Who Benefits from Pharmaceutical Price Controls? Evidence from India

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Abstract

This study examines the impacts of pharmaceutical price controls in a middle-income country setting, focusing on an implementation of pharmaceutical price ceilings in India. It finds that price controls led to declining prices for directly-impacted and competing products and increased market share for high-quality products. However, after price controls were implemented, low-priced firms were more likely to exit price-controlled markets and sales of price-controlled products declined in markets with stronger price controls. The benefits of the legislation were largest for quality-sensitive consumers, while the downsides largely affected poor and rural consumers, two groups already suffering from low access to medicines.

Keywords: Pharmaceutical Industry, Price Controls, India

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Globally, both government health departments and patients struggle with high and rising pharmaceutical prices (Abbott, 2017). In low- and middle-income countries (LMICs)[1] this issue is exacerbated by low levels of health insurance coverage, making high drug prices an important impediment to access (Towse et al., 2012). Importantly, low-income households living within LMICs are particularly affected by drug prices. Not only do these households have low income and savings levels, but they also rely heavily on medication for health treatment due to a lack of access to medical facilities and trained medical professionals (Hammond et al., 2007). While medicines represent about 30% of total public and private health expenditures in LMICs (World Health Organization, 2011), they comprise between 50-80% of total health spending amongst *low-income* households in these countries (Hammond et al., 2007).

The high prices of originator, on-patent drugs in LMICs has long been a contentious issue, but even when generic drugs are introduced into the market, this has not necessarily been sufficient to achieve affordable prices (Danzon et al., 2015). Large price dispersion often remains amongst generic formulations of the same product, even after mature generic markets develop. This is largely due to what are known as "branded generics" markets, in which producers of generic drugs are able to compete on brand name as opposed to price. Branded generic markets may develop as a result of lack of regulatory assurance that generic medicines are high-quality and equivalent to branded products. Generic producers establish a reputation for quality through a brand name, which in turn impairs price competition amongst generic equivalents that otherwise might be expected.

Given the failure of market forces to decrease drug prices and the impact these prices may have on consumers, governments have increasingly implemented price-control legislation. Using a theoretical model and a difference-in-differences analysis, this study examines the impact of one such implementation of price controls, in which the Indian government set market-based price ceilings on a subset of pharmaceutical products, including both on-patent and generic medications. There is a large body of evidence on the impacts of pharmaceutical price controls, though most empirical and theoretical evidence is in the context of high-income countries.[2] Despite this, there is little known about the impacts of such controls in LMICs. This is an important distinction as the impacts may look very different due to lower levels of insurance

[1] A list of all abbreviations used in this paper can be found in Appendix A.

[2] Not only are there economically important market differences between high-income countries and LMICs, but also the price controls tend to take different forms in these markets. Most evidence from high-income countries concerns reference prices, which determine *reimbursement* levels as opposed to directly controlled prices. See for instance, Brekke et al. (2011); Stargardt (2010); Puig-Junoy (2007); Grootendorst and Stewart (2006); Danzon and Ketcham (2004); Pavcnik (2002) and Danzon and Chao (2000), which all discuss the impacts of pharmaceutical reference prices in the high-income country context.

coverage, cost-conscious consumers, and a lack of trust in generic medication quality. Where studies on the impacts of pharmaceutical pricing policies in LMICs do exist, the analysis is generally restricted to a limited geographic area or product space (Bhaskarabhatla et al., 2017; Mohapatra and Chatterjee, 2016; Yang et al., 2013). This paper will contribute valuable empirical evidence on the short-term impact of pharmaceutical price controls throughout India, expanding the analysis to a broad range of affected products to assess whether effects are similar across product types and categories. It will also contribute to the literature on the impacts of government pharmaceutical policy in LMICs more generally (e.g. Chaudhuri et al. (2006); Goldberg (2010); Duggan et al. (2016)).

This paper also provides an interesting setting to study the impact of price controls on a vertically differentiated oligopoly market more generally – a structure that is common in other areas of health care, for instance in hospital or physician markets. In this paper, there is an objective measure of medication quality and a natural experiment which restricts prices – allowing for measurement of differential impacts for high- and low-quality firms. This is an improvement on other studies on quality in health care, which are often derived from outcomes correlated with treatment quality, but also with observable and unobservable patient characteristics.

When debating how best to improve access to medicines in LMICs, it is essential to consider behavioral response by producers to legislated price decreases. While the Indian setting is quite specific, it can more generally provide a setting to study how producers respond to price controls in branded generics markets or, more broadly, in markets with quality uncertainty. This paper shows that the consumer welfare impacts of the legislation are mixed – the legislated price decreases led to pricing spillovers, causing closely related products to decrease their prices as well. Further, it led to higher market-share for high-quality products. However, it also led to exit of low-cost producers from the market and a decrease in sales in markets with stronger price controls, suggesting potential shortages of essential medications. Importantly, these shortages are most likely to affect rural consumers and the most cost-conscious consumers, further exacerbating within-country disparities in access to medicine.

1 Empirical Setting

Generic medications are traditionally considered non-differentiated medications marketed only through the generic or active ingredient name. However, while seemingly an oxymoron, "branded generics" – or branded versions of off-patent medications not manufactured by the original developer – are common throughout most of the world, including in many LMICs. Branded generic manufacturers seek to differentiate themselves and compete on brand name to impede the price competition that occurs when generics are perceived as interchangeable. Given this, the World Health Organization considers growing branded generics markets to be an immediate challenge to ensuring access to essential medicines (World Health Organization, 2011).

Of interest to economists is how branded generics markets can occur in areas where consumers are both highly price-sensitive and largely paying for medications out-of-pocket. One primary reason these markets can exist is lack of confidence in generic bioequivalence and, potentially, manufacturing quality (Danzon et al., 2015; Danzon and Furukawa, 2008). Product brand names can serve as one counteracting institution against the impacts of quality uncertainty, providing consumers both a signal of quality and a means to retaliate against low-quality products by ceasing future purchase (Akerlof, 1970).

Globally, once branded, originator products lose patent protection, generic competitors can enter the market and compete with these products. To enter the market in high-income countries, generic producers must conduct bioequivalence studies, which are much cheaper than the expensive clinical trials required for proprietary medications. These bioequivalence studies ensure that generic and proprietary medications have the same therapeutic properties – namely that the generic mediation is absorbed in the body at the same rate and in the same amount as the originator product. Bioequivalent products are considered, at least medically, the same and thus many countries allow pharmacists to substitute therapeutically equivalent generic medications in place of more expensive proprietary medications. In India, during the time frame of this study, only generics coming to market within four years of the originator drug being approved in India were required to submit bioequivalence studies.[3] However, generics coming to market *after* this four year period only needed permission to manufacture a generic from state licensing authorities, with no bioequivalence studies required. Thus, companies selling generic medicines within India might wait until the four-year period had expired and apply to state licensing boards in the fifth year, waiving the necessity

[3]The Indian government amended laws in 2017 to make bioequivalence studies mandatory for certain – but not all – classes of generic drugs (Ministry of Health and Family Welfare, 2017). However, this is proactive as opposed to retroactive and does not ensure the bioequivalence of products already on the market.

of conducting bioequivalence studies. While companies may have conducted such studies, physicians and patients cannot be sure which generics have gone through bioequivalence tests and which have not.

Closely related to issues of bioequivalence is a potential lack of confidence in manufacturing quality due to the presence of low-quality or even fake medicines in the market. This can occur due to lax regulation or ineffective enforcement of good manufacturing practices, and leads to quality uncertainty amongst consumers. A mistrust of pharmaceutical quality can logically lead to a branded generics market, as producers can invest in establishing a reputation for quality with patients and physicians. This clearly can dampen pricing competition – if consumers are not confident about the quality of a locally-produced medication brand they are unfamiliar with, then they might not want to purchase this brand even if it is cheaper. While evidence on the prevalence of low-quality medicines is scarce, recent studies have found that about 10-15% of drugs fail quality testing in LMICs, suggesting that substandard medications pose a significant issue in these countries (Bate et al., 2011, 2015). The Indian government presents lower estimates of "non-standard quality" drugs in the Indian market, averaging around 6% of drugs.[4] However, even if incidents of harm due to substandard drugs are rare, if these incidents are publicized in local news, consumers are likely to be aware of them and lack confidence in drug quality. In a recent example, a case where 11 Indian children died after being poisoned by a tainted cough syrup made local and international news, suggesting such incidents are well publicized (Biswas, 2022).

1.1 Indian Pharmaceutical Market

The Indian pharmaceutical market is the third largest global market in volume and eleventh largest in sales (QuintilesIMS, 2016), valued at $18 billion in 2018 (IQVIA, 2018). Most medicines consumed in India are produced by the large, local generics manufacturing industry, with multinationals comprising approximately a quarter of sales (additional information about the retail market can be found in Section 3.2.). While there are an incredible number of manufacturers within the country – India's National Pharmaceutical Pricing Authority listed 10,563 total registered drug manufacturers in India during 2007 (National Pharmaceutical Pricing Authority, 2007) – over half of local sales are concentrated amongst the twenty largest local generics firms (Aggarwal, 2011). The Indian pharmaceutical industry is also a large exporter of generic medicines, with an estimated $17 billion in revenue from pharmaceutical exports in 2018 (IQVIA, 2018). As such,

[4]Table A1 in the Appendix details different estimates, which range from 11% in 2009-2010 to 3.18% in 2014-2016.

exports make up more than half of total revenues for the overall Indian pharmaceutical industry.

In India, the retail pharmaceutical supply chain flows from a pharmaceutical manufacturer to a Clearing and Forwarding Agent ("CFA"). The CFA, in turn will sell to stockists (also known as distributors or wholesalers), who in turn sell at a mark-up to retailers (generally pharmacists), who sell at an additional mark-up to consumers. Unique to India is the All India Origin of Chemists and Druggists (the "AIOCD"), a lobbying group for retail pharmacists and wholesalers with significant influence and market power. Approximately 90% of pharmacists in India belong to the AIOCD, and the organization works on their behalf to ensure a standardized minimum markup for retail pharmacists and wholesalers in their lobbying organization – generally 20% of retail price for pharmacists and 10% for wholesalers. On top of this negotiated retailer markup, pharmaceutical companies can employ other measures to encourage pharmacists to prescribe their drugs, namely sales representatives and free medication samples.

1.2 Price Control Legislation

India has a long history of regulating the prices of drugs and active pharmaceutical ingredients, dating back to the 1960s.[5] Prior to the legislation introduced in 2013, India already had in place price controls on 95 active pharmaceutical ingredients (also known as "bulk drugs"). Attempts by the government to reform and expand pharmaceutical price controls were met by significant resistance from the local pharmaceutical industry, and with reason – when the Indian government announced an intention to place price controls on essential medicines in 2006, the stock prices of local pharmaceutical firms plunged (Aggarwal, 2011).

Despite industry resistance, India expanded pharmaceutical price controls in 2013 by enacting the 2013 Drug Price Control Order. This legislation gave the government the ability to place price ceilings on formulations of the drugs in India's National List of Essential Medicines. India's National List of Essential Medicines is based on the World Health Organization (WHO)'s List of Essential Medicines, with adjustments based on local market characteristics. As with the WHO List of Essential Medicines, it is common for only certain formulations of a given molecule to be contained on the Indian National List of Essential Medicines.[6] For instance, the 250mg and 500mg dosages of amoxicillin, a commonly used antibiotic, are contained on the National List of Essential Medicines, but another commonly used

[5] Figure A1 in the appendix details the history of price controls in India dating back to the mid-1900s. Appendix Figure A2 details the timeline of the price controls studied in this paper.

[6] The process of selecting medicines to add to the WHO List of Essential Medicines has been criticized, partially for this reason. See, for instance, Barbui and Purgato (2014).

formulation – the 125mg dosage – is not. The Indian National List of Essential Medicines was first developed in 1996 and is not updated regularly – it was publicly updated in July 2011, and was not updated again until late 2015. In September 2013, the government began publishing and enforcing price ceilings for drugs on the National List of Essential Medicines. However, the process of setting price ceilings proved difficult with the large number of competitors on the market, and thus announcements of price ceilings were made gradually over the following months.

While the 2013 pharmaceutical price controls were anticipated by the pharmaceutical industry, in 2014 the Indian government implemented a second set of price controls that came as a surprise to the pharmaceutical industry. On July 10, 2014, the government announced price controls of an additional 108 formulations of diabetes and cardiovascular drugs not on the National List of Essential Medicines, citing internal guidelines that allowed for drugs to be price controlled if in the national interest. The Indian pharmaceutical industry initially refused to comply with this legislation and fought it in court. On September 29, 2014, courts ruled in favor of the pharmaceutical companies retrospectively – in other words, the price controls issued on July 10th remained in place, however moving forward only drugs on the National List of Essential Medicines could be assigned a price ceiling.

The Indian legislation uses market-based mechanisms to set price ceilings, with the rules depending on the number of drugs in a product class. Price ceilings are set using price to retailer, which is the price the pharmacist pays for medication, as opposed to maximum retail price, which is the price the manufacturer prints on the medication package. If there are multiple brands of drugs in a product class, the price ceiling is calculated by first taking the unweighted average price to retailer for all drugs with at least 1% market share, and then a 16% retailer markup is added to determine maximum retail price. If a drug is alone in its class, it receives a fixed-percentage price reduction based on the amount price ceilings reduced prices for similar categories of drugs.[7]

[7]The 2013 Drug Price Control Order did not just place ceilings on essential medicines. It also set retailer markup for price-controlled drugs at 16% for pharmacists and 8% for wholesalers, lower levels than the industry standards of 20% and 10%. This cut in retail margins raised significant furor from the pharmacist lobbying organization, AIOCD. Post-legislation there were wide-spread reports of wholesalers and pharmacists insisting on the standard 10% and 20% markups – forcing at least some producers to meet these demands (The Times of India, 2013).

2 Theoretical Impact of Pharmaceutical Price Ceilings

This section presents a theoretical model of the impacts of price ceilings on pharmaceutical prices and sales. While the traditional model of the off-patent pharmaceutical market would include two firm types – generic and branded – this scenario does not reflect India and other "branded generics" markets. To account for this, this section will include three firm types: a multinational firm ("multinational firm"), a local exporting generics firm with a strong reputation ("exporter firm"), and a less well-known, small, local generics firm ("local firm"). This model predicts that while all firms will decrease their price in response to a binding price ceiling, the high-quality multinational firm should gain market share and increase sales given constant quality parameters. Further, it shows that if marginal costs are sufficiently similar across producer types, local firms will be most likely to exit the market after the implementation of a price ceiling.

The model presented here assumes that quality levels are constant across time and that firms do not shift their quality in response to price control legislation. This may be the case when firm types are subject to different regulatory standards or liability standards which lead to minimum levels of product quality that cannot shift. The assumption of constant quality may also be justified when price controls are partial, and do not cover all products sold by a given producer. In these situations, firms are not likely to shift quality level if quality is in any way observable, as it could damage their reputation in more lucrative markets where there are no price controls.

2.1 Laissez-Faire Market

In a laissez-faire branded generics market, consumers perceive quality differences in products manufactured by different firm types. In these markets there are three types of firms operating, each with different perceived quality levels: multinational firms, who are the original developers of medicines, exporting generics firms, who invest in brand recognition, and smaller, local generics firms who sell only in the local geographic area and generally do not invest in brand name recognition. Within this framework, the perceived quality difference of the multinational drug and local drug is notated by α and the perceived quality difference of the exporter drug and local drug is denoted by β, where $\alpha > \beta > 1$. Further, consumers have different valuations of a given drug, denoted by ν, which is uniformly distributed between $[0, v]$.

Given these parameters, the utility for a consumer buying a product from producer i becomes:

$$U_\theta = \begin{cases} \alpha\nu - p_m & \text{if } i = m \\ \beta\nu - p_e & \text{if } i = e \\ \nu - p_l & \text{if } i = l \end{cases}$$

where m indexes multinational companies, e indexes well-known exporting firms, and l indexes local firms. A consumer will be indifferent between the multinational and exporter product when $p_m - p_e = \nu(\alpha - \beta)$, and will be indifferent between an exporter product and local product when $p_e - p_l = \nu(\beta - 1)$. The multinational and local products in this scenario do not directly compete, but may indirectly impact each others strategies due to their impacts on the exporter firms.

In this setting, firms first establish their quality or reputation level and then compete in a Bertrand game, simultaneously setting prices to maximize profits. It is plausible that different manufacturer types do not have the same marginal costs. Assuming, therefore, that marginal costs, denoted as c_i, are constant but differ by producer type, producer profits become:

$\pi_i = (p_i - c_i)D_i$

Given this, firms' best-response functions in reaction to a change in multinational prices are:

$$p_e(p_m) = \frac{(\beta - 1)p_m + (\alpha - \beta)\frac{c_l}{2} + (\alpha - 1)c_e}{\alpha(2 - \frac{1}{2\beta}) - \frac{3}{2}}$$

$$p_l(p_m) = \frac{(\beta - 1)p_m + 2\beta(\alpha - 1)c_l + (\alpha - 1)c_e}{4\alpha\beta - \alpha - 3\beta}$$

It can already be seen that, under these market conditions:

$\frac{\delta p_i}{\delta p_j} > 0$ for all $i \neq j$

Given these paramenters, the market share of branded products, denoted as ω, is:

$$\omega = \frac{v(\alpha - \beta) - p_m + p_e}{(v - p_l)(\alpha - \beta)}$$

2.2 Price Ceiling Legislation

Since the price ceilings in India were binding on the high-priced firm(s) by design, there is no need to consider the case of a non-binding price ceiling. If a price ceiling is binding on only the multinational firm, the multinational firm will drop its price to the ceiling price, $\bar{p}$. Given its best response function, the

exporting firm will drop its price in response to a mandated price decrease for the multinational product. In response to the drop in price amongst the exporting firms, the local firm will drop its price. Thus, even if the multinational firm is the only firm directly impacted by a price ceiling, all firm types would lower prices to the following levels:

$$p_m^{pc} = \bar{p}$$

$$p_e^{pc} = \frac{(\beta-1)\bar{p} + (\alpha-\beta)\frac{c_l}{2} + (\alpha-1)c_e}{\alpha(2-\frac{1}{2\beta}) - \frac{3}{2}}$$

$$p_l^{pc} = \frac{(\beta-1)\bar{p} + 2\beta(\alpha-1)c_l + (\alpha-1)c_e}{4\alpha\beta - \alpha - 3\beta}$$

As $\bar{p} < p_m^{lf}$, or the ceiling price is below the laissez-faire multinational price, all firm prices are clearly below laissez-faire levels. This is an intuitive response, as firms in this context are strategic substitutes and thus likely to respond to a decrease in price by competitors despite not being required by law to lower their price.

Demand for the multinational product in this market can be represented by the difference in prices and quality levels between the multinational products and its direct competitor, the exporting product as:

$$D_m = 1 - \frac{p_m - p_e}{v(\alpha-\beta)}$$

Though both products decrease price and quality levels are constant, as $\delta p_e/\delta p_m < 1$, demand for the multinational product will rise post-legislation. This result will hold even in markets where not all firm types are active, as shown in Appendix Section D.1.

The increase in demand for multinational products leads to a corresponding increase in market share for multinational products as:

$$\frac{\delta w}{\delta p_m} = \frac{(v-p_l)(\frac{\delta p_e}{\delta p_m} - 1) + \frac{\delta p_l}{\delta p_m}(p_e - p_m + v(\alpha-\beta))}{(v-p_l)^2(\alpha-\beta)} < 0$$

Even when the price ceiling is only binding on multinational firms, critical points for firms to exit markets are as follows:

Multinational firm exit will occur when: $\bar{p} < c_m$

Exporting firm exit will occur when: $\bar{p} < \frac{c_e(\alpha - \frac{1}{2} - \frac{\beta}{2}) - (\alpha-\beta)\frac{c_l}{2}}{(\beta-1)}$

Local firm exit will occur when: $\bar{p} < \dfrac{c_l(2\alpha\beta - \alpha - \beta) + (\alpha - 1)c_e}{(\beta - 1)}$

Assuming marginal cost parameters are sufficiently close or quality parameters are sufficiently different, a binding price ceiling on multinational firms is most likely to lead to *local* firm exit - a somewhat counterintuitive finding. The assumption of relatively similar marginal cost parameters is a valid one in many markets. It is not inherently more expensive to produce the same molecule under a brand name versus a generic name. Further, while quality assurance and reputation building come with associated costs, they are likely to be associated with larger firms, which have market power to negotiate with suppliers and better economies of scales than smaller firms.

An alternative way to think about this finding is that profit margins play into firm decisions to exit markets post-legislation. As shown in Section 3.2, multinational products are priced on average 25% more than exporter firms and 22% more than local firms. Exporter firms, in turn, price products on average 8% more than local firms. Unless differences in costs are larger than these pricing differences, it is multinational firms that have the highest margins, and local firms who have the narrowest margins.

2.2.1 Loosening the Constant Marginal Cost Assumption

A general assumption in models of the pharmaceutical industry is that of constant marginal costs within a country (e.g. Brekke et al. (2011), Cabrales (2003), and Jack and Lanjouw (2005)). With respect to pharmaceutical production these assumptions can generally be considered valid within reasonable bounds of production. However, an important caveat unique to LMICs are rising costs of distribution with volume, largely driven by the high costs to reach rural areas. This is known as the "last-mile" problem, with the last mile of the distribution chain being the most expensive. In rural areas of LMICs the last-mile of the pharmaceutical distribution chain is disproportionately expensive due to sparsely populated villages, lack of paved roads, and dearth of other necessary infrastructure (e.g. cold chain capabilities and health facilities) (Buckley and Gostin, 2013). While this model expands on previous analyses by allowing different firm types to have different marginal costs, as may be the case in an LMIC market, it does not allow for the increasing distribution costs.

Appendix D.2 shows that loosening the constant marginal cost assumption can have important implications on the predictions from the model. Allowing for increasing marginal costs makes the impact of price

ceilings on quantity supplied ambiguous – with firms response to the price control legislation dependent on both on the shape of the marginal cost curve and the level price ceilings are set.

2.3 Model Predictions

In summary, a price ceiling can distort the laissez-faire market equilibrium by lowering prices of not only directly-affected products, but also products priced ex-ante below the price ceiling. Demand for the high-priced, high-reputation products will increase, and these products will see an increase in market share. Further, producer exit will not necessarily result unless price ceilings are sufficiently low. However, if marginal costs are similar across firm types, price ceilings are most likely to lead to exit of low-priced firms – a somewhat counterintuitive finding as these firms are least directly affected by price ceiling legislation. This set of findings leads to three testable predictions:

Prediction 1: Prices of products will fall amongst all firm types post-legislation, even if these products were ex-ante priced below the set price ceiling.

Prediction 2: Multinational products will see both an increase in sales and in market-share post-legislation. However, when loosening constant marginal cost assumptions, the effect on multinational market share and sales is ambiguous.

Prediction 3: Assuming sufficiently similar marginal costs or sufficiently different quality parameters across producer types, producer exit is most likely to occur for local firms.

3 Methodology

The analysis makes use of the fact that the price controls implemented in India were partial in nature to compare sales and pricing of price-controlled drugs to non-controlled drugs. This section will describe the data used in the study, review characteristics of the Indian retail market, and then describe in detail the estimation strategy used to measure the impacts of the price control legislation.

3.1 Data Description

The primary data source used in this analysis is a database of retail sales data obtained from the All India Origin of Chemists and Druggists (AIOCD) Advance Warning Action & Correction System, henceforth

referred to as the "AIOCD" data. This data is collected in a joint effort between AIOCD, the national pharmacist trade union, and a private pharmaceutical research company. The data is collected electronically from a representative sample of AIOCD's member pharmacies and projected to national levels. Given that the data only includes the retail market, it does not cover products dispensed in hospital settings. The AIOCD data is primarily bought and used by private companies to track market trends in the Indian retail pharmaceutical market (AIOCD-AWACS, 2017). While the data is marketed primarily towards private companies, it has previously been used in academic research on the Indian pharmaceutical market (see for instance, Abrol et al. (2016); Mohapatra and Chatterjee (2016); Bhaskarabhatla et al. (2017)). The AIOCD data is available monthly from 2012 to 2015 at the stock keeping unit (SKU) level and includes detailed monthly pricing and sales data.

Data on price ceilings comes from the National Pharmaceutical Price Authority, the government body responsible for regulating pharmaceutical prices in India. The National Pharmaceutical Price Authority publicly lists implemented price ceilings and the date they went into effect (National Pharmaceutical Pricing Authority, 2014).

This paper segments producers into three types for analysis: *multinational* companies, large *exporting* generics firms, which typically export generics to other countries, produce branded generics locally, and generally invest in reputation, and small *local* generics firms, which often sell in smaller geographic areas, invest little in reputation, and produce a mix of unbranded and branded generics. These firm types will be referred to respectively as multinational, exporting, and local producers throughout the paper. Multinational companies are defined as being headquartered outside of India. To separate the large "exporting" firms from the smaller "local" firms, this paper identifies Indian producers as "exporters" if they have at least one World Health Organization Good Manufacturing Practices (WHO GMP) Plant Approval. Large institutional procurement agencies that operate internationally – such as UNICEF or the Global Fund – and countries purchasing bulk medicines generally require products to meet WHO GMP standards, thus this classification signifies that a company is likely to export products. This classification is also highly correlated with company size – all of the top 20 companies headquartered in India have at least one WHO GMP plant. Data on WHO GMP plant approvals for Indian producers comes from the Central Drugs Standard Control Organization, a department of the Indian government's Ministry of Health & Family Welfare. The department publishes a report "WHO GMP Certified Manufacturing Units for Certificate of

Pharmaceutical Products (COPP) in Various States of India" which contains names and addresses of all WHO GMP Certified manufacturers in India (Central Drugs Standard Control Organization, 2015).

To assess whether producer type is actually associated with drug quality, this analysis makes use of a unique set of data from the Food and Drugs Control Administration (FDCA) of India. The FDCA collects a randomized sample of drugs at various points of the drug pipeline (direct from manufacturers, wholesalers, pharmacists, and government hospitals) and tests these drugs for a wide range of quality characteristics. This data is collected over time and includes brand name, batch number, date and location of sample collection, and manufacturer name and location. If a drug fails testing, the FDCA penalizes the producing company, sends a text message to all registered pharmacists with the drug and manufacturer name and batch number, and additionally publishes the manufacturing information for drugs that fail quality testing on a website available to the public for a period of six months. Reasons for failing quality testing in this sample can be in Appendix Table A2.

The data used to determine a company's quality level comes from two sources of FDCA data. The first data source is the full set of drugs which failed FDCA quality control testing between 2010 and 2015, which was scraped over time from the publicly available website. The second source of FDCA data is a set of full testing data – which includes information on drugs that both passed and failed quality testing – for a group of field offices between 2013 and 2014. This second data set allows me to adjust for non-random sampling on the part of the FDCA.

3.2 Indian Retail Market Characteristics

The AIOCD data includes data on retail sales from 865 companies and 58,714 different drug brands. Given that there may be multiple stock keeping units (SKUs) for a given drug brand (e.g. there might be a 10-pack and 20-pack of the same brand, which would each present as a separate SKU), there are a total of 103,067 unique SKUs in the data. Despite a large number of competitors in generic markets – the median number of brands in a given market is 5, but the mean is nearly 21 – most markets are concentrated, as shown in Appendix Table A3. Prior to implementation of price controls, the mean Herfindahl-Hirschman Index (HHI) for a product market is 4890[8], with 77% of markets considered to be highly concentrated.

[8]This classification of HHI defines a market at the subgroup level, using the European Pharmaceutical Market Research Association (EPhMRA) guidelines to define a subgroup. A subgroup is generally defined as a molecule or molecule combination, e.g. ibuprofen or ibuprofen and acetaminophen.

3.2.1 Characteristics of Local, Exporting, and Multinational Firms

There are 873 manufacturers in the AIOCD data, of which 638 are local firms, 184 are exporter firms, and 51 are multinational firms. While exporting companies make up only 21% of firms operating in the retail segment, they comprise 67% of sales. Multinationals, while only 6% of firms, make up 25% of sales, and local firms, while vast in number (73% of firms), make up only 9% of sales. Not all producer types are active in a given product market. An obvious case of this is on-patent medications, where generally only a multinational firm is active. Multinational firms have only entered 50% of Indian product markets, while exporter and local firms have entered 88% and 65% of product markets, respectively. To account for the fact that firms enter different markets, Table A4 shows average price ratios for different firm types producing in the same market with the same formulation and package size prior to the implementation of price controls. In the same markets, multinational products are priced on average 25% and 22% more than products produced by exporting and local firms, respectively, and products sold by exporting firms are priced 8% more than those produced by local firms.

The pricing differences between firms producing the same medications indicate that consumers perceive some quality difference. However, it is unclear if such quality differences exist in reality. Firms often have multiple manufacturing plants, and these do not always meet the same regulatory requirements. For instance, a manufacturer might have a U.S. FDA approved manufacturing plant, a separate WHO GMP approved plant, and a third manufacturing plant that meets Indian manufacturing requirements, which are generally considered less stringent. While these standards should all guarantee a high-quality product, they require different levels of paperwork and oversight. Thus, even if a manufacturer is capable of producing medications to any regulatory standard, the products they sell in the Indian market may not be meeting the same standards as the products they export.

Table 1 presents results on quality derived from the FDCA data. Of the 865 companies in the AIOCD retail data, 230 show up in the FDCA data. Column (1) presents the average number of times a company's products show up in the data on drug failures collected by the FDCA, and Column (2) presents the average number of times a company's products show up in the sample of FDCA testing data. Column (3) shows the ratio of average drug failures to average drug tests for each company type. Local companies have the highest ratio of drug failures to drug tests at 1.8, while exporting and multinationals firms have ratios less

than half that size, at 0.89 and 0.67 respectively.[9] It is worth noting that confidence intervals on these figures are quite high, largely due to the high number of zeros in the data, but nevertheless this data does point to differential quality levels between these three firm types – local firms are more than twice and three times as likely to fail quality testing as compared to exporter and multinational firms, respectively. This quality differential is correlated to firm pricing, reflecting the fact that that multinational firms are priced on average 22% more than local firms, and exporter firms are priced on average 8% more than local firms.

Firm Type	Avg. # Failures	Avg. # Tests	Avg Ratio Failures to Tests
Local	0.20	0.11	1.82
	(0.67)	(0.41)	(1.07)
Exporter	1.11	1.25	0.89
	(1.44)	(1.72)	(0.75)
Multinational	0.53	0.78	0.67
	(1.06)	(1.72)	(1.96)

Average number of failures is measured as the average number of times a manufacturer's products appear in the FDCA "not standard quality" drug data. If a manufacturer does not appear in this data, it is included in the calculation of the average as showing up zero times. Average number of tests is the average number of times a manufacturer's products appear in the full sample of FDCA testing data. This sample is approximately 5% of total testing data for this time period.

Table 1: Average Product Failure and Test Rate by Firm Type

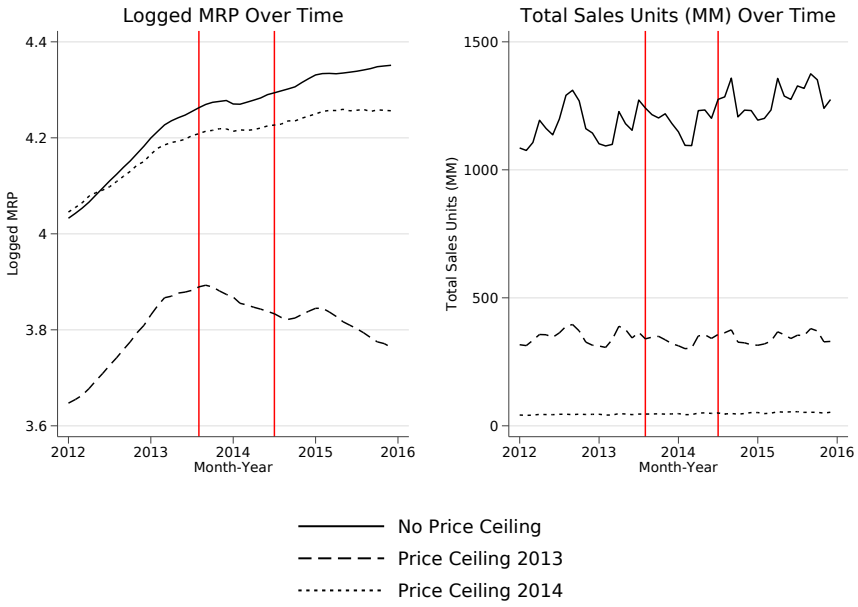
3.2.2 Characteristics of Price Controlled Products

Approximately 25% of the retail pharmaceutical market in India received a price ceiling (21% in value). Table A5 shows the characteristics of uncontrolled and controlled products. The products generally look similar, however the 2014 price controls took place in more competitive markets (lower HHI), and covered only chronic products. Table A6 shows the average markdown required by the legislation for each company type. Multinational firms see an required markdown of ₹254 for products priced above the price ceiling, versus ₹261 for exporter firms and ₹113 for local firms.

Figure 1 shows pricing and sales trends for non-controlled products and products given price controls in 2013 and 2014. Figure 2 presents market share over time for local, exporter, and multinational firms. While

[9] As the ratios in Column (3) are relatively meaningless, assuming that the testing data is approximately 5% of the total testing data for the 2010-2015 time period provides drug failure rates of 9.09%, 4.44%, and 3.33%, for local, exporter, and multinational firms, respectively.

multinational market share is declining across markets pre-legislation, the market share of multinational firms stabilizes for price-controlled products after the legislation.



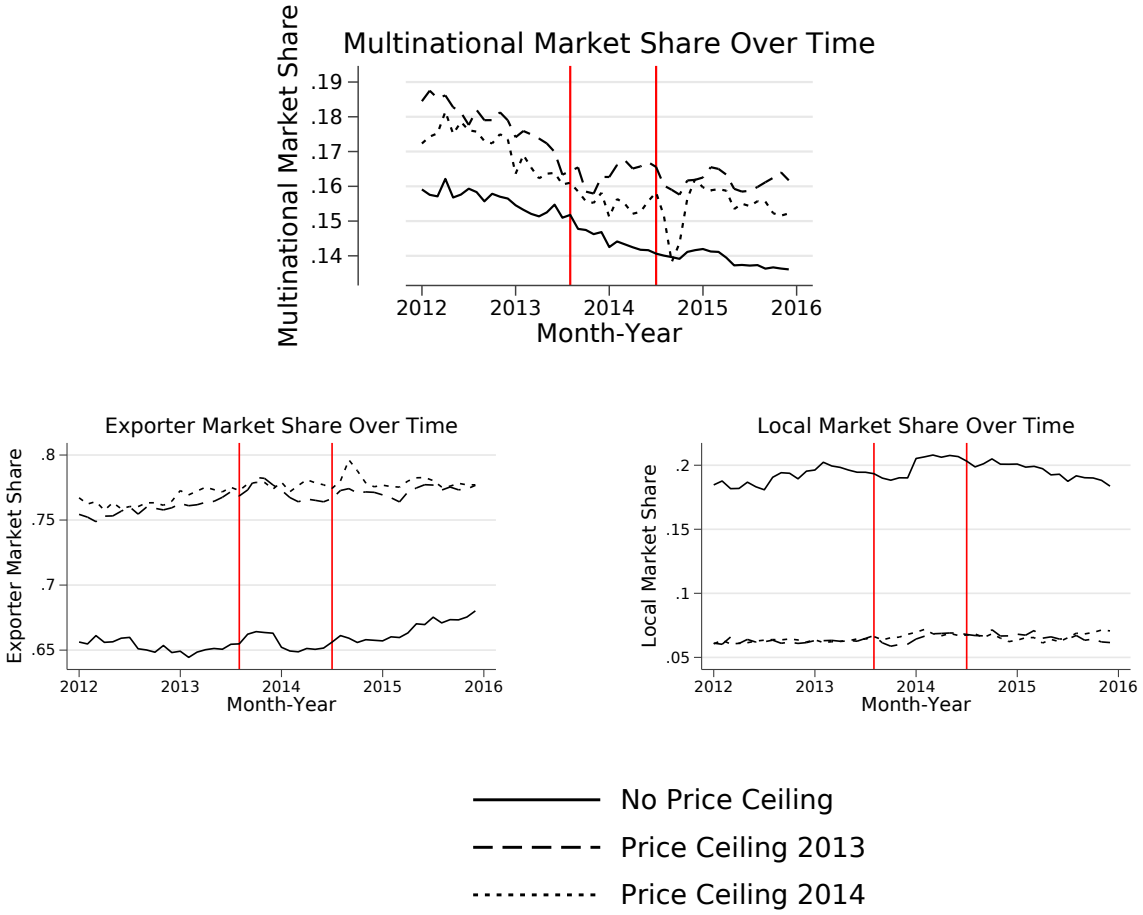
† Pricing data shown here are three-month rolling averages. Total sales units are not normalized by product dosage.

Figure 1: Time Series Trends for Logged MRP and Total Sales Units

3.3 Estimation Strategy

The empirical strategy used in this study compares changes in outcomes of interest for products placed under price controls to products not placed under price controls in a multi-period difference-in-difference framework. A key identifying assumption in this empirical strategy is that absent the price control legislation, the price-controlled products would have trended similarly to the non price-controlled products. Empirical evidence supporting this assumption follows in Section 4. Also essential to this identification strategy is avoiding issues of "spillovers" from the medications that received a price ceiling to those that did not.[10] This is particularly important given the design of India's price control legislation, in which only certain drug dosages and formulations received a price ceiling. Therefore, all analyses exclude drugs in controlled therapeutic classes that did not receive a price control because these are particularly likely to

[10]This issue of "spillovers" has been raised in other markets with partial price controls – for instance, Marks (1984) provides a discussion of this issue in the context of rent controls.



† Market share is calculated for each product, where products are defined at the EPhMRA subgroup level.

Figure 2: Time Series Trends for Branded, Exporter, and Local Firm Market Shares

see spillover effects from the legislation and thus do not serve as a clean control group. To identify these medications, products are categorized using the European Pharmaceutical Market Research Association (EPhMRA) classification system, with additional sub-groups included for products unique to the Indian market.

Further, a growing literature documents that when there are heterogeneous treatment effects, standard ordinary least squares (OLS) two-way fixed effects models can create biased estimates if the treatment effect is correlated with the timing of treatment (see, for example, Goodman-Bacon (2021); Callaway and Sant'Anna (2021); Sun and Abraham (2021); de Chaisemartin and D'Haultfœuille (2020); Borusyak et al. (2021)). Despite only having two waves of price controls, this is nonetheless a valid concern for this setting

as the first set of price controls included a much broader set of drugs and the second wave only included diabetes and cardiovascular drugs, thus impacts of price controls may differ between these two groups. Further, each wave of price controls was implemented over a number of months, making the effective number of treatment waves greater than two. To account for these concerns, I run multiple specifications based on recent literature. Specifics follow.

3.3.1 Testing Prediction 1

Prediction 1 hypothesizes that prices of products will fall amongst all firm types post-legislation, even amongst prices ex-ante priced below the price ceiling. To assess the overall magnitude of the short-term effect of the legislation on prices, the main analysis employs a difference-in-differences framework. The estimation strategy assumes the true causal outcome for SKU i in month-year t is shown in Equation 1:

$$log(y_{it}) = \alpha s_i + \lambda m_t + \delta c_{it} + \epsilon_{it} \tag{1}$$

where outcome y_{it} is maximum retail price (MRP). SKU fixed effects, s_i, control for time-invariant differences between SKUs, and month-year fixed effects, m_t, control for market-wide time effects. The binary variable c_{it} indicates whether a given SKU has been assigned a price ceiling in a given month-year, where C_i is the first month a given SKU receives a price control and $c_{it} = 1[t \geq Ci]$. Thus δ, the coefficient of interest, measures the effect of the price control legislation.

To characterize the treatment effects, I use the imputation estimator proposed by Borusyak et al. (2021). This approach consists of three steps: first, the SKU and month-year fixed effects are estimated using OLS on untreated observations only (on the subsample of data where $c_{it} = 0$) using Equation 2:

$$log(y_{it}) = \alpha s_i + \lambda m_t + \sum_{n=-12}^{-1} \gamma_n 1[t = C_i + n] + \epsilon_{it} \tag{2}$$

In this regression, $1[t = C_i + n]$ is a set of indicator variables indicating a SKU is being treated 1 to 12 months later, with the comparison group including all SKUs where treatment does not happen or happens more than 12 months later. In addition to examining the magnitude of $\hat{\gamma}_n$, I also run a conventional joint test of $\gamma_n = 0$. Importantly, though it differs from conventional methods to test for differences in pre-trends, this step provides empirical evidence for the validity of the parallel trends assumption. As noted in

Borusyak et al. (2021), this method has three main advantages over conventional pre-trend testing methods: it separates validation of the assumption of parallel trends from the estimation, it improves efficiency of treatment effect estimation as all untreated observations are used for imputation, and it removes the correlation between the treatment effect and pre-trend estimators, which can introduce bias (Roth, 2022).

In the second step of the Borusyak et al. (2021) approach, unbiased estimates of $\hat{\delta}_{it} = log(y_{it}) - \hat{\alpha}_i - \hat{\lambda}_t$ are obtained for each price-controlled observation. As shown in Borusyak et al. (2021), the average of $\hat{\delta}_{it}$ across many observations can be estimated consistently under appropriate regularity conditions. Thus, the third step estimates the average effect of price controls for all months n since implementation of the price control as:

$$\hat{\delta}_n = \frac{1}{|I_n|} = \sum_{i \in I_n} \hat{\delta}_{i,C_i+n} \tag{3}$$

where I_n is the set of SKUs with price controls in period $C_i + n$. Using these estimates, I also estimate the joint effect of $\hat{\delta}$ across all treated observations. The first set of estimates is an event study approach, while the second provides one overall average treatment effect on the treated (ATT) estimate.

The model predicts that all manufacturer types and products ex-ante priced below the price ceiling will decrease their price in response to price controls. To test this, I also run regressions separately by manufacturer type and for drugs that were ex-ante priced below and above the price ceiling. Given that price ceiling levels are only available for the treated drugs, for the control group of non-treated drugs, this analysis uses the rules set by National Pharmaceutical Pricing Authority as defined in Section 1.2 to define artificial price ceilings for non-treated drugs. This allows classification of non-treated drugs as being ex-ante below or above this artificial price ceiling.

A number of robustness tests are shown in the appendix. These include estimating Equation 1 using the estimation approach of Callaway and Sant'Anna (2021) as well as a traditional approach using OLS with two-way fixed effects. Also included are regressions excluding products which exit during the time frame of the study and results excluding low volume products. Last, the appendix includes an analysis of the effect of the legislation on the spillover products excluded from the main analysis, which are highly similar to price-controlled drugs (e.g. same molecule in a different dosage) but do not receive a direct price control.

3.3.2 Testing Prediction 2

Prediction 2 hypothesizes that multinational products will see both an increase in sales and in market-share post-legislation. To identify the impact on units sold, I use the same estimation strategy described in the test of prediction one, with the outcome variable y_{it} as units sold.

To identify the impacts of the legislation on multinational market share, I estimate the following fractional probit model:

$$E[s_{it}|m, c] = \Phi(\beta + \alpha m_t + \delta c_{it}) \tag{4}$$

where i indexes products, t indexes month-year, m_t denotes month-year, c_{it} denotes an assigned price ceiling, and s_{it} is the market share of originator, exporter, and local firms for a given molecule (e.g. ibuprofen). To estimate this model using panel data, I follow Papke and Wooldridge (2008) in using a generalized estimating equation (GEE) with standard errors robust to heteroskedasticity and serial correlation. As in Papke and Wooldridge, I also estimate average partial effects ("APEs") with bootstrapped standard errors. An alternative linear specification with fixed effects can be found in the appendix.

3.3.3 Testing Prediction 3

Prediction 3 hypothesizes that producer exit is most likely to occur for local firms. To estimate producer exit, this paper estimates the following probit model at the SKU and product-company levels:

$$E[Y|\beta \mathbf{X}_i] = \beta_0 + \beta_1 c_i + \beta_2 f_i + \beta_3 c_i * f_i + \mathbf{B}_i + \epsilon_{it} \tag{5}$$

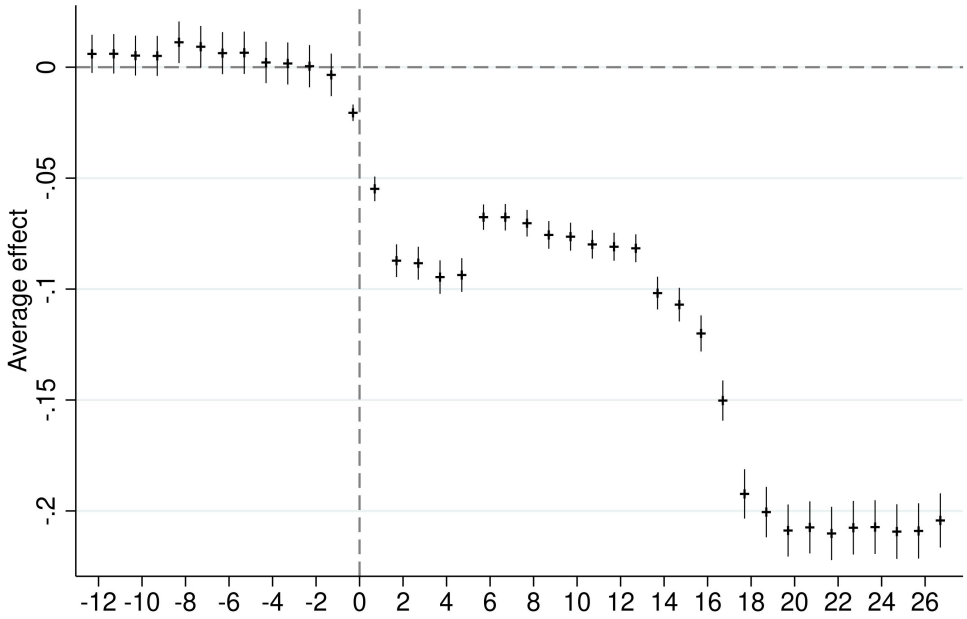
where c_i indicates a product received a price ceiling, f_i indicates manufacturer type, and Y is an indicator variable for whether a given SKU or company exits the market after September 2013, when the first legislation was launched. Controls $\mathbf{B}_i$ are product age, acute or chronic drug type, and drug formulation (e.g. pill, injection). In alternate specifications, I add an interaction between the price ceiling and market concentration, as measured by HHI.

4 Results

4.1 Testing Prediction 1: Evidence on the Impact of the Price Controls on Market Prices

Prediction 1 from the model predicts that in a vertically differentiated market, all products will decrease their prices in response to a price ceiling, even if the price ceiling is only binding on the high-quality, high-priced firm.

Results of the analysis on the impacts of price ceilings on market prices can be found in Figure 3 and Table 2. As shown in Figure 3, prices trend similarly prior to the implementation of price controls and then decline significantly for price-controlled products compared to control groups after price controls are put in place. This lends empirical support to the parallel trends assumptions, as it shows pre-trends were similar between treated and comparison groups with the exception of one month in the pre-period. Table 2 shows the joint effect of the price controls across all price-controlled observations. Column (1), which represents the overall effect of the price ceilings on logged retail price, shows that prices of price-controlled products dropped by approximately 9.2% as compared to the non-controlled market. Columns (2)-(4) shows these same results separately by company type. As predicted by the model, the three company types all decrease prices in response to the price ceiling. Unsurprisingly, multinational companies have the largest price decreases, as the price ceilings required the largest markdown for these firms. To test the mechanism in the theoretical model – that even products priced below the ceiling will decrease their price – Columns (5) and (6) presents outcomes for products that were ex-ante priced above and below the price ceiling. As predicted by the model, even products priced ex-ante below the price ceiling decrease their price in response to the legislation, though by less so than those directly impacted. Results in Appendix Section G show that these findings are not driven by producer exit, are robust to excluding small SKUs, and are similar when estimated using the strategy proposed by Callaway and Sant'Anna (2021) and by the traditional OLS two-way fixed effects approach.



† Graph displays treatment effect estimates using the Borusyak et al. (2021) imputation estimator, with point estimates and 95% confidence intervals estimated following Equation 2 and Equation 3. The outcome variable is logged MRP. Standard errors are clustered at the SKU level. Products from spillover groups are excluded from this analysis.

Figure 3: Effect of Price Ceilings on MRP

	(1)	(2)	(3)	(4)	(5)	(6)
		Manufacturer Type			Ex-Ante Price	
	Main Effect	Local	Exporter	Multinational	Above Ceiling	Below Ceiling
	Logged MRP					
ATT	-0.092***	-0.096***	-0.085***	-0.137***	-0.094***	-0.075***
	(0.003)	(0.005)	(0.004)	(0.010)	(0.004)	(0.006)
Observations	3,611,476	1,187,742	2,071,135	352,599	2,462,895	1,148,581

† Table displays joint treatment effect estimates and standard errors calculated using the Borusyak et al. (2021) imputation estimator. The outcome variable is logged MRP. Standard errors are clustered at the SKU level. Products from spillover groups are excluded from this analysis.
+p<0.10, *p<0.05, **p<0.01, ***p<0.001

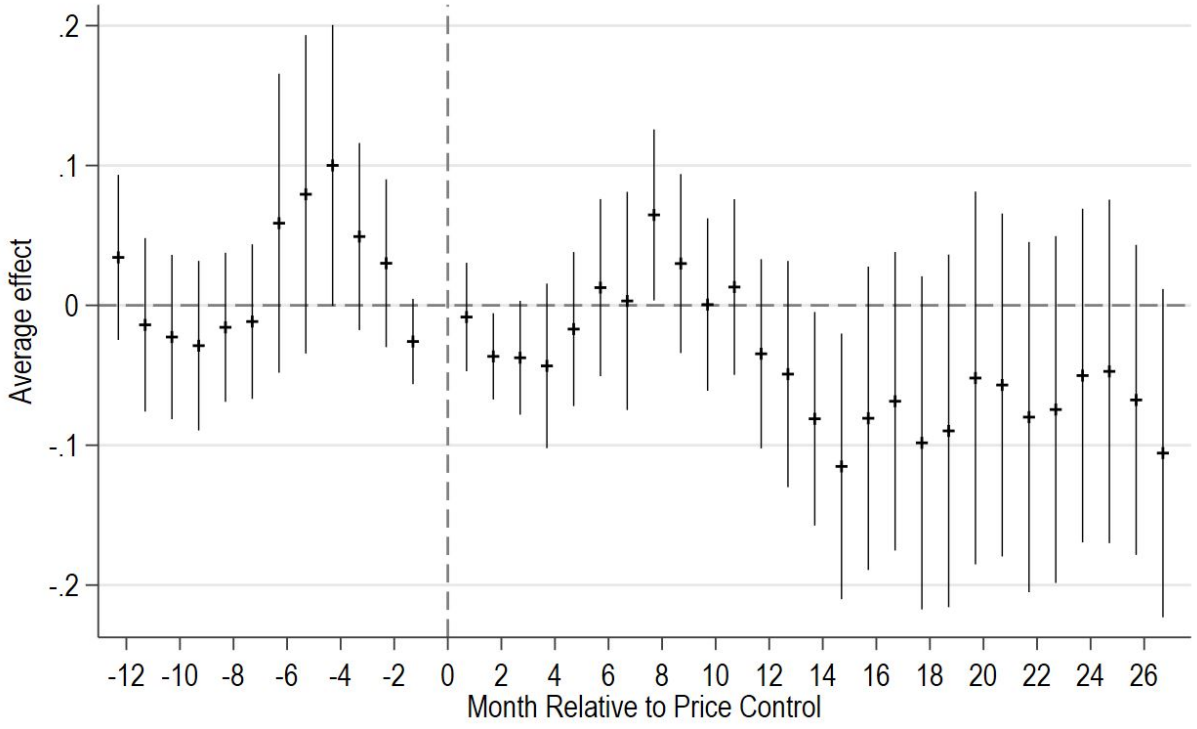
Table 2: Effect of Price Ceilings on MRP

Section G in the Appendix also analyzes the impact of the legislation on the prices of "spillover" products, which are direct competitors of price-controlled products and thus excluded from the main analysis. These results show a small but significant (-0.039, p-value: ¡0.01) decrease in the prices of spillover

products post-legislation, suggesting that the mandated price decreases had wider reaching impacts even on products that were not directly impacted by the legislation.

The results here indicate that Prediction 1 is met. The price control legislation lead to reduced prices not only for directly impacted products, but also for products priced below price-ceilings ex-ante and for close competitors of price-controlled products.

4.2 Testing Prediction 2: Evidence on the Impact of the Policy on Relevant Sales and Market Shares



† Graph displays treatment effect estimates using the Borusyak et al. (2021) imputation estimator, with point estimates and 95% confidence intervals estimated following Equation 2 and Equation 3. The outcome variable is logged sales units. Standard errors are clustered at the SKU level. Products from spillover groups are excluded from this analysis.

Figure 4: Effect of Price Ceilings on Sales Units

Figure 4 shows the impact of price controls on units of price-controlled products sold over time. While estimates are noisy, it shows sales were trending similarly prior to the implementation of price controls, but then there was a directional but mostly non-significant decrease in sales starting about one year after

Panel A: Effect of Price Ceilings by Firm Type				
	(1)	(2)	(3)	(4)
			Firm Type	
	Main Effect	Local	Exporter	Multinational
ATT	-0.015	-0.023	-0.018	-0.011
	(0.013)	(0.023)	(0.017)	(0.047)
Observations	3,611,476	1,187,742	2,071,135	352,599

Panel B: Effect of Price Ceilings by Market Impact					
	(1)	(2)	(3)	(4)	(5)
			Price-Control Impact		
	Main Effect	Low Impact	Low-Mid Impact	Mid-High Impact	High Impact
ATT	-0.015	0.048*	-0.015	-0.042	-0.127***
	(0.013)	(0.020)	(0.022)	(0.031)	(0.036)
Observations	3,611,476	3,436,954	3,389,676	3,300,935	3,281,724

† Table displays joint treatment effect estimates and standard errors calculated using the Borusyak et al. (2021) imputation estimator. The outcome variable is logged sales units. Standard errors are clustered at the SKU level. Products from spillover groups are excluded from this analysis.
+p<0.10, *p<0.05, **p<0.01, ***p<0.001

Table 3: Effect of Price Ceilings on Sales Units

implementation of price controls. This lends empirical support to the parallel trends assumptions, as pre-trends in logged sales were similar between treated and comparison groups. Panel A of Table 3 presents the overall affect of the legislation by firm type. It shows no significant effect of the price control legislation on sales by multinational firms, counter to the predictions of the model.

To understand why this might be the case, I examine an interesting quirk of the Indian legislation. Due to price ceilings being set based on *unweighted* average market prices, certain classes of medications were more impacted than others. For instance, in some markets the main producers might be the highest-priced, and that market would see a large weighted average price decrease. On the converse, the top seller in another market might be a relatively low-priced producer, and in this market the average required price decrease might be near zero. This can have important implications for producer manufacturing decisions, as the theoretical model predicts that restrictive price ceilings increasingly dampen generic competition. To test this prediction of the model, this analysis calculates the volume-weighted price decrease that was directly imposed in each price-controlled market. It then subsegments price controlled markets into quartiles based on the *weighted* markdown imposed on that market, with non-price controlled drugs as a control group. Table 3 Panel B presents results. As can be seen in Column (1), there is no significant overall impact of the

legislation on sales[11]. However, in low-impact markets, there is an increase in units sold, fitting with the economic model[12]. This increase, however, is offset by a significant decrease in units sold in markets that were highly impacted by the price control legislation. This decrease could be due to firms either decreasing production or fully exiting markets that were highly impacted. Appendix Table A11 shows that excluding firms that exit markets after price control legislation from the analysis provides similar results, suggesting that exit alone is not driving the decrease in sales in highly impacted markets.

To understand the overall impact on sales post-legislation, it is also important to also look at the "spillover markets" – in other words to look at potential substitutes for price-controlled products that did not receive a price ceiling. Appendix Table A12 aggregates sales to the broader product[13] level – combining sales of both price-controlled and spillover formulations of products – and shows that in product markets where a portion of products received price ceilings, there is no significant change (-0.199, p-value: 0.079) in sales post-legislation. Further, Appendix Table A13 shows there was no uptick in sales amongst spillover markets.

Put together, these results show that reductions in sales in highly-impacted markets are driven by decreased sales of price-controlled versus product exit or cannibalization of sales by spillover products. There are two likely explanations for this phenomenon. One might be a reduction in demand due to decreased firm marketing and promotional expenditures. Optimal advertising levels are dependent on the margins a firm can earn (Schmalensee, 1972). As prices are forced below their laissez-faire levels, firms' margins shrink and thus optimal marketing levels are likely to shrink as well. Marketing in this setting can take the form of sales representatives,[14] advertisements, and free samples or discounts to wholesalers and retailers. As most of the products receiving a price control in this setting are not new, innovative medicines, an informational component may arise through demonstrating a product's quality, however it is unlikely to educate a pharmacist or physician about the inherent benefits of the drug itself. If firm marketing is persuasive in encouraging medicine use, and this marketing decreases post-legislation, this may – at least partially – explain the decrease in sales. A corollary can be seen in evidence from high-income countries

[11] Regressions estimated using different estimation strategies find similar results, as shown in Appendix Table A9.

[12] Appendix Table A10 shows these same results by firm type. Results for multinational firms are directionaly similar to the overall results, though non-significant.

[13] For this analysis, I define a product at the molecule or molecule-combination level, regardless of dosage. As an example, all dosage-formations of ampicillin, an antibiotic, would be one product market. However, ampicillin is commonly sold as a combination drug with another antibiotic, cloxacillin - this combination would be a separate product market.

[14] A number of branded generics firms, as well as multinational firms, operate sales forces to promote products.

on total (branded + generic) unit sales after patent expiration. Though generic entry greatly lowers the average price of a drug, which should expand the drug's market size, the arrival of generics also leads to a significant reduction in advertising, which works to counterbalance this effect. This explains why the total volume prescribed for a given drug may actually *decrease* post patent expiration, despite the decrease in average price (Caves et al., 1991).

A second potential explanation for the decreasing sales volume in highly-impacted markets post-legislation may be coming from the supply side due to marginal costs rising with volume. Section D.2 in the Appendix provides theoretical evidence that if marginal costs are rising with volume, you may see a decrease in supply after price ceilings are implemented, even if firms are not price takers. Given industry context, marginal costs are often assumed to be constant or even decreasing in the context of pharmaceutical production, however in the Indian market *distribution* costs are likely to increase with volume. Pharmaceutical distribution costs in India are very high – despite significantly lower labor costs, the cost of pharmaceutical distribution in India is two to three times that in the European Union or United States (Langer and Kelkar, 2008). In particular, supply chain costs are very high in rural areas, due to what is known as the "last-mile" problem: the last leg of the pharmaceutical distribution chain in rural India is disproportionately expensive due to sparsely populated villages, lack of paved roads, and dearth of other necessary infrastructure (e.g. cold chain capabilities and health facilities) (Buckley and Gostin, 2013). Even if pharmaceutical firms are not ceasing production of price-controlled products, as the margins on these products are shrinking, either firms or distributors may be pulling price-controlled products from sub-markets with expensive distribution chains – which are most likely to be in rural areas. Exit from rural sub-markets is particularly harmful as these areas already suffer from low access to medicines – rural areas only contribute 21% of pharmaceutical sales in India (Langer and Kelkar, 2008), despite 67% of the Indian population living in rural areas (The World Bank, 2023).

To assess whether advertising might be driving the decrease in sales, I examine the impact of the legislation on one measure of marketing expenditure, bonus sales, which is the value of free samples given to wholesalers and pharmacists. Table 4 shows that bonus sales decrease significantly amongst price-controlled products after the legislation. The decrease in bonus sales is greatest amongst products that faced the highest impact of price controls. Without causal evidence it is unclear if the decrease in pharmaceutical marketing is causing the decrease in sales post-legislation, but given the significant decline in marketing

expenditure, it is one plausible cause.

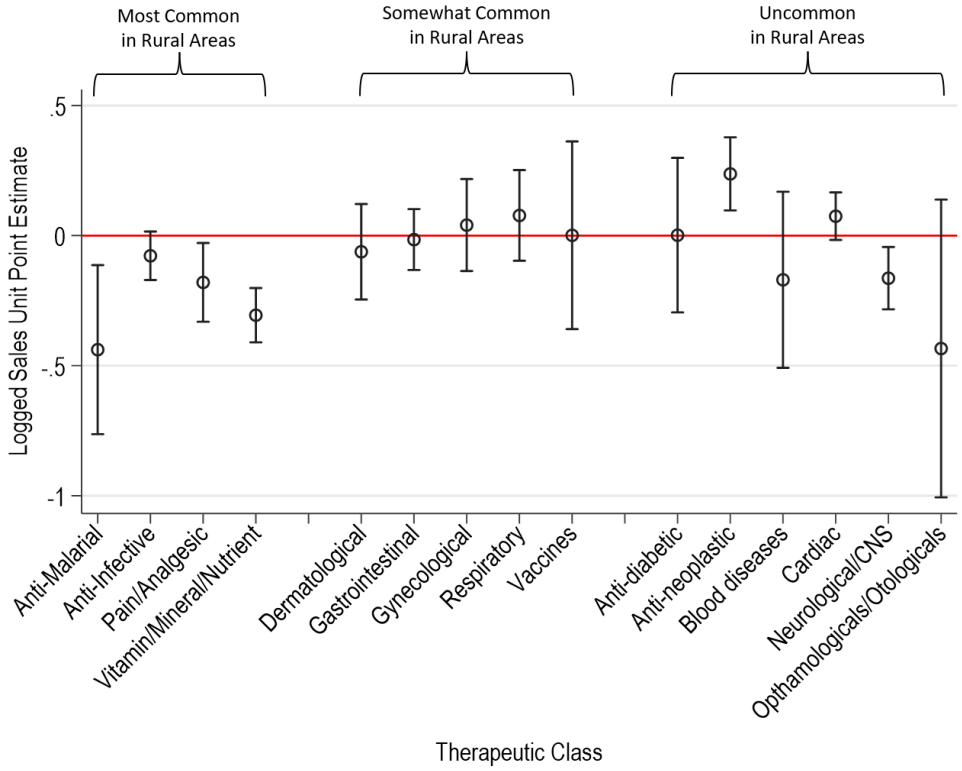
	(1)	(2)	(3)	(4)	(5)
			Price-Control Impact		
	Main Effect	Low Impact	Low-Mid Impact	Mid-High Impact	High Impact
Price Ceiling	-0.353***	-0.219***	-0.362***	-0.480***	-0.598***
	(0.021)	(0.030)	(0.034)	(0.051)	(0.061)
Observations	2,566,713	2,294,670	2,257,379	2,194,530	2,177,320

† Table displays joint treatment effect estimates and standard errors calculated using the Borusyak et al. (2021) imputation estimator. Outcome is logged value of bonus sales. Standard errors are clustered at the SKU level for all regressions shown here. Spillover products are excluded. Bonus sales are not available for all SKUs, thus results are limited to SKUs where this data is available.
$^{+}$p<0.10, *p<0.05, **p<0.01, ***p<0.001

Table 4: Effect of Legislation on Bonus Sales

To assess whether pharmaceutical companies pulled products out of costly rural sub-markets post-legislation, I examine the impacts of the legislation on different subgroups of medications. Prior to the implementation of the price control legislation, rural areas saw increased sales in products likely to be prescribed by primary care physicians as opposed to specialists – e.g. anti-infectives, pain medication, vitamins, and basic respiratory and gastrointestinal medications (Kalsekar and Kulkarni, 2011; India Brand Equity Foundation, 2017). If companies are pulling products from rural markets, then these therapeutic classes should see the largest declines in sales post-legislation. Figure 5 examines the impact of price controls in highly-impacted markets - where there is an overall decrease in units sold - by therapeutic class. Anti-malarials, analgesics, vitamins, minerals and nutrients, and neurological and CNS drugs all see a significant decrease in sales post-legislation. With the exception of neurological and CNS medications, these are all classes of medications more commonly used in rural areas prior to implementation of legislation. A second test exploits the lack of cold chain connectivity to rural areas (Samant et al., 2007). Due to lack of infrastructure and cold chain connectivity, products that require specialized storage conditions are less likely to be available in rural markets prior to the legislation enactment. Products with solid dosage formulations, such as pills or tablets, are less likely to require such storage conditions as compared to liquid, injection, or inhalant formulations. Thus if the decrease in sales volume in highly-impacted markets were occurring primarily in rural settings, one would expect "solid" product formations to have the biggest decrease in sales post-legislation. Table 5 shows results analyzing the impacts of price controls on sales separately by drug formulation. This shows that solid formulations of drugs, such as pills and tablets, saw

a significant decrease in sales post legislation. However, there was no significant change in sales units for inhalants, injectibles, or liquid drug formulations. Though these results are not conclusive, they do provide evidence that the decrease in sales may be driven by producers pulling products out of rural markets due to the increased distribution costs to reach these areas.



† Results shown are joint treatment effect estimates and 95% confidence intervals calculated using the Borusyak et al. (2021) imputation estimator. Outcome is logged sales units. Standard errors are clustered at the SKU level for all regressions shown here. Only products in highly-impacted markets are included in the analysis. Products from spillover groups are excluded from this analysis.

Figure 5: Effect of Price Controls by Therapeutic Class

The second part of Prediction 2 – that market share of multinationals will increase post-legislation – is met. Table 6 presents results on the impact of price ceilings on firm market share. The first two columns present results for all products and clearly show that local firms lost significant market share, while multinationals gained significant market share. The market share of exporter firms remained stable. In the appendix, Table A14 shows that these results hold when using a linear specification. Thus it is clear that multinational products gained significant market share post-legislation while local products lost

	(1) Inhalants	(2) Injectables	(3) Liquids	(4) Solids
Price Ceiling	-0.073	-0.030	-0.229	-0.138***
	(0.084)	(0.094)	(0.173)	(0.040)
Observations	43,597	334,928	645,766	2,233,427

† Table displays joint treatment effect estimates and standard errors calculated using the Borusyak et al. (2021) imputation estimator. Outcome is logged sales units. Standard errors are clustered at the SKU level for all regressions shown here. Only products in highly-impacted markets are included in the analysis. Products from spillover groups are excluded from this analysis. Drugs that are classified as an "Other" formulation category are excluded from this analysis.
+p<0.10, *p<0.05, **p<0.01, ***p<0.001

Table 5: Effect of Treatment by Drug Category on Logged Sales Units - Highly Impacted Markets

significant market-share.

4.3 Testing Prediction 3: Producer Exit

Prediction 3 indicates that producer exit is not necessarily more likely post-legislation assuming that price ceilings are set sufficiently high; however, if exit does occur it is most likely to be amongst local firms if marginal costs are sufficiently close. I test this proposition by examining likelihood of exit post-legislation for price-controlled medications versus non-controlled medications.

Table 7 shows results on the likelihood of producer exit after implementation of price ceilings. Columns (1) and (2) measure exit at the SKU level. These show that local firms are more likely to stop production of a given SKU after the legislation is enacted, however there is no significant impact for exporter or multinational firms. Columns (3) and (4) present the analysis at the company level – an important distinction as companies might produce multiple SKUs for a given product – and tell a similar story. Even at a broader firm level, local firms are more likely to exit a market post-legislation, however there is no significant impact on firm exit for exporter or multinational firms. Columns (2) and (4) show that market concentration does not have a significant impact on firms' decisions to exit after the legislation. Though local firms are of mixed reputation and quality, they produce low-priced medicines that are important for consumer access – particularly for consumers who are poor or live in rural areas (Dongre et al., 2010). The most price-sensitive consumers, who depend on these low-cost products, may be negatively impacted by

Model:	**Fractional Probit**	
	All Products	
	Coefficient	**APE**
Market Share of:		
Local Firms	-0.558***	-0.145***
	(0.080)	(0.026)
Exporter Firms	0.090	0.033
	(0.60)	(0.027)
Multinational Firms	0.275***	0.070***
	(0.076)	(0.019)
N	186,669	186,669

† Point estimates and standard errors are estimated using Equation 4. Outcome is combined market share by firm type for a given molecule. APE standard errors are bootstrapped and all standard errors are robust. Spillover products are excluded from this analysis.
$^{+}$p<0.10, *p<0.05, **p<0.01, ***p<0.001

Table 6: Change in Product Market Share by Firm Type

the exit of local firms.

Table A15 in the Appendix presents these same results but this time include "spillover" markets. Given the design of the legislation this distinction is quite important as companies might be able to easily shift production from a drug formulation that has a price ceiling to producing the same drug in a different dosage or formulation that is not controlled. For example, a firm might shift production of 250mg of amoxicillin, which is price-controlled, to production of 125mg of amoxicillin, which is not. These results show that at the broader product level, when including such spillover markets, that local firms do not see a significant increase in exit post-legislation. This indicates that local firms are exiting only price-controlled molecule formulations, but are continuing to produce non-controlled formulations of the same molecule.

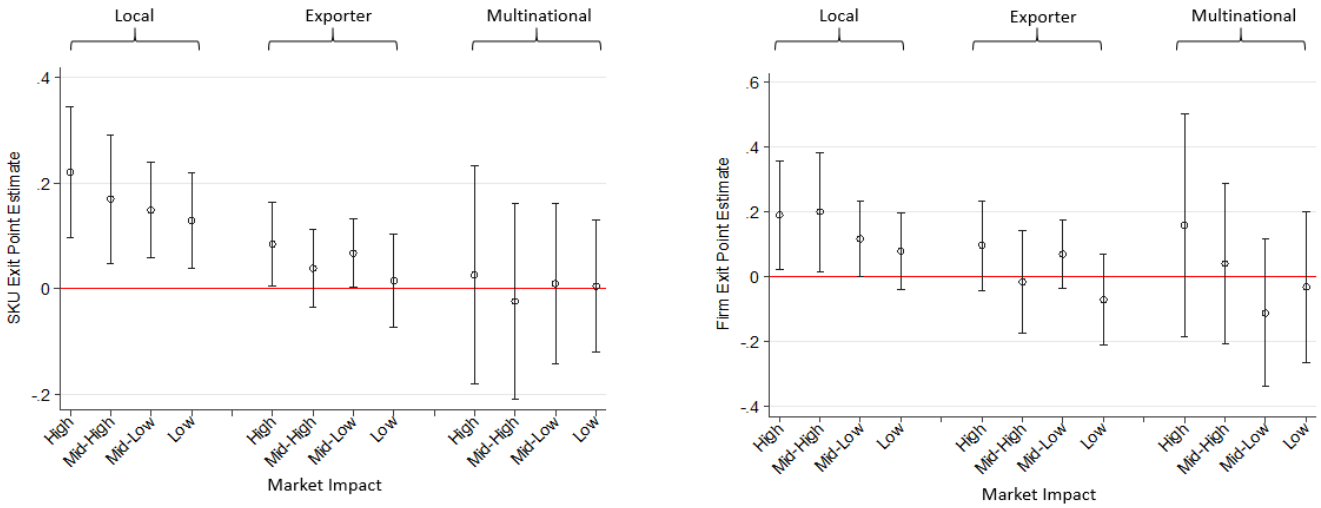
The theoretical model predicts that restrictive price ceilings increasingly dampen generic competition, and further induce exit of low-priced medications. To test this prediction of the model, this analysis again subsegments price-controlled markets into quartiles of weighted markdown required by the legislation to identify highly-impacted markets. The results are shown in Figure 6, which again shows that exit only increases amongst the control group of local firms. As predicted by the theoretical model, exit was highest for markets that were most severely impacted by price ceiling legislation. In fact, additional exit at the company-level was driven entirely by the top two quartiles of most intensely impacted markets.

	(1) SKU Exit	(2) SKU Exit	(3) Company Exit	(4) Company Exit
Price Ceiling	0.150***	0.122***	0.138***	0.114*
	(0.033)	(0.036)	(0.041)	(0.054)
Company Type				
Exporter	0.049	0.049	-0.048	-0.057
	(0.044)	(0.044)	(0.047)	(0.048)
Multinational	-0.187**	-0.194**	-0.123	-0.135
	(0.060)	(0.062)	(0.095)	(0.095)
Market Concentration				
Moderately Concentrated		0.018		0.093***
		(0.018)		(0.026)
Highly Concentrated		0.006		0.096***
		(0.022)		(0.028)
Company Type				
Price Ceiling × Exporter	-0.105**	-0.110**	-0.144*	-0.152*
	(0.041)	(0.042)	(0.059)	(0.061)
Price Ceiling × Multinational	-0.187**	-0.194**	-0.123	-0.135
	(0.060)	(0.062)	(0.095)	(0.095)
Market Concentration				
Price Ceiling × Moderately Concentrated		0.056		0.062
		(0.039)		(0.060)
Price Ceiling × Highly Concentrated		0.044		0.047
		(0.040)		(0.061)
Observations	96,654	96,654	40,412	40,412

† Point estimates and standard errors are estimated using Equation 5. Outcomes are exit by a SKU or company after initial implementation of price controls in September 2013. Standard errors are clustered at the company level. Spillover products are excluded from this analysis.
$^{+}$p<0.10, *p<0.05, **p<0.01, ***p<0.001

Table 7: Effect of Treatment on SKU and Company Exit

It is important to note that these results are all short-term and there may be increased exit in the long-term. If companies are somewhat capacity constrained, then it may become more profitable to exit markets with price ceilings as these companies make decisions to renovate long term assets, such as production facilities, or as they are able to enter new generics markets as medications lose patent protection.



† Results shown are point estimates and 95% confidence intervals calculated using Equation 5. Outcomes are exit by a SKU or company after initial implementation of price controls in September 2013. Standard errors are clustered at the company level. Products from spillover groups are excluded from this analysis.

Figure 6: Effect of Price Controls on Exit by Level of Market Impact

5 Conclusion

Lack of access to essential medicines is a serious public health issue that disproportionately affects those living in low- and middle-income countries (LMICs) (Laing et al., 2003). Nearly one-third of the world's population lack access to essential medicine, with rates in low-income countries as high as half the population (World Health Organization, 2004). Prices can serve as one barrier to medicine access, particularly in markets with low insurance coverage, as is common in LMICs. The high prices of on-patent medications in LMICs has long been a contentious issue, but even the entry of generic medications has not necessarily been sufficient to achieve affordable prices (Danzon et al., 2015). This is partially driven by uncertain quality of generic products sold in LMIC markets, which leads to branded generics markets. When generic products are viewed as being differentiated by brand, price competition is dampened - potentially in economically significant ways. Indeed, the Indian market – despite being arguably the world's most competitive generics market – shows wide price ranges for different generic brands of the same medication.

Pharmaceutical price controls are one tool LMIC governments and health departments may use to constrain medicine prices with the goal of increasing affordability. This study examines one such implementation of price controls, in which the Indian government set price ceilings on a list of essential medicines.

While these price controls benefitted consumers through broadly declining prices and higher market-level drug quality, they also harmed consumers through exit of low-cost (though lower-quality) producers, and producer exit that more heavily affected rural areas. From an equity perspective, price-sensitive and rural consumers were particularly exposed to the downsides of the legislation, while quality-sensitive consumers saw the largest benefits.

A large body of evidence from high-income countries (HICs) shows that no price control regime is perfect – each comes with realized downsides. The dearth of evidence on the impacts of pharmaceutical price regulation in LMICs is of concern, as these markets have economically important differences that can lead to vastly different outcomes than in HICs. This analysis, in fact, shows that the market differences between LMICs and HICs can lead to significantly different outcomes, even for identical policies. While marginal costs for firms may be relatively constant with volume in HICs, this is unlikely to be the case in LMICs as supply chain costs to reach rural areas are particularly high due to sparsely populated villages, lack of paved roads, and dearth of other necessary infrastructure. Theory predicts that when marginal costs are constant, the market response to price ceiling regulation is an increased supply. However, when marginal costs are increasing in volume, market response to price ceiling regulation is ambiguous, with market-level supply potentially decreasing. Empirical evidence from India indeed shows that increasing marginal costs are evident and economically important. In this setting, price ceiling legislation led to market-level supply decreasing significantly in highly-impacted markets, with evidence that firms are most likely to pull products from rural areas – a particularly dire impact, given that rural areas already suffer from lack of access to medical care.

While the Indian setting is specific, it more generally provides a setting to study how producers respond to price controls in branded generics markets. While India is unique in its substantial market size and world-class generics manufacturing industry, a number of findings from this setting may be more widely applicable. First is that price ceilings may be effective at reducing all pharmaceutical prices, however the associated pricing pressure may – somewhat counterintuitively – lead to low-priced products exiting the market. This can lead to consumer welfare decreasing, despite the price decreases, if a large portion of the population depends on these low-priced medications. Second is that, as low-priced medications are often locally produced, price ceilings may be thought of as one way to drive down pharmaceutical costs without hurting local business. However, price ceilings are likely to lead to an *increase* in market share for

multinational products at the expense of local business - a potential downside to policy-makers. Third is that there are potentially large quality differences between different drug manufacturers. Evidence from India shows that low-priced medicines are also of lower-quality on average. Thus the gain in market-share amongst multinational firms, while certainly dampening generic competition, may have health effects that overwhelm other welfare effects.

This study only covers the short-term effects of the price control legislation, but long-term effects are potentially very different. Over time, firms must make choices to pay for maintenance of long-term assets, and may not be willing to pay for the renovation or restoration of these assets if future profits are not sufficiently high. This could cause firms to either exit price controlled markets in the long-term, or to cut production or quality. Potential long-term exit would be exacerbated by reduced incentives to enter price-controlled markets.

Producer exit is a major concern of introducing price controls. Foreseeing this issue, India mandated that companies notify and receive approval to withdraw a price controlled product from the market, which may have hampered exit that would otherwise have occurred amongst multinationals. Multinationals did not exit the Indian markets at any increased rate after the price control legislation – at least in the short-term. However, the majority of the price controls studied here were on generic products that are relatively inexpensive to produce. In February 2017, India expanded price controls to cardiac stents, mandating that manufacturers and importers "maintain smooth production and supply of coronary stents of all brands." This resulted in two multinational suppliers – Abbott and Medtronic – requesting to withdraw their products from the market, and at least one other multinational company threatening to follow suit. This case highlights the trade-offs between encouraging the entry of innovative products to the Indian market and assuring affordable pricing for consumers. Monitoring long-term impacts of the legislation on not only price-controlled products but also on the launch decisions of multinational producers will provide valuable empirical evidence on these trade-offs.

This paper provides new theoretical and empirical evidence on the impacts of price control legislation in an LMIC. Nonetheless, it is only one study, examining only short-term outcomes in one country. The welfare impacts of other implementations of pharmaceutical price controls policies in LMICs, particularly in smaller markets, are very much an open area of research.

References

Abbott, F. M. (2017). Excessive pharmaceutical prices and competition law: Doctrinal development to protect public health. *UC Irvine Law Review 6*.

Abrol, D., S. Dhulap, M. Aisola, and N. Singh (2016). Pharmaceuticals, product patent and TRIPS implementation. Institute for Studies in Industrial Development, Working Paper 191.

Aggarwal, A. (2011). India pharmaceuticals sector. Credit Suisse. `https://research-doc.credit-suisse.com/docView?language=ENG&format=PDF&sourceid=emgpm&document_id=1075223631&serialid=uMceGo88kJHTmxnTbuuQfDVkynm2S2XvHzUzxBqiVl8%3D&cspId=null`. Accessed 2017-09-01.

AIOCD-AWACS (2017). White paper on methodology and salient features. Technical report.

Akerlof, G. A. (1970). The market for "lemons": Quality uncertainty and the market mechanism. *The Quarterly Journal of Economics 84*(3), 488–500.

Barbui, C. and M. Purgato (2014, July). Decisions on WHO's essential medicines need more scrutiny. *BMJ 349*, g4798–g4798.

Bate, R., G. Z. Jin, and A. Mathur (2011). Does price reveal poor-quality drugs? Evidence from 17 countries. *Journal of Health Economics 30*, 1150–1163.

Bate, R., G. Z. Jin, and A. Mathur (2015). Falsified or substandard? Assessing price and non-price signals of drug quality. *Journal of Economics & Management Strategy 24*, 687–711.

Bhaskarabhatla, A., C. Chatterjee, P. Anurag, and E. Pennings (2017). Mitigating regulatory impact: The case of partial price controls of metformin in India. *Health Policy and Planning 32*, 194–204.

Biswas, S. (2022). Cough syrup deaths: Why drugs made in India are sparking safety concerns. *BBC*. `https://www.bbc.com/news/world-asia-india-63226055`. Accessed 2023-04-01.

Borusyak, K., X. Jaravel, and J. Spiess (2021). Revisiting event study designs: Robust and efficient estimation. Working Paper.

Brekke, K. R., T. H. Holmas, and O. R. Straume (2011). Reference pricing, competition, and pharmaceutical expenditures: Theory and evidence from a natural experiment. *Journal of Public Economics 95*, 634–638.

Buckley, G. and L. O. Gostin (Eds.) (2013). *Countering the Problem of Falsified and Substandard Drugs*. National Academies Press (US). Available from: `https://www.ncbi.nlm.nih.gov/books/NBK202523/`.

Cabrales, A. (2003). Pharmaceutical generics, vertical product differentiation, and public policy. Technical report, UPF Working Paper No. 662.

Callaway, B. and P. H. Sant'Anna (2021). Difference-in-differences with multiple time periods. *Journal of Econometrics 225*(2), 200–230.

Caves, R. E., M. D. Whinston, and M. A. Hurwitz (1991). Patent expiration, entry, and competition in the U.S. pharmaceutical industry. *Brookings Papers on Economic Activity. Microeconomics*, 1–48.

Central Drugs Standard Control Organization (2015). WHO GMP certified manufacturing units for certificate of pharmaceutical products (COPP) in various states of india. `https://www.cdscoonline.gov.in/CdscoManuals/WHO_GMP.pdf`. Accessed 2017-09-01.

Chaudhuri, S., P. K. Goldberg, and P. Gia (2006). Estimating the effects of global patent protection in pharmaceuticals: A case study of quinolones in India. *American Economic Review 96*(5), 1477–1514.

Danzon, P. and L. Chao (2000). Does regulation drive out competition in pharmaceutical markets. *Journal of Law & Economics 43*, 311–357.

Danzon, P. and M. F. Furukawa (2008). International prices and availability of pharmaceuticals in 2005. *Health Affairs 27*(1), 221–233.

Danzon, P., A. Mulcahy, and A. Towse (2015). Pharmaceutical pricing in emerging markets: Effects of income, competition and procurement. *Health Economics 24*(2), 238–252.

Danzon, P. M. and J. D. Ketcham (2004). Reference pricing of pharmaceuticals for Medicare: Evidence from Germany, the Netherlands, and New Zealand. In D. M. Cutler and A. M. Garber (Eds.), *Frontiers in Health Policy Research, Volume 7*. Cambridge, MA: MIT Press.

Das, S. (2016). Made in Gujarat: Share of not standard quality drugs lower than India average. http://www.business-standard.com/article/companies/made-in-gujarat-share-of-non-standard-quality-drugs-lower-than-india-average-116060100592_1.html, Accessed 2017-09-01.

de Chaisemartin, C. and X. D'Haultfœuille (2020). Two-way fixed effects estimators with heterogeneous treatment effects. *American Economic Review 110*(9), 2964–96.

Dongre, Y., B. Mahadevappa, and R. Rohini (2010). Building access to healthcare in rural India: Possibility and feasibility of low-cost medicine. *International Journal of Pharmaceutical and Healthcare Marketing 4*, 396–407.

Duggan, M., C. Garthwaite, and A. Goyal (2016). The market impacts of pharmaceutical product patents in developing countries: Evidence from India. *American Economic Review 106*(1), 99–135.

Goldberg, P. K. (2010). Alfred Marshall lecture intellectual property rights protection in developing countries: The case of pharmaceuticals. *Journal of the European Economic Association 8*, 326–353.

Goodman-Bacon, A. (2021). Difference-in-differences with variation in treatment timing. *Journal of Econometrics 225*(2), 254–277.

Grootendorst, P. and D. Stewart (2006). A re-examination of the impact of reference pricing on anti-hypertensive drug plan expenditures in British Columbia. *Health Economics 15*(7), 735–742.

Hammond, A., W. J. Kramer, J. Tran, R. Katz, and C. Walker (2007). The next 4 billion: Market size and business strategy at the base of the pyramid. Washington, D.C.: World Resources Institute and International Finance Corporation, http://www.wri.org/publication/the-next-4-billion. Accessed 2016-10-10.

India Brand Equity Foundation (2017). Pharmaceuticals market & opportunities. https://www.ibef.org/download/Pharmaceuticals_210708.pdf. Accessed 2017-11-09.

IQVIA (2018). Winning in the Indian pharmaceutical market. https://www.iqvia.com/-/media/iqvia/pdfs/india/winning-in-the-indian-pharmaceutical-market.pdf,. Accessed 2023-03-31.

Jack, W. and J. O. Lanjouw (2005). Financing pharmaceutical innovation: How much should poor countries contribute? *The World Bank Economic Review 19*(1), 45–67.

Kalsekar, M. and M. Kulkarni (2011). Extra-urban evolution: The vast potential outside India's cities. IMS Health Report: `https://www.imshealth.com/files/web/Asia%20Pac/Asia%20Pacific%20Insights/Asia%20Pacific%20Insights%20Archive/India%20Extra%20Urban%20Evolution.pdf`. Accessed 2017-11-09.

Laing, R., B. Waning, A. Gray, N. Ford, and E. 't Hoen (2003). 25 years of the WHO essential medicines lists: Progress and challenges. *The Lancet 361*(9370), 1723–1729.

Langer, E. and A. Kelkar (2008). Pharmaceutical distribution in India. *BioPharm International 21*.

Marks, D. (1984). The effects of partial-coverage rent control on the price and quantity of rental housing. *Journal of Urban Economics 16*, 360–369.

Ministry of Health and Family Welfare (2017). Notification G.S.R. 327(E). `http://www.cdsco.nic.in/writereaddata/GSR%20327(E)%20Dated%2003_04_2017.pdf`. Accessed 2017-08-08.

Mohapatra, D. P. and C. Chatterjee (2016). Price control and access to drugs: The case of India's malarial market. Working Paper.

Narula, S. (2015). Current drug pricing status in India. *Pharmacoeconomics Open Access 01*(01).

National Institute of Biologicals (2016). 2014–2016 National drug survey. `http://www.cdsco.nic.in/writereaddata/Chapter11Sumarry.pdf`. Accessed 2017-09-01.

National Pharmaceutical Pricing Authority (2007). Directory of pharmaceutical manufacturing units in India 2007. `http://www.nppaindia.nic.in/Directory-NPPA.pdf`. Accessed 2017-08-24.

National Pharmaceutical Pricing Authority (2014). Notified prices under DPCO, 2013. `http://www.nppaindia.nic.in/`. Accessed 2017-03-15.

Papke, L. E. and J. M. Wooldridge (2008). Panel data methods for fractional response variables with an application to test pass rates. *Journal of Econometrics 145*(1–2), 121–133.

Pavcnik, N. (2002). Do pharmaceutical prices respond to potential patient out-of-pocket expenses? *RAND Journal of Economics 33*(3), 469–487.

Puig-Junoy, J. (2007). The impact of generic reference pricing interventions in the statin market. *Health Policy 84*(1), 14–29.

QuintilesIMS (2016). Outlook for global medicines through 2021: Balancing cost and value. http://static.correofarmaceutico.com/docs/2016/12/12/qiihi_outlook_for_global_medicines_through_2021.pdf. Accessed 2017-08-31.

Roth, J. (2022, September). Pretest with caution: Event-study estimates after testing for parallel trends. *American Economic Review: Insights 4*(3), 305–22.

Samant, Y., H. Lanjewar, D. Parker, L. Block, G. S. Tomar, and B. Stein (2007). Evaluation of the cold-chain for oral polio vaccine in a rural district of India. *Public Health Reports 122*(1), 112–121.

Schmalensee, R. L. (1972). *The Economics of Advertising*. North-Holland: Amsterdam.

Stargardt, T. (2010). The impact of reference pricing on switching behaviour and healthcare utilisation: The case of statins in Germany. *European Journal of Health Economics 11*, 267–277.

Sun, L. and S. Abraham (2021). Estimating dynamic treatment effects in event studies with heterogeneous treatment effects. *Journal of Econometrics 225*(2), 175–199.

The Times of India (2013). Drug shortage looms as pharma policy hurts margins. https://timesofindia.indiatimes.com/business/india-business/Drug-shortage-looms-as-pharma-policy-hurts-margins/articleshow/22177310.cms.

The World Bank (2023). World development indicators, rural population (population). https://data.worldbank.org/indicator/SP.RUR.TOTL.ZS.

Towse, A., E. Keuffel, H. E. Kettler, and D. B. Ridley (2012). Drugs and vaccines for developing countries. In P. M. Danzon and S. Nicholson (Eds.), *Oxford Handbook on the Economics of the Biopharmaceutical Industry*. Oxford University Press.

World Health Organization (2004). Equitable access to essential medicines: A framework for collective action. http://apps.who.int/medicinedocs/pdf/s4962e/s4962e.pdf. Accessed 2016-10-10.

World Health Organization (2011). The world medicines situation 2011. http://apps.who.int/medicinedocs/documents/s20054en/s20054en.pdf?ua=1,.

Yang, L., C. Liu, J. A. Ferrier, W. Zhou, and X. Zhang (2013). The impact of the national essential medicines policy on prescribing behaviours in primary care facilities in Hubei province of China. *Health Policy and Planning 28*(7), 750–760.

Appendix

A Abbreviations

- CFA: Clearing and Forwarding Agent
- DPCO: Drug Price Control Legislation; the 2013 DPCO initiated the pharmaceutical price caps in India studied in the paper
- EPhMRA: European Pharmaceutical Market Research Association; an organization which has created a standardized classification system for pharmaceutical products used in this paper
- FDCA: Indian Food and Drug Control Administration; the source of my data on drug quality
- HHI: Herfindahl-Hirschman Index; measure of market concentration
- MRP: Maximum retail price; price to consumer listed on medication box
- NLEM: (Indian) National List of Essential Medicines
- NPPA: National Pharmaceutical Pricing Authority; regulatory body that sets pharmaceutical price ceilings
- PCI: Per capita income
- SKU: Stock keeping unit
- WHO GMP: World Health Organization Good Manufacturing Practice certified pharmaceutical production plant

B Estimates of Not Standard Quality Drugs in India

Year	Estimate	Detail	Source
2009–2010	11%	N/A	Gujarat FDCA
2010–2011	7.11%	N/A	Gujarat FDCA
2011–2012	10.5%	N/A	Gujarat FDCA
2012–2013	5.6%	N/A	Gujarat FDCA
2013–2014	5.8%	N/A	Gujarat FDCA
2014–2015	4.6%	N/A	Gujarat FDCA
2015–2016	4.9%	N/A	Gujarat FDCA
2014–2016	3.18%	3.16% NSQ (3% of retail drugs, 10.2% of government supply chain), 0.0245% Spurious, State-level differences: 0-8.82% of drugs NSQ in retail setting	National Institute of Biologicals

Table A1: Not Standard Quality ("NSQ") Estimates from the Indian Government

† Estimates from the Gujarat FDCA are sourced from Das (2016). Estimates from the National Institute of Biologicals are sourced from National Institute of Biologicals (2016).

B.1 Low-Quality Data Summary Statistics

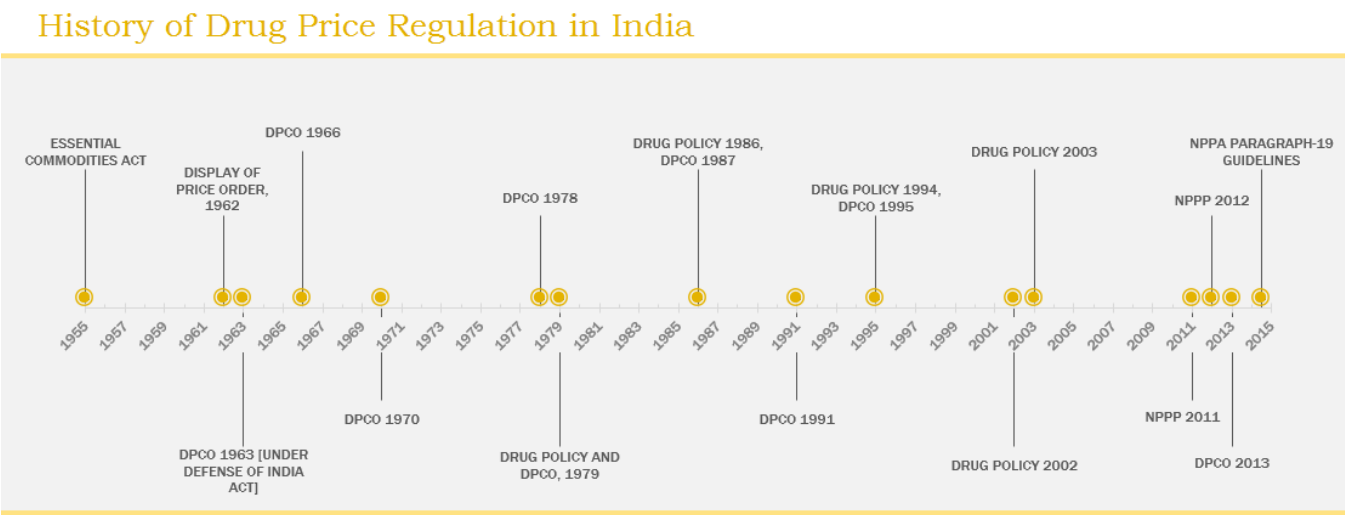
Reason for Failing	Count	Percentage
Content assay*	143	48.3%
Dissolution	80	27.0%
Disintegration time	29	9.8%
Identification	11	3.7%
Discoloration	10	3.4%
Labeling	8	2.7%
pH	6	2.0%
Particulate matter	6	2.0%
Nil content	6	2.0%
Capping, cracking, or related	4	1.4%
Sterility	4	1.4%
Water / moisture content	4	1.4%
Uniformity of weight	3	1.0%
Missing some active ingredients	3	1.0%
Contains non-listed active ingredient	3	1.0%
Microbial limit tests	2	0.7%
Glass particle	2	0.7%
Sulphated ash	2	0.7%
Refractive Index	1	0.3%
Toxicity	1	0.3%
Salisytic acid test	1	0.3%
Loss on drying	1	0.3%
Total**	296	100.0%

*The mean value of listed active ingredient(s) was 47.4% (st. dev 42.3%), with a range of 0-246.5%.

**A number of drugs failed on multiple categories, thus adding the counts or percentages will not equal the total.

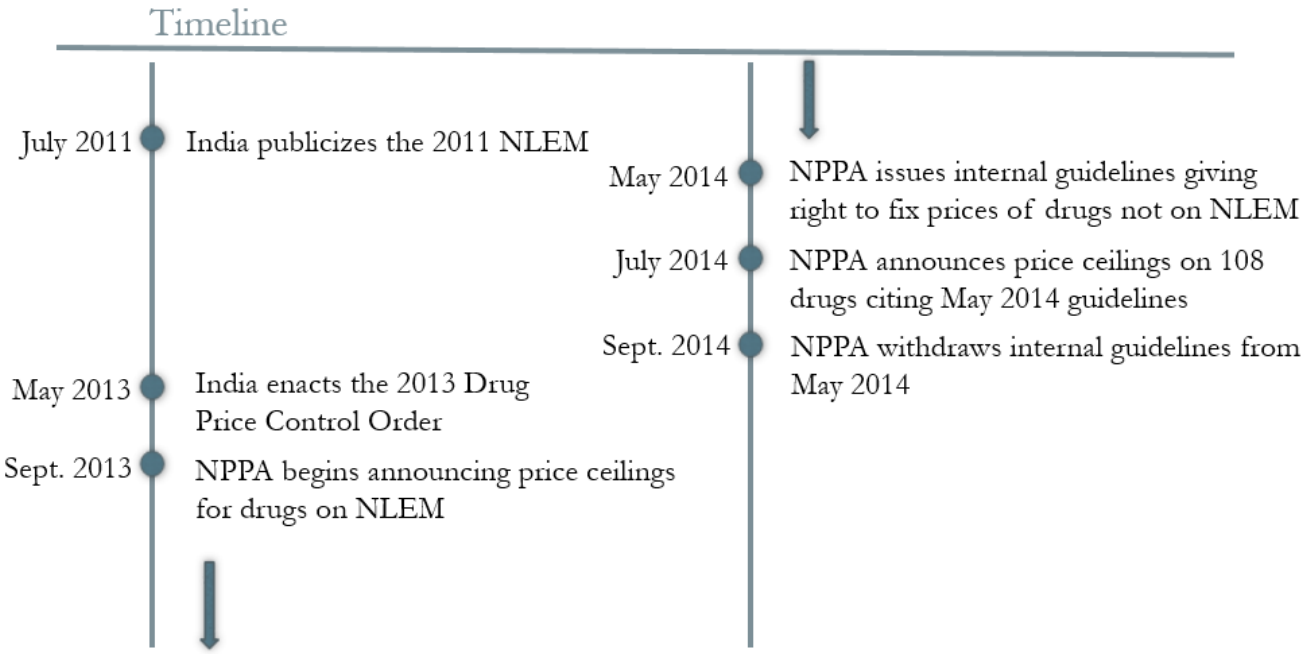
Table A2: Listed Reasons for Failing Drug Quality Testing

C History of Drug Price Regulation



In 1955, India established the Essential Commodities Act, which allowed regulators to control prices of consumer products under Section 3. Under the Essential Commodities Act, drug prices have been controlled using a series of Drugs Price Control Orders ("DPCOs"), beginning in 1970. Under a DPCO issued in 1995, India established the National Pharmaceutical Pricing Authority ("NPPA"), an organization which has limited ability to review and fix pharmaceutical prices (Narula, 2015). Under the most recent DPCO, issued in 2013, the NPPA has authority to maintain and expand the National List of Essential Medicines ("NLEM"), a list of medications based off the World Health Organization's list of essential medicines and place drugs on this list under price controls (Narula, 2015).

Figure A1: Timeline of Drug Price Regulation in India Between 1955 to Present



National List of Essential Medicines is abbreviated here as "NLEM." National Pharmaceutical Pricing Authority, the government body responsible for setting price ceilings, is abbreviated here as "NPPA."

Figure A2: Timeline of Price Controls Used in Analysis

D Theory Proofs and Extensions

D.1 Proof that Multinational Firm's Demand Will Rise

Case 1: Only the multinational firm is present in the market

If only the multinational firm is present in the market, the initial demand in the laissez-faire market is:

$$D_m^{lf} = 1 - \frac{p_m}{v}$$

Post-legislation, the multinational firm will lower their price to the ceiling, at price p_c, thus demand becomes:

$$D_m^{pc} = 1 - \frac{p_c}{v}$$

Because $p_c < p_m$ by design, $D_m^{pc} > D_m^{lf}$.

Case 2: Only multinational and exporting or local firms are present in the market

If only multinational and exporting firms are present in the market, their laissez-faire market demand is:

$$D_m^{lf} = 1 - \frac{p_m - p_e}{v(\alpha - \beta)}$$

$$D_e^{lf} = \frac{p_m - p_e}{v(\alpha - \beta)} - \frac{p_e}{v}$$

Post-legislation, the multinational firm will lower their price to the ceiling, at price p_c, and the exporting firm will lower their price in response to the new level, p_e^*. Thus demand becomes:

$$D_m^{pc} = 1 - \frac{p_c - p_e^*}{v(\alpha - \beta)}$$

where $p_e^* = \frac{p_c}{2(1 + \alpha - \beta)} + \frac{c_e}{2}$

and the change in p_e with respect to p_m is:

$$\Delta p_e(p_m) = \frac{1}{2(1 + \alpha - \beta)} < 1$$

Because $\Delta p_e(p_m) < 1$ it must be the case that $D_m^{pc} > D_m^{lf}$.

If only multinational and local firms are present in the market, their laissez-faire market demand is:

$$D_m^{lf} = 1 - \frac{p_m - p_l}{v(\alpha - 1)}$$

$$D_l^{lf} = \frac{p_m - p_l}{v(\alpha - 1)} - \frac{p_l}{v}$$

Post-legislation, the multinational firm will lower their price to the ceiling, at price p_c, and the local firm will lower their price in response to the new level, p_l^*. Thus demand becomes:

$$D_m^{pc} = 1 - \frac{p_c - p_l^*}{v(\alpha - 1)}$$

where $p_l^* = \frac{p_c}{2\alpha} + \frac{c_l}{2}$

and the change in p_e with respect to p_m is:

$$\Delta p_l(p_m) = \frac{1}{2\alpha} < 1$$

Because $\Delta p_l(p_m) < 1$ it must be the case that $D_m^{pc} > D_m^{lf}$.

Case 3: All Firm Types are in the Market

If all firm types are present in the market, the initial demand functions in the laissez-faire market are:

$$D_m^{lf} = 1 - \frac{p_m - p_e}{v(\alpha - \beta)}$$

$$D_e^{lf} = \frac{p_m - p_e}{v(\alpha - \beta)} - \frac{p_e - p_l}{v(\beta - 1)}$$

$$D_l^{lf} = \frac{p_e - p_l}{v(\beta - 1)} - \frac{p_l}{v}$$

Post-legislation, the multinational firm will lower their price to the ceiling, at price p_c, and the exporting firm will lower their price in response to the new level: p_e^* thus demand becomes:

$$D_m^{pc} = 1 - \frac{p_c - p_e^*}{v(\alpha - \beta)}$$

where $p_e^* = \frac{(\beta - 1)p_c + (\alpha - \beta)\frac{c_l}{2} + (\alpha - 1)c_e}{\alpha(2 - \frac{1}{2\beta}) - \frac{3}{2}}$

The change in p_e with respect to p_m from laissez-faire pricing is therefore:

$$\Delta p_e(p_m) = \frac{(\beta - 1)}{\alpha(2 - \frac{1}{2\beta}) - \frac{3}{2}} < 1$$

Given $\Delta p_e(p_m) < 1$ it must be the case that $D_m^{pc} > D_m^{lf}$.

D.2 Allowing for Increasing Marginal Costs

The model predicts that multinational manufacturers will see an increase in demand and market share assuming price ceilings are not set below marginal cost. Allowing for increasing marginal costs does not impact demand for the multinational product, as demand is not dependent on firm costs $D_m^{lf} = 1 - \frac{p_m - p_e}{v(\alpha - \beta)}$. However, it may impact units supplied, x_m.

To account for rising marginal costs, I assume costs are a function of units manufactured, $c_m = C(x_m)$, which is increasing in units manufactured, $C'(x_m) > 0$. Under this scenario, the multinational firm will respond to the price control by decreasing their price to the ceiling, $\bar{p}$. The demand at $\bar{p}$ is denoted by D_m^{pc}, and is equal to $1 - \frac{\bar{p} - p_e}{v(\alpha - \beta)}$. The laissez faire demand is denoted by D_m^{lf}, where $D_m^{lf} < D_m^{pc}$, since the price ceiling was binding by design. The firm will produce x_m units of the price controlled product, where:

$$x_m = \begin{cases} x_m^{pc} = D_m^{pc} & \text{if } \bar{p} \geq C(D_m^{pc}) \\ D_m^{lf} \leq x_m^{pc} < D_m^{pc} & \text{if } C(D_m^{lf}) \leq \bar{p} < C(D_m^{pc}) \\ D_m^{lf} > x_m^{pc} & \text{if } C(D_m^{lf}) > \bar{p} \end{cases}$$

In the first two cases, $x_m^{pc} > x_m^{lf}$, and the manufacturer produces more or the same number of units as compared to the laissez-faire market. In the third case, however, the multinational manufacturer will decrease units supplied as compared to the laissez-faire market, as $x_m^{pc} < x_m^{lf}$. Thus the impact on the multinational units produced, and subsequent multinational market share, will depend both on the shape of the marginal cost curve and on the level the price ceiling is set.

E Indian Pharmaceutical Market

Market Concentration Level	Count of Markets	Percentage of Markets
Non-Concentrated	379	12.77%
Moderately Concentrated	313	10.55%
Highly Concentrated	2,275	76.68%
Mean HHI	4889.86	
	(3724.16)	

† Markets are defined at the EPhRMA subgroup (generally molecule or molecule-combination) level between January 2012 and the implementation of price ceilings in 2013. Definitions of market concentration are those used to define market concentration by the U.S. Department of Justice and Federal Trade Commission. These agencies generally consider markets with an HHI over 2,500 to be highly concentrated, and those with HHI between 1,500 and 2,500 to be moderately concentrated.

Table A3: Market Concentration Summary

	Ratio Multinational-Exporter	Ratio Multinational-Local	Ratio Exporter-Local
Maximum Retail Price	1.25	1.22	1.08
	(0.65)	(0.66)	(0.46)
Sales Units	4.35	64.09	164.96
	(10.50)	(164.41)	(455.69)

† Numbers shown here are aggregated from the AIOCD Awacs data between 2012 and 2015. Price ratios are Winsorized at 1% to prevent results from being heavily influenced by outliers.

Table A4: Price Ratio by Company Type

F Characteristics of Price Controlled Markets

Firm Type	No Price Controls	2013 Price Controls	2014 Price Controls
% of Market in Sales Volume	74.81%	22.47%	2.71%
% of Market in Value	78.74%	16.98%	4.28%
% Exporter (Volume)	65.70%	68.41%	76.14%
% Multinational (Volume)	24.94%	27.31%	18.46%
Market Characteristics - Mean and SD			
Logged MRP	4.17	3.76	4.15
	(1.13)	(1.19)	(0.80)
Logged Sales Units	7.47	7.71	8.29
	(2.54)	(2.74)	(2.35)
HHI	5213	5009	3399
	(3077)	(2637)	(2227)
SKU Launch Year	2008	2005	2007
	(5.15)	(6.01)	(4.96)
Product Launch Year	2000	1992	1997
	(37.91)	(10.53)	(8.10)
% Chronic	39.68%	31.39%	100%
	(0.49)	(0.46)	(0.00)

† Statistics sourced from the AIOCD Awacs data for the time period between January 2012 through May 2013, which is when the first waves of price ceilings began. Sales volume and sales units are not adjusted for dosage. All values are unweighted. Values for HHI are at the product subgroup-month level.

Table A5: Characteristics of Price Controlled and Non-Price Controlled Products

	Local Firm	Exporter Firm	Multinational Firm
	Absolute Markdown		
Overall	4.1	10.7	24.6
	(54.8)	(210.1)	(273.8)
Above Price Ceiling	113.1	260.5	253.7
	(305.6)	(1046.2)	(873.9)
	Percentage Difference		
Overall	4.4%	4.6%	8.0%
	(0.14)	(0.14)	(0.18)
Above Price Ceiling	58.5%	55.7%	47.4%
	(0.27)	(0.26)	(0.23)

† Markdown is calculated as the amount SKUs would be required to decrease their price after price ceilings. This is calculated as the max of 0 and the ceiling price subtracted from the average SKU market price in the year prior to the adoption of price ceilings. SKUs are classified as being above the price ceiling if their average ceiling price in the year prior to the adoption of the price ceiling was above the initial price ceiling.

Table A6: Price Markdown by Company Type*

G Robustness of Results: Prediction 1

	(1) Spillover Products	(2) Excluding Exiting Products	(3) Excluding Small Products
		Logged MRP	
ATT	-0.039***	-0.106***	-0.110***
	(0.003)	(0.003)	(0.004)
Observations	3,514,067	2,864,238	1,915,830

† Table displays joint treatment effect estimates and standard errors calculated using the Borusyak et al. (2021) imputation estimator. The outcome variable is logged MRP. Standard errors are clustered at the SKU level. Only spillover products and non-price controlled products are included in Column (1). Products from spillover groups are excluded from columns (2) and (3).
+p<0.10, *p<0.05, **p<0.01, ***p<0.001

Table A7: Effect of Price Ceilings on MRP

	(1) BJS 2021	(2) CS 2021	(3) OLS TWFE
		Logged MRP	
ATT	-0.092***	-0.115***	-0.096***
	(0.003)	(0.005)	(0.003)
Observations	3,611,476	3,611,476	3,611,476

† Outcome is logged MRP. Standard errors are clustered at the SKU level for all regressions. Products from spillover groups are excluded. BJS 2021 uses estimation strategy from Borusyak et al. (2021), CS 2020 uses estimation strategy from Callaway and Sant'Anna (2021), and OLS TWFE uses a standard OLS two-way fixed effects methodology.
+p<0.10, *p<0.05, **p<0.01, ***p<0.001

Table A8: Effect of Price Ceilings on MRP

H Robustness of Results: Prediction 2

	(1)	(2)	(3)
	BJS 2021	CS 2021	OLS TWFE
	Logged Sales Units		
ATT	-0.015	0.034	0.016
	(0.013)	(0.018)	(0.013)
Observations	3,611,476	3,611,476	3,611,476

† Outcome is logged sales units. Standard errors are clustered at the SKU level for all regressions. Products from spillover groups are excluded. BJS 2021 uses estimation strategy from Borusyak et al. (2021), CS 2020 uses estimation strategy from Callaway and Sant'Anna (2021), and OLS TWFE uses a standard OLS two-way fixed effects methodology.
$^{+}$p<0.10, *p<0.05, **p<0.01, ***p<0.001

Table A9: Effect of Price Ceilings on Logged Sales Units

	Firm Type		
	Local	Exporter	Multinational
All Price Controlled	-0.023	-0.018	-0.011
	(0.023)	(0.017)	(0.047)
Low Impact	0.044	0.038	0.047
	(0.036)	(0.026)	(0.078)
Mid-Low Impact	-0.014	-0.016	-0.073
	(0.037)	(0.028)	(0.082)
Mid-High Impact	-0.084	-0.064	0.132
	(0.059)	(0.040)	(0.091)
High Impact	-0.147*	-0.110*	-0.199*
	(0.059)	(0.048)	(0.098)

† Table displays joint treatment effect estimates and standard errors calculated using the Borusyak et al. (2021) imputation estimator. The outcome variable is logged sales units. Standard errors are clustered at the SKU level. Products from spillover groups are excluded from this analysis.
+p<0.10, *p<0.05, **p<0.01, ***p<0.001

Table A10: Effect of Price Ceilings on Logged Sales Units by Firm Type

	Market Impact				
	All	High Impact	Mid-High Impact	Mid-Low Impact	Low Impact
Logged Sales Units	-0.033*	0.025	-0.029	-0.096**	-0.121**
	(0.013)	(0.020)	(0.022)	(0.032)	(0.037)
Observations	3,090,326	2,759,350	2,716,440	2,646,339	2,626,813

† Table displays joint treatment effect estimates and standard errors calculated using the Borusyak et al. (2021) imputation estimator. The outcome variable is logged sales units. Standard errors are clustered at the SKU level. Products from spillover groups and products that exit the Indian market after implementation of price controls in 2013 are excluded from this analysis.
+p<0.10, *p<0.05, **p<0.01, ***p<0.001

Table A11: Effect of Price Ceilings on Logged Sales Units Excluding Companies that Exit After Price Ceilings

	All Product Groups
Logged Sales Units	-0.199
	(0.113)
Observations	14,138

† Table displays the joint treatment effect estimates and standard errors calculated using the Borusyak et al. (2021) imputation estimator. The outcome variable is logged product sales, which are aggregated to the group level, with groups including price-controlled, non-price-controlled, and spillover products. Product groups that include price-controlled products are compared to groups where no products received a price control. Standard errors are clustered at the product-group level.
$^{+}$p<0.10, *p<0.05, **p<0.01, ***p<0.001

Table A12: Effect of Price Ceilings on Logged Sales Units by Product Group, Including Spillover Products

	All Spillover Products
Logged Sales Units	0.024
	(0.013)
Observations	3,764,000

† Table displays the joint treatment effect estimates and standard errors calculated using the Borusyak et al. (2021) imputation estimator. The outcome variable is logged sales units. Standard errors are clustered at the SKU level. Products from spillover groups are compared to non-price-controlled products in this analysis.
$^{+}$p<0.10, *p<0.05, **p<0.01, ***p<0.001

Table A13: Effect of Price Ceilings on Logged Sales Units For Spillover Products

Model:	**OLS All Products Coefficient**
Market Share of:	
Local Firms	-0.017***
	(0.004)
Exporter Firms	-0.001
	(0.009)
Multinational Firms	0.018*
	(0.008)
N	186,669

† Results are estimated using conventional OLS two-way fixed effects methods. Spillover products are excluded from this analysis.
+p<0.10, *p<0.05, **p<0.01, ***p<0.001

Table A14: Change in Product Market Share by Firm Type Using OLS

I Robustness of Results: Prediction 3

	(1)	(2)
	Company Exit	Company Exit
Price Ceiling	-0.004	0.009
	(0.028)	(0.041)
Company Type		
Exporter	-0.044	-0.052
	(0.048)	(0.048)
Multinational	0.138	0.131
	(0.098)	(0.099)
Market Concentration		
Moderately Concentrated		0.082**
		(0.027)
Highly Concentrated		0.090**
		(0.028)
Company Type		
Price Ceiling × Exporter	-0.076^{+}	-0.075^{+}
	(0.042)	(0.043)
Price Ceiling × Multinational	-0.109^{+}	-0.110^{+}
	(0.061)	(0.061)
Market Concentration		
Price Ceiling × Moderately Concentrated		-0.003
		(0.049)
Price Ceiling × Highly Concentrated		-0.015
		(0.048)
Observations	44,207	44,207

† Point estimates and standard errors are estimated using Equation 5. Outcomes are exit by a company after initial implementation of price controls in 2013. Standard errors are clustered at the company level. Directly impacted and spillover products are included in the analysis.
$^{+}$p<0.10, *p<0.05, **p<0.01, ***p<0.001

Table A15: Effect of Treatment on Company Exit Including Spillover Products