The Cost of Free Lunch

Banning Pharma from Providing Off-Site Meals to Doctors

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Abstract

This paper analyzes the impact of Massachusetts banning pharmaceutical representatives from providing off-site meals to doctors on what type of medications were prescribed, pharmaceutical and overall medical spending and self-reported health measures, using the Medical Expenditures Panel Survey (MEPS), and individual level difference-in-differences regressions. The main estimates use a pooled sample. Secondary estimates use panel estimates for a subset of the participants. The analysis focuses on medications which are still on-patent but are in the same class as a generic medication, and finds that the regulation significantly decreased the likelihood that an individual is taking one of these medications. However, due to the small sample, there is no clear evidence of overall savings. Additionally there is improvement in how respondents rated the physical or mental health, or whether they report that health limits daily activities. The regulation, which also applied to the marketing of other medical devices, also decreases the likelihood of having any medical expenses, though there is no significant impact on the cost.

1 Introduction

Health care costs in the U.S. are 17.5% of the GDP (CDC, 2016), nearly twice that of other developed nations (OECD, 2014). Spending on pharmaceuticals totaled $310 billion in 2015, increasing 8.4% from the previous year, according to a Pew Center (Coukell and Shih, 2016) summary IMS Health report. The pharmaceutical industry has healthy profits, and while down to 9.3% from a peak in 2006 of 10.4%

pharmaceutical, spending is roughly twice as much of overall health care spending as it was in the 1980's and 1990's. Additionally, some medication regimes cost thousands of dollars a month, with single pills costing around $30. The industry justifies these prices as necessary to recoup the cost of researching and developing medications. Many insurers, policy makers, and health care experts find all of this hard to swallow, thus see pharmaceutical spending as a good place to make cuts, key to reducing overall health care costs.

Aggressive marketing is the reason costs are rising, charge critics of the industry. In response, when spending on medications as a percentage of overall health care cost was near its peak, a handful of states passed legislation that restricted the gifts pharmaceutical companies could bestow upon doctors and or required that the gifts be disclosed. These gifts include meals, other goods and services (e.g., tickets to an event). Massachusetts passed one of the most stringent laws curbing these practices. Starting on July 1, 2009, pharmaceutical companies (and medical device manufactures) could no longer provide doctors and other medical providers[1] with tickets to events, cash (except for bona fide services), or off-site meals, and they had to disclose gifts worth over $50 they gave to prescribers (Massachusetts Executive Office of Health and Human Services, 2009).

The ban restricted where trainings could be held, so that manufacturers could not effectively give prescribers free vacations by holding training at resorts. Similarly, by constraining meals to offices and hospitals, the industry could not host trainings at up-scale restaurants. These restrictions not only reduce how enticing the gift is, but may also lead to shorter presentations because doctors may not allocate as much time to on-site meals. Additionally, doctors may not pay as much attention to presentations in the workplace, because they are still surrounded by all the distractions and responsibilities of work. Finally, if the off-site trainings are larger there could be more of a peer pressure effect.

The contribution of this paper is to analyze the impact of the ban, which is uncertain. To my knowledge, no published study has estimated the impact of any of these bans. If the now prohibited marketing strategies were particularly effective, a ban might be successful in reducing pharmaceutical spending. However, with so many other tools still available, the industry may still be able to persuade doctors to prescribe profitable products. The ban has a potential impact not only on pharmaceutical spending, but also on health. Some research finds that despite the rising costs, the care received is worth the costs (Lichtenberg, 2001) (Cutler and McClellan, 2001; Miller and Sarpong, 2011). Other studies claim that pharmaceutical treatment

[1]Throughout the rest of the paper I use the term "doctors" to refer to any prescriber, while it is less accurate it avoids phrases like "the prescribers prescribed..."

alone can be nearly as beneficial as surgical procedures at much lower costs. (Weintraub et al., 2008; Mark et al., 2009). If increased pharmaceutical spending produces better health or lower costs (by preventing substitution to more expensive non-drug treatments), gift bans could have harmful consequences.

The analysis focuses on the impact on branded medications with only indirect generic competition (BMIGC). Overall pharmaceutical spending is also examined. A two-stage hurdle model is used, where the first stage predicts non-zero spending and the second stage is natural log of spending. To test for unintended consequences the effects on perceived health status, whether health limits daily activities and other medical costs are estimated. Individual-level, pooled regressions are used with the larger data set. The analysis is repeated using first-difference regressions for the participants in the panel which spanned the reform.

The regulation significantly decreased the likelihood that an individual is taking one of these medications, and resulted in overall savings. There was no evidence of substitution toward generics. Additionally, there significant improvements in how respondents rated the physical or mental health, or whether they report that health limits daily activities. The regulation, which also applied to the marketing of other medical devices also decreases the likelihood of having any medical expenses, though there is no significant impact on the cost. There is evidence the regulation improved some health outcomes. This paper analyzes a particular reform that was designed to curb pharmaceutical spending, and estimates its effects on spending and health. However, as these are the medication any cuts would target, findings may generalize to other proposed programs aimed at cutting pharmaceutical spending.

2 Literature and Theory

Ubiquitous direct to consumer advertising is familiar to all of us. What may not be as evident is the industry's efforts to convince doctors and other prescribers of the benefits of the latest product. The industry spends $12 billion on marketing to prescribers and consumers. Hafemeister and Bryan (2009) outline the practices employed. "Detailing" is the practice of sending representatives to a prescriber's office to provide details about the medication, such as dosage instructions, and possible applications. These "detail men" often bring with them various small value items, pens, assorted office supplies, stress-balls, or food to curry favor with staff and doctors and help get their foot in the door. These small "swag" items prominently feature the medications name and logo, which are designed to promote salience–keep the name of the medication on the prescriber's mind, so that it is quickly associated with a patient's ailment.

Meals accompanied by presentations about the merits of the medication are provided both on and off-site. Often, particularly off-site, presenters are doctors who write many prescriptions for the product (and are being rewarded for doing so). These doctors are paid to make these presentations and may travel with their expenses paid to do so. Medical professionals are required to attend continuing medical education (CME) trainings. Pharmaceutical companies sponsor trainings that count toward CME and subsidize or discount them. Trainings may also be held in resort locations. Whether lured by the location, food served, or because it was a cheap way to fulfill CME credits, the information disseminated at these events favors the sponsors medication.

Several academic studies of various marketing practices have cast doubt upon the ideal, that decisions about what medication to prescribe are made with rational detachment or with cost effectiveness in mind. Interactions with marketing representatives start in medical school (Sandberg et al., 1997). Contact with a pharmaceutical representative is a primary mode for doctors to learn about new medications (Peay and Peay, 1988), and can lead doctors to request medications be added to formularies (Chren and Landefeld, 1994) and can increase sales and demand elasticity (Rizzo, 1999). Orlowski and Wateska (1992) not only find that seminars in attractive destinations lead doctors to prescribe the featured medications more frequently, they characterize their finding as, "suggesting that the new drugs were not replacing older alternatives, but instead that the enticements were resulting in additional and perhaps excessive use" (p.4). Additionally, it has been shown that physicians medication choice can depend on their own financial interests (Liu et al., 2009; Iizuka, 2012).

In light of this research, or a general distaste for what is often characterized as overaggressive marketing, when spending on medications as a percentage of overall health care cost was near its peak, a handful of states passed legislation that restricted the gifts pharmaceutical companies could bestow upon doctors and or required that the gifts be disclosed. These gifts include meals, other goods, and services (e.g., tickets to an event).

Proponents of the laws believed that the gifts were enticing physicians to prescribe medicines they would not otherwise prescribe. Doctors have imperfect knowledge of the various medication options, and there are search costs to improve knowledge of any individual medication. Offering meals raises the salience of information about the featured medication and lower search costs. Doctors may also be overtly seeking a reward, or feel indebted to those giving them gifts. (Katz et al., 2010). For this reason, proponents argued that curbing these marketing practices could prevent doctors from prescribing more expensive medicines in place of cheaper substitutes, thereby

reducing pharmaceutical spending. Massachusetts passed one of the most stringent laws curbing these practices. Starting on July 1, 2009, pharmaceutical companies (and medical device manufactures) could no longer provide doctors with tickets to events, cash (except for bona fide services), or off-site meals, and they had to disclose gifts worth over $50 they gave to prescribers (Massachusetts Executive Office of Health and Human Services, 2009). Minnesota has had a marketing restriction, preventing gifts totaling more than $50 retail value in a calendar year since 1993. Vermont (VT) also banned all gifts starting in 2009.

There is reasons to believe the reform might be successful, Brotzman and Mark (1992) Brotzman and Mark (1992) examine the impact of one medical schools change in policy restricting interactions between industry sales representatives and medical residents. The authors find that, after graduating, the doctors schooled with the restrictions had fewer interactions with pharmaceutical representatives. Brotzman and Mark did not measure any effects of the training on subsequent prescription patterns. Particular to meals, DeJong et al. (2016) show that even when there is not clear evidence of a medications advantages of a cheaper generic in the same class, those prescribers accepting meals from a pharmaceutical manufacture are more likely to prescribe medications. While they make a strong case for there being a relationship between the type of doctors who accept meals and those who prescribe the promoted drug, DeJong et al. did not control for likely selection bias, thus cannot say anything about what those same doctors would do had they not received these meals. Analyzing this reform allows us to answer the question what would happen if at least the off-site meals were removed. Additionally, it is at a larger scale than the policy of a single medical school, and examines more than four medications.

I will examine the effect on medications which are most likely to be impacted: branded medications with only indirect generic competition (BMIGC) I do not analyze the medications for which there is no generic competition. In these cases, consumers have no choice but to purchase expensive drugs (*Big-Name Drugs Are Falling Off The 'Patent Cliff'*, 2011), or take nothing. If there is competition, it is between two branded medications, and both firms will be hampered by the regulation, so there is no theory by which to predict results. I also do not analyze the medication for which the patent protection has expired and generic substitutes. The industry refers to this as going over the "Patent Cliff". Medications quickly lose market share to generics (Latham, 2013). In one extreme case, Prozac lost 70% of its market share in 5 months (Song and Han, 2016). Market share plummets because insurers, and in many cases, state law compel substitution from brand names to chemically equivalent generics. Often efforts to market the products are minimal after the patent expires because purchasers have so much power.

BMIGC often occur when one firm introduces a new and effective drug, and patents its particular chemical compound. Once a medication gets Food and Drug Administration (FDA) approval, the firm will immediately begin marketing it to recoup research and development expenses and maximize profits. Competitors then try to make a chemical compound that is chemically distinct enough that it can be produced with violating the patent, but chemically similar enough that it has nearly the same effect. The competitor can then patent this "copycat" medication. The original drug goes off patent first. After the first medicine is off patent, if a third firm can prove to the FDA that it can produce a "chemically equivalent" product, then it can market this generic alternative. Generics are generally on the market soon after patents expire. However, it may have taken the competitors several years to identify a similar chemical compound. Because the patents were granted years later, they expire years later. This creates a period when the copycat medications are still on patent, and the original drug is available as a generic; in other words, an appropriate and low-cost substitute for the copycat medications is available. Manufacturers of the copycats are still marketing them heavily to squeeze rents out of the patents before they expire.

Often policy and legislation is an experiment; effects are uncertain, this is particularly true when the policy is novel. However, even when adopting policy other jurisdictions have enacted outcomes are not given. There can be heterogeneity in treatment effects, due to different characteristics of the jurisdictions or population or the new policy can interact with or be moderated by other regulation or systems within the government[2]. Applying experimental methodology, we would see this as a situation in which there are multiple levels of treatment. Both groups receive at least the basic treatment whereas one group (not MA) receives additional treatment on top of the basic treatment. Admittedly, it is slightly more complicated, MA had been receiving the treatment as well, but now has it withdrawn. However, the important question is: what exactly comprises this additional treatment?

The regulation restricted where trainings could be held, so that manufacturers could not effectively give prescribers free vacations by holding training at resorts. Similarly, by constraining meals to offices and hospitals, the industry could not host trainings at high-end restaurants. These restrictions not only reduce how enticing the gift is, but may also lead to shorter presentations because doctors may not allocate as much time to on-site meals. Additionally, doctors may not pay as much attention to presentations in the workplace, because they are still surrounded by all the distractions and responsibilities of work. Perhaps given more time the pharma-

[2]For instance, a regulation like this could be moderated by medical malpractice laws, and may be really effective in one location but not as effective in another with different malpractice laws.

ceutical representatives could offer fuller arguments in favor of their products. This seems unlikely, both because the representatives seem well practiced at honing their message and because doctors constantly operate in an atmosphere where they quickly absorb the most pertinent information. Perhaps it is just opportunity to repeatedly reinforce the same message. Again it seems unlikely, as frequent office visit could do the same. I posit that the setting and the doctors role there, is the true difference. Off-site events are likely to be larger more formal presentations in which the doctor is an audience member in a conference like setting. Generally the presentation is given at least in part by another doctor the industry would describe as a "thought leader". The social pressure to accept expert advice like peers in the audience may be the true difference. Unfortunately I do not have the data to test this.

The effect of the reform is uncertain. There are four basic scenarios. The first is that there is no change. This would be the case if the off-site meals have no sway on what doctors prescribe or because the industry was able to substitute other marketing e.g. more on-site meals, to counter the effects. It is even possible that there could be a paradoxical effect, if the other marketing was effective enough. The remaining scenarios result in lower rates of prescribing BMIGC. They differ in what comes in its place.

One scenario is cheaper generic medications are substituted for the BMIGC. This would be the case if the information provided with the off-site meals influenced how the doctor treated a condition but not whether or not the patient received treatment. This scenario results in savings. The generic medication could work better, no different, or worse than the BMIGC. Clearly, the first two have positive net benefits. If the generic worked worse, the net effect would depend upon how much worse, and what the health implications were, and how that compared to the reduction in medication costs. Another basic scenario is that there is substitution toward other medical care. This might mean surgical options in place of statins, diet and exercise in place of cholesterol medications, or therapy and hospitalizations in place of psychiatric medications. Here the implications for cost are ambiguous, and the question of relative effectiveness remains.

The final scenario is that nothing comes in the place of the BMIGC, this has two variants. One is that both with and without the regulation the patient is treated with another (generic) medication and that the BMIGC was supplementing this treatment when there is no regulation. This is picking up on a suggestion from Orlowski and Wateska (1992) that the medications were not being prescribed in place of other medications, but in addition to them. The other variant is that the patient gets no treatment for the condition. This would be the case if the information accompanying the meal influenced the decision as to whether or not to treat a condition, either

through increasing awareness of the condition or drawing attention to he fact that treatment was available. The industry argues that it marketing helps patients by addressing both of these issues. In both variants, the cost of the BMIGC option is higher. In either variant, there are three outcomes. The (addition of) the BMIGC could make the condition better, no different, or worse. The latter two have net costs, while the net benefit of the former depends on how much the condition improved relative to the cost of the medication.

I analyze the ban impacts BMIGC to determine if the outcome is the first scenario or one of the latter three. I next estimate the effect on prescriptions overall. A decrease here would indicate that the BMIGCs were add-ons or new treatments. I examine if there is substitution toward generic competitors. Increases in these prescriptions would indicate that it was the third scenario. Finally, I look at the impact on other spending an increase here would indicate that it was the final scenario that was realized. In reality, there is an independent scenario for each patient medication combination. The analysis attempts to uncover which scenarios occur for a significant number of patients. To determine outcomes within scenarios, I estimate the impact on perceived health status, and whether health limits daily activities.

3 Data and Methodology

For this analysis, I use data from the Agency for Healthcare Research and Quality (AHRQ)'s Medical Expenditure Panel Survey (MEPS). AHRQ began MEPS in 1996. They survey a national representative subsample of households from the National Center for Health and Statistics National Health Interview Survey regarding "demographic characteristics, health conditions, health status, use of medical services, charges and source of payments, access to care, satisfaction with care, health insurance coverage, income, and employment". Households are surveyed for two consecutive years and assigned weights. I use data from 2000 to 2011. The ban was loosened in 2012. This was also the year when the federal "Sunshine" law for reporting gifts from drug companies took effect. State identifiers for the 29 most populous states are available through AHRQ. Vermont is among the 21 states that AHRQ will not decode. I dropped all these states and Minnesota (MN) from analysis. The number of individuals in my subsample ranges from 18,677 from 9535 households in 2007 to 34,252 from 9,535 households 11,957 in 2002. The number of subjects who had prescription ranges from 11,759 individual in 2007 to 20,488 in 2002. In all, for the 12 years, there are 329,850 person-year observations not with no missing relevant variables reports demographics for this sample.

[Insert Table 1 Here]

The Massachusetts Healthcare Reform ("RomneyCare") took effect in 2007 but took a couple years to phase in, so per Courtemanche and Zapata (2014) I implement a pair dummies to indicate implementation of RomneyCare and post years; for MA 2006 and 2007 are coded as during and 2009 is coded as post. Additionally, to control and provisions that did not take effect immediately or for any delayed impact, I run regressions in which I restrict the respondents to those unlikely to be effected by the reform. The first variant is models which only include respondents 65 and older. These models are of particular interest because these individuals are more likely to take medications. The second variant is those who have employer provided insurance. This excludes those who obtained insurance through "The Connector" that the reform established, and those with public health insurance.

Should all of these not control for RomneyCare, the effects are likely to diminish those of the marketing regulation. RomneyCare increased insurance rates and quality making it more likely that residents would have insurance that covered prescriptions. Lower out of pocket costs to consumers would make it more likely that they were on prescription medications and should increase total costs of prescribed medications.

The data on medications has a line per prescription, so there are 300,000+ observations, in some years. Each line has the medication name and overall price; there are also breakdowns of who paid what toward the overall price. Figure 1 graphs the spending per person on medication in across years for all medication and BMIGC's.

[Insert figure 1 here]

Subjects are surveyed about their health status; they are asked to rate both their physical and mental health on a five-point scale ranging from "excellent" to "poor". They are also asked about whether their health limits their ability to work, and do basic activities such as: climb stairs, socialize, and walk various distances. In addition to all variables for individual limitation, there is a variable which indicates whether they answered yes to any of the questions about limitations. Additionally, MEPS contains data on other medical expenditures. Because MEPS is so rich and contains information on both medication taken (and their costs) as well as health outcomes, it is a good data set to answer both parts of the research question: was the ban successful in curbing costs? and did that have an adverse impact on health, or other medical spending?

However, MEPS does have the limitation that it is relatively small data set. On average, there are fewer than a thousand respondents per state per year. There is also a great deal of variability in what medications a person is taking and the total cost of

those medications. Respondents cycling in and out of the sample causes the mix of respondents with high and low costs in a state vary and introduces sampling variation. This variation obscures the state trend and made it difficult to construct a synthetic control per Abadie et al. (2010). It is also not clear how to apply the synthetic control method while also utilizing MEPS strata structure. Instead, I use individual level regressions. While attempting to synthesize a control for Massachusetts, California (CA), Connecticut (CT), New Jersey (NJ) and Virginia (VA) were identified as having similar trends. I include regression limited to these states as a robustness check. While it would be natural to use the other New England states as a control, the only other New England state decoded is Connecticut.

The small size also precludes focusing on individual medications. Instead, medications that likely to be impacted by the regulations are pooled. For 2009, the first year the regulation is in effect, the 115 top grossing medications within MEPS, those for which aggregate spending in the sample was above $40,000 are identified. Then for the ones which are branded, I determine if there are any viable generic substitutes.[3] The process is described with examples in the appendix A.1. A dummy variable to note this status is created. Table 2 reports the mean costs per participant per year of these BMIGC in comparison to other medication for the three treatment years. The average cost of the BMIGC is significantly higher than other medications, though there is much variation in the other medications, as they include both cheap generics and expensive branded medication some without any competition. Also reported are average cost per year for and likely generic substitutes and other branded medications. Additionally, another dummy to note medications which were likely substitutes (generic medications in with the same classification as a BMIGC) is created. For each respondent, I calculate the total cost of the medications they took as well as subtotals based on the dummy variables. These are the variables of interest.

[Insert Table 2 here]

As it is common that individuals do not spend anything on medications (or subcategories of medications), a two-stage hurdle model is estimated, where the first stage is the probability that there any spending. The first stage was estimated using a logit, probit and linear probability models. The models yielded similar results, and in the Results, I only report on the latter two models. Natural logarithms are used in the second stage to account for the fact that the non-zero spending amounts have

[3]Substitutes were identified through various Internet resources, and the FDA's Orange Book site was used to determine when any generic substitute became available.

a right skew, a handful of observations with extremely high values. The model for both stages is:

$$Y_{ist} = \beta_1 PharmaReg_{ist} + \beta_2 Romney_{ist} + \beta_3 \vec{X}_{ist} + \beta_4 \sigma_s + \beta_5 \varphi_t + \varepsilon_{ist}$$

where Y_{ist} is the outcome for individual i in state s in year t, β_1 is the coefficient of interest, the impact of the regulation on the likelihood that an individual is taking a (BMIGC or substitute) medication, or the natural log of the total cost of all the individual's medications. *RomneyCare* is the above-mentioned pair of dummy variables to note during and post RomneyCare years in MA. $\vec{X}$ is a vector of individual level controls, including income level, education level, age, sex, dummy variables for actively smoking, being in an MSA, being black or Hispanic, or being diabetic and insulin dependent. I also include state σ_s and year φ_t dummies, and utilize the strata and PSU information provided. Regressions are implemented using Stata survey (SVY) commands, which cluster errors on strata. An alternative specification does not make use of the survey commands in order to cluster errors at the state level.

As an additional check, I limit the data to Panel 13, the participants who were surveyed in both 2008 and 2009. For these regressions, the outcome of interest is the change in spending between 2008 and 2009 between and whether that is impacted by the regulation, so increases in Massachusetts are compared to those in the control state. Table 13 reports spending from both years, their difference, and the natural log of 2009 spending divided by 2008 spending. Average spending in the control states increased from \$781 to \$872 a difference of \$90. In MA, the increase was from \$1,237 to \$1,304, a difference of \$67.

[Insert Table 13 Here]

The rightmost column is the dependent variable in the regressions. Any individual who did not reside in the same state both years is dropped. As most the independent variables in the previous model are not time varying, the only independent variable included are whether the individual is in MA and interactions of the two categorical variables for the type of insurance (private, public or none) the individual had for the respective years. Regression of the natural log of year over year totals for the BMIGC are also included as are changes in limitation status and self-assessed physical and mental health.

4 Results

For all the results, the first column is the full sample (after dropping MN and the 21 still encoded states). The second and third columns are checks for lingering results of RomneyCare. The subpopulations represented in these columns were largely unaffected by the reforms. The second column is those who are 65 or older. The third column includes only respondents insured through their employer. The fourth through sixth columns repeat the same groupings but limit the control to California, Connecticut, New Jersey, and Virginia. The top half of the table reports results of estimates which utilized the survey commands and the PSU and strata information provided. The bottom half of the table repeats all the regression clustering by state, but not making use of the survey commands or PSU and Strata information. The two methods yield the same point estimates, but differ in their estimates of standard error, due to the different assumptions of error structure. The survey command standard error estimates are larger. Greater similarity in errors within strata than within states would produce this. I will focus on these more conservative estimates.

Table 3 reports marginal effects from probit regressions of the marketing restrictions impact on the likelihood of taking medications. Within each half of the table, the top section reports results for the BMIGCs. The middle section of the table reports results for taking any medication. The bottom section reports results for taking a generic medication that is in the same class as a BMIGC. The results indicate that the marketing regulation made it less likely that an individual in any of the groups was taking a BMIGC. This result was stronger for those over 65 and weaker for those insured through their employer. This implies for at least some individuals who were not in the first scenario (no change), but leaves open the question of which of the three remaining scenarios occurred. The survey command results also indicate that the regulation did not make it any less likely that the general population or those 65 years or older were any less likely to have any medication expense. They do indicate that those insured through their employer were less likely to be taking any medication. Clustering errors by state indicate all the groups were less likely to be taking any medication, with the exception of the seniors when compared to the four state control group.

[Insert Table 3 Here]

The results also indicate that the regulation made it less likely that an individual is taking a medication in the same classification that is available generically. This is a puzzling result for which I cannot explain. One possibility is spillover from meals and detailing. That is because of the meals, the environment they create and the

information conveyed there, doctors become aware of the conditions the featured medications are meant to treat, but then do not prescribe the featured medication instead prescribe a generic competitor. There is some evidence of spillover effect from direct to consumer advertising Kravitz et al. (2005).

Combined with the results from the bottom two sections of the table, the results indicate that at least for those insured through their employers that the BMIGCs were not substitutes for generics but an additional medication. Often direct to consumer advertising the focus is subjective symptoms, stomach upset, feeling blue, etc. These are symptoms nearly, everyone experiences time to time, however if they were severe or occurred frequently enough, they could be debilitating. The question is: how frequent or severe warrants prescription medication? and does advertising lower the frequency/severity bar. A similar dynamic in detailing could persuade doctors that they were missing illness in patients that needed to be treated, and explain why the alternative to a branded medication was no treatment. There are also instances in brand name medications are promoted as adjunct therapy or as a compliment to a patient's existing medication. Table 4 reports coefficients from linear probability regressions. They confirm probit results.

[Insert Table 4 Here]

The next series of tables test what the outcomes of the scenarios were. Table 5 reports marginal effect from regressions on natural logs of the individual spending on medications. This is a second stage to the above regressions, as logs of zero are undefined. Within each half, the top section reports the impact on total cost for BMIGC's conditional on taking at least one. The second section is more policy relevant, the impact on overall pharmaceutical spending conditional on taking any medication. Given the variability of individual spending and the smaller sample, there is high variance and results are insignificant when using the more conservative standard error estimates from the survey command. The standard error estimates when clustering on states, indicate that for the whole population there was a significant reduction in the cost of an individual's medications conditional on that individual taking medication. This paired with the results from the above two tables indicate that the policy saved money. Even with the more conservative errors, the ban saved money because there was no evidence that costs conditional on taking medications changed, but there was indication people were less likely to be taking medications. Costs are reduced in estimates just for those who have employer-based insurance, though the magnitude is slightly less. The "All" group includes people on public insurance and those who bought insurance through "the Connector". The effect for the cost

of medications for seniors is ambiguous; they are less likely to have any costs but conditional on having any costs, costs are greater.

[Insert Table 5 Here]

Tables 6 and 7 present regression results for the regulation's impact on the probability that an individual has any reported medical expense. Table 6 gives the marginal effects from a probit regression, and Table 7 gives the coefficient from linear probability model. The 65 or older columns are not included in the probit table, because nearly all the individuals 65 or older had medical expenses, so the regression would not converge. All the results indicate the regulation made it less likely that individuals had any medical expenses reported. The coefficients are larger than those for the regressions for having medical expenses, so there is not any evidence of any spillover of expenses. There is also indication that there is less likely to be other expenses. This may be due to the fact that the restriction not only applied to pharmaceutical companies, but to all medical device manufacturers.

[Insert Tables 6 and 7 Here]

Table 8 reports estimates of marginal effects of the impact of the natural log of total medical costs. The top half of the table reports results when using the survey structure to estimate standard errors the bottom half when clustering errors at the state level. The only significant results are for the overall population relative to both controls, and indicate slight increases in the cost. This is conditional upon having any cost. So the overall effect given the estimates from the previous tables is ambiguous. In the larger control, the estimates for seniors and those insured through their employers have the opposite sign, indicating that this rise in cost is possible a lingering effect from RomneyCare, the rise is due to those on public insurance or who bought it through the exchange.

[Insert Table 8 Here]

The next series of tables report results on the regulations impact on self-assessed health, both physical and mental, and whether participants report that health problems cause any limitations in daily activities. Tables 9 and 10 present coefficients from ordered probit regressions on how individuals rated their respective physical and mental health. Better health was coded with lower numbers, so negative coefficients indicate improved perceived health. For the survey command estimates, the coefficients in neither table are significant, so there is a lack of evidence of negative impact from the regulation on self-assessed health, or that the BMIGC was superior

to the generic. When errors are clustered at the state level, standard errors estimates are smaller, and suggest that the regulation significantly improved how participants rated their health. This is the case for physical health for the overall population for both controls and seniors for the larger control. For seniors in comparison to the smaller control and those with employer-based insurance the results are still insignificant. The estimates for mental health indicate significant improvement for the overall population compared to the full control group. All the other coefficient estimates are in the same direction, except seniors when compared to the smaller control. However, none of them are significant. I did not report marginal effects, because for an ordered probit there is no single number.

[Insert Tables 9 and 10 Here]

Tables 11 and 12 present regression results for the regulation impacting whether a surveyed individual reports that his or her health limits his or her daily activities. Table 11 reports marginal effects of probit regressions. Table 12 reports coefficients from a linear probability model. This variable is binary (0/1) where "1" indicates that activity is limited, so again a negative sign for the coefficient has the implication of improved health. Across the board both the probit and linear probability estimates indicate individuals are less likely to report activity limitations after the regulation. Only estimates using the survey commands are reported; if they are statistically significant the less conservative clustering by state will also be significant.

[Insert Tables 11 and 12 Here]

Panel 13

MEPS Panel 13 spanned the reform; participants were surveyed for both 2008 and 2009. Regression estimates for this panel are reported as a robustness check for the primary regressions. The specification of the regressions and the outcomes regressed vary from those with the pooled sample in order to take advantage of the panel structure. Any participant who moved to another state was dropped from the regressions. In general, the results are similar to the results using all the panels, but less significant; this is likely due to the smaller sample size. In the aggregate, there is some evidence that the reform may have helped curb rising costs. As can be seen in Table 13, average changes in cost from 2008 to 2009 in MA were smaller than those in the control states with many participants in MA having decreasing costs.

As with the results above from the pooled sample, the first three columns are results for the 28 decoded states that remain after removing MN. The first column

is all the participants, the second just those over 65. The third are only those insured through their employer. The fourth through sixth columns report results using just CA, CT, NJ and VA as a control, and repeat the groupings. The first half of tables reports estimates using the survey commands and clustering on strata and primary sampling unit, the second half reports estimates when the survey commands are abandoned to cluster by states, As with the pooled data, estimates of standard errors are smaller when clustering by states, as similarities within a strata are greater than those within a state.

Tables 14 and 15 report marginal effects from probit regressions. Table 14 reports the likelihood of starting a BMIGC in 2009. The regression includes participants not taking a BMIGC in 2008; the dependent variable takes the value 1 if they are taking a BMIGC in 2009, and 0 otherwise. Table 15 is the complement, the likelihood that use of a BMIGC is discontinued. It includes participants taking a BMIGC in 2008; the dependent variable takes the value 1 if they are no longer taking a BMIGC in 2009, and 0 otherwise. None of the coefficient estimates are significant when using the survey commands. However the estimate in the first column is consistent with the estimate from Table 3. The most likely explanation be that this would be due to the reduction in sample size. When clustering by state, some of the results are significant. Using the 28 state control, participants who are insured through their employer are less likely to start taking a BMIGC after the reform. All groups regardless of the control states are more likely to discontinue use of a BMIGC after the reform. Both these results are consistent with the pooled sample estimates[4].

[Insert Tables 14 and 15 Here]

Tables 16 and 17 report marginal effects from probit regressions. Table 16 reports the likelihood of starting "substitute" medication, a generic medication in the same class as a BMIGC, in 2009. The regression includes participants not taking a substitute in 2008; the dependent variable takes the value 1 if they are taking a substitute in 2009, and 0 otherwise. Table 17 is the complement, the likelihood that use of a substitute is discontinued. It includes participants taking a substitute in 2008; the dependent variable takes the value 1 if they are no longer taking a substitute in 2009, and 0 otherwise. In the general population, relative to either control participants are significantly more likely to start a substitute after the regulation, regardless of method for calculating errors.

None of the results are significant when standard errors are estimated using survey commands. However, when errors are clustered by state the overall population

[4]These tables can be compared in the sense that we can ask: are they telling the same story? It is not expected that the estimates would be equal or within a margin of error.

and those with employer-based insurance are also less likely to discontinue a substitute medication, relative to the larger control. This result is only significantly in comparison to the larger control, but the signs match for the smaller control. These findings contradict results for the pooled sample, reported in the bottom of Table 3. In contrast to the pooled sample results, the panel estimates excepting those for seniors are in line with the expected effects of the reform and provide evidence of the scenario where there is substitution from BMIGCs to generics in the same class. While the pooled sample is larger and over a longer span, the panel has the advantage of being free from any effects of who is randomly selected into the sample for a given panel, so may provide more accurate results.

[Insert Tables 16 and 17 Here]

The panel structure allowed for the identification of participants that had been taking a BMIGC in 2008 and where not taking one in 2009, and therefore allows further opportunity to distinguish between the three scenarios. Of those participants on a BMIGC in 2008, in 2009 40% of them in MA were no longer on a BMIGC in 2009 while in the control only 24% had stopped taking a BMIGC. The existence of these participants in higher proportion than in the control indicates the regulation some change, so there are participants who were not represented by the first scenario. There were 17 participants in MA for whom this was the case. One participant was taking two BGMIC in 2009, so there were a total of 18 cases of BMIGCs being discontinued. Table 18 reports the categorization of these changes, based upon a case by case inspection.

[Insert Table 18 Here]

MEPS does not provide dates for medications beyond years, which hampers analysis. In the control there is some discontinuation of BMIGCs so we cannot attribute all of the change to the regulation, nor distinguish those which are due to the regulation from those which are not. This table also does not capture cases where the participant was not on any medication and then started a medication, and there was then a choice between a BMIGC and a generic med.

Those points aside, the first row of the table represents the scenario in which the patient switches from a BMIGC to an in class generic; there are two cases of this. There are also two cases of switching to another branded medication, which was not one of the scenarios and may not be an impact of the regulation; this is the third line. The second line and fourth lines are the cases in which the BMIGC was a supplement to another medication, a generic in line two and another branded

medication in line four. There are two and four cases of this, respectfully. I did not examine for evidence of switching to non-pharmaceutical treatments. The final line would capture the non-pharmaceutical treatments, as well as the cases where there is no treatment in the counterfactual. There are eight cases of this. As the footnote states in three cases, the participant quit both a BMIGC and an in-class generic. These discontinuations may be unrelated to the regulation or they may be an affect of removing the spillover effect from promotion of the BMIGC. This was addressed when discussing the negative coefficient on the regulation in the regressions for the likelihood of taking a substitute medication). A more thorough investigation could be done. I focused on people who were on a BMIGC in 2009 but not in 2008. This does not capture the people who were on multiple BMIGCs but reduced the number they were on between the years, or came off one BMIGC but started another one for a separate condition.

Table 19 reports marginal effects for the differences from 2008 to 2009 of the natural logs of pharmaceutical costs. When using standard error estimates from the survey commands, the regression that appears significant is for the one for participants who are 65 years or older and when comparing MA to CA, CT, NJ and VA. This is evidence that the restriction actually increased expenses. However this is the only evidence of it and this is a very small sample and may have also arisen by chance given the number of regressions. There is no table in the larger data set directly comparable to this one, because there are not observations for most the participants both before and after the regulation takes effect. When clustering errors by state results indicate that after the regulation took effect expenses for seniors rose relative to either control. Again this may be due to the small sample; it is unclear why the the regulation would effect subgroups differently. In contrast, the results for those insured by through their employer and the overall population indicate a decrease in spending after the regulation. The latter results, indicate net saving in medication costs despite the possible rise in costs for seniors.

[Insert Table 19 Here]

Not only is their evidence of savings on medication cost, as results in Table 20 indicate a decrease in overall medical cost after the regulation. None of the coefficients are significant using the standard errors from the survey commands but all are significant when clustering errors by state. The table reports the coefficient estimates on the difference of the natural logs of expenses between the years. The results are consistent with those from the pooled sample and indicate any increase in costs due substitute from pharmaceuticals to other medical care was dominated by decreases in cost due to the regulation impact on other medical manufactures.

Tables 21 and 22 report coefficients of ordered probit regressions on the difference between 2009 and 2008 in how participants rated their physical and mental health. Lower ratings indicate better health, so negative differences ($Rating_{2009} - Rating_{2008}$) indicate improvements. For example, if the participant rated health 2 "very good" in 2008 and 1 "excellent" in 2009 the dependent variable is $1 - 2 = -1$. Negative estimates of the coefficients therefore also indicate improvement. When using standard error estimates from the survey commands, all the estimates for changes in physical health ratings (Table 10) are negative but only those for those insured through their employer are significant. This is true both when using 27 and 4 states as a control (column 4 and 6). Using standard error estimates from clustering errors by state, all the results are significant. For mental health, when standard error estimates from the survey commands are used, the only estimate that is significant is Column 1, all participants with 27 states as a control. The estimates for those with employer and insurance and the smaller control group are very similar in value only the standard errors are larger. When clustering errors by state, the estimate for the overall population and those insured through their employer are significant and negative. These results from both tables indicate that the regulation may actually improve patients health rating, or that the use of off-site meals may have led to patients being prescribed drugs that were worse treatments for them. These results are consistent with results from the pooled sample (Tables 9 and 10) but more results significant for the panel. It is possible that the first difference approach attenuated the impact of unobservable characteristics and allowed for more precise results.

Table 23 reports marginal effects from a probit regression meant to capture the regulation impact on the probability a participant becomes less limited by his or her health. Only those who reported a limitation in 2008 are included in the regression. The dependent variable is coded 1 if the participant does not report a limitation in 2009, and 0 otherwise; positive coefficients indicate improvement. If standard error estimate for the survey commands are used, none of the results are significant. If standard error estimates from clustering by state are used, results indicate the reform may have had health costs. There are significant negative coefficients for the general population relative to both controls and the seniors relative to the larger control group. The estimates from this table and the following table can be compared to those in Table 11. However because these are estimates of the likelihood that a participant overcame a previous limitation rather than reported a limitation, the sign of the estimate should reverse. The estimates conflict with those from the pooled sample. The within participant comparison may improved the precision of the estimates, but only include a small number of participants.

Table 24 is the compliment to the previous table. It reports marginal effects from a probit regression meant to capture the regulation impact on the probability a participant becomes more limited by his or her health. Only those who did not report a limitation in 2008 are included in the regression. The dependent variable is coded 1 if the participant reports a limitation in 2009, and 0 otherwise. Negative coefficients are the desirable direction. None of the estimates are significant, when using standard error estimates from the survey commands. When error estimates from clustering errors by state, seniors are better off compared to the larger control after the regulation, but the general population is slightly worse of compared to the smaller control. The former is consistent with the estimates in Table 11, while the latter conflicts them.

5 Conclusion

This paper examined the impact of Massachusetts (MA) regulation which prohibited pharmaceutical manufactures from providing off-site meals to doctors and other licensed prescribers. It was expected that this would have the greatest impact of branded medications with only indirect generic competition (BMIGC)–medications which had patent protection from direct generic competition, but were in the same class as medications which no longer had patent protection.

In the Introduction, four scenarios were laid out. The first scenario was that the regulation might have no effect. Probit and linear probability regressions show that participants in MA were less likely to be taking these medications, after the regulation, so for at least some participants the regulation had an effect. Additionally, there is indication that it reduced overall medication expense. The remaining three scenarios differ in what treatment was received in place of the BMIGCs. The second scenario was that there was substitution toward generics. In the pooled sample, there is little evidence that this was the case. Results imply that the substitute generics were less likely to be prescribed, and that participants were less likely to any medications. These decreases are possibly due to the marketing having spillover effects to other medications. There is some evidence that there were substitutions toward generics in the panel sample, however there was also instances of participants quiting both a BMIGC and another in class medication, including generics.

There was also no evidence of the third scenario–substitution toward other medical care. Results indicated individuals were less likely to have any medical costs after the regulation. There was some indication that cost conditional on have any cost did rise, but this may be a lingering effect of RomneyCare, and was likely dominated by the decreased probability of having any costs. The lack of evidence may be due to

the regulation also effecting manufactures of other medical devices and products, so that there was substitution toward other care, but it was dominated by the overall decrease in medical expenses. This implies that it was the final scenario the BMIGC were in place of nothing. This scenario had two variants one was that the BMIGC was being used to supplement another medication and that other medication would be used by the individual with or without the marketing. In the panel sample there were some instances of both variants in roughly equal proportions.

The paper also examined potential negative impacts of the regulation, and lack of treatment. It appears that people rated their health better after the regulation and were less likely to report health limitations to daily activities. The analysis was limited by a relatively small dataset that is not true panel data. Also I was unable to produce a synthetic control. Additionally, I may not have been able to truly isolate the effects of the regulation from those of the Massachusetts Health Care Reform (RomneyCare).

Beyond showing that this regulation decreased the likelihood of taking a more expensive medication than was necessary, and that if anything the cheaper treatment (or lack of treatment) improved patient outcomes. This paper shows that in general there is potential cost savings, without harming patients in an array of policies dissuading the prescribing of BMIGCs. This result holds regardless of identification. Perhaps it was not the regulation that accomplished this, but some instead some delayed effect of RomneyCare. If this were the case then marketing regulation may not be the answer to reducing cost, but the finding that reducing the number of prescriptions for BMIGCs can cut cost without negative impacts on health still stands. This might be accomplished via insurer polices such as prior authorizations or tiering of medications, or provider policies, such as hospital or clinic formularies, or other restrictions on pharmaceutical marketing.

References

Abadie, Alberto, Alexis Diamond, and Jens Hainmueller, "Synthetic Control Methods for Comparative Case Studies: Estimating the Effect of California's Tobacco Control Program," *Journal of the American Statistical Association*, June 2010, *105* (490), 493–505.
Big-Name Drugs Are Falling Off The 'Patent Cliff'

***Big-Name Drugs Are Falling Off The 'Patent Cliff'**, October 2011.*

Brotzman, GI and DH Mark, *"Policies regulating the activities of pharmaceutical representatives in residency programs.," The Journal of family practice, January 1992, 34 (1), 54–57.*

CDC, *"FastStats," Technical Report, Centers for Disease Control and Prevention 2016.*

Chren, M and C S Landefeld, *"Physicians' behavior and their interactions with drug companies: A controlled study of physicians who requested additions to a hospital drug formulary," JAMA, 1994, 271 (9), 684–689.*

Coukell, Allan and Shih, *"Whats Driving Increased Pharmaceutical Spending?," 2016.*

Courtemanche, Charles J. and Daniela Zapata, *"Does Universal Coverage Improve Health? The Massachusetts Experience," Journal of Policy Analysis and Management, January 2014, 33 (1), 36–69.*

Cutler, David M. and Mark McClellan, *"Is technological change in medicine worth it?," Health affairs, 2001, 20 (5), 11–29.*

DeJong, Colette, Aguilar T, Tseng C, Lin GA, Boscardin W, and Dudley R, *"Pharmaceutical industrysponsored meals and physician prescribing patterns for medicare beneficiaries," JAMA Internal Medicine, June 2016.*

Hafemeister, Thomas L. and Sarah Payne Bryan, *"Beware Those Bearing Gifts: Physicians' Fiduciary Duty to Avoid Pharmaceutical Marketing," SSRN Scholarly Paper ID 1458582, Social Science Research Network, Rochester, NY August 2009.*

Iizuka, Toshiaki, *"Physician Agency and Adoption of Generic Pharmaceuticals," American Economic Review, October 2012, 102 (6), 2826–2858.*

Katz, Dana, Arthur L. Caplan, and Jon F. Merz, *"All gifts large and small: toward an understanding of the ethics of pharmaceutical industry gift-giving," The American Journal of Bioethics, 2010, 10 (10), 11–17.*

Kravitz, Richard L., Ronald M. Epstein, Mitchell D. Feldman, Carol E. Franz, Rahman Azari, Michael S. Wilkes, Ladson Hinton, and Peter Franks, *"Influence of patients' requests for direct-to-consumer advertised antidepressants: a randomized controlled trial," Jama, 2005, 293 (16), 1995–2002.*

Latham, Cara, *"Generics Outlook: Turning to Innovation After the Patent Cliff," Pharmacy TImes, July 2013.*

Lichtenberg, Frank R., *"Are the benefits of newer drugs worth their cost? Evidence from the 1996 MEPS," Health Affairs, 2001, 20 (5), 241–251.*

Liu, Ya-Ming, Yea-Huei Kao Yang, and Chee-Ruey Hsieh, *"Financial incentives and physicians' prescription decisions on the choice between brand-name and generic drugs: Evidence from Taiwan," Journal of Health Economics, March 2009, 28 (2), 341–349.*

Mark, Daniel B., Wenqin Pan, Nancy E. Clapp-Channing, Kevin J. Anstrom, John R. Ross, Rebecca S. Fox, Gerard P. Devlin, C. Edwin Martin, Christopher Adlbrecht, and Patricia A. Cowper, *"Quality of life after late invasive therapy for occluded arteries," New England Journal of Medicine, 2009, 360 (8), 774–783.*

Massachusetts Executive Office of Health and Human Services, *"Pharmaceutical and Medical Device Manufacturer Code of Conduct," May 2009.*

Miller, G. E. and E. M. Sarpong, *"Trends in the Pharmaceutical Treatment of Children's Asthma, 1997 to 2008.," Technical Report 31, Agency for Healthcare Research and Quality, Rockville, MD September 2011.*

OECD, *"OECD Health Statistics 2014 How does the United States compare?," 2014.*

Orlowski, James P. and Leon Wateska, *"The effects of pharmaceutical firm enticements on physician prescribing patterns. There's no such thing as a free lunch.," CHEST Journal, 1992, 102 (1), 270–273.*

Peay, Marilyn Y. and Edmund R. Peay, *"The role of commercial sources in the adoption of a new drug," Social Science & Medicine, 1988, 26 (12), 1183–1189.*

Rizzo, John A., *"Advertising and Competition in the Ethical Pharmaceutical Industry: The Case of Antihypertensive Drugs*," The Journal of Law and Economics, 1999, 42 (1), 89–116.*

Sandberg, Warren S., Ruth Carlos, Elisabeth H. Sandberg, and Michael F. Roizen, *"The effect of educational gifts from pharmaceutical firms on medical students' recall of company names or products.," Academic Medicine, 1997, 72 (10), 916–918.*

Song, Chie Hoon and Jeung-Whan Han, *"Patent cliff and strategic switch: exploring strategic design possibilities in the pharmaceutical industry," SpringerPlus, May 2016, 5 (1), 692.*

Weintraub, William S., John A. Spertus, Paul Kolm, David J. Maron, Zefeng Zhang, Claudine Jurkovitz, Wei Zhang, Pamela M. Hartigan, Cheryl Lewis, and Emir Veledar, *"Effect of PCI on quality of life in patients with stable coronary disease," New England Journal of Medicine, 2008, 359 (7), 677–687.*

Table 1: Sample Demographics

In an MSA at end of survey year	85.9 %
Presently Married	40.7 %
Black	13.1 %
Female	51 %
Hispanic	15.9 %
Currently Smoke	14.2 %
Age at end of survey year	36.3
	(22.3)
Has Private Insurance	68.9 %
Has Public Insurance	18.6 %
Has No Insurance	12.4 %
Poor	13 %
Near Poor	4.5 %
Low Income	13.8 %
Middle Income	31.2 %
High Income	37.6 %
No Degree	13.6 %
High School or GED	36.9 %
Bachelor's Degree	12.8 %
Graduate Degree	6.4 %
Observations	329,850

(Standard Deviation)

Table 2: Mean Cost per Year for Prescribed Medication

	Obs	Mean Cost	SD
BMIGC's	49	2299.45	(4588.59)
Other Meds	6298	432.01	(8333.96)
Other Branded	24	4893.42	(9331.79)
Generics	36	326.89	(400.05)

Table 3: Probit Models

Estimates using Survey Command

Are Taking A BMIGC

	28 States			5 States		
	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Marketing Restriction	-0.035**	-0.123*	-0.037**	-0.034***	-0.122*	-0.041**
	(0.013)	(0.074)	(0.018)	(0.013)	(0.072)	(0.018)
Sub-Pop Obs.	329,734	36,188	153,858	88,248	8,440	40,478

Are Taking Any Prescribed Medication

Marketing Restriction	-0.049	-0.015	-0.071**	-0.043	-0.003	-0.066*
	(0.032)	(0.045)	(0.035)	(0.034)	(0.051)	(0.037)
Sub-Pop Obs.	329,853	36,191	153,908	88,308	8,440	40,495

Are Taking a "Substitute" Medication

Marketing Restriction	-0.033***	-0.019	-0.038***	-0.031***	-0.020	-0.032**
	(0.010)	(0.065)	(0.013)	(0.010)	(0.065)	(0.013)
Sub-Pop Obs.	329,853	36,191	153,908	88,248	8,442	40,463

Estimates when Clustering by State

Are Taking A BMIGC

	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Marketing Restriction	-0.034***	-0.123***	-0.037***	-0.034***	-0.119***	-0.041***
	(0.003)	(0.012)	(0.003)	(0.003)	(0.027)	(0.004)
Observations	329,734	36,188	153,858	88,248	8,440	40,478

Are Taking Any Prescribed Medication

Marketing Restriction	-0.049***	-0.015**	-0.071***	-0.043***	-0.003	-0.066***
	(0.005)	(0.008)	(0.008)	(0.013)	(0.019)	(0.021)
Observations	329,853	36,191	153,908	88,308	8,440	40,495

Are Taking a "Substitute" Medication

Marketing Restriction	-0.033***	-0.018**	-0.038***	-0.031***	-0.019	-0.032***
	(0.003)	(0.009)	(0.004)	(0.004)	(0.015)	(0.008)
Observations	329,853	36,191	153,908	88,248	8,442	40,463

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

Table 4: Linear Probability Models

Estimates using Survey Command

Are Taking A BMIGC

	28 States			5 States		
	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Marketing Restriction	-0.050***	-0.136*	-0.049**	-0.053***	-0.144*	-0.058**
	(0.017)	(0.079)	(0.023)	(0.017)	(0.081)	(0.025)
R-squared	0.118	0.047	0.114	0.120	0.064	0.107
Sub-Pop Obs.	329,731	36,188	153,858	88,248	8,440	40,478

Are Taking Any Prescribed Medication

Marketing Restriction	-0.046	-0.016	-0.068**	-0.037	-0.006	-0.062*
	(0.029)	(0.040)	(0.031)	(0.030)	(0.046)	(0.033)
R-squared	0.156	0.043	0.105	0.164	0.050	0.104
Sub-Pop Obs.	329,853	36,192	153,908	88,308	8,444	40,495

Are Taking a "Substitute" Medication

Marketing Restriction	-0.054**	-0.029	-0.070***	-0.049**	-0.028	-0.059**
	(0.023)	(0.097)	(0.024)	(0.023)	(0.101)	(0.025)
R-squared	0.150	0.207	0.129	0.150	0.225	0.134
Sub-Pop Obs.	329,853	36,191	153,908	88,248	8,442	40,463

Estimates when Clustering by State

Are Taking A BMIGC

	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Marketing Restriction	-0.050***	-0.136***	-0.050***	-0.053***	-0.140***	-0.058***
	(0.003)	(0.013)	(0.004)	(0.005)	(0.029)	(0.005)
R-squared	0.116	0.041	0.110	0.115	0.053	0.107
Observations	329,853	36,192	153,908	88,308	8,444	40,495

Are Taking Any Prescribed Medication

Marketing Restriction	-0.046***	-0.016**	-0.069***	-0.038**	-0.006	-0.062**
	(0.005)	(0.008)	(0.008)	(0.012)	(0.021)	(0.020)
R-squared	0.152	0.041	0.100	0.159	0.048	0.104
Observations	329,853	36,192	153,908	88,308	8,444	40,495

Are Taking a "Substitute" Medication

Marketing Restriction	-0.054***	-0.028**	-0.070***	-0.049***	-0.027	-0.059**
	(0.005)	(0.012)	(0.006)	(0.007)	(0.018)	(0.013)
R-squared	0.149	0.203	0.128	0.148	0.220	0.133
Observations	329,853	36,192	153,908	88,308	8,444	40,495

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

Table 5: Natural Logs of Total Cost of:

Estimates using Survey Command

BMIGC's

	28 States			5 States		
	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Marketing Restriction	0.006	-0.025	-0.057	0.005	-0.004	-0.063
	(0.029)	(0.045)	(0.042)	(0.033)	(0.048)	(0.047)
Sub-Pop Obs.	33,692	10,746	17,082	7,161	2,270	3,606

All Prescribed Medications

VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Marketing Restriction	-0.035	0.014	-0.025	-0.032	0.041	-0.026
	(0.024)	(0.040)	(0.034)	(0.026)	(0.044)	(0.037)
Sub-Pop Obs.	192,493	32,792	97,353	47,022	7,527	23,616

Estimates when Clustering by State

BMIGC's

	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Marketing Restriction	0.007	-0.025***	-0.057***	0.005	-0.003	-0.063
	(0.006)	(0.007)	(0.008)	(0.016)	(0.010)	(0.032)
Observations	33,692	10,746	17,082	7,161	2,270	3,606

All Prescribed Medications

VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Marketing Restriction	-0.034***	0.015*	-0.025***	-0.032**	0.042**	-0.026
	(0.004)	(0.008)	(0.006)	(0.008)	(0.010)	(0.014)
Observations	192,493	32,792	97,353	47,022	7,527	23,616

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

Table 6: Probit Model of Likelihood that Individual Has Any Medical Expenses

Estimates using Survey Command

	28 States		5 States	
	(1)	(2)	(3)	(4)
VARIABLES	All	Empr Insrd	All	Empr Insrd
Marketing Restriction	-0.068***	-0.069***	-0.070***	-0.073**
	(0.024)	(0.027)	(0.026)	(0.030)
Sub-Pop Obs.	329,850	153,908	88,308	40,115

Estimates when Clustering by State

	(1)	(2)	(3)	(4)
VARIABLES	All	Empr Insrd	All	Empr Insrd
Marketing Restriction	-0.069***	-0.070***	-0.071***	-0.075***
	(0.004)	(0.005)	(0.009)	(0.010)
Observations	329,853	153,908	88,308	40,115

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

Table 7: Linear Probability Model of Likelihood that Individual Has Any Medical Expenses

Estimates using Survey Command

	28 States			5 States		
	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Marketing Restriction	-0.044***	-0.025**	-0.055***	-0.041**	-0.030**	-0.055**
	(0.017)	(0.010)	(0.021)	(0.018)	(0.013)	(0.023)
R-squared	0.146	0.049	0.064	0.161	0.070	0.069
Sub-Pop Obs.	329,853	36,192	153,908	88,308	8,444	40,495

Estimates when Clustering by State

	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Marketing Restriction	-0.044***		-0.055***	-0.041***		-0.056***
	(0.004)		(0.005)	(0.008)		(0.009)
R-squared	0.144		0.062	0.158		0.066
Observations	329,853		153,908	88,308		40,495

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

Table 8: Natural Log of Individuals' Medical Expenses

Estimates using Survey Command

	28 States			5 States		
	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Marketing Restriction	0.009	-0.002	-0.000	0.012	0.013	0.001
	(0.017)	(0.036)	(0.015)	(0.018)	(0.037)	(0.016)
R-squared	0.237	0.073	0.187	0.233	0.091	0.186
Sub-Pop Obs.	266,006	34,686	134,000	68,417	8,057	34,377

Estimates when Clustering by State

	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Marketing Restriction	0.009***	-0.002	-0.000	0.012**	0.013	0.001
	(0.002)	(0.005)	(0.003)	(0.003)	(0.009)	(0.006)
Observations	266,006	34,686	134,000	68,417	8,057	34,377

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

Table 9: Ordered Probit Model of Individuals' Self-Assessed Physical Health

Estimates using Survey Command

	28 States			5 States		
	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Marketing Restriction	-0.038	-0.105	0.024	-0.037	-0.038	0.018
	(0.072)	(0.168)	(0.112)	(0.078)	(0.174)	(0.116)
Sub-Pop Obs.	328,933	35,626	153,669	88,110	8,325	40,436

Estimates when Clustering by State

	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Marketing Restriction	-0.037***	-0.105***	0.025	-0.036**	-0.040	0.020
	(0.011)	(0.034)	(0.018)	(0.016)	(0.046)	(0.033)
Observations	328,933	35,626	153,669	88,110	8,325	40,436

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

Table 10: Ordered Probit Model of Individuals' Self-Assessed Mental Health

Estimates using Survey Command

	28 States			5 States		
	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Marketing Restriction	-0.039	-0.041	-0.034	-0.041	0.071	-0.069
	(0.094)	(0.155)	(0.135)	(0.098)	(0.167)	(0.136)
Sub-Pop Obs.	328,891	35,626	153,656	88,107	8,326	40,434

Estimates when Clustering by State

	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Marketing Restriction	-0.037***	-0.040	-0.033	-0.040	0.068	-0.067
	(0.013)	(0.037)	(0.021)	(0.035)	(0.097)	(0.044)
Observations	328,891	35,626	153,656	88,107	8,326	40,434

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

Table 11: Probit Model of Likelihood that Individual Has Activity Limitation

	28 States			5 States		
	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Marketing Restriction	-0.028***	-0.136***	-0.021***	-0.024***	-0.135**	-0.025***
	(0.007)	(0.052)	(0.008)	(0.007)	(0.055)	(0.009)
Sub-Pop Obs.	302,771	35,568	144,275	81,137	8,313	37,890

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

Table 12: Linear Probability Model of Likelihood that Individual Has Activity Limitation

	28 States			5 States		
	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Marketing Restriction	-0.036***	-0.139**	-0.027**	-0.034**	-0.142**	-0.033***
	(0.013)	(0.059)	(0.011)	(0.014)	(0.061)	(0.012)
R-squared		0.104	0.068	0.145	0.124	0.071
Sub-Pop Obs.	302,788	35,572	144,342	81,141	8,317	37,917

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

Table 13: Means of Pharmaceutical Spending for Panel 13

	Obs	2008	2009	$ Δ	ln(2009/2008)
Full Control	15,162	781.4	871.76	90.36	.011
		(2,085.28)	(2,850.7)	(2,320.99)	(1.406)
CA, CT, NJ & VA	4,180	728.99	842.58	113.59	.024
		(2,255.24)	(3,642.33)	(3,241.2)	(1.443)
MA	268	1,237.4	1,304.67	67.28	-.057
		(3,170.56)	(3,527.6)	(1,379.07)	(1.267)

Table 14: Probit Estimates for Starting BMIGC in 2009

Estimates using Survey Command

	28 States			5 States		
	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Massachusetts	0.002	0.028	-0.030	0.006	0.020	-0.022
	(0.026)	(0.120)	(0.040)	(0.025)	(0.126)	(0.036)
Sub-Pop Obs.	13,745	1,007	5,829	4,068	261	1,825

Estimates when Clustering by State

	(1)	(2)	(3)	(4)	(5)	(6)
Massachusetts	0.002	0.028*	-0.030***	0.006		-0.022
	(0.005)	(0.017)	(0.007)	(0.016)		(0.021)
Observations	13,745	1,007	5,829	4,068		1,825

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

Table 15: Probit Estimates for Ending BMIGC in 2008

Estimates using Survey Command

	28 States			5 States		
	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Massachusetts	0.086		0.140	0.086		0.127
	(0.000)		(0.100)	(0.097)		(0.110)
Sub-Pop Obs.	1,685		828	380		182

Estimates when Clustering by State

	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Massachusetts	0.086***		0.140***	0.086***		0.127***
	(0.009)		(0.010)	(0.020)		(0.020)
Observations	1,685		828	380		182

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

Table 16: Probit Estimates for Starting "Substitute" in 2009

Estimates using Survey Command

	28 States			5 States		
	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Massachusetts	0.033**	0.025	-0.000	0.039**	0.032	-0.005
	(0.016)	(0.095)	(0.033)	(0.017)	(0.100)	(0.035)
Sub-Pop Obs.	13,914	1,008	5,952	4,076	275	1,807

Estimates when Clustering by State

	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Massachusetts	0.033***	0.025	-0.000	0.039***		-0.005
	(0.005)	(0.017)	(0.006)	(0.009)		(0.014)
Observations	13,914	1,008	5,952	4,076		1,807

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

Table 17: Probit Estimates for Ending "Substitute" in 2008

Estimates using Survey Command

	28 States			5 States		
	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Massachusetts	-0.058	0.044	-0.064	-0.041	0.065	-0.037
	(0.000)	(0.120)	(0.097)	(0.064)	(0.114)	(0.097)
Sub-Pop Obs.	1,516	479	705	372	111	200

Estimates when Clustering by State

	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Massachusetts	-0.058***	0.044**	-0.064***	-0.041		-0.037
	(0.018)	(0.018)	(0.024)	(0.047)		(0.050)
Observations	1,516	479	705	372		200

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

Table 18: Categorization of MA participants on a BMIGC in 2008 but not in 2009

On generic med in same class as BMIGC in 2009	2
On generic med in same class as BMIGC in 2008 and 2009	2
On branded med in same class as BMIGC in 2009	2
On branded med in same class as BMIGC in 2008 and 2009	4 [a]
On no med in same class as BIMGC in 2009	8 [b]

[a] In 1 case, the participant was on three meds in the same class in 2008 a BMIGC and two branded meds (both available generically) but was only one of these and not the BMIGC in 2009.

[b] In 3 cases, the participant was on both a BMIGC and a generic med in the same class for it in 2008, but no longer on that med nor the BMIGC in 2009.

Table 19: Estimates for Logged Change in Pharmaceutical Costs

Estimates using Survey Command

	28 States			5 States		
	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Massachusetts	-0.085	0.418	-0.195	-0.107	0.566*	-0.234
	(0.112)	(0.289)	(0.149)	(0.120)	(0.298)	(0.152)
R-squared	0.006	0.011	0.000	0.026	0.033	0.002
Sub-Pop Obs.	6,939	1,299	3,329	1,799	325	912

Estimates when Clustering by State

	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Massachusetts	-0.085***	0.418***	-0.195***	-0.107	0.566***	-0.234
	(0.016)	(0.060)	(0.030)	(0.055)	(0.048)	(0.113)
R-squared	0.006	0.011	0.000	0.026	0.033	0.002
Observations	6,939	1,299	3,329	1,799	325	912

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

Table 20: Estimates for Logged Change in Medical Costs

Estimates using Survey Command

	28 States			5 States		
	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Massachusetts	-0.128	-0.219	-0.162	-0.106	-0.156	-0.196
	(0.122)	(0.284)	(0.196)	(0.127)	(0.301)	(0.202)
Sub-Pop Obs.	10,932	1,389	5,260	3,005	352	1,528

Estimates when Clustering by State

	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Massachusetts	-0.128***	-0.219***	-0.162***	-0.106**	-0.156**	-0.196**
	(0.015)	(0.032)	(0.023)	(0.032)	(0.049)	(0.045)
Observations	10,932	1,389	5,260	3,005	352	1,528

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

Table 21: Ordered Probit Estimates for Changes in Rating of Physical Health

Estimates using Survey Command

	28 States			5 States		
	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Massachusetts	-0.084	-0.125	-0.199*	-0.097	-0.068	-0.219**
	(0.080)	(0.206)	(0.108)	(0.081)	(0.230)	(0.110)
Sub-Pop Obs.	15,053	1,416	6,570	4,330	365	1,978

Estimates when Clustering by State

	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Massachusetts	-0.084***	-0.125***	-0.199***	-0.097***	-0.068	-0.219***
	(0.017)	(0.035)	(0.019)	(0.011)	(0.061)	(0.020)
Observations	15,053	1,416	6,570	4,330	365	1,978

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

Table 22: Ordered Probit Estimates for Changes in Rating of Mental Health

Estimates using Survey Command

	28 States			5 States		
	(1)	(2)	(3)	(4)	(5)	(6)
Massachusetts	-0.141*	0.029	-0.137	-0.125	0.068	-0.135
	(0.077)	(0.188)	(0.091)	(0.076)	(0.203)	(0.089)
Sub-Pop Obs.	15,049	1,415	6,568	4,329	365	1,977

Estimates when Clustering by State

	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Massachusetts	-0.141***	0.029	-0.137***	-0.125***	0.068	-0.135***
	(0.016)	(0.037)	(0.013)	(0.013)	(0.118)	(0.013)
Observations	15,049	1,415	6,568	4,329	365	1,977

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

Table 23: Probit Estimates for Participant Became Less Limited

Estimates using Survey Command

	28 States			5 States		
	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Massachusetts	-0.119	-0.085	-0.063	-0.133	-0.074	-0.169
	(0.000)	(0.095)	(0.176)	(0.085)	(0.124)	(0.190)
Sub-Pop Obs.	941	290	200	218	64	53

Estimates when Clustering by State

	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Massachusetts	-0.119***	-0.085**	-0.063	-0.133***	-0.074	-0.169
	(0.021)	(0.039)	(0.055)	(0.024)	(0.086)	(0.143)
Sub-Pop Obs.	941	290	200	218	64	53

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

Table 24: Probit Estimates for Participant Became More Limited

Estimates using Survey Command

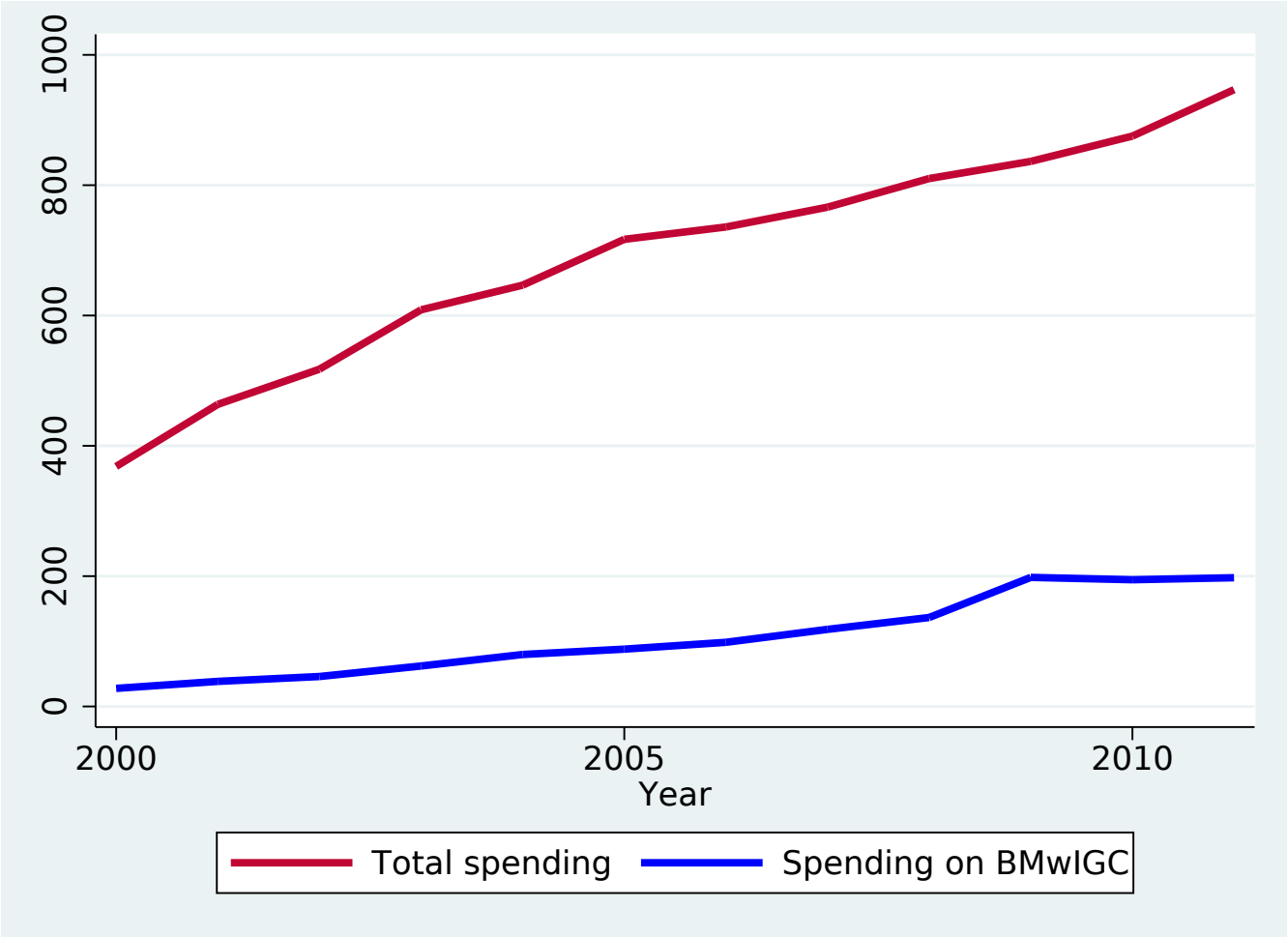
	28 States			5 States		
	(1)	(2)	(3)	(4)	(5)	(6)
Massachusetts	0.002	-0.056	0.002	0.004	-0.017	0.004
	(0.015)	(0.119)	(0.007)	(0.015)	(0.098)	(0.008)
Sub-Pop Obs.	12,781	1,126	5,953	3,727	301	1,786

Estimates when Clustering by State

	(1)	(2)	(3)	(4)	(5)	(6)
VARIABLES	All	65+	Empr Insrd	All	65+	Empr Insrd
Massachusetts	0.002	-0.056***	0.002	0.004**	-0.017	0.004
	(0.002)	(0.017)	(0.003)	(0.002)	(0.025)	(0.005)
Sub-Pop Obs.	12,781	1,126	5,953	3,727	301	1,786

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

Figure 1: Annual Spending per Person on Medications



Appendices

A.1 Medication Categorization

I identified which of the top grossing medications were branded medications with only indirect generic competition (BMIGC). First, I ascertain which were still under patent in the relevant years, via the Food and Drug Administration (FDA)'s Orange Book website. Next, I identified the medication's class and what other medications were in the class. I also noted if there were any medication was clearly superior, e.g. much more effective or tolerable. Then I checked to see if any of these had generic equivalents in the Orange Book. If there was a generic equivalent for one of the other medications in the class, I marked the medication as a BMIGC, and likely to be affected by the regulation. I also marked the generic equivalent as a likely substitute.

A few the top grossing medications serve as examples and illustrate how the categorization worked. Abilify was under patent protection until 2015, so was a branded medication with no generic equivalent. It is an "atypical antipsychotic", but there are other atypical antipsychotics, chiefly risperidone, for which there were generic equivalents as early as 2008. Accordingly, I mark Abilify as a BMIGC, and risperidone as a medication toward which there is likely to be substitution.

Celebrex was the first Cox 2 inhibitor. These represent a significant innovation in treatment and as Celebrex is the first there are no generics in the class. Accordingly, I do not mark Celebrex as a BMIGC.

Simvastatin was available as a generic as early as 2006, so also is not a BMIGC, but is marked as a substitute for other statins.

Medication	Class	Generic	Substitutes	Gen. of Sub.	BMIGC	Sub
Abilify	atypical antipsychotic	No	Yes, resperidone	Yes	✓	✗
Celebrex	Cox 2 inhibitor	No	Yes, but it was 1^{st}	No	✗	✗
Simvastatin	statin	Yes, Jun06			✗	✓
Lipitor	statin	No	Yes, Simvastatin	Yes	✓	✗