Queen's Economics Department Working Paper No. 1474

Collusion in the US Generic Drug Industry

Robert Clark
Queen's University

Christopher Anthony Fabiilli
Competition Bureau Canada

Laura Lasio
McGill University

Department of Economics
Queen's University
94 University Avenue
Kingston, Ontario, Canada
K7L 3N6

11-2021

Collusion in the US Generic Drug Industry*

Robert Clark[a], Chris Fabiilli[b] & Laura Lasio[c]

November 17, 2021

Abstract

We study cartels that operated in the US generic drug industry, leveraging quarterly Medicaid data from 2011-2018 and a difference-in-differences approach comparing the evolution of prices of allegedly collusive drugs with a group of competitive control drugs. Our analysis highlights (i) the difficulty of establishing a suitable control group when collusion is pervasive, (ii) the importance of accounting for market structure changes when defining the control period, and (ii) the existence of across- and within-drug heterogeneity. We focus on six drug markets that that were part of the expanded initial complaint and where there was no entry in the same class during the collusive period, permitting a clean measure of the causal impact of collusion on prices. Our most conservative estimates suggest that collusion led to price increases of between 0% and 166% for each of the six drugs, and damages of between $0 and $3 million for the Medicaid market.

*The views presented in the paper are those of the authors and do not necessarily reflect those of the Competition Bureau of Canada. We thank Francesco Decarolis, Matt Grennan, Luca Maini, Fiona Scott-Morton, and seminar participants at the 2021 ASHEcon conference for helpful comments. Correspondence to: [a]Robert Clark - Queen's University, Dunning Hall, 94 University Avenue, Kingston, Ontario, K7L 3N6, Email: clarkr@econ.queensu.ca; [b]Chris Fabiilli - Competition Bureau Canada, 50 Victoria Street, Gatineau, Quebec, K1A 0C9, Email: 12caf5@queensu.ca; [c]Laura Lasio - McGill University, Leacock Building, 855 Sherbrooke St W - Montreal, H3A 2T7, Email: laura.lasio@mcgill.ca

1 Introduction

Over the past decade, the generic drug industry has been a focus of attention as a result of large price spikes for many of its products. For example, in 2013-2014, albuterol sulphate, used to treat asthma and other breathing conditions, increased in price from $11 to $434 for a bottle of 100 2 mg tablets. Similarly, doxycycline hyclate, an antibiotic used to treat various infections, increased in price from $20 to $1849 for a bottle of 50 100 mg tablets, and glycopyrrolate, used to prevent irregular heartbeats during surgery, increased in price from $65 to $1277 for a box of 10 0.2 mg/L 20 mL vials.[1]

The price spikes experienced in the market were in fact even more widespread than the anecdotal examples listed above. A recent paper by Conti, Nguyen, and Rosenthal (2018) examines which drugs would be affected by new price gouging legislation using data from 2013-2014 on quantities and wholesale dollar sales of all approved prescription drugs.[2] Their findings show that the mean adjusted price increase among all generic products was 38%.[3]

These price hikes ultimately led to increased antitrust oversight and in July 2014 Connecticut launched an investigation into generic drug pricing. The offices belonging to some manufacturers were raided in September 2016 and the first charges were announced December 14th 2016 against the former CEO and former president of Heritage. Both were said to have conspired to fix prices, rig bids and allocate customers for the antibiotic doxycycline hyclate and for the anti-diabetic medication glyburide. The next day, state attorneys general from 20 states filed a civil lawsuit against six pharmaceutical companies alleging they colluded to increase prices for the two aforementioned drugs. The former CEO and former President of Heritage pled guilty and agreed to cooperate in the antitrust probe. The complaint expanded in October 2017, increasing the number of manufacturers under investigation from 6 to 18 and the number of drugs from 2 to 15. On May 12th, 2019, a second complaint led by Attorney General William Tong increased the number of generic manufacturers to 20 and the number of drugs to over 100.

The objective of this paper is to quantify the causal impact of collusive behavior in the generic pharmaceutical industry.[4] To do so we take advantage of quarterly prescription and reimbursement

[1] Stephen Barlas, "Generic Prices Take Flight," P & T 39, no.12 (2014): 843, accessed July20, 2019 (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4264670/pdf/ptj3912833.pdf).

[2] Their sample includes oral, infused, injected or otherwise formulated generic drugs dispensed through all channels and covered by insurer pharmacy and medical benefits. To identify what would be considered price gouging, the authors use a senate bill sponsored by senators Franken and Klobuchar to identify which price spikes would be considered price gouging and be affected by the proposed legislation. More specifically the senate bill defines price spikes as annual price increases above the medical CPI, with higher penalties given to products that experience annual price increases of 15% and 20%.

[3] More specifically, 50% of all products exceeded the Medical CPI, with a mean-inflation adjusted price increase of 93% and a mean price of $43.35. Furthermore, 28% of all generic products exceeded the 15% price increase threshold and 23% of all products exceeded the 20% threshold, with mean inflation-adjusted price increases of 162% and 191% and mean prices of $30.72 and $22.63.

[4] This article's goal is to analyze the alleged cartel case strictly from an economic point of view. We base our understanding of the facts mostly on data and information obtained from Medicaid's state drug utilization datasets

Medicaid state drug utilization data for the period 2011-2018 and information from the court documents. The latter are employed in particular to define the start and end dates of collusive activity for each drug. Then, using a difference-in-differences approach in which we compare the evolution of prices of allegedly collusive drugs to the evolution of prices for a group of competitive control drugs, we derive the *overcharge* generated by the alleged collusive behavior. To quantify damages, we multiply the volumes sold during the collusive period by the overcharge.

Currently there are well over 100 generic products being investigated, but we concentrate our attention on six of these: (i) doxycycline monohydrate (henceforth doxy mono), (ii) meprobamate, (iii) nystatin, (iv) paromomycin, (v) theophylline, and (vi) verapamil. We focus on these six drugs for three reasons: (i) they were part of the expanded first complaint, (ii) in each case Heritage, whose CEO and president pled guilty, manufactured a product in the class, and (iii) there was no entry of new drugs in the same class during the collusive period, allowing us to get a clean measure of the causal impact of collusion on prices.

An important and challenging part of our analysis is establishing an appropriate competitive control group against which to compare the evolution of prices for each of these drugs. To do so we combine information from the World Health Organization's Anatomical Therapeutic Chemical (ATC) classification with court documents and identify drugs that are comparable to those under analysis, but that are not directly affected by the alleged cartel. We exploit the hierarchical structure of the ATC system to identify drugs in similar therapeutic classes that are *not* direct competitors of the treatment drug (one of the six drugs listed above), i.e. that belong to a different ATC class, defined at the ATC level 4. Among the large pool of candidates, we keep drugs that meet three criteria: (1) they are off-patent oral drugs available throughout the period to Medicaid enrolees, (2) they are not listed in the complaints as being a target of investigation and (3) they do not have any direct competitor involved in a cartel. This process results in between one and six control drugs for each of our treatment drugs.

Having established the control group for each drug, we must next determine the appropriate competitive control period in order to implement our difference-in-differences analysis. For the competitive control period we have three choices: (i) the period prior to the start of the cartel, (ii) the period after its collapse, or (iii) both. We elect to focus our attention on period before the cartel gets off the ground for two reasons. First, as pointed out by Harrington (2004), if firms understand that antitrust authorities may use post-cartel prices in their determination of the overcharge, they may attempt to strategically maintain prices above competitive levels after the collapse in order to reduce the overcharge and the resulting damages. Second, there are important market structure changes in the post-cartel period that would seriously affect the overcharge calculation. In particular, for three of the six drugs that we consider, the market structure changes are such that one firm

and from the complaints filed in this case. The investigation into, and prosecution of, firms involved in the alleged conspiracy is ongoing. The allegations have not been proven in a court of justice. However, for the purpose of this analysis, we take these facts as established.

is left in what amounts to a monopoly position following the cartel's collapse. For meprobamate, one of the two manufacturers (Heritage) exited the market at the end of the cartel period, leaving the remaining firm (Dr. Reddy's) to act as a de facto monopolist. Not surprisingly, prices did not collapse following the start of the investigation. The same is true of paromomycin, where Heritage became the only supplier after the exit of Sun. For theophylline, the two alleged colluders exited roughly a year after the collapse of the cartel, leaving recent entrant Alembic serve the entire market. Overall, we conclude that using the post-cartel time period as part of the competitive control period would bias downward any damage estimate for these three drugs.

Taking these challenges into consideration, we estimate the overcharge for each of the six drugs. Our findings suggest that collusion had heterogeneous effects on prices both *across* and *within* the drugs we analyze, with some drugs and/or manufacturers experiencing significant increases in price and others no change at all, despite claims in the court documents of important effects. After controlling for time and product fixed effects we estimate that the cartel caused prices for meprobamate to increase by \$7.57 per defined daily doses. Meprobamate's average price in the pre-cartel period is \$4.57 and so this represents a 166% increase in price. Similarly, for nystatin we estimate a price increase of \$0.21, which represents a 13% price increase. Finally, for theophylline we estimate a price increase of \$0.16, which represents a 46% increase in price. We find no significant effect for doxy mono, paromomycin, and verapamil.

The finding of no significant overcharge in the case of doxy mono is unexpected, because, as we will see below, graphically it appears that there is a sharp increase in price during the period of alleged collusion. We investigate further what is going on by looking *within* drugs at the evolution of prices for different manufacturers. Our findings suggest that, in the case of doxy mono, two of the four manufacturers allegedly involved in the doxy mono cartel did not experience any price increase at all during the cartel period. Surprisingly, one of these was Heritage, whose CEO and president pled guilty. The other was Mylan, whose offices were raided, precipitating the investigation. The price increase was entirely driven by the two other manufacturers, Par and Lannett. Restricting attention just to these two manufacturers and looking at them separately reveals that the overcharge was \$1.61 for Lannett (equivalent to an increase by 85% over the pre-cartel price) and \$0.22 for Par, although for the latter the estimate is not significant.

Although our aggregate damage estimates do not appear to be particularly large, it is worth pointing out that they are estimated on the Medicaid population only and hence capture just a fraction of the increase in the costs borne by US patients: in the period under study, Medicaid represented roughly 10% of all prescription drug expenditures, with Medicare covering over a fourth of them and private insurance making up the rest. Also, Medicaid beneficiaries tend to use prescription drugs to a lesser extent than do Medicare Part D enrolees (Garthwaite, Sachs, and Stern 2021).

Interestingly, the alleged cartel is likely to have contributed to a large increase in *public* ex-

penses on pharmaceuticals. Spending on outpatient drugs comprises 5% of total Medicaid benefits expenditure, and it has increased substantially over time, totalling around $30 billion in 2017. Generic drugs accounted for the vast majority of Medicaid prescriptions in 2014-2017. The fixed dollar copayment paid by Medicaid beneficiaries may have shielded them from bearing the price increases directly, which might partially explain why demand did not drop significantly as a result of the price hikes. As a result, most of the increased expenses were likely covered by Medicaid and only partially compensated by manufacturer rebates. Previous work has shown how Medicaid rules, including its rebates program, have effects on price levels in private insurance markets (Duggan and Scott-Morton 2006, Feng, Hwang, and Maini 2021), making our results relevant for understanding the impact of collusion on a larger scale. Patients covered by different insurance programs (Medicare Part D or private) who used these drugs during the cartel likely experienced significantly larger out-of-pocket costs.

Related literature

Our paper is related to a growing body of literature focusing on the determinants of competition in generic pharmaceutical markets. Generic drugs have been shown to significantly lower market prices and much attention has been devoted to the conditions for successful generic entry to take place. Earlier works emphasize the role of market characteristics, including market size, pre-expiration revenues and the type of disease treated by the drug, as well the strategic behavior of incumbent firms (Grabowski and Vernon 1992, Scott-Morton 1999, Scott-Morton 2000). However, the impact of generic drugs on prices is highly heterogeneous across markets (Danzon and Chao 2000a) and both firm-specific and institutional factors have been blamed for sometimes ineffective competition. First, heterogeneous generic manufacturers may target markets that are more similar to those of existing drugs (Scott-Morton 1999), with specialization limiting entry. Second, pharmaceutical price regulation may deter or delay new drug launches (Kyle 2007, Maini and Pammolli 2021), eventually leading to fewer and later generic entrants. Price controls may render generic competition ineffective or even counterproductive (Danzon and Chao 2000b) and policies that encourage patients to favor generics by capping price differences, such as reference pricing, may result in shifting sales towards branded versions (Dubois and Lasio 2018). Similarly, policies that aim at speeding up entry may increase the likelihood that a firm enters a crowded market and hence could reduce the total number of generic entrants and consumer welfare (Ching 2010). Third, incumbents may strategically react to generic entry, outweighing the downward pressure of generics on average market prices (Frank and Salkever 1997).[5]

While earlier policies in the US were successful at stimulating entry, by reducing entry costs for generic firms, the standard generic drug market paradigm of low concentration and low prices is less prevalent today. Several recent papers document increasing generic prices for the US and

[5]For a survey of some of the earlier literature see Scott-Morton and Kyle (2012).

identify the likely cause as a combination of manufacturer market power and constraints to free entry, due to institutional factors. Berndt, Conti, and Murphy (2017) show that the majority of generic drug markets in the US have low sales and are served by few firms (2-3, with a sizeable share of monopolies), due to falling entry rates and increasing exit rates. This low number of competitors may not be enough to drive prices close to marginal costs (Reiffen and Ward 2005). Ganapati and McKibbin (2021) further show that US markups are largely driven by generic manufacturer market power, rather than concentration at other levels of the supply chain, and that entry may be limited by costs that are higher in the US than in comparable countries. Cuddy (2020) investigates the interplay between the collusive behavior of generic manufacturers and the potential constraints to free entry due to the FDA backlog in generic drug applications. Using a model of the retail procurement process, she shows that the competitive effect of entry on prices fades away beyond the third competitor and thus that reducing entry costs may only partially lower prices. She finds that the high and stable prices observed in recent years are mostly due to the collusive behavior of firms. She estimates damages of the collusive ring during its 18-month existence at $2.2 billion. A back-of-the-envelope estimate based on the findings from her model of the total market damage imposed by the ring is over $12 billion.

The difference-in-differences approach adopted in this paper has been used to study the impact of alleged price fixing in many markets (see for instance Erutku and Hildebrand 2010, Hüschelrath, Müller, and Veith 2013, Clark and Houde 2014, Miller and Weinberg 2017, Clark, Coviello, Gauthier, and Shneyerov 2018, and Miller, Remer, and Weinberg 2020). More recently, using a similar approach, Barkley (2021) reports substantial effects from a major cartel controlling insulin provision in Mexico: the collapse of the cartel led not only to sizeable savings for the Mexican public health system, but also to a large increase in demand, which resulted in lower mortality and reduced complications for diabetic patients. There is also a lengthy literature studying the organization and impact of cartels. See for instance Pesendorfer (2000), Genesove and Mullin (2001), Roller and Steen (2006), Asker (2010), Clark and Houde (2013), and Igami and Sugaya (2021). Alé-Chilet (2018) studies the rise of collusion in retail pharmacies.

Outline

The rest of the paper proceeds as follows. In the next section we describe institutional details and characterize market structure. In Section 3 we provide background on the cartel and the investigation. In Sections 4 and 5 we present the data and describe our empirical approach for assessing the impact of the cartel on prices. Sections 6 and 7 present our estimates of the overcharge and damage calculations, respectively. Finally, Section 8 concludes.

2 The US Generic Drug Market

In 2016, the US spent $329 billion on prescription drugs and spending is expected to experience the fastest average annual growth among major health care goods and services over the next 10 years (Cuckler, Sisko, Poisal, Keehan, Smith, Madison, Wolfe, and Hardesty 2018). Increasing the use of generic drugs is often advocated as one way to balance access to medicines with controlling prescription drug expenditures. Generics are safe and cheap alternatives to expensive brand-name medications and using them frees public resources for conditions requiring use of more expensive patent-protected pharmaceuticals.

The origins of today's generic drug industry in the United States can be traced back to 1984, when the Hatch-Waxman Act was passed. The law simplified the approval and entry process for generic drugs via an Abbreviated New Drug Application (ANDA): to be approved as a substitute to an existing brand-name drug, a generic drug had only to prove that it was identical in strength, dosage form, and route, and that it was bioequivalent. Overall, the Act was successful in stimulating generic entry, as the new approval process entailed much lower costs of entry than the previous regime (Scott-Morton 1999). Generic drugs, which accounted for only 13% of the market before 1984 (OECD 2015), represented 36% of all sales in the US in 1994 and 87% in 2015 (Berndt, Conti, and Murphy 2017), but only 28% in value, as their price is a fraction of their brand-name substitutes. Generic products that entered the market between 2002 and 2014 reduced the price of medicines by 51% in the first year and 57% in the second year following loss of exclusivity (IMS 2016) and this reductions reached 66% and 74% respectively for oral drugs. After five years, the price of generic oral products represents only 20% of the pre-expiry brand prices.

However, in recent years, generic drugs have increasingly experienced shortages, especially for old, off-patent, largely non-oral drugs, and episodes of price gouging, sometimes massive. In 2012-2013 prices of many incumbent generic drugs increased for the first time in several years and prescription drug expenditures grew significantly. The early-period paradigm of vigorous competition has evolved into increased concentration for many molecule markets, which are supplied by a small number of firms. Berndt, Conti, and Murphy (2017) show that more than half of generic drug markets in the US are either monopolies or duopolies and the share is larger for non-oral formulations. The median number of manufacturers in a molecule market was between two and three until 2007, and two afterwards, with a declining entry rate and an increasing exit rate since 2013.

Prescription drugs sold in pharmacies in the US are covered by three main sources: private insurance, Medicare Part D, and Medicaid. Medicaid is US main public health insurance program for people with low income, covering nearly 70 million Americans. Between 2011 and 2018, Medicaid accounted for 9% of all prescription drug expenditures and a quarter of public expenditures.[6]

[6] Authors' calculations from CMS National Health Expenditure: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical

Medicaid's mandate to provide health care access to its vulnerable enrollees translates into low and fixed beneficiary cost-sharing: individuals with incomes at or below 150% of the federal poverty level pay up to $4 for preferred drugs and $8 for non-preferred drugs, those with higher incomes a slightly larger amount. Yet, not all states impose cost-sharing for prescription drugs, and some beneficiary groups are exempt from cost-sharing requirements. To control expenditures, the Medicaid Prescription Drug Rebate Program (MDRP) imposes to manufacturers that want their drugs covered under Medicaid to rebate a specified portion of the Medicaid payment for the drugs to the states, which in turn share the rebates with the federal government. The goal is to guarantee that Medicaid pays a price at least as low as the lowest net price paid by any private insurer. For generic drugs, the rebate amount is set at 13% of the average manufacturer price and did not change during our sample period.

3 The Alleged Conspiracy

The first lawsuit filed against generic pharmaceutical companies occurred in December 2016, when six manufacturers of two drugs were charged. An expanded complaint filed on October 31st, 2017 added nine other drugs including the six we focus on in our analysis. The complaints describe an arrangement whereby participants avoided competing with one another and eroding prices. Upon entry, defendants communicated with each other to determine market shares and allocate customers. Participants implemented the agreement by avoiding head-to-head competition for particular customers and/or by submitting cover bids that were sure to lose. According to the complaint, the defendants' objective was to *maintain inflated prices within and across their respective broad product portfolios...without triggering a "fight to the bottom among existing competitors".*

The arrangement was maintained through communication achieved by the defendants via their interactions at industry trade shows, at customer conferences and other events.[7] The complaints also refer to frequent conversations taking place at "industry dinners," "girls nights out," lunches, parties, frequent telephone calls, emails and text messages.

The 2017 complaint gathers nine drugs from different classes, all of which see Heritage as the main driver of the alleged conspiracy. Two top executives of the firm plead guilty and started collaborating with authorities to uncover a broader conspiracy. Our focus in this paper is on six out of the nine drugs which are part of this complaint. We select those from classes that did not experience any entry during the cartel period, to identify more cleanly any effect the cartel had on prices. Common elements for all of the six are frequent and open communication between Heritage and its competitors in each market, clear plans on how much to increase the price, and how to

[7]Other recently uncovered cartels have operated through trade associations and/or been born at industry trade events. Alé-Chilet and Atal (2020) empirically examine the role of a trade association for facilitating collusion amongst physicians in Chile. Asker and Hemphill (2020) study conduct in the Canadian sugar industry where the Dominion Grocers Guild was established to enforce a price-fixing arrangement. Clark, Horstmann, and Houde (2021) describe how a recently uncovered cartel in the Canadian bread industry was initiated at a trade event.

achieve it (for instance by "walking away" from customers or not challenging price increases by competitors).

We assume the cartel for all drugs collapsed in the fourth quarter of 2016, after the FBI raided the headquarters of Mylan in September. The DOJ subsequently filed its first charges in December 2016. We define the start of the cartel period separately for each drug: we refer to the court documents and define the start based on evidence of the first price increase for each drug; if this information is not available, we take the date of the first contact between Heritage and its competitors.

While for some drugs contacts started early in 2013, on April 22nd, 2014, Heritage held a teleconference to discuss large over the board price increases for eighteen different drugs, including those we analyze except meprobamate. Members of the sales team were instructed to reach out to their contacts at each competitor for each drug in an effort to reach agreement over the slated price increases.[8] Over the next several weeks, Heritage employees continued to negotiate with their competitors about price increases. According to the court documents, Heritage was able to increase prices for at least nine drugs (acetazolamide ER; fosi/HCTZ; glipizide-metformin; glyburide; leflunomide; nimodipine; nystatin; and paromomycin[9]), though it is not clear whether Heritage was ever fully successful in raising its price for some of the others.

4 Data

We use publicly available Medicaid state drug utilization data for the period 2011-2018. In line with the requirements of the Medicaid Prescription Drug Rebate Program, every state reports utilization for covered outpatient drugs paid for by state Medicaid agencies. We use quarterly data from the national total dataset, which report the number of prescriptions and the total amounts and units reimbursed for each covered drug (uniquely identified by its NDC code at a very fine level) by state and utilization type (fee-for-service or managed care).[10] The reimbursement amounts are pre-Medicaid rebates paid to the state by the manufacturers.

The advantage of using Medicaid data is that we can retrieve price and quantity information at the manufacturer level, which is crucial for exploring potential heterogeneity in the effects of the alleged cartel for firms with different levels of involvement in the price fixing scheme. Also, the reimbursement amounts are net of pharmacy dispensing fees, which allows us to attribute the effect to manufacturer pricing and not to the pharmacist margin.

We select the drugs of interest using the NDC, the 10- or 11-digit code which uniquely identifies each drug approved by the FDA at the molecule-strength-format-manufacturer-package size level.

[8] MDL 2724 at para 269.

[9] MDL 2724 at para 293.

[10] Under fee-for-service, the state pays providers directly for each covered service received by a Medicaid beneficiary, while in managed care organization the state pays a fee to a managed care plan for each person enrolled in the plan.

When drugs are available under different strengths and formats, we use the information in the court documents to identify the correct level of aggregation: when all firms cited in the complaints are present in all dosage-format markets and the markets display similar trends (in prices and quantities), we aggregate the data at this level and perform the analysis for the molecule market as a whole (for instance, for meprobamate); when some firms only compete in some format-dosage markets (for example only sell tablets and not capsules of a certain dosage and not others, such as for theophylline), we instead focus on these. Details of such selections and their rationale are described in each drug subsection below.

The average retail price for each drug is calculated as the ratio between the total amount reimbursed by quarter and the number of units (FFSU and MCOU types both included), further filtered by labeler code to define the firm-specific retail price. We exclude outlier observations from specific firms that sell very low quantities, which generate very large spikes in prices.[11] To allow for comparisons across drugs, we transform all units in defined daily doses (DDD), using the WHO Anatomical Therapeutic Chemical (ATC) classification tables, and define the price at this level. One DDD is the assumed average maintenance dose per day for a drug used for its main indication in adults.

4.1 Doxycycline Monohydrate

Doxycycline monohydrate is an oral tetracycline, an antibiotic used to treat numerous types of bacterial infections, from acne to malaria. The WHO ATC classifies the molecule in class J01AA, tetracyclines. Our analysis focuses on doxy mono 100 mg oral tablets: 50 mg and 75 mg tablets are also available, but the 100 mg is the mostly prescribed version and we found no evidence that collusion was ever successful for the other two dosages. While being available also as capsules, we discard them from the analysis, as Heritage does not produce them. Summary statistics are presented in Table 1. Over the eight-year sample, the utilization of the drug increases steadily. Its price displays a gradual drop in the first three years of the sample, followed by a change in trend between 2014 and 2016, when the price increases significantly before dropping again and stabilizing to a much lower level than the beginning of the period. This pattern traces quite consistently the alleged conspiracy. The average annual price decrease in 2016 also coincides with the first charges made in December 2016.

4.2 Meprobamate

Meprobamate is an anxiolytic (WHO ATC class N05BC), a category of drugs used to prevent and treat anxiety related to several anxiety disorders. In the Medicaid data, oral meprobamate is

[11] They tend to be the same few manufacturers across several drug classes, which we discard from all for consistency.

Table 1: The market for doxy mono

Year	Units (DDD)	Revenues ($)	Price ($/DDD)	Market share by firm					
				Heritage	Lannett	Mylan	Par	Ranbaxy	Zydus
2011	200,484	399,314	2.0		0.15	0.30	0.09	0.46	
2012	203,426	490,793	1.9	0.10	0.18	0.28	0.07	0.37	
2013	507,650	1,050,012	1.9	0.31	0.17	0.36	0.14	0.02	
2014	1,221,085	2,573,853	2.0	0.35	0.26	0.24	0.16		
2015	2,800,361	6,011,782	2.3	0.29	0.20	0.18	0.34		
2016	3,476,056	4,805,678	1.3	0.34	0.42	0.19	0.05		
2017	4,094,273	2,979,514	0.8	0.41	0.44	0.15			
2018	4,371,688	2,950,291	0.7	0.62	0.34	0.01			0.03

available in two strengths, 200 mg and 400 mg. Summary statistics are presented in Table 2. During the sample period, a total of four manufacturers supplied meprobamate at some point in time, but only two of them were active consistently throughout the period, Heritage and Dr. Reddy's, the two firms under investigation for the cartel. At the end of 2016 Heritage left the market, leaving Dr. Reddy's as a de facto monopolist of both meprobamate versions: Alembic entered the market in 2016, but only provided a limited supply of the drug. As the 200 mg and 400 mg versions follow the same trend and show the same evolution for both prices and quantities, we perform the analysis aggregating the two dosages. Sales of meprobamate decrease steadily over time. The price increases in 2013 and never drops back to the level of 2011-2012.

Table 2: The market for meprobamate

	Units (DDD)	Revenues ($)	Price ($/DDD)	Market share by firm			
				Actavis	Alembic	Dr. Reddy's	Heritage
2011	69,504	326,654	4.7	0.45		0.23	0.32
2012	51,144	236,057	4.6	0.38		0.23	0.38
2013	38,788	273,556	6.7	0.08		0.33	0.59
2014	34,407	390,335	10.9	0.01		0.26	0.73
2015	35,993	488,559	14.0			0.18	0.82
2016	33,807	458,738	16.0			0.76	0.24
2017	26,534	301,859	11.8		0.08	0.92	
2018	21,281	226,650	10.0		0.09	0.91	

4.3 Nystatin

Nystatin is a medication used to fight fungal infections of the skin, including diaper rash, thrush, esophageal candidiasis, and vaginal yeast infections. It is classified as an intestinal anti-infective in ATC class A07AA. Nystatin is available in oral form and a single dosage supplied by a triopoly

of Heritage, Sun, and Teva, with varying market shares over time. The market for nystatin grows over time, despite an increase in average price that starts in 2015 and only seems to fade slightly at the very end of the sample period. Summary statistics are presented in Table 3.

Table 3: The market for nystatin

Year	Units (DDD)	Revenues ($)	Price ($/DDD)	Market share by firm		
				Heritage	Sun	Teva
2011	218,457	338,443	1.6		0.38	0.62
2012	192,216	305,555	1.6	0.08	0.56	0.36
2013	207,980	319,865	1.6	0.33	0.26	0.41
2014	296,396	490,878	1.6	0.29	0.17	0.53
2015	339,132	599,888	1.8	0.28	0.27	0.45
2016	375,644	699,670	1.9	0.30	0.19	0.51
2017	383,602	730,397	1.9	0.32	0.20	0.48
2018	355,134	598,851	1.7	0.29	0.21	0.49

4.4 Paromomycin

Paromomycin is a broad spectrum antibiotic used to treat amoeba infections of the intestines and complications of liver disease. It belongs to the same ATC class as nystatin (A07AA, intestinal anti-infectives) and is sold as a 250 mg capsule. While being on on the World Health Organization's List of Essential Medicines for its crucial use in developing countries, its sales are limited in the US, although they increase during the sample period. Summary statistics are presented in Table 4. Paromomycin is a duopoly until 2017, when Sun leaves the market, leaving Heritage as the sole supplier of the drug. Paromomycin's price displays some fluctuations during the beginning of the period. Yet, between 2015 and 2017, the price level increases by 3 dollars per DDD and drops back only in 2018.

4.5 Theophylline

Theophylline is a medication used to treat airway narrowing associated with long-term asthma or other lung problems, such as chronic bronchitis and emphysema. It is a xanthine, classified by the WHO as a systemic drug for obstructive airway disease, under class R03DA. Theophylline is available as an extended release medication under different strengths and formats. Since Heritage only produces tablets, we discard capsules and we focus on the 300 mg tablet market, as the 450 mg has negligible sales. Summary statistics are presented in Table 5. Units of theophylline decrease

Table 4: The market for paromomycin

Year	Units (DDD)	Revenues ($)	Price ($/DDD)	Market share by firm Heritage	Sun
2011	1,713	78,830	42.4	0.98	0.02
2012	1,926	92,032	47.8	0.86	0.14
2013	1,774	80,456	45.7	0.58	0.42
2014	2,027	91,587	45.0	0.62	0.38
2015	2,219	104,823	48.4	0.74	0.26
2016	2,205	105,540	47.8	0.90	0.10
2017	2,064	100,688	48.7	1.00	
2018	2,368	103,727	43.8	1.00	

significantly over time, with the market halving by the end of the period. Conversely, revenues increase, due to a large price hike in 2016 that further increases in the last two years of the sample. Until 2016, Teva is the largest supplier of the product, with Heritage increasing its presence over time. However, in 2017 both firms exit the market and are replaced by Alembic, which becomes a monopolist by the end of the sample. The higher price and lower quantity of 2018 seem to be consistent with monopoly.

Table 5: The market for theophylline

Year	Units (DDD)	Revenues ($)	Price ($/DDD)	Market share by firm Alembic	Heritage	Teva
2011	3,398,391	1,259,152	0.4		0.01	0.99
2012	2,919,640	1,048,202	0.4		0.14	0.86
2013	2,500,881	875,504	0.3		0.21	0.78
2014	2,344,421	974,502	0.4		0.26	0.73
2015	2,300,686	1,211,206	0.5		0.39	0.60
2016	1,987,436	2,321,789	1.0	0.37	0.27	0.36
2017	1,794,325	4,602,554	1.4	0.94	0.02	0.04
2018	1,470,594	4,645,384	1.8	0.98		0.02

4.6 Verapamil

Verapamil is a selective calcium channel blocker with direct cardiac effects (WHO ATC class C08DA). It is used to treat hypertension, angina and certain heart rhythm disorders and it works by relaxing the muscles of the heart and blood vessels. Verapamil is sold under three different strengths, 40 mg, 80 mg, and 120 mg. It is also available as an extended release medication, but it is not produced by Heritage, so we drop it from the analysis. Summary statistics are presented in Table 6. Three firms supply the standard version: Heritage, Actavis, and Mylan. However, the

only firm active in all three dosage markets is Actavis: Mylan only supplies the 80 mg and 120 mg versions, while Heritage enters the 40 mg market in 2015, eroding some sales from Actavis. The market for verapamil across all dosages increases by 30% by 2018, while the aggregate average price does not display the hike implied by the court documents after 2014Q2, when verapamil was among 18 drugs targeted for price increases.

Table 6: The market for verapamil

Year	Units	Revenues	Price	Market share by firm		
	(DDD)	($)	($/DDD)	Actavis	Heritage	Mylan
2011	1,563,895	647,505	0.5	0.39	0.02	0.60
2012	1,567,085	627,743	0.4	0.32	0.10	0.59
2013	1,589,105	654,974	0.4	0.33	0.25	0.41
2014	1,972,270	783,198	0.4	0.33	0.36	0.31
2015	2,220,680	868,325	0.4	0.29	0.43	0.28
2016	2,300,307	924,830	0.5	0.24	0.46	0.30
2017	2,277,228	1,015,500	0.5	0.21	0.49	0.29
2018	2,054,118	901,618	0.5	0.21	0.52	0.27

5 Empirical Approach

To evaluate the impact of the cartel, we employ a difference-in-differences strategy, in which we compare changes in prices in each treatment drug market to those in control drug markets, during the alleged cartel and in non collusive periods. Our difference-in-differences approach rests on a number of important assumptions. The first is that we can properly identify the cartel period. The second is that we can identify suitable competitive control groups and time periods. Finally, the third is that we can adequately control for market-specific developments.

The cartel period To define the cartel period we rely on information from the court documents. The documents report information on the first date of contact between Heritage and its competitors in each of the six markets. For several drugs, including doxy mono and meprobamate, contacts started as early as 2013Q1 or 2013Q2. The rest of the drugs (nystatin, paromomycin, theophylline and verapamil) were targeted for price increases in 2014, as part of a more general strategy that included several drugs, which was discussed in communications among competitors in April 2014. We use the date of the first communication as the start of the cartel, unless the complaint reports further details about the date at which firms took action to increase prices (for instance, by sending notices to customers).

The court documents report that contacts between Heritage and its competitors for doxy mono, Lannett, Par, and Mylan, started as early as February 2013, when Heritage learned from one customer that there would be a significant increase in demand for the drug as a result of a significant price increase for a different form of doxycycline, as well as supply problems faced by certain manufacturers. The plan was to increase the price by more than four times its price at the time.[12] However, due to reported supply problems, Heritage was not successful at doing so throughout 2013. In April 2014, price increases for doxy mono were further discussed with competitors and Heritage was successful in agreeing with Lannett and Mylan. For this reason, we only consider the collusion for doxy mono to start in 2014Q2. Interestingly, it is not clear from the court documents if Heritage was ever fully successful in raising its price for doxy mono.

Communication on a price increase for meprobamate began in March 2013 between Heritage and Dr. Reddy's, at the time the only manufacturers of the drug. The agreement set via phone calls and email exchanges specified the price increase as well as market-share allocation, with each firm contacting the competitors each time they were faced with supply requests by customers. As a result, Heritage and Dr. Reddy's were able to successfully increase prices across-the-board, starting in the spring of 2013 (April for Heritage and May for Dr. Reddy's). We therefore consider the cartel to start in 2013Q2.

Contacts between Heritage, Sun and Teva about price hikes for nystatin started in early 2014. Teva began implementing price increases for nystatin in April 2014, while Heritage began sending out price-increase notices to its customers in June. Sun followed during the summer. Based on this evidence, we consider the cartel for nystatin to start in 2014Q2.

In 2014, paromomycin was a duopoly between Heritage and Sun. The two firms had frequent communications about significantly increasing the price for the drug and agreed to do so in April 2014. However, paromomycin kept appearing on the list of drugs targeted for prices increases for the next several weeks. Although Sun had production issues due to a need to transfer its manufacturing operations to another facility, Heritage sent price increase notices to customers in June 2014. Thus, we consider the cartel to start in 2014Q2.

Teva and Heritage began to consider raising the price of theophylline in early 2014 and agreed to do so by April, with Teva taking the lead on implementing the price increases as early as April 4 and Heritage following in June. Therefore, based on the court filings, the conspiracy started in 2014Q2 and by early July Heritage had been able to successfully increase prices to at least twenty different customers nationwide, in line with what Teva had done three months earlier.

Starting in April 2014 and for the next couple of months, Heritage exchanged frequent communications with Mylan and Actavis, its competitors for verapamil. Heritage reached an agreement to increase the price of verapamil separately with each competitor in late April 2014. In June, verapamil appeared again on the list of drugs targeted for a price increase. Therefore we assume

[12] MDL 2724 at para 251.

that the conspiracy started in 2014Q2. The court documents cast doubts on Heritage's success in increasing the price of verapamil and report that the price increase was not market wide as for other drugs, though at least one customer was notified by July 2014.

We assume that the cartel collapsed for the six drugs in the fourth quarter of 2016, after the FBI raided the head- quarters of Mylan in September and the DOJ filed its first charges in December 2016.

When estimating the overcharge we use the periods prior to the start of the cartel as our competitive control period. As mentioned in the Introduction, we do so for two reasons. First, as pointed out by Harrington (2004), using the post-collapse period as a competitive benchmark can bias overcharge estimates. This is because, knowing that damages might be based on the difference between cartel prices and post-cartel prices, firms may strategically maintain prices above competitive levels in order to reduce the overcharge estimate and the resulting damages. Second, it is also the case that market-structure changes in the post-collapse period in some of the markets could also influence overcharge estimates. For meprobamate, Heritage exited the market at the end of the cartel period, leaving Dr. Reddy's to act as a de facto monopolist. Similarly, Sun stopped selling paromomycin in 2017 and Heritage remained the sole supplier. For theophylline, the two alleged colluders, Heritage and Teva, left the market roughly a year after the cartel's collapse and the recent entrant Alembic took over.

The control group Our approach hinges on the identification of a suitable control group for each of our six drugs. Control drugs must be similar enough to treatment drugs, while not being direct competitors, to guarantee that the price evolution of control drugs both before and during the cartel traces how prices of treatment drugs would have evolved in the absence of collusion. To do so, we rely on the World Health Organization ATC (Anatomical Therapeutic Chemical) classification system, which divides active substances (molecules or drugs) into different groups according to the organ or system on which they act (level 1), their therapeutic and pharmacological characteristics (level 2-4), and their chemical properties (level 5, the molecule). We exploit the hierarchical structure of the ATC system to identify drugs that treat similar conditions and have similar therapeutic and pharmacological characteristics, without being direct substitutes (i.e. a physician would not prescribe them interchangeably for the same condition).[13] This is not a straightforward task in this setting given the large number of drugs under investigation (including later complaints) and the extent to which different drugs can be used as substitutes for others. In what follows, we describe our process for systematically establishing a control group for each drug.

Specifically, we select molecules to be part of the control group if they meet the following three criteria: (C1) they are comparable but not direct competitors of the treatment drugs; (C2) they are not under investigation for the alleged price conspiracy; (C3) they do not compete directly

[13] A similar approach to control selection is used in Tkachenko (2020) to study the impact of vertical integration in pharmaceutical procurement.

with other drugs that are under investigation. We define competition based on the WHO ATC classification and consider direct competitors all those molecules that belong to the same ATC4.

The pool of candidates we consider for each treatment drug is all molecules from adjacent ATC4 classes, i.e. ATC4 classes that are in the same ATC3. If the structure of the class is such that there are no other ATC4 classes in the treatment drug's ATC3, we start the search from ATC4 markets in adjacent ATC3 classes. This is the case for doxy mono, which belongs to ATC4 class J01AA, the only one in its ATC3 (J01A, tetracyclines). We therefore consider ATC4 classes in adjacent ATC3, J01B-J01X (details are reported in Appendix A.2).

From this pool, we check sequentially whether drugs meet the three criteria. To meet C1, molecules from the initial pool of candidates must be: (i) approved by the FDA (in the Orange Book); (ii) off-patent, i.e. available as generics, (iii) sold as tablets, capsules, and other oral forms and (iv) available throughout the period to Medicaid enrolees. Combination products or drugs sold as injectable, solution, suspension, gel, or cream do not meet C1 and are therefore excluded, since these different forms generally have very different manufacturing costs and tend to treat different conditions even when they are classified in the same ATC4. The exclusion of drugs that enter during the sample period is due to the different trends in prices and sales from those of older molecules, such as those under analysis. From the drugs that meet C1, we next discard those that are listed in the court documents of any complaint, even the most recent one (C2), and we retain only those from ATC4 classes that have no drug listed in these complaints (C3).

Given the pervasiveness of the cartel, for all drugs except meprobamate this process does not produce any control drugs. When this is the case, we expand our search to higher levels of the hierarchy. We consider the pool of molecules from adjacent ATC3 classes and perform the same analysis for each ATC4. If we cannot find any controls even at this level, we expand our search to ATC4 classes in adjacent ATC2. This happens for theophylline (R03DA), where no drug meeting all three conditions is found in adjacent ATC4 classes (R03DB, R03DC, R03DX), nor in any ATC4 market in adjacent ATC3 (R03A, R03B, R03C). Only after we search in all ATC4 in adjacent ATC2 (R01-R07) do we find one suitable control (guaifenesin, R05CA). We follow the same approach for verapamil, C08DA, for which controls are found in class C03BA. For nystatin and paromomycin (A07AA) no controls can be found in adjacent ATC4 classes (A07AB, A07AD, A07AX), nor in any ATC4 in adjacent ATC3 classes (A07B-A07X). Instead of exploring ATC4 in other ATC2 classes, which include very different drugs, we turn to other antibiotics listed in ATC class J01, antibacterials for systemic use. While belonging to a different ATC category, drugs in J01 are comparable to those in A07AA but are not direct substitutes. We therefore use the same controls identified for doxy mono, from classes J01EA, J01EC and J01XX.

Our selection criteria guarantee that prices of control drugs are comparable to those of the treatment drugs, while not being directly affected by the conspiracy either via participation in it or by competitive effects. We confirm that the trends in the price of the treatment and control

groups are parallel before the conspiracy using standard tests.

Ideally, we would not include a drug in the control group if its manufacturer were under investigation for the alleged cartel in any other market. Unfortunately, due to the pervasiveness of the agreement, this condition is never met: at least one of the manufacturers in each molecule market is cited in the courts documents. However, the investigation uncovered evidence of collusion taking place at the molecule market level, with no clear evidence that price fixing would automatically extend to other molecule markets. While generic manufacturers are multi-product firms and multi-market contacts are frequent, the number and identity of competitors varies across molecules, making collusion easier to sustain in some markets while unstable in others. Our selection process generates control groups of different sizes for each of the six drugs we analyze, from only one molecule for theophylline, to six for meprobamate. These differences are a function of how many drugs belong to adjacent classes and how many were directly or indirectly affected by the cartel and hence had to be dropped. We report the specific controls used for each drug and the rationale behind their inclusion in Appendix A.2.

The empirical specification Once the cartel period and the control groups have been identified, we run the following difference-in-differences regression:

$$price_{jt} = \alpha + \beta I\left(t \in T_C\right) \cdot I\left(j \in D_C\right) + \gamma_j + \delta_t + \varepsilon_{jt}, \tag{1}$$

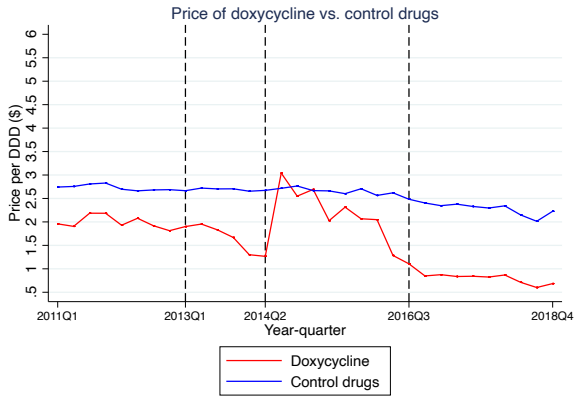
where $price_{jt}$ is the price of drug j in period (year-quarter) t, $I(\cdot)$ is an indicator function, T_C is quarters during which collusion took place and D_C is allegedly collusive drugs, γ_j are drug fixed effects, δ_t are year-quarter fixed effects, and ε_{jt} is a mean-zero uncorrelated deviation.

The coefficient of interest is β, which captures the difference between the change in the price of the treatment drug relative to the change in price in the control group due to the cartel. To account for serial correlation in the price of each drug, we use robust standard errors. To investigate potential heterogeneous effects across manufacturers, we also run regression (1) at the firm level.

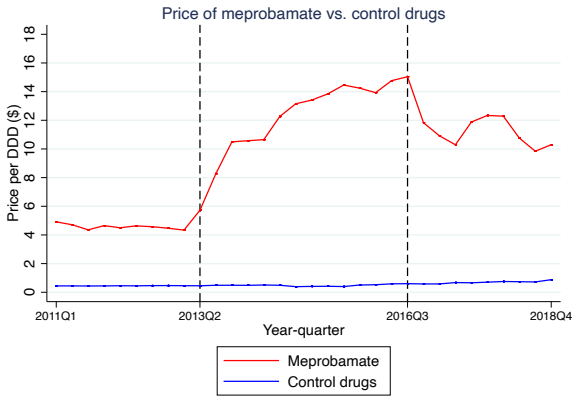
6 Results – Overcharge Estimates

In this section we present the results from our empirical analysis. Figure 1 plots the price per DDD for each of the six drugs against the prices of their respective control groups. The figure provides the first evidence of the impact of collusion on prices for some of the drugs.

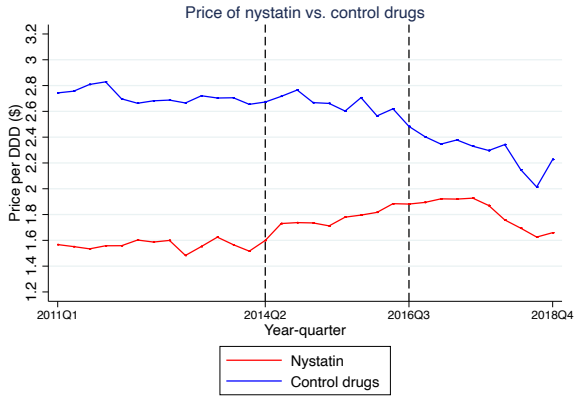
Starting with panel (a), we can see that prices for doxy mono are much higher than prices of the control drugs during the cartel period (2014Q2-2016Q3). The trends in the treatment and control were common for the 2011-2014 period, except for the last quarter of 2013 and the first of 2014, when the price for doxy mono falls more compared to the control group, before a large price increase in 2014Q2, which coincides with the evidence of the timing of the first price hikes reported



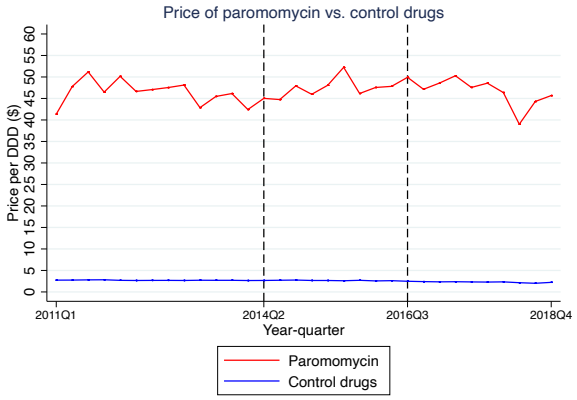
(a) Doxycycline



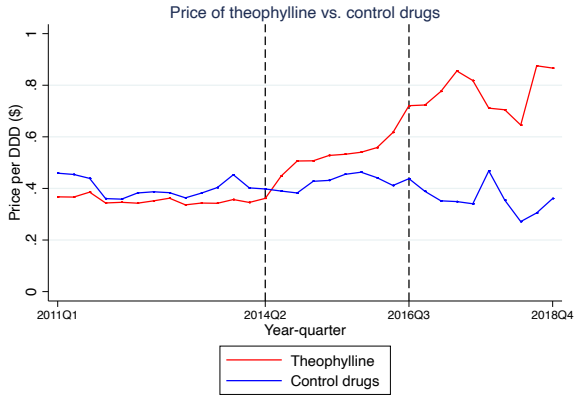
(b) Meprobamate



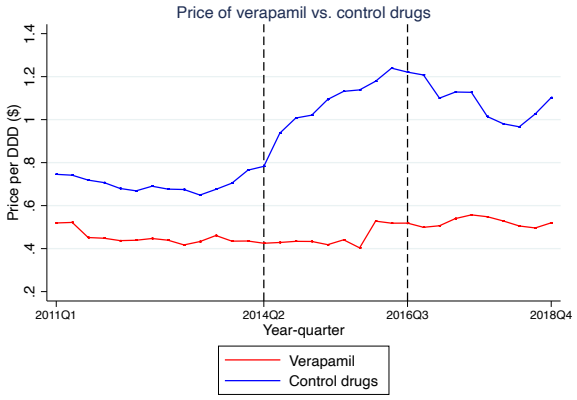
(c) Nystatin



(d) Paromomycin



(e) Theophylline



(f) Verapamil

Figure 1: Price evolution for treatment drugs and their respective control groups

in the court documents. The price of doxy mono remains high until the end of 2015, after which it falls drastically. We formally test the parallel trends assumption using both a linear regression and an event study analysis. Results are reported in Table 10 in Appendix A.3. While we cannot reject that the prices of doxy mono and the control drugs are on different trajectories before 2014Q2, the difference is very small. Although it is statistically different from zero, it corresponds to 3 cents out of an average price of $1.9. The event study analysis confirms these results: while we reject that all interaction terms are zero, the trends are similar, to diverge significantly after 2014Q2 (see panel (a) of Figure 8 in Appendix A.3).

Panel (b) plots the price per DDD of meprobamate against the price of the control group. The graph illustrates that before 2013Q2 the prices of the two groups moved in a similar way, to diverge significantly after that date. The results of a formal test of the parallel trends assumption are reported in Table 10 in Appendix A.3. While not being fully parallel in a statistical sense, the difference is 4.5 cents out of a price of $4.6, so economically the prices of meprobamate and its controls are undistinguishable before 2013Q2. From this panel we can also see that meprobamate's price increases steadily for several periods. Unlike was the case for doxy mono, meprobamate's price remains elevated even after the supposed collapse of the cartel in 2016Q3. This is because of the exit of Heritage that we have mentioned already.

Turning to panel (c), which presents results for nystatin, we can see that the effect looks less pronounced than for the previous two drugs, mostly due to the different scale of prices of the control group. Our formal tests reported in Appendix A.3 confirm the parallel trends assumption. Nonetheless a noticeable increase in price can be observed between the start of the cartel period and 2017, with the price steadily increasing from an average $1.56 before 2014Q2 to $1.9 in 2016Q3.

Panel (d) presents results for paromomycin. From the figure, there is no clear effect of collusion. Note that this is despite the fact that the court documents report on a plan to increase price by 100% for paromomycin and point out that Heritage sent price increase notices to customers in June 2014. Sun had production issues and had to transfer its manufacturing operations to another facility, but continued to sell its inventory through at least January 2015. It eventually left the market in 2017.

Panel (e) displays pricing for theophylline and shows that manufacturers began implementing the price increases across the board in April 2014 and Heritage followed shortly after: theophylline was slated for a 150% increase. A sharp increase in 2014Q2 is clear from the graph. The price almost doubles by 2016Q3 and keeps increasing throughout 2017. Interestingly, the entry of Alembic in late 2016 does not seem to disrupt the price hikes: on the contrary, the firm sets a high price that persists in the following quarters and increases even more after the exit of the two alleged cartel members. While less clear from the graph, our analysis confirms that theophylline and its control drug were on parallel trajectories before the conspiracy (Table 10 in Appendix A.3).

Finally, panel (f) reports results for verapamil. The court documents report frequent and

continuous communications between Heritage and its competitors about verapamil throughout 2014, with the intention to increase prices for the drug. At the same time, the documents raise doubts about the ability of the firms to increase prices, stating that Heritage was not successful at raising prices market wide, like it did for many other drugs, but that it did raise price to at least one customer. The price pattern displayed in the figure follows closely that of the control group (formal test in Table 10 in Appendix A.3) before 2014Q2 and remains mostly flat, except for an increase in 2015, which is driven entirely by Heritage. Our data show that this increase was due to Heritage entering the more profitable 40mg dosage market, where Actavis had been a monopolist until then (which also explains the higher price level of Actavis vis à vis its competitors). Further analysis at the dosage level provide no evidence of any significant price change consistent with collusion. The most striking feature of this figure is the sharp price increase for the *control* drugs. Although we selected drugs for which there are no allegations of collusion, the pricing patterns follow similar trajectory to other collusive drugs. As we will see when we turn to the regression analysis, this increasing control price implies that there will be no finding of a significant effect of collusion on prices for verapamil.

Table 7: Difference-in-differences results for the six drugs

	(1) Doxycycline	(2) Meprobamate	(3) Nystatin	(4) Paromomycin	(5) Theophylline	(6) Verapamil
$I(t \in T_C) \cdot I(j \in D_C)$	0.152	7.569***	0.212***	1.368	0.155***	-0.376***
	(0.214)	(0.500)	(0.0556)	(0.948)	(0.0262)	(0.0784)
Observations	247	668	223	197	178	460
R-squared	0.622	0.935	0.903	0.995	0.243	0.487
Time FE	YES	YES	YES	YES	YES	YES
Product FE	YES	YES	YES	YES	YES	YES
Collusion starts	2014Q2	2013Q2	2014Q2	2014Q2	2014Q2	2014Q2
Price pre	1.990	4.572	1.561	46.09	0.350	0.450

Notes: $I(t \in T_C) \cdot I(j \in D_C)$ is an indicator for quarters during which collusion took place for each of the six allegedly collusive drugs. Robust standard error in parentheses. Significance at 10% (*), 5% (**), and 1% (***).

To confirm the patterns observed in Figure 1, we turn to regression analysis. Table 7 presents results by drug from the estimation of equation (1). Consistent with the observations from panels (d) and (f), we estimate no effect on prices for paromomycin and verapamil. In fact, as a result of rapidly increasing prices for the control drugs that is not matched by verapamil, we estimate a negative effect on prices during the alleged cartel period. After controlling for time and product fixed effects we estimate that the cartel caused prices for meprobamate to increase by $7.57 per DDD. Meprobamate's average price in the pre-cartel period is $4.57 and so this represents a roughly 166% increase in price: a month of supply of meprobamate costs $227 more during the cartel.

Similarly, for nystatin we estimate a price increase of $0.21, which represents a roughly 13% increase in price, increasing a month's of supply by $6 during the cartel. Finally, for theophylline we estimate a price increase of $0.16, which represents a roughly 46% increase in price, increasing a month's of supply by $5 during the cartel. Surprisingly, we find no significant effect for doxy mono, which requires additional analyses, which we turn to next.

Overall, these results highlight the importance of taking *across*-drug heterogeneity into account.

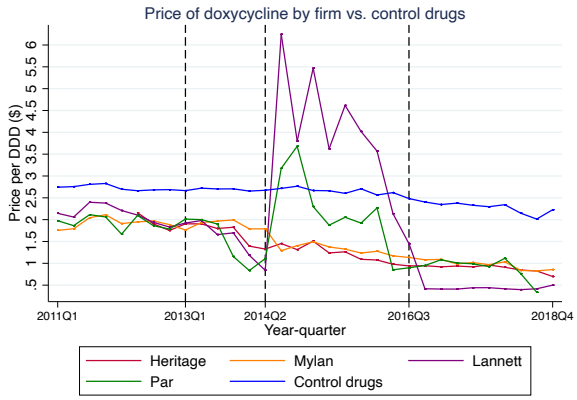
6.1 Firm-level analysis

As just mentioned, one surprising result from Table 7 is that there is no significant effect for doxy mono, despite the fact that from Figure 1 there appears to be a noticeable positive price spike starting right around the time collusion was occurring, according to the court documents. To investigate this further in Figure 2 we present the same pricing trends as in Figure 1, but this time broken down by manufacturer.

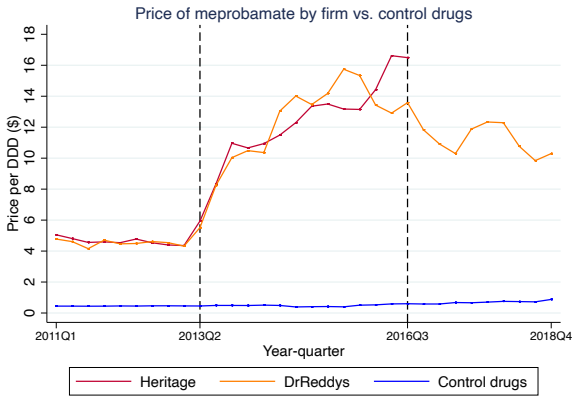
Focusing our attention on panel (a), we can see that the price increase for doxy mono is driven entirely by two manufacturers: Lannett and Par. Prices for Heritage and Mylan did not increase at all during the cartel period relative to the control drugs. In fact, in the case of Heritage prices seem to have fallen. Given this, we rerun equation (1), this time at the manufacturer level and report results in Table 8 for Lannett and Par, both jointly and individually. Our findings confirm that the increase in the average price for doxy mono was mostly due to higher prices set by these two manufacturers. Again, somewhat surprisingly, we find that for Par the effect of collusion appears to be insignificant, despite the fact that from the graph its price rises dramatically at the start of the cartel period. The insignificance is mostly driven by the fact that prices fall sharply just before the date we are using to capture the collapse of the cartel.

Using the results from Table 8, we estimate an overcharge for Lannett of $1.61 per DDD. Lannett's average price for doxy mono in the pre-cartel period is $1.95 and so this represents a roughly 83% increase in price: a month of supply of doxy mono from Lannett cost almost $50 more during the cartel. We estimate no significant effect of collusion for the other three manufacturers. These results highlight the importance of taking *within*-drug heterogeneity into account.

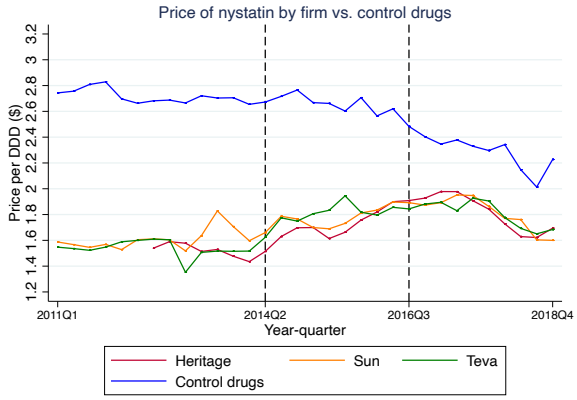
Turning back to Figure 2, from panels (b) and (d) we can see that, in addition to being the last period of cartel operation, 2016Q3 is also the last quarter during which, for each of meprobamate and paromomycin, both major producers are active. For meprobamate, Heritage leaves the market and Dr. Reddy's remains the only manufacturer (with the exception of Alembic, a small entrant that supplies very low quantities). For paromomycin, Sun exits the market leaving Heritage as the only producer. As discussed above, in our estimation of the overcharge we have used the pre-cartel period as our competitive-control period in part because of these market-structure changes. For meprobamate, since Dr. Reddy's is able to operate as a de facto monopolist, prices do not return to a competitive level following the collapse of the cartel. As a result the overcharge estimated



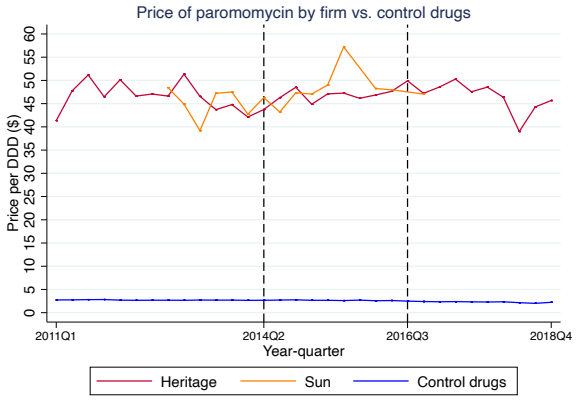
(a) Doxy mono



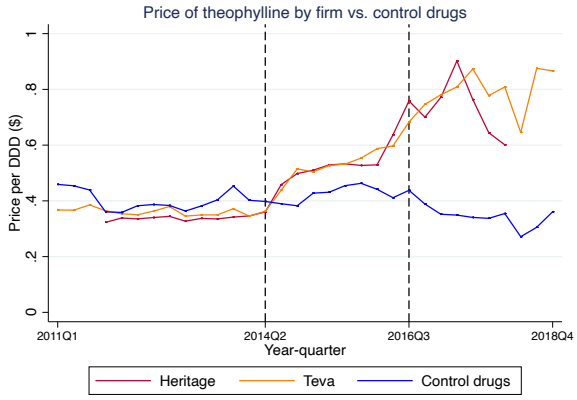
(b) meprobamate



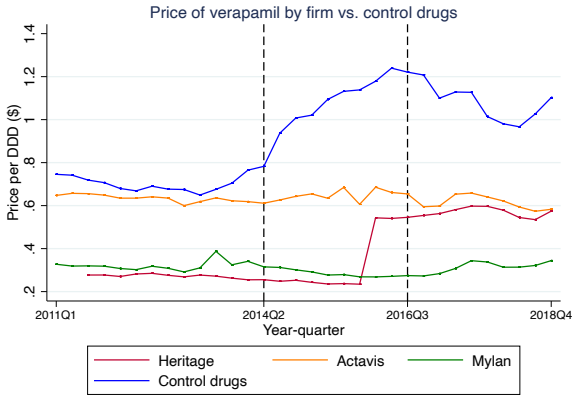
(c) Nystatin



(d) Paromomycin



(e) Theophylline



(f) Verapamil

Figure 2: Price evolution for treatment firms and their respective control groups

Table 8: Diff-in-diff results for doxy mono: only successful colluders

	(1) Lannett + Par	(2) Lannett	(3) Par
Doxy $\times I\,(t \in T_C)$	0.912***	1.611***	0.217
	(0.327)	(0.490)	(0.276)
Observations	206	183	183
R-squared	0.678	0.750	0.832
Time FE	YES	YES	YES
Product FE	YES	YES	YES
Collusion starts	2014Q2	2014Q2	2014Q2
Period	no post	no post	no post
doxy price pre	1.878	1.951	1.796

Notes: Doxy $\times I\,(t \in T_C)$ is an indicator for quarters during which collusion took place for doxy mono. Robust standard error in parentheses. Significance at 10% (*), 5% (**), and 1% (***).

using both the before- and after-collusion periods would be understated. Similarly, Heritage can act as a monopolist in the post-cartel period for paromomycin. Note that if we were calculating damages by manufacturer, there would be no change in overcharge estimate for the firm that exits the market, but results would change significantly for the stayer. For theophylline, exit occurs a bit later, but the end result is the same, that one firm is left as a monopolist.

7 Results - Damage Calculation

In this section we calculate damages from collusion. To do so we use the estimates derived in the previous section to determine the overcharge due to collusion and multiply this amount by the number of units sold during the cartel period. We do this separately for each of the four drugs for which we uncover effects of collusion and results are presented in Table 9. In Appendix A.5 we report damages by a firm by firm breakdown.

Table 9: Damages

	Doxy mono (Lannett)	Meprobamate	Nystatin	Theophylline
Overcharge in $	1.61	7.57	0.21	0.16
Quantity of collusive period in DDD	1,870,463	124,601	859,976	5,212,805
Damages in $	3,014,149	943,128	182,256	809,108

We estimate damages of $3,014,149 for doxy mono, coming entirely from Lannett. We estimate damages of $943,128 for meprobamate. From Figure 1 we can see that the price increase during

the cartel period looks similar for both manufacturers of meprobamate, but to investigate any possible heterogeneity across manufacturers, in Appendix A.5 we compute the manufacturer-level overcharges and damages. Finally, we estimate damages of $182,256 for nystatin and $809,108 for theophylline, with manufacturer-level breakdowns once again presented in Appendix A.5.

Overall, we estimate damages to be $4,948,641. These damage estimates may appear to be somewhat low, but of course they are for six drugs only. Furthermore, it should be noted that they are estimated on the Medicaid population only and therefore represent only a fraction of the increase in the costs imposed on US patients. During our sample period, Medicaid accounted for approximately 10% of all prescription drug expenditures, while Medicare made up over a quarter and private insurance the remainder. Furthermore, Medicaid beneficiaries tend to use prescription drugs to a lesser extent than do Medicare Part D enrolees (Garthwaite, Sachs, and Stern 2021).

8 Conclusion

In this paper we investigate the impact of alleged price fixing in the generic drug industry. Our analysis highlights (i) the difficult of establishing a suitable control group when collusion is pervasive, and (ii) the existence of across- and within-drug heterogeneity in outcomes. Our findings show that the cartel raised the price of the four of the drugs we study by a significant amount relative to their respective control groups: $0.21 for nystatin, $0.16 for theophylline, $7.57 for meprobamate, and $1.61 for doxy mono coming through Lannett, respectively, based on our most conservative estimates. These correspond to increases of 13%, 46%, 166%, and 83%, respectively. Based on these, we estimate damages of of $3,014,149 for doxy mono, coming entirely from Lannett. We estimate damages of $933,807 for meprobamate, $182,256 for Nystatin and $809,108 for Theophylline. Our analysis also suggests the overcharge estimate in the case of meprobamate depends crucially on the time period used as the competitive control period because of the exit of one of the cartel manufacturers.

These damage estimates are for the Medicaid population only. As a result they capture only a small fraction of the costs imposed on US patients by the cartel. In the period under study, Medicaid accounted for approximately 10% of all prescription drug expenditures. The estimates are also for just six out 100 drugs that make up the complaints. Our focus is on the markets for these six particular drugs since they were part of the expanded first complaint and in each case Heritage, whose CEO and president pled guilty, manufactured a product in the class. Furthermore, there was no entry of new drugs in the same class during the collusive period. Together these features allow us to quantify a clean measure of the causal impact of collusion on prices.

References

Alé-Chilet, J. (2018). Gradually rebuilding a relationship: The emergence of collusion in retail pharmacies in chile.

Alé-Chilet, J. and J. P. Atal (2020). Trade associations and collusion among many agents: Evidence from physicians. *RAND Journal 51*, 1197–1221.

Alpern, J., L. Zhang, W. Stauffer, and A. Kesselheim (2017). Trends in pricing and generic competition within the oral antibiotic drug market in the united states. *Clinical Infectious Diseases 65*, 1848–1852.

Asker, J. (2010). A study of the internal organization of a bidding cartel. *American Economic Review 100*(3), 724–762.

Asker, J. and S. Hemphill (2020). A study of exclusionary coalitions: The canadian sugar combination, 1887–1889. *Antitrustf Law Journal 83*, 99–126.

Barkley, A. (2021). The human cost of collusion: Health effects of a mexican insulin cartel.

Berndt, E., R. Conti, and S. Murphy (2017). The landscape of US generic prescription drug markets, 2004-2016. NBER Working paper No. 23640.

CDC (2018). Outpatient antibiotic prescriptions – united states, 2018. Technical report, Centers for Disease Control and Prevention.

Ching, A. (2010). A dynamic oligopoly structural model for the prescription drug market after patient expiration. *International Economic Review 51*, 1175–1207.

Clark, R., D. Coviello, J.-F. Gauthier, and A. Shneyerov (2018). Bid rigging and entry deterrence in public procurement: Evidence from an investigation into collusion and corruption in Quebec. *Journal of Law, Economics and Organization 34*(3), 301–363.

Clark, R., I. Horstmann, and J. Houde (2021). Hub-and-spoke collusion: Theory and evidence from the grocery industry.

Clark, R. and J.-F. Houde (2013). Collusion with asymmetric retailers: Evidence from a gasoline price fixing case. *American Economic Journal: Microeconomics 5*(3), 97–123.

Clark, R. and J.-F. Houde (2014). The effect of explicit communication on pricing: Evidence from the collapse of a gasoline cartel. *Journal of Industrial Economics 62*, 191–228.

Conti, R., K. Nguyen, and M. Rosenthal (2018). Generic prescription drug price increases: which products will be affected by proposed anti-gouging legislation? *Journal of Pharmaceutical policy and Practice 11*, 1–10.

Cuckler, G., A. Sisko, J. Poisal, S. Keehan, S. Smith, A. Madison, C. Wolfe, and J. Hardesty (2018). National health expenditure projections, 2017–26: Despite uncertainty, fundamentals primarily drive spending growth. *Health Affairs 37*, 482–492.

Cuddy, E. (2020). Competition and collusion in the generic drug market.

Danzon, P. and L. Chao (2000a). Cross-national price differences for pharmaceuticals: How large, and why? *Journal of Health Economics 19*, 159–195.

Danzon, P. and L. Chao (2000b). Does regulation drive out competition in pharmaceutical markets? *Journal of Law and Economics 43*, 311–358.

Dubois, P. and L. Lasio (2018). Identifying industry margins with price constraints: Structural estimation on pharmaceuticals. *American Economic Review 108*, 3685–3724.

Duggan, M. and F. Scott-Morton (2006). The distortionary effects of government procurement: Evidence from Medicaid prescription drug purchasing. *The Quarterly Journal of Economics 121*, 1–31.

Erutku, C. and V. Hildebrand (2010). Conspiracy at the pump. *Journal of Law and Economics 53*, 351–367.

Feng, J., T. Hwang, and L. Maini (2021). Profiting from most-favored customer procurement rules: Evidence from Medicaid.

Frank, R. and D. Salkever (1997). Generic entry and the pricing of pharmaceuticals. *Journal Economics and Management Strategy 6*, 75–90.

Ganapati, S. and R. McKibbin (2021). Markups and fixed costs in generic and off-patent pharmaceutical markets.

Garthwaite, C., R. Sachs, and A. Stern (2021). Which markets (don't) drive pharmaceutical innovation? Evidence from U.S. Medicaid expansions.

Genesove, D. and W. P. Mullin (2001). Rules, communication, and collusion: Narrative evidence from the sugar institute case. *American Economic Review 91*(3), 379–398.

Grabowski, H. and J. Vernon (1992). Brand loyalty, entry, and price competition in pharmaceuticals after the 1984 drug act. *Journal of Law and Economics 35*, 331–350.

Harrington, J. (2004). Post-cartel pricing during litigation. *Journal of Industrial Economics 52*, 517–533.

Hüschelrath, K., K. Müller, and T. Veith (2013). Concrete shoes for competition: The effect of the german cement cartel on market price. *Journal of Competition Law and Economics 9*(1), 97–123.

Igami, M. and T. Sugaya (2021). Measuring the incentive to collude: The vitamin cartels, 1990-1999. Forthcoming, *Review of Economic Studies*.

IMS (2016). Price declines after branded medicines lose exclusivity in the u.s. Technical report, IMS Institute for Healthcare Informatics, Parsippany, NJ.

Kyle, M. (2007). Pharmaceutical price controls and entry strategies. *Review of Economics and Statistics 89*, 88–99.

Maini, L. and F. Pammolli (2021). Reference pricing as a deterrent to entry: Evidence from the European pharmaceutical market.

Miller, N., M. Remer, and M. Weinberg (2020). The canned tuna cartel.

Miller, N. and M. Weinberg (2017). Understanding the price effects of the Miller/Coors joint venture. *Econometrica 85*, 1763–1791.

OECD (2015). Health at a glance 2015. Technical report, OECD Indicators, OECD Publishing, Paris.

Pesendorfer, M. (2000, Jul.). A study of collusion in first-price auctions. *Review of Economic Studies 67*(3), 381–411.

Reiffen, D. and M. Ward (2005). Generic drug industry dynamics. *Review of Economics and Statistics 87*, 37–49.

Roller, L.-H. and F. Steen (2006). On the workings of a cartel: Evidence from the Norwegian cement industry. *American Economic Review 96*(1), 321–338.

Scott-Morton, F. (1999). Entry decisions in the generic pharmaceutical industry. *RAND Journal of Economics 30*, 421–440.

Scott-Morton, F. (2000). Barriers to entry, brand advertising, and generic entry in the US pharmaceutical industry. *International Journal of Industrial Organization 18*, 1085–1104.

Scott-Morton, F. and M. Kyle (2012). Markets for pharmaceutical products. In T. M. Mark Pauly and P. P. Barros (Eds.), *Handbook of Health Economics*. Elsevier.

Tkachenko, A. (2020). Competitive effect of vertical integration in auctions.

A Appendix

A.1 The drugs

Doxycycline monohydrate is an oral tetracycline antibiotic used to treat numerous types of bacterial infections such as acne, rosacea, urinary tract infections, sexually transmitted diseases and even malaria and Lyme disease. Prescriptions of antibiotics in the US totalled an average 270 million yearly between 2011 and 2018, equivalent to more than 800 prescriptions per 1000 persons each year (CDC (2018)). Despite their widespread use and their vital role in treating infections, only a few new molecules were approved in the past two decades. This represents a major threat to public health systems, as it limits the potential substitution available to clinicians, especially in light of the growing antimicrobial resistance. Also, the market for generic antibiotics is highly concentrated and dominated by few large firms. Limited generic competition is also linked to shortages: between 2001 and 2013, there were 148 shortages of antibiotics in the US (Alpern, Zhang, Stauffer, and Kesselheim (2017)), some of which affecting direct competitors of doxy mono, as reported in the court documents.

Meprobamate is an anxiolytic used to treat insomnia, tension and short-term anxiety. It is a carbamate derivate with hypnotic, anti-anxiety, sedative, anticonvulsant and some indirect muscle relaxant properties. It works by slowing activity in the brain to allow for relaxation. meprobamate was introduced into medical use in the 1950s and quickly became one of the most popular psychotropic agents and was approved to treat anxiety or symptoms of anxiety. However, beginning in the 1960s, it was largely replaced in the treatment of anxiety by benzodiazepines, as they were found to be more effective. Its use today is mostly to treat the short-term symptoms of anxiety and insomnia, but its prescription is constrained by its potential for abuse, shared by many anxiolytic drugs.

Nystatin is an antifungal medication used to treat or prevent Candida infections of the skin including diaper rash, oral thrush, esophageal candidiasis, and vaginal yeast infections. It is sold under many different forms, including solution and topical preparation. Oral nystatin is often used as a preventive treatment in people who are at risk for fungal infections, such as AIDS patients or oncological patients under chemotherapy. It is safe and effective both in elderly patients (for example to treat oral candidiasis in elderly people who wear dentures) and in infants, even those with very low birth-weight to prevent invasive fungal infections. Discovered in 1950s as the first polyene macrolide antifungal, nystatin is on the World Health Organization's List of Essential Medicines.

Paromomycin (also known as aminosidine) is a nonabsorbable aminoglycoside antibiotic that is active against several types of bacteria and is used to treat a number of parasitic infections including amebiasis, giardiasis, leishmaniasis, and tapeworm infection. It is available as an oral medication, a topical preparation to be applied to the skin, or a solution to be injected into a muscle.

Paromomycin came into medical use in the 1960s and is on the World Health Organization's List of Essential Medicines.

Theophylline is used to treat various respiratory conditions that obstruct the airways, such as asthma and chronic obstructive pulmonary disease (COPD). It is a bronchodilator, it works by relaxing the smooth muscles located in the bronchial airways and pulmonary blood vessels. It also reduces the airway responsiveness to histamine, adenosine, methacholine, and allergens. Theophylline can be used as an oral agent (rapid or slow-release tablets, solution, syrup, or capsule) or in a more soluble form such as aminophylline (an ethylenediamine salt of theophylline) that can be dosed orally or intravenously. Intravenous use is for acute bronchospasm, while oral forms can be taken more consistently. It is prescribed as a second-line drug when other treatments have proven ineffective or if cost is a factor.

Verapamil is a calcium channel blocker medication used for the treatment of high blood pressure, angina (chest pain from not enough blood flow to the heart), and supraventricular tachycardia. It may also be used for the prevention of migraines and cluster headaches. Calcium channel blockers work by preventing calcium from entering the cells of the heart and arteries: as calcium causes the heart and arteries to contract, by blocking calcium, calcium channel blockers allow blood vessels to relax and open. There are three main classes of calcium channel blocker drugs, based on their chemical structure and activity: verapamil is a phenylalkylamine, which works mostly on the heart muscle. Verapamil was approved for medical use in the United States in 1981 and is on the World Health Organization's List of Essential Medicines. It is available as an oral drug or a solution to be administered intravenously.

A.2 Control selection

A.2.1 Doxycycline Monohydrate

To define the control group satisfying the three conditions explained above, we identify all antibiotics that share the same therapeutic subgroup ATC2 as doxy mono (J01), but belong to different pharmaceutical subgroups ATC3. While our definition of the market is at the ATC4 level, the class of tetracyclines J01A only contains one ATC4, J01AA, which includes doxy mono and several substitutes. Hence, we explore controls in ATC4 markets of adjacent ATC3 classes. We exclude those that are not approved by the FDA, are sold only as combination products, are not available in oral forms, or that enter during the period (criterion C1), that are listed in any complaint (criterion C2) or that belong to ATC4 classes with at least one listed drug (criterion C3). The final control group for doxy mono includes three drugs: methenamine hippurate (J01XX), sulfadiazine (J01EC) and trimethoprim (J01EA). These drugs are approved for different indications and have different mechanisms of action from doxy mono. Doxy mono is a broad-spectrum antibiotic commonly used to treat several conditions, from bacterial pneumonia, urinary tract infections and acne, to certain

sexually transmitted infections. The drugs in the control group are not direct substitutes: either they treat different conditions or similar ones (like urinary tract infections) but caused by different bacteria. For example, methenamine is indicated only when long term therapy is deemed necessary and after the infection is eliminated by other antimicrobial drugs. Figure 3 illustrates the process of control selection for doxy mono.

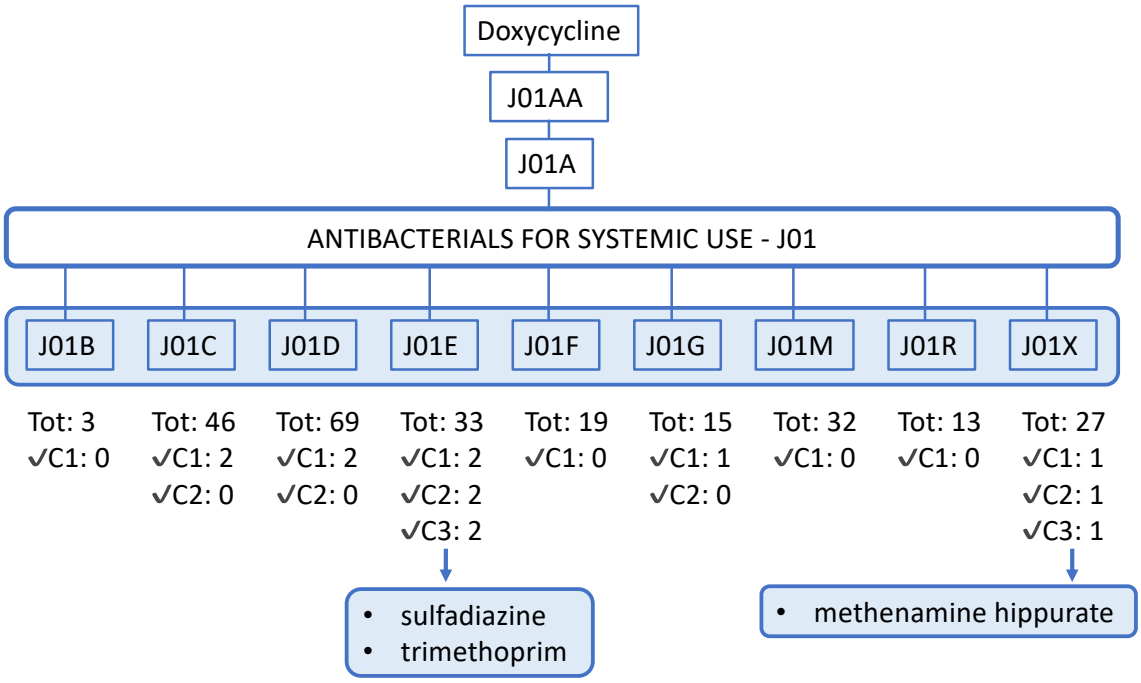


Figure 3: Control selection process for doxycycline monohydrate.
The picture shows the sequential selection of control drugs for the treatment drug doxycycline monohydrate. It displays how many drugs out of the total included in each ATC level 4 market meet each of the three criteria.
Tot. refers to the number of molecules in each ATC4 class, which is our measure of the market.
C1 is criterion 1 of our selection: it is met for all drugs in a class that are: (1) approved by the FDA (i.e. in the Orange Book); (2) off-patent, i.e. available as generics, (3) sold as tablets, capsules, and other oral forms; and (4) available throughout the period to Medicaid enrolees.
C2 reports how many drugs out of those that meet criterion C1 do *not* appear on any complaint or court documents on the alleged cartel.
C3 reports the number of drugs that meet both C1 and C2 that have no competitor (drug in the same ATC4) listed on any complaint or court documents on the alleged cartel.

A.2.2 Meprobamate

To identify the drugs for the control group, we consider all drugs in different ATC4 classes in the same ATC3 as meprobamate (N05B, anxiolytics). Out of the many molecules in the five pharmacological subgroups (N05BA, N05BB, N05BD, N05BE, N05BX), we select those that meet criterion C1. Excluding any ATC4 class with any drug involved in the conspiracy (criteria C2 and C3) leaves only one ATC4 class (N05BA, benzodiazepine derivatives), including 6 molecules (alprazolam, chlordiazepoxide, potassium clorazepate, diazepam, lorazepam, and oxazepam). Figure 4 sketches out this process graphically.

All of the drugs in the control group are benzodiazepine-based, a class of drugs that largely replaced meprobamate over time in the treatment of anxiety. However, they are not direct substitutes of meprobamate for the treatment of anxiety. Due to their potential for physical dependence (higher than for meprobamate) and their limited physical tolerance, benzodiazepines themselves are now regarded as a secondary or an emergency choice for treating anxiety disorders, for which antidepressants are first line options (SSRIs and SNRIs). The use of benzodiazepines in the treatment of many mental disorders is mostly off-label, limited the very first weeks of treatment when multiple first and second line treatments fail, or in severe cases where they should not be used for more than a short period of time (2-4 weeks). Hence, the potential for substitution between meprobamate and benzodiazepines is low.

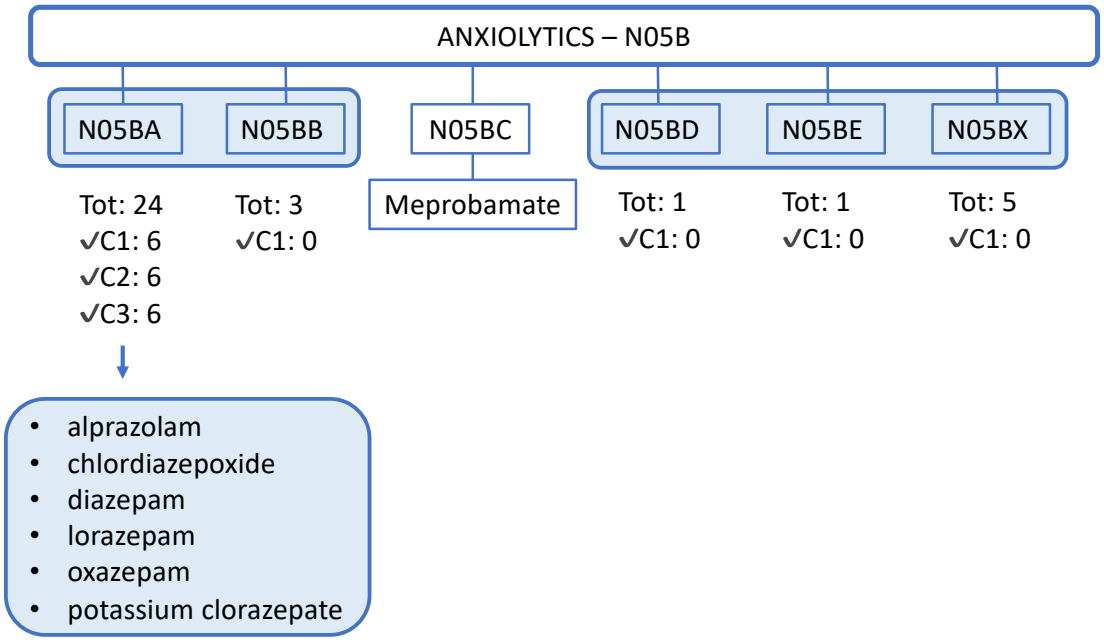


Figure 4: Control selection process for meprobamate.
The picture shows the sequential selection of control drugs for the treatment drug meprobamate. It displays how many drugs out of the total included in each ATC level 4 market meet each of the three criteria.
Tot. refers to the number of molecules in each ATC4 class, which is our measure of the market.
C1 is criterion 1 of our selection: it is met for all drugs in a class that are: (1) approved by the FDA (i.e. in the Orange Book); (2) off-patent, i.e. available as generics, (3) sold as tablets, capsules, and other oral forms; and (4) available throughout the period to Medicaid enrolees.
C2 reports how many drugs out of those that meet criterion C1 do *not* appear on any complaint or court documents on the alleged cartel.
C3 reports the number of drugs that meet both C1 and C2 that have no competitor (drug in the same ATC4) listed on any complaint or court documents on the alleged cartel.

A.2.3 Nystatin and paromomycin

Nystatin and paromomycin belong to the same class of antibiotics A07AA, hence they share the same control drugs. To identify them, we explore all molecules in adjacent ATC4 classes (other types of intestinal anti-infectives, classes A07A-B, -D and -X). However, no drug satisfies all three criteria, as at least one molecule in each of these classes is mentioned in one of the complaints on the alleged cartel, violating criteria C2 or C3. We hence move one level up the ATC classification and expand the search to all ATC4 markets in adjacent ATC3 classes (A07-B, -C, -D, -E, -F, X). However, each class has at least one drug cited in the complaint, making it ineligible due to

violation of criterion C3.

Rather than moving to the ATC2 level and risking losing the comparability of these drugs to the treatment molecules, we exploit the fact that other antibiotics are present in ATC class J01, antibacterials for systemic use. While belonging to a different ATC category, drugs in J01 meet the first criterion, i.e. they are not direct competitors of nystatin and paromomycin, while being highly comparable. Class A07A gathers antibiotics that are specifically indicated for infections of the intestines, while molecules in J01 are antibiotics that treat a broader set of conditions. As we have already identified molecules that satisfy the three criteria from classes J01-B, -C, -D, -E, -F, -G, -M, -R, -X in the control selection for doxycycline monohydrate, we use the same set of controls for nystatin and paromomycin: methenamine hippurate (J01XX), sulfadiazine (J01EC) and trimethoprim (J01EA).

Figure 5 sketches out this process graphically.

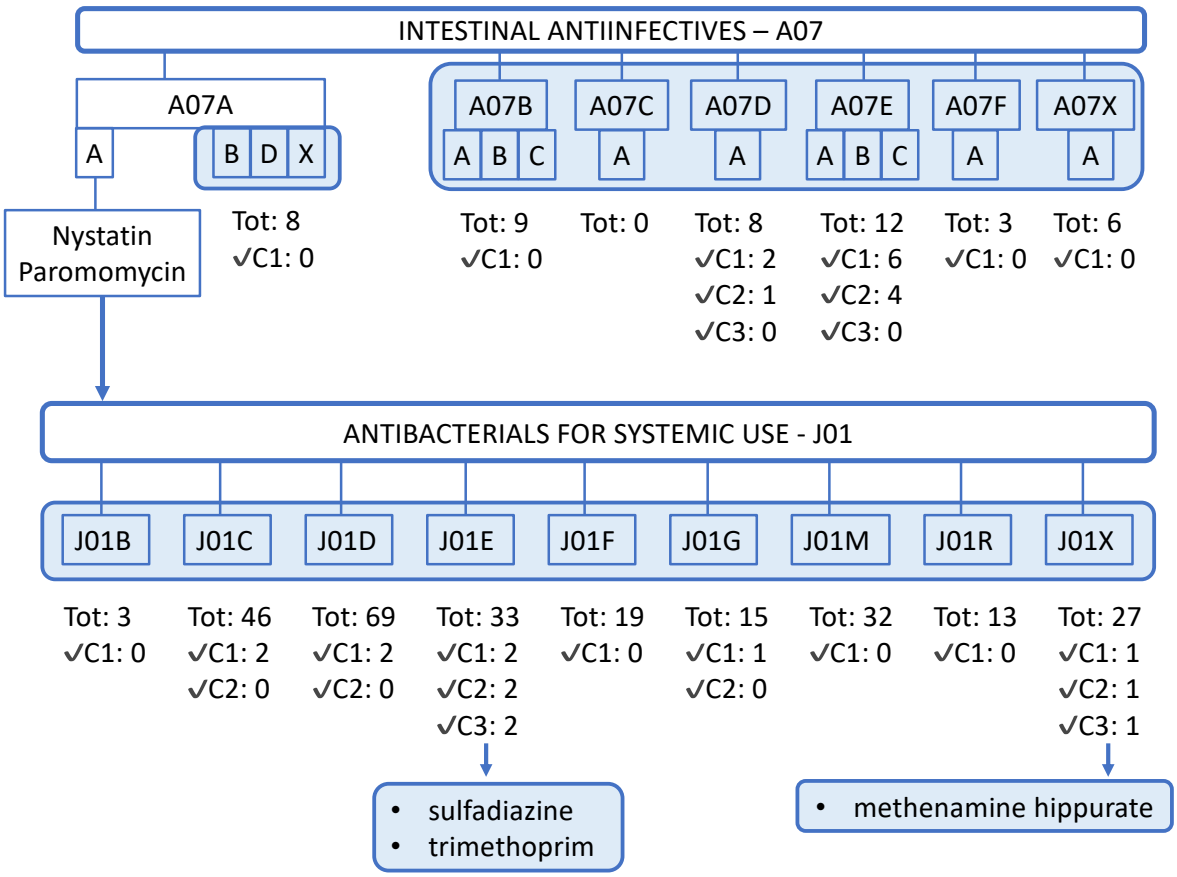


Figure 5: Control selection process for nystatin and paromomycin.
The picture shows the sequential selection of control drugs for the two treatment drugs nystatin and paromomycin. It displays how many drugs out of the total included in each ATC level 4 market meet each of the three criteria.
Tot. refers to the number of molecules in each ATC4 class, which is our measure of the market.
C1 is criterion 1 of our selection: it is met for all drugs in a class that are: (1) approved by the FDA (i.e. in the Orange Book); (2) off-patent, i.e. available as generics, (3) sold as tablets, capsules, and other oral forms; and (4) available throughout the period to Medicaid enrolees.
C2 reports how many drugs out of those that meet criterion C1 do *not* appear on any complaint or court documents on the alleged cartel.
C3 reports the number of drugs that meet both C1 and C2 that have no competitor (drug in the same ATC4) listed on any complaint or court documents on the alleged cartel.

A.2.4 Theophylline

Theophylline is classified in ATC4 R03DA, which includes xanthines. Following our approach, control candidates come from other systemic drugs for obstructive airway diseases from classes

R03D-C, and -X, excluding combinations with adrenergics in class R03D-B. However, out of the two drugs that meet criterion C1 in class R03DC, one is under investigation in one of the most recent complaints (montelukast), violating criterion C2 and making its competitor ineligible due to violation of criterion C3. As we move one level up, to ATC4 in adjacent ATC3 classes, only one drug from R03C meets the first criterion C1: molecules in R03A and R03B do not, as they are inhalants, hence not comparable to oral drugs such as theophylline. However, terbutaline (R03CC) is mentioned in recent complaints, violating criterion C2. We move further up in the ATC classification and expand our search to all ATC4 in other ATC2 from class R. We exclude drugs not in oral forms, which rules out R01 and R02 entirely, antihistamines in class R06 as they are not comparable products, as well as combination products (present in several classes). Eventually, we are able to identify only one control drug for theophylline, guaifenesin, an oral expectorant intended to help cough out phlegm from the airways from class R05CA: this is the only drug in its class that meets all three criteria.

Figure 6 sketches out this process graphically.

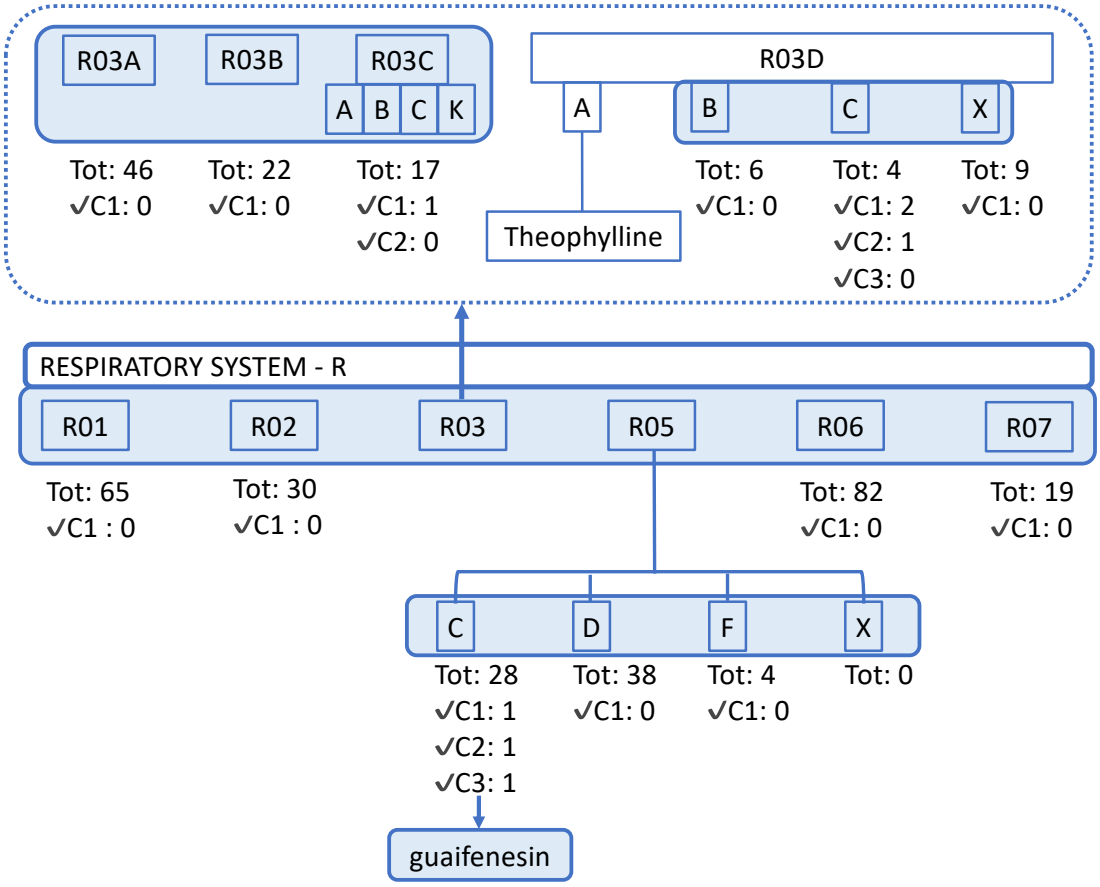


Figure 6: Control selection process for theophylline.
The picture shows the sequential selection of control drugs for the treatment drug theophylline. It displays how many drugs out of the total included in each ATC level 4 market meet each of the three criteria.
Tot. refers to the number of molecules in each ATC4 class, which is our measure of the market.
C1 is criterion 1 of our selection: it is met for all drugs in a class that are: (1) approved by the FDA (i.e. in the Orange Book); (2) off-patent, i.e. available as generics, (3) sold as tablets, capsules, and other oral forms; and (4) available throughout the period to Medicaid enrolees.
C2 reports how many drugs out of those that meet criterion C1 do *not* appear on any complaint or court documents on the alleged cartel.
C3 reports the number of drugs that meet both C1 and C2 that have no competitor (drug in the same ATC4) listed on any complaint or court documents on the alleged cartel.

A.2.5 Verapamil

Verapamil is a selective calcium channel blocker with direct cardiac effect classified under C08DA, phenylalkylamine derivatives. The only drug in the adjacent ATC4 (C08DB), diltiazem, meets

criterion C1 but is listed in the second complaint and hence violates criterion C2. As we expand our search to ATC4 in adjacent ATC3 classes, only few drugs meet criterion C1, all from class C08C, while no drug from C08G, which only includes combination products, nor C08E, which has no off-patent molecules. However, C08CA has one drug listed (nimodipine), invalidating the use of the class due to violation of criteria C2 and C3. We next consider drugs in ATC4 in adjacent ATC2 classes: no drug meets criterion C1 from C07 (beta blocking agents), C01 (cardiac therapy) and C02 (antihypertensives), as they are often used as substitutes for calcium channel blockers in certain patients. Similarly, C04 (peripheral vasodilators) and C05 (vasoprotectives) are not approved in the US or only available as minor OTC products, as they are based on plants, which limits their comparability to calcium channel blockers. We are left with ATC4 markets from three ATC2 classes: C03 (diuretics), C09 (agents acting on the renin-angiotensin system), and C10 (lipid-modifying agents). In this group, no drugs from ATC4 in C09B and C09D meet criterion C1, as they only include combination products. From those that meet C1 in C09A (ACE inhibitors) and C09C (Angiotensin II receptor blockers, plain), none meets criteria C2 or C3, as several drugs are listed in a complaint (enalapril, benzapril, fosinopril and moexipril in C09A and valsartan and irbesartan from C09C). Similarly, both some statins and fenofibrates (different subclasses of C10A) are listed in a complaint, making this class ineligible due to violation of criteria C2 and C3. Among the remaining classes in C03, several do not meet criterion C1 as they include only combination products or have no generic available (such as C03X). Drugs from ATC4 in C03A and C03B that meet criterion C1 do not meet criteria C2 and C3 (fosinopril, bumetanide, eplerenone and amiloride are all listed in the court documents). We are left with two drugs from C03BA, indapamide and metolazone, which meet the three criteria.

Figure 7 sketches out this process graphically.

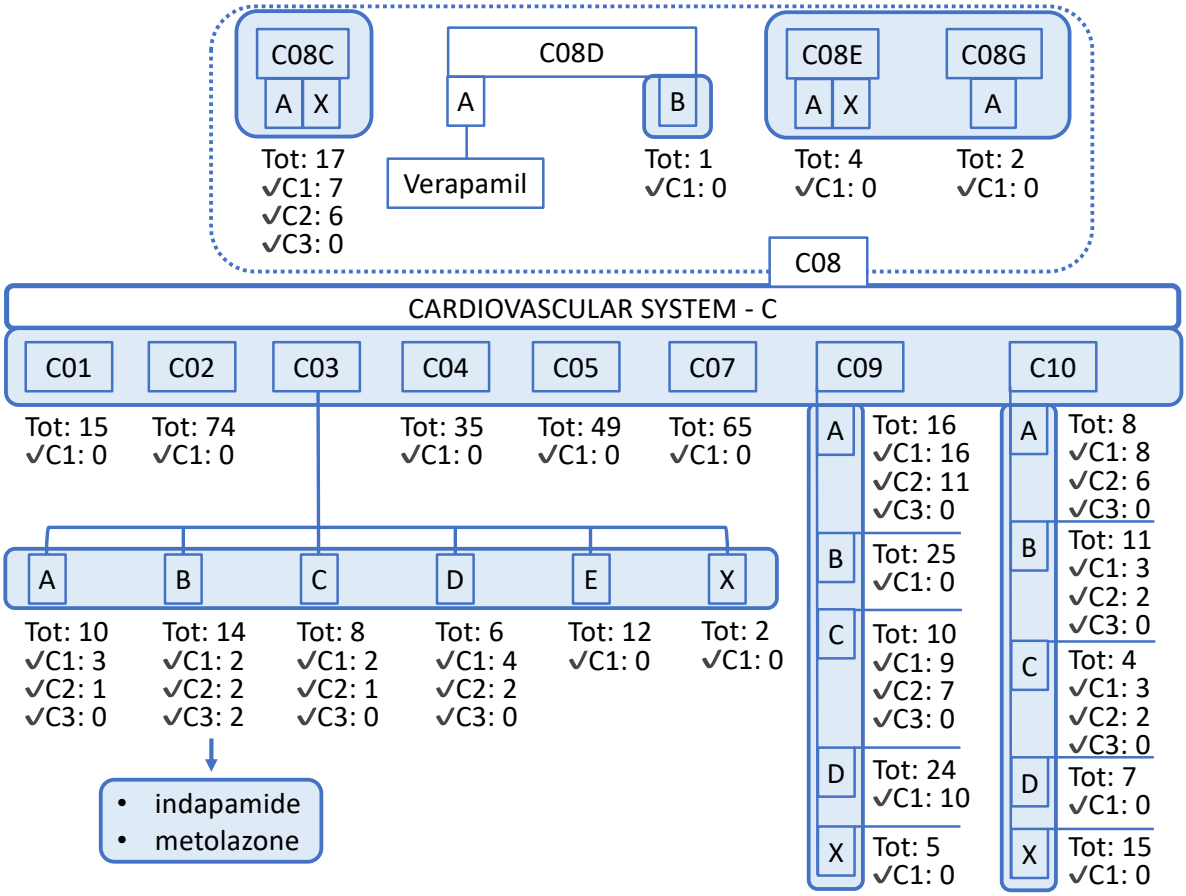


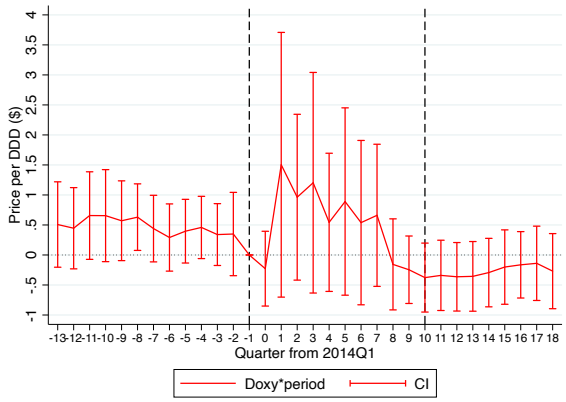
Figure 7: Control selection process for verapamil.
The picture shows the sequential selection of control drugs for the treatment drug verapamil. It displays how many drugs out of the total included in each ATC level 4 market meet each of the three criteria.
Tot. refers to the number of molecules in each ATC4 class, which is our measure of the market.
C1 is criterion 1 of our selection: it is met for all drugs in a class that are: (1) approved by the FDA (i.e. in the Orange Book); (2) off-patent, i.e. available as generics, (3) sold as tablets, capsules, and other oral forms; and (4) available throughout the period to Medicaid enrolees.
C2 reports how many drugs out of those that meet criterion C1 do *not* appear on any complaint or court documents on the alleged cartel.
C3 reports the number of drugs that meet both C1 and C2 that have no competitor (drug in the same ATC4) listed on any complaint or court documents on the alleged cartel.

A.3 Parallel Trends

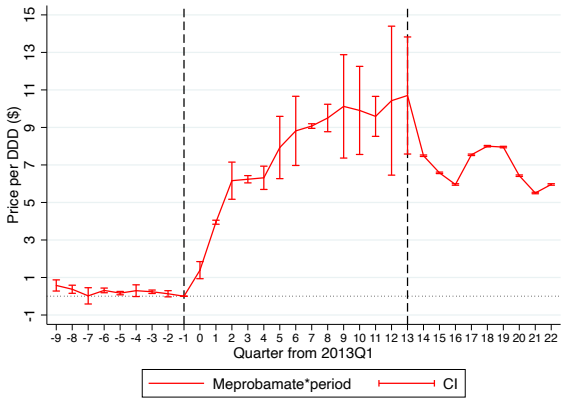
Table 10: Parallel trends

	(1) Doxycycline	(2) Meprobamate	(3) Nystatin	(4) Paromomycin	(5) Theophylline	(6) Verapamil
drug_time	-0.0330**	-0.0450***	-0.00645	-0.266	-0.00112	-0.00290
	(0.0146)	(0.0130)	(0.0154)	(0.217)	(0.00436)	(0.0123)
Observations	148	269	121	107	94	257
R-squared	0.860	0.968	0.912	0.995	0.107	0.441
Time FE	YES	YES	YES	YES	YES	YES
Product FE	YES	YES	YES	YES	YES	YES
Collusion starts	2014Q2	2013Q2	2014Q2	2014Q2	2013Q1	2014Q2
Price pre	1.909	4.572	2.399	46.09	0.350	0.450

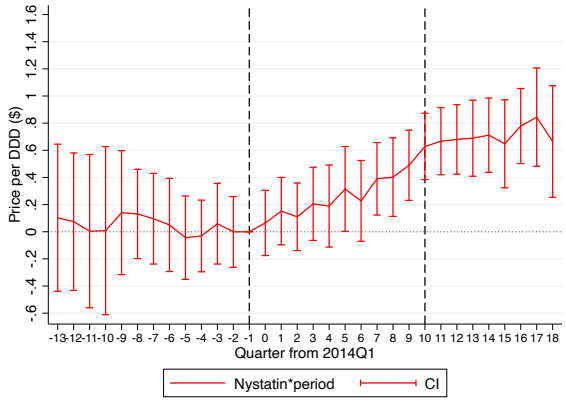
Robust standard errors in parentheses. Significance at 10% (*), 5% (**), and 1% (***).



(a) Doxycycline

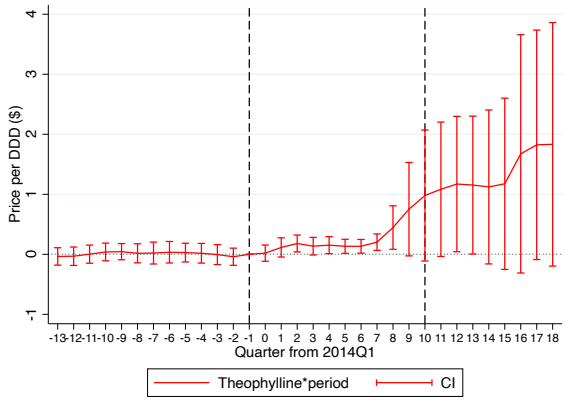


(b) Meprobamate

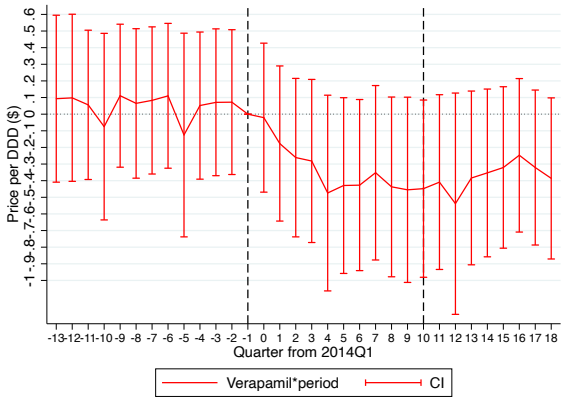


(c) Nystatin

(d) Paromomycin



(e) Theophylline



(f) Verapamil

Figure 8: Event study for treatment drugs and their respective control groups

A.4 Overcharge by firm

Table 11: Overcharge by firm, meprobamate

	(1) Heritage	(2) Dr. Reddy's
Meprobamate × collusion	7.554***	7.588***
	(0.723)	(0.729)
Observations	645	645
R-squared	0.922	0.920
Time FE	YES	YES
Product FE	YES	YES
Collusion starts	2013Q2	2013Q2
Period	no post	no post
mepro price pre	4.627	4.520

Robust standard error in parentheses.
Significance at 10% (*), 5% (**), and 1% (***).

Table 12: Overcharge by firm, nystatin

	(1) Heritage	(2) Teva	(3) Sun
Nystatin × collusion	0.226***	0.269***	0.169**
	(0.0705)	(0.0699)	(0.0680)
Observations	139	183	183
R-squared	0.950	0.888	0.887
Time FE	YES	YES	YES
Product FE	YES	YES	YES
Collusion starts	2014Q2	2014Q2	2014Q2
Period	no post	no post	no post
nystatin price pre	1.523	1.535	1.572

Robust standard error in parentheses.
Significance at 10% (*), 5% (**), and 1% (***).

Table 13: Overcharge by firm, theophylline

	(1) Heritage	(2) Teva
Theophylline × collusion	0.162***	0.148***
	(0.0359)	(0.0305)
Observations	155	158
R-squared	0.177	0.163
Time FE	YES	YES
Product FE	YES	YES
Collusion starts	2014Q2	2014Q2
Period	no post	no post
theophylline price pre	0.337	0.360

Robust standard error in parentheses.
Significance at 10% (*), 5% (**), and 1% (***).

A.5 Damages by firm

Table 14: Damages by firm, meprobamate

	Units (DDD)	Overcharge $	Damages $
All	124,601	7.57	943,128
Heritage	80,236	7.55	606,102
Dr Reddy's	44,365	7.59	336,633

Table 15: Damages by firm, nystatin

	Units (DDD)	Overcharge $	Damages $
All	859,976	.21	182,256
Heritage	246,904	.23	55,774
Sun	189,468	.17	32,080
Teva	423,604	.27	114,121

Table 16: Damages by firm, theophylline

	Units (DDD)	Overcharge $	Damages $
All	5,212,805	.16	809,108
Heritage	1,896,545	.16	306,325
Teva	3,316,260	.15	490,892