	0.0046 (0.0190)	-0.0449*** (0.0022)	-0.0067 (0.0106)
Field Experience	- -	0.0578*** (0.0135)	- -	0.0389*** (0.0083)
Therapeutic Field (0/1)	YES	YES	YES	YES
Dosage Form (0/1)	YES	YES	YES	YES
Year Expiry (0/1)	YES	YES	YES	YES

Notes:
The outcome variable in this analysis is the entry time of generic drug.
Robust standard errors in parentheses.
*** p¡0.01, ** p¡0.05, * p¡0.1

Table 3.6: Effect of Authorized Generics on Drug Utilization

	Overall Drugs	brand name Drugs	brand name Drugs and Authorized Generics	Generics Drugs
	B+AG+G	B	B+AG	G
	2SLS	2SLS	2SLS	2SLS
Average Treatment Effect	0.222*** (0.018)	-0.037*** (0.019)	0.019** (0.019)	-0.160*** (0.073)
Dynamci Effects				
Relative Years				
-4	0.163 (0.022)	-0.163* (0.022)	-0.137 (0.022)	- -
-3	-0.014 (0.021)	-0.310 (0.021)	-0.285 (0.021)	- -
-2	-0.244 (0.023)	-0.512 (0.023)	-0.486 (0.023)	- -
-1	- -	- -	- -	- -
0	0.150*** (0.023)	-0.019* (0.024)	0.030*** (0.024)	-0.369*** (0.072)
1	0.071*** (0.020)	-0.176*** (0.025)	0.120*** (0.025)	-0.015** (0.068)
2	0.014*** (0.021)	-0.210*** (0.027)	0.154*** (0.027)	-0.020* (0.071)
Number of observations	104,189	52,675	62,896	41,293

Notes:
This table shows the 2SLS results of the effects of authorized generic drugs on the utilization of overall drugs, brand name drugs and generic drugs. B represents brand name drugs. AG represents authorized generic drugs. G represents generic drugs. The outcome variable is the log of number of prescriptions and is calculated as the per-100 population rate by dividing the outcome variables by Census Bureau estimates of the non-elderly adult population. Results are similar if I use the log of number of prescriptions as my outcome variable and do not divide it by adult population.
Robust standard errors in parentheses.
*** p¡0.01, ** p¡0.05, * p¡0.1

Table 3.7: Effect of Authorized Generics on Medicaid Reimbursement

	Overall Drugs	brand name Drugs	brand name Drugs and Authorized Generics	Generic Drugs
	B+AG+G	B	B+AG	G
	2SLS	2SLS	2SLS	2SLS
Average Treatment Effect	0.348*** (0.023)	-0.230*** (0.020)	0.139*** (0.018)	-0.521*** (0.085)
Dynamic Effects				-
-4	0.012 (0.028)	0.767 (0.033)	0.153 (0.028)	- -
-3	-0.033 (0.027)	0.830 (0.030)	0.124 (0.027)	- -
-2	0.245 (0.031)	-0.055 (0.036)	-0.208 (0.030)	- -
-1	- -	- -	- -	- -
0	0.365*** (0.031)	-0.018*** (0.040)	0.179*** (0.031)	-0.032 (0.118)
1	0.241 (0.028)	-0.174* (0.035)	0.151*** (0.031)	-0.413** (0.119)
2	0.179 (0.027)	0.330 (0.041)	0.142*** (0.034)	-0.615*** (0.122)
Number of Observations	104,189	52,675	62,896	41,293

Notes:
Notes: This table shows the 2SLS results of the effects of authorized generic drugs on the reimbursement of overall drugs, brand name drugs and generic drugs. B represents brand name drugs. AG represents authorized generic drugs. G represents generic drugs. The outcome variable is the log of number of prescriptions calculated as the per-100 population rate by dividing the outcome variables by Census Bureau estimates of the non-elderly adult population. Results are similar if I use the log of number of prescriptions as my outcome variable and do not divide it by adult population.
Robust standard errors in parentheses.
*** p¡0.01, ** p¡0.05, * p¡0.1

Table 3.8: Summary Statistics in selected years

	2001	2003	2005	2007	2009	2011	2013
num of obs	3,420	1,725	1,461	1,560	1,318	5,944	8,055
age (mean)	59.8	61.1	60.1	59.8	58.9	60.7	60.6
total inc (mean)	$20,850.74	$18,562.60	$24,238.48	$28,188.66	$26,727.04	$25,372.49	$25,528.51
num of employed	1,363	616	664	746	627	2,419	3,264
	39.85%	35.71%	45.45%	47.82%	47.57%	40.70%	40.52%
num of unemployed	2,057	1,107	797	794	673	3,485	4,756
	60.15%	64.17%	54.55%	50.90%	51.06%	58.63%	59.04%
number of insured	3,139	1,617	1,379	1,447	1,149	5,410	7,301
	91.78%	93.74%	94.39%	92.76%	87.18%	91.02%	90.64%
family income: poor/negative	486	381	299	251	244	1,273	1,973
	14.21%	22.09%	20.47%	16.09%	18.51%	21.42%	24.49%
family income: poor	189	70	100	90	70	398	533
	5.53%	4.06%	6.84%	5.77%	5.31%	6.70%	6.62%
family income: low	690	433	234	286	226	1,087	1,459
	20.18%	25.10%	16.02%	18.33%	17.15%	18.29%	18.11%
family income: middle	1,115	431	361	456	451	1,779	2,266
	32.60%	24.99%	24.71%	29.23%	34.22%	29.93%	28.13%
family income: high	940	410	467	477	327	1,407	1,824
	27.49%	23.77%	31.96%	30.58%	24.81%	23.67%	22.64%

Notes: numbers in the bracket are the percent of total observations.

Table 3.9: Summary statistics of outcome variables

	2001	2003	2005	2007	2009	2011	2013
num of obs	3,420	1,725	1,461	1,560	1,318	5,944	8,055
phyexe = 1	1,334	597	480	588	534	2,083	2,863
	39.01%	34.61%	32.85%	37.69%	40.52%	35.04%	35.54%
nofat = 1	920	1,272	1,086	1,082	914	4,000	5,976
	26.90%	73.74%	74.33%	69.36%	69.35%	67.29%	74.19%
18.9 <= BMI <= 24	299	120	108	198	55	517	596
	8.74%	6.96%	7.39%	12.69%	4.17%	8.70%	7.40%
BMI <19	112	63	32	39	56	215	312
	3.27%	3.65%	2.19%	2.50%	4.25%	3.62%	3.87%
BMI >24	3,009	1,542	1,321	1,323	1,207	5,212	7,149
	87.98%	89.39%	90.42%	84.81%	91.58%	87.69%	88.75%
smoking	459	325	138	170	184	1,027	1,211
	13.42%	18.84%	9.45%	10.90%	13.96%	17.28%	15.03%

Notes:
phyexe = 1 if currently spends half hour or more in moderate to vigorous physical activity at least five times a week.
nofate = 1 if currently restrict high cholesterol food.
smoking = 1 if currently smoking.

Table 3.10: Summary statistics of drugs

Name	Approval date	# of purchases	Average total cost	Average self-payment
GLUCOPHAGE	3-Mar-95	8,055	$77.96	$29.58
metformin hydrochloride	24-Jan-02	30,512	$21.05	$6.42
AMARYL	30-Nov-95	4,540	$41.93	$21.08
glimepiride	6-Oct-06	6,267	$15.94	$6.81
ACTOS	15-Jul-99	17	$235.05	$137.13
piohlitazone hydrochloride	17-Aug-12	214	$192.72	$11.69
STARLIX	22-Dec-00	843	$129.85	$29.88
nateglinide	9-Sep-09	136	$128.88	$27.15
PRECOSE	6-Sep-95	0	$0.00	$0.00
acarbose	7-May-08	25	$85.86	$36.26
PRANDIN	22-Dec-97	251	$125.64	$30.31
repaglinide	11-Jul-13	0	$0.00	$0.00
AVANDIA	25-May-99	0	$0.00	$0.00
rosiglitazone	17-Aug-12	0	$0.00	$0.00

Notes:
For each drug, on the top is the brand-name drug and the generic drug is on the bottom.
# of purchases, average total cost and average self-payment for brand-name drugs are using the data from one year before the launch date of their generic drugs.
# of purchases, average total cost and average self-payment for generic drugs are using the data from one year after the launch date.

Table 3.11: Variable List

variable name	description
phyexe	=1 if moderate or vigorous physical activity 3 times or more per week
nofat	=1 if restrict high fat/cholesterol food
smoke	=1 if currently smoke
bmi	adult body mass index
DUPERSID	person id
fams	family size
region	census region
age	age
sex	sex
raceth	race/ethnicity
marry	marital status
eduyrdg	years of education
hideg	highest degree
totinc	person's total income
povcat	family income as percent of poverty
emp	employment status
inpri	ever have private insurance during this year
intri	ever have TRICARE during this year
inmedc	ever have MEDICARE during this year
inmedd	ever have MEDICAID during this year
unins	uninsured during this year
ins	health insurance coverage indicator
rthlth	perceived health status
unable	completely unable to do activity
ashma	asthma diagnosis
highbp	high blood pressure diagnosis
chd	coronary health disease diagnosis
angi	angina diagnosis
heartatt	heart attack (MI) diagnosis
stroke	stroke diagnosis
emph	emphysema diagnosis
adexe	advised to exercise more

Table 3.12: Physical Activity

	All Individuals (main equation)	Generic Users (sub-analysis)
Average Treatment Effect	-0.021*	
	(0.009)	
k = -5	-0.129***	
	(0.0273)	
k = -4	-0.150***	
	-0.0133	
k = -3	-0.0279	
	(0.0266)	
k = -2	-0.0740	
	(0.0501)	
k = -1	-	-
	-	-
k = 0	-0.129***	-0.000490
	(0.0257)	(0.0684)
k = 1	0.0158	-0.0298
	(0.0359)	(0.0863)
k = 2	-0.0443	0.141***
	(0.0378)	(0.0303)
k = 3	-0.169***	0.0000225
	(0.0146)	(0.0330)
k = 4	-0.102**	-0.0387**
	(0.0352)	(0.0157)
k = 5	-0.0391	-0.0967***
	(0.0417)	(0.00615)
k = 6	-0.0816*	0.0813
	(0.0376)	(0.0573)
k = 7	-0.118***	0.0305
	(0.00790)	(0.0162)
k = 8	-0.0279	0.350***
	(0.0238)	(0.00896)

Notes:
Years is relative years to the launch year of generic drugs.
Standard errors in parentheses.
*** significant at 1 percent level
** significant at 5 percent level
* significant at 10 percent level

Table 3.13: Physical Activity - by age group

Age	PHYEXE
age <30	-5.88e-05
	(0.0929)
30 <= age <40	0.0266
	(0.0286)
40 <= age <50	0.0376**
	(0.0112)
50 <= age <60	0.0302
	(0.0294)
60 <= age <65	0.0405
	(0.0224)
65 <= age <70	0.000118
	(0.00928)
70 <= age <75	-0.0223
	(0.0127)
75 <= age <80	-0.149*
	(0.0733)
80 <= age <90	-0.0343
	(0.0317)

Notes:
Years is relative years to the launch year of generic drugs.
Standard errors in parentheses.
*** significant at 1 percent level
** significant at 5 percent level
* significant at 10 percent level

Table 3.14: Diet

	All Individuals (main equation)	Generic Users (sub-analysis)
Average Treatment Effect	-0.093*** (0.029)	
k = -5	-0.204** (0.0578)	
k = -4	-0.392** (0.126)	
k = -3	-0.442*** (0.0577)	
k = -2	-0.165*** (0.0407)	
k = -1	- -	- -
k = 0	-0.343*** (0.0882)	-0.149 (0.0950)
k = 1	-0.0378 (0.0369)	-0.240*** (0.0901)
k = 2	0.0689* (0.0324)	-0.174*** (0.0644)
k = 3	-0.0765 (0.0683)	-0.0874 (0.163)
k = 4	-0.177** (0.0670)	-0.129*** (0.0392)
k = 5	0.0236 (0.0248)	-0.941*** (0.219)
k = 6	0.0237 (0.0243)	-0.368*** (0.0945)
k = 7	-0.156*** (0.019)	-0.355*** (0.110)
k = 8	-0.133*** (0.0348)	-0.490*** (0.0510)

Notes:
Years is relative years to the launch year of generic drugs.
Standard errors in parentheses.
*** significant at 1 percent level
** significant at 5 percent level
* significant at 10 percent level

Table 3.15: Diet - by age group

Age	Diet
age <30	-0.587***
	(0.214)
30 <= age <40	-0.147**
	(0.0650)
40 <= age <50	-0.266***
	(0.0487)
50 <= age <60	-0.290***
	(0.0440)
60 <= age <65	-0.186***
	(0.0588)
65 <= age <70	-0.0915
	(0.0613)
70 <= age <75	-0.137**
	(0.0683)
75 <= age <80	-0.361***
	(0.0579)
80 <= age <90	-0.691***
	(0.0904)

Notes:
Years is relative years to the launch year of generic drugs.
Standard errors in parentheses.
*** significant at 1 percent level
** significant at 5 percent level
* significant at 10 percent level

Table 3.16: BMI

	All Individuals (main equation)		Generic Users (sub-analysis)	
	raw BMI	grouped BMI	raw BMI	grouped BMI
Average Treatment Effect	-0.130	-0.044		
	(0.183)	(0.019)		
k = -5	-0.147	-0.0611**		
	(0.626)	(0.0241)		
k = -4	-0.135	0.0179		
	(1.183)	(0.0289)		
k = -3	-0.639	-0.0561		
	(1.094)	(0.170)		
k = -2	-2.754***	-0.343***		
	(0.490)	(0.0737)		
k = -1	-	-	-	-
	-	-	-	-
k = 0	-0.234	-0.0399	1.615**	0.378***
	(0.580)	(0.0439)	(0.796)	(0.0958)
k = 1	-0.936	-0.00559	1.754**	0.129
	(1.090)	(0.144)	(0.800)	(0.0886)
k = 2	-2.121***	-0.138	1.775***	0.153**
	(0.548)	(0.0781)	(0.652)	(0.0768)
k = 3	-0.823	0.0275	1.726***	0.224***
	(0.599)	(0.0670)	(0.527)	(0.0644)
k = 4	-1.553***	-0.112**	0.937	0.0196
	(0.332)	(0.0321)	(0.663)	(0.0612)
k = 5	-1.827*	-0.0236	0.808	0.0666
	(0.893)	(0.126)	(0.722)	(0.0749)
k = 6	-0.991**	-0.0621	0.460	0.110
	(0.345)	(0.0440)	(0.917)	(0.107)
k = 7	-1.177***	-0.073**	0.0533	0.0336
	(0.146)	(0.019)	(0.831)	(0.0987)
k = 8	-0.629**	-0.0706***	-3.971***	-1.125***
	(0.174)	(0.0159)	(0.394)	(0.0474)
Observations	16,745	16,745	16,745	16,745

Notes:
Years is relative years to the launch year of generic drugs.
Standard errors in parentheses.
*** significant at 1 percent level
** significant at 5 percent level
* significant at 10 percent level

Table 3.17: BMI - by age group

Age	raw BMI	grouped BMI
age <30	4.111***	0.0215
	(1.396)	(0.117)
30 <= age <40	1.778***	0.121**
	(0.546)	(0.0523)
40 <= age <50	0.695**	0.0849**
	(0.348)	(0.0344)
50 <= age <60	0.571*	0.0572*
	(0.307)	(0.0324)
60 <= age <65	1.246***	0.185***
	(0.355)	(0.0395)
65 <= age <70	1.942***	0.279***
	(0.378)	(0.0473)
70 <= age <75	1.437***	0.173***
	(0.416)	(0.0514)
75 <= age <80	1.523***	0.226***
	(0.425)	(0.0534)
80 <= age <90	1.109**	0.00964
	(0.439)	(0.0598)

Notes:
Years is relative years to the launch year of generic drugs.
Standard errors in parentheses.
*** significant at 1 percent level
** significant at 5 percent level
* significant at 10 percent level

Table 3.18: Smoking

	All Individuals (main equation)	Generic Users (sub-analysis)
Average Treatment Effect	0.068	
	(0.053)	
k = -5	0.396***	
	(0.0860)	
k = -4	-0.0469	
	(0.204)	
k = -3	-1.145***	
	(0.307)	
k = -2	-0.364	
	(0.327)	
k = -1	-	-
	-	-
k = 0	-0.0357	0.262**
	(0.205)	(0.126)
k = 1	-0.384	0.599***
	(0.238)	(0.207)
k = 2	-0.0835	-0.300**
	(0.301)	(0.152)
k = 3	-0.446*	-0.118
	(0.197)	(0.215)
k = 4	-0.197	-0.512***
	(0.217)	(0.0965)
k = 5	-0.323	0.118
	(0.243)	(0.130)
k = 6	-0.129	-0.113
	(0.0883)	(0.285)
k = 7	0.0112	0.901***
	(0.131)	(0.197)
k = 8	-0.254**	-0.158
	(0.076)	(0.108)

Notes:
Years is relative years to the launch year of generic drugs.
Standard errors in parentheses.
*** significant at 1 percent level
** significant at 5 percent level
* significant at 10 percent level

Table 3.19: Smoking

Age	Smoking
age <30	0.256
	(0.312)
30 <= age <40	-0.0150
	(0.104)
40 <= age <50	0.271***
	(0.0860)
50 <= age <60	0.0209
	(0.0771)
60 <= age <65	-0.246***
	(0.0783)
65 <= age <70	0.278**
	(0.129)
70 <= age <75	-0.104
	(0.111)
75 <= age <80	-0.192
	(0.119)
80 <= age <90	-0.169
	(0.136)

Notes:
Years is relative years to the launch year of generic drugs.
Standard errors in parentheses.
*** significant at 1 percent level
** significant at 5 percent level
* significant at 10 percent level

Table 3.20: State Generic Substitution Laws in 2006

	Law Type 1		Law Type 2	
State	Mandatory	Permissive	Presumed Consent	Explicit Consent
AL		✓	✓	
AK		✓		✓
AR		✓		✓
CA		✓		✓
CO		✓		✓
CT		✓		✓
DC		✓		✓
FL	✓			✓
GA		✓		✓
HI		✓		✓
IL		✓		✓
IN		✓		✓
IA		✓		✓
KS		✓		✓
KY	✓			✓
LA		✓		✓
MA	✓		✓	
ME		✓		✓
MD		✓		✓
MI		✓		✓
MN		✓		✓
MS		✓		✓
MT		✓		✓
ND		✓		✓
NE		✓		✓
NH		✓		✓
NJ	✓		✓	
NM	✓		✓	
NV		✓		✓
NY		✓		✓
OH		✓		✓
OR	✓		✓	
PA		✓		✓
RI	✓		✓	
SC		✓		✓
SD		✓		✓
TN	✓		✓	
TX		✓		✓
UT		✓		✓
VT		✓		✓
VA		✓		✓
WA	✓		✓	
WI		✓		✓
WY	✓		✓	

Table 3.21: Changes of State Generic Substitution Laws from 2006 to 2012

State	Year	Law Type 1		Law Type 2	
		Permissive to Mandatory	Mandatory to Permissive	Explicit Consent to Presumed Consent	Presumed Consent to Explicit Consent
HI	2007	✓			
NV	2007	✓			
MN	2008	✓			
MS	2008	✓			
NY	2008	✓			
PA	2008	✓			
OR	2009		✓		
WY	2009		✓		
IL	2009			✓	
MI	2012			✓	
AL	2009				✓

Notes: This table shows the law changes from 2006 to 2012. There are 7 states changing from permissive laws to mandatory laws, and two state changing from explicit consent laws to presumed consent laws.

Table 3.22: Mean of Outcome Variables, 2006 to 2012

	Mean
Units Reimbursed by Medicaid	37,636.27
Number of Prescriptions	1,186.95
Amount Reimbursed by Medicaid	23,679.52

Notes: This table shows the mean of outcome variables. All means are estimated using data from the 2006 to 2012 Medicaid Utilization data files.

Table 3.23: Effect of Generic Substitution Laws on Logarithm Utilization of Generic Drugs

	Law changed from permissive to mandatory		Law changed from permissive to mandatory from explicit consent to presumed consen	
	(1)	(2)	(3)	(4)
Outcome variable: log of number of prescriptions				
Average Treatment Effect	0.029*	0.056**	0.001	0.001
	(0.015)	(0.022)	(0.013)	(0.018)
P-value of F-Test of Joint Significance for Pre-policy Coefficients	0.172	0.167	0.069	0.562
Outcome variable: log of units				
Average Treatment Effect	0.060**	0.043*	0.029	0.002
	(0.017)	(0.237)	(0.065)	(0.019)
P-value of F-Test of Joint Significance for Pre-policy Coefficients	0.593	0.582	0.002	0.001
Outcome variable: log of amount reimbursed				
Average Treatment Effect	1.193**	0.232	0.830	0.837
	(0.440)	(0.398)	(0.436)	(0.412)
P-value of F-Test of Joint Significance for Pre-policy Coefficients	0.000	0.000	0.005	0.005
State Linear Trend	No	Yes	No	Yes
Number of observations	1,120,903	1,120,903	1,120,903	1,120,903

Notes: The outcome variables of generic utilization are: log units reimbursed by Medicaid, log number of prescriptions, and log amount reimbursed by Medicaid. The unit of observation is the state-year-quarter-drug. All regression models include utilization type fixed effect, year-quarter fixed effect, season(quarter) fixed effect, drug market fixed effect (ATC3), dummy variables for each drug's life, a dummy variable for market with/without authorized generic drugs, and a dummy variable indicating whether the state has changed its drug formulary from 2006 to 2012. In columns (2) and (4), I also add state linear trend. Standard errors have been constructed allowing for non-independence of observations within a state.
* p-value > 0.05
** $0.01 <=$ p-value $<= 0.05$
*** p-value $4 < 0.01$

Table 3.24: Effect of Generic Substitution Laws on Logarithm Utilization of Brand-name Drugs

	Law changed from permissive to mandatory		Law changed from permissive to mandatory from explicit consent to presumed consen	
	(1)	(2)	(3)	(4)
Outcome variable: log of number of prescriptions				
Average Treatment Effect	-0.053	-0.129	-0.035	-0.095*
	(0.077)	(0.066)	(0.061)	(0.055)
P-value of F-Test of Joint Significance for Pre-policy Coefficients	0.082	0.262	0.363	0.097
Outcome variable: log of units				
Average Treatment Effect	-0.074	-0.084*	-0.064	-0.074
	(0.111)	(0.096)	(0.083)	(0.068)
P-value of F-Test of Joint Significance for Pre-policy Coefficients	0.354	0.231	0.184	0.548
Outcome variable: log of amount reimbursed				
Average Treatment Effect	-1.176**	-1.164**	-0.856*	-0.868*
	(0.501)	(0.430)	(0.480)	(0.410)
P-value of F-Test of Joint Significance for Pre-policy Coefficients	0.582	0.006	0.356	0.337
State Linear Trend	No	Yes	No	Yes
Number of observations	264,886	264,886	264,886	264,886

Notes: The outcome variables of generic utilization are: log units reimbursed by Medicaid, log number of prescriptions, and log amount reimbursed by Medicaid. The unit of observation is the state-year-quarter-drug. All regression models include utilization type fixed effect, year-quarter fixed effect, season(quarter) fixed effect, drug market fixed effect (ATC3), dummy variables for each drug's life, a dummy variable for market with/without authorized generic drugs, and a dummy variable indicating whether the state has changed its drug formulary from 2006 to 2012. In columns (2) and (4), I also add state linear trend. Standard errors have been constructed allowing for non-independence of observations within a state.
* p-value $>$ 0.05
** 0.01 <= p-value <= 0.05
*** p-value 4 $<$ 0.01

Table 3.25: Effect of State Generic Substitution Laws on Medicaid Expenditure of All Prescription Drugs

	Law changed from permissive to mandatory		Law changed from permissive to mandatory or from explicit consent to presumed consent	
	(1)	(2)	(3)	(4)
Outcome variable: log of amount reimbursed				
Average Treatment Effect	1.195**	1.220***	0.839*	0.843**
	(0.439)	(0.390)	(0.438)	(0.405)
P-value of F-Test of Joint Significance for Pre-policy Coefficients	0.104	0.230	0.028	0.102
State Linear Trend	No	Yes	No	Yes
Number of observations	1,385,789	1,385,789	1,385,789	1,385,789

Notes: The outcome variable is log amount reimbursed by Medicaid of all drugs (brand-name drug, standard generic drug, and authorized generic drug). The unit of observation is the state-year-quarter-drug. All regression models include utilization type fixed effect, year-quarter fixed effect, season(quarter) fixed effect, drug market fixed effect (ATC3), dummy variables for each drug's life, a dummy variable for market with/without authorized generic drugs, and a dummy variable indicating whether the state has changed its drug formulary from 2006 to 2012. In columns (2) and (4), I also add state linear trend. Standard errors have been constructed allowing for non-independence of observations within a state.
* p-value $>$ 0.05
** 0.01 <= p-value <= 0.05
*** p-value 4 $<$ 0.01

Table 3.26: Effect of State Generic Substitution Laws on Prescription Drug Market Shares and HHI

	Brand-name Drug	Standard Generic Drug	Authorized Generic Drug	HHI
Law change from permissive to mandatory				
Average Treatment Effect	-0.383*	0.218	0.286	44.763
	(0.907)	(0.766)	(0.930)	(108.68)
P-value of F-Test of Joint Significance for Pre-policy Coefficients	0.008	0.825	0.856	0.161
Law change from permissive to mandatory or from explicit consent to presumed consent				
Average Treatment Effect	-0.095	0.148	0.125*	-2.802
	(0.627)	(0.587)	(0.714)	(81.160)
P-value of F-Test of Joint Significance for Pre-policy Coefficients	0.056	0.342	0.939	0.062
State Linear Trend	Yes	Yes	Yes	Yes
Number of Observations	264,886	1,072,316	48,587	1,385,789

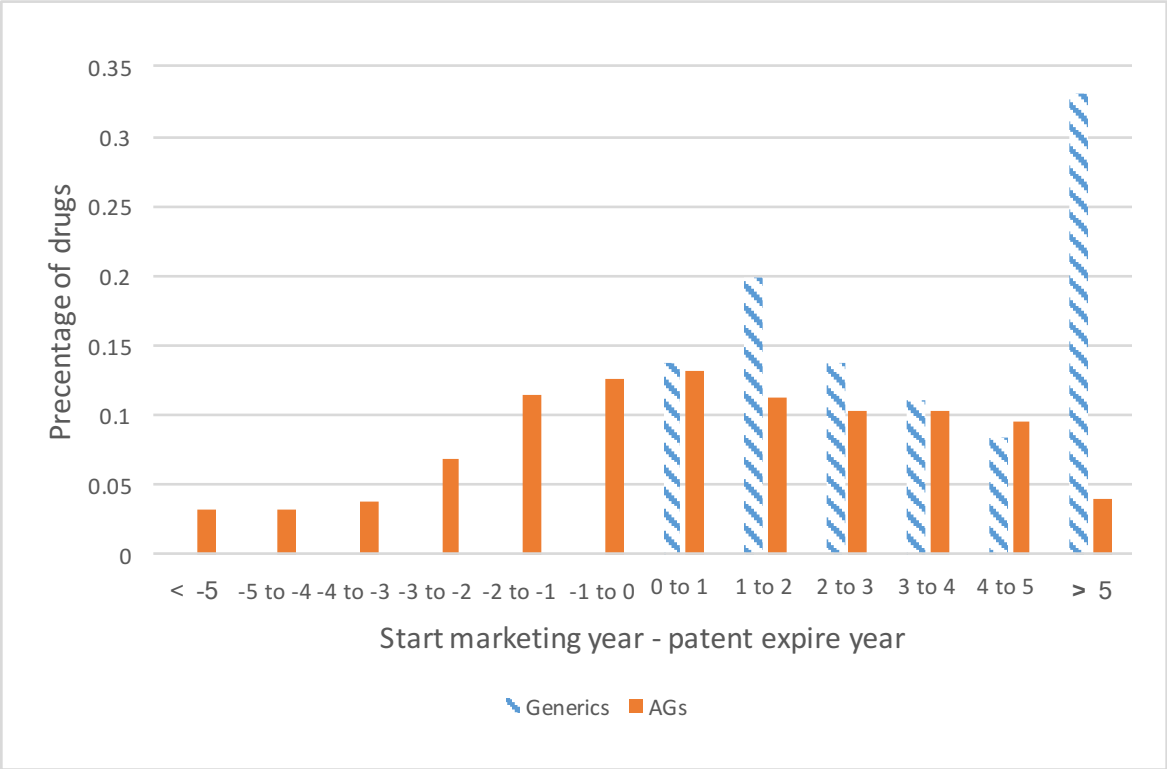
Notes: The outcome variables in this table are prescription drug market shares and HHI. The unit of observation is the state-year-quarter-drug. All regression models include utilization type fixed effect, year-quarter fixed effect, season(quarter) fixed effect, drug market fixed effect (ATC3), dummy variables for each drug's life, a dummy variable for market with/without authorized generic drugs, a dummy variable indicating whether the state has changed its drug formulary from 2006 to 2012, and state linear trend.
* p-value $>$ 0.05
** 0.01 <= p-value <= 0.05
*** p-value 4 $<$ 0.01

Table 3.27: Effect of State Generic Substitution Laws on Average Reimbursed Drug Prices

	Brand-name Drug	Standard Generic Drug	Authorized Generic Drug
Law change from permissive to mandatory			
Average Treatment Effect	35.62**	-2.138*	4.525**
	(16.96)	(1.083)	(1.892)
P-value of F-Test of Joint Significance for Pre-policy Coefficients	0.126	0.106	0.539
Law change from permissive to mandatory or from explicit consent to presumed consent			
Average Treatment Effect	22.3	-1.590*	3.450**
	(17.51)	(0.87)	(1.345)
P-value of F-Test of Joint Significance for Pre-policy Coefficients	0.739	0.300	0.820
Mean of Dependent Variable	225.08	29.17	37.17
State Linear Trend	Yes	Yes	Yes
Number of Observations	264,886	1,072,316	48,587

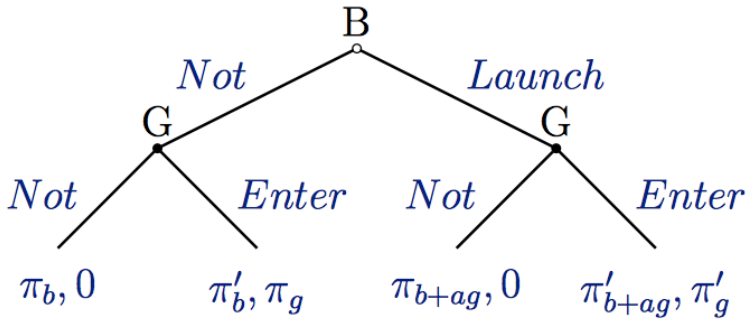
Notes: The outcome variables in this table is average drug price. The average drug price is calculated by taking amount reimbursed and dividing number of prescriptions. The unit of observation is the state-year-quarter-drug. All regression models include utilization type fixed effect, year-quarter fixed effect, season(quarter) fixed effect, drug market fixed effect (ATC3), dummy variables for each drug's life, a dummy variable for market with/without authorized generic drugs, a dummy variable indicating whether the state has changed its drug formulary from 2006 to 2012, and state linear trend.
* p-value > 0.05
** $0.01 <=$ p-value $<= 0.05$
*** p-value $4 < 0.01$

Figure 3.1: Relative Entry Year of Authorized Generics and Generics



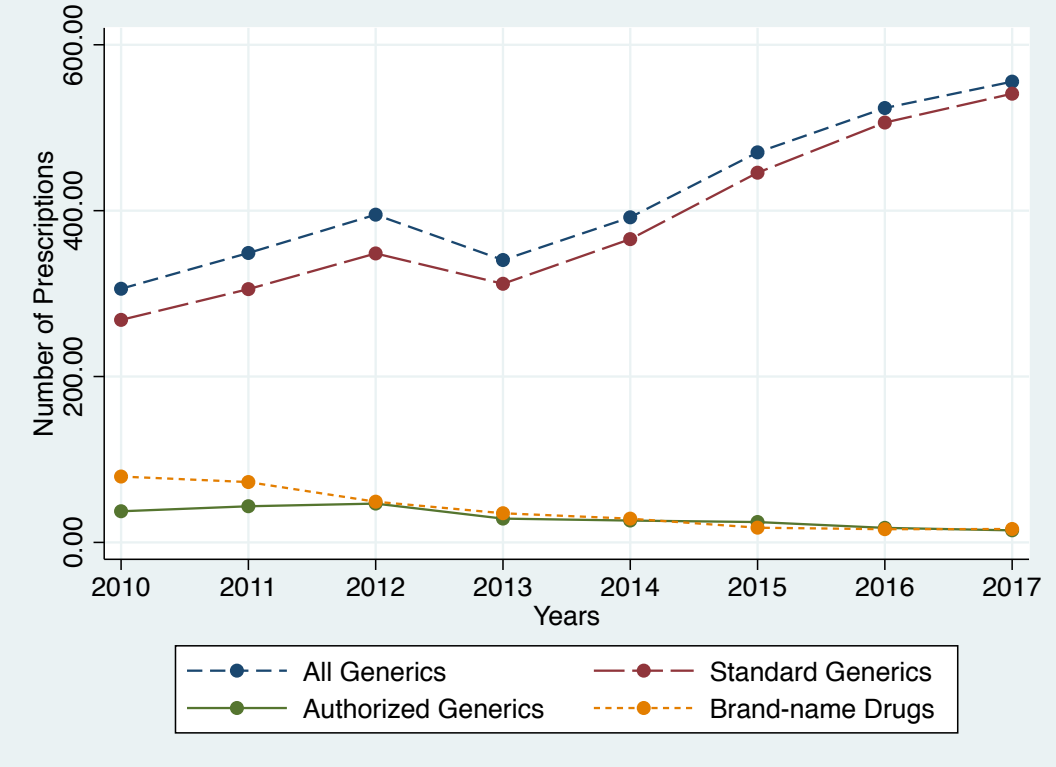
Notes: This figure shows the start marketing years of authorized generics and generics relative to the patent expiration year. The x axis is the relative years. The y axis is the percentage of drugs in the market.

Figure 3.2: Extensive Form Game



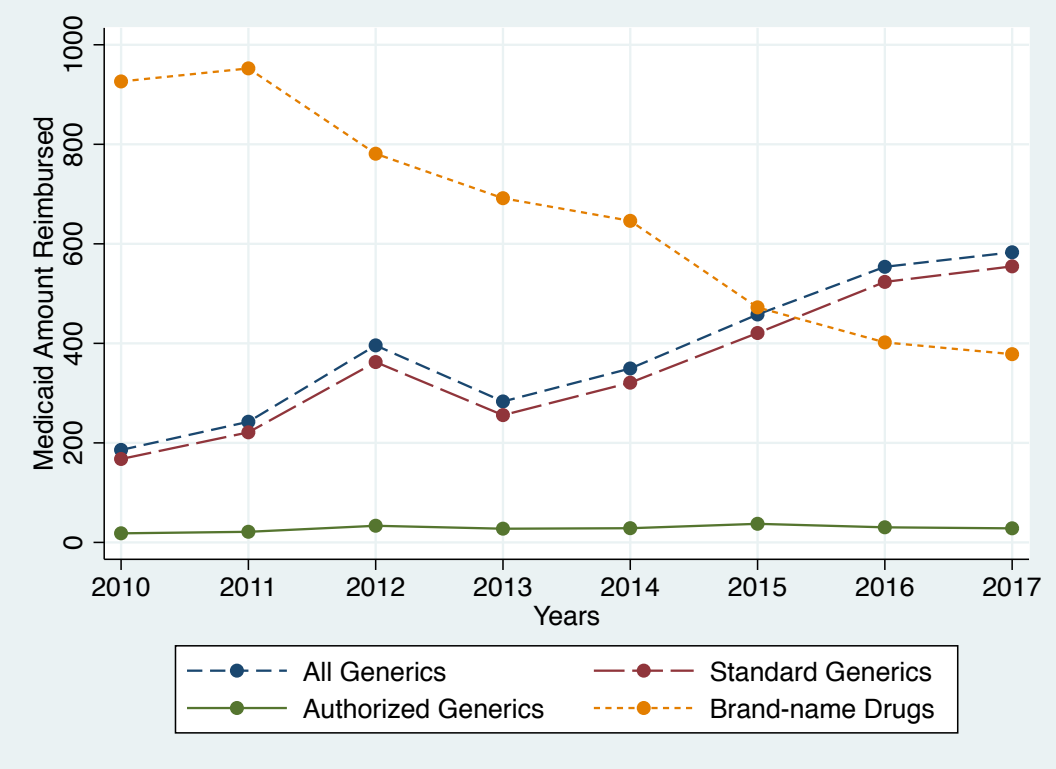
Notes: This figure shows the extensive-form game played by brand manufacturer and generic manufacturer. Brand manufacturer is contemplating launching authorized generic drug or not and generic manufacturer can either enter the market or not.

Figure 3.3: Number of Prescriptions by State



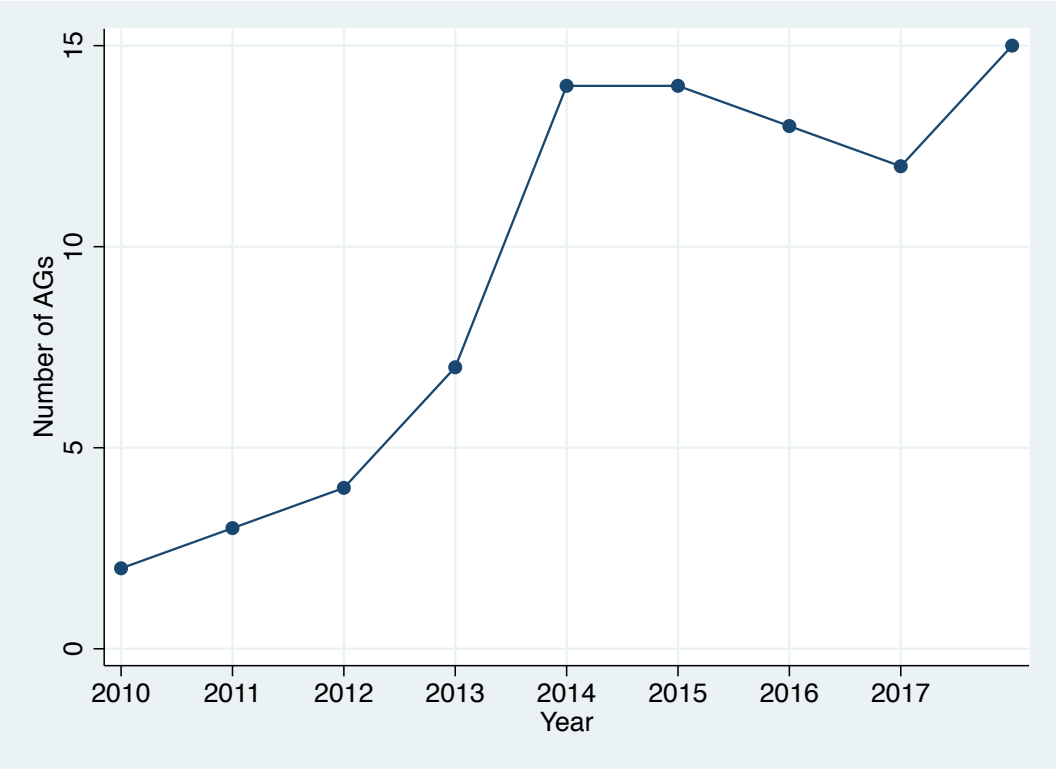
Notes: This figure shows the average number of prescriptions by year and state (50 states plus the District of Columbia).

Figure 3.4: Medicaid Reimbursement



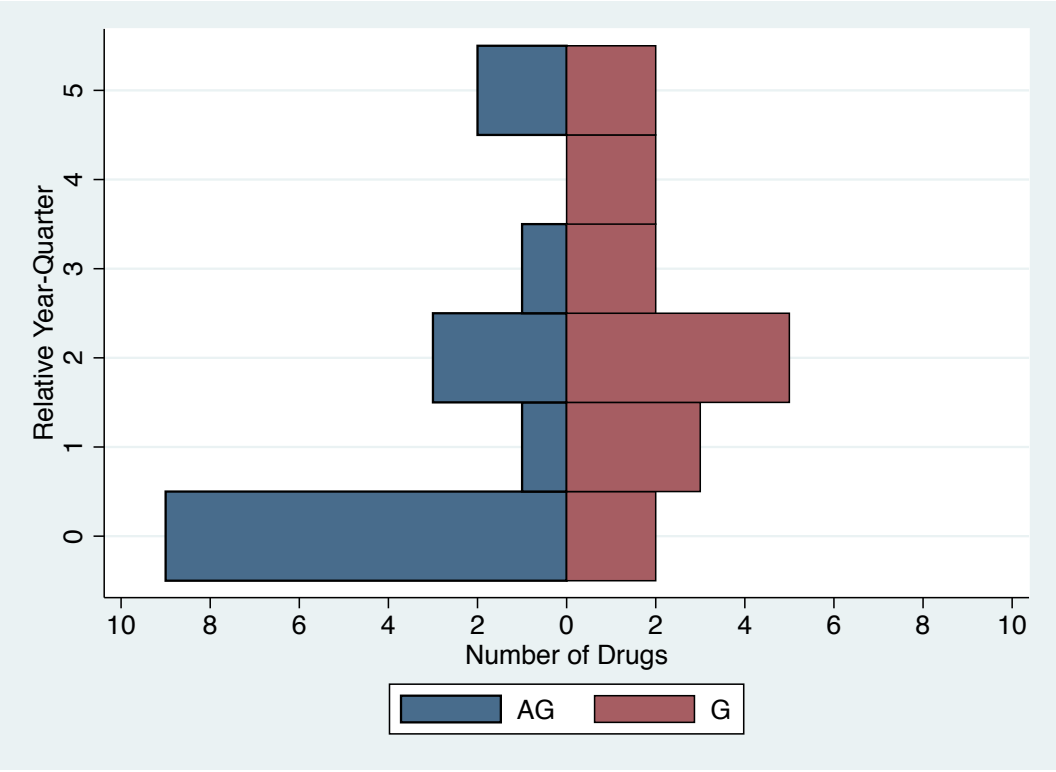
Notes: This figure shows the average Medicaid amount reimbursed by year and state (50 states plus the District of Columbia).

Figure 3.5: Cumulative Number of Authorized Generic Drugs



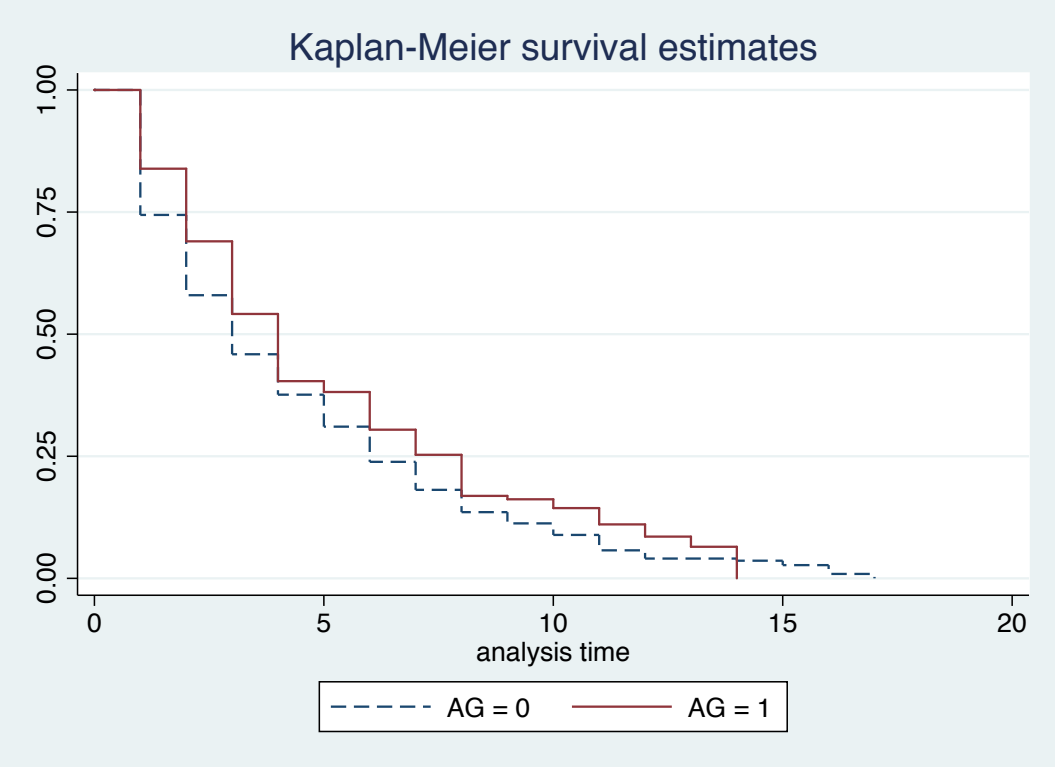
Notes: This figure shows the accumulated number of authorized generic drugs in the market by year.

Figure 3.6: Drug Entry Times for Authorized Generics and Generics Relative to Patent Expiration



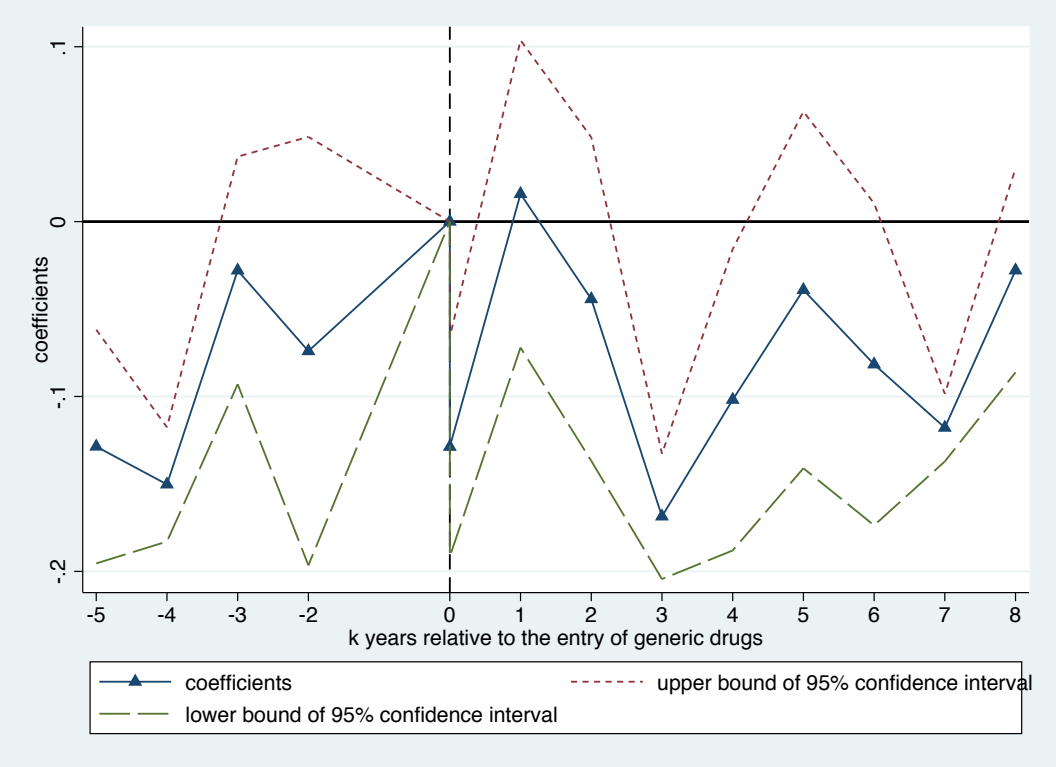
Notes: This figure shows the drug entry times relative to patent expiration. Bars on the left represent the authorized generic drugs, while bars on the right represent standard generic drugs. Most of the authorized generic drugs in my data sample entered the market in the same year-quarter as the patent expiration date. All drugs entered after the first year are included in category 5.

Figure 3.7: Kaplan-Meier Survival Estimates - Data Sample 1



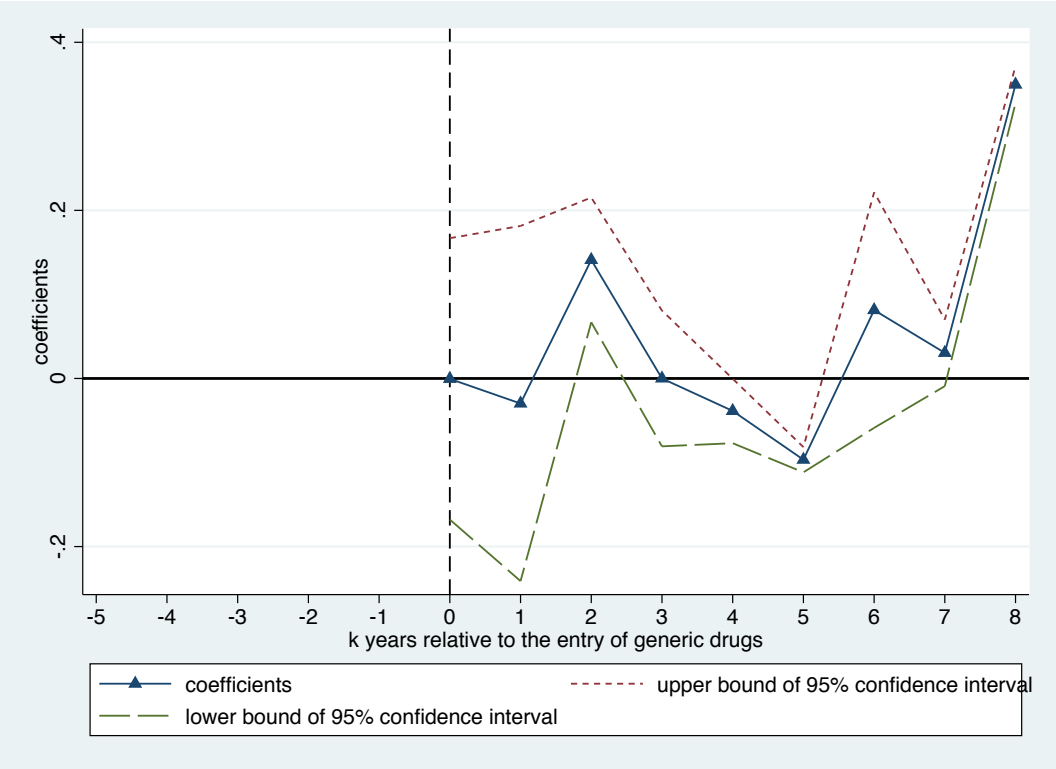
Note: The solid line represents the markets with authorized generic drugs, while the dashed line represents the markets without authorized generic drugs. Fail equals to one when the generic drug enters the drug market. The x axis is the relative years after patent loss.

Figure 3.8: Physical Exercise



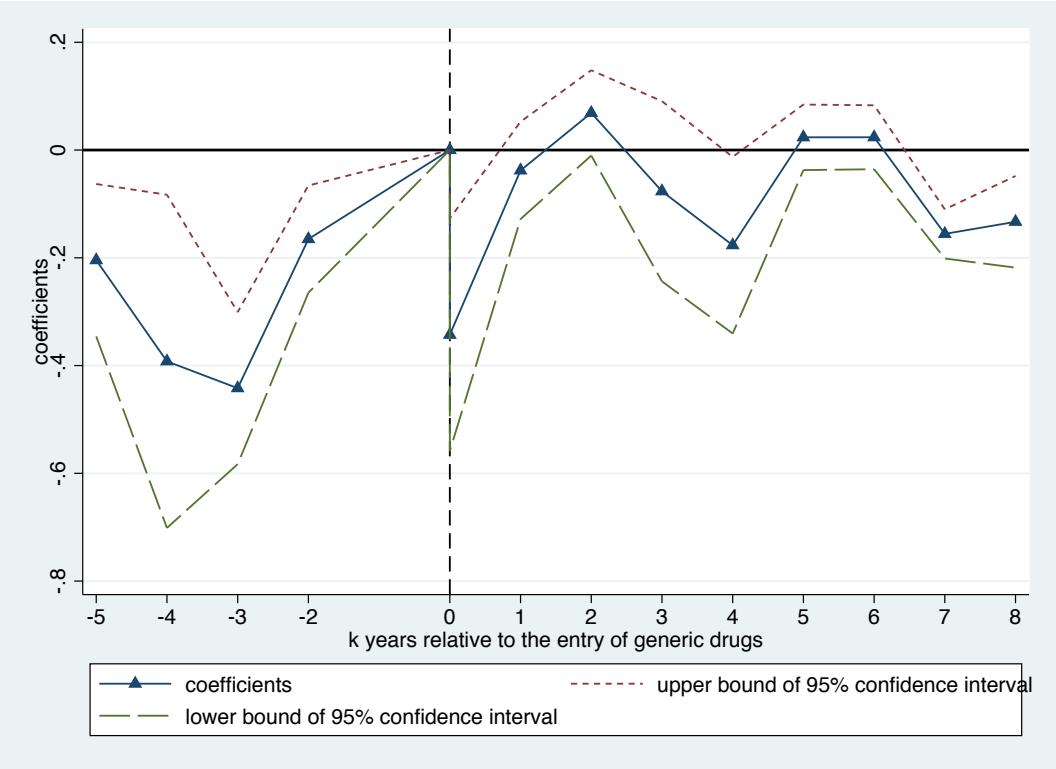
Notes: This figure plots the coefficients of my regression. The y axis is the coefficients and the x axis is the relative years to the entry year of generic drugs.

Figure 3.9: Physical Exercise - Generic User



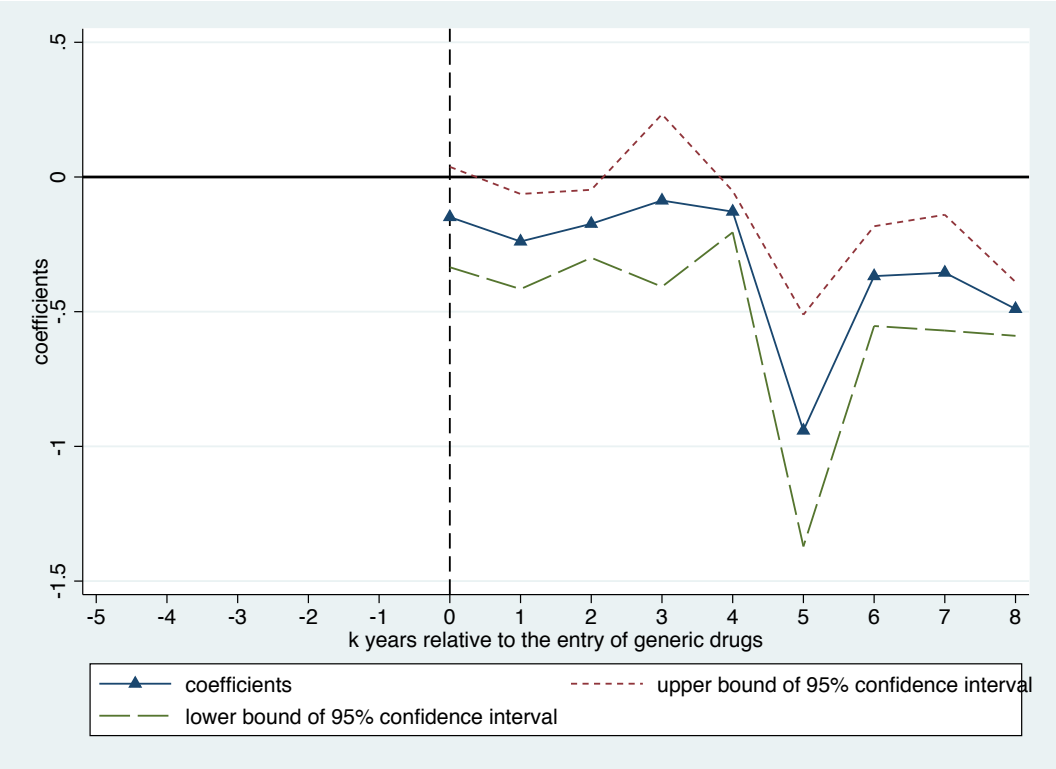
Notes: This figure plots the coefficients of my sub-analysis. The y axis is the coefficients and the x axis is the relative years to the entry year of generic drugs.

Figure 3.10: Diet



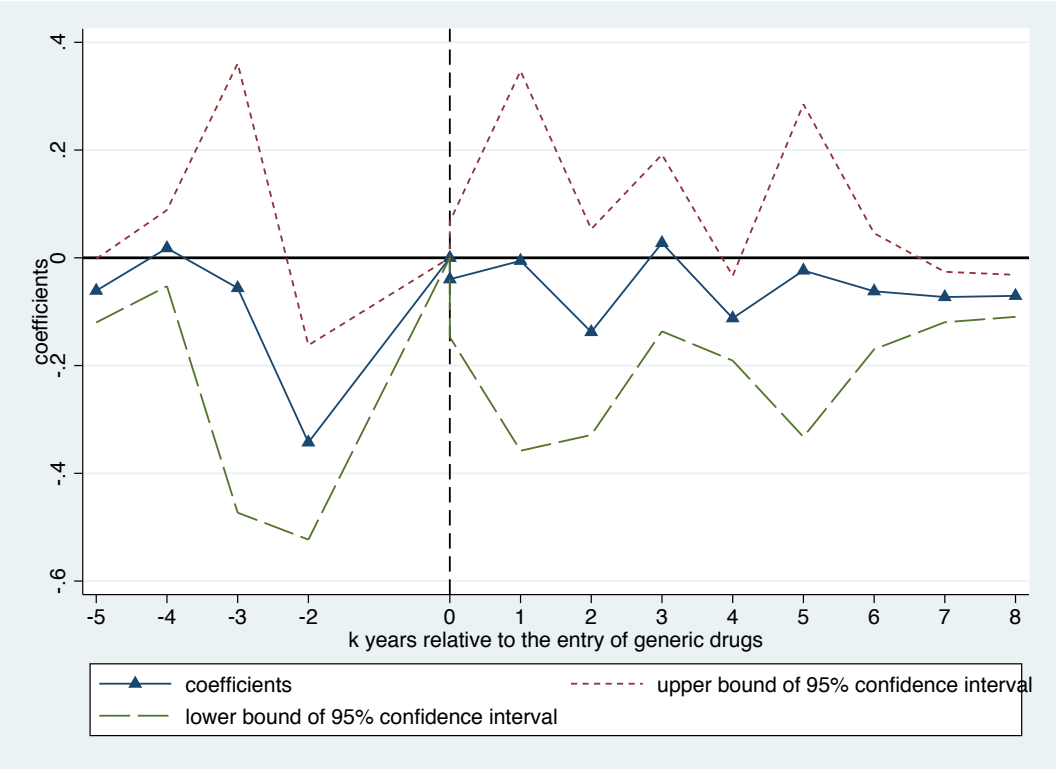
Notes: This figure plots the coefficients of my regression. The y axis is the coefficients and the x axis is the relative years to the entry year of generic drugs.

Figure 3.11: Diet - Generic User



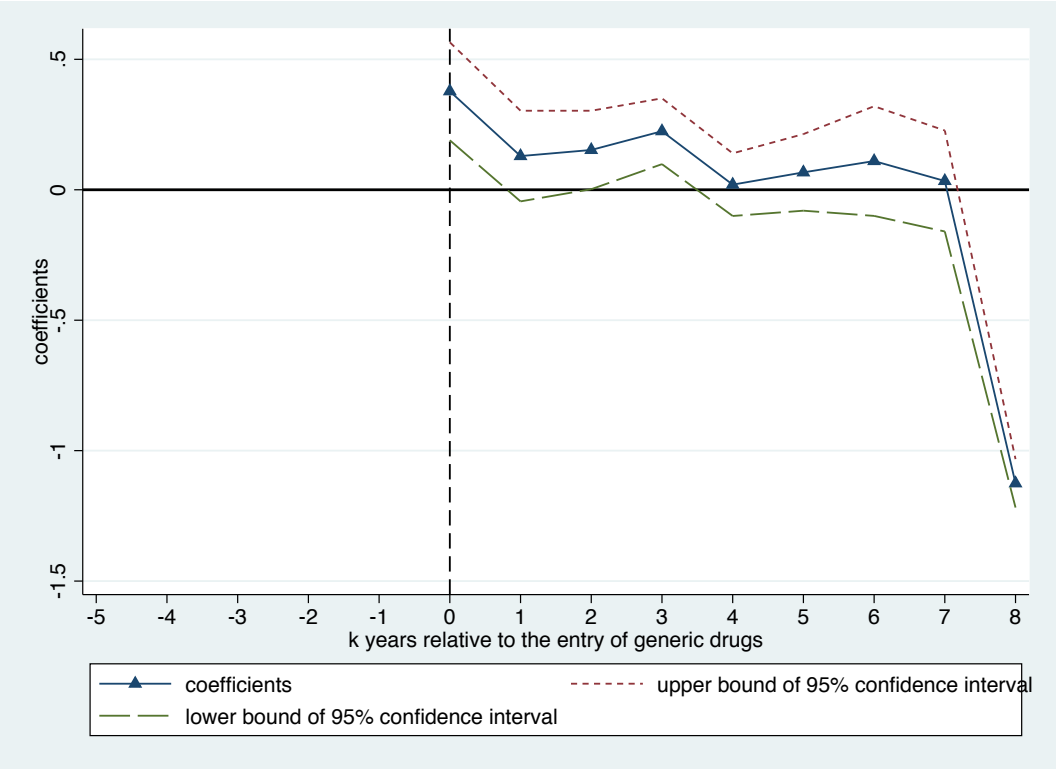
Notes: This figure plots the coefficients of my regression. The y axis is the coefficients and the x axis is the relative years to the entry year of generic drugs.

Figure 3.12: BMI



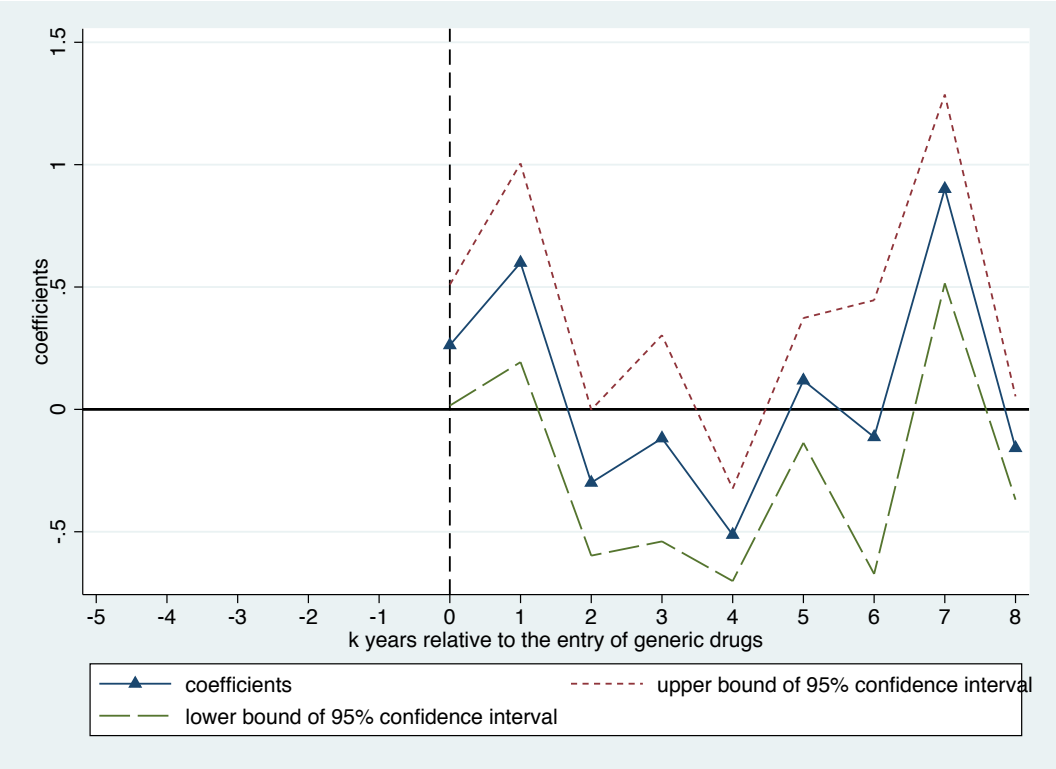
Notes: This figure plots the coefficients of my regression. The y axis is the coefficients and the x axis is the relative years to the entry year of generic drugs.

Figure 3.13: BMI - Generic User



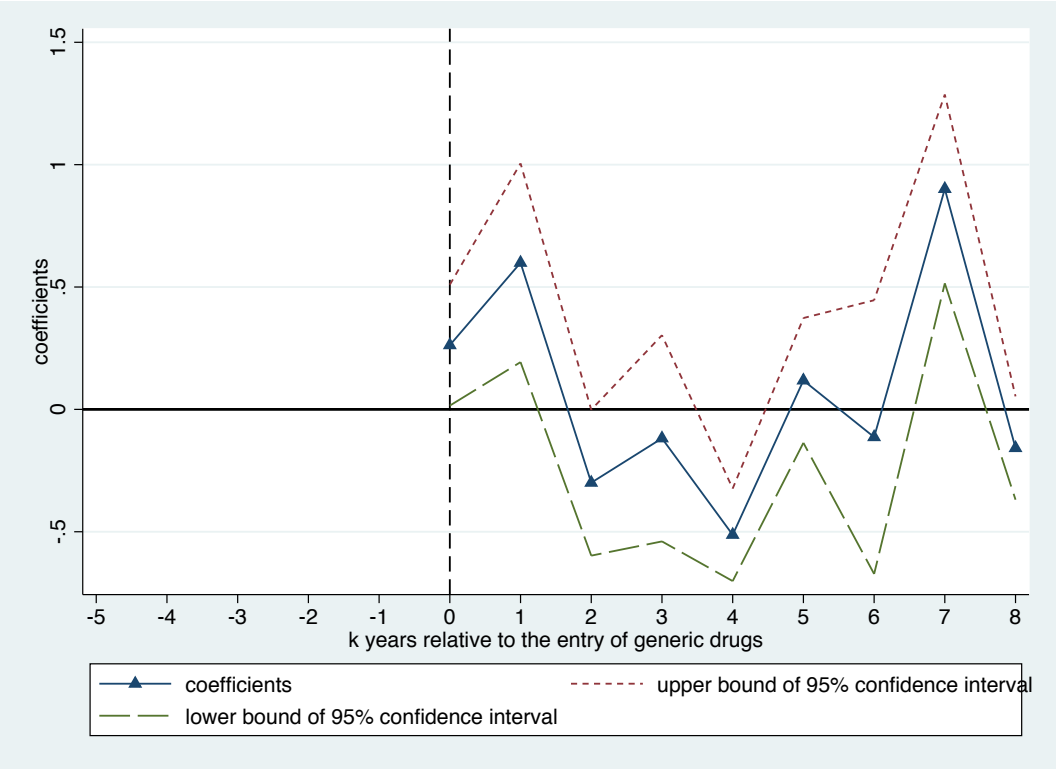
Notes: This figure plots the coefficients of my sub-analysis. The y axis is the coefficients and the x axis is the relative years to the entry year of generic drugs.

Figure 3.14: Smoking



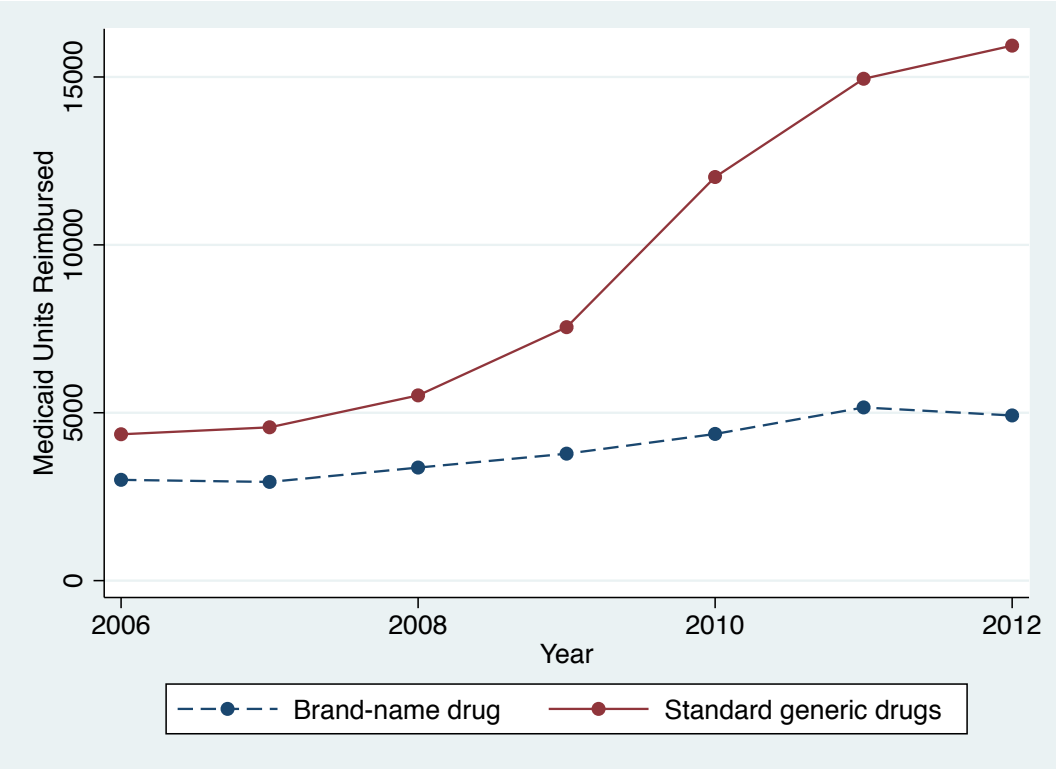
Notes: This figure plots the coefficients of my regression. The y axis is the coefficients and the x axis is the relative years to the entry year of generic drugs.

Figure 3.15: Smoking - Generic User



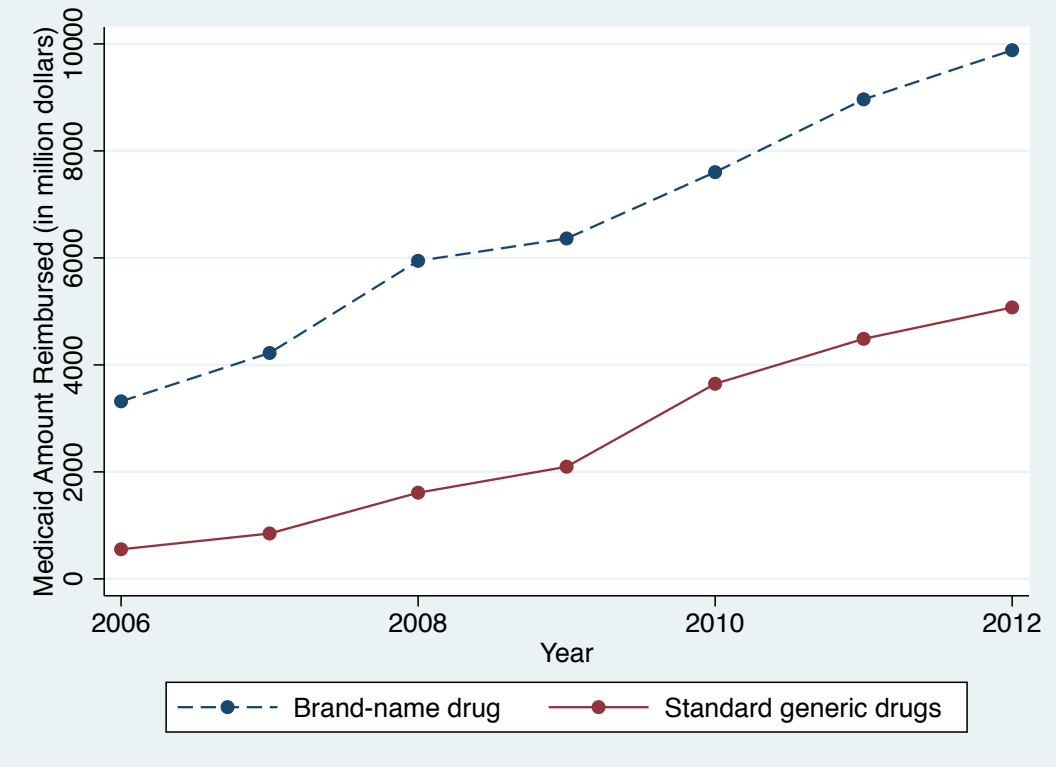
Notes: This figure plots the coefficients of my sub-analysis. The y axis is the coefficients and the x axis is the relative years to the entry year of generic drugs.

Figure 3.16: Medicaid Units Reimbursed - by State and Year



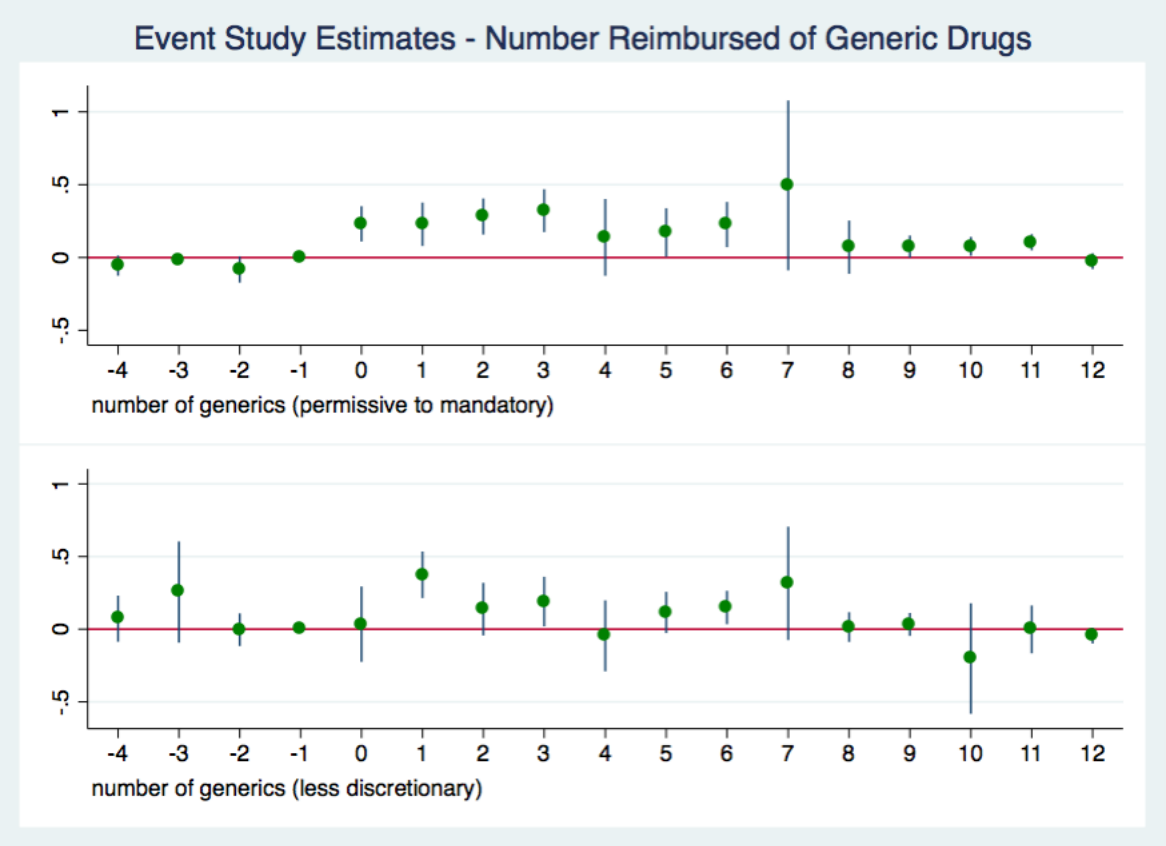
Notes: This figure shows the average units of prescription drugs reimbursed by Medicaid by years and state.

Figure 3.17: Medicaid Amount Reimbursed - by State and Year



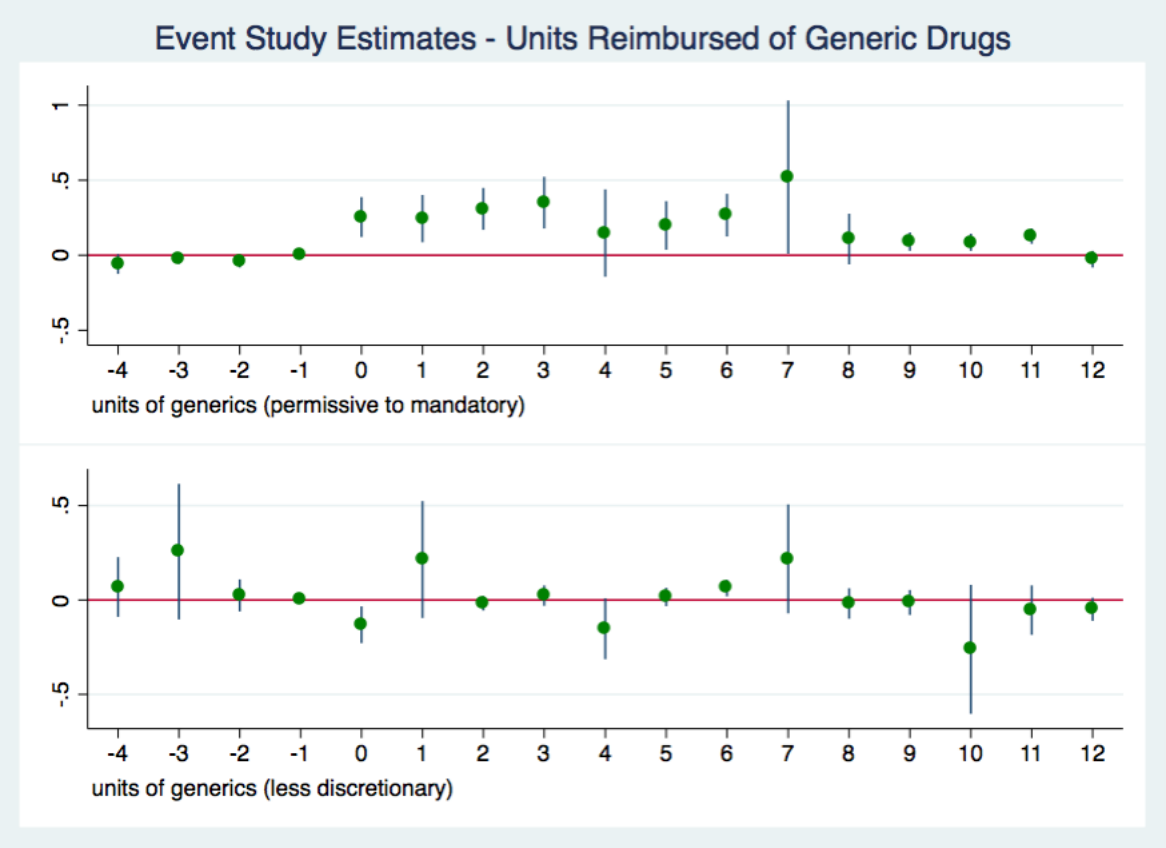
Notes: This figure shows the average amount reimbursed by Medicaid by years and state.

Figure 3.18: Event Study Coefficients of the Effect of State Generic Substitution Laws on Logarithm Number of Prescriptions of Generic Drugs, 2006-2012



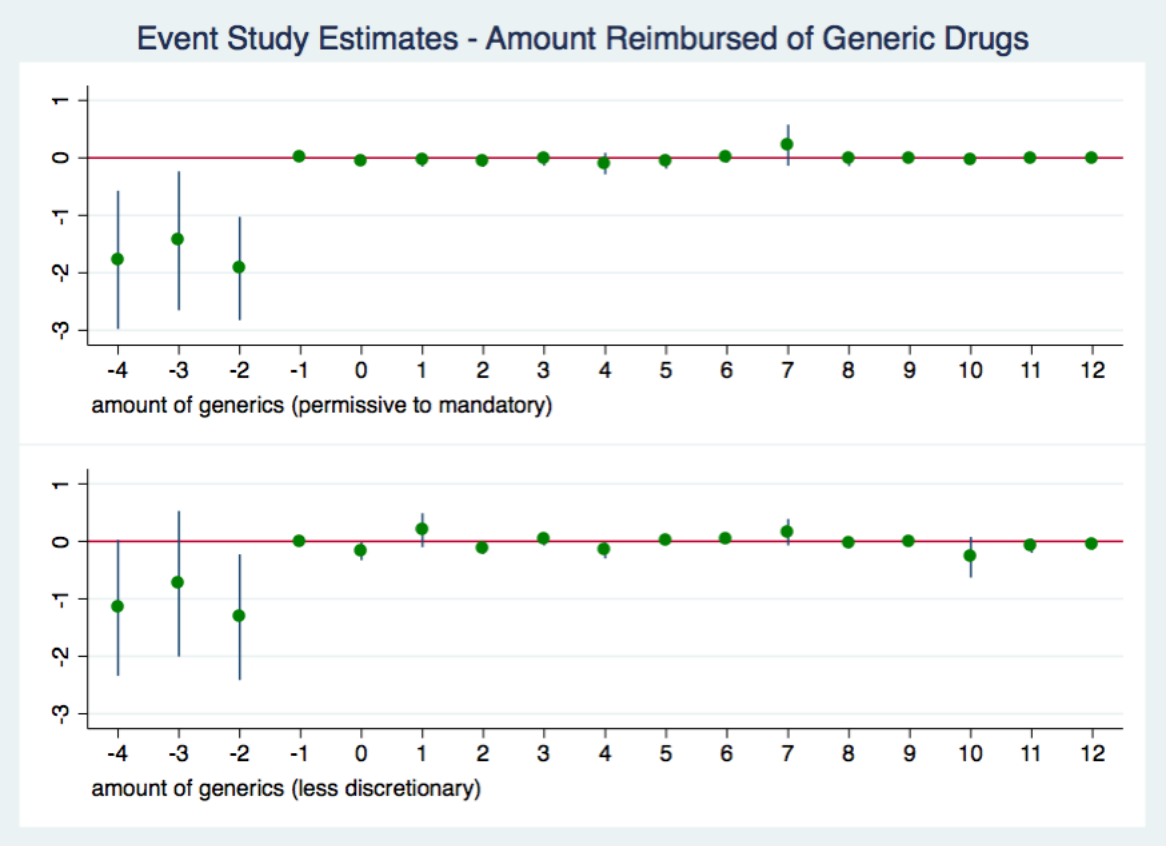
Notes: This figure shows coefficients of the effect of state generic substitution laws on Logarithm number of prescriptions of generic drugs reimbursed by Medicaid. The dataset is balanced to 4 quarters before the policy change and 12 quarters after the policy change. All the coefficients are estimated by using equation 2 with state year linear trend.

Figure 3.19: Event Study Coefficients of the Effect of State Generic Substitution Laws on Logarithm Units Reimbursed of Generic Drugs, 2006-2012



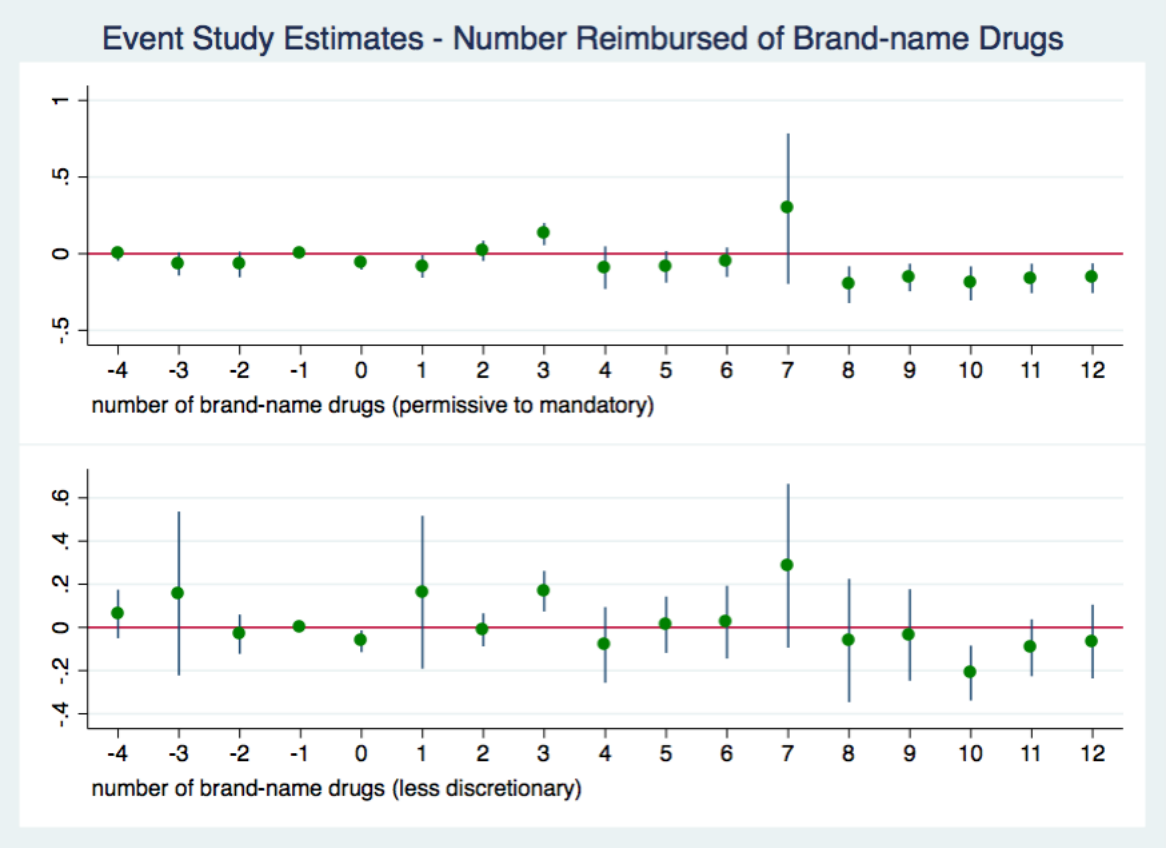
Notes: This figure shows coefficients of the effect of state generic substitution laws on Logarithm units reimbursed of generic drugs reimbursed by Medicaid. The dataset is balanced to 4 quarters before the policy change and 12 quarters after the policy change. All the coefficients are estimated by using equation 2 with state year linear trend.

Figure 3.20: Event Study Coefficients of the Effect of State Generic Substitution Laws on Logarithm Amount Reimbursed of Generic Drugs, 2006-2012



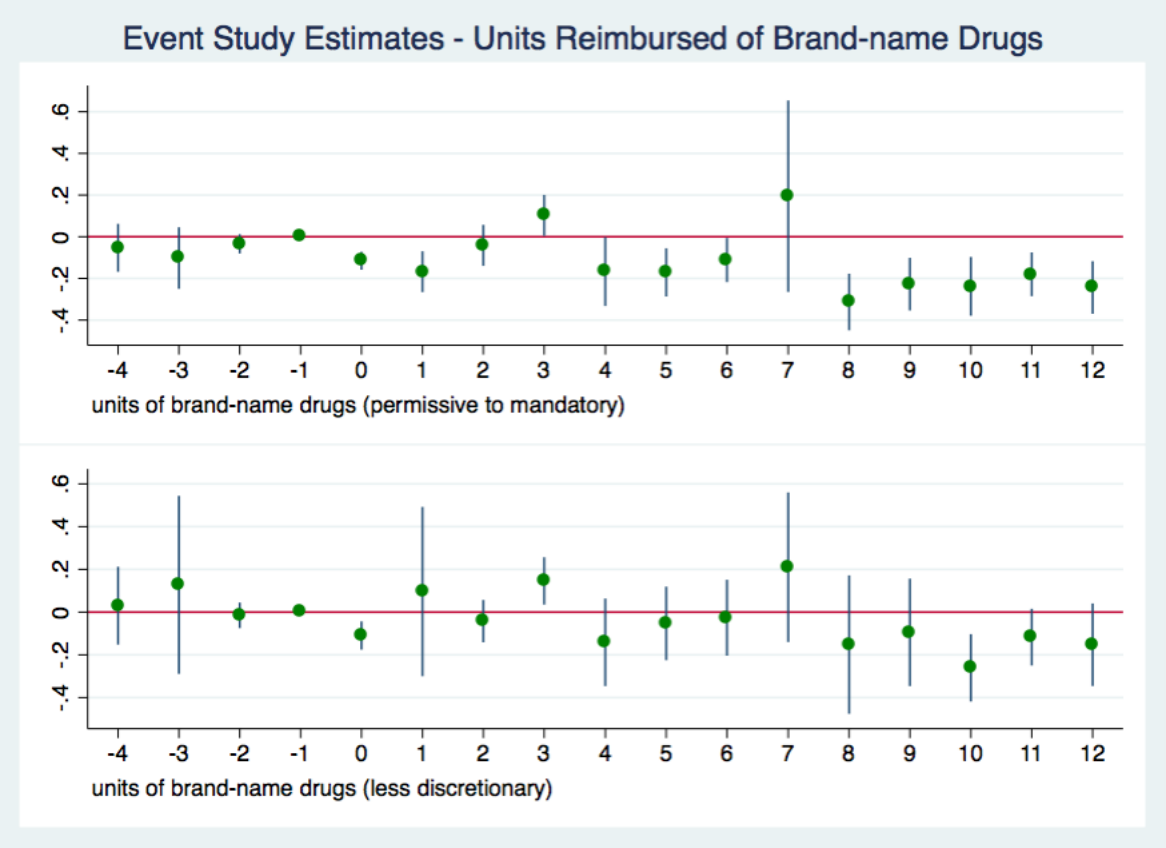
Notes: This figure shows coefficients of the effect of state generic substitution laws on Logarithm amount reimbursed of generic drugs reimbursed by Medicaid. The dataset is balanced to 4 quarters before the policy change and 12 quarters after the policy change. All the coefficients are estimated by using equation 2 with state year linear trend.

Figure 3.21: Event Study Coefficients of the Effect of State Generic Substitution Laws on Logarithm Number of Prescriptions of Brand-name Drugs, 2006-2012



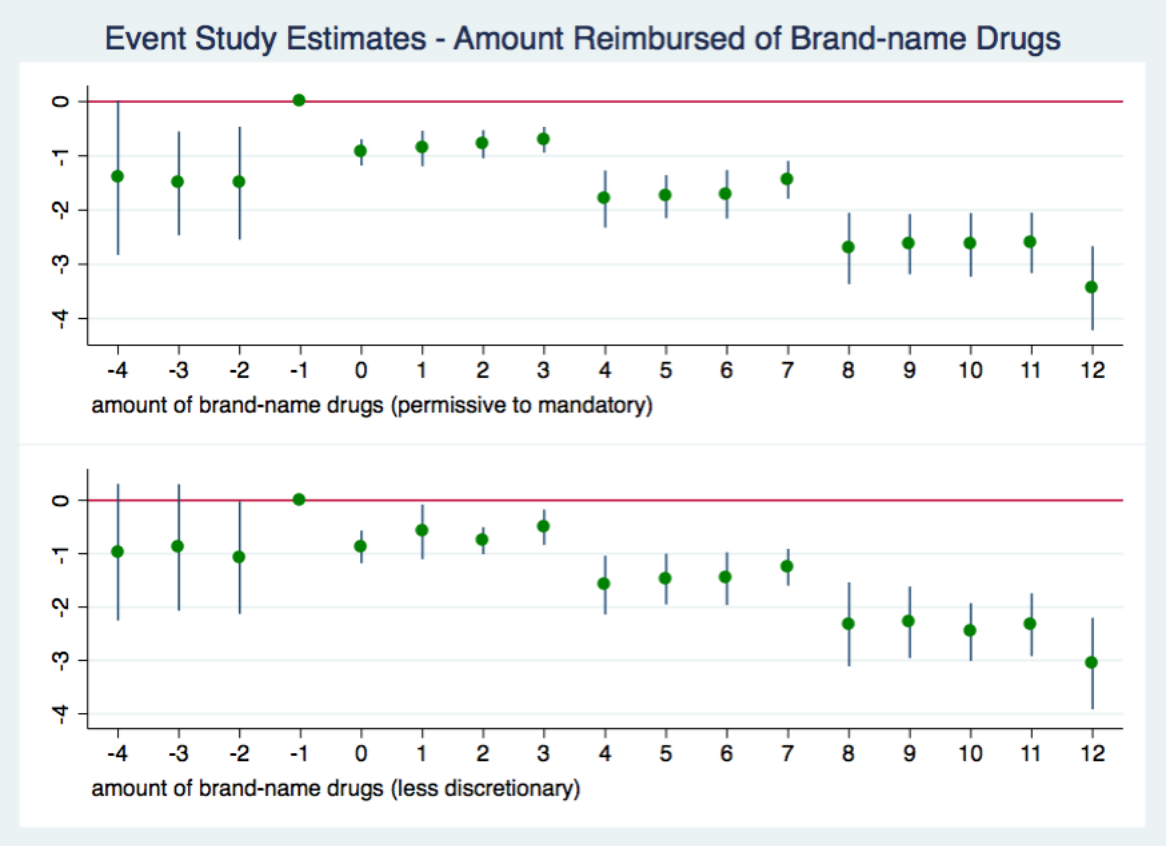
Notes: This figure shows coefficients of the effect of state generic substitution laws on Logarithm number of prescriptions of brand-name drugs reimbursed by Medicaid. The dataset is balanced to 4 quarters before the policy change and 12 quarters after the policy change. All the coefficients are estimated by using equation 2 with state year linear trend.

Figure 3.22: Event Study Coefficients of the Effect of State Generic Substitution Laws on Logarithm Units Reimbursed of Brand-name Drugs, 2006-2012



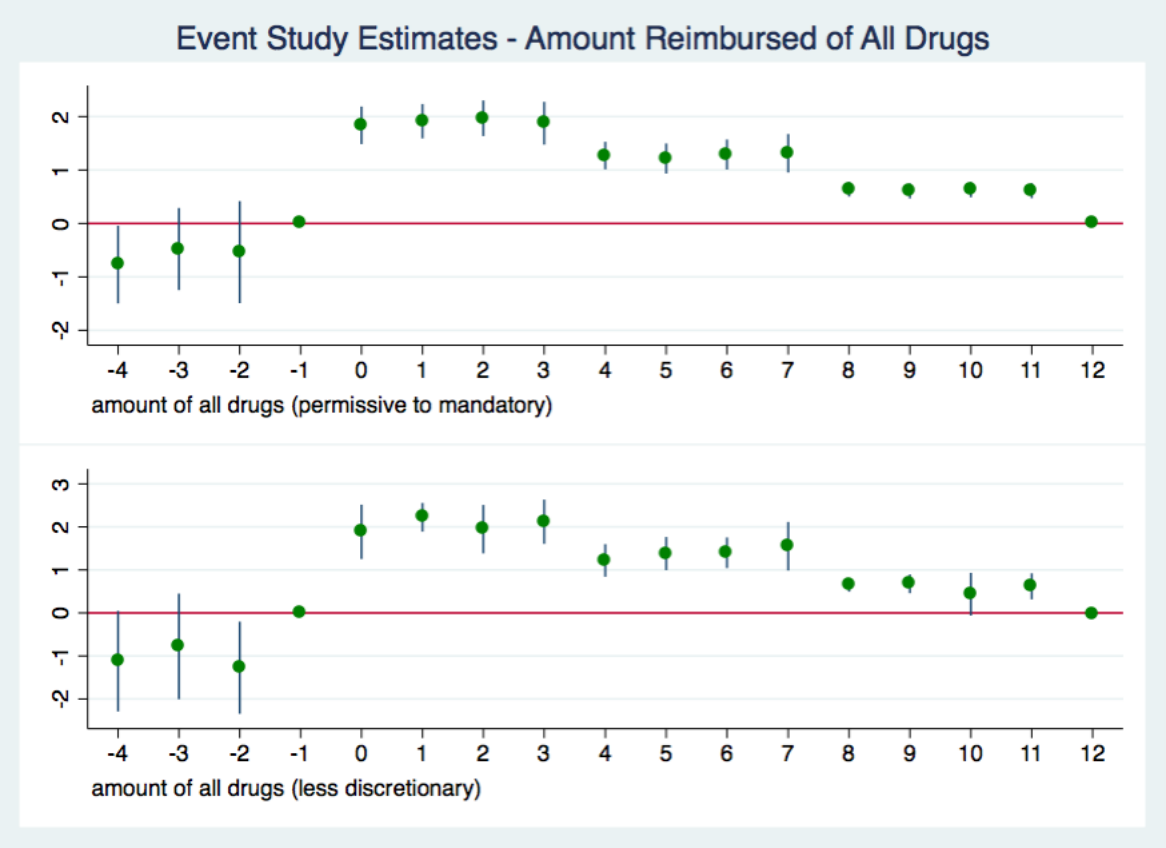
Notes: This figure shows coefficients of the effect of state generic substitution laws on Logarithm units reimbursed of brand-name drugs reimbursed by Medicaid. The dataset is balanced to 4 quarters before the policy change and 12 quarters after the policy change. All the coefficients are estimated by using equation 2 with state year linear trend.

Figure 3.23: Event Study Coefficients of the Effect of State Generic Substitution Laws on Logarithm Amount Reimbursed of Brand-name, 2006-2012



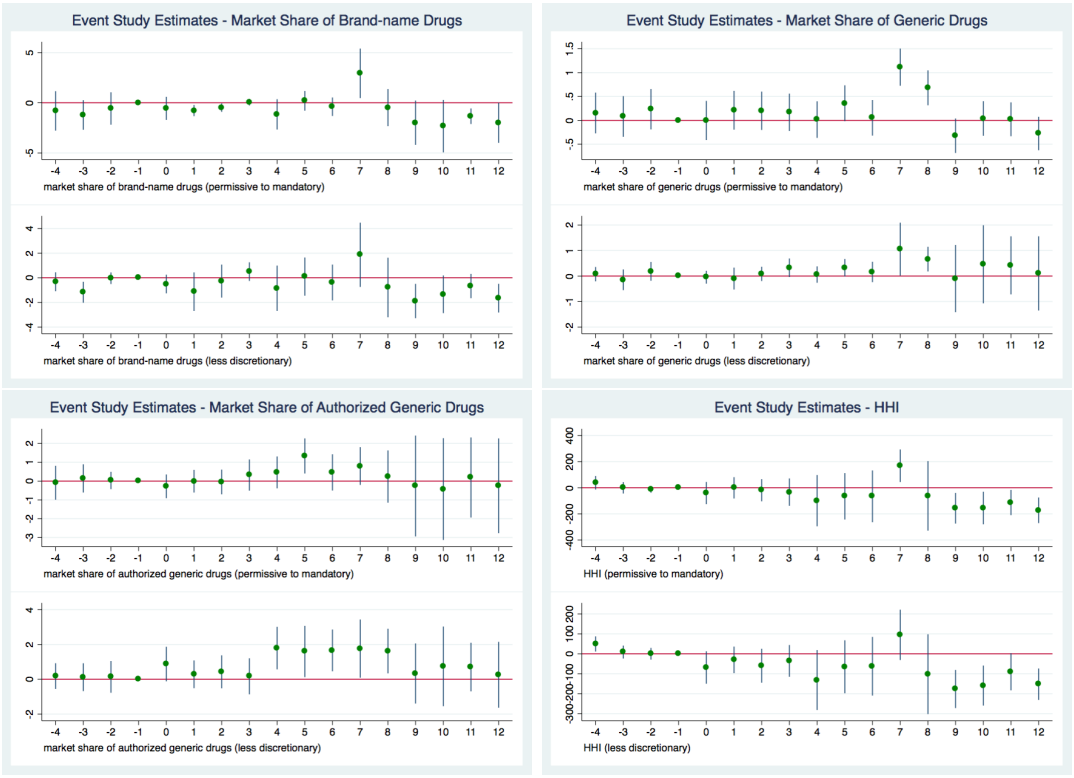
Notes: This figure shows coefficients of the effect of state generic substitution laws on Logarithm amount reimbursed of brand-name drugs reimbursed by Medicaid. The dataset is balanced to 4 quarters before the policy change and 12 quarters after the policy change. All the coefficients are estimated by using equation 2 with state year linear trend.

Figure 3.24: Event Study Coefficients of the Effect of State Generic Substitution Laws on Logarithm Amount Reimbursed of All Drugs, 2006-2012



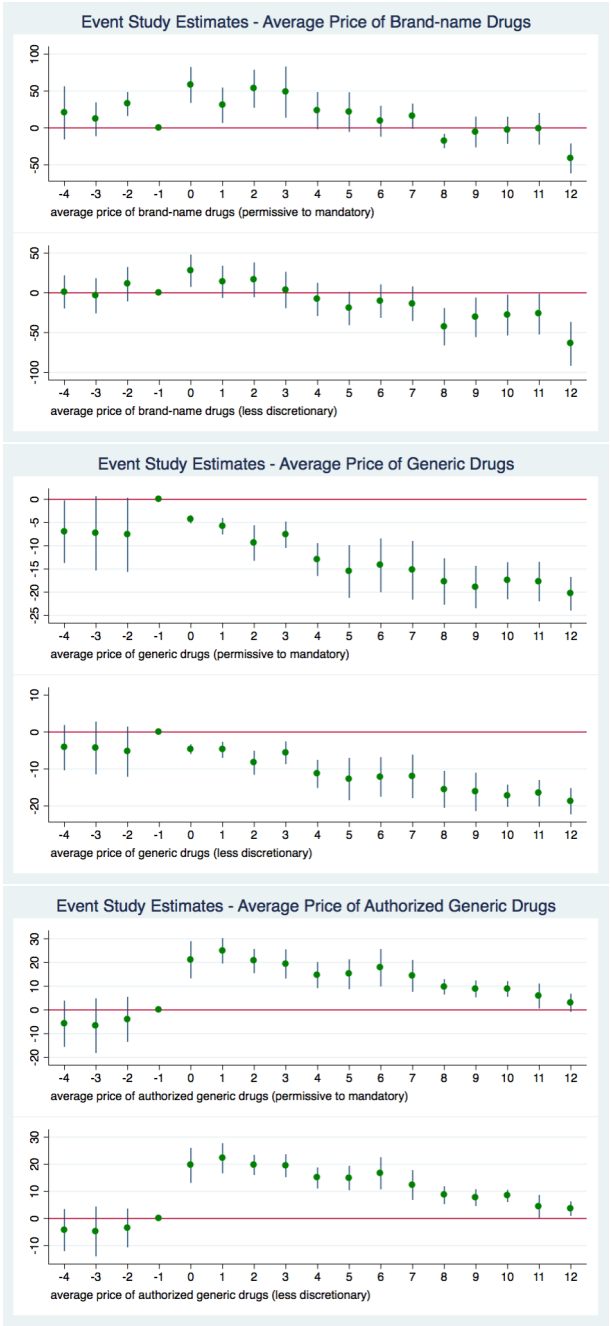
Notes: This figure shows coefficients of the effect of state generic substitution laws on Logarithm amount reimbursed of all prescription drugs reimbursed by Medicaid. The dataset is balanced to 4 quarters before the policy change and 12 quarters after the policy change. All the coefficients are estimated by using equation 2 with state year linear trend.

Figure 3.25: Event Study Coefficients of the Effect of State Generic Substitution Laws on Prescription Drug Market Shares and HHI, 2006-2012



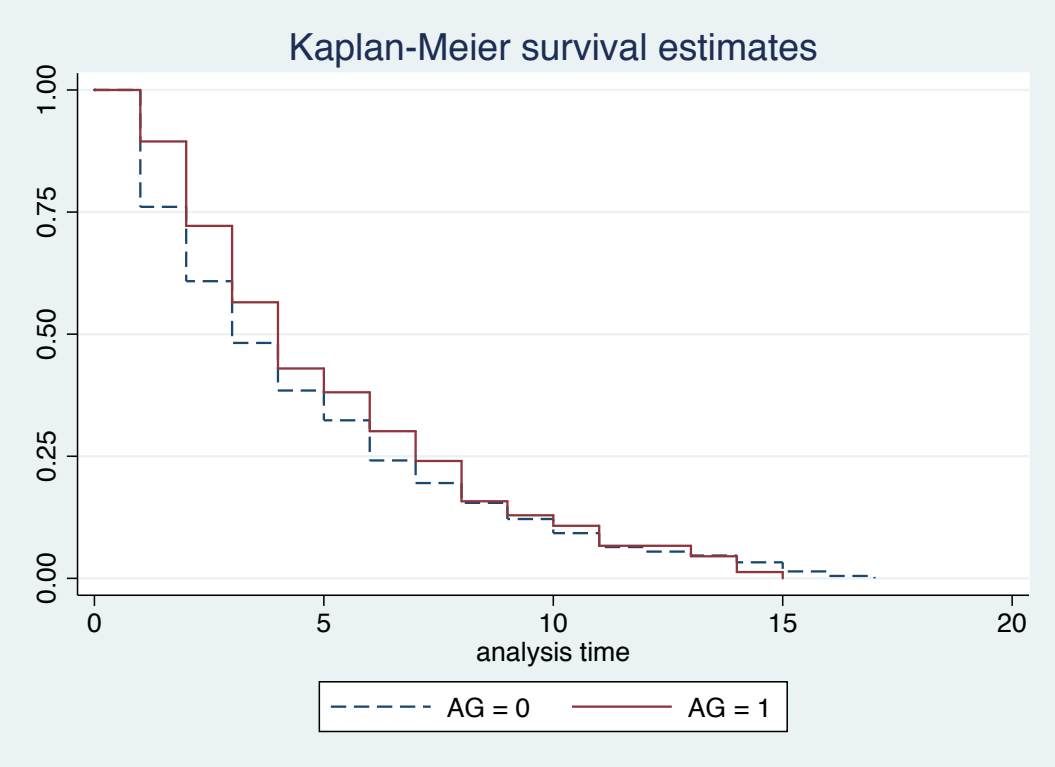
Notes: This figure shows coefficients of the effect of state generic substitution laws on prescription drug market shares of brand-name drugs, generic drugs, authorized generic drugs, and HHI. The dataset is balanced to 4 quarters before the policy change and 12 quarters after the policy change. All the coefficients are estimated by using equation 2 with state year linear trend.

Figure 3.26: Event Study Coefficients of the Effect of State Generic Substitution Laws on Average Reimbursed Prices, 2006-2012



Notes: This figure shows coefficients of the effect of state generic substitution laws on average reimbursed prices of brand-name drugs, generic drugs, and authorized generic drugs. The dataset is balanced to 4 quarters before the policy change and 12 quarters after the policy change. All the coefficients are estimated by using equation 2 with state year linear trend.

Figure A1: Kaplan-Meier Survival Estimates - Data Sample 2



Note: The solid line represents the markets with authorized generic drugs, while the dashed line represents the markets without authorized generic drugs. Fail equals to one when the generic drug enters the drug market. The x axis is the relative years after patent loss.

Table A1: List of Control Variables

Variable Name	Descriptions
Year-quarter fixed effect	
Drug fixed effect	
State fixed effect	
Seasonal effect	Four quarters in each year
Utilization type	FFSU - Fee For Service Utilization Records MCOU - Managed Care Organization utilization record
Marketing category	ANDA - generic drugs NDA - brand name drug NDA AUTHORIZED GENERIC - authorized generic drugs
Start marketing year	
Therapeutical Field (ATC3)	
Brand competitors	number of brand name drug competitors
Monopoly years (originator)	Monopoly durations years of the originator (Patent expire year - start marketing year)
2014 Medicaid Eexpansion	In 2014, 30 states expand their Medicaid program
Drug specific time trends	

Notes: Expansion states: AR, AZ, CA, CO, CT, DE, DC, HI, IL, IN, IA, KY, MD, MA, MI, MN, NV, NH, NJ, NM, NY, ND, OH, OR, PA, RI, VT, WA, WV.

Table A2: Effect of Authorized Generics on Standard Generic Entry Decision: Simple Probit Model

	Data Sample 1 (N = 25,614)	Data Sample 2 (N = 7,648)
AG Entry	0.42*** (0.09)	0.31*** (0.09)
Share of New Medical Devices (IV)	-0.08 (0.08)	-0.20 (0.17)
Pre-entry Revenue (log)	0.07*** (0.01)	0.06*** (0.01)
Monopoly Duration (years)	0.01 (0.01)	0.01 (0.01)
Substitutes Brands	0.02*** (0.01)	0.02*** (0.01)
Substitutes Generics	0.02*** (0.01)	0.03*** (0.01)
Field Experience	0.08*** (0.01)	0.0578*** (0.0135)
Therapeutic Field (0/1)	YES	YES
Dosage Form (0/1)	YES	YES
Year Expiry (0/1)	YES	YES

Notes: This table provides the results of the simple probit model. The outcome variable is the likelihood of generic entry.
Robust standard errors in parentheses.
*** p¡0.01, ** p¡0.05, * p¡0.1

References

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Biography

Lu Yao is a Ph.D. in the Department of Economics at Tulane University. Her research interests are in the fields of health economics, public economics, labor economics and applied micro-econometrics. She is deeply interested in how the firms' strategic behavior affects market competition in drug markets. She is also interested in the effects of generic drug use on patients' health behaviors. Her job market paper uses an instrumental variable approach to examine the effect of authorized generic drug entry on the entry decisions made by generic manufacturers and the timing of generic entry in the U.S. market. Her study contributes to the broader economic literature that has examined the consequences of entry deterrence strategies and strategic behaviors of brand manufacturers. Her primary findings indicate that the introduction of authorized generic drugs both deters and delays the entry of standard generic drugs. In addition to her research, her teaching experience has provided invaluable experience in developing my teaching abilities and philosophy. Her main goal as an instructor is to cultivate students' curiosity and relate economic concepts to real-life events that students understand and care about. So far she held crowded office hours and discussion sessions for a wide range of courses including Introduction to Microeconomics, Introduction to Macroeconomics, Intermediate Microeconomics, Game Theory, and Econometrics.