Who Benefits from Pharmaceutical Price Controls? Evidence from India*

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Abstract

With the goal of driving down drug costs, governments across the globe have instituted various forms of pharmaceutical price control policies. Understanding the impacts of such policies is particularly important in low- and middle-income countries, where lack of insurance coverage means that prices can serve as a barrier to access for patients. In this paper, we examine the theoretical and empirical effects of one implementation of pharmaceutical price controls, in which the Indian government placed price ceilings on a set of essential medicines. We find that the legislation resulted in broadly declining prices amongst both directly-impacted products and competing products. However, the legislation also led to decreased sales of price-controlled and closely related products, preventing trade that would have otherwise occurred. The sales of small, local generics manufacturers were most impacted by the legislation, seeing a 14.5% decrease in market share and a 5.3% decrease in sales. These products tend to be inexpensive, but we use novel data to show that they are also of lower average quality. We provide evidence that the legislation impacted consumer types differentially. 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.

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1 Introduction

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 developing countries (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. While generics are considered non-differentiated products in high-income countries, many LMICs do not require generic manufacturers to conduct bioequivalence trials, which ensure that generic medicines are absorbed in the body in the same strength and timeline as originator products. Furthermore, lax government enforcement of manufacturing standards can lead to inadequate quality-control in the manufacturing process of locally-produced generic medications. In turn, this leads to substandard and falsified medicines on the market – a serious issue in LMICs where studies estimate that 10-15% of medicines are substandard or pure fakes (Bate et al., 2011, 2015). This lack of regulatory assurance creates quality uncertainty in the market, which generic producers may work to overcome by establishing a reputation for quality through a brand name. However, this system of brand-name generics impairs the 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 have on consumers, governments have increasingly implemented price-control legislation that covers not only on-patent originator medications, but also generic medications. This study examines the impact of one such imple-

[1] All abbreviations used in this paper are listed in the appendix in Section A.

mentation 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. Market-based price controls such as the ones introduced in India have been praised as having potentially important upsides. Not only are they reasonably easy to develop and implement, but also by basing price controls on current market prices they arguably still allow for drug companies to earn a profit, thus may be sustainable in the long term. However, this type of legislation has been criticized as having potentially serious downsides as well. Companies could in theory react to this legislation by discontinuing or lowering production of price-controlled drugs and shifting this manufacturing capacity to more lucrative medications, leading to lower competition or regional shortages. Further, while price controls are enacted to lower medical spending, companies who were ex-ante pricing below the price ceiling are not required to lower their prices, meaning the most price-sensitive consumers do not necessarily benefit. Assessing the empirical effects of price controls in the Indian market can provide important information on the magnitude of both its intended and unintended effects.

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 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 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 healthcare,

[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.

for instance in certain hospital or physician markets. In this paper, we have an objective measure of medication quality and a natural experiment which restricts prices – allowing us to measure differential impacts for high- and low-quality firms. This is an improvement on other studies on quality in healthcare, 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. 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. However, it also led to exit of low-cost producers from the market, and an overall decrease in sales of price-controlled products, suggesting potential shortages of essential medications.

2 Empirical Setting

This paper examines the impact of price controls implemented in India between 2013 and 2014. The common conception of pharmaceutical price controls are reference prices or price ceilings set by a government insurer for on-patent originator medications. The goals of these price controls are to use payer monopsony power to lower high medicine prices arising from producer monopoly power and consumer moral hazard. India's price controls differ from these in that they largely covered off-patent medications – an economically important difference in that multiple producers are typically active in these price-controlled markets – in a market with low insurance coverage. These price controls address a different market failure – a failure of the market to drive pricing competition amongst generic drugs.

To fully address the background of these price controls, this section proceeds as follows. Section 2.1 presents background on generic pharmaceutical markets globally and then identifies how the generic market in India differs. Section 2.2 presents background about the overall Indian pharmaceutical industry, with specific regards to different producer types that operate in this market. Last, Section 2.3 details the price controls studied within this paper.

2.1 Background on Generic Pharmaceutical Markets Globally and in India

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.

As it is relatively inexpensive for generics to come to market, in a competitive market there are often multiple companies producing generic versions of an originator medication. In high-income countries, generics are generally sold as unbranded medications – meaning they are sold by the generic molecule name (e.g. ibuprofen as opposed to the brand name, Advil). To save the health system money on pharmaceutical costs, countries use different methodologies to encourage generic substitution and pricing competition amongst generics.

India's generics market operates very differently, and a number of factors dampen price competition that might otherwise occur in a competitive off-patent pharmaceutical market. While India does have a number of unbranded generics in the market, as with many LMICs, it is primarily a branded generics market, meaning generics compete on brand name as opposed to competing solely on price. Additionally, in India pharmacists are not allowed to substitute generic equivalents by law.[3] Further, pharmacies generally receive a percentage of a product's market price as their mark-up. Thus, a pharmacist selling a more expensive product will likely receive a larger payment. The combination of these factors dampens the price competition between different generic brands and between originator and generic products.

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"

[3]Current Prime Minister Narendra Modi has advocated changing this to have physicians write prescriptions with a generic name, allowing pharmacists to dispense a less expensive product.

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).

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.[4] 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 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. Given India's large export market, it is important to note that generic firms exporting to other markets must follow the manufacturing laws within those countries – thus Indian firms exporting to countries that require bioequivalence trials must conduct these trials for exported products.

A further, closely related, issue 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 and 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.[5] 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.

[4]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.

[5]Table D2 in the Appendix details different estimates, which range from 11% in 2009-2010 to 3.18% in 2014-2016.

2.2 Indian Pharmaceutical Market

The Indian pharmaceutical market is the third largest global market in volume and eleventh largest in sales (QuintilesIMS, 2016), valued at $13.8 billion in 2012 (PwC, 2013) and $16.2 billion in 2016 (Care Ratings, 2017). As of 2014, 4.7% of India's GDP was spent on health, 70% of which was from private spending (The World Bank, 2017). Estimates on the percentage of total health spending towards pharmaceuticals in India vary by source, but range from 17-31% of total health spending (Burns, 2014).[6] Of the public expenditure on health, only about 10% goes towards pharmaceuticals – however, there are significant differences by state, with pharmaceuticals comprising less than 2% of public health spending in Punjab and 17% in Kerala (Sakthivel, 2005).

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 4.2.). 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 $16.8 billion in revenue from pharmaceutical exports in 2016 (Care Ratings, 2017). As such, 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

[6] However, these estimates may be understated - a 2005 expenditure survey conducted across Indian states found that 61-90% of household out-of-pocket spending on health was spent on pharmaceuticals (Sakthivel, 2005).

pharmacists to prescribe their drugs, namely sales representatives and free medication samples.

2.3 Price Control Legislation

India has a long history of regulating the prices of drugs and active pharmaceutical ingredients, dating back to the 1960s.[7] 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, and again in 2014. This study will examine the impact of these two sets of price controls, the timeline of which is available in Figure 1. The first set of price controls were enacted when the Indian government released the 2013 Drug Price Control Order, giving a local regulatory body, the National Pharmaceutical Pricing Authority, 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.[8] 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 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.

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

[7] Figure B1 in the appendix details the history of price controls in India dating back to the mid-1900s.

[8] 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).

meet these demands (The Times of India, 2013).

The National Pharmaceutical Pricing Authority 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.

In September 2013, the National Pharmaceutical Pricing Authority 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 the National Pharmaceutical Pricing Authority did not announce all price ceilings at the same time, rather 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 May 29, 2014, the National Pharmaceutical Pricing Authority issued an internal guideline which gave their organization the right to place price controls on drugs not contained on the National List of Essential Medicines if these controls were in the public interest. Shortly after, on July 10, 2014, the National Pharmaceutical Pricing Authority announced price controls of an additional 108 formulations of diabetes and cardiovascular drugs not on the National List of Essential Medicines, citing the internal guidelines issued on May 29th of that year. This legislation incensed the Indian pharmaceutical industry, which initially refused to comply with the legislation and fought it in court. On September 29, 2014, courts ruled in favor of the pharmaceutical companies and the National Pharmaceutical Pricing Authority withdrew the May 29th internal guidelines. However, this withdrawal was retroactive and not retrospective. 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.[9]

[9]India's pharmaceutical industry fought to have the July 10th price controls revoked in court as well, but in this case lost, allowing those controls to remain.

3 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. For major markets, such as Brazil and India, multinational and exporting generics firms may have multiple plants meeting different manufacturing standards (e.g. a plant approved by the U.S. FDA for products shipped to the United States and a plant approved by the Indian Food and Drugs Control Administration for the Indian market), and this may not hold. However, in reality it may be difficult for a small, local generics firm to invest in advertising and improve reputation to the point that it will be seen as similar in quality to larger, exporting firms. 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.

3.1 Laissez-Faire Market

In a laissez-faire branded generics markets, 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 may have have different valuations of a given drug, which is denoted by ν and is uniformly distributed between $[0, v]$.

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

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

where p notates price and 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.

Assuming all three products are active in a given market, this provides the following demand functions:

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

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

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

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:

$$\pi_i = (p_i - c_i)D_i$$

This allows for the derivation of a producer's best-response function to a change in competitors' prices:

$$p_m(p_e) = \tfrac{1}{2}[v(\alpha - \beta) + p_e + c_m]$$

$$p_m(p_l) = \frac{(\alpha-\beta)p_l + (2\alpha - \frac{5}{2})(v(\alpha-\beta)+c_m) + (\alpha-1)c_e}{4\alpha\beta - \alpha - 3\beta}$$

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

$$p_e(p_l) = \frac{(\alpha-\beta)p_l + \frac{1}{2}(\beta-1)[v(\alpha-\beta)+c_m] + (\alpha-1)c_e}{2\alpha - \frac{3}{2} - \frac{1}{2}\beta}$$

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

$$p_l(p_e) = \frac{p_e + \beta c_l}{2\beta}$$

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

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

or in other words, that firms will respond to competitors price changes.

In this market setting, the market share of branded products, denoted as ω, is:

$$\omega = \frac{1 - \frac{p_m - p_e}{v(\alpha-\beta)}}{1 - \frac{p_l}{v}} = \frac{v(\alpha-\beta) - p_m + p_e}{(v-p_l)(\alpha-\beta)}$$

3.2 Price Ceiling Legislation

Since the price ceiling in India was binding on the high-priced firm(s) by design, we do not 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, we would expect all firm types to 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:

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

As $\delta p_e / \delta p_m < 1$, it is clear that demand for the multinational product will rise post-legislation. Further, as the price ceiling becomes increasingly binding on the multinational product, the demand for the multinational product will increasingly rise compared to laissez-faire levels. This result will hold even in markets where not all firm types are active, as shown in the short proof in Appendix Section F.1.

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

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

with $\frac{\delta p_e}{\delta p_m} = \frac{(\beta - 1)}{\alpha(2 - \frac{1}{2\beta}) - \frac{3}{2}}$ and $\frac{\delta p_l}{\delta p_m} = \frac{(\beta - 1)}{4\alpha\beta - \alpha - 3\beta}$.

As with the demand function, increasingly binding price ceilings will lead to a rising increase in market share for multinational products. These results taken together show that price ceilings, even those only binding only on multinational firms, will increasingly dampen generic competition.

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: $\bar{p} < \dfrac{c_e(\alpha - \frac{1}{2} - \frac{\beta}{2}) - (\alpha - \beta)\frac{c_l}{2}}{(\beta - 1)}$

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 4.2, multinational products are priced on average 28% more than exporter firms and 29% more than local firms. Exporter firms, in turn, price products on average 15% 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.

3.3 Necessary Conditions for Results to Hold

The model above makes several assumptions - which, while justified, may drive results. This section will discuss implications of loosening two of these assumptions: the constant marginal cost assumption and the uniform consumer distribution assumption.

3.3.1 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)) or even zero marginal costs (e.g. Merino-Castelló (2003)). With respect to pharmaceutical production these assumptions can generally be considered valid. 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, eds, 2013). While the model presented earlier already 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.

Loosening the constant marginal cost assumption can have important implications on the predictions from the model above, particularly with respect to volume responses by producers. Allowing for increasing

marginal costs makes the impact of price ceilings on quantity supplied ambiguous – firm quantity will depend both on the shape of the marginal cost curve and the level price ceilings are set. As a simple illustration of how this might be the case, Figure F2 in the Appendix presents an illustration of how, 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.

3.4 Loosening the Uniform Patient Preferences Assumption

Following previous theoretical literature on pharmaceutical price controls (e.g. Brekke et al. (2011)), the model presented above allows consumers to have different valuations of a drug, denoted by ν, where ν is uniformly distributed between $[0, v]$. A distribution of valuations may also be thought of as a preference for drug quality and is likely to be highly correlated with income levels. As LMICs have, on average, higher income inequality as measured by both Gini coefficients and Palma ratios (United Nations Development Programme, 2016), this assumption may be less likely to hold in LMIC markets. Realistically ν may be represented as asymmetrical, with a large mass of consumers on the low end of ν and a long right tail.

Loosening the uniform distribution of ν to allow for the asymmetric distribution described above may impact model predictions. While prices for all products will continue to drop in such a distribution, the magnitude may be smaller or larger depending on the exact distributional form of ν. The impact on multinational market share, however, becomes ambiguous, depending on how the distribution form of ν shifts exporting firm responses. Despite the mass of consumers on the lower end of the distribution, the impact on firm exit remains when assuming constant marginal costs.

3.5 Model Predictions

To summarize, 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 ex-ante 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 and uniform patient preferences assumptions, the effect on multinational market share and sales is ambiguous.

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

4 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.

4.1 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 sold primarily 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)). Importantly in this setting, the data also served as one source of data used by the Indian government in setting the price ceilings studied here. The AIOCD data is available monthly from 2010 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 to Fight AIDS, Tuberculosis, and Malaria – 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.[10]

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 us to adjust for any non-random sampling on the part of the FDCA.

4.2 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 highly concentrated, as shown in the Appendix in Table C1. The mean Herfindahl-Hirschman Index (HHI) for a product market is 4890[11], with 94% of markets considered to be highly concentrated.

4.2.1 Characteristics of Local, Exporting, and Multinational Firms

Table 1 details retail market characteristics by producer type. 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 approximately a quarter of sales, and local firms, while vast in number (73% of firms), make up less than 10% 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 38% of Indian product markets, while local and exporter firms have entered 49% and 73% of

[10]The current link to this website is available here: http://xlnindia.gov.in/gp_failedsample.aspx.

[11]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. If the market is expanded to a EPhMRA group level, the average HHI is 3347, with 65% of pharmaceutical markets considered highly concentrated. A subgroup is generally classified at the molecule-dose or molecule combination-dose level.

product markets, respectively. Table 2 details average logged prices, monthly sales, and market share by firm type. Though multinationals are in fewer markets than local firms, in the markets they enter they tend to sell more units on a monthly basis and have a higher market share. Prices are highest amongst multinational companies, and lowest amongst local firms. These higher prices are not due solely to the different markets companies choose to enter. Table 3 shows average price ratios for different firm types operating in the same markets. In the same markets, multinational products are priced on average 28% and 29% more than products produced by exporting and local firms, respectively, and products sold by exporting firms are priced 15% 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 4 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. 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. As the ratios in Column (3) are relatively meaningless, Column (4) computes the estimated drug failure rates for each company type. This estimated failure rate is calculated by dividing the figures in Column (3) by 20, as the sample of testing data is approximately 5% of the total testing data for the 2010–2015 time period. This percentage clearly

shows large differences between 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 29% more than local firms, and exporter firms are priced on average 15% more than local firms.

4.2.2 Characteristics of Price Controlled Products

Approximately 25% of the retail pharmaceutical market in India received a price ceiling (21% in value). Table 5 shows the characteristics of uncontrolled and controlled products. The products generally look similar, however the 2014 price controls took place in more crowded markets (lower HHI), and covered only chronic products. Figure 2 shows pricing and sales trends for non-controlled products and products given price controls in 2013 and 2014. Pre-trends are relatively similar for each of these groups, and a clear drop in prices can be seen in controlled products after the 2013 legislation was enacted. Figure 3 presents market share over time for local, exporter, and multinational firms. While multinational market share is declining across markets pre-legislation, the market share of multinational firms stabilizes for price-controlled products after the legislation.

Table 6 shows the average markdown required by the legislation for each company type. Multinational firms see the largest required markdowns from ex-ante prices – an average of ₹42 for products priced above the price ceiling, versus ₹31 for exporter firms and ₹19 for local firms.

4.3 Estimation Strategy

The empirical strategy used in this study will compare changes in outcomes of interest for products placed under price controls as compared to products not placed under price controls. To assign the directionality of the legislation impact and ensure pre-trends will not drive any results from this analysis, the analysis begins with an empirical specification with month-year and treatment group interactions, as shown in Equation 1:

$$log(y_{it}) = \alpha m_t + \lambda d_i + \lambda m_t \times d_i + \mathbf{B}_i + \epsilon_{it} \tag{1}$$

where m_t are month-year fixed-effects, d_i is a fixed effect for price-controlled products, and controls $\mathbf{B}_i$ include drug formulation (e.g. pill, liquid, inhalent), drug pack size (e.g. 10 ml or 10 pills) and its square,

firm type, a dummy for chronic drugs, product therapeutic class, and the age of the product launched earliest in a given drug class. Outcomes y_{it} are maximum retail price ("MRP"),[12] and units sold. The coefficient of interest in this equation, λ, represents the interaction between month-year and price-controls. If there are no pre-trends, then λ should be statistically indistinguishable from 0 prior to the initial price control implementation in September 2013. Results for this analysis are shown in Figure 4. It is clear from these graphs that after the beginning of the legislation, noted with red lines in the graphs, prices and product-level sales begin to decline amongst price-controlled products with respect to non-controlled products. The graphs show that pre-trends were similar across products receiving and not receiving price controls, with one clear jump in pricing trends seen in the first quarter of 2012. This jump does not correspond with any announcement or implementation of price ceiling legislation, as detailed in Figure 1. Instead, it corresponds with the timing of the significant price increases in the first quarter of 2012. While the timing of this jump in trends does not correspond to announcement of price ceiling legislation, it is not possible to rule out that the announcement of the legislation contributed to this jump in pricing trends amongst price-controlled medications. Assuming this was the case, it is clear how this finding would bias study results – impacts on prices would be *upward* biased, with actual pricing impacts potentially lower, while impacts on sales units would be *downward* biased, given the overstatement of pricing effects.

To assess the overall magnitude of the short-term effect of the legislation on prices and sales units, the main analysis employs a difference-in-differences framework, following the approach of Bertrand et al. (2004). The estimation strategy is shown in Equation 2:

$$log(y_{it}) = \alpha m_t + \lambda s_i + \delta c_{it} + \epsilon_{it} \tag{2}$$

where outcomes y_{it} include maximum retail price and units sold. 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. Thus δ, the coefficient of interest, measures the effect of the price control legislation. Standard errors are clustered at the SKU-level to allow for serial correlation and heteroskedasticity.

Sub-analyses include a regression that is similar to Equation 2, but with an interaction term, as shown

[12]MRP is the central measure of price to consumer, however it is an imperfect measure. MRP is the tax-inclusive price printed on a medication box and is determined by the manufacturer. While the pharmacist can offer discounts below the MRP, this cuts into their margin, which is 20% of the MRP in the retail setting.

in Equation 3.[13]

$$log(y_{it}) = \alpha m_t + \lambda s_i + \delta c_{it} + \omega c_{it} * v_i + \epsilon_{it} \tag{3}$$

with a number of different interaction variables, v_i. The first is a dummy for whether a product is ex-ante priced below the price ceiling. Given that this variable is 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 2.3 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. The second interaction variable is firm type, with firms classified into three groups: multinational, exporting, and local. A number of robustness tests are shown in the appendix. These robustness tests are discussed in more detail throughout the results section, but include regressions excluding products which exit during the time frame of the study, results excluding low volume products, and results run separately by company type.

To identify the impacts of the legislation on originator market share, we 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, we 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, we also estimate average partial effects ("APEs") with bootstrapped standard errors. Alternative specifications for this analysis can be found in the appendix, including a linear specification with fixed effects.

Last, to estimate producer exit, this paper estimates the following probit model at the SKU and product-company levels:

$$E[Y|\beta \mathbf{X}_i] = \beta_0 + \beta_1 c_i + \beta_2 f_i + \beta_4 \times c_i + \mathbf{B}_i + \epsilon_{it} \tag{5}$$

where c_i indicates a product received a price ceiling, f_i indicates company type, and Y is an indicator

[13] As company and product characteristics are time invariant and perfectly correlated with SKU fixed effects, they only enter into the equation as part of the interaction term.

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. In alternate specifications, we add interaction terms between the price ceiling and market concentration measures.

The key identifying assumption in the empirical strategy is that absent the price control legislation, the price-controlled products would have trended similarly to the non price-controlled products. Essential to this identification strategy is avoiding issues of "spillovers" from the medications that received a price ceiling to those that did not.[14] 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 see spillover effects from the legislation and thus do not serve as a clean control group. To identify these spillover 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.

5 Results

5.1 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 Table 7. Column (1), which represents the overall effect of the price ceilings on logged retail price, shows that prices of controlled products dropped by approximately 11.6% as compared to the non-controlled market. Column (2) shows these same results with an interaction term for company type, where local firms serve as the baseline. As predicted by the model, the three company types all decrease prices in response to the price

[14] 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.

ceiling. As predicted by the theoretical model, multinational companies show the largest price decreases – not surprising given that the price ceilings required the largest markdowns for these firms. To test the mechanism in the theoretical model – that even products priced below the ceiling will decrease their price – Column (3) presents analysis including an interaction term for products that were ex-ante priced 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. Results in Appendix G show that these findings are not driven by producer exit and are robust to excluding small SKUs and to running regressions separately for each company type.

Section I in the Appendix analyzes the impact of the legislation on the prices of "spillover" products, which are likely direct competitors of price-controlled products and thus excluded from the main analysis. These results show a small but significant 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 clearly 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 competitors of price-controlled products.

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

Table 8 presents results on the impacts of price control legislation on logged sales units. As can be seen in the top row of the first column, the overall impact of the legislation on sales is an approximately 4.3% decrease at the SKU-level. However, as can be seen in the remaining columns, there are significant differences by company type. Sales for local and exporting firms drop significantly after the legislation, by 5.3% and 4.7%, respectively. However, amongst multinational firms, there was no significant drop or growth in sales units overall. This runs counter to the predictions of the model, which indicate that the multinational products should see an increase in sales units and that total market sales should either remain stable or increase. While there is firm exit, as discussed in the following section, this exit is not driving the decrease in sales – the results are robust to narrowing the sample to firms who do not exit the market.

An interesting quirk of the Indian legislation is that, 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 weighted average required price decrease might be near zero. This can have important implications, 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 8 indeed shows that the decrease in sales is primarily driven by local firms in markets that were highly impacted by the price control legislation, supporting the theoretical model.

To understand the decrease in sales post-legislation, it is important to look at the "spillover markets" – in other words to look at potential substitutes for price-controlled products that did not receive a price ceiling. Aggregating sales to the broader product[15] level – combining sales of both price-controlled and spillover formulations of products – shows that in product markets where even a portion of products received price ceilings, there is a significant 5.3% decrease (p-value: 0.024) in sales post-legislation. This is explained by a lack of an uptick in sales amongst spillover markets – which would be a logical result given the shrinking size of the price-controlled markets. Section I in the Appendix presents results of the effect of legislation on spillover markets alone and shows that even though these markets have significant, though modest, price decreases post-legislation, there is only an increase in sales for close competitors of price-controlled products, with no effect on broader competitors. The uptick in sales amongst close competitors does not make up for the decrease in price-controlled products, accounting for the market-level 5.3% decrease in price controlled product markets.

There are two likely explanations for this phenomenon. One of these is 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,[16]

[15]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.

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

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 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 post-legislation may be due to marginal costs rising with volume. Section F.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, eds, 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, 2016).

To assess whether advertising might be driving the decrease in sales, we 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. The first panel in Table 9 shows that bonus sales decrease significantly – by over 50% – amongst price-controlled products after the legislation. The second panel in this table shows that bonus sales decrease for spillover formulations of price-controlled drugs as well, but to a much smaller extent. Table J17 in the appendix examines the correlation between bonus units as a percentage of sales and sales volume, controlling for SKU and month-year fixed effects. This finds a positive correlation between bonus sales and product sales volume, but this is not causal evidence and there are clear endogeneity concerns. 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.

To assess whether pharmaceutical companies pulled products out of costly rural sub-markets post-legislation, we 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 shows the main results by therapeutic class. Anti-malarials, anti-infectives, neurological and CNS drugs, analgesics, and vitamins, minerals and nutrients 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 were occurring primarily in rural settings, we would expect "solid" product formations to have the biggest decrease in sales post-legislation. Table 10 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. Injections saw a semi-significant decrease in sales post-legislation, while there was no significant change in sales units for inhalants 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.

While overall sales volume decreases, the second prediction of Prediction 2 – that market share of multinationals will increase post-legislation – is met. Table 11 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 (approximate 14.5% loss), while multinationals gained significant market share (approximate 7.5% gain). The market share of exporter firms remained stable. In the appendix, Table K20 shows that these results hold when using a linear specification and Table K19 shows that these results also hold when including spillover products. Thus it is clear that multinational products gained significant market share post-legislation, particularly in acute markets, while local products lost significant market-share.

5.3 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. We test this prediction by examining likelihood of exit post-legislation for price-controlled medications versus non-controlled medications.

Table 12 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

the exit of local firms.

Table H10 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.

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.

6 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 low-quality) producers, and producer exit from 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. Economic theory shows 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, with firms 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 high-priced medications are often produced by foreign manufacturers, 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.

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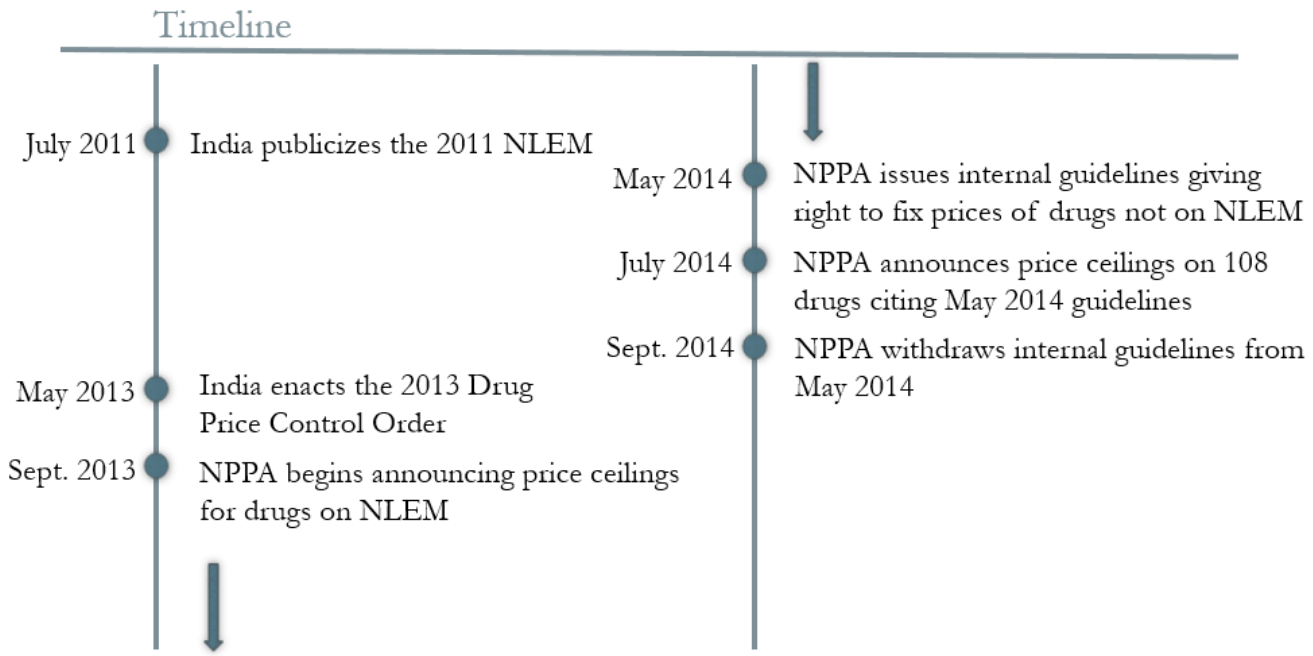
7 Graphs and Figures



† 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 1: Timeline of Price Controls Used in Analysis

	Number of Firms		Total Sales in MM (Units)		Total Sales in MM (Value)	
Firm Type	Count	% of Total	Total	% of Total	Total	% of Total
Local	630	73%	9,167	8%	417,312	9%
Exporter	185	21%	74,906	67%	2,976,625	67%
Multinational	50	6%	27,124	24%	1,047,408	24%
Total	865	100%	111,197	100%	4,441,345	100%

† Summary statistics are aggregated from the AIOCD Awacs data between 2010 through 2015. Unit sales presented here are not standardized by dosage.

Table 1: Firm Count and Retail Sales in MM by Firm Type - 2010 Through 2015

	Mean	S.D.	Min	Max
Logged MRP				
Local	4.05	0.88	-4.61	12.71
Exporter	4.23	1.19	-4.61	11.96
Multinational	4.55	1.47	-4.61	12.36
Logged Sales Units				
Local	6.58	2.25	0.00	15.28
Exporter	7.98	2.55	0.00	17.67
Multinational	8.21	2.77	0.00	16.30
Market Share				
Local	3%	12%	0%	100%
Exporter	9%	21%	0%	100%
Multinational	18%	30%	0%	100%

† Numbers shown here are aggregated from the AIOCD Awacs data between 2010 through 2015. Sales units presented here are not standardized by dosage. Market share is shown at the SKU-level.

Table 2: Summary Statistics by Producer Type

	Ratio Multinational-Exporter	Ratio Multinational-Local	Ratio Exporter-Local
MRP	1.28	1.29	1.15
	(0.83)	(0.88)	(0.69)
Sales Units	12.21	127.31	195.50
	(32.93)	(381.40)	(693.05)

† Numbers shown here are aggregated from the AIOCD Awacs data between 2010 through 2015. Data is Winsorized at 1% to prevent results from being heavily influenced by outliers.

Table 3: Price Ratio by Company Type

Firm Type	Average # Failures†	Average # Tests*	Ratio Failures to Tests	Estimated Failure Rate
Local	0.20	0.11	1.82	9.09%
	(0.67)	(0.41)	(6.11)	
Exporter	1.11	1.25	0.89	4.44%
	(1.44)	(1.72)	(1.58)	
Multinational	0.52	0.78	0.67	3.33%
	(1.06)	(1.72)	(1.58)	

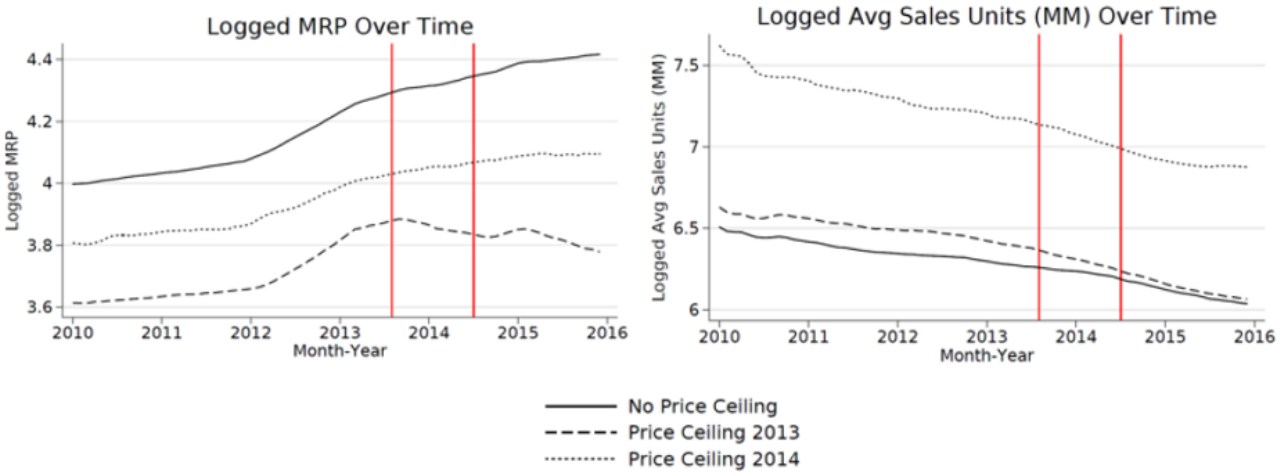
† Average number of failures is measured as the average number of times a manufacturer's products appear in the FDCA "not standard quality" drug data. If a manufacturer does not appear in this data, it is included in the calculation of the average as showing up zero times.
*Average number of tests is 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 4: Average Product Failure and Test Rate by Firm Type

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 Retailer Markup	2.64	2.27	2.62
	(1.20)	(1.29)	(0.87)
Logged Sales Units	7.47	7.71	8.29
	(2.54)	(2.74)	(2.35)
HHI	3015	3567	1340
	(2365)	(2999)	(613)
SKU Launch Year	2008	2007	2007
	(4.28)	(4.32)	(4.56)
Product Launch Year	2000	1996	2000
	(5.06)	(3.34)	(3.99)
% Chronic	39.68%	31.39%	100%
	(0.49)	(0.46)	(0.00)

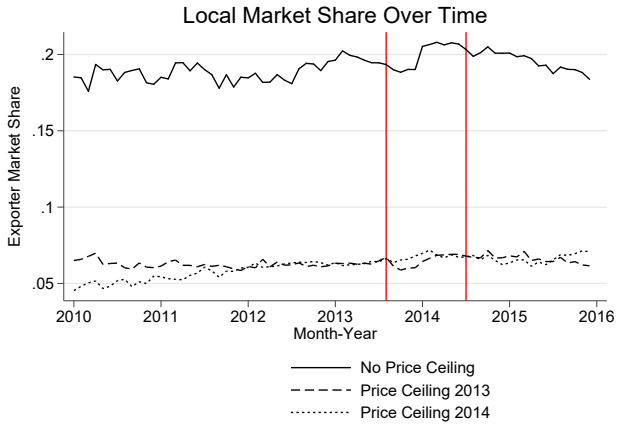
† Statistics sourced from the AIOCD Awacs data for the time period between January 2010 through May 2013, which is when the first waves of price ceilings began. Sales volume and sales units are not adjusted for dosage. All values are unweighted.

Table 5: Characteristics of Price Controlled and Non-Price Controlled Products

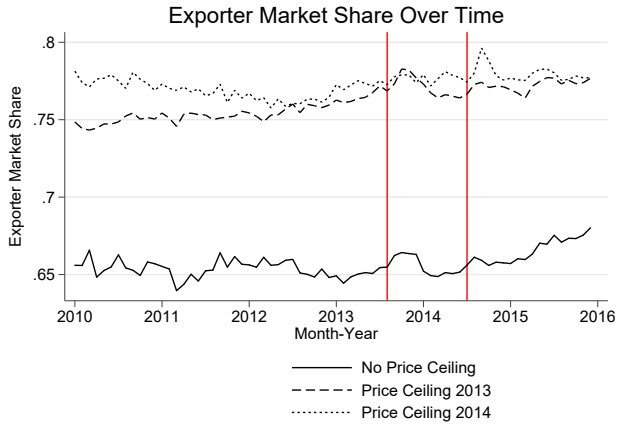


† Data shown here are rolling averages due to seasonal nature of the data. Average sales units are calculated at the SKU-level. Average and total sales units are not adjusted for dosage.

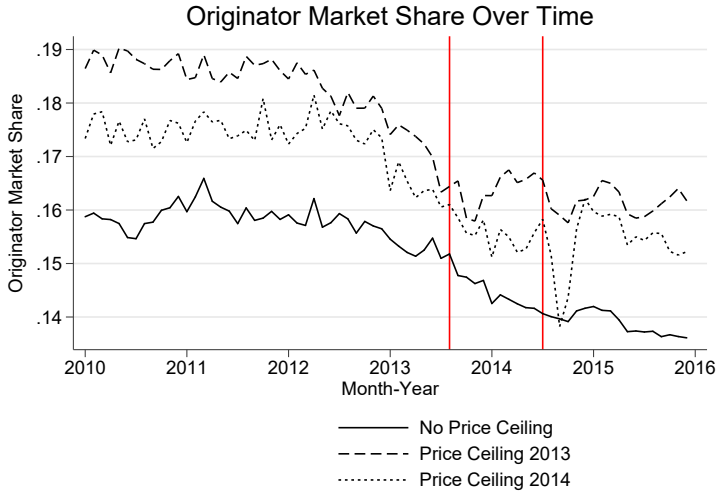
Figure 2: Time Series Trends for Logged MRP and Sales Units



(a)



(b)



(c)

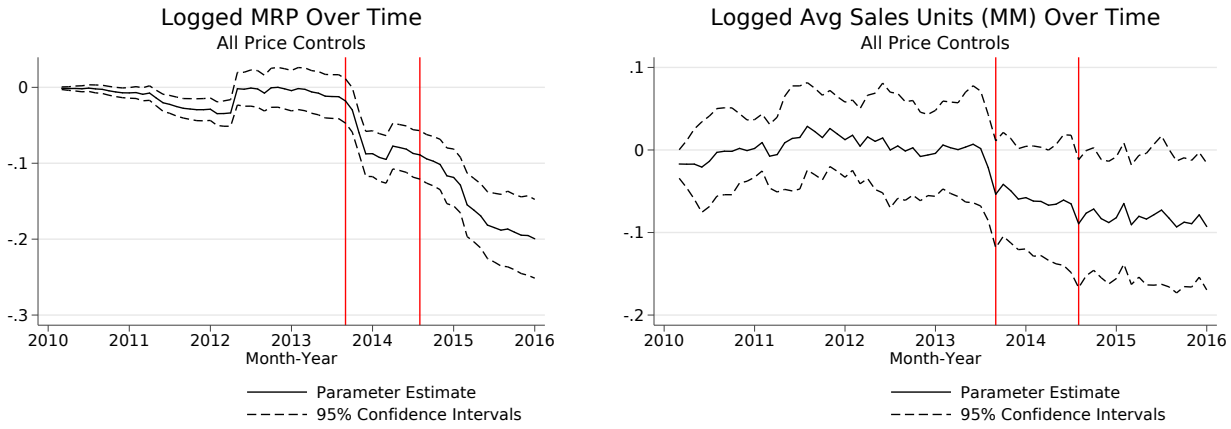
† Market share is calculated at the product level, defined at the EPhMRA subgroup level.

Figure 3: Time Series Trends for Branded, Exporter, and Local Firm Market Shares

	Local Firm	Exporter Firm	Multinational Firm
	Absolute Markdown		
Overall	4.7	4.2	-6.0
	(36.2)	(57.6)	(65.5)
Above Price Ceiling	-18.8	-30.6	-42.3
	(36.6)	(61.9)	(72.8)
Below Price Ceiling	18.2	23.9	20.9
	(28.2)	(44.2)	(43.1)
	Percentage Difference		
Overall	15.9%	16.2%	5.3%
	(0.55)	(0.58)	(0.50)
Above Price Ceiling	-22.7%	-24.0%	-27.3%
	(0.20)	(0.23)	(0.23)
Below Price Ceiling	38.1%	39.0%	29.4%
	(0.56)	(0.60)	(0.51)

† Markdown is calculated as the ceiling price subtracted by the average SKU market price in the month price ceilings are adopted. Data is Winsorized at 1% to prevent results from being heavily influenced by outliers.

Table 6: Price Markdown by Company Type*



(a) (b)

Figure 4: λ_{it} For Logged MRP and Sales Units

	(1) Main Effect	(2) Company Type Interaction	(3) Price Ceiling Interaction
		Logged MRP	
Price Ceiling	-0.109***	-0.111***	-0.107***
	(0.003)	(0.005)	(0.005)
Company Type			
Exporter × Price Ceiling		0.012^{+}	
		(0.007)	
Multinational × Price Ceiling		-0.054***	
		(0.012)	
Non-Binding Ceilings			
Under Ceiling × Price Ceiling			-0.004
			(0.007)
Observations	2,656,065	2,656,065	2,656,065
Adj. R-squared	0.112	0.112	0.112

† Standard errors are clustered at the SKU level for all regressions shown here. Products from spillover groups are excluded from this analysis.
$^{+}$p<0.10, *p<0.05, **p<0.01, ***p<0.001

Table 7: Effect of Price Ceilings on MRP

	Firm Type			
	All	Local	Exporter	Multinational
All Price Controlled	-0.043**	-0.053*	-0.047**	-0.052
	(0.014)	(0.024)	(0.018)	(0.048)
High Impact	-0.083*	-0.189**	-0.061	-0.067
	(0.035)	(0.073)	(0.042)	(0.102)
Mid-High Impact	-0.018	-0.001	-0.016	-0.068
	(0.037)	(0.072)	(0.047)	(0.094)
Mid-Low Impact	-0.036	-0.039	-0.028	-0.131
	(0.022)	(0.036)	(0.029)	(0.082)
Low Impact	-0.041	-0.033	-0.069*	0.046
	(0.022)	(0.037)	(0.028)	(0.084)
Observations	3,205,914	1,058,121	1,828,295	319,498
Adj. R-squared	0.0152	0.0229	0.0114	0.0242

† Standard errors are clustered at the SKU level for all regressions shown here. Products from spillover groups are excluded from this analysis.
+p<0.10, *p<0.05, **p<0.01, ***p<0.001

Table 8: Effect of Price Ceilings on Logged Sales Units

	(1)	(2)	(3)	(4)
	Main Effect	Local Firms	Exporting Firms	Multinational Firms
	Price-Controlled Products			
Price Ceiling	-0.528***	-0.898***	-0.422***	-0.452***
	(0.035)	(0.078)	(0.040)	(0.127)
Observations	1,520,799	478,842	904,341	137,616
Adj. R-squared	0.274	0.274	0.274	0.327
	Spillover Products			
Price Ceiling	-0.189***	-0.504***	-0.107**	0.085
	(0.034)	(0.074)	(0.039)	(0.117)
Observations	1,521,547	488,266	896,904	136,377
Adj. R-squared	0.277	0.275	0.277	0.340

† Standard errors are clustered at the SKU level for all regressions shown here. Spillover products are excluded from the regressions on price-controlled medications and price-controlled medications are excluded from the regressions on spillover medications.
+p<0.10, *p<0.05, **p<0.01, ***p<0.001

Table 9: Effect of Legislation on Bonus Sales

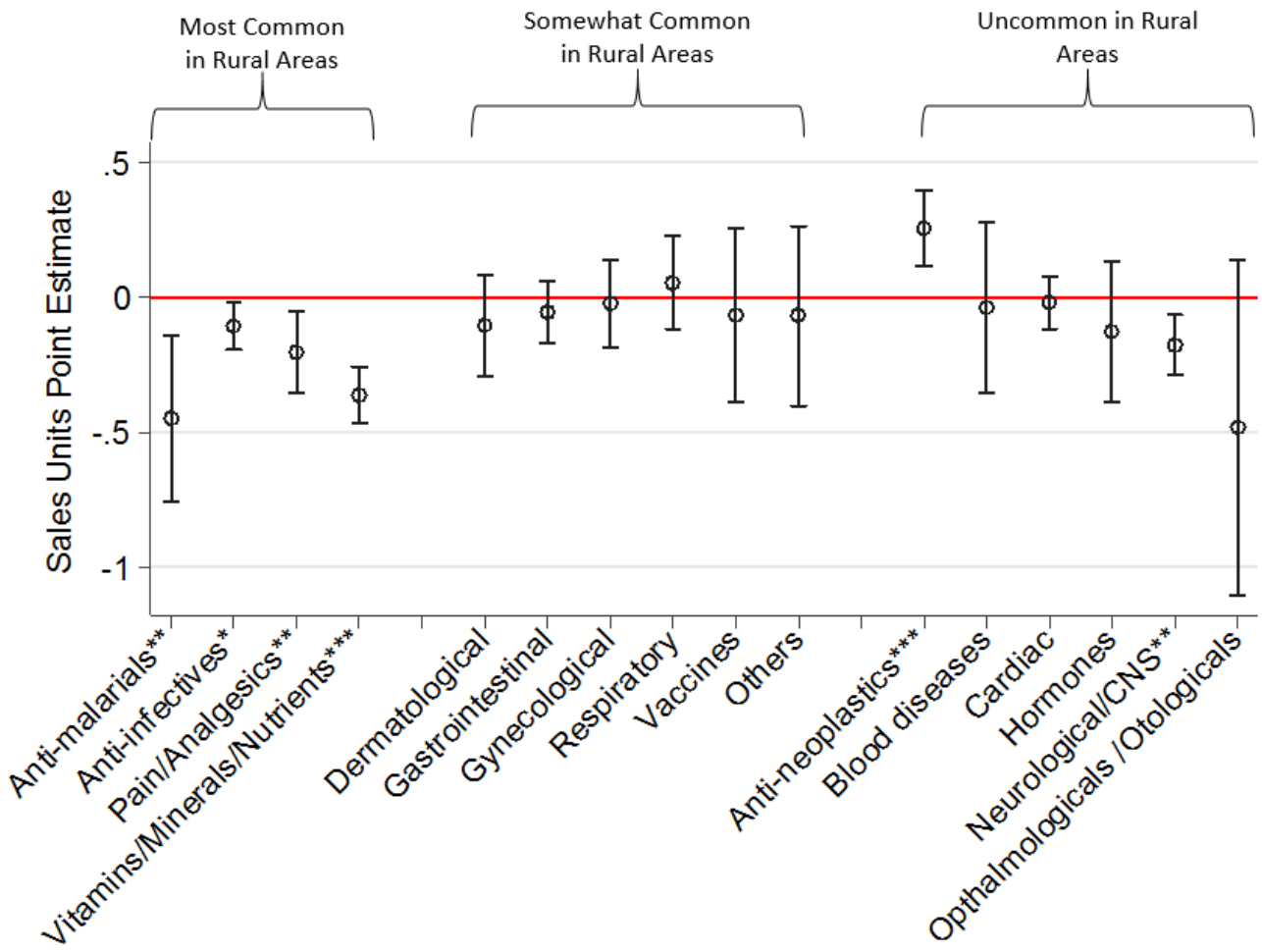


Figure 5: Effect of Price Controls by Therapeutic Class

	(1) Inhalants	(2) Injectables	(3) Liquids	(4) Solids
Price Ceiling	0.073	-0.067^{+}	-0.005	-0.042**
	(0.117)	(0.038)	(0.051)	(0.016)
Observations	39,725	351,489	592,361	2,202,645
Adj. R-squared	0.0213	0.00915	0.0196	0.0178

† Standard errors are clustered at the SKU level for all regressions shown here. Products from spillover groups are excluded from this analysis. Drugs that are classified as an "Other" category are excluded from this analysis.
$^{+}$p<0.10, *p<0.05, **p<0.01, ***p<0.001

Table 10: Effect of Treatment by Drug Category on Logged Sales Units

Model:	**Fractional Probit**	
	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	0.299***	0.075***
	(0.065)	(0.020)
N	180,051	180,051

† 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 11: Change in Product Market Share by Firm Type - Excluding Spillover Products

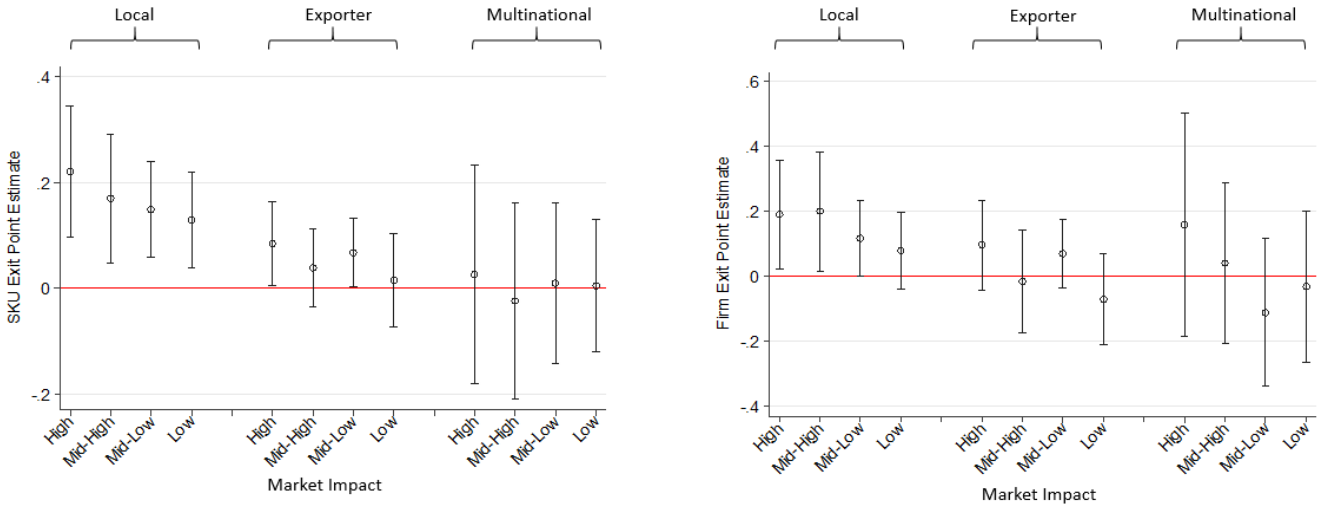


Figure 6: Effect of Price Controls on Exit by Level of Market Impact

	(1) SKU Exit	(2) SKU Exit	(3) Company Exit	(4) Company Exit
Price Ceiling	0.162***	0.176***	0.095*	0.097^{+}
	(0.033)	(0.039)	(0.042)	(0.055)
Company Type				
Exporter	0.049	0.048	-0.048	-0.058
	(0.044)	(0.044)	(0.048)	(0.048)
Multinational	0.166^{+}	0.166^{+}	0.116	0.106
	(0.091)	(0.091)	(0.097)	(0.098)
Market Concentration				
Not Concentrated		-0.041^{+}		-0.077*
		(0.023)		(0.033)
Highly Concentrated		-0.011		0.050*
		(0.017)		(0.025)
Company Type				
Price Ceiling × Exporter	-0.103*	-0.105*	-0.127*	-0.139*
	(0.041)	(0.042)	(0.054)	(0.056)
Price Ceiling × Multinational	-0.184**	-0.186**	-0.148^{+}	-0.162*
	(0.060)	(0.062)	(0.079)	(0.078)
Market Concentration				
Price Ceiling × Not Concentrated		-0.031		0.028
		(0.045)		(0.066)
Price Ceiling × Highly Concentrated		-0.007		0.032
		(0.032)		(0.054)
Constant	5.928***	5.499**	-0.174	-0.206
	(1.764)	(1.781)	(2.077)	(2.098)
Observations	96,654	96,654	40,412	40,412

† 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 12: Effect of Treatment on SKU and Company Exit

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 History of Drug Price Regulation

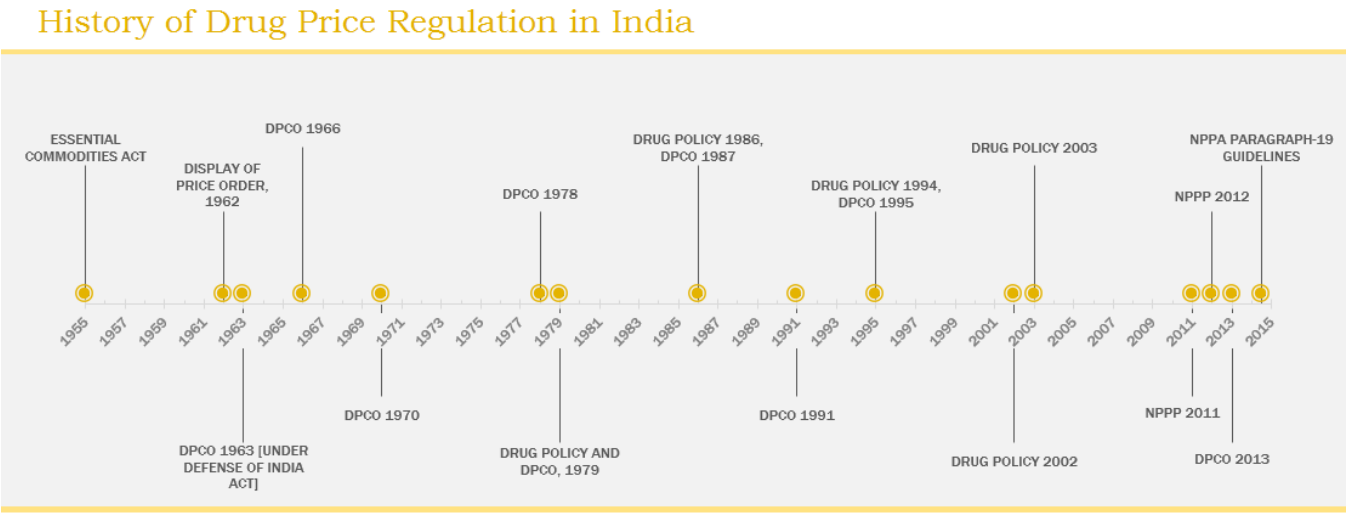


Figure B1: Timeline of Drug Price Regulation in India Between 1955 to Present

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).

C Market Concentration

Table C1: Market Concentration Summary

Market Concentration Level	Count of Markets	Percentage of Market
Non-Concentrated	52	1.75%
Moderately Concentrated	125	4.21%
Highly Concentrated	2,790	94.03%
Mean HHI	4889.86	
	(3724.16)	

† Markets are defined at the EPhRMA subgroup (generally molecule or molecule-combination) level between 2010 and the implementation of price ceilings in 2013. Definitions of market concentration are those generally 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.

D Estimates of Not Standard Quality Drugs in India

Table D2: Not Standard Quality ("NSQ") Estimates from the Indian Government

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

† 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).

D.1 Likelihood of FDCA Testing

Table D3 presents results of a Poisson regression estimating the how often a companies products will be tested by the FDCA. The outcome variable is count of times a companies' products appear in the FDCA testing data, and independent variables include the following company characteristics: logged total sales value, percentage of products priced below the price ceiling, number of unique products a company produces, and company type. I estimate a Poisson regression in place of a negative binomial regression as the dispersion parameter is not statistically different from zero.

	(1)
	FDCA Testing
Logged Total Sales Volume	0.338***
	(0.036)
% of Products Under Ceiling	-2.784***
	(0.782)
# Unique Products	-1.476
	(1.006)
Company Type	
Exporter	1.188***
	(0.213)
Multinational	0.924***
	(0.269)
Constant	-6.303***
	(0.509)
Observations	410

Table D3: Likelihood of a Company's Product Being Tested by the FDCA

E 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 E4: Listed Reasons for Failing Drug Quality Testing

F Theory Proofs and Extensions

F.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 $D_m^{pc} > D_m^{lf}$.

F.2 Allowing for Increasing Marginal Costs

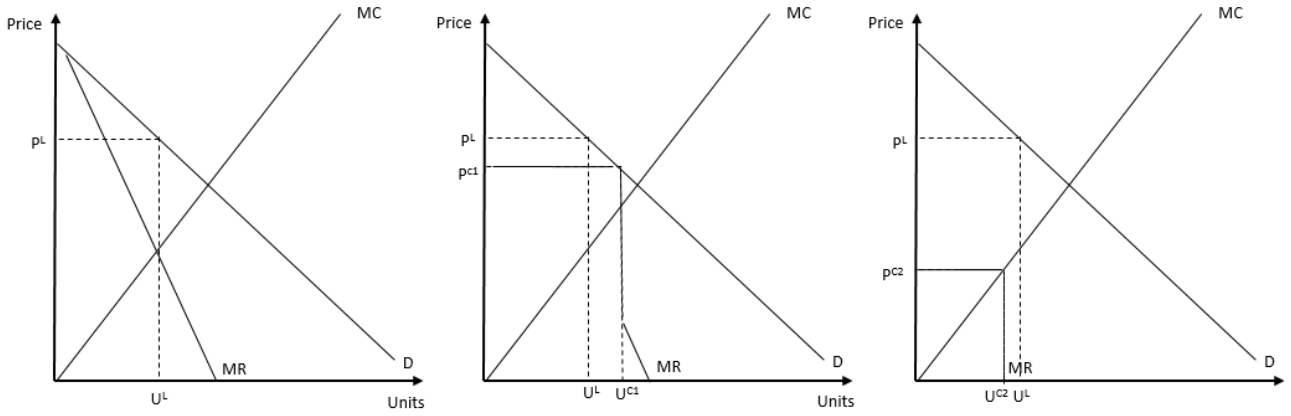


Figure F2: Price Ceilings with Firm Market-Power and Increasing Marginal Costs

Figure F2 shows how price ceilings that are set sufficiently low can lead to a decrease in supply – but not full market exit – after price ceilings are implemented, even for firms with market-power, if marginal costs are increasing in volume. In the first graph P^L and U^L denote the laissez-faire market price and quantity supplied by a monopolist producer. In the second graph, P^{C1} and U^{C1} indicate the prices and quantities supplied at Price Ceiling 1 = P^{C1}. This clearly leads to an increase in supply. In the third graph, the price ceiling is set significantly lower, at P^{C2}. At this, significantly lower price, quantity supplied shrinks to $U^{C2} < U^L$.

G Robustness - Test of Proposition 1

	(1) Main Effect	(2) Price Ceiling Interaction	(3) Company Type Interaction
		Logged MRP	
Price Ceiling	-0.116***	-0.118***	-0.119***
	(0.003)	(0.006)	(0.006)
Under Ceiling × Price Ceiling		0.002	
		(0.007)	
Company Type			
Exporter × Price Ceiling			0.013+
			(0.007)
Multinational × Price Ceiling			-0.058***
			(0.013)
Observations	2,263,423	2,263,423	2,263,423
Adj. R-squared	0.124	0.124	0.125

† Standard errors are clustered at the SKU level for all regressions shown here. Products from spillover groups are excluded from this analysis, as are SKUs that exit the market after May 2013 when the first wave of price ceilings went into place.
+p<0.10, *p<0.05, **p<0.01, ***p<0.001

Table G5: Effect of Price Ceilings on MRP and Sales Units Sold - Excluding SKUs that Exit the Market

	(1) Main Effect	(2) Price Ceiling Interaction	(3) Company Type Interaction
		Logged MRP	
Price Ceiling	-0.041***	-0.035***	-0.059***
	(0.003)	(0.006)	(0.008)
Under Ceiling × Price Ceiling		-0.009	
		(0.007)	
Company Type			
Exporter × Price Ceiling			0.024**
			(0.009)
Multinational × Price Ceiling			0.013
			(0.013)
Observations	1,523,005	1,523,005	1,523,005
Adj. R-squared	0.153	0.153	0.153

† Standard errors are clustered at the SKU level for all regressions shown here. Products from spillover groups and SKUs that had less than 1% market share for a given product in the year before relevant price controls were enacted are excluded from this analysis.
+p<0.10, *p<0.05, **p<0.01, ***p<0.001

Table G6: Effect of Price Ceilings on MRP – Products with Greater than 1% Market Share

	(1) Main Effect	(2) Price Ceiling Interaction
	Logged MRP	
Price Ceiling	-0.106***	-0.108***
	(0.005)	(0.009)
Under Ceiling × Price Ceiling		0.004
		(0.011)
Observations	976,362	976,362
Adj. R-squared	0.127	0.127

† Standard errors are clustered at the SKU level for all regressions shown here. Products from spillover groups are excluded from this analysis. Only products manufactured by local producers, as defined in Section 4.1, are included.
+p<0.10, *p<0.05, **p<0.01, ***p<0.001

Table G7: Effect of Treatment on Price - Local Products Only

	(1) Main Effect	(2) Price Ceiling Interaction
	Logged MRP	
Price Ceiling	-0.103***	-0.105***
	(0.004)	(0.007)
Under Ceiling × Price Ceiling		0.004
		(0.009)
Observations	1,433,045	1,433,045
Adj. R-squared	0.111	0.111

† Standard errors are clustered at the SKU level for all regressions shown here. Products from spillover groups are excluded from this analysis. Only products manufactured by exporting producers, as defined in Section 4.1, are included.
+p<0.10, *p<0.05, **p<0.01, ***p<0.001

Table G8: Effect of Treatment on Price - Exporter Products Only

	(1) Main Effect	(2) Price Ceiling Interaction
	Logged MRP	
Price Ceiling	-0.168***	-0.123***
	(0.012)	(0.016)
Under Ceiling × Price Ceiling		-0.078***
		(0.022)
Observations	246,658	246,658
Adj. R-squared	0.108	0.109

† Standard errors are clustered at the SKU level for all regressions shown here. Products from spillover groups are excluded from this analysis. Only products manufactured by multinational producers, as defined in Section 4.1, are included.
$^{+}$p<0.10, *p<0.05, **p<0.01, ***p<0.001

Table G9: Effect of Treatment on Price - Multinational Products Only

H Exit Including Spillover Drugs

	(1) SKU Exit	(2) SKU Exit	(3) Company Exit	(4) Company Exit
Price Ceiling	0.162***	0.176***	0.015	0.002
	(0.033)	(0.039)	(0.044)	(0.059)
Chronic	-0.079***	-0.078***	-0.088***	-0.082***
	(0.020)	(0.020)	(0.023)	(0.023)
Company Type				
Exporter	0.049	0.048	-0.046	-0.057
	(0.044)	(0.044)	(0.048)	(0.048)
Multinational	0.166+	0.166+	0.133	0.122
	(0.091)	(0.091)	(0.098)	(0.099)
Market Concentration Not Concentrated		-0.041+		-0.068*
		(0.023)		(0.030)
Highly Concentrated		-0.011		0.060*
		(0.017)		(0.025)
Price Ceiling × Chronic	-0.032	-0.034	0.070	0.062
	(0.038)	(0.038)	(0.055)	(0.055)
Company Type				
Price Ceiling × Exporter	-0.103*	-0.105*	-0.128*	-0.135*
	(0.041)	(0.042)	(0.055)	(0.056)
Price Ceiling × Multinational	-0.184**	-0.186**	-0.153+	-0.162+
	(0.060)	(0.062)	(0.085)	(0.084)
Market Concentration				
Price Ceiling × Not Concentrated		-0.031		0.072
		(0.045)		(0.070)
Price Ceiling × Highly Concentrated		-0.007		0.038
		(0.032)		(0.056)
Constant	5.928***	5.499**	-1.459	-1.549
	(1.764)	(1.781)	(1.981)	(1.992)
Observations	96,654	96,654	44,207	44,207

† Standard errors are clustered at the SKU level for all regressions shown here.
+p<0.10, *p<0.05, **p<0.01, ***p<0.001

Table H10: Effect of Treatment on SKU and Company Exit

I Spillover Group Analysis

	(1) Main Effect	(2) Company Type Interaction
	Logged MRP	
Price Ceiling	-0.023***	-0.024***
	(0.002)	(0.002)
Company Type		
Exporter × Price Ceiling		0.012***
		(0.002)
Multinational × Price Ceiling		0.006
		(0.004)
Observations	2,481,755	2,481,755
Adj. R-squared	0.120	0.120

† Standard errors are clustered at the SKU level for all regressions shown here. Price-controlled products are excluded from this analysis.
+p<0.10, *p<0.05, **p<0.01, ***p<0.001

Table I11: Effect of Treatment on Price of Spillover Products - Broad Definition of Spillover

	(1)
	Main Effect
	Narrow Product Market
Price Ceiling	0.042**
	(0.015)
Observations	3,183,919
Adj. R-squared	0.0146
	Broad Product Market
Price Ceiling	0.001
	(0.009)
Observations	3,183,919
Adj. R-squared	0.0146

† Standard errors are clustered at the SKU level for all regressions shown here. Price-controlled products are excluded from this analysis.
+p<0.10, *p<0.05, **p<0.01, ***p<0.001

Table I12: Effect of Treatment on Logged Unit Sales of Spillover Products - Narrow and Broad Definition of Spillover

	(1)
	Main Effect
	Local Firms
Price Ceiling	-0.026***
	(0.002)
Observations	837,539
Adj. R-squared	0.138
	Exporter Firm
Price Ceiling	-0.022***
	(0.002)
Observations	1,404,801
Adj. R-squared	0.118
	Multinational Firm
Price Ceiling	-0.030***
	(0.005)
Observations	239,415
Adj. R-squared	0.113

Table I13: Effect of Treatment on Logged MRP on Spillover Products By Company Type - Broad Definition of Spillover

	(1)
	Main Effect
	Interaction
	Local Firms
Price Ceiling	0.031*
	(0.014)
Observations	1,077,665
Adj. R-squared	0.0219
	Exporter Firm
Price Ceiling	-0.010
	(0.012)
Observations	1,795,675
Adj. R-squared	0.0109
	Multinational Firm
Price Ceiling	-0.110***
	(0.033)
Observations	310,579
Adj. R-squared	0.0231

Table I14: Effect of Treatment on Logged Sales Units on Spillover Products By Company Type - Broad Definition of Spillover

J Additional Results from Analysis on Markup and Legislation Effects by Product Category

	(1) Inhalants	(2) Injectables	(3) Liquids	(4) Solids
Price Ceiling	-0.113	-0.098***	-0.136***	-0.101***
	(0.075)	(0.009)	(0.009)	(0.004)
Observations	30,955	271,715	450,075	1,736,604
Adj. R-squared	0.152	0.0622	0.213	0.111

Table J15: Effect of Treatment by Drug Category on Logged MRP

	(1) Inhalants	(2) Injectables	(3) Liquids	(4) Solids
Price Ceiling	-0.107	-0.130***	-0.166***	-0.139***
	(0.109)	(0.014)	(0.015)	(0.005)
Observations	30,948	270,819	448,945	1,731,440
Adj. R-squared	0.127	0.0837	0.118	0.100

Table J16: Effect of Treatment by Drug Category on Logged Retailer Markup

	(1) Main Effect	(2) Local Firms	(3) Exporting Firms	(4) Multinational Firms
Bonus Sales	0.224***	0.162***	0.249***	0.181*
	(0.022)	(0.041)	(0.028)	(0.081)
Observations	2,094,259	718,541	1,173,700	202,018
Adj. R-squared	0.0163	0.0191	0.0134	0.0306

† Standard errors are clustered at the SKU level for all regressions shown here. Price-controlled and spillover products are excluded from this analysis.
+p<0.10, *p<0.05, **p<0.01, ***p<0.001

Table J17: Correlation Between Bonus Sales and Sales Units

	Acute Medications					
	Prior to Price Control Legislation			**Post Price Control Legislation**		
	Ratio MNC-Exporter	Ratio MNC-Local	Ratio Exporter-Local	Ratio MNC-Exporter	Ratio MNC-Local	Ratio Exporter-Local
MRP	1.20	1.28	1.05	1.09	1.08	1.04
	(0.69)	(2.11)	(0.56)	(0.51)	(0.58)	(0.58)
Retailer Markup	1.15	1.37	1.27	1.07	1.25	1.35
	(1.06)	(2.24)	(0.95)	(1.15)	(1.63)	(1.40)
Sales Units	2.71	12.41	16.06	3.16	11.63	15.08
	(7.17)	(19.06)	(19.45)	(8.66)	(20.00)	(19.18)
	Chronic Medications					
	Prior to Price Control Legislation			**Post Price Control Legislation**		
	Ratio MNC-Exporter	Ratio MNC-Local	Ratio Exporter-Local	Ratio MNC-Exporter	Ratio MNC-Local	Ratio Exporter-Local
MRP	1.26	1.34	1.11	1.19	1.27	1.12
	(0.46)	(0.56)	(0.43)	(0.53)	(0.63)	(0.57)
Retailer Markup	1.25	1.42	1.24	1.18	1.33	1.29
	(0.88)	(1.14)	(1.12)	(1.13)	(1.35)	(2.05)
Sales Units	2.95	10.15	11.75	2.86	10.25	12.88
	(8.20)	(16.05)	(16.22)	(7.74)	(17.94)	(17.52)

Table J18: Ratios of MRP, Retailer Markup and Sales Units for Acute and Chronic Products Prior to and Post Price Control Legislation: Price-Controlled Products Only

K Alternative Specifications of Market Share Analysis

K.1 Main Results Including Spillover Products

Model:	**Fractional Probit**	
	Coefficient	**APE**
Market Share of:		
Local Firms	-0.529***	-0.138***
	(0.067)	(0.023)
Exporter Firms	0.116*	0.043+
	(0.54)	(0.024)
Multinational Firms	0.256***	0.064***
	(0.061)	(0.019)
N	181,305	181,305

Table K19: Change in Product Market Share by Firm Type - Including Spillover Groups

K.2 Linear Approximation with Fixed Effects

	(1)	(2)	(3)
	Local Firm	Exporter Firm	Multinational Firm
		All Data	
Price Ceiling	-0.015***	0.002	0.013***
	(0.002)	(0.004)	(0.004)
Observations	180,051	180,051	180,051
Adj. R-squared	0.00140	0.000948	0.00706

Table K20: Effect of Legislation on Market Share by Firm Type