Equilibrium Effects of Pharmaceutical Bundling: Evidence from India*

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Abstract

We study the equilibrium effects of competitive bundling on market outcomes and social welfare in the context of the Indian pharmaceutical industry. Fixed-dose combinations (FDCs), which bundle two or more drugs in a single pill, account for over 50% of pharmaceutical revenue in India. Using an equilibrium model of drug demand and supply, we show that the price and welfare effects of FDCs are theoretically ambiguous. Empirically, we find that FDCs on average sell at a 28% discount but increase standalone component prices by 3%. New FDCs significantly increase sales of drug bundles. To quantify the welfare effects of FDCs, we estimate the model in the market for Alzheimer's drugs. We find that FDCs increase consumer surplus by 21% and firm profits by 13% because of significant market expansion and cost savings. Counterfactual analysis shows that applying FDC regulations from the US to India could deter FDC entry and forestall potential welfare benefits.

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1 Introduction

Competitive bundling is a phenomenon whereby competing multiproduct firms sell a package of products at a discount. Examples include TV–internet–phone bundles, connecting flights, home and auto insurance, fast-food value meals, and so on. Theoretically, bundle discounts could make markets more competitive, but bundling may also hurt some consumers through price discrimination or choice distortions. Despite the prevalence of competitive bundling, there is limited empirical evidence on its equilibrium effects on market outcomes and social welfare.

In this paper, we study competitive bundling in the context of the Indian pharmaceutical industry. Pharmaceutical companies implement competitive bundling with fixed-dose combinations (FDCs), which combine two or more drugs in a single pill. In India, FDCs are de facto unregulated, and they account for over 50% of total pharmaceutical revenue. The industry also resembles a typical product market, where most consumers pay for goods out of pocket and patent protection is uncommon. We thus have a rich and tractable setting from which to gain general insights into the economics of competitive bundling. In addition, many countries such as the US require costly, large-scale clinical trials to support new FDCs. Lessons from FDCs in India could also help inform policy discussions on FDC regulations.[1]

Our analysis consists of three main parts. We begin with a model of drug demand and supply to highlight key market forces that shape the equilibrium effects of FDCs. We then provide model-free evidence on the effects of FDCs on drug prices and sales, leveraging rich variation from FDCs in a wide range of therapeutic markets. Finally, we focus on the market for Alzheimer's drugs and estimate the model to characterize the welfare implications of FDCs and FDC regulations. Our results show that FDCs could potentially benefit both consumers and firms because of procompetitive effects and cost savings, though the welfare effects may be reversed under certain market conditions. Counterfactual analysis suggests that uniformly strict FDC regulations may deter FDC entries and forestall potential welfare benefits.

To develop intuition on the potential equilibrium effects of FDCs, we first consider a model of drug demand and supply with two drugs and an FDC that bundles both. On the demand side, consumers have five types of drug choices: the outside option, a product of either drug, a bundle of the two drugs purchased separately, or an FDC product. Within each type, there are different drug bundles offered by different firms. An FDC is equivalent to a two-drug bundle from the same firm, except that it has its own price and that consumers may prefer the FDC for reasons such as convenience or mistaken beliefs on product varieties. We allow heterogeneity in consumers' drug preferences and firm preferences and

[1] Policy debates on regulating FDCs have focused mostly on their potential health impacts. In particular, many discussions focus on the trade-off between improved medication adherence and the risks to patients from unneeded FDC prescriptions and overtreatment (World Health Organization, 2005; Evans and Pollock, 2015; Vendoti, 2018). The potential equilibrium effects of pharmaceutical bundling have rarely been considered, in part due to the lack of empirical evidence.

in the (dys)synergy from taking both drugs. Such preference heterogeneity determines the types of consumers that FDCs attract. On the supply side, firms set prices to maximize profits under Nash–Bertrand competition. The marginal cost of an FDC may be different from the sum of its components' costs.

Our model provides intuition for key market features that determine the price and welfare effects of FDCs. First, FDCs may sell at a premium due to FDC preferences or at a discount because of cost savings or price discrimination. The price discrimination incentive diminishes when consumers tend to buy both drugs from the same firm anyway. Second, FDCs have ambiguous effects on standalone component prices. Competition from FDCs pushes component prices down, but firms that sell FDCs tend to increase component prices to steer consumers towards their FDCs. Finally, the welfare effects of FDC discounts depend on the net outcome of two countervailing forces: a market expansion effect and a cannibalization effect. FDC discounts usually increase social surplus when they increase drug sales but may reduce allocative efficiency when they divert consumer choices from other two-drug bundles.[2]

With this theoretical intuition in mind, we turn to our empirical setting to measure the effects of FDCs on market outcomes and social welfare. Our primary data set covers monthly prices and sales of all main drugs sold in India between April 2007 and December 2019.[3] We also leverage three ancillary data sets. The first contains information on coprescriptions, where we observe the monthly prescription count of each drug and the coprescription count of each pair of drugs. The second contains transaction-level data from one of the leading e-pharmacy platforms in India. The third is the Medicare Part D Prescription Drug Event data from the US, which allow us to observe patterns of drug choices in a setting in which most FDCs are absent.

We begin with a descriptive analysis of the effects of FDCs on drug prices and sales. First, we show that FDCs on average sell at a 28% discount relative to the sum of their components' prices. Using drug coprescription rates in the US as a proxy for counterfactual coprescription rates in India in the absence of FDCs, we show that the FDC discount is indeed smaller when consumers tend to buy the drug bundle anyway.[4] A 10% increase in the coprescription rate is associated with a 2.8% smaller discount among two-molecule FDCs.

Second, we measure the effects of FDCs on the prices of their component molecules. Using an event study framework, we find that entries of FDCs on average increased prices of their component molecules by around 3% relative to prices of other molecules. Using cross-sectional variation in drug prices, we

[2]Part of the market expansion effect could also be driven by FDC preferences. The welfare effects of such market expansion depend on whether the FDC preferences capture convenience benefits or mistaken beliefs on product varieties.

[3]Manufacturers set drug prices at the national level, and we observe drug sales for 23 regions of India. Our main empirical analysis is done at the national level.

[4]The coprescription rate is a number between 0 and 1 that measures consumers' propensity to take two drugs together. A coprescription rate of 0 means no consumer is prescribed the two drugs together, while a coprescription rate of 1 means all consumers who are prescribed a drug are also prescribed the other drug.

show that firms that sells FDCs of a molecule indeed set a 7% higher price for that molecule compared to firms that do not sell the FDCs. Taken together, our results suggest that the price effects of FDCs significantly benefit consumers who need the full bundle of drugs but on average harm consumers who need just one component. Consistent with our theoretical intuition, the price effects depend on factors such as drug coprescription rates and firms' product portfolios.

Third, we measure the market expansion and cannibalization effects of 81 new two-molecule FDCs. We find that the median new FDC increased the total coprescription rate of its components by 189% and reduced the non-FDC coprescription rate by 25%.[5] A strong market expansion effect and a modest cannibalization effect imply potentially large welfare gains from many FDCs, though the welfare effects still depend on whether the market expansion is driven by FDC discounts or potentially distortionary FDC preferences.

Next, we focus on the market for Alzheimer's drugs and estimate the model to quantify the welfare effects of FDCs and FDC regulations. We choose this market because it is important for the well-being of the elderly and because it offers a tractable setting with two main drugs and one FDC. We define the national market in a quarter as one market and focus on donepezil and memantine, which account for over 95% of Alzheimer's drug sales in India. FDC products of the two drugs were first introduced in 2008 and on average sell at a 25% discount. The efficacy of the FDC has been well established by the medical literature (Tariot et al., 2004), and the FDC was approved in the US in 2015.

We combine aggregate moments with consumer-level data to identify key market features that determine the equilibrium effects of FDCs. First, we estimate price elasticities by using a price control policy that led to a sharp price reduction in a subset of drug products in 2016. Second, we use the coprescription data to directly measure the fraction of consumers who buy both drugs before and after FDC entry. Demand for FDCs that is not explained by the FDC discount reveals the size of consumer FDC preferences. Finally, we use panel data on repeated drug purchases by individual consumers on the e-pharmacy platform to identify the remaining time-invariant components of consumer preferences. For example, the drug purchase histories of consumers who switch to a new FDC product provide information on the types of consumers that FDCs attract. On the supply side, the residual FDC discounts after firms' strategic pricing incentives are accounted for reveal the cost savings from FDCs.

Our estimates shed light on several market features that are key to the welfare effects of FDCs. First, the marginal costs of FDC products are on average 23% lower than the sum of their components' costs. The cost savings are potentially due to streamlined production, storage, and distribution (World Health Organization, 2005), and they explain around half of the FDC discount. Second, we find a strong market expansion effect and a modest cannibalization effect: 33% of FDC consumers substitute from

[5]The total coprescription rate between two drugs measures the fraction of consumers who take them together, either separately or as an FDC. The non-FDC coprescription rate measures the fraction of consumers who take the two drugs separately.

the outside option, 49% from a single drug product, and only 18% from other two-drug bundles. This result highlights that FDC discounts could play a pivotal role in helping patients afford the treatment that they prefer when consumers are uninsured and drug prices are high relative to income. Finally, consumers' FDC preferences are on average negligible: the market expansion effect of FDCs can be entirely explained by FDC discounts and additional product variety from firms that did not sell both components before introducing the FDCs.

We use the model to quantify the welfare effects of FDCs for consumers and firms. We find that FDCs increase consumer surplus by 21%. FDC discounts and additional product variety explain two-thirds and one-third of the gains, respectively. On the firm side, FDCs increase producer surplus by 13% because of significant market expansion and cost savings. These results, though specific to the market for Alzheimer's drugs, show that FDCs could potentially benefit both consumers and firms. We also show that the welfare effects of FDCs may be reversed under different market conditions. For example, FDCs may lead to overtreatment and reduce consumer surplus when there are strong, distortionary FDC preferences. Firms may face a prisoner's dilemma and lose profits when the cannibalization effects of FDCs dominate the market expansion effects.

Finally, we simulate the effects of applying various FDC regulations from the US to India. In the US, firms run clinical trials to support new FDCs and are granted patent protection for approved FDCs. We find that giving an FDC patent to one firm would increase its FDC price by less than 2%. Competition from component molecules is largely effective in disciplining the pricing of an FDC by a monopolist. Such competition, however, also limits the expected profit gains from the FDC. For all firms, the expected profit gains from the FDC over the length of patent protection fall short of the estimated clinical trial costs for new drug approvals in the US (Moore et al., 2020). Our results suggest that uniformly strict FDC regulations may deter entries of medically sound FDCs and forestall potential welfare benefits.

Our paper relates to several distinct literatures. There is a large medical literature on the clinical benefits and risks of FDCs. Many clinical studies show that FDCs significantly improve medication adherence (see Bangalore et al. (2007) and Du et al. (2018) for detailed meta-analyses), which may lead to better clinical outcomes and patient satisfaction (Thom et al., 2013; Verma et al., 2018). However, several other studies document overuse of FDCs when a single drug is the recommended first-line treatment (Gadzhanova et al., 2013; Evans and Pollock, 2015; Ahmad et al., 2016; Bortone et al., 2021). Our study highlights that FDCs' equilibrium effects on drug prices and sales, which have received little focus in the medical literature or policy debates, could have significant welfare consequences.

Our study is grounded in the theory literature on competitive bundling. Most studies in this literature focus on a stylized two-firm two-product case (Matutes and Regibeau, 1992; Anderson and Leruth, 1993; Thanassoulis, 2007; Armstrong and Vickers, 2010; Hurkens et al., 2019). One exception

is Zhou (2021), which studies a setting similar to ours in oligopoly markets. We consider a richer setting where we allow product complementarity, market expansion effects, and asymmetry in firms' product menus and product qualities. Our paper also contributes to a small empirical literature on bundling, including the works by Chu et al. (2011) on bundle-sized pricing by a theater company, Crawford and Yurukoglu (2012) on bundling in multichannel television markets, and McManus et al. (2018) on bundling and steering in the telecommunication industry. Our empirical setting has two novel features. First, we observe competitive bundling in a large number of quasi-independent therapeutic markets. Second, in some markets, we directly observe market outcomes before and after FDC entries. These features allow us to document novel, model-free evidence on the equilibrium effects of competitive bundling under various market conditions.

We also contribute to a small literature on the modeling of demand and supply when consumers can choose a bundle of products. Examples of earlier studies include Gentzkow (2007) on print and online newspapers, Berry and Haile (2014) on video and broadband services and Song et al. (2017) on cancer drugs. We apply the framework in a setting of competitive bundling and develop an empirical strategy to estimate the model without observing the market share of each individual product bundle. In addition, identification in most earlier studies relies on variation in prices and choice sets between different markets. Our identification strategy relies on micromoments of consumer choices. Our strategy provides an alternative way to estimate the model when variation in choice sets across markets is insufficient or likely endogenous.

Finally, our paper relates to a number of empirical studies on the Indian pharmaceutical industry. Earlier studies have examined patent policy (Chaudhuri et al., 2006; Dutta, 2011; Duggan et al., 2016), price controls (Mohapatra and Chatterjee, 2016; Dean, 2019), and drug quality (Bennett and Yin, 2019). Interestingly, some of these studies have focused on single-molecule medicines. Our paper complements them by focusing on FDCs. Since FDCs account for over half of pharmaceutical revenue in India, we believe that understanding the role of FDCs is an important step forward for policy analysis in the Indian pharmaceutical industry.

The rest of this paper is organized as follows. Section 2 describes the setting. In Section 3, we develop a model of drug demand and supply to provide intuition for the potential equilibrium effects of FDCs. Section 4 introduces the data for our empirical analysis. Section 5 documents model-free evidence on the effects of FDCs on drug prices and sales. In Section 6, we estimate the model and quantify the welfare effects of FDCs in the market for Alzheimer's drugs. Section 7 concludes.

2 Background

2.1 Fixed-Dose Combinations (FDCs)

Medical treatment for many diseases involves more than a single drug. Some treatments combine drugs that target the same disease with different action mechanisms, while others include a secondary component to enhance the efficacy of the main drug. Compared to single-drug treatment, combination therapy may improve treatment response, reduce risks of drug resistance, or lower the incidence of adverse drug reactions (U.S. Food and Drug Administration, 2013). Combination therapy has become the standard of care for many diseases, including human immunodeficiency virus (HIV), tuberculosis, cardiovascular diseases, type 2 diabetes, and various types of cancer.

FDCs simplify combination therapy by combining multiple drugs into a single pill. A lower pill burden leads to better medication adherence (Bangalore et al., 2007), which in turn improves clinical outcomes and patient satisfaction (Thom et al., 2013; Verma et al., 2018). FDCs also simplify the logistics of drug distribution and improve the reliability of drug supply (World Health Organization, 2005). Today, FDCs are commonly used for treatment of many diseases, especially chronic care. FDCs constitute 52 out of 588 drugs in the 21st World Health Organization List of Essential Medicines (World Health Organization, 2019).

There are, however, some concerns about unjustified uses of FDCs. Some combinations may have adverse drug-drug interactions that compromise therapeutic efficacy. In addition, some FDCs may include redundant component(s) that lead to overtreatment and encourage imprecise diagnosis. An example is the frequent use in many countries of antibiotic FDCs when only one component is needed (Bortone et al., 2021).

2.2 FDC Regulation

In light of the potential benefits and risks of FDCs, different countries have taken different approaches to FDC regulation. Regulation is strict in most high-income countries but tends to be lax in low- and middle-income countries.

For example, in India, our primary empirical setting of interest, firms have been de facto free to introduce FDCs without much government oversight. In principle, to introduce a new FDC in India, firms need approval from the Central Drugs Standard Control Organization (CDSCO). In practice, enforcement of the regulation has been lax: out of over 6,000 FDCs sold in India in 2018, only 1,292 have been approved by the CDSCO (Vendoti, 2018). With growing public concerns over unjustified uses of FDCs, the Indian government issued a ban on 344 FDCs in 2016 based on recommendations by an expert committee. The scale of the ban was small: banned products accounted for around 2% of FDC revenue in 2015.

In contrast, the standard for approving new FDCs is significantly higher in the US. To introduce a new FDC in the US, the sponsor needs to provide evidence that the proposed FDC satisfies the "combination rule" (21 CFR 300.50). This rule states that i) each component must make a contribution to the claimed effects and that ii) the dosage of each component (amount, frequency, duration) is such that the combination is safe and effective for the intended patient population. Achieving compliance with the combination rule is a costly and time-consuming process. The sponsor needs to run laboratory and clinical studies to assess drug-drug interactions, document side effects, and determine appropriate doses of each component. In most applications, the sponsor also needs to implement at least one large-scale clinical trial with a factorial design to demonstrate the therapeutic contribution of each component molecule.[6] For example, for an FDC that combines molecules A and B, a four-arm clinical trial is usually required to show that the FDC is superior to each component alone and to the placebo (AB v. A v. B v. placebo). Such clinical trials usually involve hundreds or thousands of human subjects and could take years to complete.[7]

Patent protection is typically granted to the firm that successfully sponsors a new FDC.[8] The patent grants monopoly status for FDC production but does not prevent patients from buying the components from other firms separately. As a result, compared to patents for new single-molecule drugs, the monopoly power and expected profit gains from an FDC patent are significantly smaller. These limited profit gains and high costs of clinical trials may dampen firms' incentives to invest in new FDCs. Indeed, these FDC regulations have been consequential: in 2015, FDCs accounted for 50% of pharmaceutical revenue in India but only 17% among the elderly population in the US.[9]

2.3 The Indian Pharmaceutical Industry

Our primary empirical setting is the Indian pharmaceutical industry. The industry serves over 1.3 billion people and is the third largest pharmaceutical sector in the world. India is also the largest exporter of generic medicines globally, earning it the title "the pharmacy of the world".

Affordability of essential medicines has been a longstanding policy concern in India. According to the latest National Sample Survey on healthcare consumption, less than 20% of the population had

[6] Exemptions are made in cases when it is not feasible or ethical to expose patients to single-drug treatment (e.g., for HIV drugs). In addition, for combinations whose safety and efficacy have been rigorously established in the scientific literature, firms that sponsor the FDCs can cite existing results through the 505(b)(2) pathway and be exempted from conducting their own trials.

[7] Among 119 FDCs approved in the US since 2000, 79% have gone through a pivotal clinical trial. According to the estimates by Moore et al. (2020), the median cost of a pivotal clinical trial for a new drug application is $19 million. The cost of a clinical trial for an FDC is likely to be higher because it requires more arms of treatment.

[8] Around 80% of FDCs approved in the US are awarded patent protection, and the average patent length is 11.3 years. The award rate and patent length are both similar to those of patents for new single-molecule drugs.

[9] In Appendix Figure A.1, we compare FDC revenue shares between 28 different countries. Overall, FDCs are more commonly used in low and middle-income countries than in high-income countries where FDC regulations are stricter. These cross-country differences persist after controlling for variation in disease burdens.

any form of health insurance as of 2018 (National Sample Survey Office, 2019). Pharmaceutical drugs account for 51% of out-of-pocket health expenses, and about 7% of households fall below the poverty line on account of health expenses (Singh et al., 2020).

In its efforts to reduce drug prices, the Indian government has fostered a highly competitive domestic pharmaceutical industry. The Patents Act of 1970, which disallowed patent protection for pharmaceutical products, fueled the growth of many indigenous pharmaceutical manufacturers and led to intense competition in generics.[10] Today, close to 1,000 firms compete in the Indian pharmaceutical industry, and generic drugs account for over 85% of pharmaceutical revenue.[11]

The Indian government also maintains direct price controls on drugs that it considers essential for public health. The Drug Price Control Order (DPCO) of 2013 sets price ceilings for all drugs included in the National List of Essential Medicines (NLEM) of India.[12] The price ceiling for a drug product is based on the average price of all products of the same formulation in the prior year. Firms must adjust prices below the ceiling and can only change prices annually to match inflation in subsequent years. Today, price controls cover 376 drugs, which account for around 20% of total pharmaceutical revenue. Most drugs under price control are single-molecule drugs, and only 6% are FDCs.

These market features all point to a potentially important role of FDCs in the Indian pharmaceutical industry. A well-developed domestic pharmaceutical sector sets the ground for competitive bundling. The potential price effects of FDCs can be pivotal in helping cash-constrained patients afford the medicines that they need. On the other hand, firms may use FDCs as a tool to circumvent price controls, which increases concerns over unjustified uses of FDCs (Bhaskarabhatla et al., 2021).

3 Theoretical Framework

We develop a model of drug demand and supply to provide intuition for the potential equilibrium effects of FDCs. One main goal of the model is to highlight key market features that determine the price and welfare effects of pharmaceutical bundling. These market features will be the focus of our empirical analysis that follows the theoretical framework.

[10] India started recognizing drug patents in 2005, as stipulated by the Trade-Related Intellectual Property Rights (TRIPS) agreement. Duggan et al. (2016) shows that the impact of the policy change was limited because of the country's robust domestic pharmaceutical manufacturing sector and compulsory licensing requirements.

[11] The total number of firms exceed 8,000 if we include all small local manufacturers that are not tracked by our data (Bennett and Yin, 2019).

[12] The NLEM may be updated from time to time, allowing the set of drugs under price control to change. DPCO 2013 was first based on NLEM 2011 and currently applies to drugs listed in NLEM 2015.

3.1 Model

Demand Consider an oligopoly market with two drugs, A and B, and an FDC that bundles both. These may be two drugs that target the same disease (e.g., different antiviral drugs for HIV) or treat different diseases that occur together (e.g., cough and fever medicines). Each drug can be used alone, and the two drugs can be used in combination. Patients can implement the combination treatment by taking the two drugs separately or by using an FDC.

Define a drug product k as a drug j by a firm f, with $j \in \{A, B, FDC\}$. Each consumer chooses a bundle of product(s) $\mathcal{B}_r$ indexed by r. There are five types of drug choices: the empty bundle, one drug A product, one drug B product, one bundle of the two drugs purchased separately, and one FDC product. Within each type, there may be different drug bundles offered by different firms.

We define the utility of bundle r for consumer i as:

$$u_{ir} = \sum_{k \in \mathcal{B}_r} v_{ik} + \Gamma_i \iota_r - \sum_{k \in \mathcal{B}_r} p_k, \tag{1}$$

The first component is total value of drug products in the bundle. The second component, where ι_r takes value 1 for two-drug bundles (including FDCs) and 0 otherwise, represents the (dys)synergy between drugs A and B for consumer i. $\Gamma_i > 0$ indicates complementarity between the two drugs, while $\Gamma_i < 0$ means that the marginal benefit from a drug is lower when consumer i is taking the other drug.[13] The last component is the disutility from paying for the drug bundle.

For drug A or drug B, the value of product k to consumer i is:

$$v_{ik} = \delta_k + \nu_{ij(k)} + \nu_{if(k)}, \tag{2}$$

which consists of the average product value δ_k and consumer i's idiosyncratic preferences for drug $j(k)$ and firm $f(k)$. We allow vertical quality differences between different products of the same drug, which reflects the lack of quality assurance in the generic drug markets in many developing countries (Bate et al., 2011; Bennett and Yin, 2019). Consumer drug preferences, ν_{iA} and ν_{iB}, depend on each consumer's medical conditions. Consumer firm preferences, $\vec{\nu}_{if}$, could form for many reasons. For example, consumers who value quality more would prefer firms that consistently offer higher-quality drug products. Consumer preference heterogeneity gives rise to market power and determines the types of consumers that FDCs would attract.

[13] For example, drug complementarity is significant when the drugs are perfect complements (e.g., HIV cocktails). Dyssynergy arises when two drugs treat the same disease with similar action mechanisms. For the same disease, patients with more advanced conditions may need both drugs to achieve some threshold efficacy ($\Gamma_i > 0$), while patients with mild conditions may need only one drug ($\Gamma_i < 0$).

For the FDC, the value of drug product k to consumer i is:

$$v_{ik} = v_{ik_A} + v_{ik_B} + \gamma_k, \tag{3}$$

which is the sum of its components' values plus some FDC preference γ_k. A positive γ_k may capture convenience benefits or a mistaken belief on product variety. γ_k can also be negative for reasons such as reduced flexibility in dosage adjustment. Combining Equation 1 and Equation 3, we see that buying an FDC is equivalent to buying its components separately except for the FDC preference and the price difference.

Each consumer chooses the drug bundle that maximizes her utility. Let s_r denote the market share of bundle r. The market share of drug product k is given by:

$$s_k = \sum_r \mathbb{1}(k \in \mathcal{B}_r) s_r, \tag{4}$$

which is the sum of market shares of all drug bundles that contain the product.

Supply We take the product offering as given and assume that firms set prices to maximize profits under Nash-Bertrand competition. Let $\mathcal{K}_f$ denote the set of products sold by firm f and c_k the marginal cost of product k. The marginal cost of an FDC product may differ from the sum of its components' costs. Firm f's profit maximization problem is:

$$\max_{\{p_k\}, k \in \mathcal{K}_f} = \sum_{k \in \mathcal{K}_f} (p_k - c_k) s_k. \tag{5}$$

Equilibrium prices can be written as:[14]

$$\vec{p} = \vec{c} + \Delta^{-1} \vec{s}, \tag{6}$$

where the (m, n) element of Δ is given by:

$$\Delta_{(m,n)} = \begin{cases} \frac{\partial s_n}{\partial p_m}, & \text{if products m, n are produced by the same firm} \\ 0, & \text{otherwise} \end{cases} \tag{7}$$

One feature of our setting is that drug A and drug B can be complements or substitutes: an increase in the price of a drug A product increases standalone sales of drug B products but reduces sales of two-drug bundles. The net effect depends on the distribution of Γ_i. The FDC products are by construction

[14] In Equation 6, we assume that Δ is invertible, which is not guaranteed in settings with potential product complementarity. We revisit this potential issue when we discuss model estimation.

substitutes with drug A and drug B products because of the discrete choice framework.

Discussion Our model is related to the random-utility framework on competitive bundling in Zhou (2021). Our main theoretical contribution is to incorporate several new features that allow us to more flexibly characterize the equilibrium effects of competitive bundling. First, we relax the "full market coverage" assumption that each consumer always chooses both products.[15] Second, we incorporate product complementarity.[16] Finally, we allow bundle (FDC) preferences, cost savings from bundling, and asymmetry in product menus and product qualities between firms. These market features have important implications for the price and welfare effects of competitive bundling, which we discuss next.

3.2 Equilibrium Effects of FDCs on Prices and Welfare

3.2.1 FDC Pricing

Our model highlights three ways in which the price of an FDC may differ from the sum of its components' prices. First, FDC preferences may lead to an FDC premium. Second, potential cost savings may lead to an FDC discount. Third, firms may use FDC discounts to attract consumers to buy both drugs from them. Zhou (2021) shows that absent bundle preferences or cost savings, firms offer bundle discounts when consumers' valuations of the two products are independent, negatively dependent, or limitedly positively dependent.[17] We focus on the size of the FDC discount and its determinants.

To develop intuition for firms' strategic incentives to offer bundle discounts, we revisit the classic problem of bundling by a monopolist. Appendix Figure A.2, which replicates Figure III in McAfee et al. (1989), shows the trade-offs when a two-product monopolist introduces a bundle discount. The firm gains additional sales to marginal consumers who respond to the discount but loses the discount for every inframarginal consumer who would have bought its both products anyway. The incentive to offer a bundle discount is thus weaker when there are more such inframarginal consumers. A similar intuition applies to competitive bundling in oligopoly markets.

Proposition 1. *Starting from a competitive mixed bundling equilibrium with the component prices held fixed, a firm will reduce its bundle discount if more consumers would buy its both products at the current prices, ceteris paribus.*

Proof. See Appendix B. ■

[15] Full market coverage is a standard assumption in the theory literature on competitive bundling. One exception is Thanassoulis (2007), who considers an additional type of consumer who always buys only one product. This treatment relaxes the full market coverage assumption but does not allow a market expansion effect of bundling. The market expansion effect of competitive bundling has also been considered in Armstrong and Vickers (2010).

[16] Product complementarity has been considered in the monopolist's bundling problem (Long, 1984; Armstrong, 2013). Our approach to model product complementarity closely follows the formulation in Gentzkow (2007).

[17] All discussions in this section assume the existence of a pure-strategy mixed bundling equilibrium. See Zhou (2021) for a discussion on the existence of this equilibrium.

Intuitively, the price of a bundle increases (i.e. bundle discount decreases) when demand for the bundle increases, *ceteris paribus*. Demand for a two-drug bundle increases when more consumers want both drugs together (because of stronger drug complementarity or more positively correlated drug preferences) and would buy from the same firm (because of stronger firm preferences). In Appendix B, we use simulations to illustrate the effects of drug complementarity, drug preference correlation, and firm preferences on the size of optimal FDC discounts in an oligopoly market.

3.2.2 Effects of FDCs on Component Prices

FDCs also influence the prices of their component molecules in equilibrium. Our model suggests that this effect is ambiguous. Since FDCs and their components are substitutes, competition from FDCs pushes component prices down, but firms that sell the FDC have an offsetting incentive to increase component prices to steer consumers towards their FDC products. In addition, FDCs may lead to market segmentation and change the price elasticity of consumers who consider standalone components. The net impact of FDCs on standalone component prices thus depends on firms' product portfolios and consumer preference heterogeneity.

3.2.3 The Welfare Effects of FDCs

FDCs influence social welfare through their price effects, FDC preferences, and potential cost savings. The welfare implication of the price effects depends on the net outcome of two countervailing forces: a market expansion effect and a cannibalization effect.

Proposition 2. *Assume that there are no FDC preferences or cost savings and that no component is priced below its marginal cost. FDCs always increase total social welfare when they lead to additional drug sales but may reduce total social welfare when they attract consumers from other two-drug bundles.*

Proof. See Appendix B. ■

Intuitively, since drug sales under imperfect competition is below the socially optimal level, additional sales, absent frictions such as distortionary FDC preferences, increases social surplus.[18] However, for consumers who would have bought both drugs anyway, FDC discounts may reduce allocative efficiency by pushing them to buy from the same firm. For example, consider a scenario in which firm 1 produces high-quality drug A and firm 2 produces high-quality drug B. Consumers tend to mix and match under separate pricing. FDC discounts, which are transfers from firms to consumers, induce some consumers to one-stop shop and end up with one low-quality product. Consumers are better-off

[18] There is potentially an additional market expansion (shrinkage) effect when the FDC leads to a reduction (increase) in the components' prices. The intuition is similar to that behind the market expansion effect from the FDC discount.

by revealed preference, but firms lose profits in a prisoner's dilemma, and total social welfare decreases due to reduced allocative efficiency.

The race between the market expansion and cannibalization effects depends on the types of consumers whom the FDCs attract, which in turn depend on consumer preference heterogeneity. The scope for market expansion is larger when fewer consumers buy both drugs under separate pricing and when consumers are responsive to FDC discounts. Given the fraction of consumers who would buy both drugs anyway, FDCs are more likely to cannibalize sales of other two-drug bundles when the variance in drug complementarity is larger across consumers.

The welfare effects of FDCs are more nuanced when there are FDC preferences or cost savings. FDC preferences add to the welfare gains from FDCs when they are driven by true benefits such as convenience and improved medication adherence. Conversely, if there is a mistaken belief on product variety, FDCs may lead to overtreatment, which reduces consumer welfare and potentially social welfare. In characterizing the welfare effects of FDCs, it is therefore important to separate the roles of FDC discounts and FDC preferences in driving demand for FDCs. Cost savings always increase social welfare.

To summarize, our model highlights key market features that determine the price and welfare effects of FDCs. The price effects of FDCs depend on, among other things, consumer preferences for two-drug bundles and firms' product portfolios. The welfare effects of FDCs depend on FDC preferences, cost savings, and substitution patterns as determined by consumer preference heterogeneity. These market features will be the focus of our empirical analysis, which we turn to next.

4 Data and Summary Statistics

Our primary data set is monthly drug price and sales data between April 2007 and October 2019, provided by All India Organization of Chemists and Druggists (AIOCD). The data source is a panel of stockists, who are appointed by drug companies to distribute drug products to retail pharmacies. AIOCD collects data from 10,000 stockists, who cover around 65% of the national market, and projects sales for the remaining 35%.

Each product in our data set is a stock-keeping unit (SKU). We observe the active substance(s), dosage form, and packet size of each SKU. For example, "IBUGESIC 200 MG TABLET 15" includes 15 200-mg ibuprofen tablets; "IBUGESIC PLUS 200/325 MG TABLET 15" includes 15 FDC tablets, and each tablet contains 200 mg of ibuprofen and 325 mg of paracetamol. For each SKU, we also observe the firm, product launch date, therapeutic class, and monthly sales in 23 different regions.

In addition, we observe the monthly maximum retail price (MRP) of each SKU. Manufacturers set the MRP at the national level and are required to print the MRP on the product packaging. Wholesale prices are usually 25% below the MRP, giving pharmacies some room to offer discounts to consumers.[19]

[19] Conversations with industry experts reveal that discounts were usually small in early years, though larger discounts

We show using our e-pharmacy data (to be introduced soon) that the discount rates are similar between FDCs and plain molecules and that there is no additional joint-purchase discount for non-FDC drug bundles (see Appendix D.1 for details). As a result, we follow earlier studies on this industry and use the MRP as a proxy for the prices that consumers pay (Chaudhuri et al., 2006; Mohapatra and Chatterjee, 2016).

We restrict the data sample in two ways. First, we focus on SKUs in tablet or capsule form, which account for 61% of total pharmaceutical revenue. We choose this sample because the dosage strengths of all such drugs are measured in milligrams, which makes it straightforward to link FDC products to standalone component products of the same dosage strengths.[20] Second, we exclude drugs for which we do not observe all the active ingredients. These include products whose drug name is a broad category (e.g. "other diuretics", "Chinese medicines") and all mineral supplements and vitamin products.[21] SKUs dropped in this step account for 29% of revenue for FDCs and 4% of revenue for plain molecules. We aggregate the data to the drug-dosage-firm level, which we define as a drug product.[22] Our final sample consists of 55,478 products of 1,626 drugs (818 plain molecules and 808 FDCs) from 971 different firms.

A first look at the data confirms two facts. First, FDCs have proliferated in India since the early 2000s. Panel A of Figure 1 shows that the revenue share of FDCs in our sample grew from 30% in 2007 to 42% by the end of 2015. It continued to grow, albeit at a slower rate, after the ban on 344 FDCs in 2016. Panel B of Figure 1 shows a sharp increase in FDC entries in India around 2000. Around 35 new FDCs were introduced every year between 2000 and 2015, outpacing the entries of new plain molecules. Appendix Table A.1 shows the market shares of FDCs in 14 main therapeutic classes in 2019. FDCs are commonly used in most therapeutic classes, especially the larger ones such as conditions related to the alimentary tract and metabolism (e.g., diabetes), cardiovascular diseases, and antibiotics.

Second, we see that the Indian pharmaceutical industry is indeed highly competitive. Appendix Table A.2 reports the breakdown of drugs by the number of firms selling them in January 2019 separately for plain molecules and FDCs. Panel A shows that plain molecules are on average sold by 13 different firms and that molecules sold by more than 5 firms account for 91% of drugs sales. Panel B shows a similar pattern for FDCs: FDCs are on average sold by 12 different firms, and FDCs sold by more than 5 firms account for 86% of FDC sales. We also find significant price dispersion across different products

have become more common recently due to increased competition from e-pharmacies. Bennett and Yin (2019) shows that Medplus, a large pharmacy chain known for offering lower drug prices, gave consumers a 10% discount off the MRP around 2010. The median discount rate in our e-pharmacy data is 19% off the MRP.

[20] In contrast, drug in other forms (e.g., injection, syrup, cream) have different volumes and concentrations. Linking FDCs with component molecules is sometimes difficult. In 2019, FDCs accounted for 52% of revenue for drugs in tablet and capsule form and 47% of revenue for drugs in other forms.

[21] Mineral supplements and vitamin products often contain a large number of additives, but our data record only one or a few main active ingredients.

[22] A drug product is almost equilvalent to an SKU, except that firms occasionally offer different SKUs of the same drug at the same dosage strength.

of the same drug formulation. The lack of quality assurance gives rise to market power despite the large number of firms.

We leverage three ancillary data sets that provide additional information on consumers' drug choices. The first is drug coprescription data from IQVIA, a leading healthcare research company. The data are based on prescriptions written by a panel of 50,000 physicians between 2007 and 2017. The panel of physicians covers a wide range of specialties, with the physicians selected to be representative of all those in 170 major Indian cities. For each month, the data set records the total number of prescriptions for each drug and the frequency at which each pair of drugs is prescribed together. The coprescription data directly measure consumers' propensity to buy two drug-bundles before and after FDC entries.

The second data set comes from Tata 1mg, a leading e-pharmacy platform in India. The platform was started in 2013 and has been growing rapidly since then. We obtain data on all drug orders on the platform for diabetes and Alzheimer's drugs between October 2013 and July 2021. For each order, we observe the SKUs purchased, the list price of each SKU, and the final price after coupons and discounts. The e-pharmacy data allow us to observe repeated drug purchases by individual consumers over time and reveal rich information on substitution patterns between different drug products.[23]

The third data set is the Medicare Part D Prescription Drug Event data from the Centers for Medicare & Medicaid Services (CMS) in the US. We observe transaction-level data for all prescriptions filled by 20% of Medicare Part D beneficiaries between 2006 and 2015. This data set allows us to measure the coprescription rates of drugs in a setting in which most FDCs are absent. In the last part of the paper, we also use this data set to assess the impacts of FDC regulations in the US.

5 Model-Free Analysis: Effects of FDCs on Drug Prices and Sales

In this section, we document model-free evidence on the effects of FDCs on drug prices and sales, leveraging variation from FDCs in a wide range of therapeutic markets. Following the discussions under our theoretical framework, we examine FDC pricing, the effects of FDCs on component prices, and the market expansion and cannibalization effects of FDCs.

5.1 FDC Pricing

As discussed in Section 3.2, FDCs may sell at a premium due to FDC preferences, or a discount because of cost savings or price discrimination. We compare FDC prices to the sum of their components' prices and examine how consumer preferences for two-drug bundles influence FDC pricing.

Our main analysis uses a cross-section of drug products from January 2013, prior to the implementation of the drug price control policy. The unit of analysis is an FDC formulation, or FDC by dosage

[23] We show in Appendix C that the coprescription data and e-pharmacy data are broadly consistent with our main data sample in terms of prescription and sales quantities.

strength (e.g., 400 mg ibuprofen + 500 mg paracetamol). For each FDC formulation, we first calculate the average per-pill price of the FDC and of each component. We then calculate the "FDC price ratio" by dividing the FDC price by the sum of the components' prices.[24] To remove outliers, we truncate the sample at the 1st and 99th percentiles of the distribution of FDC price ratios. Our final sample consists of 720 FDC formulations (of 359 FDCs) for which each component is also sold individually.

FDCs on average sell at a steep discount, as shown in Table 1. Column (1) shows an average discount of 28%. Column (2) shows a significantly larger discount of over 40% for FDCs that have more than two components. Column (3) shows that the discount is larger for more popular FDCs: the average discount increases to 34% if weighted by sales quantity. One potential concern about the results is that FDC discounts could be driven by a different mix of firms. In columns (4) and (5), we repeat the analysis at the FDC-firm level and compare FDC prices to components prices set by the same firm. The average FDC discount is 18% under this specification and 24% if weighted by sales. Panel A of Figure 2 shows the distribution of the FDC price ratios. We see significant heterogeneity across different FDCs, and around 8% of FDC formulations sell at a premium.[25]

Our theoretical framework predicts that a smaller FDC discount when consumers tend to buy both drugs anyway. To test this prediction, we focus on 298 two-molecule FDCs that are not available in the US and use drug coprescription rates in the US as a proxy for consumers' propensity to buy both drugs in India in the absence of FDCs.[26] We define the coprescription rate between two drugs as the number of coprescriptions divided by the smaller number of total prescriptions of the two. A coprescription rate of 0 means no consumer is prescribed the two drugs together, while a coprescription rate of 1 means all consumers who are prescribed a drug are also prescribed the other drug. Panel B of Figure 2 shows that a 10% increase in the coprescription rate is associated with a 2.8% smaller FDC discount (p-value = 0.02). Consistent with our theoretical intuition, firms do offer smaller FDC discounts when consumers tend to buy both drugs anyway.

5.2 Effects of FDCs on Component Prices

Next, we examine the effects of FDCs on standalone component prices. We first leverage FDC entries to estimate the average effects of FDCs on their components' prices and then use cross-sectional price

[24] For example, the average price of a 400 mg ibuprofen + 500 mg paracetamol pill is 1 rupee. The average price is 0.51 for a 400 mg ibuprofen pill and 0.58 for a 500 mg paracetamol pill. The FDC price ratio of this FDC formulation is $\frac{1}{0.51+0.58} = 0.92$.

[25] We describe some additional results on FDC pricing in Appendix D.1. We show that patterns of FDC discounts are robust to different sample selections and different ways of constructing FDC price ratios. We also show that firms that also sell standalone components offer smaller FDC discounts, which may explain the smaller average discount found in the firm-level analysis.

[26] Appendix Figure A.3 shows a binned scatter plot of the coprescription rate in India against the coprescription rate in the US for over 16,007 pairs of drugs that have not become FDCs in either country. The almost perfect linear relationship implies that the coprescription rate in the US is a reasonable proxy for the coprescription rate in India.

variation to gauge different pricing incentives by firms that do and do not sell the FDCs.

For the FDC entry analysis, we focus on the first half of our sample between April 2007 and June 2013, prior to the implementation of the price control policy. We define a period as a quarter t and a product k as a molecule-dosage-firm (j-d-f) combination. We define the treated group as molecules that are part of exactly one FDC, and we require the FDC to be introduced in the sample period. We use molecules that are not part of any FDC as the control group. In addition, we restrict the sample to products sold in every quarter. This gives us a balanced sample of 319 treated products (39 molecules) and 1,485 control products (228 molecules).

We estimate the effects of FDC entries on standalone component prices with the following event study framework:

$$log(p_{kt}) = \sum_{i \neq -1} \beta_i \mathbb{1}(t - d_{j(k)} = i) + \lambda_k + \lambda_t + \varepsilon_{kt}, \tag{8}$$

where $d_{j(k)}$ is the quarter when the FDC of molecule j was introduced. λ_k and λ_t refer to product and quarter fixed effects, respectively. Standard errors are two-way clustered at the product and molecule-by-quarter level.

Panel A of Figure 3 shows the results. Prior to FDC entry, the coefficients are small and not significantly different from 0. Within a year after FDC entry, prices of the component molecules increase by around 3.2% relative to prices of other molecules. The estimates are stable over time and borderline significant at the 95% confidence level. These price increases may be driven by firms' strategic price adjustments to increase their FDC sales or by market segmentation if FDC discounts attract more price-elastic consumers. On the other hand, the procompetitive effects of FDCs may be muted because the markets for most component molecules are already quite competitive.[27]

A potential confounder of the results above is that the timing of FDC entry may be endogenous. In particular, firms could introduce an FDC when they expect demand for the component molecule to increase, which would bias our estimates upwards. To investigate this concern, we use Equation 8 to estimate the effects of FDC entry on component sales. Appendix Figure A.4 shows that sales of component molecules drop after FDC entry, consistent with our causal interpretation of the price effects.[28]

Next, we use cross-sectional price variation to measure the difference in component prices set by firms that do and do not sell the FDCs. Here we leverage variation from a larger sample of drugs,

[27] The average number of firms that sells each treated molecule is 13. In Appendix D.2, we repeat the analysis using a small subset of molecules sold by only one firm throughout the sample period. We find that FDC entries reduce component prices in these more concentrated markets where the scope for procompetitive effects is larger.

[28] We discuss some additional robustness analysis in Appendix D.2. Our results are robust across a number of alternative specifications incorporating, for example, weights for different products by sales quantity or controls for firm-specific time trends, therapeutic-market-specific time trends, or the number of firms.

including older, more popular FDCs that may have larger price effects. We estimate the following equation using all single-molecule drug products available in January 2013:

$$log(p_k) = \beta_0 \mathbb{1}(s_{jf(k)} > 0) + \beta_1 s_{jf(k)} + \lambda_{jd(k)} + \lambda_{f(k)} + \varepsilon_k, \tag{9}$$

where $s_{jf(k)}$ measures firm f's market share in all FDC products of molecule j by sales quantity. $\lambda_{jd(k)}$ and $\lambda_{f(k)}$ stand for molecule-dosage fixed effects and firm fixed effects, respectively.[29]

Table 2 summarizes the results. Firms that sell FDCs of a molecule set a 7.1% higher price for that molecule relative to the prices set by firms that do not sell the FDCs. In addition, a 10% increase in the firm's market share in the FDCs is associated with a 1.7% higher component price. These results are consistent with our theoretical intuition that firms that sell FDCs have some additional incentive to increase component prices to steer consumers towards their own FDC products.

Taken together, we find that the price effects of FDCs significantly benefit consumers who need the full bundle of drugs but on average harm consumers who need just one component. Consistent with our theoretical intuition, the price effects depend on factors such as drug coprescription rates and firms' product portfolios.

5.3 Market Expansion and Cannibalization Effects of FDCs

As discussed in Section 3.2, the welfare effects of FDCs depend crucially on whether they lead to additional drug sales or mostly cannibalize sales of other two-drug bundles. In this section, we measure the market expansion and cannibalization effects of FDCs.

We focus on a sample of 81 two-molecule FDCs introduced in India some time between 2008 and 2016. We use the IQVIA coprescription data to measure the coprescription rates for each pair of drugs one year before FDC entry and in 2017. We construct the total coprescription rate, which measures the fraction of consumers who buy both drugs (including the FDC), and the non-FDC coprescription rate, which measures the fraction of consumers who buy the two drugs separately.[30] The percentage change in the total coprescription rate after an FDC entry measures its market expansion effect, while the percentage change in the non-FDC coprescription rate measures its cannibalization effect.

Figure 4 shows the market expansion and cannibalization effects of the 81 new FDCs. There is significant heterogeneity across different FDCs. The median FDC increases the total coprescription rate by 189% and reduces the non-FDC coprescription rate by 25%. A strong market expansion effect

[29] A different approach is to use the event study framework to estimate heterogeneous effects of FDC entries on firms that do and do not sell the FDCs. We show in Appendix D.2 that the estimates are noisy and we do not find significantly different price effects on component molecules sold by these two types of firms. The small sample size may have limited the statistical power of the analysis, which motivates the alternative design using cross-sectional price variation.

[30] A challenge in constructing the coprescription rates with FDCs is that many new FDCs are not captured by the IQVIA coprescription data. In Appendix C, we discuss this issue and the steps we take to construct the total coprescription rate and non-FDC coprescription using both the coprescription data and aggregate drug sales data.

and a modest cannibalization effect imply that there could potentially be large welfare gains, but the welfare effects still depend on whether the market expansion is driven by FDC discounts or potentially distortionary FDC preferences. To assess the welfare effects of FDCs, we first need to estimate the model and quantify a number of key market features, which we turn to in the next section.

6 Estimation and Welfare Analysis: the Case of Alzheimer's Drugs

In this section, we estimate the model and quantify the welfare effects of FDCs in the market for Alzheimer's drugs. We choose this market for two reasons. First, Alzheimer's is the seventh leading cause of death globally (World Health Organization, 2020), and the market for Alzheimer's drugs is important for the well-being of the elderly population and their families. Second, this market offers a tractable setting with two drugs and one FDC: donepezil, memantine and their FDC account for over 95% of Alzheimer's drugs sales. While it is straightforward to extend our model to describe more complex market structures, this simple setting allows us to focus on the core economic forces in competitive bundling in the most transparent way.

6.1 The Market for Alzheimer's Drugs in India

Alzheimer's disease is a brain disorder that slowly destroys memory and thinking skills and eventually the ability to carry out the simplest tasks. According to the Dementia India Report 2010 by the Alzheimer's and Related Disorders Society of India (ARDSI), around 3.7 million people in India suffered from dementia in 2010, with at least 50% of the cases caused by Alzheimer's disease.

Two main drugs that treat Alzheimer's disease are donepezil and memantine.[31] Both drugs work by regulating neurotransmitters of the brain, but each targets a different chemical. Medical studies have shown that because of the different action mechanisms, combining the two drugs may further improve patient outcomes, especially for patients with moderate or advanced disease conditions (Tariot et al., 2004). An FDC of the two drugs was first introduced in India in June 2008 and approved in the US in October 2015.

We define a market as the national market in a quarter and the market size as the total number of people with Alzheimer's disease in that quarter.[32] According to the ARDSI report, the market size was around 1.85 million in Q4 of 2010 and grew by around 0.9% per quarter. We define a drug product at the drug-daily dosage-firm level and measure sales of each product in units of 90-day supply, which

[31] Currently, there is no cure for Alzheimer's disease. The intended effect of most medications is to slow disease progression and maintain mental function. In July 2021, the US FDA approved Aducanumab, the first approved disease-modifying therapy for Alzheimer's disease. The approval was done through FDA's Accelerated Approval Program, which requires an additional postmarketing study to confirm the anticipated clinical benefit.

[32] Though we do observe drug sales by region, we estimate the model at the national level because all pricing decisions are made at the national level. In addition, most major drug products are introduced in all regions at the same time.

approximate the number of patients taking the product in each quarter.[33]

Appendix Figure A.5 shows the time trend in drug sales. Less than 3% of potential consumers took the drugs at the beginning of the sample. The low treatment rate reflects limited awareness of the disease among both patients and physicians (Ghandi, 2020). Drug costs have been another barrier to treatment: in 2007, a single-drug treatment cost about 4,000 rupees a year, which amounted to 12% of per-capita income in India in that year. The total market share grew steadily over the sample period, reaching around 7.5% in 2019. The FDC products experienced the fastest growth since their introduction in 2008 and accounted for 24% of drug sales by the end of 2019.

Appendix Table A.3 shows the summary statistics of the drug products before and after donepezil was included under price controls in Q2 of 2016. There are five main firms in the market.[34] Throughout the sample, four firms sell donepezil (Alkem, Cipla, Eisai, Intas), two firms sell memantine (Intas, Sun Pharma), and one firm sells both drugs (Intas). The FDC products were first introduced by Sun Pharma in Q2 of 2008 and were offered by all five firms by 2016. In Q4 of 2015, right before the price control policy took effect, the FDC products on average sold at a 25% discount, similar to the average discount rate of 28% across all therapeutic markets.

6.2 The Econometric Model

Our empirical specification closely follows the theoretical model outlined in Section 3.1. In this section, we revisit the theoretical model and introduce some additional parametric assumptions.

Demand Patients with Alzheimer's disease choose a treatment option to maximize utility under the supervision of physicians and family members. We focus on two main drugs, donepezil (drug A) and memantine (drug B), and the FDC that bundles both drugs. A product k is a drug-daily dosage-firm (j-d-f) combination, with $j \in \{A, B, FDC\}$. Each consumer chooses one drug bundle $\mathcal{B}_r$ indexed by r. As before, there are five types of drug bundles: the empty bundle, one drug A product, one drug B product, one bundle of the two drugs purchased separately, and one FDC product.

The indirect utility of bundle r to consumer i in market t is:

$$u_{irt} = \sum_{k \in \mathcal{B}_r} v_{ikt} + \Gamma_i \iota_r - \sum_{k \in \mathcal{B}_r} p_{kt} + \sigma_\varepsilon \varepsilon_{irt}. \tag{10}$$

Equation 10 is identical to Equation 1 in our theoretical model except for two differences: product value

[33] Both donepezil and memantine are available in 5 mg and 10 mg tablets, and the FDC is available in "5/5 mg" and "5/10 mg" tablets. According to US FDA dosing and administration guidelines and purchase patterns in our e-pharmacy data, donepezil is usually taken once a day, while memantine and the FDC are usually taken twice a day. We therefore measure donepezil sales in units of 90 tablets and memantine and FDC sales in units of 180 tablets.

[34] We exclude from the sample products that on average account for less than 1% of sales in periods when they are offered. Based on this sampling criterion, we exclude 11 firms whose products together account for 3.7% of total sales.

and price vary by market, and we introduce an additional shock $\sigma_\varepsilon \varepsilon_{irt}$ that represents the idiosyncratic match value between consumer i and bundle r in market t.[35] We assume that ε_{irt} follows the type I extreme value distribution, with a scale parameter σ_ε that measures how consumers trade off utils against price. As before, Γ_i represents consumer-specific drug complementarity and is turned on when bundle r contains both drugs A and B.

The value of drug product k of drug A or B to consumer i in market t is:

$$v_{ikt} = \underbrace{\lambda_k + \lambda_{j(k)t} + \xi_{kt}}_{\delta_{kt}} + \nu_{ij(k)} + \nu_{if(k)}. \tag{11}$$

The average product value δ_{kt} consists of three components: the time-invariant product value λ_k, a drug-level demand shock $\lambda_{j(k)t}$, and a product-level demand shock ξ_{kt}. As before, $\nu_{ij(k)}$ and $\nu_{if(k)}$ represent consumer i's preferences for drug j and firm f. The value of an FDC product k to consumer i in market t is:

$$v_{ikt} = v_{ik_At} + v_{ik_Bt} + \gamma_{kt}, \tag{12}$$

which is the sum of the components' values plus an FDC preference.[36]

Finally, we make the following parametric assumptions:

1. $\begin{pmatrix} \nu_{iA} \\ \nu_{iB} \end{pmatrix} \sim \mathcal{N}\left(\begin{pmatrix} 0 \\ 0 \end{pmatrix}, \begin{pmatrix} \sigma_D^2 & \rho\sigma_D^2 \\ \rho\sigma_D^2 & \sigma_D^2 \end{pmatrix}\right)$

2. $\nu_{if} \sim \mathcal{N}\left(0, \sigma_f^2\right)$ for each firm

3. $\Gamma_i \sim \mathcal{N}\left(\bar{\Gamma}, \sigma_\Gamma^2\right)$

Let $F(\nu_i)$ denote the distribution of consumer preferences parameterized by Θ, where $\nu_i = \{\sigma_\varepsilon, \nu_{iA}, \nu_{iB}, \Gamma_i, \vec{\nu}_{if}\}$. Integrating over idiosyncratic match value ε_{irt} and $F(\nu_i)$, we can write the market share of drug bundle r in market t as:

[35] Idiosyncratic match values ε_{irt} rationalize the remaining variation in drug choices that is not explained by the rest the model. For example, our theoretical model implies that buying an FDC with a discount strictly dominates buying the components separately from the same firm. ε_{irt} helps rationalize why some consumers continue to buy the components separately despite the FDC discount, as we observe in our e-pharmacy data.

[36] For firms that sell the FDC but not some component(s), the component value v_{ik_At}(or v_{ik_Bt}) is undefined. A more general formulation for the value of an FDC product is $v_{ikt} = \delta_{kt}^{FDC} + \nu_{iA} + \nu_{iB} + 2\nu_{if(k)}$, which is equivalent to Equation 3 when firm $f(k)$ sells both components.

$$s_{rt}(\Theta, \boldsymbol{\delta_t}, \boldsymbol{p_t}) = \int_i \frac{\exp\left(\frac{\sum_{k\in\mathcal{B}_r} v_{ikt} + \Gamma_i \iota_r - \sum_{k\in\mathcal{B}_r} p_{kt}}{\sigma_\varepsilon}\right)}{1 + \sum_q \exp\left(\frac{\sum_{k\in\mathcal{B}_q} v_{ikt} + \Gamma_i \iota_q - \sum_{k\in\mathcal{B}_q} p_{kt}}{\sigma_\varepsilon}\right)} dF(\nu_i), \tag{13}$$

where $\boldsymbol{\delta_t}$ and $\boldsymbol{p_t}$ are vectors of average product values and prices in market t.

Supply We focus on markets prior to the implementation of the price control policy. Following the model of drug supply outlined in Section 3.1, we take the product offering as given and assume firms set prices to maximize profits under Nash-Bertrand competition.

6.3 Identification and Estimation

We are interested in recovering consumer preference heterogeneity $\Theta = \{\sigma_\varepsilon, \sigma_D, \rho, \bar{\Gamma}, \sigma_\Gamma, \sigma_f\}$, FDC preferences $\vec{\gamma}$, and potential cost savings from FDCs.[37] There are two main challenges in estimating this model with the standard aggregate drug sales data. First, with aggregate data, we would only observe the total sales of each drug product, but not how often it is sold alone and how often together with the other drug. Second, identifying substitution patterns with aggregate data would require strong assumptions on the time trends of drug sales and exogenous variation in choice sets over time. To address these challenges, we leverage a policy shock and novel coprescription and epharmacy data. In this section, we describe the identifying variation for each parameter and the estimation procedure.

Identification The first parameter of interest is σ_ε, which governs the price elasticity. Since prices are likely positively correlated with unobserved demand shock ξ_{kt}, we need an instrument to consistently estimate σ_ε. Since we include drug-market fixed effects λ_{jt} in our utility specification, we need an instrument that shifts prices of a subset of products of a specific drug. The price control policy, which imposed a price ceiling on drug A in Q2 of 2016, provides such an instrument. Panel A of Figure 5 shows that two drug A products that were priced above the ceiling experienced an immediate price drop of between 30% and 40% in Q2 of 2016, while the prices of the other two products were unaffected. Panel B of Figure 5 shows sharp sales increases for the two affected products in response to the price reductions. Our instrument Z_{kt} takes value 1 for the two affected products starting in Q2 of 2016 and 0 otherwise.

The exclusion restriction of the instrument is that the price control policy does not affect drug sales through any mechanism other than the price changes. One potential concern is that the imposition of

[37] We measure the average FDC preference in each market by using the difference between the sales-weighted average product value of FDC products and the sum of the sales-weighted average product values of drug A and drug B products. We cannot measure γ_{kt} at the product-market level because most firms do not sell both drugs A and B.

price controls followed the inclusion of drug A in the National List of Essential Medicines in January 2016, which may have led to a positive demand shock for all drug A products. The drug-market fixed effects address this concern by controlling for all drug-level demand shocks. Our assumption is that such demand shocks, if any, are not systematically different for the two products that experienced the price cut.[38]

Parameters ρ and $\bar{\Gamma}$ both influence consumers' propensity to choose two-drug bundles. Consumers tend to buy both drugs together if drug preferences are more positively correlated or if drug complementarity is stronger. We directly measure the fraction of consumers who buy both drugs using the IQVIA coprescription data. Figure 6 shows that the coprescription rate between the two drugs was between 20% and 30% prior to FDC entry. This moment identifies sets of ρ and $\bar{\Gamma}$ but does not separate them.

To separate ρ and $\bar{\Gamma}$ and identify other parameters of consumer preference heterogeneity (i.e. σ_D, σ_Γ, and σ_f), we use transaction-level data on repeated drug purchases by 6,694 consumers in our e-pharmacy data. Our identification strategy leverages the panel structure of the data and shocks from the price control policy and an FDC entry event. We assume that demand responses to the FDC entry and price cuts are driven by changes in the product space rather than by changes in consumer preferences. Under this assumption, the panel data help us identify the time-invariant components of consumer preferences.

First, we separate ρ and $\bar{\Gamma}$ using substitutions to the two drug A products affected by the price control policy. Among consumers who do not consider two-drug bundles, drug A products are equally likely to attract consumers from other drug A products and from drug B products when $\rho = 1$.[39] The extent to which consumers of other drug A products responded more to the price control policy, as shown in Panel A of Figure 7, helps separate ρ from $\bar{\Gamma}$.

Second, we identify σ_D and σ_Γ using patterns of substitution to a new FDC product introduced in Q3 of 2016. A larger σ_D implies that FDCs are less likely to attract consumers from the outside option, while a larger σ_Γ implies that FDCs compete more with other two-drug bundles. Panel B of Figure 7 shows that that 31% of consumers of the new FDC product substitute from the outside option, 40% from a single drug product, and 29% from other two-drug bundles.[40] For perspective, the overall market shares of these three types of drug choices are 93.4%, 5.1%, and 1.5% respectively.

[38] Another potential threat to identification is that the lower profit margin after the price cut may trigger other supply-side responses, such as reduced detailing activities and regional product exits. While we cannot directly rule out this threat, we find no evidence for such supply-side responses. Both affected firms continued to offer drug A products in all regions of India, including poorer, less profitable regions, after the price control policy took effect.

[39] The two firms directly affected by the price control policy, Alkem and Eisai, do not sell drug B. As a result, firm preferences do not affect these substitution patterns.

[40] We identify the drug bundle that each consumer bought, if any, prior to their purchase of the new FDC product. Consumers who did not purchase any other drug bundle may have substituted from the outside option or may be new customers whose purchase histories we do not observe. We use data on purchases of other drug products to estimate the arrival rate of new consumers to the platform and infer the number of existing consumers who substituted from the outside option. We provide additional details in Appendix E.

Proportionally speaking, FDCs are least likely to attract consumers from the outside option (σ_D) and most likely to divert sales from other two-drug bundles (σ_Γ).

Third, we identify the variance in firm preferences σ_f using firm choices by consumers who bought a drug A product and an FDC product at different points in time. Table 3 shows that 71% of such consumers bought both drugs from the same firm, while 36% would have done so if firm choices were random. Under the assumption that firm preferences remain unchanged when consumers change their drug choices, a larger fraction who chose the same firm for both drugs implies stronger firm preferences.

Two remaining market features of interest are FDC preferences and potential cost savings. Market expansion by FDCs that is not explained by the FDC discounts reveals the magnitude of FDC preferences. With estimates of FDC preferences and consumer preference heterogeneity, our model could predict the optimal FDC discounts in the absence of cost savings. The wedge between predicted and observed discounts reveals the magnitude of cost savings.

Overall, our identification strategy departs in some ways from the methods used in prior studies that estimate consumer demand for product bundles, such as Berry and Haile (2014) and Song et al. (2017). Identification in these earlier studies relies on variation in prices and choice sets between different markets. Our identification strategy relies on a policy shock and micromoments of consumer choices. Our strategy thus provides an alternative way to estimate the model when variation in choice sets across markets is insufficient or likely endogenous.

Estimation We estimate the model using simulated method of moment (SMM), following Berry et al. (1995) and Petrin (2002).[41] We match the following model-predicted moments to their empirical counterparts as we have described in the identification discussions above: i) the orthogonality condition between the unobserved demand shocks ξ_{kt} and the price instrument Z_{kt}; ii) the coprescription rate in each market up to Q4 of 2017; iii) among consumers of the new FDC product, the fraction who substitute from the outside option and the fraction who substitute from other two-drug bundles; iv) among new consumers of the two drug A products affected by the price control policy, the fraction who substitute from another drug A product instead of from a drug B product; and (v) among consumers who have bought one drug A product and one FDC product, the fraction who buy both from the same firm.

The estimation procedure is in large part standard. To account for the sampling variance in our micromoments, we obtain bootstrapped estimates of standard errors by resampling markets and consumers in our e-pharmacy data for 100 bootstrap samples. We provide additional details of the estimation procedure in Appendix E.

[41] A potential challenge in our setting is that inversion of average product values $\vec{\delta}$ from the observed market shares is not guaranteed to be a contraction mapping due to potential product complementarity (Berry, 1994; Berry et al., 2013). It turns out that drug complementarity is very weak between the two Alzheimer's drugs, and the procedure works as in other standard settings.

6.4 Estimation Results

In this section, we discuss the parameter estimates and the implied substitution patterns, FDC preferences and cost savings. Unless otherwise noted, we discuss the results in the context of Q4 of 2015, the market right prior to the announcement of the price control policy.

Table 4 summarizes the parameter estimates. The scale parameter $\hat{\sigma}_\varepsilon = 0.54$ implies a median own-price elasticity of -2.42 and a median markup-to-price ratio of 52% in the full sample. This result is consistent with findings from several earlier studies—for example, Chaudhuri et al. (2006) find a median own-elasticity of -2.51 in the market for quinolones in India.

The other parameters (except ρ) are measured in money-metric terms. As a benchmark to interpret the magnitudes of the estimates, we observe that the average price of a 10/10 mg two-drug bundle is 2.85 (thousand rupees) in Q4 of 2015. First, we find that drug preferences have a large variance ($\hat{\sigma}_D = 1.28$) and are positively correlated between the two drugs ($\hat{\rho} = 0.86$). Consumers differ significantly in their tastes for the outside option, which depend on, for example, whether they have been formally diagnosed with Alzheimer's disease. Conditional on consumers needing some treatment, their tastes for the two drugs are quite similar. Second, drugs A and B are neither complements nor substitutes on average. There is, however, substantial heterogeneity in drug complementarity across consumers. $\hat{\sigma}_\Gamma = 0.75$ implies that consumers with a one standard deviation higher draw of drug complementarity value two-drug bundles more by around 26% of their average price. This result is consistent with the medical guideline that the combination treatment is usually intended for a subset of patients with more advanced medical conditions. Third, $\hat{\sigma}_f = 0.79$ implies strong firm preferences: a one standard deviation increase in the preference for one firm implies that the consumer is willing to pay 0.79 (thousand rupees) more for one drug from the firm.

By comparing the relative magnitudes of different utility components, we can see that the logit error $\sigma_\varepsilon \varepsilon_{irt}$ contributes to less than 5% of the variance in consumer preferences for an FDC product.[42] The usual concerns about incorporating logit errors in estimating the value of new products are therefore not a major issue in our setting.

Our estimates shed light on three main market features that are key to the welfare effects of FDCs. First, we find a strong market expansion effect and a modest cannibalization effect, consistent with the descriptive patterns in Figure 6. We simulate the substitution patterns after the removal of all FDC products from the market and summarize the results in Figure 8. We find that 33% of FDC consumers substitute from the outside option, 49% from a single drug product, and only 18% from two-drug bundles. The large market expansion is chiefly the outcome of a small baseline fraction of consumers who would buy both drugs under separate pricing. This result highlights that FDC discounts could

[42] For a new FDC product, the variance of the logit error is $\hat{\sigma}_\varepsilon^2 \frac{\pi^2}{6} = 0.48$. The sum of the variance of the other utility components is $\text{Var}(\nu_{iA}) + \text{Var}(\nu_{iB}) + 2\text{Cov}(\nu_{iA}, \nu_{iB}) + \text{Var}(2\nu_{if}) + \text{Var}(\Gamma_i) = 2\hat{\sigma_D}^2 + 2\hat{\rho}\hat{\sigma_D}^2 + 4\hat{\sigma}_f^2 + \hat{\sigma}_\Gamma^2 = 10.7$, which is one order of magnitude larger than the variance of the logit error.

play a pivotal role in helping patients afford the treatment they prefer when consumers are uninsured and drug prices are high relative to income.

Second, consumers' FDC preferences turn out to be negligible. The market expansion effect of FDCs can be entirely explained by FDC discounts and additional product variety from firms that did not sell both components before introducing the FDCs.

Finally, we find that FDCs lead to significant cost savings. The marginal costs of FDC products are on average 23% lower than the sum of their components' costs. By combining multiple drugs into one pill, FDCs simplify the logistics of storage and distribution, which are major components of marginal costs given the warm and humid climate in India (World Health Organization, 2005). Shutting down cost savings would reduce FDC discounts by around half.

6.5 The Welfare Effects of FDCs and FDC Regulations

We use our model to assess the welfare effects of FDCs and potential FDC regulations. We quantify welfare effects of FDCs in the market for Alzheimer's drugs and discuss how the results would change under different market conditions. Our goal is to highlight main policy trade-offs in healthcare regulations on FDCs and in antitrust regulations on competitive bundling. Details on simulations of various counterfactuals are provided in Appendix F.

6.5.1 The Welfare Effects of FDCs

We follow Train (2015) and allow a wedge between consumers' "anticipated utility" and "actual utility". The former determines drug choices, while the latter determines consumer surplus. The wedge, if any, captures misjudged FDC preferences. Formally, we define consumer surplus in market t as:

$$\text{CS}_t = \int_i \text{E}(\max_r(u_{irt}))dF(\nu_i) - \sum_k s_{kt}\tilde{\gamma}_{kt}, \tag{14}$$

where u_{irt} is consumer i's anticipated utility from bundle r, and $\tilde{\gamma}_{kt}$ is misjudged FDC preference for FDC product k. If FDC preferences only capture true benefits such as convenience, we have $\tilde{\gamma}_{kt} = 0$ for all k. If FDC preferences only capture consumer mistakes, we have $\tilde{\gamma}_{kt} = \gamma_{kt}$, and FDCs could reduce consumer surplus through choice distortions. The size of FDC preferences thus defines a region of ambiguity in the welfare effects of FDCs that depends on the nature of FDC preferences. In the market for Alzheimer's drugs, this region of ambiguity vanishes because FDC preferences are negligible, and we have the standard measure of consumer surplus based on revealed preferences.

FDCs also influence consumer welfare through FDC discounts, equilibrium effects on component prices, and additional product varieties from firms that did not sell both components previously. Panel A of Figure 9 shows these welfare effects in the market for Alzheimer's drugs in Q4 of 2015. When we

remove all FDCs and allow firms to reset the components' prices, consumer surplus is 46.3 rupees ($0.6) per potential consumer. Under the current market equilibrium, the average consumer surplus is 55.9 rupees, a 21% increase relative to the no-FDC counterfactual. Additional product varieties increase consumer surplus by 7%, and FDC discounts explain the remaining 14% increase. The effects of FDCs on components' prices are small and do not have an appreciable effect on consumer surplus.

On the firm side, we find that FDCs increase producer surplus by 13% because of significant market expansion and cost savings. Panel B of Figure 9 shows large profit gains from consumers who substitute from the outside option or a single drug product to an FDC, though substitutions from two-drug bundles to FDCs reduce profits. Shutting down cost savings would reduce the profit gains to 8%. Overall, our results show that competitive bundling could potentially benefit both consumers and firms.

It is also important to note that these results are specific to the market for Alzheimer's drugs, and the welfare effects of FDCs may be reversed under different market conditions. For example, if FDC preferences play a large role in driving the demand for some FDCs, our model would imply a large region of ambiguity in the effects of the FDCs on consumer surplus. In such cases, additional clinical analysis is needed to examine the potential concern of overtreatment. In some other diseases like active tuberculosis, consumers' need for medications is less elastic and the scope for market expansion is limited. In such cases, firms could face a prisoner's dilemma: each firm has a unilateral incentive to introduce an FDC discount, but in equilibrium all firms lose profits because of the cannibalization effects of FDC discounts. Another main takeaway from our analysis is a framework to think about how the welfare effects of competitive bundling depend on market features such as consumer preference heterogeneity, bundle preferences, and cost savings.

6.5.2 Clinical Trial Requirement and FDC Patents

We end by evaluating the welfare implications of some real-world FDC regulations. As discussed in Section 2.2, the US FDA usually requires large-scale clinical trials to support new FDCs and grants patent protection to firms that sponsored approved FDCs. We simulate these regulations in the market for Alzheimer's drugs in India. We focus on two potential policy impacts: the price effects of FDC patents and the implications of compliance costs for FDC entry.

We grant an FDC monopoly to each of the four firms in Q4 of 2015 and simulate the equilibrium prices and profits. Table 5 shows that firms with monopoly power would increase the FDC price by less than 2%[43] The results suggest that competition from the component molecules is effective in disciplining FDC pricing and that the monopoly power from FDC patents need not be a major concern. On the other hand, this curtailed monopoly power may limit expected profit gains and dampen the incentive to introduce FDCs. Assuming a patent length of 11 years, we find that the expected profit gain from the

[43]For simplicity, we take the simple average of the prices of the 10/10 mg and 10/20 mg products.

FDC is between 11.4 million and 530.2 million rupees, which falls below the estimated median clinical trial cost for new drug approvals in the US.[44] The clinical trial requirement may thus deter FDC entries and forestall their potential welfare benefits.

The clinical trial requirement is certainly well intentioned and serves an important purpose of screening out potentially unjustified combinations. Our results on the potential equilibrium effects of FDCs highlight another policy consideration that has so far been largely overlooked. In Appendix G, we use the Medicare Prescription Drug Event data and FDA Orange Book data on new drug approvals to directly assess the implications of FDC regulation in the US. We find that many commonly prescribed combinations do not become FDCs in the US and that approved FDCs on average enter the US market four years after they enter India. These results point to potential welfare gains from allowing an easier approval process for combinations that doctors consider appropriate to prescribe together.

7 Conclusion

In this paper, we study the equilibrium effects of pharmaceutical bundling on market outcomes and social welfare in India. Using an equilibrium model of drug demand and supply in oligopoly markets, we show that the effects of FDCs on drug prices and social welfare are theoretically ambiguous. Firms offer FDC discounts to attract one-stop shoppers but may strategically increase the components' prices. FDC discounts in general increase total social welfare when they increase drug sales but may reduce allocative efficiency when they divert sales from other two-drug bundles. In addition, we characterize major market features that determine these equilibrium effects, such as drug coprescription rates, consumer firm preferences, heterogeneity in consumer drug preferences, and so on.

We confirm the theoretical intuition from the model using empirical evidence from a wide range of therapeutic markets in India, where FDCs account for over 50% of pharmaceutical revenue. We find that FDCs on average sell at a 28% discount but increase components' prices by 3.2%. The price effects depend on factors such as consumers' preferences for two-drug bundles and firms' product portfolios, consistent with theoretical intuition from the model. We therefore consider our model a useful framework to understand the price effects of competitive bundling in pharmaceutical markets or beyond.

Finally, we estimate the model in the market for Alzheimer's drugs to quantify the welfare effects of FDCs and FDC regulations. We find that FDCs in this market increase consumer surplus by 21% and producer surplus by 13%. We also show that the cost of complying with FDC regulations, such as clinical trial requirements, may deter FDC entries and forestall their welfare benefits. These results highlight a potentially important but so far overlooked consideration in the design of FDC regulations. While our

[44] The average patent length for a new drug in the US after approval is 11.3 years and is similar for new molecules and FDCs. Moore et al. (2020) estimates that the median clinical trial cost for new drug approval in the US between 2015 and 2017 was $48 million, or approximately 990 million rupees by purchasing power parity.

quantitative findings are specific to the market for Alzheimer's drugs, our model can accommodate a variety of settings, and the theoretical intuition on the different economic forces at play helps us think about how the welfare effects of competitive bundling will differ in other settings with different market conditions.

While this paper has characterized the major equilibrium effects of FDCs and their determinants, there are still several unanswered, policy-relevant questions. First, we have largely abstracted from the potential health effects of FDCs, in particular the public health externality from the overuse of, for example, antibiotic FDCs. Our analysis is thus meant to complement other important medical research on these potential health effects. Second, while we have estimated the model for a simple market with two main drugs and one FDC, many therapeutic markets, such as the market for HIV treatment, may have tens of different molecules and FDCs. Though it is conceptually straightforward to extend our model to more complex settings and the economic forces at play are largely similar, the pricing strategy space becomes much more complicated, and the model becomes less tractable (Armstrong and Vickers, 2010; Chu et al., 2011). We consider it a promising direction for future research to characterize the equilibrium effects of FDCs in these more complex markets and see if there are any interesting economic forces not present in the two-drug setting. Finally, measuring the long-run effects on product entries and exits and market structure is also important in understanding the equilibrium effects of competitive bundling.

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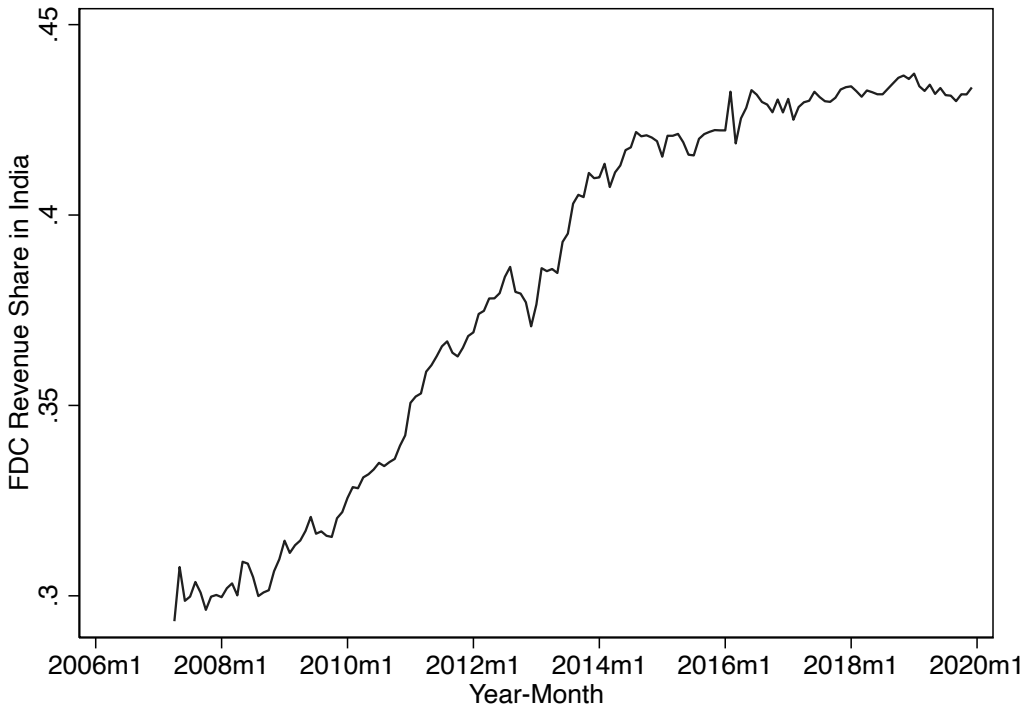
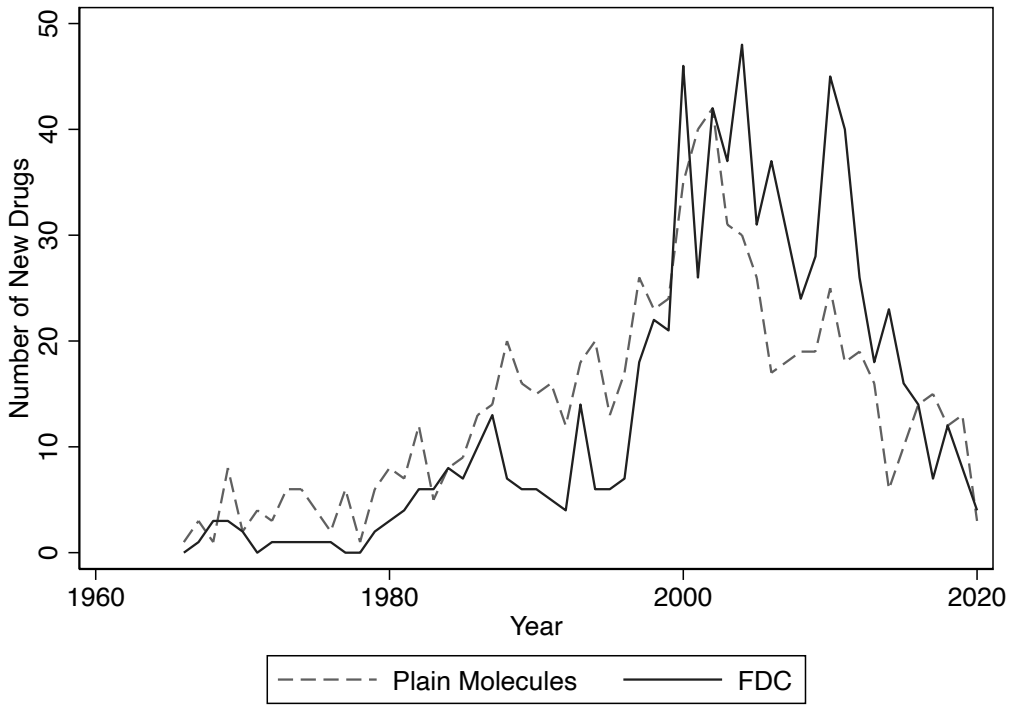
Figure 1: Time Trends in FDC Revenue Share and Drug Entries In India

Panel A: FDC Revenue Share over Time



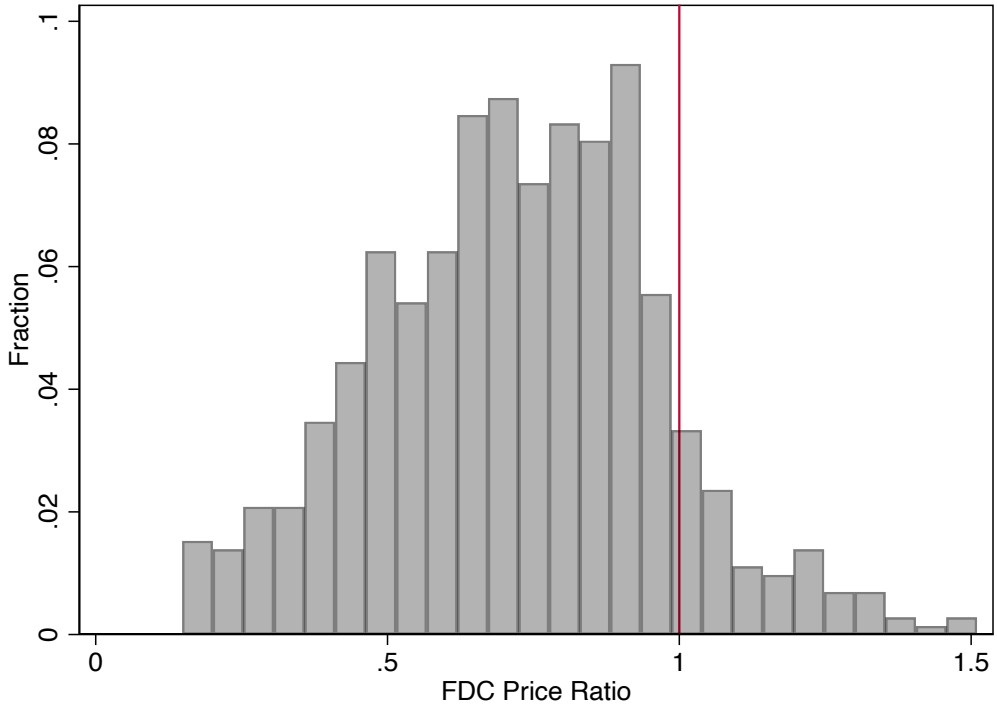
Panel B: Number of New Drugs over Time



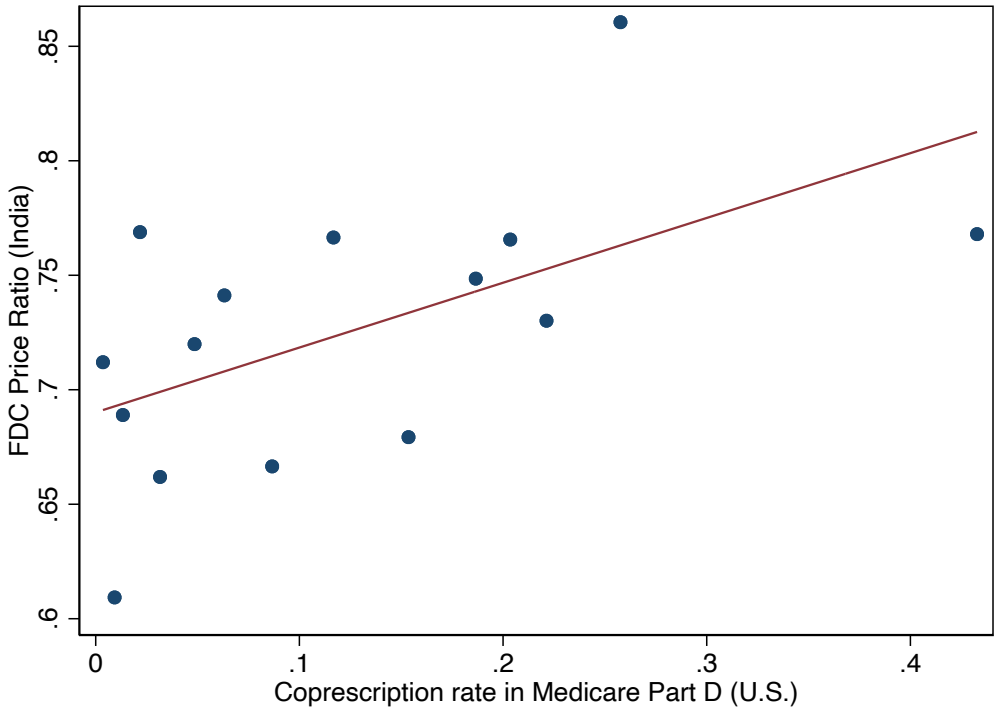
Notes: This figure shows the time trend of the FDC revenue share and new drug entries in India based on our main estimation sample. The FDC revenue share shown in Panel A is somewhat lower than the FDC revenue share in the full sample because of our sampling criteria. In particular, we exclude mineral supplements and vitamin products, most of which are FDCs.

Figure 2: Patterns of FDC Discounts

Panel A: Histogram of FDC Price Ratio

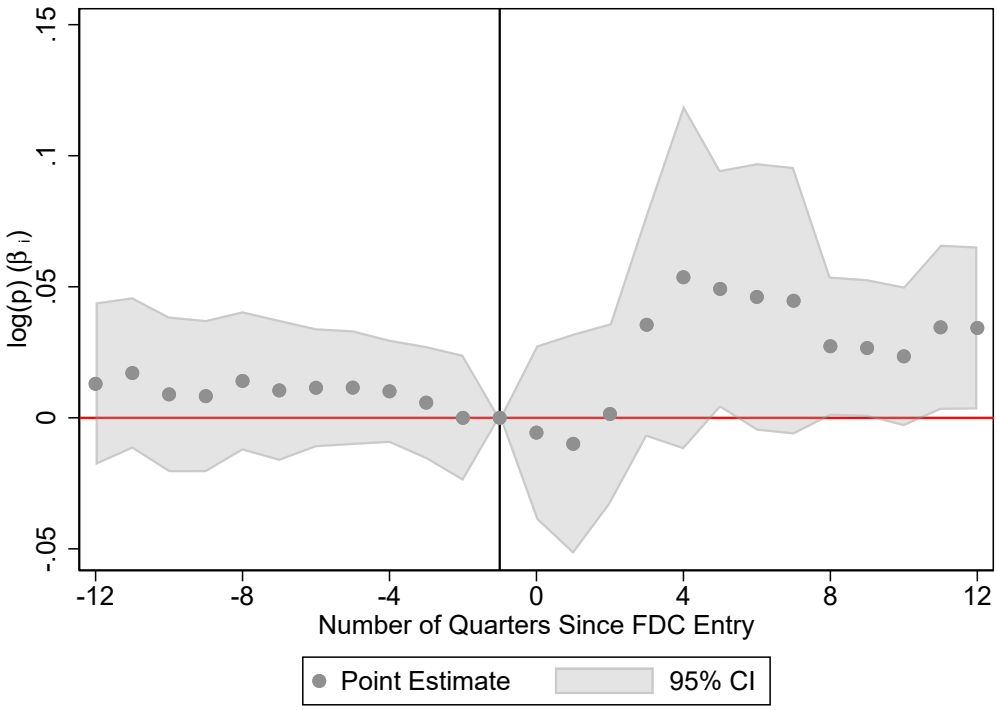


Panel B: Coprescription Rate and FDC Price Ratio



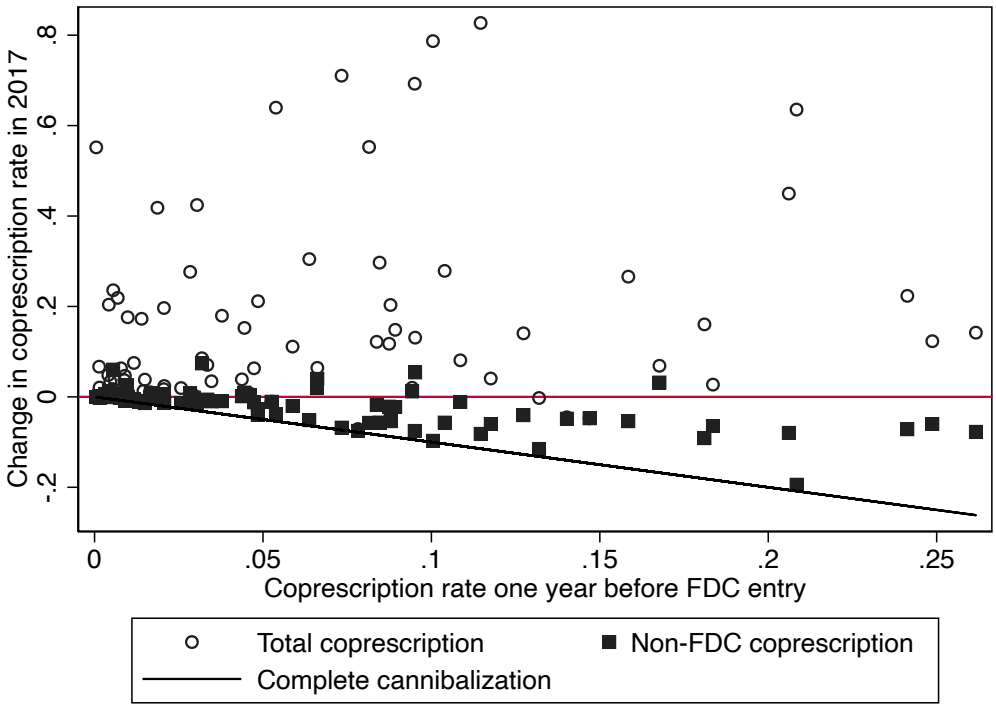
Notes: This figure documents some stylized facts on FDC discounts in India. Panel A shows the distribution of FDC price ratios in 720 FDC formulations in January 2013. Panel B shows the correlation between the FDC price ratio in India and the coprescription rate in Medicare Part D in the US for 298 two-molecule FDCs that are available in India but not approved in the US. The coprescription rate between two drugs is defined as the number of coprescriptions divided by the smaller number of the two components' total prescriptions.

Figure 3: Effect of FDC Entries on Prices of Component Molecules



Notes: This figure shows the effects of FDC entries on the prices of component molecules. Each dot represents an estimate of β_i in Equation 8. We take the quarter prior to FDC entry as the baseline period and normalize β_{-1} to 0. The sample consists of 319 treated products (39 molecules) and 1,485 control products (228 molecules). The gray band represents 95% confidence interval, with standard errors two-way clustered at the product and molecule-by-quarter level.

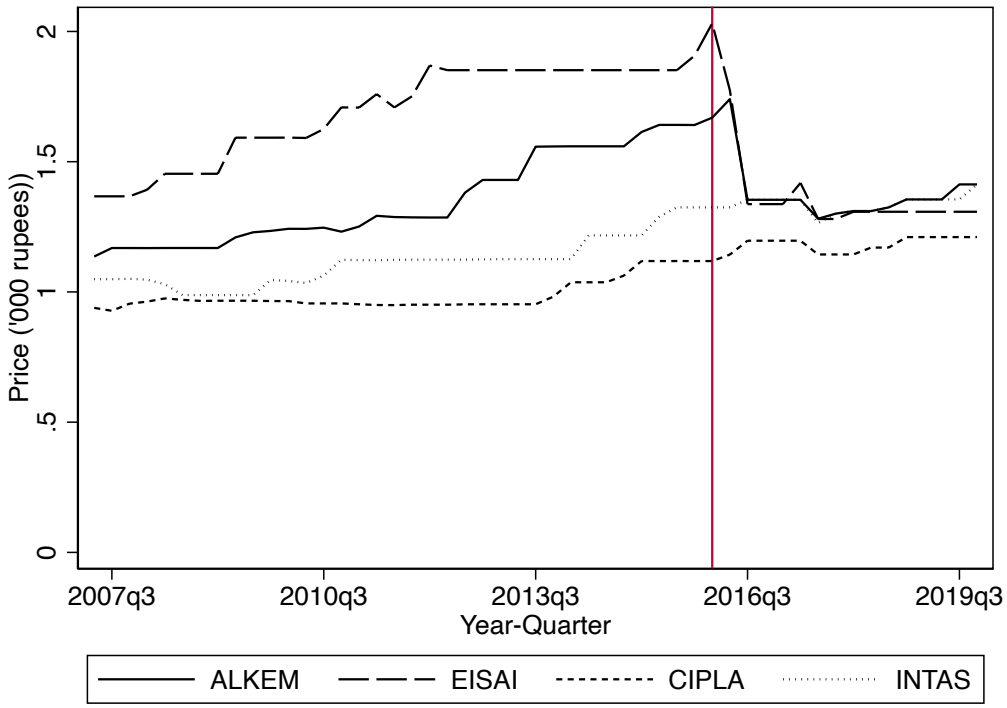
Figure 4: Market Expansion and Cannibalization Effects of FDCs



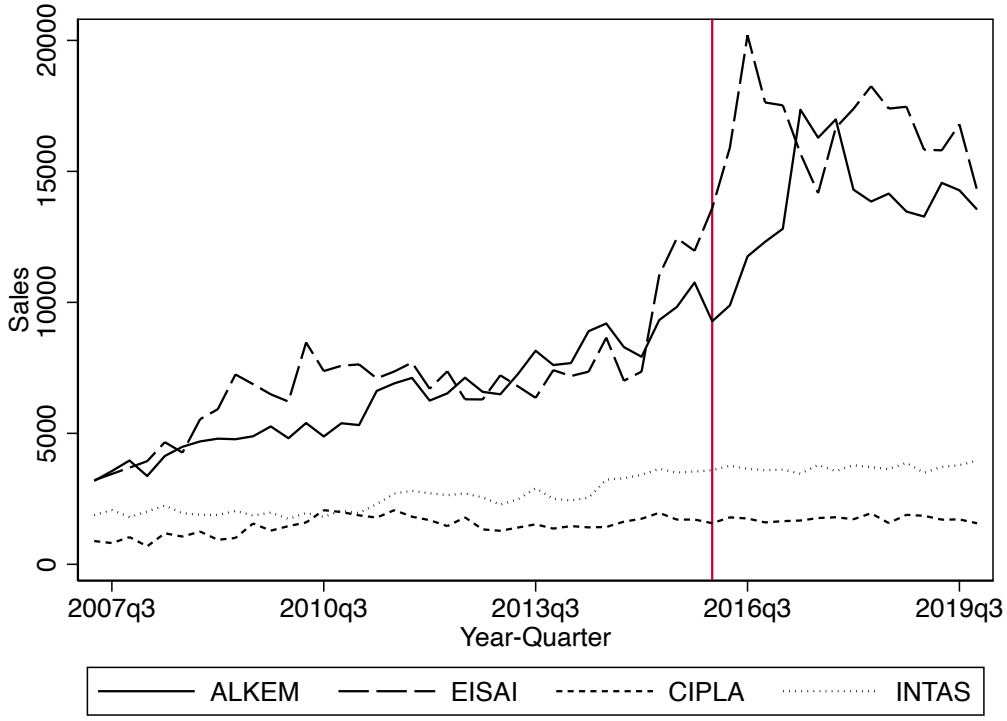
Notes: This figure shows the market expansion and cannibalization effects of 81 two-molecule FDCs that were introduced in India between 2007 and 2016. We plot the change in coprescription rates before and after FDC entry. Coprescription rate one year before FDC entry is the ratio between the number of coprescriptions and the smaller number of total prescriptions of the two components. In 2017, the the total coprescription rate (in circles) measures the fraction of consumers who buy both drugs (including the FDC). The non-FDC coprescription rate (in squares) measures the fraction of consumers who buy both drugs separately. Squares on the negative 45°line indicates complete cannibalization (i.e. non-FDC coprescription rate equals 0 in 2017).

Figure 5: Effects of the Price Control Policy

Panel A: Effects on Drug Price

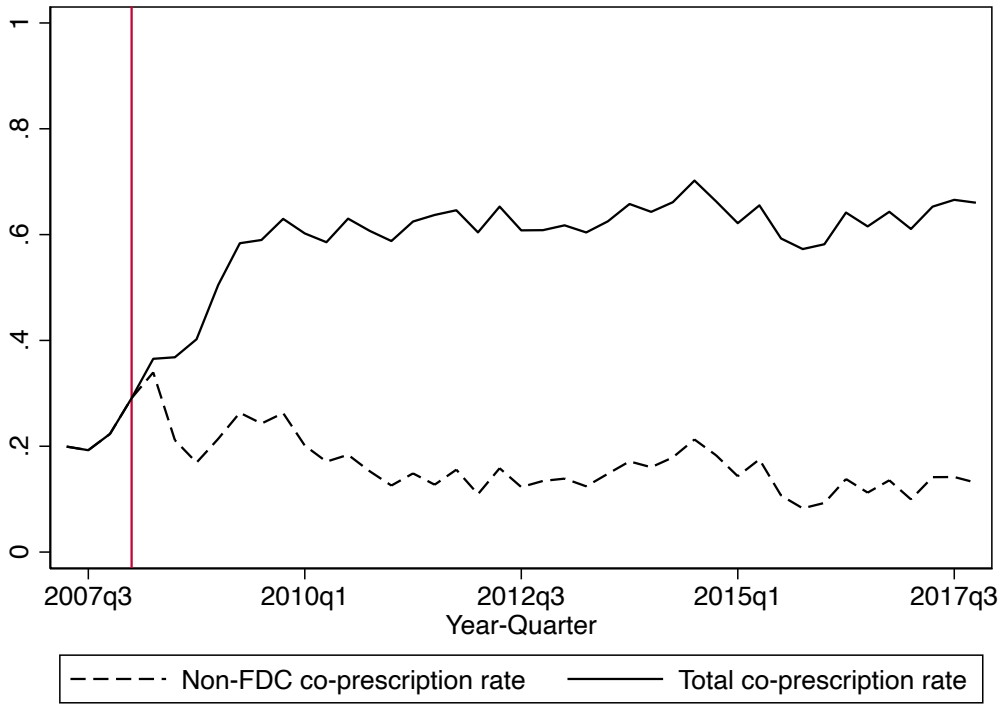


Panel B: Effects on Drug Sales



Notes: This figure shows the effects of the price control policy on prices (Panel A) and sales (Panel B) of four 10 mg donepezil (Drug A) products. The red vertical line marks Q1 of 2016, the quarter when the inclusion of of donepezil in the NLEM was announced. The price control policy was implemented in the following quarter (Q2 of 2016).

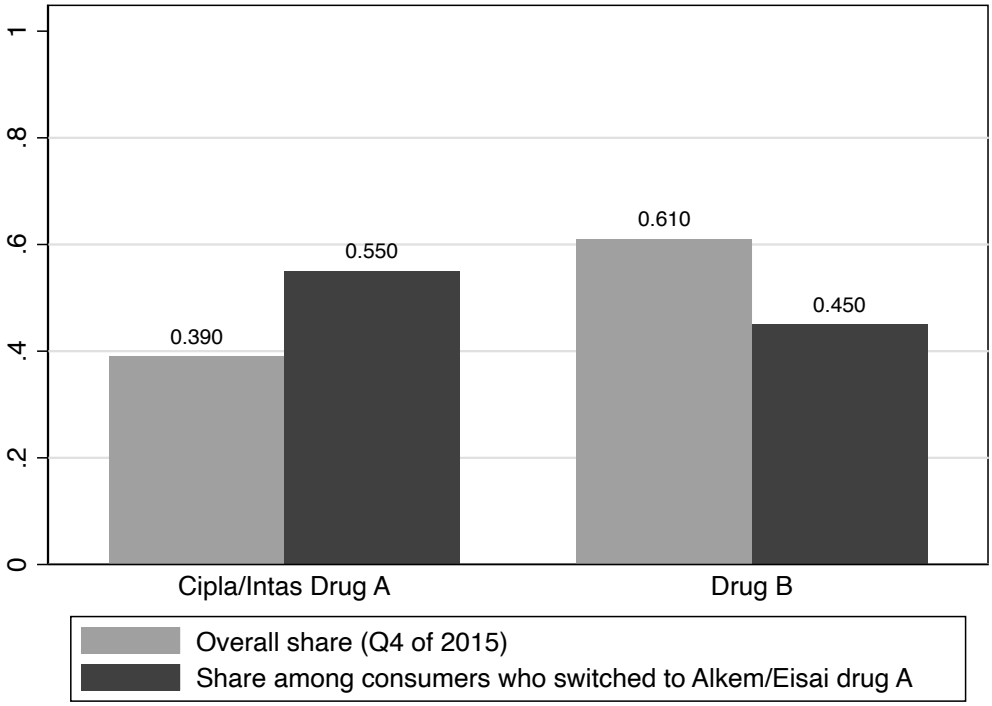
Figure 6: Time Trend in Coprescription Rates in the Market for Alzheimer's Drugs



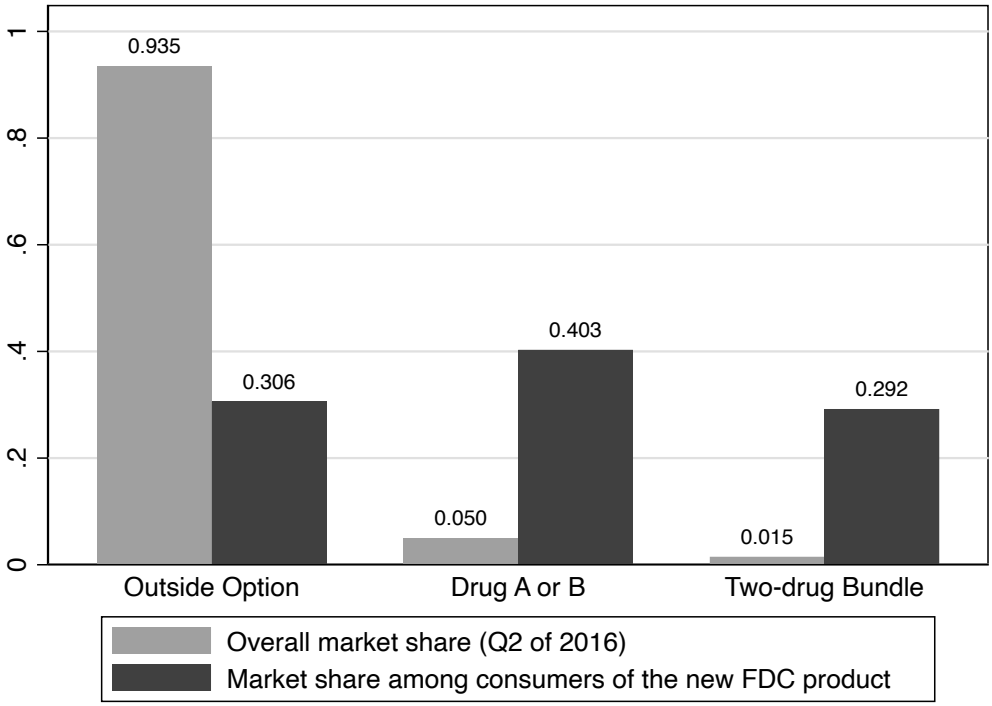
Notes: This figure shows the time trend in the coprescription rates of donepezil (drug A) and memantine (drug B). The coprescription rate measures the fraction of drug B consumers who also take drug A. The green line, the non-FDC coprescription rate, measures the fraction of drug B consumers who buy drugs A and B separately. The orange line, the total coprescription rate, measures the fraction of drug B consumers who buy both drugs, including the FDC.

Figure 7: Substitution Patterns in Response to FDC Entry and Drug Price Control

Panel A: Substitution Patterns after Drug A Price Control

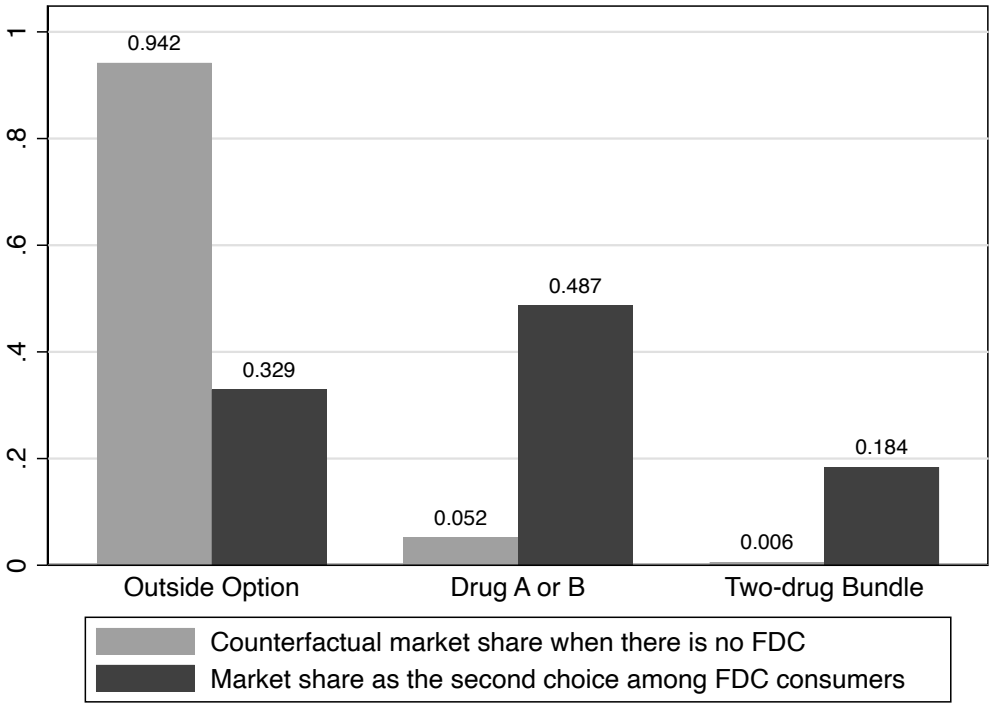


Panel B: Substitution Patterns to New FDC



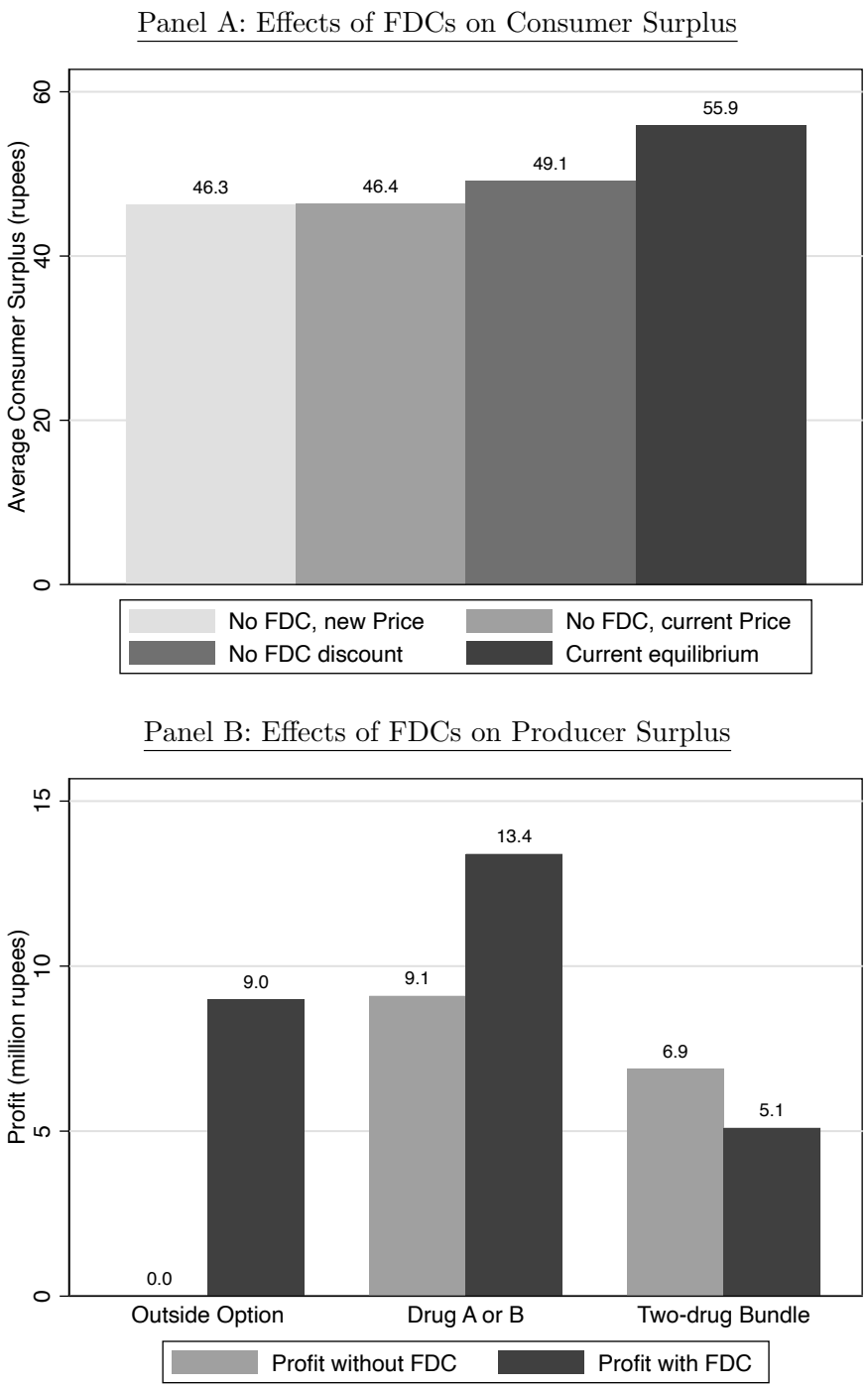
Notes: This figure shows the substitution patterns in response to the drug price control policy and an FDC entry event. The gray bars show the overall market share of each type of drug product right before the event in our main data sample, and the black bars show the distribution of prior drug choices among consumers who responded to the price control or the FDC entry shock in the e-pharmacy sample. Panel A uses a subsample of consumers who always choose only one individual product (drug A or B) at a time.

Figure 8: Counterfactual Substitution Patterns after Removal of All FDC Products



Notes: This figure shows substitution patterns when we remove all FDC products in Q4 of 2015. The gray bars show the market shares of the three types of drug choices after the FDCs are removed. The black bars show the distribution of second choices among consumers of the FDC products.

Figure 9: Welfare Effects of FDCs in the Market for Alzheimer's Drugs



Notes: This figure shows the welfare effects of FDCs in the market for Alzheimer's drugs in Q4 of 2015. Panel A shows the effects of FDCs on the average consumer surplus per potential consumer. In the "No FDC" counterfactuals, we remove FDCs from the market, with and without the firms resetting the components' prices. In the "No FDC discount" counterfactual, we scale FDC prices so that they are on average equal to the sum of the components' prices. Panel B shows the effects of FDCs on profits from different subsets of consumers who substitute to the FDC from the outside option, from a drug A or B product, or from other two-drug bundles. The gray bars show total profits from each type of consumer in the absence of the FDC. The black bars show profits from the FDCs.

Table 1: Bundle Discount for FDCs

Dependent Variable: FDC Price Ratio

	(1)	(2)	(3)	(4)	(5)
Constant	0.721***	0.743***	0.656***	0.815***	0.758***
	(0.013)	(0.014)	(0.030)	(0.016)	(0.034)
More than Two Components		-0.153***			
		(0.030)			
Observations	720	720	720	1,224	1,224
By Formulation	✓	✓	✓		
By Firm-Formulation				✓	✓
Sales Weighted			✓		✓

Notes: This table shows patterns of FDC discounts in January 2013. The dependent variable "FDC price ratio" is the ratio between the average FDC price and the sum of average prices of the components. Each observation is an FDC formulation in columns (1) to (3) and an FDC firm-formulation in columns (4) and (5). Observations in columns (3) and (5) are weighted by sales. The sample for each column is truncated at the 1st and 99th percentiles of the FDC price ratios. *** implies significance at the 0.01 level, ** at 0.05, and * at 0.1.

Table 2: Effects of FDCs on Component Prices: Heterogeneity across Firms

Dependent Variable: log(Price)		
	(1)	(2)
Sells FDC(s)	0.071***	0.059***
	(0.024)	(0.025)
Sells FDC(s) × FDC Market Share		0.172*
		(0.093)
Observations	4,906	4,906
Fixed Effects:		
Formulation FE	✓	✓
Firm FE	✓	✓

Notes: This table compares component prices set by firms and do and do not sell their FDCs. The sample consists of all plain molecules in January 2013 that are part of some FDCs. An observation is at the molecule-dosage-firm level. Sell FDC(s) take value 1 if the firm sells any FDC of the molecule. FDC Market Share, which takes a value between 0 and 1, measures the firm's market share in all FDC products of the molecule. *** implies significance at the 0.01 level, ** at 0.05, and * at 0.1.

Table 3: Substitution Pattern between FDC and Drug A Products

Drug A \ FDC	Alkem	Cipla	Eisai	Intas	Sun Pharma
Alkem	39	1	4	2	28
Cipla	2	0	0	0	1
Eisai	9	0	14	3	31
Intas	6	2	1	19	10

Notes: This table shows firm choices by consumers who bought a drug A product and an FDC product on the e-pharmacy platform at different points in time. Consumers along the diagonal buy both drugs from the same firm. Ignoring consumers who buy the FDC from Sun Pharma, which does not sell drug A, we find that 70.6% of consumers buy both products from the same firm, in comparison to the 36.1% who would do so if firm choices were random.

Table 4: Estimated Demand Parameters

σ_ε	0.54	σ_1	1.28	ρ	0.86
	(0.15)		(0.13)		(0.05)
$\bar{\Gamma}$	-0.02	σ_Γ	0.75	σ_f	0.79
	(0.21)		(0.20)		(0.11)

Notes: This table shows estimates of nonlinear parameters. The unit for the estimates (except for ρ) is 1,000 rupees. Standard errors are based on 100 bootstrap samples with resampling of markets and consumers in our e-pharmacy data.

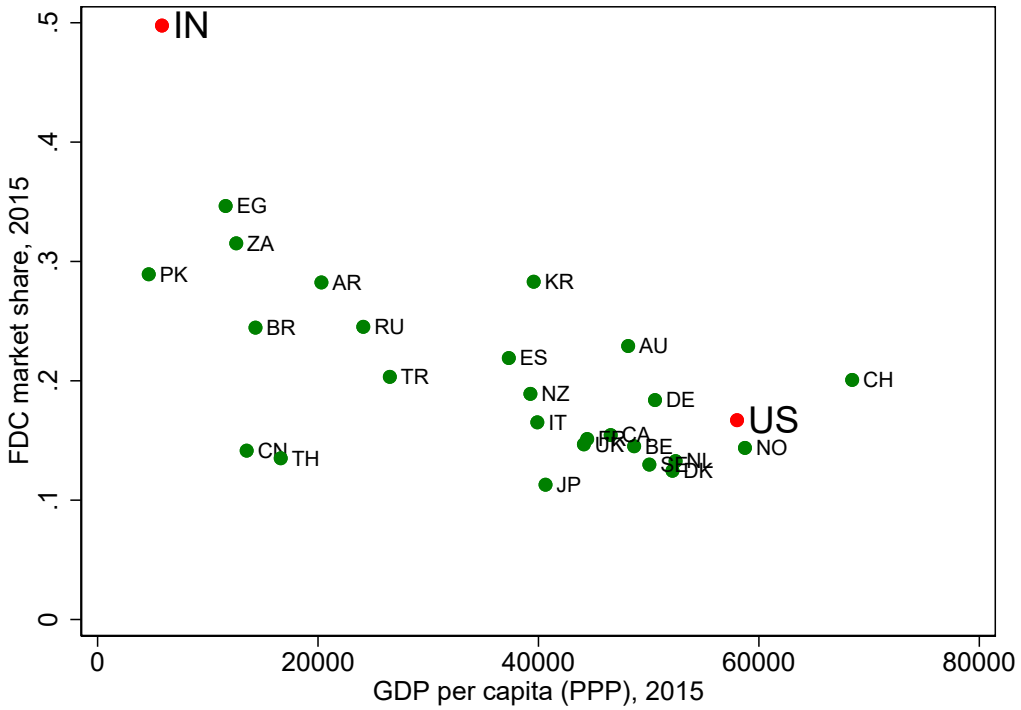
Table 5: Implications of Patent Protection for FDCs

Firm	Current Sales ('000)	Current Price ('000 rupees)	Monopoly Price ('000 rupees)	% Price Increase	Profit Gain (million rupees)
Alkem	7.4	2.56	2.59	1.1%	245.1
Cipla	0.4	2.19	2.20	0.3%	11.4
Intas	5.2	2.52	2.57	2.0%	180.0
Sun	14.1	2.44	2.47	1.3%	530.2

Notes: This table shows the price and profit impacts of granting an FDC patent to each of the four firms that sell the donepezil-memantine FDC in Q4 of 2015. The last column shows the expected profit gain from the FDC over 11 years of patent protection.

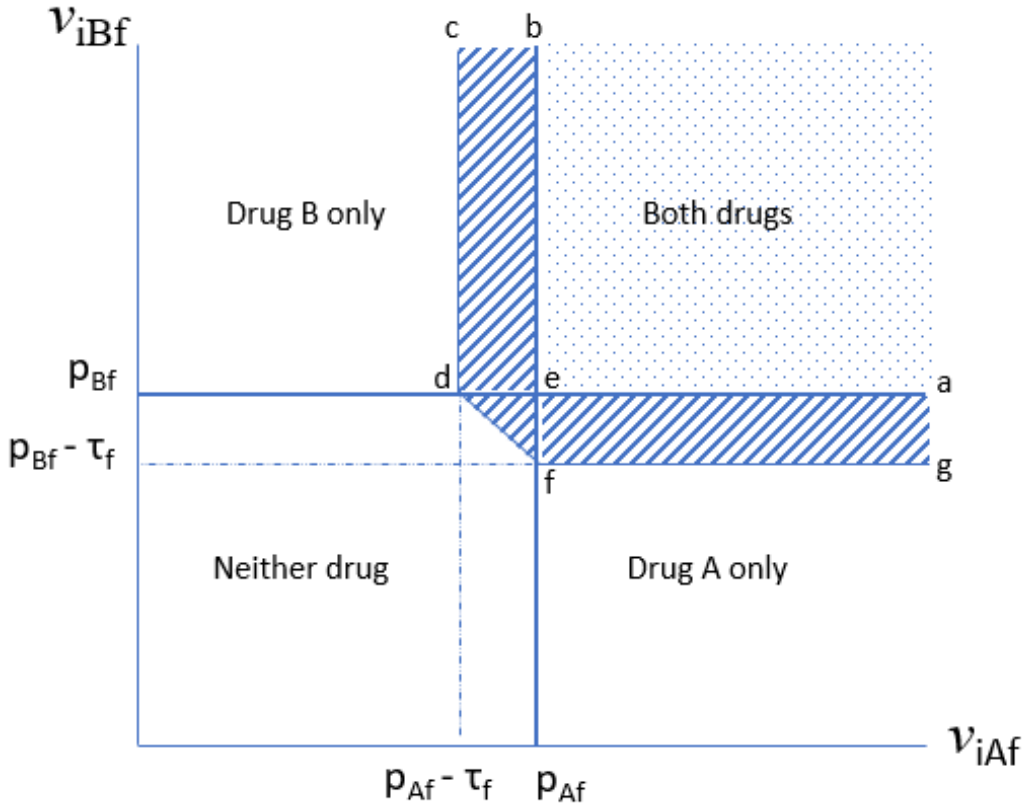
A Additional Figures and Tables

Figure A.1: Cross-country Comparison in FDC Revenue Shares



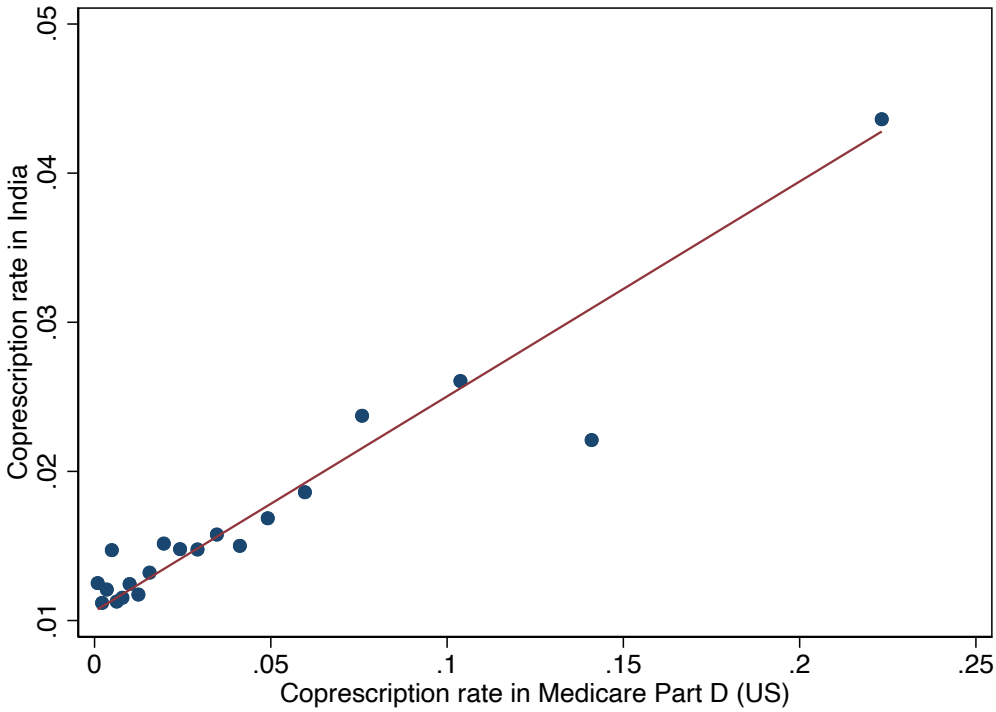
Notes: This figure shows FDC revenue shares in 28 countries in 2015. The FDC revenue shares in 27 countries other than the US are constructed using the IQVIA MIDAS data. Since we do not have access to the IQVIA MIDAS data for the US, we construct the FDC revenue share in the US using the Medicare Part D Prescription Event data, which cover patients at age 65 or above. Since the use of combination therapy is significantly more common among the elderly population, the FDC revenue share among the entire US population is likely to be lower than the 16.7% shown in this figure.

Figure A.2: Effects of Bundle Discount of Drug Demand (a Monopolist's Example)



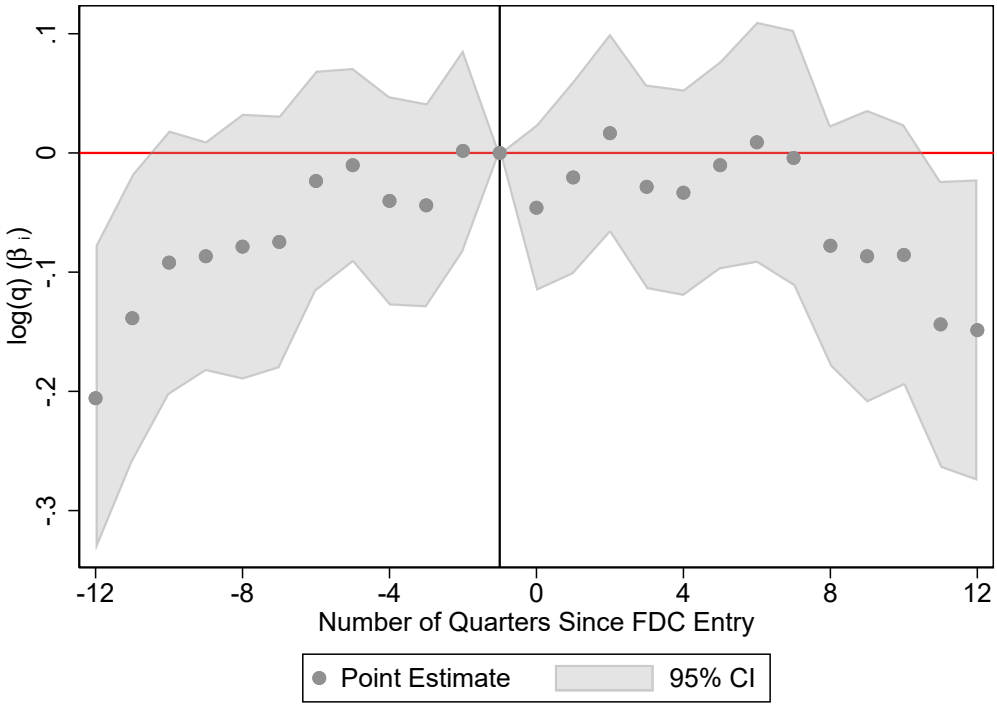
Notes: This figure replicates Figure III in (McAfee et al., 1989), and illustrates the trade-offs when a two-product monopolist offers a bundle discount.

Figure A.3: Comparison between Coprescription Rates in India and the US



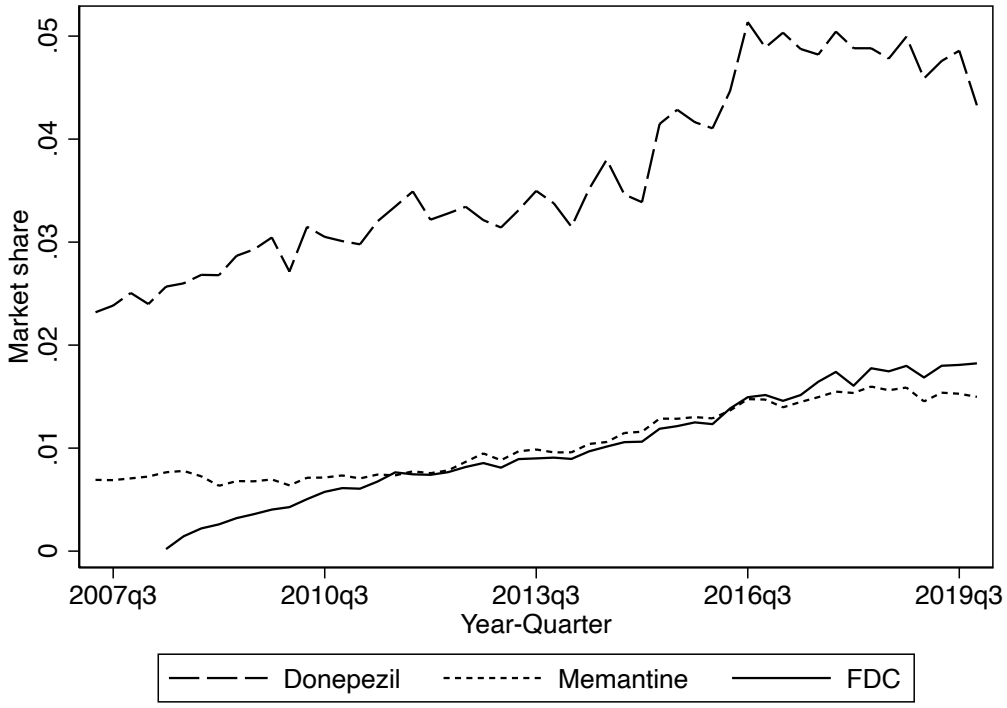
Notes: This figure compares the coprescription rates in India and the US for 16,007 pairs of drugs that have been coprescribed in both countries but have not become FDCs in either country. The coprescription rate is the number of coprescriptions divided by the smaller number of total prescriptions of the two drugs. Among these drug combinations, the coprescription rates in India are significantly lower because most commonly coprescribed drugs in India have become FDCs.

Figure A.4: Effects of FDC Entries on Component Sales



Notes: This figure shows the impact of FDC entries on sales of component molecules. Results are based on the full sample, which consists of 319 treated products (39 molecules) and 1,485 control products (228 molecules). Each dot represents an estimate of β_k in Equation 6. We take the quarter prior to FDC entry as the baseline period and normalize β_{-1} to 0. The gray band represents the 95% confidence interval, with standard errors two-way clustered at the product and molecule-by-quarter level.

Figure A.5: Trends in Drug Sales in the Market for Alzheimer's Drugs



Notes: This figure shows the time trend in the market share of Alzheimer's drugs. The market share of each drug is defined as drug sales (in units of 90-day supply) divided by the market size, which is the estimated number of people with Alzheimer's disease in that quarter.

Table A.1: FDC Revenue Share by Therapeutic Class

ATC Code	Therapeutic Class	Revenue Share	FDC Share
A	Alimentary Tract and Metabolism	0.27	0.59
C	Cardiovascular System	0.21	0.44
J	General Anti-infectives	0.15	0.37
N	Central Nervous System	0.11	0.26
M	Musculoskeletal System	0.07	0.60
G	Genitourinary System	0.07	0.29
R	Respiratory System	0.05	0.63
B	Blood and Blood-Forming Organs	0.03	0.40
L	Cancer and Immune System	0.02	0.00
H	Systemic Hormone Preparations	0.02	0.00
P	Parasitology	0.006	0.26
D	Dermatologicals	0.005	0.02
V	Others	0.004	0.30
S	Sensory Organs	0.0003	0

Notes: This table shows the revenue shares of 14 different therapeutic classes and the FDC revenue share within each therapeutic class in 2019. The revenue share is the the ratio between the pharmaceutical revenues of a therapeutic class and total pharmaceutical revenues in 2019. The FDC share is the ratio between the FDC revenues and total revenues of a therapeutic class. Since our main sample consists of products in tablet or capsule forms only, revenues are low for therapeutic classes where most drugs are in other forms (e.g., most drugs are in topical forms for ATC D and ATC S).

Table A.2: Summary Statistics: Market Competition for Plain Molecules and FDCs

	Panel A: Plain Molecules		Panel B: FDCs	
Number of Firms	Percent of Drugs	Percent of Sales	Percent of Drugs	Percent of Sales
1	23.7	1.8	29.1	1.0
2	10.6	2.6	15.2	4.8
3	11.5	3.4	8.3	4.7
4	4.2	0.6	8.2	2.3
5	3.1	0.9	4.1	1.7
6 - 10	16.2	16.7	12.6	8.7
11 - 20	13.2	9.9	9.0	9.2
21 - 50	11.8	27.1	7.8	16.9
51- 100	3.3	17.8	3.9	25.6
100 +	2.2	19.1	1.8	25.2

Notes: This table shows the distribution of drugs by the number of firms that sold each drug in January 2019. A drug is either a molecule or an FDC. Sales stands for sales units.

Table A.3: Summary Statistics: The Market for Alzheimer's Treatment before and after Price Controls

	Panel A: Q4 2015			Panel B: Q4 2019		
Variable	# of Firms	Sales ('000)	Avg. Price ('000 rupees)	# of Firms	Sales ('000)	Avg. Price ('000 rupees)
Donepezil 5mg	4	64.1	1.2	4	77.2	0.9
Donepezil 10mg	4	28.0	1.6	4	33.4	1.4
Memantine 10mg	2	16.9	1.2	2	22.4	1.5
Memantine 20mg	2	11.9	2.4	2	15.8	2.7
FDC 10mg + 10mg	4	19.8	2.1	5	32.6	2.5
FDC 10mg + 20mg	3	7.9	3.0	5	13.9	3.4

Notes: This table shows the summary statistics for six drug formulations in the market for Alzheimer's treatment before and after the implementation of the price control policy. Sales is measured in units of 90-day supply of each drug formulation. Average price is calculated over 90-day supply of all products of each formulation.

B Theory Appendix

In this section, we provided some simulation results and omitted proofs for the theoretical predictions outlined in Section 3.2.

B.1 FDC Pricing

Proof of Proposition 1 Without loss of generality, we assume the marginal costs of all products to be 0. Firm f's profits can be written as:

$$\pi_f = s_{A,f}p_{A,f} + s_{B,f}p_{B,f} + s_{FDC,f}(p_{A,f} + p_{B,f} - \tau_f), \tag{B.1}$$

where τ_f refers to the FDC discount. Consider a deviation of raising the FDC discount τ_f but keeping the component prices unchanged. The profit impact of this local deviation is:

$$\begin{aligned}\frac{\partial \pi_f}{\partial \tau_f} &= -s_{FDC,f} + \frac{\partial s_{A,f}}{\partial \tau_f}p_{A,f} + \frac{\partial s_{B,f}}{\partial \tau_f}p_{B,f} + \frac{\partial s_{FDC,f}}{\partial \tau_f}(p_{A,f} + p_{B,f} - \tau_f) \\ &= -s_{FDC,f} + (\frac{\partial s_{A,f}}{\partial \tau_f} + \frac{\partial s_{FDC,f}}{\partial \tau_f})p_{A,f} + (\frac{\partial s_{B,f}}{\partial \tau_f} + \frac{\partial s_{FDC,f}}{\partial \tau_f})p_{B,f} - \frac{\partial s_{FDC,f}}{\partial \tau_f}\tau_f, \end{aligned} \tag{B.2}$$

where the first term, $-s_{FDC,f}$, represents the profit loss from the inframarginal consumers and the remaining terms represent the net profit gain from additional sales to the marginal consumers.[45]

In a mixed bundling equilibrium, we have $\frac{\partial \pi_f}{\partial \tau_f} = 0$. A change in consumer preferences that increases $s_{FDC,f}$ makes $\frac{\partial \pi_f}{\partial \tau_f} < 0$ at the current FDC discount and reduces the optimal FDC discount unless it also leads to an offsetting increase in the density of marginal consumers. ■

Model Simulation Consumer demand for a two-drug bundle from the same firm depends on, among other things, drug complemenentarity, drug preference correlation, and firm preferences. We illustrate the comparative statics of FDC discounts to these market features under our empirical specification of the model in Section 6.2. The key parameters of interest are $\bar{\Gamma}$, ρ, and σ_f (see section 6.2 for definitions of the parameters). We fix the other parameters at the following values:

1. Average product values $\delta_k = 0$ for all products
2. Marginal costs $c_k = 0$ for all products
3. FDC preference $\gamma_k = 0$ for both FDC products
4. Variance of drug preferences $\sigma_1 = 1$
5. Variance of drug complementarity $\sigma_\Gamma = 0$

[45] The first component $(\frac{\partial s_{A,f}}{\partial \tau_f} + \frac{\partial s_{FDC,f}}{\partial \tau_f})p_{A,f}$ represents profit gains from additional drug A sales, which is the drug A price times the density of consumers who would switch from drug B or the outside option to the FDC. Similarly, the second component $(\frac{\partial s_{B,f}}{\partial \tau_f} + \frac{\partial s_{FDC,f}}{\partial \tau_f})p_{B,f}$ represents profit gains from additional drug B sales to marginal consumers. The last component subtracts the FDC discount τ_f from additional FDC sales.

6. Variance of the logit error $\sigma_\varepsilon = 0.5$ [46]

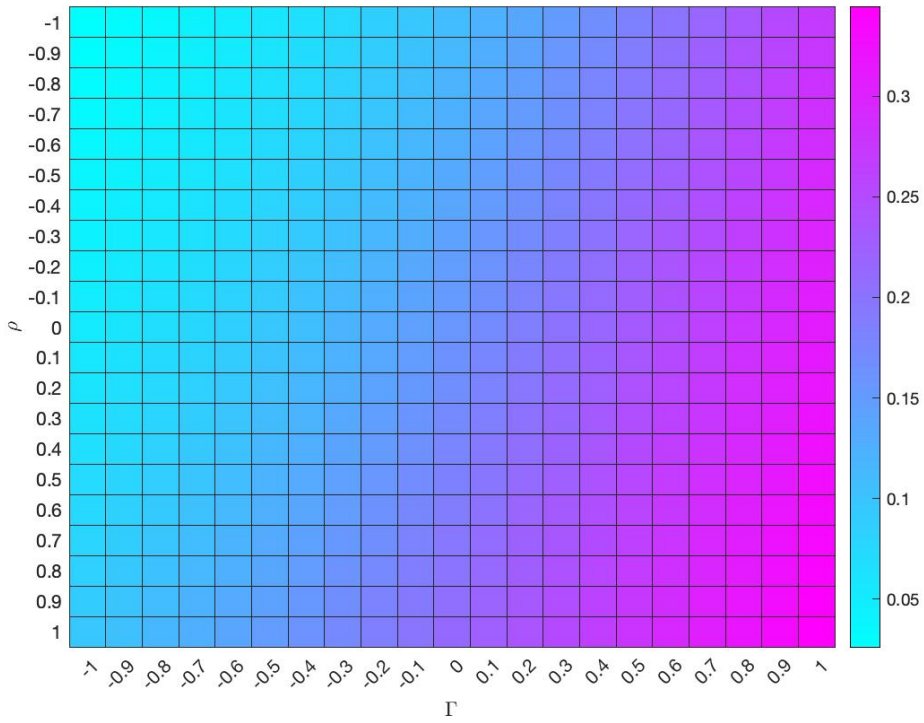
We perform the following simulation exercises. First, we fix $\sigma_f = 1$ and simulate market outcomes at different values of $\bar{\Gamma}$ and ρ. Next, we fix $\bar{\Gamma} = 0$ and $\rho = 0$ and simulate market outcomes at different values of σ_f. At each set of parameter values, we calculate i) the fraction of consumers who buy both drugs from the same firm when there is no FDC discount and ii) the optimal FDC discount when both firms introduce the FDC. Details on how we calculate market shares and equilibrium prices can be found in Appendix E.

Figures B.1 and B.2 show the results. We see that more consumers would buy both drugs from the same firm when there is stronger drug complementarity, more positively correlated drug preferences, or stronger firm preferences. The optimal FDC discount decreases when demand for two-drug bundles from the same firm increases.

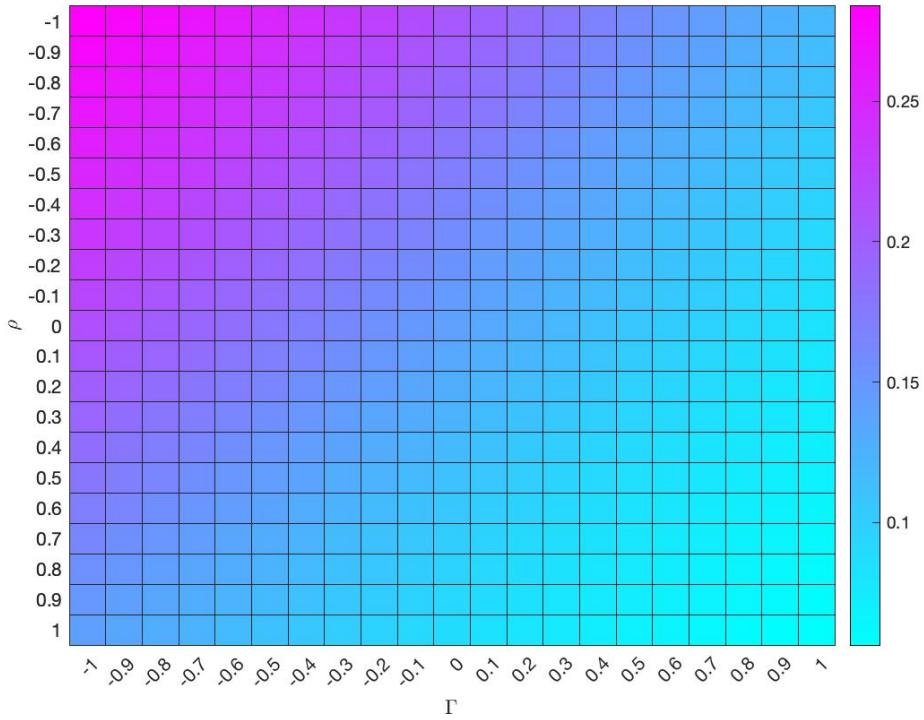
[46] The logit errors help smooth the objective functions in firms' pricing decisions and do not qualitatively affect the results.

Figure B.1: Comparative Statics with Respect to ρ and $\bar{\Gamma}$

Panel A: Fraction Who One-Stop Shop for Both Drugs without the FDC



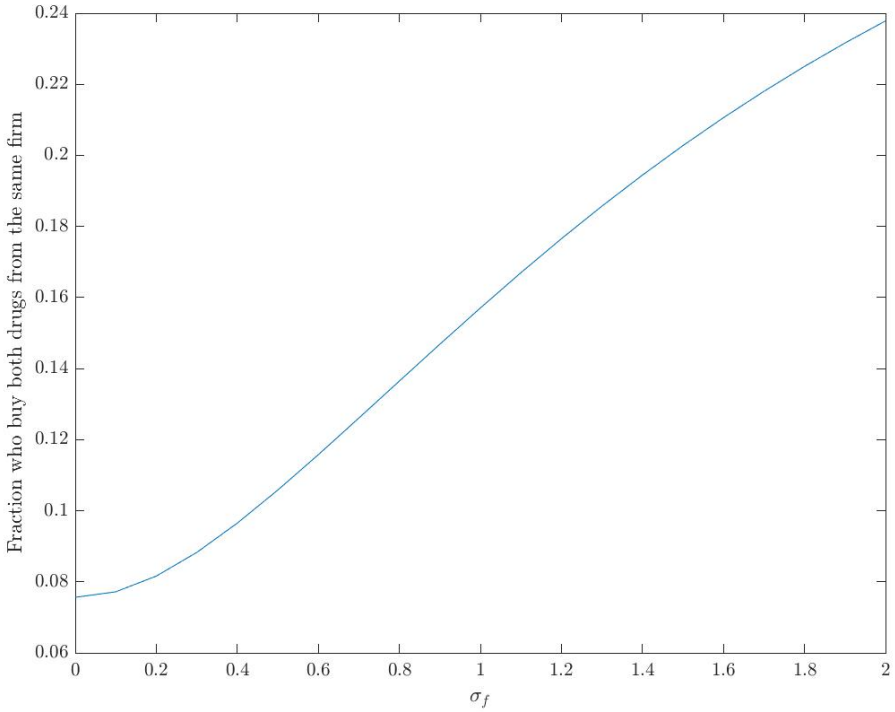
Panel B: Percentage FDC Discount



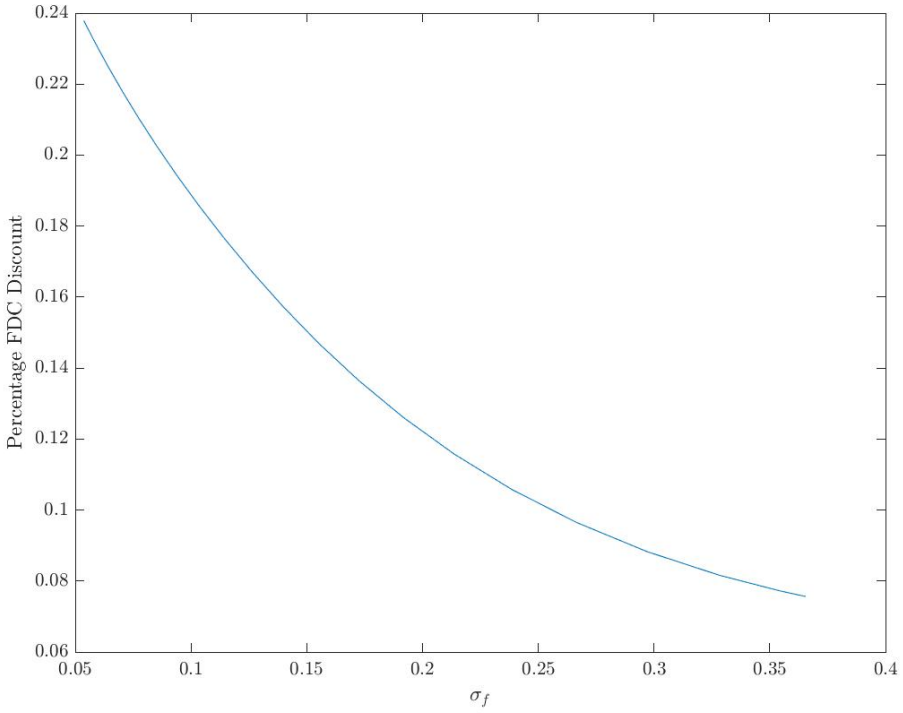
Notes: This figure shows the comparative statics of market outcomes with respect to ρ and $\bar{\Gamma}$, fixing $\sigma_f = 1$. Panel A tracks the fraction of consumers who will one-stop shop for both drugs under separate pricing. Panel B tracks the percentage FDC discount. Different colors represent different values for the outcome variables, as labeled in the scale on the right.

Figure B.2: Comparative Statics with Respect to σ_f

Panel A: Fraction Who One-Stop Shop for Both Drugs without the FDC



Panel B: Percentage FDC Discount



Notes: This figure shows the comparative statics of market outcomes with respect to σ_f, fixing ρ and $\bar{\Gamma}$ at 0. Panel A tracks the fraction of consumers who will one-stop shop for both drugs under separate pricing. Panel B tracks the percentage FDC discount.

B.2 The Welfare Effects of FDCs

Proof of Proposition 2 When the FDC discount leads to additional sales, it increases total social welfare if and only if the consumer values the additional product more than its marginal cost. Without loss of generality, consider a case where a consumer substitutes from drug A to the FDC from the same firm f. Let $\tilde{v}_{iBf}$ denote the incremental value of the drug B product to consumer i, which includes its product value and drug complementarity Γ_i. We have:

$$\tilde{v}_{iBf} \geq p_{FDC,f} - p_{A,f} \geq c_{B,f}. \tag{B.3}$$

The first inequality follows from revealed preference: consumer i's incremental value from drug B is weakly higher than the additional price she needs to pay for the bundle. The second inequality follows from the assumption that no component is priced below its marginal cost. As a result, $\tilde{v}_{iBf} \geq c_{B,f}$, and the additional drug B sales increase social welfare. By a similar intuition, social welfare increases when consumers substitute from the outside option to an FDC product.

Among consumers who substitute from other two-drug bundles to FDCs, total welfare is determined solely by the match quality between consumers and products. FDC discounts may lead to excessive one-stop shopping and reduce social welfare.[47] ■

[47] Without assuming symmetry between firms, consumer welfare may also increase when FDC discounts cause consumers to switch to one-stop shop at a firm that

C Data Appendix

In this section, we provide additional details on our data preparations, with a focus on several data issues and the way that we address them.

C.1 Primary Drug Price and Sales Data

Inconsistency between Data Segments We receive the AIOCD drug price and sales data in three separate segments: April 2007 to October 2013, January 2011 to December 2014, and January 2015 to December 2019.[48] There are several data discrepancies between different segments. First, SKU names may change between segments. Second, we observe drug sales in 23 different regions in the first segment but in 30 different regions in the other two segments.[49] Finally, there are occasional large changes in drug sales for some SKUs at the boundaries of the segments. Consultation with the data provider reveals that AIOCD makes corrections to its projections after receiving feedback from pharmaceutical companies but does not apply these corrections to the cached data on the earlier segments.

While we are not able to fix all the data issues for all the drug products, we take several precautions to ensure that these issues do not interfere with our empirical analysis. First, we define a drug product at the molecule-dosage-firm level. This allows us to link products over time even when we cannot match the SKU names. Second, for most of our empirical analysis that involves panel data, we focus on one data segment for consistency (e.g., we use the first segment for the FDC entry event study). Third, for exercises where we need to track drug products over all 13 years (e.g., for the Alzheimer's drug market in the model estimation), we cross-reference with other data sources such as IQVIA coprescription data and IQVIA MIDAS drug sales data and verify the data consistency.

Missing or Incorrect Dosage Information For a subset of SKUs, especially the FDC SKUs, the dosage information may be missing or incorrect. We manually check the dosage information for each individual SKU against data from several major e-pharmacy websites (e.g., Tata 1mg, MedPlus) and fill in missing data or correct obvious data errors.[50] For example, we make corrections for 1,273 out of 15,907 FDC SKUs, with 1,140 missing dosages and 133 mistakes, in the third data segment between January 2015 and December 2019.

Linking Datasets We link our main data set with multiple ancillary data sets, including the National Lists of Essential Medicines from 2011 and 2015 (i.e., the list of drugs under price control), the list of FDCs covered by the 2016 FDC ban, the IQVIA coprescription data, the Tata 1mg e-pharmacy data, the Medicare Part D Prescription Drug Event data, and the FDA Orange Book data on new drug approvals. Drug names may differ across different data sets, and data linking is done with manually prepared crosswalks.

[48] AIOCD revised its data reporting format in 2013 and did backdated correction through January 2011.

[49] The 30 regions are finer cuts of the 23 regions based on the same underlying micro data. We can therefore aggregate the data to the 23 regions in the second and third segments if needed.

[50] The most common data error is that the dosages of two components in an FDC SKU are swapped.

C.2 Ancillary Data Sets

IQVIA Coprescription Data One major issue in the IQVIA coprescription data is that they report the prescription information only for a subset of commonly prescribed drugs and combine less commonly prescribed drugs into categories (e.g., other beta blockers, other antidiabetic combinations). For this reason, we are able to match 782 out of 1,626 (48%) of the drugs in our main sample to the coprescription data. The incomplete match creates some challenges in constructing the coprescription rates after FDC entry because for many new FDCs, we do not observe the FDC prescriptions until many years after they were introduced.

To address this issue, we use the aggregate drug sales data to complement the coprescription data in constructing the coprescription rates. Consider a setting where drug B is less commonly prescribed than drug A. We construct the coprescription rates between drugs A and B using the following steps:

1. In each quarter t, construct the baseline coprescription rate as the ratio between the coprescription count and drug B prescription count
2. Multiply the baseline coprescription rate with drug B sales $s_{B,t}$ to recover the separate sales of the two drugs $s_{AB,t}$
3. The total coprescription rate is $\frac{s_{AB,t}+s_{FDC,t}}{s_{B,t}+s_{FDC,t}}$
4. The non-FDC coprescription rate is $\frac{s_{AB,t}}{s_{B,t}+s_{FDC,t}}$

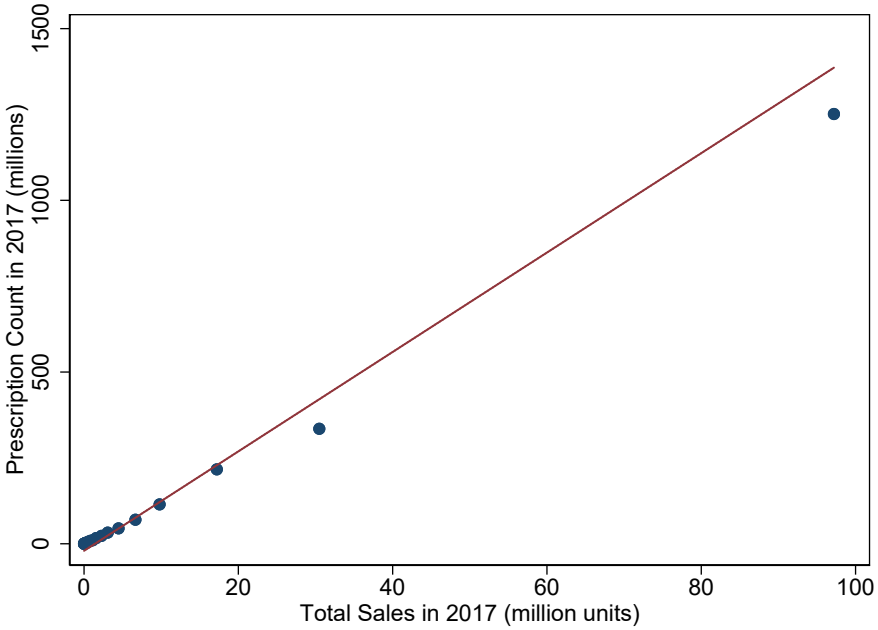
Tata 1mg E-Pharmacy Data Our e-pharmacy data include all purchases of diabetic and Alzheimer's drugs on Tata 1mg. These two therapeutic markets accounted for 13% of total pharmaceutical revenue in India in 2019. The e-pharmacy data are sparse for earlier years, but sales on the platform grew rapidly over time. In 2019, Tata 1mg accounted for about 0.5% of all drugs sales in India.

In Figure C.1, we show that our coprescription data and e-pharmacy data are broadly consistent with our main data sample in terms of product-level sales.

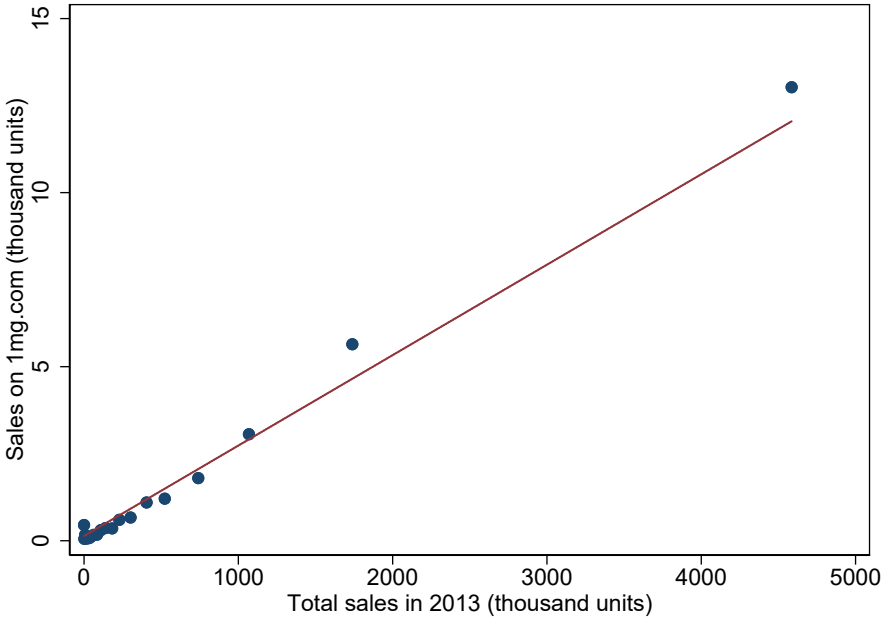
Data on Drug Approvals in the US We review new drug applications (NDAs) for 127 new FDCs approved by the US FDA since 2,000. For each FDC, we manually go through the medical review reports on Drugs@FDA, the FDA database for new drug applications and approvals. We record information on the number of clinical trials and the phase of each trial, the number of human subjects involved, and the number of years between applications and approval. In addition, we collect information on drug patents and market exclusivity from the Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book), which is an annual publication by the US FDA on drug approvals and patents.

Figure C.1: Data Comparisons in Terms of Drug Sales

Panel A: Coprescription Data and Main Sample



Panel B: E-Pharmacy Data and Main Sample



Notes: Panel A of this figure compares drug-level prescription counts in the IQVIA coprescription data and SKU-level sales in the Tata 1mg e-pharmacy data to our main sample. We match 782 drugs between the coprescription data and our main sample. Panel A shows that the prescription counts are broadly proportional to total drug sales for 2017. We match 2,682 SKUs between the e-pharmacy data and our main sample. The matched SKUs account for 94% of revenue from diabetic and Alzheimer's drugs for 2019. Across different SKUs, sales on the platform are proportional to total sales.

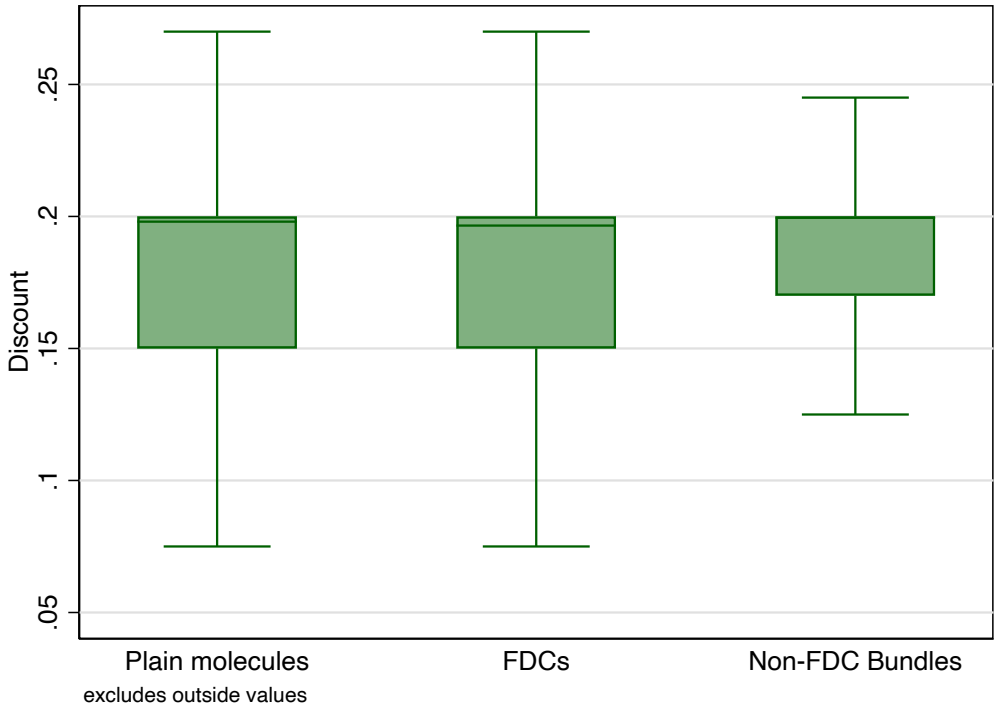
D Additional Descriptive Analysis

D.1 FDC Discounts

Discounts for Non-FDC Bundles Our measure of FDC discounts may overstate the price savings from FDCs if pharmacies routinely offer joint-purchase discounts for non-FDC drug bundles. We examine such joint purchase discounts by using our e-pharmacy data.

Figure D.1 shows the distribution of percentage discounts for different types of drug orders in the e-pharmacy data. The median discounts are almost identical between orders that contain one plain molecule, one FDC product, or multiple products. This result suggests that informal joint-purchase discounts are not common in India.[51] We therefore consider our measure of FDC discounts using the maximum retail prices an informative metric for the price savings from FDCs.

Figure D.1: FDC Discount over Time



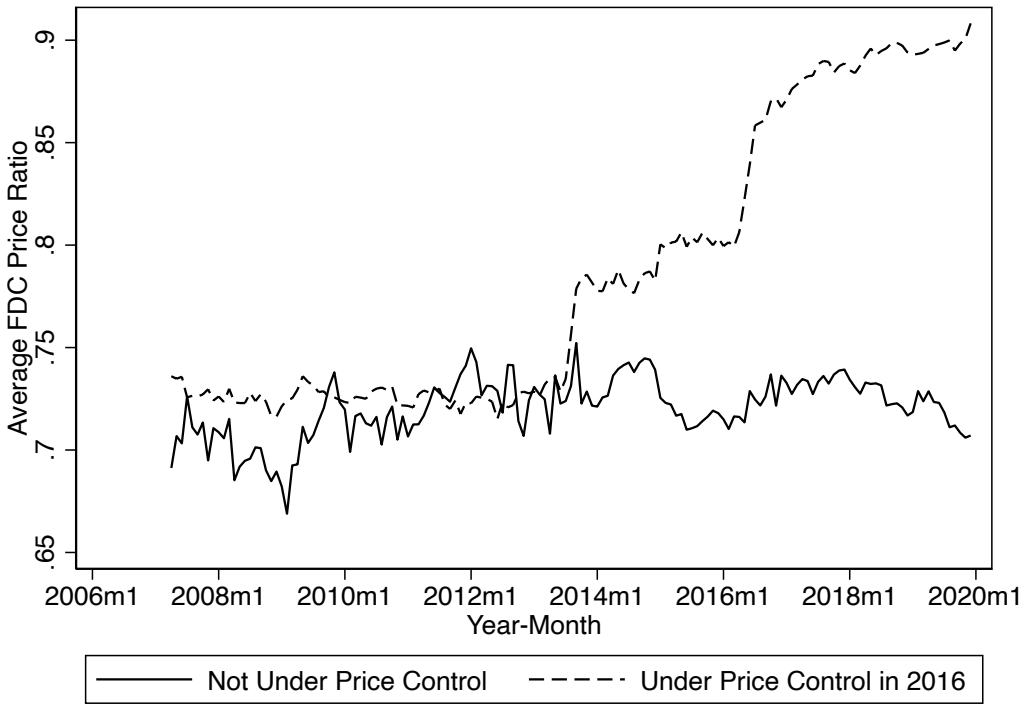
Notes: This figure shows the distribution of discounts (percentage off list prices) for different types of drug purchases in the e-pharmacy data. The data consist of 3,181,439 orders of diabetic or Alzheimer's medications on the platform. A total of 667,847 contain just one plain molecule product, 1,142,476 contain one FDC product, and 1,371,116 are bundles of two or more drug products

The Time Trend in FDC Discounts We show that the patterns of FDC discounts are robust across our sample period. Figure D.2 shows the time trend in the average FDC discount. For FDCs

[51] E-pharmacy platforms have technologies that make it easy to administer bundle discounts. We infer that informal discounts for non-FDC bundles, to the extent that they exist, are likely even less common in retail pharmacies.

whose components are not covered by price controls, the average discount was stable at approximately 28% throughout the sample. For FDCs that have at least one component covered by price controls, the average discount was approximately 27% up to September 2013, immediately prior to the implementation of the price control policy. It shrank to around 10% after the expansion of the price control policy in 2016 because of price ceilings on the component molecule(s).

Figure D.2: FDC Discount over Time



Notes: This figure shows the time trend in the average FDC price ratio over our sample period. The green line tracks the average FDC price ratio for FDCs whose components are not under price controls. The orange line tracks the average FDC price ratio for FDCs with at least one component under price controls. The price control policy was first implemented in October 2013 and then expanded to cover more molecules in April 2016.

Alternative Measures of FDC Discounts We show that the patterns of FDC discounts are robust to different ways of constructing the FDC price ratios. In an alternative measure, we calculate per mg price for each plain molecule and use that to construct the sum of the components' prices for each FDC formulation. We find that the average FDC discount is 27% based on this measurement.

Between-Firm Heterogeneity in FDC Discounts We use cross-sectional price variation to measure the differences in FDC prices between firms that do and do not sell the components. We estimate the following equation by using all two-molecule FDC products available in January 2013:

$$log(p_k) = \beta_0 \mathbb{1}(s_{jf(k)} > 0) + \beta_1 s_{jf(k)} + \lambda_{jd(k)} + \lambda_{f(k)} + \varepsilon_k, \tag{D.1}$$

where $s_{jf(k)}$ measures firm f's maximum market share in standalone sales of the two components of FDC j . $\lambda_{jd(k)}$ and $\lambda_{f(k)}$ stand for FDC-dosage fixed effects and firm fixed effects, respectively.

Table 2 summarizes the results. Firms that sell one component set 9.8% higher FDC prices and firms that sell both components set 13.7% higher FDC prices than firms that do not sell either component. In addition, a 10% increase in the firms' maximum market share in the components is associated with a 2.0% higher FDC price. These results show that FDC discounts depend on firms' product portfolios. Firms that sell the component molecules set higher FDC prices to reduce intrafirm cannibalization.

Table D.1: Mechanisms behind FDC Discounts: Evidence on Strategic Bundle Pricing

Dependent Variable: log(Price)

	(1)	(2)	(3)
Sells Either Component	0.103***		0.079***
	(0.018)		(0.019)
Sells One Component		0.098***	
		(0.018)	
Sells Both Components		0.137***	
		(0.026)	
Sells Either Component × Maximum Market Share			0.199***
			(0.053)
Observations	5,853	5,853	5,853
Fixed Effects:			
Formulation FE	✓	✓	✓
Firm FE	✓	✓	✓

Notes: This table shows the difference between the FDC prices set by firms that do and do not sell the component molecule(s). The sample consists of all two-molecule FDC products in January 2013, and each observation is an FDC product. The dependent variable is log price. We consider that a firm sells a component molecule if its products account for at least 1% of the market share of total sales of the molecule. "Maximum Market Share" is the maximum of the firm's market shares in the two component molecules, measured between 0 and 1. *** implies significance at the 0.01 level, ** at 0.05, and * at 0.1.

D.2 Effects of FDCs on Prices of Component Molecules

We show in Section 5.2 that FDC entries on average increased component prices by 4%. In this section, we implement some robustness analysis and investigate the mechanisms of the price effects.

Robustness Analysis We estimate Equation 8 under different model specifications. Figure D.3 shows that our results are robust across a number of alternative specifications incorporating, for example,

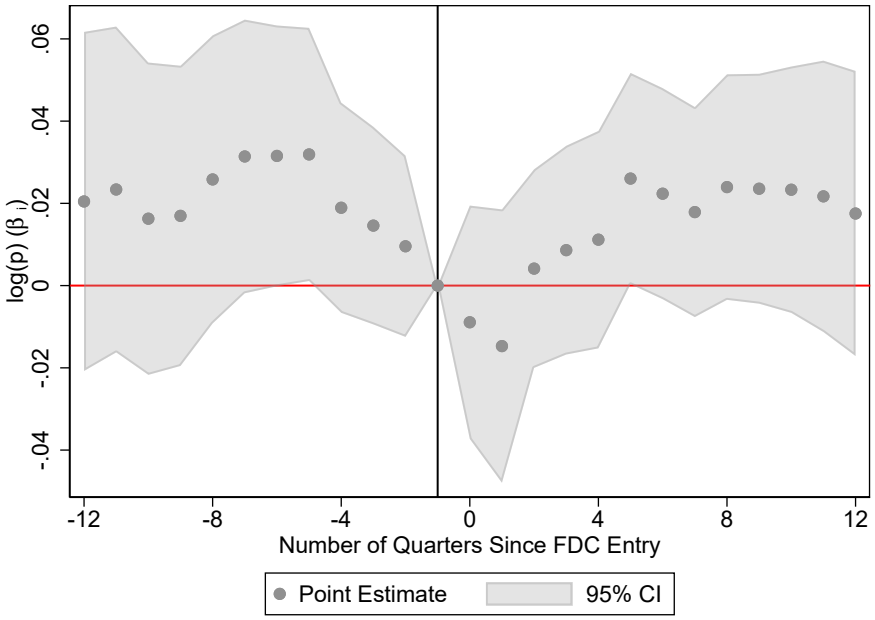
weights for different products by sales quantity or controls for firm-specific time trends, therapeutic-market-specific time trends, or the number of firms.

Mechanisms of the Price Effects We estimate heterogeneous effects of FDC entries on component prices set by firms that do and do not sell the FDCs. Figure D.4 shows that there are no significant differences in the price effects between the two types of firms. A possible explanation is that the overall price increase is primarily driven by market segmentation: the FDC discount attracts the more price-elastic consumers, and all firms increase the component prices to target the remaining less price-elastic consumers. The small sample size may limit the statistical power to detect heterogeneous price responses between firms that do and do not sell the FDCs.

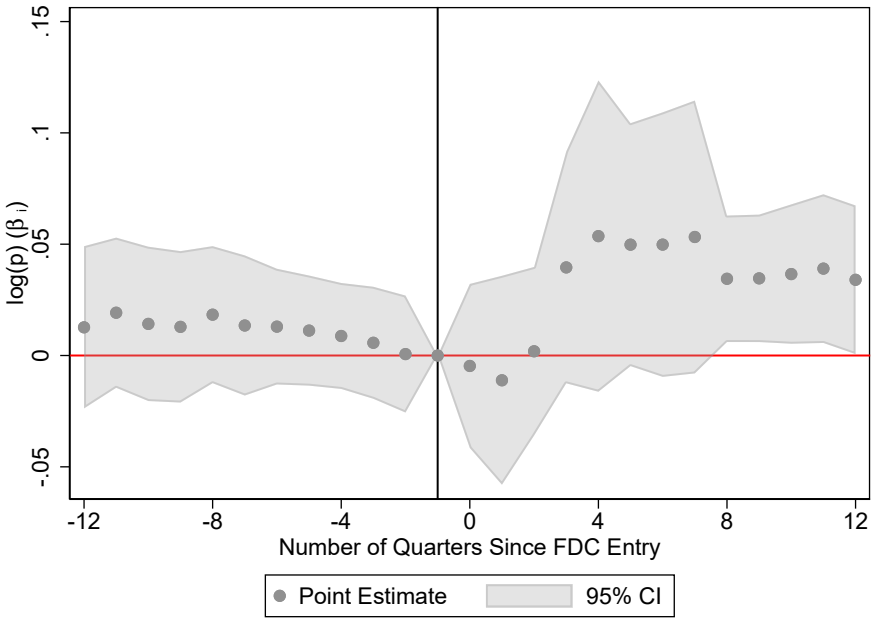
Finally, we examine how the price effects of FDC entries depend on the pre-existing market structures for the component molecules. We estimate Equation 8 for a subset of molecules sold by only one firm throughout the sample period. This subsample consists of 4 treated molecules and 27 control molecules. Figure D.5 shows that FDC entries reduced the prices of component molecules by up to 10%. This result provides some suggestive evidence that the procompetitive effect of FDCs can be large in concentrated markets, though it is muted in the full sample because the markets for most component molecules are already highly competitive.

Figure D.3: Robustness Analysis on the Effects of FDCs on Component Prices

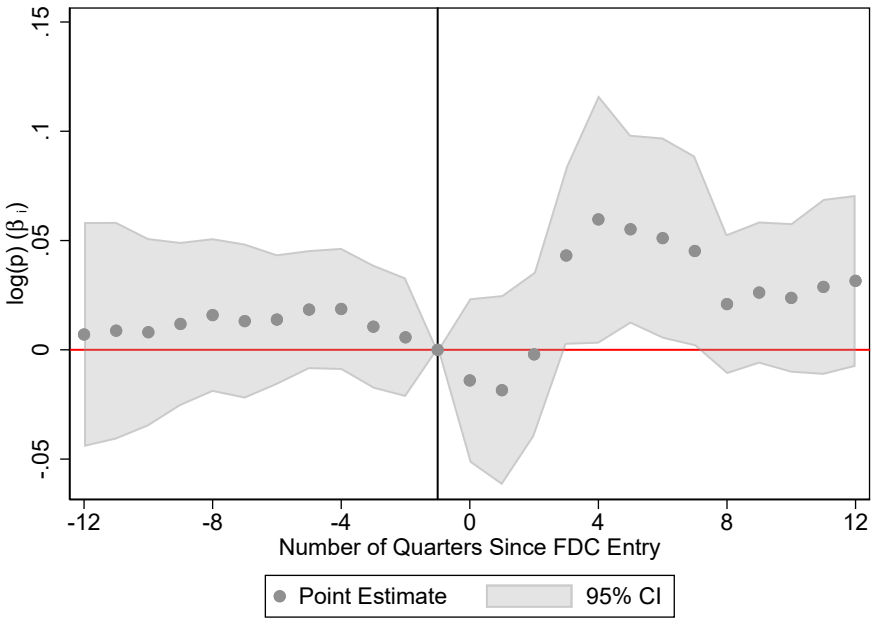
Panel A: Sales-Weighted Regressions



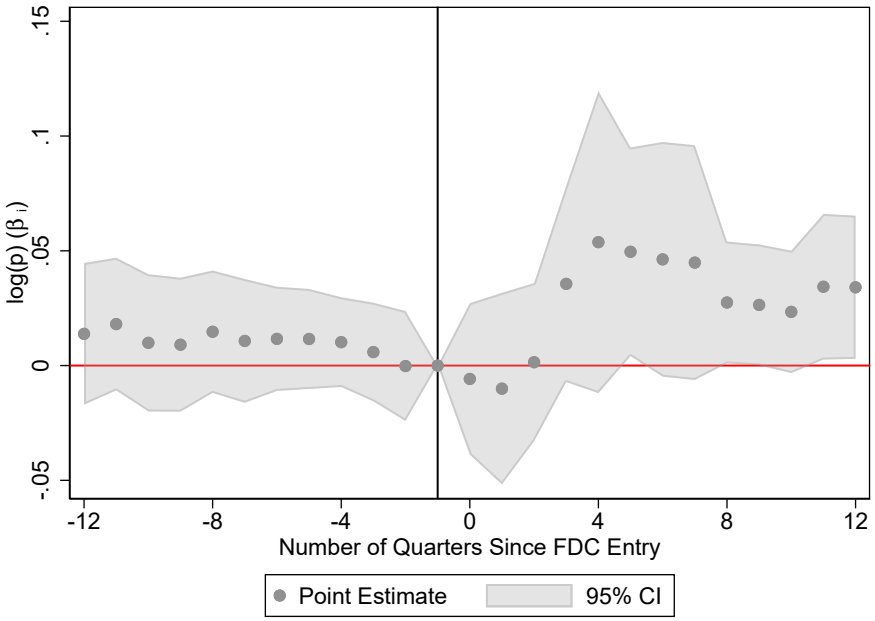
Panel B: Firm-Specific Time Trend



Panel C: Therapeutic-Market-Specific Time Trend



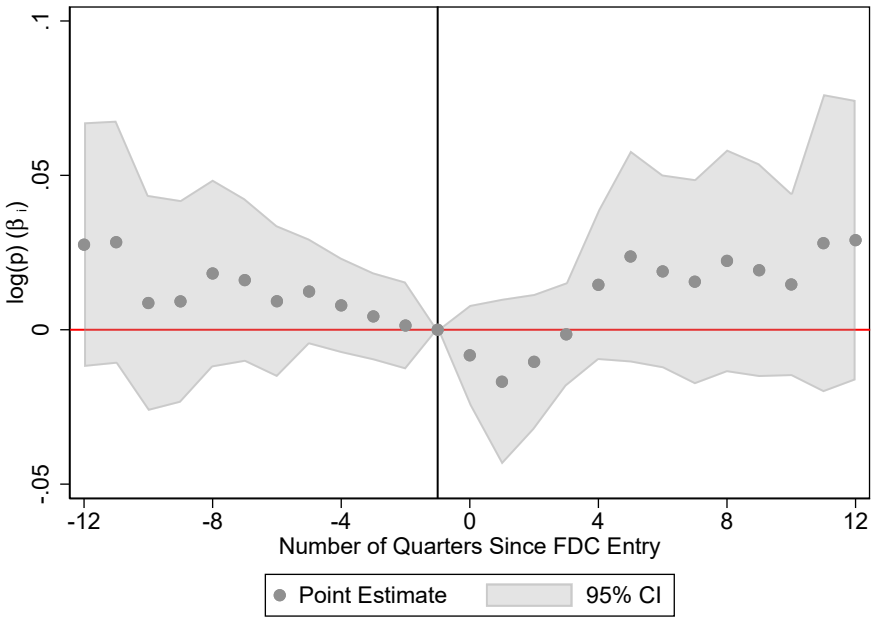
Panel D: Estimates with Controls for the Number of Firms



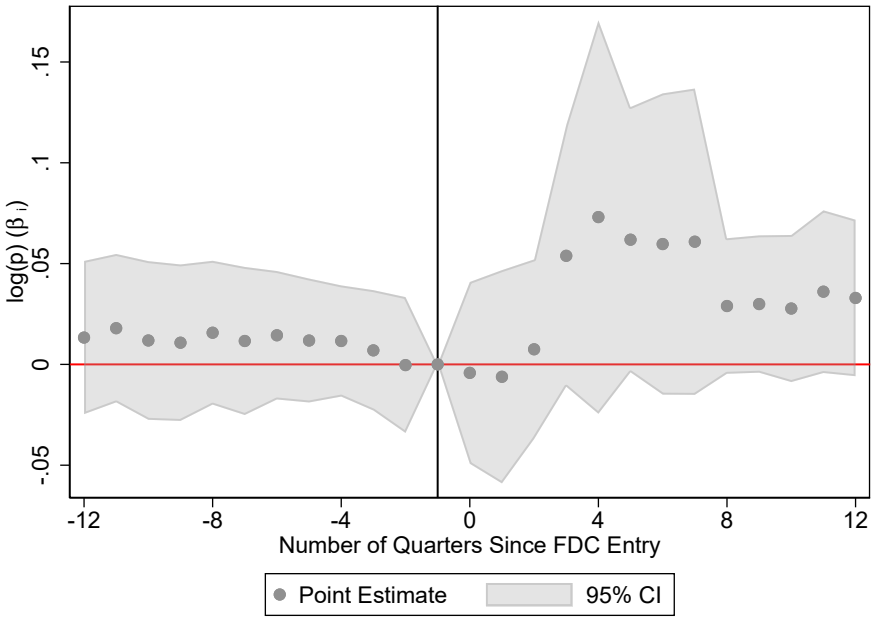
Notes: This figure shows results from four alternative specifications of Equation 8, which measures the effects of FDC entries on prices of the FDCs' component molecules. All four specifications are estimated by using the main sample of 319 treated products (39 molecules) and 1,485 control products (228 molecules). In Panel A, we weight each drug product based on the ratio between total sales of the product and total sales of the molecule over the sample period. In Panel B, we add firm-quarter fixed effects to capture the time trend in each firm's pricing decisions. In Panel C, we add therapeutic-market fixed effects so that each treated product is compared to control products in the same therapeutic market. In Panel D, we control for log of the number of firms that sell each molecule in each quarter.

Figure D.4: Effects of FDC Entry on Firms that Do and Do Not Sell FDCs

Panel A: Price Effects on Firms that Sell FDCs

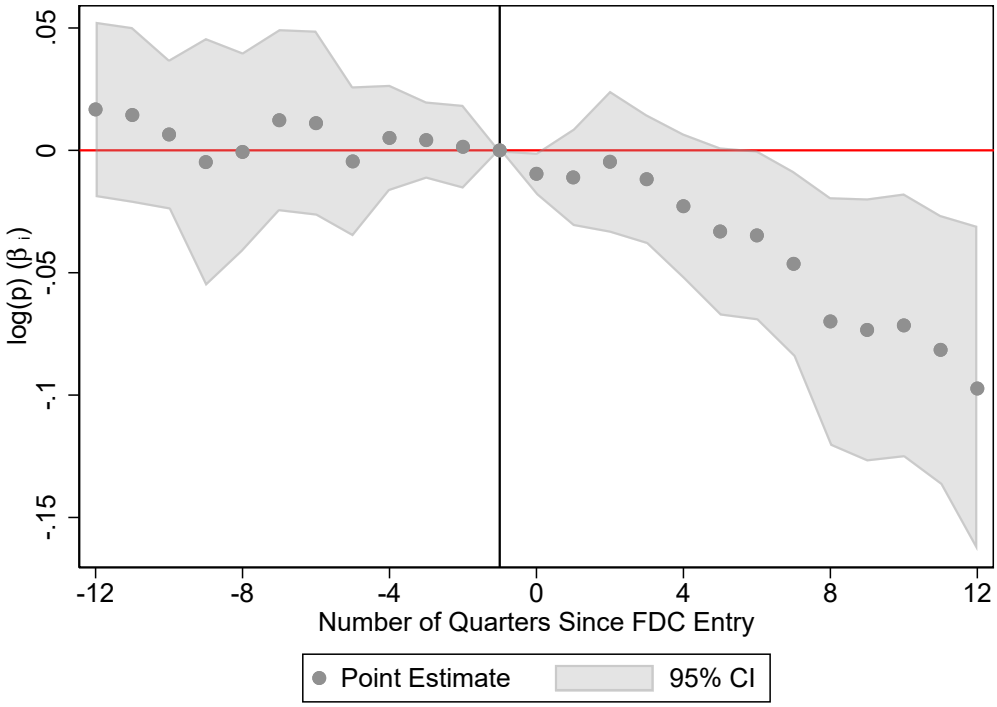


Panel B: Price Effects on Firms that Do Not Sell FDCs



Notes: This figure shows the impact of FDC entries on prices of component molecules separately for firms that do and do not sell the FDCs. The treated group in Panel A consists of 102 products where the firms sell the FDCs, and the treated group in Panel B consists of 217 products where the firms do not sell the FDCs. The control group is the same for both panels. We take the quarter prior to FDC entry as the baseline period and normalize β_{-1} to 0. The grey band represents the 95% confidence interval, with standard errors two-way clustered at the product and molecule-by-quarter level.

Figure D.5: Effects of FDC Entry on Component Prices in Monopoly Markets



Notes: This figures shows the effects of FDC entries on component prices in a subsample in which each molecule is sold by only one firm. This subsample consists of 4 treated molecules and 27 control molecules. The grey band represents the 95% confidence interval, with standard errors two-way clustered at the product and molecule-by-quarter level.

E Model Estimation: Additional Details

We estimate the demand model by using the simulated method of moments (SMM). In this section, we provide some additional details on the estimation procedure, with a focus on how we construct the empirical moments and their model-predicted counterparts.

E.1 Price Instrument and Empirical Moments

Price Instruments As discussed in Section 6.3, our price instrument Z takes value 1 for the two drug A products affected in the price control policy starting in Q2 of 2016 and 0 otherwise. Our estimates are robust to different choices of price instruments, such as separate dummies for the two affected products or the distance between the 2015 price and the price ceiling for the two affected products (with value 0 otherwise).

Coprescription Moments We measure the coprescription rate in each quarter by using the ratio between the coprescription count and the drug B prescription count. Note that in markets after the FDC entry, this measure, which does not include FDC sales, does not directly match either the total coprescription rate or the non-FDC coprescription rate shown in Figure 6. However, since we match the market shares of all drug B and FDC products in the estimation, targeting the baseline coprescription rate also automatically targets the other coprescription measures.

E-Pharmacy Moments As we have discussed in Section 6.3, it is overall straightforward to construct the moments that summarize the substitution patterns in the e-pharmacy data. As an example, we discuss how we construct the moments related to substitutions to the new Eisai FDC, for which we need an additional step to measure substitutions from the outside option.

We focus on a subset of 366 consumers who have bought the Eisai FDC and identify the drug bundle that each consumer bought, if any, prior to purchasing the Eisai FDC. One empirical challenge is that consumers who did not purchase any other drug bundle may have substituted from the outside option or may be new consumers whose purchase history we do not observe. To estimate the number of new arrivals, we use data on drug products that have been offered throughout the sample period and were not directly affected by the price control policy. We measure the fraction of new consumers who show up in the data for the first time in each month. We then multiply the new arrivals share with the sales of the Eisai FDC in each month to estimate the number of new arrivals among the Eisai FDC consumers. We drop these new arrivals and construct the moments based on substitution patterns among the remaining consumers, as shown in Figure 7.

E.2 Predicted Moments

We describe the main steps that we take to construct the model-predicted moments. Recall that the set of parameters of interest is $\Theta = \{\sigma_\varepsilon, \sigma_1, \rho, \bar{\Gamma}, \sigma_\Gamma, \sigma_f\}$. We simulate a sample of $NC = 10,000$ consumers, with the preferences of each consumer $\nu_i = \{\nu_{iA}, \nu_{iB}, \Gamma_i, \vec{\nu}_{if}\}$ drawn from the distribution

described by Θ. Given a guess of Θ, we recover the vector of average product values $\boldsymbol{\delta}$ so that the model-predicted product market shares exactly match the observed product market shares, following the standard contraction mapping procedure described in Berry (1994).

Orthogonality Condition Given a vector of $\boldsymbol{\delta}$, we recover the unobserved demand shocks as the residuals from the following linear regression:

$$\delta_{kt} = \lambda_k + \lambda_{j(k)t} + \xi_{kt}. \tag{E.1}$$

The first moment condition is given by the orthogonality condition between the unobserved demand shocks and the price instrument:

$$\bar{g}^{\xi}(\Theta) = \frac{1}{N}\sum_{kt}(\xi_{kt} \times Z_{kt}), \tag{E.2}$$

where N is the total sample size.

Coprescription Moments Let $s_{rt}(\Theta)$ denote the market share of drug bundle r in market t implied by Θ. The model-predicted coprescription rate in market t is:

$$\bar{f}_t^c(\Theta) = \frac{\sum_{rt} s_{rt}(\Theta)\mathbb{1}(|\mathcal{B}_r| = 2)}{\sum_{rt} s_{rt}(\Theta)\mathbb{1}(j(k) = B \; \exists \; k \in \mathcal{B}_r)}, \tag{E.3}$$

where the numerator is the total sales of non-FDC two-drug bundles and the denominator is the total sales of all non-FDC bundles that contain drug B. Let f_t^c denote the corresponding empirical coprescription rate in market t. The set of coprescription moments can be written as a 43-by-1 vector $\bar{g}^c(\Theta)$, whose tth element is equal to $\bar{f}_t^c(\Theta) - f_t^c$.

E-Pharmacy Moments To construct the model-predicted e-pharmacy moments, we need to simulate the substitution patterns when there is a product entry or exit or a large price change. For example, when we remove drug bundle r_1 from the market, the fraction of consumers who substitute to bundle r_2 is given by:

$$P_{(r_1,r_2)t}(\Theta) = \frac{\sum_{i=1}^{NC} s_{ir_1t}(\Theta) \times \frac{s_{ir_2t}(\Theta)}{1-s_{ir_1t}(\Theta)}}{\sum_{i=1}^{NC} s_{ir_1t}(\Theta)}, \tag{E.4}$$

where $s_{irt}(\Theta)$ is the predicted probability of consumer i choosing bundle r in market t, which follows the standard logit functional form as in the integrand in Equation 13. Intuitively, the fraction of consumers who substitute from bundle r_1 to r_2 is the weighted average of each consumer's probability of choosing r_2 when r_1 is removed from the choice set, with the weights being the probability that the

consumer views r_1 as the top choice. Following this approach, we can simulate substitution patterns that correspond to each of the empirical e-pharmacy moments. We do so for each market and match the average model-predicted moments over the relevant markets to the empirical moments.[52] We refer to this set of moments as $\vec{g}^{e}(\Theta)$, which is a 4-by-1 vector.

The final set of moments that we use in our estimation is:

$$\vec{g}(\Theta)_{=}[\vec{g}^{\xi}(\Theta); \vec{g}^{c}(\Theta); \vec{g}^{e}(\Theta)], \tag{E.5}$$

and we estimate parameters $\Theta = \{\sigma_\varepsilon, \sigma_1, \rho, \bar{\Gamma}, \sigma_\Gamma, \sigma_f\}$ by using the two-step generalized method of moments (Hansen, 1982). In the first step, we use the identity matrix as the weighting matrix to derive a consistent set of estimates and the optimal weight matrix. In the second step, we re-estimate the model with the optimal weight matrix. To account for the sampling variance in our empirical moments, we obtain bootstrapped estimates of standard errors by resampling markets and consumers in our e-pharmacy data for 100 bootstrap samples. We resample the markets before and after the implementation of the price control policy separately to ensure that in each bootstrap sample we have the policy variation to identify the price elasticities.

[52] The relevant market are all markets after the event time (e.g., Q2 of 2016 for the price control and Q3 of 2016 for the Eisai FDC entry).

F Additional Details about the Counterfactual Analysis

Simulation Details In Section 6.5, we simulate counterfactual market outcomes when we remove FDCs from the market. We use the following Monte Carlo procedure to simulate the counterfactual scenario:

1. For each pseudoconsumer in market t, we simulate an N_t-by-1 vector of idiosyncratic match values, which are i.i.d. draws from the type I extreme value distribution with scale parameter $\hat{\sigma}_\varepsilon$. N_t stands for the number of bundles (including the outside option) in market t.

2. For each pseudoconsumer i, we calculate the utility u_{irt} from each bundle and identify the most preferred bundle y_i^1.

3. We remove all FDCs from the market (keeping the prices of other drugs fixed) and identify the most preferred bundle for each pseudoconsumer y_i^0.

4. We identify the subset of consumers for whom y_i^1 is an FDC product. We group these consumers by whether y_i^0 is the outside option, a drug A or B product, or another two-drug bundle.

5. For each consumer in step 4, we calculate the differences in the following metrics between y_i^1 and y_i^0.

   (a) Bundle utility excluding prices

   (b) Bundle utility including prices

   (c) Profit

   (d) Profit assuming no cost savings from FDCs

6. We aggregate the outcomes in step 5 across consumers in each group, divide by 10,000 (i.e., the total number of pseudo consumers) and multiply by the market size to recover the market-level effects.

7. Repeat steps 1-5 for 100 sets of draws and calculate the average market-level effects.

Using the steps above, we recover the substitution patterns after we remove FDCs from the market. We also quantify changes in consumer surplus and firm profits within each type of substitution. The results on firm profits are shown in Panel B of Figure 9.

FDC Preference and Consumer Surplus When consumer demand for FDCs is in part driven by FDC preferences, the welfare effects of FDCs depend on the nature of those preferences. FDC preferences turn out to be negligible in the market for Alzheimer's drugs but may play a major role in other therapeutic markets. We discuss a framework to bound consumer welfare in settings with FDC preferences.

We follow Train (2015)'s framework to measure consumer surplus when consumers' anticipated and experienced attributes differ. Let $\tilde{\gamma}_k$ denote the part of the FDC preference for FDC product k that is driven by misinformation.[53] We can write consumer surplus as:

$$\begin{aligned} \tilde{\text{CS}}_t &= \int_i (\text{E}(\max_r (\sum_{k \in \mathcal{B}_r} (v_{ikt} - p_{kt}) + \Gamma_{ir}) - \sum_k s_{ik} \tilde{\gamma}_k)) dF(\nu_i) \\ &= \underbrace{\int_i \text{E}(\max_r (\sum_{k \in \mathcal{B}_r} (v_{ikt} - p_{kt}) + \Gamma_{ir})) dF(\nu_i)}_{\text{CS}_i} - \sum_k s_k \tilde{\gamma}_k, \end{aligned} \tag{F.1}$$

which is consumer surplus under the revealed preference assumption minus the "illusory surplus" from FDC preferences whenever FDCs are chosen. When FDC preferences are entirely driven by true benefits, $\tilde{\gamma}_k = 0$ for all FDC products, and we have the standard consumer surplus measure in Equation **??**.

Equation F.1 provides a simple way to bound consumer surplus in the presence of an FDC preference. It shows the economic intuition on why consumers are worse off when the FDC preference is misperceived: $\tilde{\gamma}_k$ may mislead consumers into choosing an FDC product when some other would be preferred in the absence of $\tilde{\gamma}_k$.

[53] $\tilde{\gamma}_k$ is by assumption 0 for all non-FDC bundles.

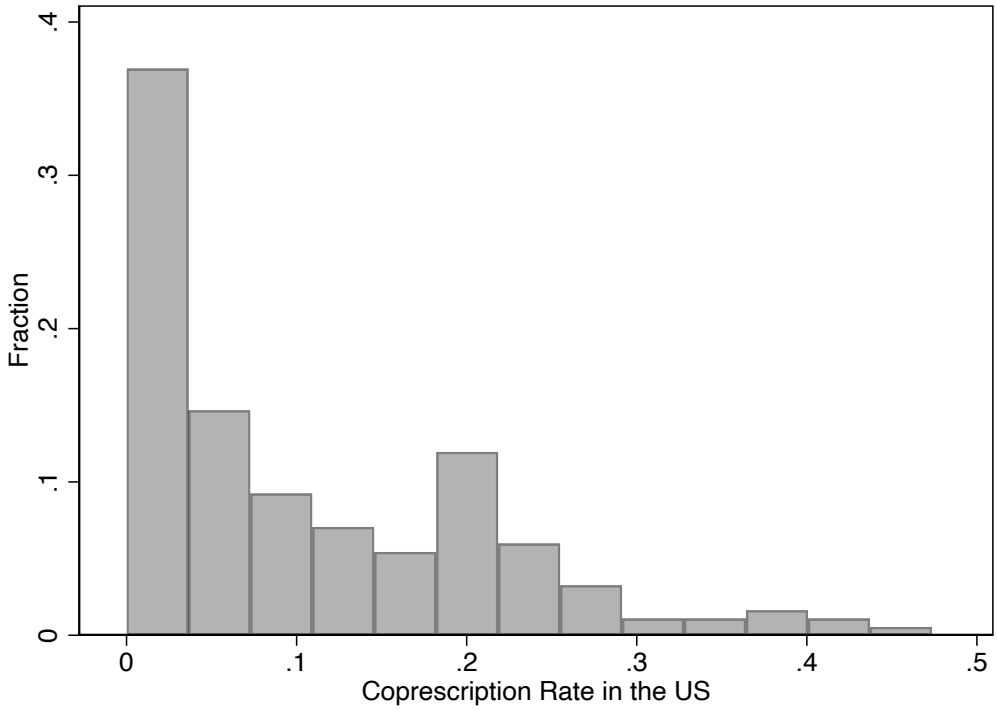
G Stylized Facts on the Effects of FDC Regulations in the U.S.

In this section, we document some stylized facts on the effects of FDC regulations in the US. We show that these regulations may have deterred or delayed entries of many medically sound FDCs.

We first examine 182 two-molecule FDCs in India whose two components were sold in the US in 2015 but the FDC was not. Figure G.1 shows the coprescription rates of these combinations in the US in 2015. Two patterns stand out. First, many such combinations are rarely coprescribed in the US: the coprescription rate is below 1% for 13% of the sample. Panel A of Table G.1 shows that the majority of these least commonly coprescribed combinations involve two antibiotics. There has been robust evidence that antibiotic FDCs are overused in many countries, resulting in a public health crisis of antimicrobial resistance (Ahmad et al., 2016). The results thus show that the combination rule imposed by the US FDA has helped screen out unjustified FDCs. On the other hand, there are also many commonly coprescribed combinations: the coprescription rate is above 20% for one quarter of the sample. Panel B of Table G.1 shows that many of the commonly coprescribed combinations are used in treating chronic diseases such as diabetes and cardiovascular diseases. FDC regulations may have precluded FDC entries of these combinations that physicians have considered appropriate to prescribe together.

In addition, FDC regulations have delayed FDC entries in the US. Using a sample of 29 FDCs that have been approved in both India and the US, we show in Figure G.2 that on average the FDCs were approved in the US four years after they were introduced in India. For perspective, we also show in Figure G.2 that new plain molecules are on average introduced in US four years before they are introduced in India. These facts show that the regulatory requirements delayed the entries of medically sound FDCs and consequently their welfare benefits.

Figure G.1: US Coprescription Rates of FDCs Used in India



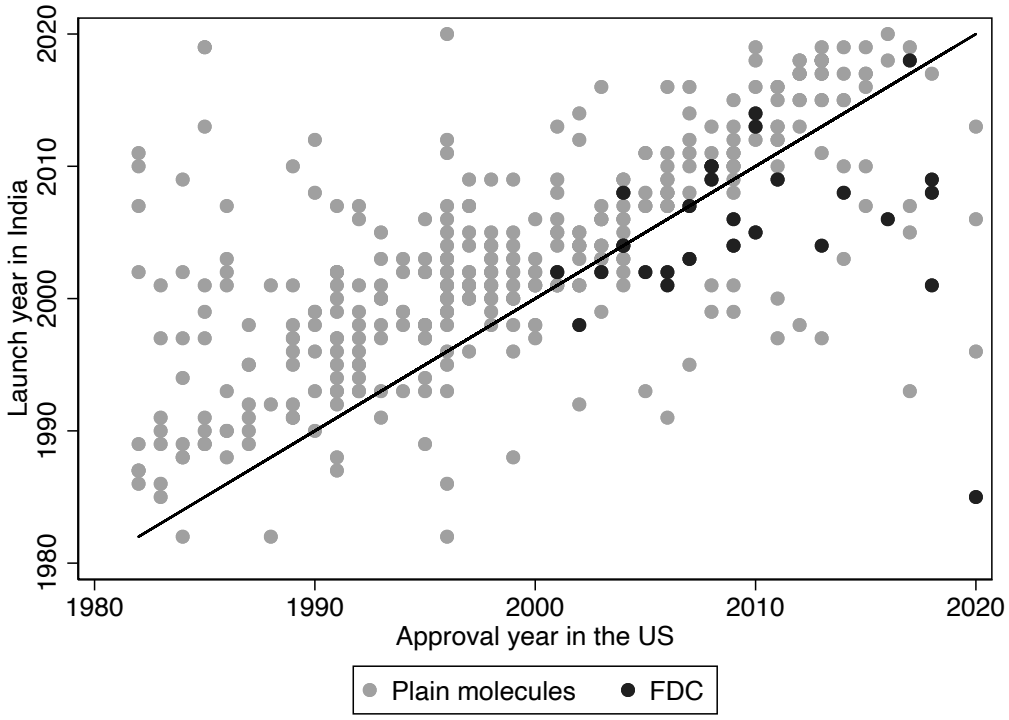
Notes: This figure shows the 2015 coprescription rates of 182 FDCs whose two components were sold in the US in 2015 but the FDC was not.

Table G.1: Examples of Least and Most Commonly Coprescribed Combinations

Combination	Disease Target	Coprescription Rate
Panel A: Least Commonly Coprescribed		
CEFIXIME + MOXIFLOXACIN	Antibiotic	0
CEFIXIME + OFLOXACIN	Antibiotic	0.1%
GATIFLOXACIN + METRONIDAZOLE	Antibiotic	0.1%
OLMESARTAN + RAMIPRIL	Hypertension	0.2%
RAMIPRIL + TELMISARTAN	Hypertension	0.2%
FLAVOXATE+ OFLOXACIN	Antibiotic	0.3%
METRONIDAZOLE + OFLOXACIN	Antibiotic	0.3%
CHLORDIAZEPOXIDE + TRIFLUOPERAZINE	Anxiety	0.3%
ASPIRIN + PRASUGREL	Antiplatelet	0.3%
CEFPODOXIME + OFLOXACIN	Antibiotic	0.3%
Panel B: Most Commonly Coprescribed		
GLIMEPIRIDE + METFORMIN	Diabetes	47.4%
FINASTERIDE + TAMSULOSIN	Benign Prostatic Hyperplasia	41.1%
ACARBOSE + METFORMIN	Diabetes	40.7%
ISOSORBIDE-5-MONONITRATE+ METOPROLOL	Chest Pain	38.2%
FRUSEMIDE + SPIRONOLACTONE	Ascites	37.5%
METFORMIN + MIGLITOL	Diabetes	36.7%
METFORMIN + NATEGLINIDE	Diabetes	33.3%
CLOPIDOGREL + S-METOPROLOL	Hypertension	33.1%
ATORVASTATIN + CLOPIDOGREL	Cardiovascular Diseases	32.3%
IVABRADINE + METOPROLOL	Chest Pain	31.0%

Notes: This table shows the ten least commonly and ten most commonly prescribed combinations in the US among combinations that have become FDCs in India but not in the US.

Figure G.2: Drug Entry Time in India and the US



Notes: This figure compares drug entry time between India and the US separately for FDCs and plain molecules. On average, FDCs are introduced in the US four years after they are introduced in India, while new plain molecules are introduced in the US four years before they are introduced in India.