Erasmus University Rotterdam
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Firms alleviating the impact of price ceiling regulation

The case of Diclofenac tablets in India

This paper examines how pharmaceutical firms tried to mitigate the impact of price ceiling regulation of Diclofenac tablets. Using a difference in difference methodology on price data before and after regulation, I show a selective price increase of unregulated dosages compared to the regulated dosage. This increase was combined with a shift in production from regulated to unregulated dosages. Moreover, firms on whose prices the ceiling price would be based selectively increased the price of the regulated formulation in the period leading up to regulation and exploited the higher price of tablets with a special delivery feature to additionally raise the price ceiling. Lastly, trade margins offered to retailers suddenly quadrupled to further manipulate the ceiling price.

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LIST OF USED ABBREVIATIONS

DPCO	Drug Price Control Order
NLEM	National List of Essential Medicine
RoR	Rate of Return
FDC	Fixed Dose Combination
NPPP	National Pharmaceutical Pricing Policy
WAP	Weighted Average Price
API	Active Pharmaceutical Ingredient
DiD	Difference in Difference
NSAID	Nonsteroidal Anti-Inflammatory Drug
NPPA	National Pharmaceutical Pricing Authority
AIOCD	All Indian Origin Chemists & Distributors

TABLE OF CONTENTS

1 INTRODUCTION

"In the development of new drugs, financial returns for pharmaceutical companies are leading, not health benefits or societal impact", is how Ernst Kuipers (2022), the Dutch Minister of Health opened his opinion piece in *Het Financieele Dagblad*. This was the conclusion of large-scale international research commissioned by his ministry. The concern of politicians that large pharmaceutical companies value profit more than human lives is nothing new.

This paper examines how pharmaceutical companies tried to mitigate the impact of government intervention. In India, the government has attempted to limit exorbitant pricing for essential drugs since the 1970s by introducing price ceilings. In an overview of the historic price ceilings, Selveraj (2007) questions the effectiveness of the interventions. The government, aware that new regulation might be necessary to overcome these caveats, set out to formulate a new Drug Price Control Order (DPCO).

In 2013, the new DPCO was implemented. The prices of 652 formulations of 348 drugs were regulated by introducing a price ceiling based on the average price of all brands with more than 1% market share. The regulated drugs were based on the National List of Essential Medicines (NLEM), which lists formulations of drugs that satisfy the priority health care needs of the population. It is important to note only certain formulations of drugs were regulated, not all.

The new DPCO came with its own set of problems, from implementation to enforcement and compliance. This paper specifically looks at the strategies firms implemented to mitigate the impact of the DPCO by exploiting certain caveats. Bhaskarabhatla (2018) identified multiple strategies firms used in response to the DPCO 2013.

Firstly, he showed that in the case of Metformin, a drug essential to diabetics, pharmaceutical firms selectively increased the price of the regulated formulation compared to the unregulated formulations in the period leading up to regulation, leading to a higher price ceiling.

In the case of painkiller Paracetamol, pharmaceutical firms selectively increased the price of unregulated formulations compared to the regulated formulation, combined with a shift of

production from regulated to unregulated formulations, thus partly circumventing the regulation.

A third example also found in paracetamol was a temporary increase in trade margins. This is the difference between the retail price listed on the package and the price the manufacturer receives from the retailer. In August 2013, trade margins for Paracetamol averaged more than 250%, substantially higher than the 16% trade margin the Indian government uses in calculations.

The anecdotal evidence from these different drugs shows firms might use one strategy for a certain drug and another strategy for another drug. A combination of strategies is also possible. Further research should be conducted to get a better overview of the prevailing strategies and to provide support for more effective regulation. Therefore, the research question of this paper forms as follows:

"What strategies were implemented by pharmaceutical firms to mitigate the impact of the price ceiling imposed on Diclofenac tablets in India in 2013"

To answer this research question, a difference in difference analysis on the price data of Diclofenac tablets between 2011 and 2016 is used. This method allows the comparison of the evolution of price for the regulated and unregulated dosages in the period before and after the regulation. This comparison will be used to document how the pharmaceutical firms adjusted their prices in response to the regulation.

Diclofenac will provide an interesting addition to the anecdotal evidence in the literature, as Diclofenac falls under a different category in the NLEM. The healthcare system in India follows a three-tier system with primary, secondary, and tertiary levels having different health care concerns and medicine requirements. The NLEM also lists the care level for which the drug formulation is essential. Whilst Metformin and Paracetamol are essential at all three levels, Diclofenac is only deemed essential at the tertiary level. As tertiary care deals with more complex cases than primary or secondary care, there is likely more information asymmetry between patients and healthcare professionals. This information asymmetry can be exploited by drug manufacturers by incentivizing healthcare professionals to prescribe overpriced drugs.

The remainder of this paper is organized as follows. In Section 2 the theoretical framework will be presented. Section 3 describes the data and methodology. Section 4 examines the results of the analyses. The results are discussed in Section 5 and Section 6 concludes this thesis.

2 THEORETICAL FRAMEWORK

2.1 FOUNDATIONS OF PRICE CAP REGULATION

Government intervention is extensively discussed in both economics and politics. Traditional views following the classical school of economics advocate for the freedom of the market, minimizing government intervention. However, critics such as Pigou (1938) proclaim that free markets often fail, due to excessive market power or externalities. Government intervention may be able to overcome these market failures, for example through price regulation.

Price regulation is widely used as a measure to prevent exorbitant pricing, especially to regulate monopolistic firms. The traditional form of price regulation implemented by governments is Rate of Return (RoR) regulation. RoR regulation determines a price at which the firm's costs are recovered and a reasonable rate of return on investment is provided. Liston (1993) argues that this takes away the firm's incentive to produce efficiently since a cost reduction does not lead to an increase in profit. Furthermore, the regulatory body faces high administrative costs to gain knowledge about the firm's costs. RoR regulation also entails a risk of over-investment in capacity if the allowed return is greater than the required return, as shown in the model developed by Averch and Johnson (1962).

Another form of price regulation that overcomes these obstacles is price cap regulation. Price cap regulation determines a ceiling price, whilst maintaining a firm''s freedom to choose a price below the ceiling. In contrast to RoR regulation, there is an incentive to produce efficiently. Moreover, there is no administrative burden to determine a firm''s costs and no predetermined allowed return rate that entails a risk of over-investment.

Additionally, Vogelsang (1989) and Brennan (1989) find that price cap regulation will over time converge the price to a level that maximizes social welfare (sum of producer and consumer surplus) given the price constraint. Therefore, price cap regulation is generally

viewed as superior to RoR regulation, as it instigates both efficient production and efficient pricing. (Abbott, 1995)

2.2 CRITIQUE ON PRICE CAP REGULATION

However, price cap regulation does not come without caveats either. Neu (1993) and Abbott and Crew (1994) argue the findings of Vogelsang (1989) and Brennan (1989) only hold up when the demand functions remain constant. This is hardly ever the case in a market like the pharmaceutical market; if a firm expects one dosage of a drug to have a higher demand growth rate than another dosage of the same drug and the price cap would be established on the weighted average of all dosages, then the firm would be incentivized to increase the price for the higher growth rate dosage and decrease the price for the lower growth rate dosage.

The pharmaceutical industry is known for volatile demand and relatively short product cycles. (Abbott, 1995) Price caps can thus be easily manipulated by changing prices to match their respective demand growth rates. These adverse effects could be mitigated if the regulator defined the price caps for individual products and/or dosages. Abbott (1995) argues however that the nature of the pharmaceutical industry makes it difficult to define this. One might argue that two pills containing a single dosage are different from one pill containing double the dosage. Drugs can come in a variety of forms as well, such as a tablet, an injection, or gel.

Another aspect of the pharmaceutical industry hindering effective price cap regulation is the excessive use of Fixed Dose Combinations (FDC). FDCs are combinations of two or more Active Pharmaceutical Ingredients (APIs) in a single dosage form. This is justifiable if an FDC has a proven advantage over the single APIs administered separately. FDCs are not common in most developed countries, as it is generally accepted there is rarely any proven advantage. Gupta and Ramachandran (2016) conclude that a lot of FDCs in India lack adequate justification, suggesting that APIs were not added because of medical reasons. However, as Gautham and Saha (2008) point out, FDCs are highly popular in the Indian pharmaceutical market. This leads to an unnecessary risk of adverse drug reactions. Moreover, it makes it harder for the regulator to compare and regulate different dosages of an API.

Even if a regulator manages to address all these challenges, the effectiveness of price cap regulation might disappoint in practice. Price cap regulation is not implemented overnight. Firms under regulatory threat can manipulate their pre-implementation prices to influence

the ceiling price, therefore weakening its effectiveness. (Glazer and McMillan 1992; Foreman, 1995; Cowan, 1997) If firms anticipate that the ceiling is determined by a weighted average of prices, it further incentivizes firms to coordinate a collective price increase. (Law, 1997)

2.3 Drug price control in India

India has controlled drug prices since the 1970s, through multiple Drug Price Control Orders (DPCOs). However, these DPCOs have shown to be ineffective. An overview of the DPCOs provided by Selveraj (2007) concluded that they proved to be inadequate in curbing exorbitant prices and ensuring affordability to the common man, the main objectives of the DPCOs. A task force set up by the Indian government to address shortcomings in drug pricing policy recommended that a ceiling price should be introduced for drugs included in the National List of Essential Medicines (NLEM). (Sen, 2005)

A new DPCO based on the task force recommendations took a while, but in 2011 the National Pharmaceutical Pricing Policy (NPPP) was finally drafted. This draft proposed to introduce a price ceiling on all drugs included in the NLEM. The price ceiling would be determined through market-based pricing, instead of the cost-based pricing previous DPCOs used. The price ceiling would be based on the Weighted Average Price (WAP) of the top 3 brands by market share. Another change compared to the previous DPCO was that the prices would be regulated for specific formulations, instead of the API. The reasoning behind this was that APIs may not always reflect the essentiality of a certain formulation. However, flaws to the NPPP 2011 were quickly pointed out.

The market-based pricing is justified by the assumption that the price is determined by regular market conditions and market forces. This fails to acknowledge the reality of the industry, which is characterized by supplier-induced demand. (Evans, 1974) Whilst the patient is the consumer of a prescribed drug, it is often a healthcare professional who decides and chooses on behalf of the patient. This information asymmetry can be exploited by drug manufacturers, who can provide incentives to healthcare professionals to prescribe their products.

This phenomenon is visible in the Indian pharmaceutical market as well. The market is characterized by a large number of manufacturers producing similar medicine. This should result in competitive pricing, with market leaders having relatively low prices. However, Selveraj (2012) shows that market leaders tend to be price leaders as well, suggesting that

competitive pricing is not prevalent in the Indian pharmaceutical market. Since the price ceiling would be based on the top 3 market leaders, it would essentially just top off the high prices, legitimizing possible exorbitant prices.

The NLEM also limits the effectiveness of regulation by only listing certain dosages and strengths of an API. Selveraj (2012) shows that in several markets, a significant share of the dosages and strengths of NLEM-listed drugs would be left out of regulation. Moreover, FDCs are completely overlooked by the NLEM. When you combine this with the supplier-induced demand, it provides ample space for manufacturers to retain exorbitant profits by shifting to unregulated dosages and strengths.

2.4 Introduction of the DPCO 2013

Despite the clear shortcomings of the NPPP 2011, the draft was largely realized in the new DPCO 2013. The WAP of the top 3 brands was changed to a simple average of all brands with a market share of more than 1%. However, Selveraj (2012) found that the change resulted in a price ceiling either mostly similar to or only marginally different from the previous formula. Only a few distinct markets would benefit from the change.

As pointed out in the previous chapter, price cap regulation is not implemented overnight. If firms anticipate a market-based price ceiling, as is the case for the DPCO 2013, they are incentivized to raise their pre-implementation prices to end up with a higher price ceiling. This is exactly what Bhaskarabhatla et al. (2017) show in their study on Metformin. They find that firms selectively increased their prices for the regulated dosage relative to the unregulated dosages in the period leading up to the implementation in 2013. The coordination is stronger among the larger firms on which the price ceiling would be based.

Moreover, the DPCO 2013 lacked distinction between plain tablets and tablets with a special delivery feature (such as extended release). Bhaskarabhatla et al. (2017) showed that firms exploited the higher price of tablets that had a special delivery feature, by selectively increasing the price of regulated special delivery tablets in the period leading up to the implementation.

Bhaskarabhatla et al. (2018) show another way firms were able to limit the effect of regulation on their bottom line for the case of Paracetamol. They find that firms were able to use their

market power to shift the market from regulated to unregulated dosages. Firms combined this shift with a relative price increase for the unregulated dosages, thus absorbing a potential decline in profits for regulated dosages by increasing profitability for unregulated dosages.

Another way to manipulate the price ceiling is by increasing trade margins. Trade margins are the difference between the retail price, which is put on the pack by the manufacturer, and the price for which the drug is sold to the retailer. Trade margins incentivize healthcare professionals to prescribe/sell drugs with high trade margins, as they can make more money that way. As discussed before, market leaders tend to be price leaders in the pharmaceutical market. By providing high trade margins, they can retain high market shares combined with high prices.

The increasing trade margins might also come in handy if price cap regulation based on the retail price is coming. A firm can increase the retail price to end up with a substantially higher price ceiling, providing ample room for the price to the retailer to not be limited by a price ceiling, as the price ceiling is too high to seriously cap the price to the retailer. Combined with the high market share this likely brings about due to the supplier-induced demand, this provides an excellent opportunity for firms to weaken the effects of price cap regulation.

Historically, DPCOs in India have been based on the retail price. (Gulhati, 2004) As discussed previously, this was also the expectation after the NPPP 2011. However, in the DPCO 2013, the price to the retailer multiplied by 1.16 was used. This was announced in the NPPP 2012, which was published in December 2012. Bhaskarabhatla (2018) finds that whilst average trade margins for drugs included in the NLEM 2011 increased modestly from 29% in January 2011 to 33% in March 2012, they suddenly increased to 73% in April 2012, reaching a high of 105% in January 2013. When you compare this to the fact that the NPPP 2011, NPPP 2012, and DPCO 2013 view the year on which things such as price indexes are based runs from April to April, the reason for the sudden increase becomes apparent. This suggests a clear motive for the pharmaceutical firms to manipulate the price cap regulation by using trade margins, although the results of the manipulation have probably been weakened by the decision made in December 2012 to change the price on which the ceiling would be based.

3 DATA & METHODOLOGY

3.1 DICLOFENAC

We look into the case of Diclofenac. Diclofenac is a Nonsteroidal Anti-Inflammatory Drug (NSAID), one of the most commonly used medicine classes worldwide. It is estimated that over 30 million people take NSAIDs daily. (Singh and Triadafilopoulos, 1999) NSAIDs are used to relieve pain and reduce inflammation. Diclofenac is by far the most used NSAID. (McGettigan and Henry, 2013). Diclofenac can be used if Paracetamol does not provide enough relief. In contrast to Paracetamol, which is a household remedy that can be sold over the counter, Diclofenac can only be sold with a prescription. (The Drugs and Cosmetics Rules, 1945) This results in more supplier-induced demand than Pparacetamol, as healthcare professionals are more involved in the brand choice process. Moreover, its 50mg dosage is included in the NLEM and thus in the DPCO 2013, while other dosages, including the widely used 100mg tablet escape regulation. The previous NLEM 2003 did list the 100mg dosage as essential, but it was removed in the NLEM 2011. The usual dose is 75mg to 150mg per day, with no significant clinical difference between them. (Todd and Sorkin, 1988) Derry et al. (2015) show in clinical trials that 25mg, 50mg, and 100mg tablets all provide good relief, indicating that patients may use either dosage to meet their daily requirements. Diclofenac was first introduced in 1973. With its patents long expired, the market for Diclofenac is now characterized by dozens of brands, with both generic brands and well-known brands such as Voltaren.

3.2 DATA

The dataset, called PharmaTrac, is obtained from the AIOCD AWACS Pvt. Ltd, a pharmaceutical market research company formed by All Indian Origin Chemists & Distributors Ltd. (AIOCD). AIOCD is the pharmaceutical retailers' trade association, with 550.000 members. Since this data is produced by the union of the pharmaceutical retailers themselves, it is regarded as highly accurate. The dataset contains aggregate monthly prices of Diclofenac tablets for the period between January 2011 and July 2016. 320 observations are dropped from the dataset, as these tablets are FDCs, which are not easily comparable to drugs with a single API. A further 620 observations are deleted because the strength of the tablet is not

recorded. During this period Diclofenac tablets were sold by 91 companies spanning 100 brands. Figure 1 shows the number of firms and brands in the Diclofenac tablet market over time. After a substantial exit in the first half of 2011, the number of firms in the market remained relatively stable at around 40 firms. This relatively high number suggests quite intense competition and makes the ability to effectively coordinate prices seem unlikely. However, only 9 of these firms have a market share of more than 1%, and the market leader has over 70% market share across 4 brands. Therefore, the large number of firms in the market does not abate the possibility of large-scale price coordination, as most brands lack market power and are likely price followers.

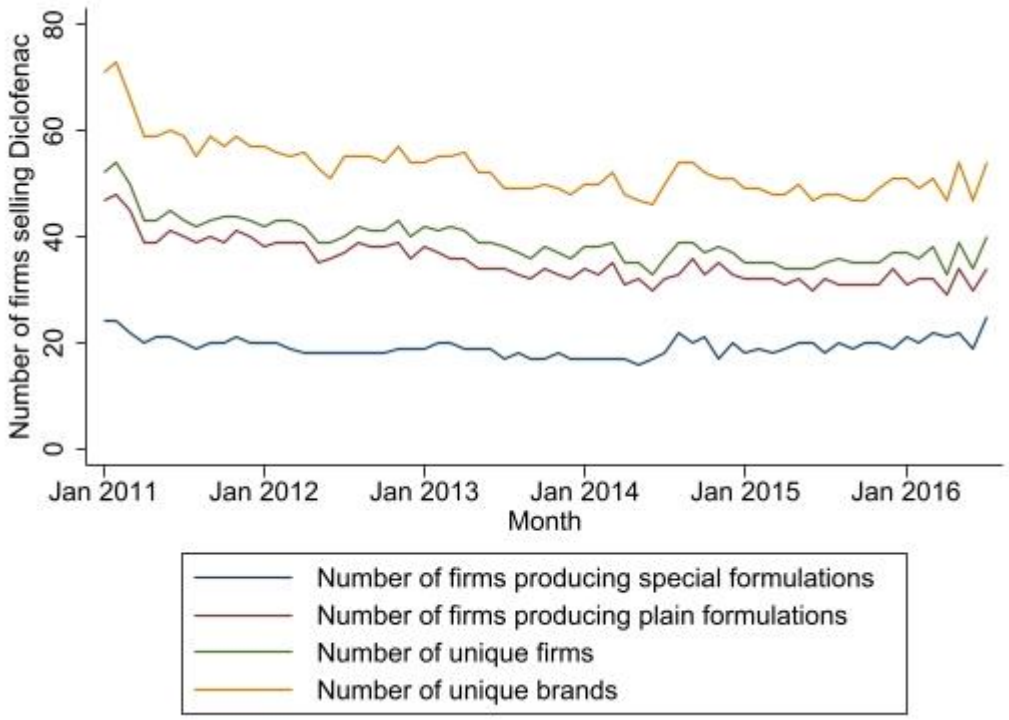

Figure 1. *Number of firms and brands selling Diclofenac in India.*

Table 1: *Market share of dosage strengths before and after regulation.*

	25 MG	50 MG	75 MG	100 MG	125 MG	150 MG	200 MG
Before regulation	0.12%	37.42%	7.84%	54.19%	-	0.41%	0.02%
After regulation	0.11%	28.67%	9.17%	61.20%	0.06%	0.74%	0.05%

The dataset contains details of the brands sold. Dosage strengths included 25mg, 50mg, 75mg, 100mg, 125mg, 150mg, and 200mg. As shown in table 1, 50mg, 75mg, and 100mg

make up most of the market, accounting for over 99% of Diclofenac tablets sold. Diclofenac tablets delivery types included mainly plain tablets, sustained release tablets, and gelatin coated tablets. Dispersible tablets were sold to a lesser extent, and mouth dissolving did not accumulate any significant market share. 92 percent of tablets were sold in packs of 10, but packs of 1, 4, 5, 15, 20, and 50 were also sold. In total, the dataset contains 5846 observations over 67 months.

The price used in the analysis is the price to the retailer, which is the price the manufacturer receives, multiplied by 1.16, the same calculation used in the DPCO 2013 to determine the ceiling price. To enable comparison of prices between different dosage strengths and pack sizes, the price is normalized per 50mg tablet of Diclofenac using the following formula:

$$Price\ per\ 50mg = 50 / Dosage\ Strength \times Price\ of\ Pack / Number\ of\ tablets\ in\ Pack$$

The period can be divided into 3 by 2 key moments of policy change regarding Diclofenac regulation. Six months after the start of the dataset, the NLEM 2011 was disclosed, including the 50mg dosage of Diclofenac. In July 2013, the DPCO 2013 was implemented, regulating the 50mg dosage of Diclofenac. Therefore, we define 3 period dummies: 1) before NLEM 2011 was disclosed; 2) after the disclosing of NLEM 2011 but before implementation of the DPCO 2013; and 3) after DPCO 2013.

3.3 Methodology

To analyze the price effects of the price cap regulation on Diclofenac tablets, the Difference in Difference (DiD) regression method is used (Angrist and Pischke, 2008). The DiD method will estimate the difference between regulated and unregulated formulations before and after regulation. Using an Ordinary Least Squares regression, I estimate the impact of regulation on price for firm i in dosage market j in month t with the following equation:

$$Price\ per\ 50mg_{ijt} = \alpha + \beta \times Regulated_{ijt} + \gamma \times Regulated_{ijt} \times Period_2 + \delta \times Regulated_{ijt} \times Period_3 + \phi \times NotPlain + \eta_i + \omega_t + \varepsilon_{ijt} \quad (1)$$

where Regulated is a binary variable assuming 1 if the dosage strength is equal to 50mg. α represents the constant, while $Period_x$ is the period dummy, assuming 1 for that particular period. NotPlain is a control variable assuming 1 if the tablet is not plain, I.e. a special delivery method is used. η controls for firm fixed effects, while ω controls for time fixed effects. ε is

the error term. Firm fixed effects prevent the result from being biased by firm-specific, time-invariant characteristics. Time fixed effects prevent the result from being biased by changes over time that affect both the regulated and unregulated dosages equally. The DiD effect is captured by the interaction terms γ and δ.

To be able to interpret the results of a DiD regression, we assume that the price of the regulated dosage would have followed the same trend as the unregulated dosages if the NLEM 2011 and DPCO 2013 would not have affected Diclofenac. Since it concerns the same API, it is unlikely different dosages would have different relative growth rates, as the components that make up the price will be largely affected the same by changes.

Since the ceiling price is determined by the simple average of all firms with a market share of more than 1%, we expect these firms to have an even stronger effect on the price. We use the data source used by the regulator to calculate the market share, which is published as a working sheet on their website. (National Pharmaceutical Pricing Authority, 2013) Using this data, we identify 9 companies selling 21 brands that are used to calculate the price ceiling. The price ceiling I calculate based on these brands exactly corresponds to the price ceiling determined by the regulator, verifying the correctness. To determine the relative effect of these large firms on price, we include a dummy LargeBrand which assumes 1 if the brand is one of these 21 brands. We estimate the following equation:

$$Price\ per\ 50mg_{ijt} = \alpha + \beta \times Regulated_{ijt} + \gamma \times Regulated_{ijt} \times Period_2 + \delta \times Regulated_{ijt} \times Period_3 + \zeta \times LargeBrand_i + \lambda \times LargeBrand_i \times Period_2 + \mu \times LargeBrand_i \times Period_3 + \nu \times Regulated_{ijt} \times LargeBrand_i + \rho \times Regulated_{ijt} \times LargeBrand_i \times Period_2 + \sigma \times Regulated_{ijt} \times LargeBrand_i \times Period_3 + \phi \times NotPlain + \eta_i + \omega_t + \varepsilon_{ijt} \quad (2)$$

Since plain tablets are generally cheaper than tablets with a special delivery feature, and the regulation does not distinguish between delivery features, we expect firms to exploit the higher price by selectively increasing the price for the special delivery featured tablets in the period leading up to regulation. To test this, we interact the NonPlain dummy with the periods, and a triple interaction between the dummy, the period, and the regulated dummy. We estimate the following equation:

$$Price\ per\ 50mg_{ijt} = \alpha + \beta \times Regulated_{ijt} + \gamma \times Regulated_{ijt} \times Period_2 + \delta \times Regulated_{ijt} \times Period_3 + \phi \times NotPlain + \tau \times NotPlain \times Period_2 + \theta \times NotPlain \times Period_3 + \kappa \times Regulated_{ijt} \times NotPlain + \iota \times Regulated_{ijt} \times NotPlain \times Period_2 + \psi \times Regulated_{ijt} \times NotPlain \times Period_3 + \eta_i + \omega_t + \varepsilon_{ijt} \quad (3)$$

Combing the first three equations leads to the equation for the full model leads to the following equation:

$$Price\ per\ 50mg_{ijt} = \alpha + \beta \times Regulated_{ijt} + \gamma \times Regulated_{ijt} \times Period_2 + \delta \times Regulated_{ijt} \times Period_3 + \zeta \times LargeBrand_i + \lambda \times LargeBrand_i \times Period_2 + \mu \times LargeBrand_i \times Period_3 + \nu \times Regulated_{ijt} \times LargeBrand_i + \rho \times Regulated_{ijt} \times LargeBrand_i \times Period_2 + \sigma \times Regulated_{ijt} \times LargeBrand_i \times Period_3 + \phi \times NotPlain + \tau \times NotPlain \times Period_2 + \theta \times NotPlain \times Period_3 + \kappa \times Regulated_{ijt} \times NotPlain + \iota \times Regulated_{ijt} \times NotPlain \times Period_2 + \psi \times Regulated_{ijt} \times NotPlain \times Period_3 + \eta_i + \omega_t + \varepsilon_{ijt} \quad (4)$$

4 RESULTS

4.1 PRICE TRENDS

In figure 2, the normalized average price of a 50mg and a 100mg tablet of Diclofenac is plotted. Both dosages see a similar substantial increase in the period between NLEM 2011 and DPCO 2013, with the 50mg tablet being priced slightly higher. After regulation, the price increase seems to halt, and the two price lines converge.

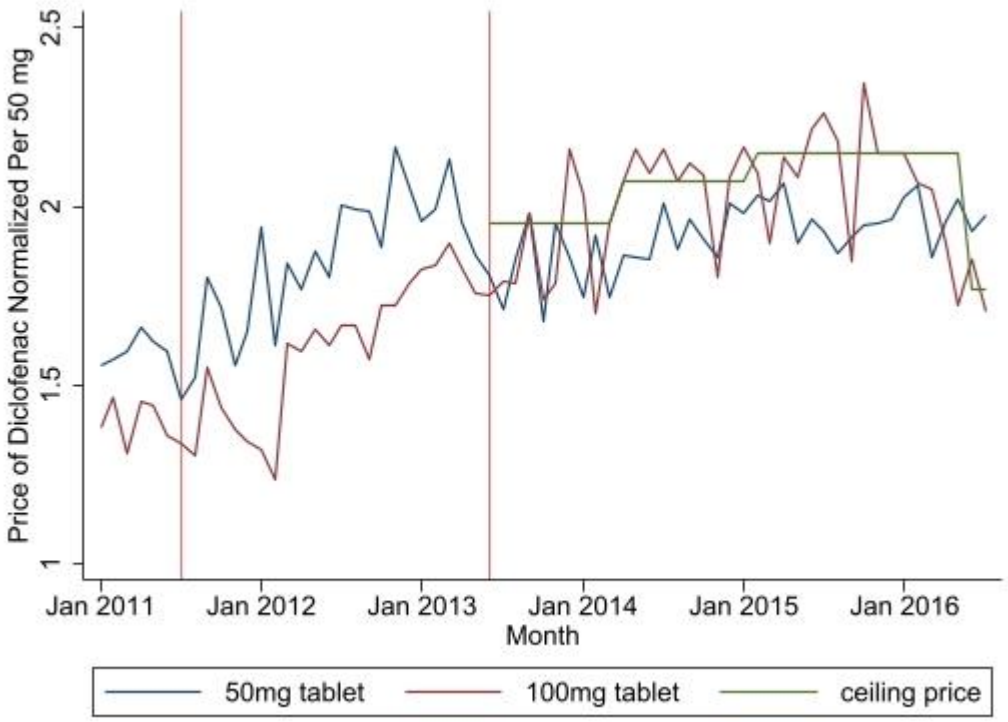

Figure 2: *Average price of a Diclofenac tablet normalized per 50mg by dosage strengths.*

This convergence is confirmed by table 2, which shows the prices were significantly different before regulation, but shows no significant difference in normalized price after regulation.

Table 2: *Average normalized price for 50 mg and 100 mg formulations of Diclofenac, before and after implementation of the DPCO 2013.*

	50 mg	100 mg	difference
Before regulation	1.792	1.542	0.250*
After regulation	1.915	2.006	0.092

*Notes: * the difference is statistically significant at P < .001*

4.2 DIFFERENCE IN DIFFERENCE ANALYSIS

Table 3: *Estimates of price per 50mg for various dosages from January 2011 to July 2016.*

VARIABLES	(1)	(2)	(3)	(4)
Regulated (=1 if 50 mg)	-0.15	0.05	-0.20	-0.01
	[0.11]	[0.12]	[0.14]	[0.15]
Regulated x Period2	-0.30***	-0.62***	-0.64***	-0.99***
	[0.12]	[0.14]	[0.15]	[0.17]
Regulated x Period3	-0.68***	-0.88***	-0.99***	-1.19***
	[0.11]	[0.13]	[0.15]	[0.16]
NotPlain (=1 if not a plain tablet)	-0.38***	-0.38***	-0.36**	-0.35**
	[0.05]	[0.05]	[0.15]	[0.15]
Regulated x NotPlain			0.26	0.33
			[0.31]	[0.31]
Period2 x NotPlain			-0.50***	-0.54***
			[0.17]	[0.17]
Period3 x NotPlain			-0.41**	-0.41**
			[0.16]	[0.16]
Regulated x Period2 x NotPlain			0.79**	0.75**
			[0.33]	[0.33]
Regulated x Period3 x NotPlain			0.61*	0.54*
			[0.32]	[0.32]
Regulated x Largefirm		-0.56***		-0.56***
		[0.16]		[0.16]
Largefirm x Period2		-0.27***		-0.31***
		[0.10]		[0.10]
Largefirm x Period3		*omitted*		*omitted*
Regulated x Period2 x Largefirm		0.86***		0.89***
		[0.19]		[0.19]
Regulated x Period3 x Largefirm		0.54***		0.54***
		[0.16]		[0.16]
Constant	2.03***	2.09***	2.10***	2.16***
	[0.15]	[0.16]	[0.17]	[0.18]
Observations	5,846	5,846	5,846	5,846
R-squared	0.616	0.618	0.622	0.623
Month Fixed Effects	YES	YES	YES	YES
Company Fixed effects	YES	YES	YES	YES

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

4.2.1 Equation (1)

The increase in table 2 does not indicate whether this relates to the regulation, which is why we employ the difference in difference analysis with monthly fixed effects. The results of equation (1) are shown in column 1 of table 3. The coefficient of regulated is insignificant, indicating no significant price difference in the period before the introduction of the NLEM 2011. The first interaction term shows regulated prices significantly decreased relative to unregulated prices in the period between the NLEM 2011 and de DPCO 2013 compared with the period before regulation. The second interaction term captures the relative effect in the period after regulation. The coefficient is again negative and significant. Moreover, the relative decrease in regulated prices is more substantial than in the previous period, with a coefficient more than twice as large. A larger decrease in period 3 than in period 2 is not surprising, as firms need to comply with a price ceiling for regulated dosages in period 3, forcing some firms to lower their prices. The control variable NotPlain is surprisingly negative and significant, indicating tablets with special delivery features are generally lower priced than plain tablets. However, special delivery features are unequally distributed across dosage strengths. Higher strengths are far more likely to have a sustained release feature, as one 100mg sustained release tablet should be effective for the same period as two plain 50mg tablets taken on interval. Since table 2 shows an average lower price for 100mg tablets compared to 50mg tablets, a negative coefficient is in line with expectations.

4.2.2 Equation (2)

The results of equation (2), which tests if there is a stronger effect for the large firms on whose prices the price ceiling will be determined, are presented in column 2. The addition of large firms substantially enlarges the coefficient of the relative price decrease for the regulated dosage in period 2. This suggests smaller firms relatively decreased the price of the regulated dosage more so than large firms. This is confirmed by the triple interaction term for period 2, which is positive and significant. Combining these two coefficients to estimate the relative price change for large firms in period 2, the price of the regulated dosage increased compared to unregulated dosages. The coefficient of the relative price decrease for the regulated dosage in period 3 also strengthens, al though~~beit~~ less substantial than in period 2. The triple interaction term in period 3 confirms this, as it is positive and significant, but lower than for period 2. This is in line with expectations, as firms are confronted with the price ceiling in period 3. As the price ceiling is based on the simple average of the large firms, the firms above

the average must decrease their prices. Combining the interaction terms for period 3 shows that although large firms decrease the relative prices of the regulated dosage less than small firms, they still decrease the price of the regulated dosage compared to the unregulated dosage.

4.2.3 Equation (3)

Column 3 shows the results of equation (3), which is equation (1) interacted with the NonPlain dummy. Tablets with a special delivery feature typically are more expensive than plain tablets of similar strength. We expect firms to exploit this price difference by selectively increasing the prices of tablets with a special delivery feature. The interaction terms between the regulated dummy and the period dummies are similar to these terms in column 2. The triple interaction term with the NonPlain dummy for period 2 is positive and significant on a 5% level. Combining these coefficients leads to a positive coefficient, meaning that tablets with a special delivery feature not only increased relative to plain tablets, but tablets with a special delivery feature also had a larger increase in relative price than plain tablets had a decrease in relative price. The triple interaction term for period 3 is positive and significant on a 10% level. This indicates that after regulation the price regulated tablets with a special delivery feature increased compared to plain regulated tablets. The coefficient is smaller than the negative coefficient of the double interaction term for period 3, thus suggesting that albeit a relative price increase compared to plain tablets, regulated tablets with a special delivery feature still experienced a relative price decrease.

4.2.4 Equation (4)

The results of the full model, represented by equation (4), are shown in column 4. The results remain broadly similar to columns 2 and 3. The price of regulated tablets generally decreased compared to unregulated tablets in period 2 and more substantially in period 3. Compared to smaller firms, the large firms increased their regulated prices compared to unregulated prices in period 2, and in period 3 to a lesser extent. Firms also selectively increased the prices of their regulated tablets with a special delivery feature in period 2, and in period 3 to a lesser extent.

4.3 PRODUCTION SHIFT

As discussed previously, price is not the only factor pharmaceutical firms can influence to mitigate the effect of regulation. The supplier-induced demand characterizing the

pharmaceutical market makes it so that the firms can influence demand, and thus shift demand to formulations that might be outside the scope of regulation, favoring their profitability. Table 1 shows a 9 percentage point shift in market share from the regulated dosage to unregulated dosages. Moreover, table 4 shows the market share of plain tablets, which was over 25% before regulation, more than halved after regulation. Plain tablets are generally cheaper than tablets with a special delivery method.

Table 4: *Market share of delivery types before and after regulation.*

	Plain	Sustained release	Gelatin coated	Dispersible	Mouth dissolving
Before regulation	25.60%	57.96%	11.42%	5.02%	-
After regulation	11.95%	67.75%	16.80%	3.50%	0.00%

4.4 TRADE MARGINS

The price ceiling was based on the price to the retailer, not on the price of the consumer. This change was brought forward by the regulator in December 2012. As discussed in section 2.4, I expect a steep increase in April 2012. In 2013 the trade margins could be dropped again, as the price manipulation would not serve its purpose anymore. Figure 3 shows the trade margins of the 50mg and 100mg tablets of Diclofenac. The trade margins almost quadrupled in April 2012. However, after the publication of the NPPP 2012, the trade margins remain high. A possible explanation is the retailers' trade organization, AIOCD. This organization holds a lot of market power. Bhaskarabhatla et al. (2016) describe its cartel-like practices, which include sales embargoes on pharmaceutical firms. The AIOCD might not have tolerated a decline in the newly gained high trade margins.

The trade margins for the 50mg and 100mg dosage follow a similar trajectory, even though the 100mg dosage was not going to be regulated, making it less necessary to pump up the price through trade margins to end up with higher price ceilings. A possible explanation could be that both dosages are not sold separately to retailers. The powerful AIOCD might have demanded similarly high trade margins for the 100mg dosage.

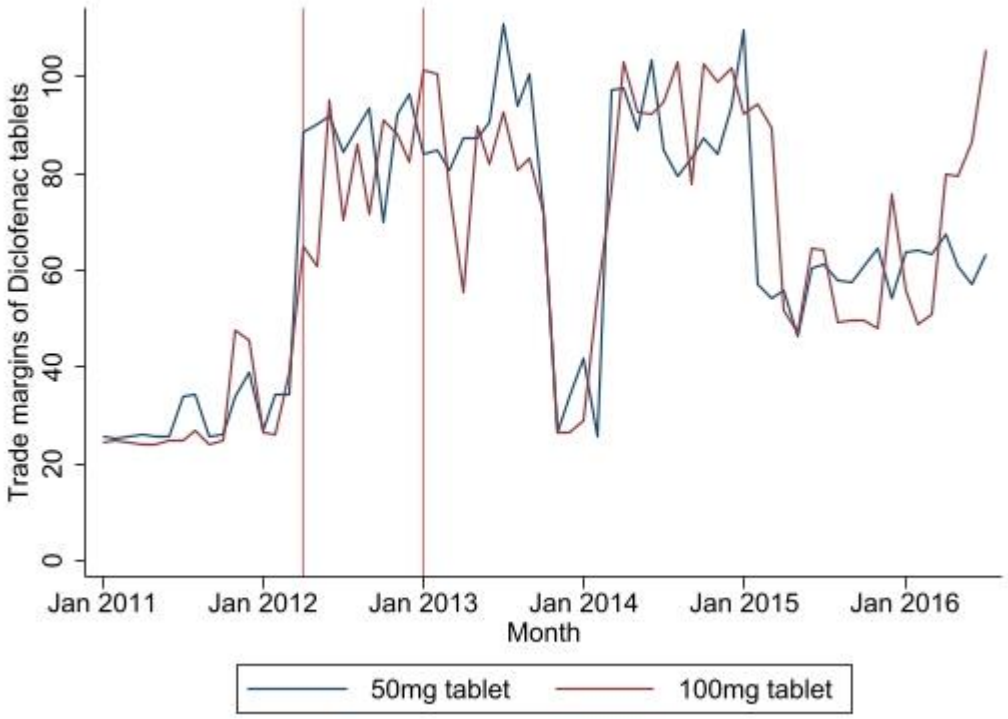

Figure 3: *Trade margins of 50mg and 100mg Diclofenac tablets.*

5 DISCUSSION

5.1 INTERNAL VALIDITY

Our analysis uses a Difference in Difference method. This method is hinged on the similar trends assumption. This means that if no Diclofenac dosage was regulated, the normalized price for all dosages would have grown at a similar rate. As discussed before, this is likely justified because we look at different dosages of the same API. A solid indicator that the trends would have been similar in absence of regulation would be a similar trend before regulation. However, since our dataset starts in January 2011, six months before the publication of the NLEM 2011. The consultation for the NLEM 2011 already began in 2009. One might suggest firms already started to treat the 50mg dosage differently before the consultation period, as the committee led by Sen (2005) already recommended a price ceiling based on the NLEM 2003. However, in the NLEM 2003, both the 50mg and 100mg dosages of Diclofenac were considered essential. Therefore, the pharmaceutical firms likely successfully lobbied for the removal of the 100mg dosage from the list in the consultation period. A

dataset where the parallel trends can be tested before 2009, also providing the effects in the consultation period in the process, would result in more solid results.

Difference in difference analysis does not account for time-variant unobservables. Although we control for month fixed effects to account for these unobservables, time-variant unobservables that affect different strengths differently would still cause omitted variable bias. This would for example be the case if prescription guidelines change for different dosages. While no medical reason suggests this, we did find the relative importance of the treatment group changed. Namely, the market share of the regulated dosage substantially changed. This likely biases our results.

Another concern is that some dosages might be more prevalent in hospitals, invalidating the argument that it just concerns different dosages of the same medicine. This is amplified by the fact that the 50mg dosage is considered essential only for tertiary care, leaving the possibility open that the 50mg plain dosage is meant for hospital use, while sustained release 100mg dosage is targeted directly at the consumer. However, our dataset only contains direct sales from pharmacies to the consumers, hospital usage characteristics are not likely to be driving our results.

The dataset does come with some caveats concerning correctness and completeness. First of all, 620 observations are deleted because no strength was recorded. These are likely not recorded because they are FDCs, but if it would concern dosages used in our analysis it would likely bias our results. Secondly, I found multiple brands which have SR in their brand name, therefore likely being sustained release tablets, but listed a plain tablet as the drug type. This biases our results.

Table 5 in the appendix shows the results of equation (4) with different period definitions. Column 3 shows the results also shown in column 4 of table 3. Column 1 shows the results of equation (4) with the start of period 3 moved from July 2013 to January 2013. The results do not change substantially. A slight change in the coefficients of terms interacting with period two further underwrites the depositions made in section 4.2.2. Column 2 shows a merge between periods 1 and 2. Most coefficients are insignificant, and no conclusions can be drawn from these results. Therefore, the periods used in the main results are likely the most correct.

Table 6 in the appendix shows the results of equation (4) with certain data exclusions. Column 3 shows the results also shown in column 4 of table 3. Column 1 shows the results if the 200mg dosage is excluded. Since the maximum daily dosage is 150mg, a 200mg tablet might serve other uses and be less comparable to lower dosages. 200mg tablets account for 1.67% of observations. The exclusion does not substantially change our results. In column 2 certain pack sizes are excluded. Pack sizes 1 and 4 are excluded because they appear in the dataset used in this research, but not in the dataset the National Pharmaceutical Pricing Authority (NPPA) used to determine ceiling prices. Such small pack sizes could be meant for hospital use. Furthermore, packs with 50 tablets are excluded, as a pack size of more than 20 is likely a spurious entry. (Bhaskarabhatla et al., 2017) This exclusion does substantially change our results either.

5.2 External validity

The results might be biased, doubting the internal validity. This makes the external validity less relevant. If the result would not be biased, external validity is still limited. Pharmaceutical markets are complex, and characteristics might differ per country. Moreover, Bhaskarabhatla et al. (2016) identified the retail trade organization as a cartel, further distinguishing the Indian market from markets in similar countries. Therefore, these results can not be generalized to other countries. Furthermore, this paper only analyses a single medicine. As we have seen in previous research, firms used different strategies for different medicine affected by the Indian price ceiling. (Bhaskarabhatla et al., 2017; Bhaskarabhatla et al., 2018) Therefore, these results should only be interpreted for Diclofenac, and not generalized to other medicine affected by the DPCO 2013.

5.3 Limitations

In addition to the limitations discussed in the internal and external validity sections, this has several more limitations. First, the dataset did not give information on FDCs. Adding dosage strengths with additional APIs to the analysis would provide a completer view of the strategies implemented by pharmaceutical firms to mitigate the impact of the price ceiling imposed on Diclofenac tablets.

Another strategy that this research does not look into is noncompliance. Table 4 shows a shift in market share towards gelatin coated tablets after regulation. Novartis, the sole producer of this type of Diclofenac, has argued that gelatin coated 50mg tablets do not fall under the regulation. The NPPA disagreed, and a still ongoing legal battle ensued. Since then, Novartis' gelatin coated 50mg tablets have grown to a market share of 56 percent, and other companies have started producing their own gelatin coated tablets. (Pharmabiz, 2021)

6 CONCLUSION

Pharmaceutical firms implemented multiple strategies to mitigate the impact of the price ceiling imposed on Diclofenac tablets in India in 2013. Both the 50mg and 100 mg dosages saw a substantial increase in the price to the retailer in the period leading up to the implementation of the price ceiling. Overall, firms increased the price of the unregulated dosages significantly more than the regulated dosage in the period leading up to the regulation. After regulation, this price increase was even more substantial, as the regulation dosage was confronted with the price ceiling. Pharmaceutical firms, armed with supplier-induced demand, combined this price increase with a production shift from the regulated dosage to the unregulated dosages.

The pharmaceutical firms also tried to manipulate the price ceiling in the period leading up to the regulation. Firstly, in anticipation of the price ceiling, the trade margins on both the regulated 50mg and the unregulated 100mg dosage suddenly quadrupled in one month. Moreover, the firms exploited the generally higher price of tablets with a special delivery feature by selectively increasing the price of those regulated tablets compared to plain regulated tablets in the period prior to the regulation. This selective price increase was combined with a production shift from plain tablets to tablets with a special delivery feature. On top of that, firms on whose prices the price ceiling would be based selectively increased the price of the regulated dosage in the period prior to the regulation to further raise the ceiling price.

This research points out several flaws in the price ceiling regulation introduced in India in 2013 and how pharmaceutical firms actively tried to mitigate its impact. The substantial price increases suggest that in contrast to the policy goals of curbing exorbitant pricing and

ensuring availability to the common man, the regulation might have caused adverse effects. Policymakers striving for similar goals should avoid the flaws of the DPCO 2013 when drafting new policies.

To draw stronger conclusions on the effects of the DPCO 2013 on Diclofenac tablets, further research should include earlier data to better establish the different dosages would have followed a similar price trend in absence of regulation. Moreover, interviews with industry experts should be done to determine if there might have been changes in prescription guidelines or recommended usage.

To provide a completer view of the strategies implemented in the Diclofenac tablet market, further studies could investigate the role of FDCs played as a possible way to circumvent regulation. Another strategy that went beyond the scope of this research is to what extent pharmaceutical firms complied with the regulation, and if the government body tasked with the enforcement has enough striking power to force the large pharmaceutical industry to comply.

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8 APPENDIX

Table 5: *Estimates of price per 50mg for various dosages from January 2011 to July 2016.*

	(1)	(2)	(3)
Period 1	Jan 2011 – Jun 2011	Jan 2011 – Jun 2013	Jan 2011 – Jun 2011
Period 2	Jun 2011 – Dec 2012	Jul 2013 – Jul 2016	Jul 2011 – Jun 2013
Period 3	Jan 2013 – Jul 2016		Jul 2013 – Jul 2016
Regulated (=1 if 50 mg)	-0.00	-0.69***	-0.01
	[0.15]	[0.09]	[0.15]
Regulated x Period2	-0.88***	-0.54***	-0.99***
	[0.18]	[0.10]	[0.17]
Regulated x Period3	-1.21***		-1.19***
	[0.16]		[0.16]
NotPlain (=1 if not a plain tablet)	-0.35**	-0.74***	-0.35**
	[0.15]	[0.09]	[0.15]
Regulated x NotPlain	0.32	0.88***	0.33
	[0.31]	[0.14]	[0.31]
Period2 x NotPlain	-0.42**	-0.02	-0.54***
	[0.17]	[0.10]	[0.17]
Period3 x NotPlain	-0.47***		-0.41**
	[0.16]		[0.16]
Regulated x Period2 x NotPlain	0.65*	-0.01	0.75**
	[0.34]	[0.17]	[0.33]
Regulated x Period3 x NotPlain	0.62*		0.54*
	[0.32]		[0.32]
Regulated x Largefirm	-0.57***	-0.01	-0.56***
	[0.16]	[0.09]	[0.16]
Largefirm x Period2	-0.43***	*omitted*	-0.31***
	[0.11]		[0.10]
Largefirm x Period3	*omitted*		*omitted*
Regulated x Period2 x Largefirm	0.96***	0.09	0.89***
	[0.20]	[0.09]	[0.19]
Regulated x Period3 x Largefirm	0.57***		0.54***
	[0.16]		[0.16]
Constant	2.17***	2.44***	2.16***
	[0.18]	[0.15]	[0.18]
Observations	5,846	5,846	5,846
R-squared	0.624	0.621	0.623
Month Fixed Effects	YES	YES	YES
Company Fixed effects	YES	YES	YES

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

Table 6: *Estimates of price per 50mg for various dosages from January 2011 to July 2016.*

Variables	(1)	(2)	(3)
Regulated (=1 if 50 mg)	-0.04	-0.01	-0.01
	[0.16]	[0.15]	[0.15]
Regulated x Period2	-1.05***	-0.98***	-0.99***
	[0.18]	[0.17]	[0.17]
Regulated x Period3	-1.27***	-1.26***	-1.19***
	[0.16]	[0.16]	[0.16]
NotPlain (=1 if not a plain tablet)	-0.36**	-0.35**	-0.35**
	[0.16]	[0.15]	[0.15]
Regulated x NotPlain	0.35	0.30	0.33
	[0.31]	[0.30]	[0.31]
Period2 x NotPlain	-0.59***	-0.53***	-0.54***
	[0.17]	[0.17]	[0.17]
Period3 x NotPlain	-0.48***	-0.50***	-0.41**
	[0.17]	[0.16]	[0.16]
Regulated x Period2 x NotPlain	0.80**	0.78**	0.75**
	[0.34]	[0.33]	[0.33]
Regulated x Period3 x NotPlain	0.62*	0.69**	0.54*
	[0.32]	[0.32]	[0.32]
Regulated x Largefirm	-0.51***	-0.51***	-0.56***
	[0.17]	[0.16]	[0.16]
Largefirm x Period2	-0.32***	-0.28***	-0.31***
	[0.10]	[0.10]	[0.10]
Largefirm x Period3	-	-	*omitted*
Regulated x Period2 x Largefirm	0.89***	0.78***	0.89***
	[0.20]	[0.19]	[0.19]
Regulated x Period3 x Largefirm	0.55***	0.44***	0.54***
	[0.16]	[0.16]	[0.16]
Constant	2.15***	2.18***	2.16***
	[0.18]	[0.18]	[0.18]
Observations	5,750	5,766	5,846
R-squared	0.620	0.633	0.623
Month Fixed Effects	YES	YES	YES
Company Fixed effects	YES	YES	YES

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