

INVESTIGATING AND CALCULATING DAMAGES DUE TO COLLUSION IN THE
U.S GENERIC DRUG INDUSTRY

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1.Introduction

Today's generic drug industry in the United States of America has its modern origins that can be traced all the way back to 1984, when the Hatch-Waxman Act was passed. Before its introduction, generic drugs played a small role in the American Healthcare system, as generic drugs only accounted for 13% of the prescription drug market share, and 35% of top-selling branded drugs with expired patents had generic competition by 1983.¹ The relatively few generic drug products in the United States was partly due to previous acts that made the process of gaining approval to enter the market extremely costly and lengthy. "With the exception of antibiotics, generic drugs were approved via a paper NDA process which required filing scientific literature to support the safety and efficacy of a generic drug, since the FDA regarded the safety and efficacy data filed by the innovator as proprietary."² To make things worse, for the majority of branded drug products, the innovator companies did not publish sufficient scientific literature to enable justification of safety and efficacy via the paper NDA route for the generic competition.³ Therefore, the Hatch-Waxman Act of 1984 tried to rectify this issue by balancing two contradictory interests, increasing competition between brand and generic drugs to hopefully lower drug prices and at the same time encourage drug innovation. When it came to promoting drug innovation, the act instituted patent extension options to brand drug manufacturers since branded drug manufacturers tended to lose much of their revenue when generic drug competition entered the market. The

¹ Gareth Boehm et al, "Development of the Generic Drug Industry in the US after the Hatch-Waxman Act of 1984," *Acta Pharmaceutica Sinica B*(2013):2-15 , doi:10.1016/j.apsb.2013.07.004,

² Gareth Boehm et al, "Development of the Generic Drug Industry in the US after the Hatch-Waxman Act of 1984," page 2.

³ Gareth Boehm et al, "Development of the Generic Drug Industry in the US after the Hatch-Waxman Act of 1984," page 2.

patent granted the innovator a period of exclusive rights to sell and market the drug, where the innovator with no competition could set high prices. To promote price competition, the Act created a new route of approval which did not rely on the generic manufacturer proving the safety and efficacy of its product. Instead, “Generic manufacturers would submit an Abbreviated New Drug Application (ANDA) which allowed approval of the generic product as an equivalent product to an existing brand on the basis of bio-equivalence to the original brand name drug.”⁴ Furthermore, once the patent expired for a brand name drug the first generic manufacturer to have its ANDA approved was granted a 180-day marketing exclusivity period, causing the sole generic manufacturer to experience high price margins and profits. Once the 180-day period had been completed, other generic manufacturers were allowed to enter.⁵ This gave generic manufacturers the incentive to file their ANDA’s as quickly as possible, as without the 180-day market exclusivity, the market would be characterized with fierce competition and low margins. The Act also introduced requirements that the FDA publicly make available a list of approved drug products with therapeutic equivalence to their brand name substitute referred to as the “Orange-book” to help health care providers have the ability to substitute between brand products and their generic equivalent.⁶ Overall, the act was successful in both of its goals, as drug innovation has continued and prices have decreased drastically. For example, an independent study by IQVIA found that generic products that entered the market between “2002 and 2014 reduced the price of medicines

⁴ Gareth Boehm et al, “Development of the Generic Drug Industry in the US after the Hatch-Waxman Act of 1984,” page 2.

⁵ Gareth Boehm et al, “Development of the Generic Drug Industry in the US after the Hatch-Waxman Act of 1984,” page 3.

⁶ Gareth Boehm et al, “Development of the Generic Drug Industry in the US after the Hatch-Waxman Act of 1984,” page 2.

by 51% in the first year and 57% in the second year following loss of exclusivity. Prices of oral medicines were reduced further, by 66% in the first year and 74% in the second year.”⁷ This price decrease reached up to 80% for generic oral products from their pre-expiry brand prices after around five years.⁸ With the significant lower prices, generic drugs have by 2012 accounted for around 84% of all dispensed prescriptions in the USA compared to 13% before the Hatch-Waxman Act was passed.⁹

However, over the previous few years, the Generic Drug Industry which some call the shining light of the American healthcare system, has gotten lots of negative attention due to large price spikes for many of its products. For example, in 2013-2014 alone:

- Albuterol sulphate, used to treat Asthma and other lung prescriptions increased in price, from \$11 to \$434 for a bottle of 100 2-mg tablets.¹⁰
- Doxycycline Hyclate, an antibiotic used to treat various infections, increased in price from \$20 to \$1849 for a bottle of 50 100mg tablets¹¹
- Glycopyrrolate, used to prevent irregular heartbeats during surgery increased in price from \$65 to \$1277 for a box of 10 0.2mg/L, 20-mL vials.¹²

⁷ “Price Declines after branded medicines Lose Exclusivity in the U.S,” January 2016, <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/price-declines-after-branded-medicines-lose-exclusivity-in-the-us.pdf>

⁸ “Price Declines after branded medicines Lose Exclusivity in the U.S,” January 2016, <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/price-declines-after-branded-medicines-lose-exclusivity-in-the-us.pdf>

⁹ Gareth Boehm et al, “Development of the Generic Drug Industry in the US after the Hatch-Waxman Act of 1984,” page 2.

¹⁰ 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>

¹¹ Stephen Barlas, “Generic Prices Take Flight,” page 843

¹² Stephen Barlas, “Generic Prices Take Flight,” page 843

The price spikes experienced in the market were however more widespread than the anecdotal examples above. A recent paper by Conti et al (2018),¹³ found that large price hikes in the generic drug market were more common than previously thought. The authors studied which drugs would be affected by new price gouging legislation by using data from the 2013-2014 period on quantities and wholesale dollar sales of all prescription drugs approved for sale. Their sample included 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 used 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 experienced annual price increases of 15% and 20%. The authors' results found that the mean adjusted price increase among all generic products was 38%. Going into more detail, 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 total products exceeded the 20% threshold, with mean inflation-adjusted price increases of 162% and 191% and mean prices of \$30.72 and \$22.63.¹⁴ Some possible explanations that have been cited is that the large increases in generic drug prices are due to the fact that a large proportion of the

¹³ Conti et al, Generic prescription drug price increases: which products will be affected by proposed anti-gouging legislation?", *Journal of Pharmaceutical policy and Practice* 11, no. 29 (2018): 1-10, accessed July 20th 2019, Doi: [10.1186/s40545-018-0156-8](https://doi.org/10.1186/s40545-018-0156-8).

¹⁴ Conti et al, Generic prescription drug price increases: which products will be affected by proposed anti-gouging legislation?", page 4-5.

generic drug industry over the past few decades has gradually fallen into the hands of a few large manufacturers. This is partly due to the fact that major purchasers of generic drugs prefer to deal with only a few well known and established manufacturers. This had the effect that by 2009, nearly 50% of the generic drug supply in the United States was produced by the top four companies in the industry.¹⁵ The consequences of this phenomena were that the supply of many different types of drugs could face severe shortages if there were production problems experienced by one firm or more. However, the outrage caused by the price spikes evolved into political pressure and during July of 2014, the state of Connecticut began an antitrust investigation into the Generic Drug Industry. The antitrust investigation, which to this day is an ongoing multidistrict litigation (MDL), announced its first charges on December 14th 2016, charging the former CEO of Heritage Pharmaceuticals and also the former president of the same company, where both were said to have conspired to fix prices, rig bids and allocate customers for an antibiotic Doxycycline Hyclate and also for a medicine used to treat diabetes called glyburide. ¹⁶ The very next day, on December 15th, 2016, state attorneys generals from 20 states filed a civil lawsuit against six pharmaceutical companies alleging that they colluded to increase prices over the two already mentioned drugs. The former CEO and former President of Heritage Pharmaceuticals plead guilty to their charges and both agreed to cooperate in the antitrust probe. Although the two were senior executives,

¹⁵ Garth Boehm et al, "Development of the generic drug industry in the US after the Hatch-Waxman Act of 1984" page 9

¹⁶ "Former Top Generic Pharmaceutical Executives Charged with Price-Fixing Bid-Rigging and Customer Allocation Conspiracies," Press Release from *The United States Department of Justice*, last modified March 9th 2017, <https://www.justice.gov/opa/pr/former-top-generic-pharmaceutical-executives-charged-price-fixing-bid-rigging-and-customer>

they were considered to be lower on the totem pole in the collusive ring. The investigation expanded in October of 2017 with a first complaint lead by Attorney General George Jepson, which increased the number of manufacturers under investigation from six to 18 and the number of drugs at issue in the litigation from 2 to 15. The case was also transferred at this time to the Eastern District of Pennsylvania. On May 12th, 2019, a second complaint lead by Attorney General William Tong increased the number of generic manufacturers to 20 and the number of drugs said to be affected by collusive behavior to over 100, and also included 15 individual senior executive defendants.

The on-going investigation, said by some as possibly the biggest anti-trust case in United States history has greatly harmed American consumers and to a greater extent the economy of the United States, as the collusive behavior of many of the top U.S pharmaceutical companies affected distributors, pharmacies, hospitals, and every tier of the economy, all the way down to the average citizen. The objective of this paper will therefore be to try to quantify and calculate the impact collusive behavior had on two generic pharmaceutical drug products listed in the court documents, and also try to estimate the damages of said collusive behavior by using Medicaid-State drug Utilization data and by using a difference-in-difference analysis. The two particular drugs that will be studied in this paper are Doxycycline Monohydrate 100mg oral tablets and Meprobamate 200mg oral tablets. Currently there are well over 100 generic products being investigated, so for the sake of brevity, this paper will act as a preliminary study into this ongoing topic. The paper will be split mainly into two main sections, with the first half summarizing the court documents on how certain generic pharmaceutical manufacturers communicated to one another and how they illegally agreed to substantially raise prices, allocate markets and rig bids so that all involved could benefit.

The second part of the paper involves quantifying the effect collusion had on the prices of Doxycycline Monohydrate 100mg oral tablets and Meprobamate 200mg oral tablets and also calculate the damages collusion had on the Medicaid program and to American citizens. The main empirical tests used in this paper do this by comparing the changes in prices of the generic drugs said to be affected by collusion with changes in pricing of a chosen alternative generic drug used as a control. In other words, this empirical testing involves using a difference-in-difference analysis to compare the changes in the pricing of the collusive drugs named above to prices of the control drugs. The difference-in-difference analysis has the benefit of addressing possible trends in drug pricing that could influence more than one drug market, something that an alternative analysis like the “Before and After approach” does not control for and also controls for permanent differences between the drug prices (something the Yardstick Approach fails to do). In order to run the analysis, data on prices and quantity supplied were collected from Medicaid’s State Drug Utilization data sets, where a sample period ranging from 2011 to 2018 was used.

The results in this paper show that in the case of Doxycycline Monohydrate, collusion between manufacturers if looking at a firm-by-firm level; raised the price-per-unit (the price of one oral tablet) significantly; and resulted in damages equating to around \$4,739,802.83. Alternatively, collusive behavior between manufacturers of the generic drug meprobamate was estimated to have increased the price for one tablet by approximately \$1.81 dollars and costing the consumer an additional overcharge of \$350,092.01. Overall, these results reflect the anecdotal evidence and reports written before any investigations began into the generic pharmaceutical industry. It must be said however that this essay’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 obtained from Medicaid's State-Drug Utilization datasets. 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.

2. Related Literature

This paper is related to a broad empirical literature on collusion and calculating the changes in price due to illegal activity by using a difference-in-difference model. For example, Laitenberger and Smuda (2015) investigated the damages of a laundry detergent cartel in Germany that took place between 2002 to 2005.¹⁷ Using panel data consisting of over 16000 German customer surveys, the authors calculated the percentage overcharge of collusion by categorizing the detergents in question into three categories: cartel brands, competitive private brands and competitive manufacturer brands, and then use a before and after approach to obtain a reference brand category for detergents (control group). After employing this method, the authors use a difference-in-differences model to calculate the effects collusion had on detergent prices. McCluer and Starr (2013) also uses a difference-in-difference model to analyze the effects of collusive behavior to a case against a clinic who were found to have illegally allocated markets for physician services in Central Wisconsin.¹⁸ Using individual-level claims data, the authors use patients who

¹⁷ Laitenberger et al. "Estimating Consumer Damages in Cartel Cases," *Journal of Competition Law & Economics*, Volume 11, Issue 4, December 2015: 955-973, <https://doi.org/10.1093/joclec/nhv030>

¹⁸ McCluer et al. "Using Difference in Differences to Estimate Damages in Healthcare Antitrust: A Case Study of Marshfield Clinic," *International Journal of the Economics of Business*, Volume 20, Issue 3, July 3rd 2013: 447-469, <https://doi.org/10.1080/13571516.2013.800323>

received more than 50%, 75% or 90% of the value of their payments for their care from the collusive clinic as the treatment group and Wisconsin residents living outside the area of influence who were not patients of Marshfield in the year in question as a control. Hüscherlath et al. (2013) use a difference-in-difference model to calculate the price overcharge of a cartel in the German cement industry. The authors show that the cartel was able to increase prices in a range from 20.3% to 26.5% depending on whether one looks to their “before and after” or difference-in-difference approach.¹⁹

This paper is also related to empirical literature that studies explicit collusion. A paper by Clark et al. (2018) investigates collusive behavior in the greater Montreal construction market, narrowing their attention to the asphalt or road paving section, which was considered a closed market.²⁰ The authors try and estimate the effects of the investigation had on both collusive behavior between already established firms and entry deterrence by collusive firms by using a difference-in-difference model, using the Quebec City construction industry as a control group. The authors find that entry and participation increased following the investigation, increasing the total amount of firms by 50% and a 61% increase in the participation rate in Montreal compared to Quebec City. Another paper, by Clark and Houde (2014) studies the collapse of collusion in Quebec’s retail gasoline market following an investigation.²¹ The authors compare changes in pricing

¹⁹ Hüscherlath et al. “Concrete Shoes for Competition: The Effect of the German Cement Cartel on Market Price,” *Journal of Competition Law & Economics*, Volume 9, Issue 1, March 2013: 97-123, <https://doi.org/10.1093/joclec/nhs036>

²⁰ Clark et al. “Bid Rigging and entry deterrence: Evidence from an anti-collusion investigation in Quebec,” *Journal of Law, Economics and Organization*, Volume 34, Issue 3, August 2018: 301-363, <https://doi.org/10.1093/jleo/ewy011>

²¹ R. Clark et al. “The Effect of Explicit Communication on Pricing: Evidence From the Collapse of a Gasoline Cartel.” *The Journal of Industrial Economics*, 62 (2), (2014): 191-228. <http://dx.doi.org/10.1111/joie.12042>

behavior of stations located in targets cities, with changes in pricing behavior amongst stations throughout the province by using a difference-in-difference approach; to compare stations in the collusive cities to stations in two control groups: competitive markets and cyclical markets. The authors use this method to quantify the impact of explicit communication on pricing by studying the collapse of the four cartels following the announcement of the Competition Bureau's investigation. The authors find that collusion was successful in the four markets targeted in the investigation, and that the primary function of explicit communication was to limit the amount of undercutting during price decreases. This paper is also related to a paper on the same topic by Erutku and Hildebrand (2010) who studied the same topic as Clark and Houde's 2014 paper. Erutku and Hildebrand also use a difference-in-difference model to determine whether the announcement of the anti-trust case the Competition Bureau announced had an effect on the behavior of gas prices in one of the targeted markets.²²

The paper is also related to a growing body of literature focusing on generic pharmaceutical prices. Although not explicitly about generic drug prices and collusion, a paper by Berndt et al. (2017) study's market structures within the U.S generic drug industry, particularly the supply side of the generic drug market and focusing on entry, exit, the extent of supplier competition and two measures of market performance to see how they affect inflation adjusted generic drug prices.²³ The authors use quarterly national data on quantities, wholesale dollar sales and manufacturers and a sample period

²² Erutku et al. "Conspiracy at the Pump," *The Journal of Law & Economics* 53, no. 1 (2010): 223-237, doi:10.1086/597761.

²³ Ernest R. Berndt et al. "The Landscape of US Generic Prescription Drug Markets, 2004-2016," *NBER working paper series, working paper 23640*, doi:10.3386/w23640

that ranges from the fourth quarter of 2004 to the third quarter of 2016. Using many methods including reduced form OLS regressions, the authors find that firstly the median number of manufacturers in each market is two, the mean about four, and also evidence that the number of suppliers is decreasing over the sample period. The authors also find that approximately 40% of markets are supplied by one or two manufacturers, with this share increasing over time and finally that prices of generic drugs are increasing over time and are positively correlated with reduced manufacturer count and increased supplier concentration. Another working paper by Berndt et al. (2019) tries to put into perspective the recent price spikes of certain generic drugs by constructing two chained “Laspeyres” consumer price indexes using data collected for the years 2007-2016.²⁴ The authors find that the chained direct out of pocket CPI for generic drugs declined by approximately 50% and the total CPI by 80% over the sample period; partly due to consumers moving towards coinsurance or a mixed package of coinsurance and copayments .

Outline: The remainder of this paper is the following. Section 3 contains a description of the alleged conspiracy in the Doxycycline Monohydrate and Meprobamate markets. Section 4 contains a description of the Data used in the paper along with descriptive statistics. Section 5 contains the discussion of the empirical approach used to calculate the effect collusion had on pricing of the two mentioned generic drugs. Section 6 contains the estimation and test results and finally Section 7 of the paper concludes.

²⁴ Ernest R. Berndt et al. “The Price to Consumers of Generic Pharmaceuticals: Beyond the Headlines,” *NBER working paper series, working paper 26120*, doi: 10.3386/w26120.

3. The Alleged Conspiracies

3.1: The Alleged Conspiracy of Doxycycline Monohydrate.

The first lawsuit filed against generic pharmaceutical companies occurred in December of 2016 where six firms were charged. An expanded complaint on October 31st, 2017 included Doxycycline Monohydrate to the list of generic products said to be targeted for collusion. Doxycycline monohydrate is an oral tetracycline generic antibiotic used to treat numerous types of bacterial infections such as acne, rosacea, urinary tract infections, sexually transmitted infections and even malaria and Lyme disease. In February 2013, Heritage pharmaceuticals heard from one of their customers that there would be a significant increase in demand for doxycycline monohydrate due to large price increases that had recently occurred for a different form of Doxycycline as well as certain manufacturers experiencing supply problems.²⁵ With this in mind, Heritage decided to increase the price of Doxycycline Monohydrate. In order to do so successfully, Heritage had to contact its competitors, who were at the time: Lannett Company Inc., Par Pharmaceutical Companies Inc., and Mylan Pharmaceuticals Inc. Contact between the competitors began in March of 2013 and on March 13th 2013, members of Heritage discussed with Lannett their desire to increase Doxycycline Monohydrate prices.²⁶ Over a week later the then president of Heritage informed the then CEO that he planned on increasing the price of Doxy Monohydrate by more than four times its current price.²⁷ The four competitors overall kept in contact with one another over the course of 2013.

²⁵ MDL 2724 In Re: Generic Pharmaceuticals Pricing Antitrust Litigation (ED Pa. 2017), https://portal.ct.gov/-/media/AG/Press_Releases/2017/20171031finalgdmconsolidatedamendedcomplaintpublicredactedversion-pdf.pdf?la=en, See paragraph 247.

²⁶ MDL 2724 at para 249

²⁷ MDL 2724 at para 251

For example, when Lannett increased its price for Doxy Mono on June 12th, 2013, the other competitors were made aware.²⁸ Heritage, thought to be the initiator of the collusive agreement, was much slower to raise its price for Doxycycline Monohydrate due to supply problems throughout 2013. As of March 2014, the initiator, Heritage was successful in raising its price to at least one customer.²⁹ However, a much larger across the board price increase for Doxycycline Monohydrate along with other products was planned for later in 2014. On April 22nd, 2014, Heritage held a teleconference, where it was discussed that eighteen different drugs (including Doxycycline Monohydrate) would be targeted for price increases. Members of the sales team who attended the teleconference were given spreadsheets where each of the eighteen drugs were listed along with their competitors and their respective market shares.³⁰ Here, the members of the sales team were instructed to reach out to their contacts at each competitor for the drugs listed on the spreadsheet and attempt to reach an agreement with them over the slated price increases. Members of Heritage's sales team almost immediately began negotiating price increases with their contacts at competitor firms. On April 22nd, 2014, a member of Heritage's sale team held a twenty-nine-minute phone call with a contact at Lannett, during which they agreed to raise prices for Doxycycline Monohydrate.³¹ The next day, Heritage was successful in agreeing with Mylan on increasing the price of Doxycycline Monohydrate and two other drugs.³² On May 9th, 2014, another teleconference was held to discuss the price increases for the 18 targeted drugs, and by

²⁸ MDL 2724 at para 257

²⁹ MDL 2724 at para 266

³⁰ MDL 2724 at para 269

³¹ MDL 2724 at para 275

³² MDL 2724 at para 276

May 15th, a sales team representative was able to reconfirm with their contact at Lannett the intended price increase for Doxycycline Monohydrate.³³ Over the next several weeks, Heritage employees continued to negotiate with their competitors about price increases. “Ultimately, Heritage was able to increase prices on at least nine (9) of the drugs: Acetazolamide ER; Fosi/HCTZ; Glipizide-Metformin; Glyburide; Leflunomide; Nimodipine; Nystatin; and Paromycin.”³⁴ From the court documents, it is not clear if Heritage was ever fully successful in raising its price for Doxycycline Monohydrate. This is further shown in the next sections of the paper, where the data collected suggests that Heritage was in fact not able to agree or did not partake in raising its price for Doxycycline Monohydrate.

3.2 The Alleged Conspiracy for Meprobamate

Along with Doxycycline Monohydrate, Meprobamate, a generic pharmaceutical drug used to treat insomnia, tension and short-term anxiety was added to the October 31st, 2017 expanded complaint. The alleged conspiracy states that communication between the generic manufacturers for this drug began in March 2013. At this time, Heritage Pharmaceuticals and Dr. Reddy’s were the only manufacturers of Meprobamate. On March 21st, 2013, Heritage pharmaceuticals contacted Dr. Reddy’s via email expressing their interest to raise the price of meprobamate significantly³⁵. The next day, the two manufacturers held a conversation, and during the nine-minute conversation, both agreed to raise the price for Meprobamate.³⁶ An email the same day was also sent to confirm the agreement made on the phone. The two manufacturers also at the same time

³³ MDL 2724 at para 287

³⁴ MDL 2724 at para 293

³⁵ MDL 2724 at para 167

³⁶ MDL 2724 at para 169

communicated illegally in order to allocate market share. For example, when a large national wholesaler contacted Heritage requesting them for a bid for Meprobamate, Heritage pharmaceuticals would contact Dr. Reddy's about what they should do.³⁷ Alternatively, on April 2013, Dr Reddy's contacted Heritage stating that they were interested in obtaining more market share for Meprobamate, specifically wanting to gain a contract to supply a large pharmacy chain.³⁸ Due to this agreement of market allocation and also a desire for both firms to raise prices and not compete with one another on price, both Heritage and Dr. Reddy's were able to significantly increase prices successfully "across-the-board" and also almost at the same time. Heritage was said to successfully raise its price for Meprobamate in late April of 2013 and Dr. Reddy's was successful in raising its price for Meprobamate effective May 10th, 2013.³⁹ Due to the fact that the market structure for Meprobamate was a duopoly and that the two firms were successful in their agreements, the price of Meprobamate remained very stable and inflated for the next several years and both firms experienced high profit margins due to the lack of competition.

4. Data and Descriptive Statistics

The dataset used in this paper is Medicaid State Drug Utilization data which is publicly available for free on the "[medicaid.gov](http://www.medicaid.gov)" website. Since the start of the Medicaid Drug Rebate Program, every state in the United States of America reports drug utilization for covered outpatient drugs paid for by state Medicaid agencies. Within this dataset one can simply gather data by state or also can view national totals as well. Data

³⁷ MDL 2724 at para 171

³⁸ MDL 2724 at para 173

³⁹ MDL 2724 at para 177

are collected quarterly and range from 1991 all the way to 2019. The paper studies the price of Doxycycline Monohydrate 100mg tablets and Meprobamate 200mg oral tablets by using National Total datasets. The State Drug Utilization Dataset provides data utilization type, a two-character post abbreviation to know what state the data is collected from, the Labeler code (first segment of the NDC code which identifies the manufacturer, labeler, re-labeler, packager, re-packager or distributor of the drug), product code (second segment of NDC), package size, year, quarter, product name (first 10 characters of a products name), units reimbursed (the number of units based on unit type reimbursed or the number of units dispensed during the quarter/year covered by the state), the number of prescriptions, total amount reimbursed (total amount reimbursed by both Medicaid and non-entities to pharmacies for the 11-digit NDC drug; inclusive of dispensing fees), and also the NDC code for the drug. To collect the necessary data for each generic drug studied, for each national total dataset, the first 10 letters of the product were typed in, then the data were further filtered by entering NDC codes collected from the National Center of Biomedical Ontology for the desired drug and dosage form. The retail price for each drug is calculated by taking the total amount reimbursed by quarter and then dividing that number by the number of units reimbursed. This gives an aggregated per-unit price of the drug in question. To get a per-unit price for each firm, the total amount reimbursed, and units reimbursed for each quarter are additionally filtered by labeler code. Overall, national totals were collected for the years 2011 to 2018, as the collusive periods were said to have started in the first quarter of 2013.

4.1 Doxycycline Monohydrate and Azithromycin

Tables 1 and 2 describe the total amount reimbursed, units reimbursed along with prices over the sample period. Since the dataset used is quarterly, the amounts are summed through the year and the price is averaged throughout the year. Azithromycin is the control drug that will be used in the difference-in-difference estimation for Doxycycline Monohydrate. The reason why it was chosen as a suitable control will be discussed in Section 4.

Table 1: Descriptive Statistics for Doxycycline Monohydrate 100mg Oral Tablets

Year	Units Reimbursed	Total Amount Reimbursed	Price- Per Unit (Tablet)
2011	199,030.35	\$397,275.09	\$2.00
2012	203,318.52	\$390,773.8	\$1.92
2013	507,499.89	\$933,184.84	\$1.84
2014	1,213,906.33	\$2,572,119.65	\$2.12
2015	2,776,771.14	\$5,979,764.92	\$2.15
2016	3,452,981.37	\$4,790,593.12	\$1.39
2017	3,966,791.50	\$2,820,498.99	\$0.71
2018	4,291,431.50	\$2,883,486.19	\$0.67
Total 2011-2013	909,848.76	\$1,721,233.73	\$1.89
Total 2014-2016	7,443,658.84	\$13,342,477.70	\$1.79
Total 2017-2018	8,258,223	\$5,703,985.18	\$0.69

As we can see from **Table 1** over the eight-year sample, the amount of Doxycycline Monohydrate 100mg oral tablets reimbursed has steadily increased. However, the price per tablet follows a different pattern. The price per-unit for a tablet starts off with an average annual price of around \$2.00 and gradually declines over the next two years. However, the price per unit then spikes by 28 cents if compared to the

previous year’s annual average price. The price keeps on increasing until 2016, where it drastically falls by 76 cents. This pattern is consistent to the time period of the alleged conspiracy. The conspiracy is believed to start in the first quarter but does not seem to be successful until 2014 (note: Heritage had difficulty increasing prices due to supply issues throughout 2013). The average annual price decrease in 2016 also coincides with the first charges made in December of 2016.

Table 2: Descriptive Statistics for Azithromycin 250mg Oral Tablets

Year	Units Reimbursed	Total Amount Reimbursed	Price-Per Unit (tablet)
2011	26,422,300.32	\$58,784,601.32	\$2.22
2012	26,509,191.07	\$51,307,787.75	\$1.94
2013	23,505,816.49	\$40,601,469.94	\$1.73
2014	25,125,820.18	\$39,196,256.73	\$1.56
2015	28,254,109.62	\$38,765,070.27	\$1.37
2016	28,617,376.75	\$34,142,329.16	\$1.19
2017	28,107,594.08	\$33,938,832.23	\$1.21
2018	25,077,327.31	\$30,901,178.46	\$1.23
Total 2011-2013	76,437,307.88	\$150,693,859.01	\$1.97
Total 2014-2016	81,997,306.55	\$112,103,656.16	\$1.37
Total 2017-2018	53,184,921.39	\$64,840,010.69	\$1.22

If we compare the average pricing trend for Azithromycin, we can see the opposite, where over-time the annual average price-per unit decreases, except in 2017 and 2018, where the price increases by 2 cents a year.

4.2 Meprobamate and Triazolam

Tables 3 and 4 describe the total amount reimbursed, units reimbursed along with prices over the sample period. Since the dataset used is quarterly, the amounts are summed through the year and the price is averaged throughout the year. Triazolam is the control drug that will be used in the difference-in-difference estimation for Meprobamate. The reason why it was chosen as a suitable control will be discussed in Section 4.

Table 3: Descriptive Statistics for Meprobamate 200mg Oral Tablets

Year	Units Reimbursed	Total Amount Reimbursed	Price-Per Unit (tablet)
2011	78,940	\$87,355.04	\$1.11
2012	54,390	\$59,163.79	\$1.09
2013	42,019	\$65,796.76	\$1.57
2014	39,430	\$81,565.08	\$2.07
2015	68,415	\$236,524.54	\$3.46
2016	62,512	\$230,297.28	\$3.68
2017	24,907	\$71,941.15	\$2.89
2018	21,983	\$75,052.91	\$3.41
Total 2011-2013	175,349	\$212,315.59	\$1.21
Total 2014-2016	170,357	\$548,386.90	\$3.22
Total 2017-2018	46,890	\$146,994.06	\$3.13

Table 4: Descriptive Statistics for Triazolam 0.25mg Oral Tablets

Year	Units Reimbursed	Total Amount Reimbursed	Price-Per Unit (tablet)
2011	3,112,688	\$1,381,157.29	\$0.44
2012	3,170,856	\$1,305,859.29	\$0.42
2013	1,416,910	\$679,714.05	\$0.48
2014	880,149	\$731,578.35	\$0.83
2015	1,281,179	\$1,154,542.22	\$0.90
2016	557,474	\$677,761.81	\$1.22
2017	246,420	\$360,173.63	\$1.46
2018	894,237	\$1,323,735.16	\$1.48
Total 2011-2013	7,700,454	\$3,366,730.63	\$0.44
Total 2014-2016	2,718,802	\$2,563,882.38	\$0.94
Total 2017-2018	1,140,657	\$1,683,908.79	\$1.48

What can be clearly seen in **Table 3** is that the price per unit, increases in 2013, which coincides to the start date of the alleged conspiracy. Compared to the annual average price in 2012, the price per unit increases by 48 cents. The next year, the price again jumps up by 50 cents. In 2015, compared to the previous year (2014) the price increases again by \$1.39 a tablet. In 2016 the average price per unit increases again, but by only 22 cents however, and then in the next year decreases to \$2.89 a unit. This again can be explained by the first charges laid into Heritage pharmaceuticals on December

2016. The prices increase back up to collusion era prices only due to the fact that in the data, only one labeler was supplying Meprobamate 200mg tablets into the Medicaid program. Overall, the units reimbursed for Meprobamate follows a decreasing trend before the collusive period; where this trend continues for the first two years of the collusive period, before the units reimbursed increases drastically in 2015 and stay relatively high in 2016, even though prices remain at their highest during the collusive period. After however, the amount reimbursed sharply falls, possibly due to the announcement of collusion, and the fact that one labeler is now only providing the Medicaid market with the product. Triazolam on the other hand begins to see a jump in price in 2014, however the increases in price are never as large as the ones seen in the Meprobamate market. Overall as well, the number of units reimbursed is decreasing overtime like Meprobamate.

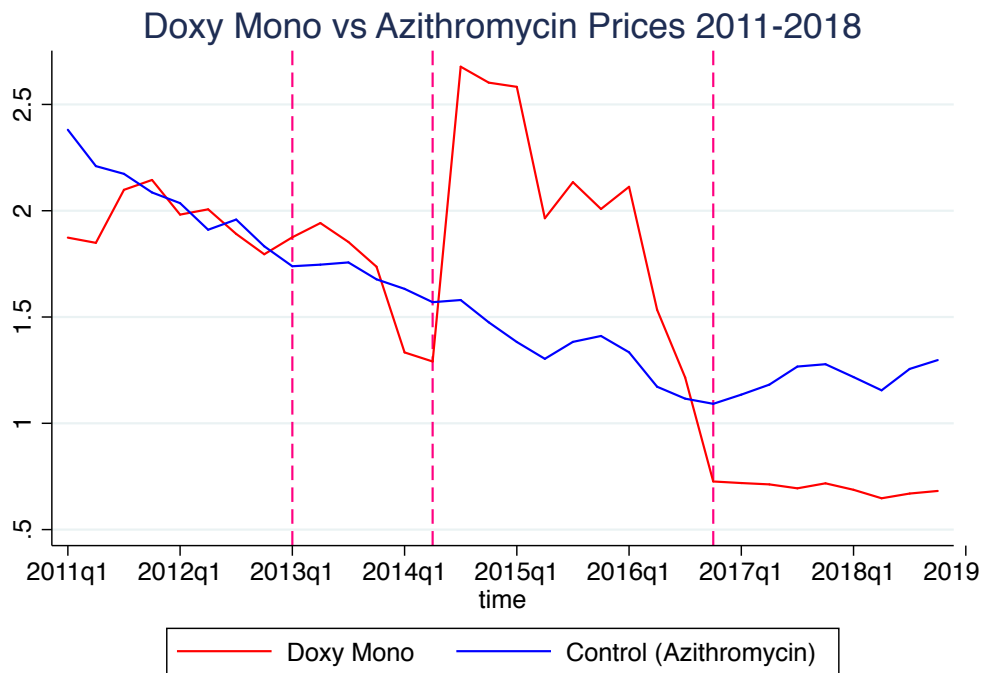
5. Empirical Analysis of the Impact of Collusion on Drug Prices

This section of the paper describes the procedure used to calculate the overcharge that collusive behavior had on the prices of Doxycycline Monohydrate 100mg oral tablets and Meprobamate 200mg Oral Tablets. In order to do so, difference-in-difference model is employed to compare changes in prices in the treatment market (Doxycycline monohydrate 100mg oral tablets and Meprobamate 200mg oral tablets) to those in the control market (Azithromycin 250mg oral tablets and Triazolam 0.25mg tablets). This however requires us to identify the correct cartel period. In the case of Doxycycline Monohydrate, 100mg tablets were chosen to be investigated. Other dosage sizes are available such as 50mg and 75mg variants, however the court documents did not state whether only one dosage form was specifically targeted or not. Azithromycin oral tablets were chosen as a suitable control due to the fact that firstly, Azithromycin oral tablets

have not been cited in any of the court documents as being targeted for collusive behavior. Secondly, Azithromycin is a generic antibiotic that also treats very similar bacterial infections that Doxycycline Monohydrate does. Like Doxycycline Monohydrate, Azithromycin can be prescribed for bacterial infections, with crossover between the two evident in the treatment of STI's. Azithromycin Oral tablets come in either 250mg or 500mg dosages, in which the 250mg variant was chosen as its closer in dosage size than the 500mg variant is. It is mentioned in the court documents that Heritage was partly interested in raising its price due to the fact that other forms of doxycycline had large increases in price. This may have a problem in contaminating our difference-in-difference analysis if our control drug was affected as well. However, Azithromycin is usually prescribed to patients that suffer from respiratory or intestinal bacterial infections and can also be used to treat certain types of sexually transmitted infections (like Doxycycline). The reason therefore why I believe Azithromycin wasn't affected is because patients who were prescribed doxycycline originally, would substitute away instead to Doxycycline Monohydrate (a more similar drug with the difference in salt form) than choosing an entirely different class of antibiotic like Azithromycin. Furthermore, collusion in the Doxycycline Monohydrate market did not exist or was not yet known to consumers at the time of the price increase for the alternative doxycycline, and on top of that, collusive behavior during this time (2013) period was not successful for Doxycycline Monohydrate. This means then that Doxycycline Monohydrate would be seen as the preferred cheaper and similar alternative, which can be seen in the decrease in its price in 2013 and its increase in units reimbursed (300,000 +) during the same time. Due to these reasons, it would be appropriate to conclude that the increase in pricing for other forms of Doxycycline will not contaminate the analysis. Another possible issue that may arise

with using Azithromycin 250mg oral tablets as a suitable control is that as we can see in the descriptive statistics in the previous section of the paper, Azithromycin is much more widely used than Doxycycline Monohydrate. Although this is not ideal, what matters more, is the parallel trend in the pre-cartel period.

Figure 1:



Note: The first horizontal line represents the start of the communication between the four manufacturers of Doxycycline Monohydrate. The second Horizontal line corresponds to the large increase in price due to the agreement of large-across the board price increases by the four manufactures. Lastly the third horizontal line corresponds to the 4th quarter of 2016, where the first charges were filed against Heritage pharmaceuticals.

Figure 1 plots the aggregated price for Doxycycline Monohydrate 100mg oral tablets and Azithromycin 250mg oral tablets. As we can see, prices for the two drugs follow one another very closely and also follow the same trend for the 2011-2013 period (except the very start of 2011). The two prices also follow a same pattern overall between the first quarter of 2013 up until the first quarter of 2014 where we see a sharper decrease in price

for Doxycycline Monohydrate compared to Azithromycin before there is a large price increase in the second quarter of 2014. This coincides with the court documents, where in the second quarter, Heritage and its competitors planned on a more comprehensive across-the-board price increase. Therefore, the start of the cartel period can be properly identified as starting in the second quarter of 2014. The end of the cartel period will be set at the third quarter of 2016, since the first charges filed against Heritage was in the 4th quarter. This decision is further backed up by the fact that the price of Doxycycline Monohydrate remains higher than average until the third quarter where it then falls drastically. Therefore, the cartel period in my analysis will run from quarter two of 2014 until quarter three of 2016. Due to the fact that the data set is quarterly, and the time period is only eight periods, if I were to only use aggregated data, I would only have 64 observations. In an effort to increase observations and accuracy, Doxycycline Monohydrate prices will also be disaggregated at the firm level. It is worth noting that in periods before and after the collusive period, there were more than the four collusive firms producing Doxycycline Monohydrate. However, their observations do not span over the whole sample period, with the firms either leaving the market before the collusive period or entering well after the collusive period. Due to this fact, only observations from the collusive firms (Heritage, Par, Lannett, and Mylan) will be used. Below is **Figure 2** where firm level prices are plotted against the aggregated Azithromycin 250mg oral tablet price.

Figure 2

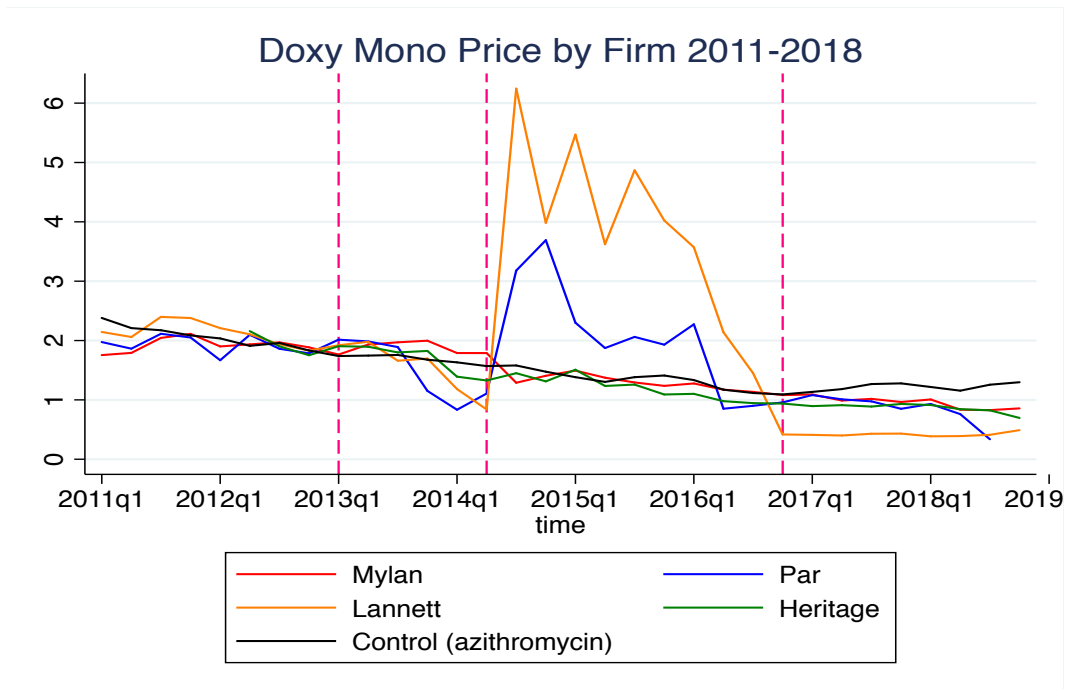


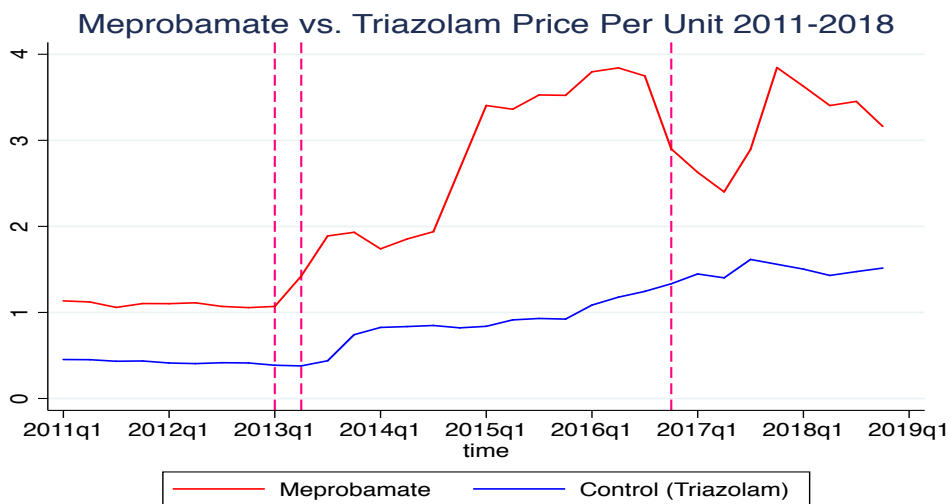
Figure 2 overall shows that the four collusive manufacturers posted prices that generally were close to the Aggregated Azithromycin price before the collusive period. However, in the collusive period, only two out of the four firms drastically raised their price, indicating that the collusive agreement was not totally successful. Therefore, this paper will not only run difference-in-difference regressions on the aggregated Doxycycline monohydrate price, but also on the firm-level aggregated price and individual firms as well.

In the case of Meprobamate, choosing to investigate the price of the 200mg oral tablet variant was chosen as once again, the court documents were not specific if one dosage form was targeted or not, so the choice between the 400mg or 200mg was not necessarily important. Triazolam 0.25mg oral tablets were chosen as a suitable control as firstly, it was not listed on any of the court documents as being affected by collusive behavior. Secondly, Meprobamate for a time was a best-selling minor tranquilizer but has

many pharmacological effects and dangers. Due to this, Meprobamate has been largely replaced by benzodiazepines and is therefore not a first-choice prescription when it comes to treating anxiety or insomnia. Therefore, I decided to find a benzodiazepine generic drug that treats similar ailments as Meprobamate. Triazolam, although not prescribed to patients who suffer from anxiety, is used to treat insomnia like Meprobamate (although Meprobamate is only licensed as an anti-anxiety drug). Once again, one issue that may arise with using Triazolam 0.25mg tablets is that triazolam is more widely used than Meprobamate. Although this is not ideal, what matters again is that the parallel trend in the pre-cartel period is similar. Below, **Figure 3** plots the aggregated price for Meprobamate 200mg oral tablets versus the control aggregated price (Triazolam 0.25mg Oral Tablet). As we can see from **Figure 3**, the pre-cartel parallel trend between Meprobamate 200mg oral tablets and Triazolam 0.25mg oral tablets is almost near identical, which confirms that triazolam is a suitable control. Furthermore, the beginning of the cartel period further coincides with the time period mentioned in the court documents (Quarter 2 of 2013). Therefore, the beginning of the cartel period can be properly identified as starting the second quarter of 2013. It is worth noting that the control drug's price begins to increase with the price of Meprobamate starting in the 4th quarter of 2013, but then diverges significantly in the latter half of 2014. This divergence can be explained by the fact that Meprobamate was also targeted again for a price increase by Heritage, as it was one of 18 drugs listed in company spreadsheets for a coordinated (collusive) price increase. The end of the cartel period is in quarter four of 2016, which coincides with the first charges filed against Heritage. This date (end of cartel) is further proven correct by the noticeable decrease in the price for Meprobamate during this time in Figures 3 and 4. The price of Meprobamate eventually increases until

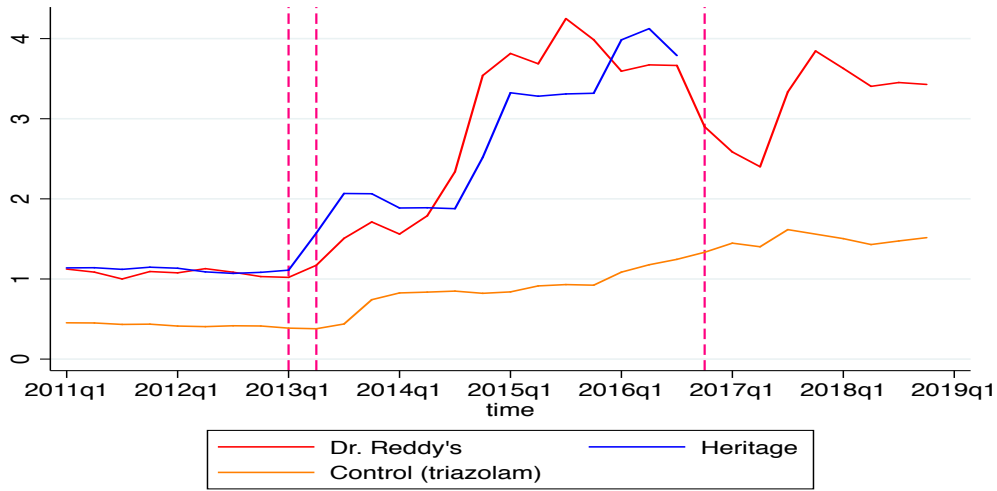
it returns to cartel period levels. This price increase can be explained by the fact that Dr. Reddy's was effectively the only firm supplying Meprobamate in the Medicaid program from the fourth quarter of 2016 and onwards. Alembic Pharmaceuticals did seem to enter the Meprobamate market in 2016, but only registers four observations from the first quarter of 2016 and onwards. Actavis was also a manufacturer of Meprobamate, but their last observation is in the first quarter of 2013. Therefore, observations from Dr. Reddy's and Heritage will be used. **Figure 4** plots the firm level prices for Meprobamate 200mg tablets against the aggregated Triazolam price. As we can see, Heritage stops supplying the Medicaid program. Therefore, due to this fact, all difference-difference regressions for Meprobamate will focus on the pre-collusion and collusion periods only.

Figure 3



Note: The first horizontal line corresponds the initial communication between Heritage and Dr. Reddy's, the second horizontal line represents the beginning of the price increases of the duopoly. The third line represents the first charges made against Heritage in December 2016.

Figure 4



6. Difference-in Difference Regression

The main econometric specification used in this paper is the following:

$$(1) P_{d,t} = \alpha + \delta_1 Drug_{d,t} * Collusionperiod_{d,t} + \delta_2 Drug_{d,t} + \delta_3 Collusionperiod_{d,t} + \beta X_{d,t} + \varepsilon_{d,t}$$

Where $P_{d,t}$ is the price of drug d in time t and where $X_{d,t}$ includes year, and firm-level effects and a variable that captures the number of firms in the particular market for drug d in a given time period (quarter) t . $Drug$ is a market dummy variable that equals one to indicate which observations are within the collusive market. $Collusionperiod$ indicates the start of the collusive period. $Drug * Collusionperiod$ is the difference-in-difference variable and therefore its parameter δ_1 is of interest in this study. The parameter can be described as the change in price in the drug affected by collusion relative to the change in price of the control drug from before to after the collusion began. Finally, $\varepsilon_{d,t}$ represents Robust standard errors.

Results from the estimation of equation 1 for the aggregated prices for Doxycycline Monohydrate 100mg oral tablets are presented in **Table 5**. Columns 1 and 2 represent regressions using pre-collusion, collusion, and post-collusion time periods, whereas columns 3 and 4 only use pre-collusion and collusion periods and finally columns 5 and 6 using collusion and post-collusion periods only. Columns 1, 3, and 5 are just simply basic difference-in-difference regressions with only the minimum required variables needed; meaning no time or firm(market) level effects or the *firm* variable capturing the number of manufacturers for drug *d* at time *t* were added. Columns 2, 4, and 6 include time and market(firm) effects as well as the firm number explanatory variable. It is worth noting that including these effects and variables significantly increases the R-Squared values for each regression, which suggests that the specification does fairly well in explaining the variation in the drug prices. As presented in the table, the parameter of interest (Drug*Collusionperiod) is seen to be significant at the 1% significance level for each regression. Overall, depending on which section of time one was to use, these results predict that collusion in the Doxycycline Monohydrate 100mg oral tablet market had the effect of raising prices in the range of approximately \$0.67 - \$1.11 a tablet. During the collusive period, from the 2nd quarter of 2014 to the third quarter of 2016, 6,315,830.85 100mg tablets were reimbursed by the Medicaid program. Therefore, estimations of damage would therefore range from \$4,231,606.67 - \$7,010,572.24. It is helpful to remember that Medicaid prescription drug spending accounts for roughly 10% of U.S prescription drug spending, meaning that these results would quantify much larger results if data was collected representing the whole prescription drug market.

Table 5: Difference-In-Difference for Doxycycline Monohydrate Aggregated Data

	All periods		Before & During		During & After	
	(1)	(2)	(3)	(4)	(5)	(6)
Variables	Price	Price	Price	Price	Price	Price
<i>Drug*Collusionperiod</i>	0.884*** (0.233)	0.862*** (0.1566)	0.698*** (0.1928)	0.669*** (0.1855)	1.153*** (0.1767)	1.11*** (0.2405)
<i>Collusionperiod</i>	-0.265*** (0.0993)	-0.561* (0.3294)	-0.561*** (0.0800)	-0.407 (0.3739)	0.1639*** (0.0536)	0.245* (0.1386)
<i>Drug</i>	-0.245 (0.158)	0.204 (0.1862)	-0.058 (0.0850)	Omitted	-0.514*** (0.0254)	-0.360 (1.0087)
<i>Firms</i>		0.084** (0.0306)		-0.031 (0.05997)		0.022 (0.1414)
<i>Constant</i>	1.637*** (0.0875)	1.564*** (0.35479)	1.933*** (0.0644)	2.393*** (0.5176)	1.2089*** (0.0238)	0.938 (1.4958)
<i>Observations</i>	64	64	46	46	38	38
<i>R-squared</i>	0.182	0.9087	0.401	0.8045	0.7519	0.9082
<i>Time Effects</i>	No	Yes	No	Yes	No	Yes
<i>Market Effects</i>	No	Yes	No	Yes	No	Yes

Robust standard errors in parentheses

*** p<0.01, ** p<0.05, * p<0.1

Note: Coefficient (standard error in parenthesis) of the effect of collusion on the price of Doxycycline Monohydrate 100mg Oral Tablet. Drug is a dummy variable = 1 if the observations are for Doxycycline Monohydrate. Collusionperiod is a dummy variable = 0 if the observations are not in the collusive period.

The next regressions used firm level pricing observations. This was done to gather more observations and therefore hopefully get a more accurate result. **Table 6** shows the estimated results when firm level prices are used. Once again columns 1 and 2 represent regressions using all periods. Columns 3 and 4 portray results using only the pre-collusion and collusion period observations and finally columns 5 and 6 only use collusion and post-collusion period observations. Observations are only 154 and not the full 160 because Heritage does not enter the market until the second quarter of 2012 and Par leaves the market in the fourth quarter of 2018. Columns 1,3 and 5 once again derive estimates from only using a simple difference-in-difference model. The results show that interestingly, once again, the difference-in-difference parameter is positive and significant at the 1% significance level for each regression regardless of what time period was used. The dummy variable for the collusion time period (Collusionperiod) is significant at the 1% level for all regressions except in column 6 and negative for all except column 5. This reflects that prices during the collusive period regardless of market, decreased. This result is not surprising, as 2 out of the four collusive firms and the control experienced a decreasing trend in price over the collusive period. Only Lannett and Par seemed to actually raise prices as shown in **Figure 2**. However, the time dummy variable is insignificant when using only collusion and post collusion time periods. The explanatory variable “Firms” which captures the number of firms supplying the drugs being investigated during the sample period is found to be insignificant when added to the regressions except when the whole sample period is used. The coefficient reads that an extra firm that enters the market increases the price of drug d in time t by approximately 7 cents all else being equal. This result may be due to the fact that prices were on average higher in the pre-collusive period for all four collusive firms, and there were around 6

firms in the market as well. When the collusive period begins, prices drop for two out of the four collusive firms and control, and the total number of firms drops from 6 to four. However, the coefficient is rather small, and it is only significant at the 10% level. It is worth noting again that the introduction of time effects and firm effects once again vastly increases the R-Squared values for each regression, which suggests that the specification does a better job in explaining the variation in the drug prices. Overall the price overcharge, depending on which observations you use ranges from \$0.76 - \$1.09 cents. Damages therefore are estimated to range from \$4,800,031.45 - \$6,884,255.63. However, as shown in **Figure 2**, only two out of the four alleged conspirators were successful in raising their prices. This result was unexpected but may coincide with the court documents as they do not say whether Heritage pharmaceuticals were successful in raising their prices or not. However, one last set of tests were run to quantify the impact of collusion on the price for Doxycycline Monohydrate 100mg oral tablets. This test involved using observations from only one firm and comparing them to the control. The results from these tests are shown in **Table 7**, where observations encompassing the pre-collusion, collusion, and post collusion periods were used.

Table 6: Difference-in-Difference for Doxycycline Monohydrate using firm level Data

	All Periods		Before & During		During & After	
	(1)	(2)	(3)	(4)	(5)	(6)
Variables	Price	Price	Price	Price	Price	Price
<i>Firms</i>		0.068* (0.03896)		-0.0094 (0.0825)		0.013 (0.18289)
<i>Drug</i>	-0.229** (0.0974)	Omitted	-0.056 (0.0779)	Omitted	-0.432*** (0.0484)	Omitted
<i>Collusionperiod</i>	-0.265*** (0.0973)	-1.631*** (0.2956)	-0.561*** (0.0779)	-1.443*** (0.3712)	0.164*** (0.0518)	-0.466 (0.6960)
<i>Drug*Collusionperiod</i>	0.908*** (0.2452)	0.882*** (0.2512)	0.734*** (0.2331)	0.762*** (0.2773)	1.111*** (0.2265)	1.086*** (0.3972)
<i>Constant</i>	1.637*** (0.0857)	1.563*** (0.2141)	1.933*** (0.0627)	1.699*** (0.3824)	1.209*** (0.0230)	0.297 (1.0512)
<i>Observations</i>	154	154	110	110	94	94
<i>R-Squared</i>	0.0999	0.5374	0.0467	0.4684	0.2940	0.5428
<i>Time Effects</i>	No	Yes	No	Yes	No	Yes
<i>Firm Effects</i>	No	Yes	No	Yes	No	Yes

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

Note: Coefficient (standard error in parenthesis) of the effect of collusion on the price of Doxycycline Monohydrate 100mg Oral Tablet. Drug is a dummy variable = 1 if the observations are for Doxycycline Monohydrate. Collusionperiod is a dummy variable = 0 if the observations are not in the collusive period. "Firms" represents the number of firms for drug d in time t.

Table 7: Difference-in-Difference by Firm for Doxycycline Monohydrate

	Mylan	Heritage	Par	Lannett
	(1)	(2)	(3)	(4)
Variables	Price	Price	Price	Price
<i>Firms</i>	0.053* (0.0295)	0.088*** (0.0189)	0.031 (0.0466)	0.125** (0.0602)
<i>Drug</i>	0.173 (0.1965)	0.330** (0.1243)	-0.039 (0.2825)	0.366 (0.3226)
<i>Collusionperiod</i>	-0.691* (0.3408)	-1.311*** (0.0547)	-0.975*** (0.2293)	-0.857*** (0.3086)
<i>Drug*Collusionperiod</i>	0.073 (0.0695)	-0.033 (0.0616)	0.843*** (0.2747)	2.522*** (0.5297)
<i>Constant</i>	1.688*** (0.4242)	1.765*** (0.1322)	2.026*** (0.4210)	1.389*** (0.5036)
<i>Observations</i>	64	59	63	64
<i>R-Squared</i>	0.9379	0.9705	0.7955	0.8346
<i>Time Effects</i>	Yes	Yes	Yes	Yes
<i>Firm Effects</i>	Yes	Yes	Yes	Yes

Robust standard errors in parentheses

*** p<0.01, ** p<0.05, * p<0.1

Note: For each regression column, the all three periods (pre-collusion, collusion, and post-collusion) were used.

Results from **Table 7** broadly reflect what was plotted in **Figure 2**. We see that the difference-in-difference estimator is not significant at any level for both Mylan And Heritage, which reflects that they did not raise prices successfully during the collusive period. However, for the other two firms, Par and Lannett, which showed in the plotting of prices in **Figure 2** signs of colluding have positive coefficients at the 1% significance level; with coefficients of 0.84 and 2.52 respectively. The rather large coefficient for Lannett also fits **Figure 2** and the data, as this firm raised its price at some points in the sample by almost four dollars per-tablet. During the collusive period, Par Pharmaceuticals supplied 1,226,097 tablets and Lannett supplied 1,472,175.14. Therefore, damages per firm are estimated as \$1,029,921.48 for Par and \$3,709,881.35 for Lannett.

6.2 Results for Meprobamate

Results from the estimation of equation 1 for the aggregated prices for Meprobamate 200mg oral tablets are presented in **Table 8**. As stated before, since Heritage pharmaceuticals does not have any observations past the third quarter of 2016, only observations from the pre-collusion period and collusion period will be used. Column 1 in **Table 8** represents a model with no time or firm- level effects and no explanatory variable representing the number of firms in the market for drug d in time t . This was done to show what a basic simple difference-in-difference analysis would produce. Column 2 includes these effects and variables. Results showed that firstly the time dummy variable “Collusionperiod” was positive and significant for both regressions. This result means that prices increased for both the treatment and control drug during the collusive period. The dummy variable representing the collusive drug or market (Drug) was also significant at the 1% significance level and positive, but only for the first column regression. Finally, the parameter of interest, the difference-in difference parameter is

positive and significant at all standard significance levels but falls in magnitude when time and market level effects are added as well as the explanatory variable that captures the number of producers. During the collusive period (2nd quarter of 2013- 3rd quarter of 2016) 193,421 200mg oral tablets were reimbursed by the Medicaid Drug Rebate program. Therefore, using the parameter in the second column, damages can be calculated to equal \$353,960.43.

Table 9 presents results when firm-level price observations were used. Column 1 represents estimates derived from using only a simple difference-in-difference model. Once again, the time dummy variable (Collusionperiod) is found to be positive and significant at the 1% significance level, meaning prices in both markets increased during the collusive period. Overall, the parameter of interest (Drug*Collusionperiod) is found to be positive and significant at all standard significance levels. The coefficients are also quite large at 1.304 and 1.812 respectively. The damages due to collusive behavior (if using the second column results) results in an estimate of \$350,092.01.

Table 8: Difference-in-Difference for Meprobamate 200mg oral tablets (Aggregated)

	(1)	(2)
Variables	Price	Price
<i>Drug*Collusionperiod</i>	1.234*** (0.2558)	1.834*** (0.0084)
<i>Collusionperiod</i>	0.434*** (0.0646)	1.053** (0.4702)
<i>Drug</i>	0.669*** (0.0119)	0.022 (0.2151)
<i>Firms</i>		0.647*** (0.2151)
<i>Constant</i>	0.423*** (0.0072)	-0.834* (0.4688)
<i>Observations</i>	46	46
<i>R-Squared</i>	0.7714	0.9336
<i>Time Effects</i>	No	Yes
<i>Market Effects</i>	No	Yes

Robust standard errors in parentheses

*** p<0.01, ** p<0.05, * p<0.1

Table 9: Difference-in-Difference for Meprobamate 200mg oral tablets (Firm Level)

	(1)	(2)
Variables	Price	Price
<i>Firms</i>		0.547** (0.2222)
<i>Drug</i>	0.670*** (0.0124)	0.143 (0.2402)
<i>Collusionperiod</i>	0.434*** (0.0636)	0.787*** (0.01797)
<i>Drug*Collusionperiod</i>	1.304*** (0.2005)	1.812*** (0.0756)
<i>Constant</i>	0.423*** (0.0071)	-0.635 (0.4448)
<i>Observations</i>	69	69
<i>R-Squared</i>	0.7099	0.9216
<i>Time Effects</i>	No	Yes
<i>Firm Effects</i>	No	Yes

Robust standard errors in parentheses

*** p<0.01, ** p<0.05, * p<0.1

7. Conclusion

This paper has documented that collusion in the generic pharmaceutical drug industry was successful in raising prices and thus overcharged consumers and the government Medicaid program in the two products that were studied: Doxycycline Monohydrate 100mg oral tablets and Meprobamate 200mg. Using Medicaid State-Drug Utilization data covering a sample period spanning from January 2011 to December 2018, a difference-in-difference model was created to estimate the price overcharge and damages collusive activity had on the former mentioned generic products. This method has been used extensively in Industrial Economics literature to calculate damages of collusion like this paper has done, with examples being from Laitenberger and Smuda (2015), McCluer and Starr (2013,) and Hüschelrath et al. (2013) to name just a few. Using court documents to help identify the cartel period and plotting pricing over the sample period to help find a suitable control by confirming a similar pre-collusion parallel trend, a difference-in-difference model was applied to calculate the damages of alleged collusion. Although the control drugs used in both regressions had different levels of use and can be seen as alternative medications in some areas, the parallel trends were able to confirm them as satisfactory controls.

The results showed that in the case of Doxycycline Monohydrate, only two of the four alleged conspirators were successfully able to raise prices when using Medicaid data. Therefore, running difference-in-difference models separately for each firm resulted in estimating damages to be around \$4,739,802.83 in total. For Meprobamate, damages due to collusion were calculated to be \$350,092.01.

The results from this paper are significant, as firstly, the ongoing investigation into the generic drug industry has to date hundreds of products being investigated along with many manufacturers. The results from this paper only cover two products using data that represents around 10% of all prescription drug spending. This means that the results from this paper are only a small fraction of the true cost the American citizen has endured from collusion. Therefore, because of this alone, this topic is left for future research as more investigation into this topic is needed in order to truly quantify the impact of the documented illegal activity in the Generic Pharmaceutical Industry.

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