Entry and Pricing with Fighting Brands: Evidence from Generics and Authorized Generics*

Rubaiyat Alam Rena Conti

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Abstract

Branded drug manufacturers often respond to generic entry by releasing an Authorized Generic (AG), which is chemically identical to the brand drug but without the brand label attached. The branded drug charges a high price and AG charges low price to compete with generics. In recent years the FDA has focused on speeding up generic approval rates, while the FTC has raised concerns regarding the impact of AGs on generic entry and prices. Using quarterly drug sales and revenue data on the US for 2004-2016, we develop a stylized structural model of entry and pricing to study how faster generic approval rates and a ban on AG can impact market outcomes. We build and estimate a structural model of prescription drug demand, generic entry, AG release, and pricing. This is used to simulate the following policy counterfactuals. We find that a faster generic approval rate leads to weakly fewer generic entrants, strictly lower prices in the early periods of the market, and ambiguous effect on prices in later periods of the market. An authorized generic is less likely to be released, and entering generics are more likely to fully recoup their entry cost. Next we show that a ban on authorized generics leads to weakly more generic entrants but ambiguous effect on overall prices.

*Corresponding author: Rubaiyat Alam, rubaiyat@ksu.edu. Rubaiyat Alam: Assistant Professor of Economics, Kansas State University. Rena Conti: Associate Professor, MPPL, Questrom School of Business. The authors thank IQVIA Institute's Human Data Science Research Collaborative for providing access to the National Sales Perspectives™dataset for use in this project and the American Cancer Society and Arnold Ventures for grants supporting Rena Conti's efforts on this project. We are grateful to Marc Rysman for his time and invaluable guidance. We also benefited greatly from extensive discussions with Farasat Bokhari, Randall P. Ellis, Jihye Jeon, and Albert Ma. We would like to thank Eric Hardy, Chuqing Jin, Ginger Jin, Tim Lee, Brett Wendling, and participants at seminars in Boston University and other institutions for useful comments.

1 Introduction

Prescription drugs in the US can be broadly classified into two categories: i) branded drugs, which are pioneer molecules temporarily protected by patents and market exclusivities from competitors, and ii) generic drugs that are bioequivalent to their branded counterparts. Branded drugs initially enjoy monopoly power in the market and charge high prices. After loss of market exclusivity – usually through patent expiration – generic drugs enter the market and compete on prices. The branded drug manufacturer sometimes responds by releasing an Authorized Generic (AG). AGs are chemically identical to the branded drug but without the brand name attached, and are intended to compete with generics. Branded drug prices stay elevated, while generics and the AG are priced very low. Such "fighting brand" strategy is observed in many industries besides pharmaceuticals. Since generic competition during this period results in significantly lower prices and spending, understanding its economic mechanisms is key to crafting policies.

There are two policy concerns within this setting. First, generics have to gain approval from the Food and Drug Administration (FDA) to launch. In the past, slow approval rates have been blamed for persistent high drug prices after loss of market exclusivity as generics wait to launch. The FDA has taken steps to speed up the approval process; however the resulting impact on market outcomes is unclear. Second, there are concerns about the impact of AGs on market outcomes and deterring generic entry, with some advocating for AGs to be banned.

We study how faster generic approval rates and a ban on authorized generics can affect market outcomes. To do so, we build a stylized structural model of pharmaceutical demand, generic entry, AG release, and price competition. This model is estimated using national sales and revenue for prescription drugs in the US between 2004-2016. We use our model to simulate the impact of the above policies. A faster approval rate leads to weakly fewer generic entrants, strictly lower prices in the early periods of the market, and ambiguous effect on prices in later periods of the market. An AG is also less likely to be released, and entering generics are more likely to fully recoup their entry costs. A ban on AG leads to weakly more generic entrants but has

an ambiguous effect on overall prices.[1]

An outline of our stylized structural model is as follows. The demand side is a discrete choice model where the consumer first chooses a group - brand, nonbrand (generics and AG), or outside option - then chooses a product within the group.[2] The supply side of the industry is modeled as two separate stages. In the first stage, generic manufacturers make a static entry decision on whether to enter a molecule-formulation market. In the second stage, a dynamic game begins where every period, generics who decided to enter are randomly approved for product launch by the FDA, the branded drug manufacturer decides whether to release an AG, and market participants compete on prices. This two-stage model setup is because unlike generics, AGs do not need FDA approval to launch. We solve the two-stage supply model by backward induction, and as a result allow for AG and generics to form expectations about each others' entry and pricing decisions when making a choice.

We use data on national sales and revenue for prescription drugs in the US between 2004-2016 (IQVIA National Sales Perspective). The demand model is estimated using the methods of Berry et al. (1995) and Maggio et al. (2022). Our demand estimation recovers the price sensitivity of consumers and their preferences for branded and non-branded drugs. Our supply side estimation pins down the entry cost distribution of AGs and variance of choice-specific shocks. We calibrate generic entry costs for our counterfactuals. Following previously published papers, our market definition is the molecule-formulation pair (Conti and Berndt (2020), Wang et al. (2022), Yurukoglu et al. (2017)).

To understand the counterfactual results, we first discuss key elements of the model dynamics. The early quarters of a market are most profitable for generics and AGs –

[1]While generic approval rates have increased over the past few years, cleanly isolating their impact on competition from data is difficult. This is because their implementation happened alongside other policy changes and market upheavals. Instead, using a structural model to simulate the policy allows us to see how the core economic mechanisms work out under such a policy. Besides, the AG ban is not a realized policy, so running a counterfactual with a structural model is the only way to predict its impact.

[2]In this setting, a "consumer" is an aggregation of the individual patient and all the other intermediaries who influence her decision, e.g. physicians, pharmacies, insurers, PBMs, wholesalers, providers, etc. Rather than model them separately, our demand model captures the outcome from the joint-decision making by all these agents together; i.e., our demand model reflects the final demand curve faced by pharmaceutical manufacturers.

there are few generics present as the rest wait to get FDA approval, resulting in lower price competition and high markups. This also means a later generic entrant may not be able to fully recoup its entry cost – a later launch means the generic manufacturer joins the market with already high generic competition, and subsequently makes low profits over its lifetime. Generics face greater entry deterrence from the AG if the AG is expected to avoid production delays and launch earlier during the profitable periods of the market.

Our first set of counterfactuals study how faster generic approval by the FDA affects market outcomes. Faster generic approval has been a priority of the FDA since the 2010s (Berndt et al. (2018)). We find that a faster approval rate leads to weakly fewer generic entrants, strictly lower prices in the early periods of the market, and ambiguous effect on prices in later periods of the market. Why does a faster generic approval rate lead to lower generic entry? While a faster approval rate means a longer stream of revenue accruing to a generic from earlier launch, it is counteracted by greater presence of rivals upon launch. The latter means greater price competition and lower profits upon launch. Greater competition upon launch offsets the advantage from an early launch, reducing lifetime generic profits and therefore weakly reducing generic entry. It also means that, while prices are lower in the early periods of the market, the reduction in generic entry leads to ambiguous effects on prices in later periods of the market. We also find that an AG is less likely to be released, and entering generics are more likely to fully recoup their entry costs.

Our second set of counterfactuals study the impact of an AG ban, which has been discussed by the Federal Trade Commission (FTC) and advocated for by generic manufacturers. We show that a ban on AG leads to weakly more generic entrants but has an ambiguous effect on overall prices. The latter happens because while there is increased price competition from weakly more generic entrants in the later stages of the market, it is counteracted by lack of an additional competitor through the AG in the early stages of the market. We also highlight how the impact of an AG ban turns on whether the AG in question is expected to avoid production delays and launch earlier. We conclude with a brief discussion on no-AG settlements through the lens of our model.

Contributions and related literature: Studying entry dynamics and compe-

tition between generics and AGs is important for several reasons. First, high prescription drug prices impede access to treatment among patients, result in significant spending by payers, and consequently have been a source of great controversy in the US for several decades. Significant cost savings to payers results from generic competition. By studying market dynamics after loss of exclusivity, we can better understand the economic incentives in the pharmaceutical industry and craft more targeted policies to improve product access and affordability. Second, the release of AG is quite similar to strategies undertaken by incumbents when faced with rival entry in other industries as well. When facing new entrants, one commonly observed strategy is price discrimination through release of "fighting brands". In a fighting brand strategy, the incumbent releases a low brand-value version of its existing product, called a fighting brand. The high brand-value product charges high price and the fighting brand charges low price. This segments the market, with fighting brand competing with new entrants and original product serving the higher end of the market.[3] However, there is only a nascent empirical IO literature looking at this phenomenon.

This paper contributes to the following strands of literature. First, we contribute to a small literature on Authorized Generics. We are the first to study the impact of AGs on generic firms by using a structural model of entry. Moreover, our model incorporates this interaction in a rational expectations framework. This allows us to trace out feedback between AG and generic decisions, and in particular allows us to study how the presence/absence of AG affects generics' decisions. Furthermore, our model allows us to explore a wider variety of economic effects from the presence of the AG. A few papers have used reduced-form evidence to study Authorized Generics. Notably, Appelt (2015) uses a recursive bivariate probit regression to show that AG entry does not impact generic entry in Germany. An important source for us is a report from the Federal Trade Commission (FTC (2011)) that leveraged many information sources to explain the decision to release the AG and generic manufacturers' reactions to it.

Second, we add to the literature on generic drug entry. While many papers have

[3]Examples of fighting brands (from Bourreau et al. (2021)) include: Intel with the Pentium series (brand) and Celeron (fighter brand) to compete with AMD; Lufthansa (brand) with a low-cost subsidiary Germanwings (fighter brand) to fight against low-cost carriers; Canadian telecom providers Rogers (brand) marketing low-cost alternative (Chatr).

studied generic entry in the US, few use structural methods to model such decisions. Doing so allows us to see how changing key economic parameters affects entry incentives by generics. An important paper for our purposes is Ching (2010), who studies generic entry and brand's dynamic pricing in 1984-1990 to model learning dynamics. We adopt part of our entry model from this paper. Other notable papers are Gallant et al. (2017), Morton (1999), Reiffen and Ward (2005), and Starc and Wollmann (2022).

A paper that we think of as closely complementing ours is Wang et al. (2022), which uses a static entry model to understand the factors that promote generic entry into a molecule-formulation. Our papers each focus on one aspect of the industry while abstracting away from another. In contrast to our paper, Wang et al. (2022) capture heterogeneity on the generics side, look at more molecule-formulations, and consider markets where generics never entered. In particular, they investigate how firm-specific covariates affect entry decisions, while our paper instead assumes that generics are homogeneous. On the other hand, unlike our paper, they i) do not explicitly account for dynamics, ii) do not allow for authorized generics, and iii) do not estimate a demand system and price competition (instead using a reduced-form expression to proxy for per-period profits). Our paper can track how market shares and prices change as the competitive landscape or policy environment changes, and use it to illustrate the knock-on effect on entry behavior. Furthermore, by accounting for dynamics, we can better simulate the impact of dynamic changes like faster FDA approvals and bans. As a result, we believe we are better positioned to answer how the number of generic entrants change due to faster FDA approval rates, something Wang et al. (2022) study, and we reach the opposite conclusion to their paper. In short, Wang et al. (2022) is better for understanding how firm-specific heterogeneity affects generic entry decisions into a wide range of markets, while our paper is better for thinking about market dynamics and authorized generics.

Third, we contribute to a very sparse Empirical IO literature on fighting brands. We are one of the very few papers to build and estimate a model of an incumbent releasing a fighting brand. There is a theoretical literature on fighting brands, notably Anderson and Dana (2009), Deneckere and McAfee (1996), Johnson and Myatt (2003), and Nocke and Schutz (2018). An important empirical paper studying fighting

brands is Bourreau et al. (2021). They show that in the French mobile telecommunications market, releasing fighting brands occurred due to a breakdown of collusion, and use a structural model of demand and supply to study this phenomenon.

Fourth, we construct a parsimonious structural model of pharmaceutical product entry that is quick to solve and can be easily extended in various directions (such as consumer heterogeneity, firm heterogeneity, presence of intermediaries, etc.) in future research. In doing so, we contribute to an extensive literature on static entry games and dynamic single-agent and oligopoly games. For static entry, key references include Berry (1992), Berry et al. (2016), Bresnahan and Reiss (1991), Mazzeo (2002), and Seim (2006). For dynamic single-agent and oligopoly games, some important references are Aguirregabiria and Mira (2007), Benkard (2004), Gowrisankaran and Rysman (2012), Igami (2017), Igami (2018), Ericson and Pakes (1995), Pakes et al. (2007), Rust (1987), and Ryan (2012). We adopt part of our model and estimation method from Igami (2018).

Finally, our paper relates to a large literature on pharmaceuticals. A vast amount of work has been done on the theoretical and empirical side of this industry. Frank and Salkever (1992) was the first to lay out a theoretical model for why branded drug prices often stayed above generic prices. A non-exhaustive list of references that informed the current paper include Arcidiacono et al. (2013), Berndt et al. (2007), Bhattacharya and Vogt (2003), Bokhari and Fournier (2013), Bokhari et al. (2020), Dubois et al. (2022), Dubois and Majewska (2022), Ellison and Ellison (2011), Fowler et al. (2023), Frank and Salkever (1997), Grennan et al. (2021), Hermosilla and Ching (2023), Olson and Wendling (2018), Reiffen and Ward (2007), Tenn and Wendling (2014), and Tunçel (2022). More specifically, we contribute to the literature of using structural models to understand the economics of the pharmaceutical industry; see Ching et al. (2019) for a detailed overview. Berndt et al. (2017), Berndt et al. (2018), and Conti and Berndt (2020) provide important descriptive evidence about the aggregate dynamics and inner workings of the industry which we use to motivate our model.

2 Institutional Background

After the branded drug manufacturer loses market exclusivity, generics enter the market by applying for FDA approval. However, gaining FDA approval is lengthy, costly, and takes an uncertain amount of time. The brand drug manufacturer can respond by releasing an authorized generic (AG). The AG is chemically identical to the brand drug but without the brand label attached. Unlike generics, the AG can be launched at any time without having to wait for FDA approval. The general patterns after loss of exclusivity are: branded drug prices stay elevated, generics and AG charges low price which further declines with more competition, and the branded drug loses most of its market share to generics and AGs over time.

2.1 Pharmaceutical product life cycle

For completeness we lay out the life-cycle of a pharmaceutical product and specify which stage of this life-cycle we focus on in our paper. A pharmaceutical product can be thought of as going through 3 stages (Lakdawalla (2018)):

1. A pharmaceutical manufacturer invests in R&D to discover a drug, then patents the molecule and conducts tests for efficacy and safety. This drug is commonly referred to as the "branded drug" (see Dubois et al. (2015) and Khmelnitskaya (2023), and the references therein).

2. Once approved for marketing, the patent means that the branded drug has a monopoly on that molecule structure. The resulting monopoly profits are what incentivizes the costly and risky R&D stage.

3. After loss of market exclusivity - including through patent expiration - bioequivalent products called generic drugs enter the market. The resulting competition leads to significantly lower drug prices and is the primary driver behind low pharmaceutical prices. This also leads to significant loss of market share for the branded drug and increased market share for the generics.

This paper focus on Stage 3 of the life-cycle. Throughout we refer to the manufacturer that pioneered the molecule as the "branded drug manufacturer" and the

pioneer molecule as the "branded drug". We use the term "nonbrand" to indicate both generics and AGs.

2.2 Generic Drugs and FDA approval

After loss of exclusivity, generic drugs enter the market by applying for approval from the FDA. The approval process is costly for the generic manufacturer, lengthy, and has uncertain duration.

To gain FDA approval, generic manufacturers need to prove to the FDA that their products are "bioequivalent" to the branded drug and can be produced at scale. Bioequivalence is defined to mean "product has the same active ingredient, dosage form, strength, route of administration and conditions of use" as the reference branded drug.[4] Generic manufacturers have to give further evidence that they can manufacture the drug accurately, at scale for commercial distribution, and according to Good Manufacturing Practices.[5] This might further involve a back and forth between the FDA and generic applicant until the FDA is satisfied with the production line.[6] An important aspect of proving bioequivalence is that the generic firm needs to reverse-engineer the branded drug. Since some aspects of the manufacturing process for the branded drug may be undocumented or kept as trade secrets by the branded manufacturer, generic firms must experiment with production to meet regulatory requirements. Estimates of the cost of ANDA application range from $2 million to $20 million.

The generic manufacturer then needs to submit an Abbreviated New Drug Application (ANDA) with all the relevant information attached. The mean approval time for an ANDA is between 32-40 months for our data period. Approval times of generics vary due to the amount of work involved in verifying the evidence submitted in support of the entrant's ANDA, as well as the FDA's workload. In the past several

[4]Source: https://www.fda.gov/media/71401/download

[5]See information from the FDA on Good Manufacturing Practices: www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations.

[6]Bioequivalence ensures that generic drugs are not lower quality compared to their equivalent branded drugs - by definition, their bioequivalence means that they can be substituted with the branded product and have the same effect. Thus, generic drugs compete with their branded equivalents in the US on the basis of their availability and price.

decades, the FDA has experienced a significant backlog of pending ANDA applications. Policies such as the GDUFA – and its reauthorization every 5 years – have given the FDA more resources to reduce the time and increase the scope of generic drug approvals (Berndt et al. (2018), Wang et al. (2022)).

In this paper, we refer to applying for ANDA approval as "generic entry", and refer to generics marketing their product after FDA approval as "product launch". Thus, generics *enter* a market by applying for FDA approval, and *launch* their product after receiving FDA approval.

2.3 Authorized Generics

In response to generic entry, the branded drug manufacturer can release an Authorized Generic (AG). The AG is chemically identical to the branded drug in terms of molecule structure and formulation, except that it doesn't have the brand label attached.

A key detail about product launch in this setting is that, unlike generics, AGs can be introduced anytime and without FDA approval. This is because they are riding on the branded drug's approval from the FDA.

Why would a branded drug manufacturer choose to not release an AG? There are several reasons. First, the AG could cannibalize the branded drug's sales. Second, the AG would lead to generics lowering their prices in response, further increasing the price gap between brand and generics products; this causes branded drug sales to fall. Finally, it could be due to supply side reasons such as entry costs. In our model we account for all three factors.

2.4 Evolution of Market Shares and Prices

In terms of market prices and shares, the general pattern we see in the data is as follows. After loss of market exclusivity by the branded drug, generics enter the market and undercut the brand's price. The branded drug's price typically remains stable or increases. An AG is sometimes released by a branded drug manufacturer in response to generic entry. The AG and generics price their products close to each other. Over time, the branded drug's market share dramatically falls, while those of nonbrand drugs rises. Examples of this pattern can be seen in Figure 1 for three

different molecule-formulations.

3 Data and Descriptive Statistics

We leverage data on quarterly sales and revenue of prescription drugs in the US from 2004-2016, and use this to construct market shares and prices. We define a market to be a molecule-formulation; and of the 241 molecule-formulations we restrict our attention to, about 45% see an AG released. Most AGs are released soon after the first generic entry occurs. Most markets have between 1-6 competitors.

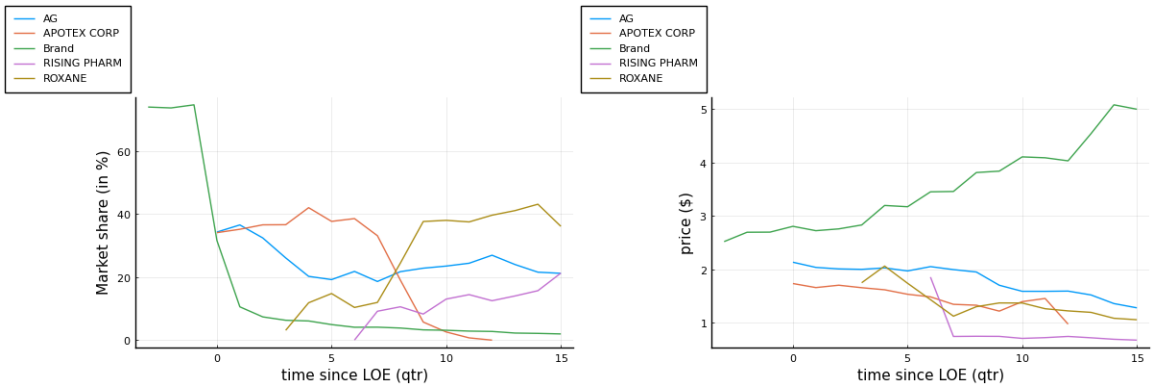
3.1 Data

The data for this paper comes from IQVIA's National Sales Perspective™(NSP) database and covers sales in US for 2004 - 2016. NSP™ data contains national sales of prescription drugs to pharmacies, clinics, hospitals, and other distribution channels, aggregated to the quarterly level. Each observation includes the name of the molecule (active ingredient) and branded name (if relevant), quarter, sales amount in drug unit volume, sales amount in U.S. dollars, supplier of the product, distribution channel, product form (e.g., oral, injectable), and other information including therapeutic class, product launch date, etc. Following previous literature (Conti and Berndt (2020), Wang et al. (2022), Yurukoglu et al. (2017)), we refer to a drug as a group of products having the same molecule (or active ingredient) and product form.

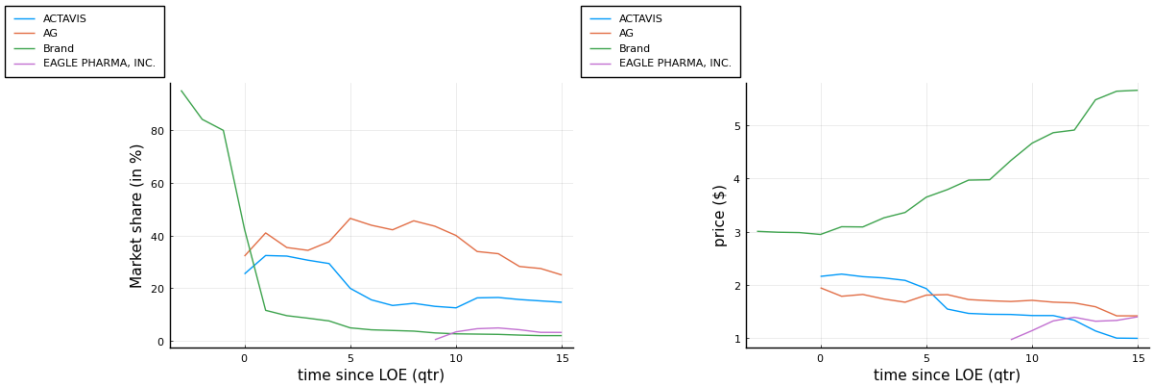
For our purposes, a drug's *therapeutic class* describes what broad diagnoses it targets; a drug's *molecule* structure describes the active ingredients present; and a drug's *formulation* is its method of delivery, e.g. oral, injectable, etc.

We now give a brief overview of the NSP™ database; this closely follows Berndt et al. (2017), which contains a more detailed description of the entire dataset.

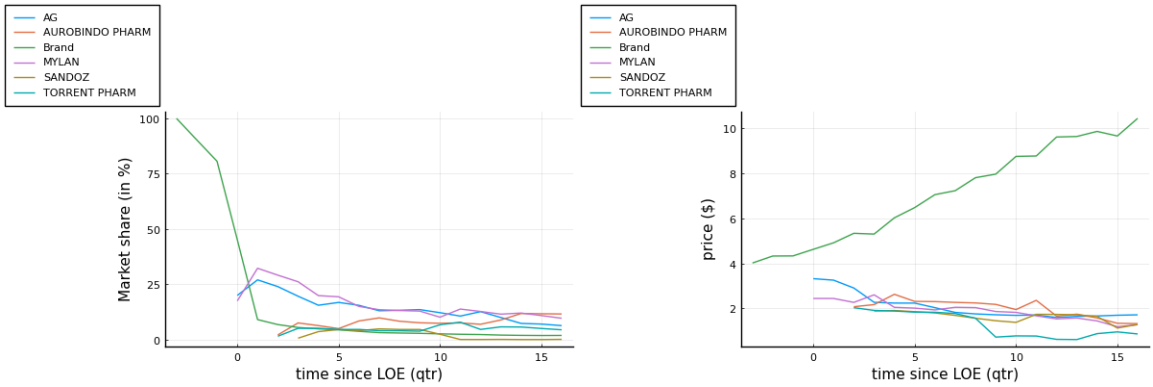
The database is constructed through a projected audit that tracks drug sales from manufacturers or wholesalers to pharmacies and other distribution outlets. The measure of "revenue" for each drug is the total amount paid for the purchase of a product to the manufacturer. Notably, this measure of revenue does not include rebates that drug manufacturers give back to other intermediaries. Generic manufacturers do



(a) Cevimeline (oral formulation).



(b) Diclofenac-Misoprostol (oral formulation).



(c) Metformin-Pioglitazone (oral formulation).

Figure 1: Evolution of market shares (left) and prices (right) for three molecule-formulations.

not pay rebates, but branded drugs do, so this creates potential measurement error for branded drug prices. To address this, we rerun our demand estimation allowing branded drugs to be charging 30% rebates (following the findings in Kakani et al. (2020) and Kakani et al. (2022)), and obtain very similar results. [7]

Furthermore, the NSP database reports volumes of each drug sold in "standard units", where a standard unit is defined as the smallest unit of the drug standardized across dosage and therapeutic form (Dubois and Lasio (2018)). We compute prices as the ratio of total revenue to total quantity in standard units, following Dubois et al. (2022) among others.

In addition, data on Authorized Generics and Paragraph IV lawsuits were hand-collected. AGs were identified from FDA's maintained list of AGs, an online source maintained by some producers of AGs, and verifying with news reports on AG release. The list of molecules facing Paragraph IV lawsuits were collected from a publicly available list maintained by the FDA.[8]

To summarize, for each drug product we see quarterly sales in the US, revenue generated, list of active ingredients, formulation of the drug (oral, injectable, or other), and therapeutic class (ATC3). Sales for a drug-molecule-formulation are aggregated by dosage and strength.

We define a market at the molecule-formulation level. This raises the question of why we define a market at the molecule-formulation level instead of a higher level, such as the therapeutic class. First, we include a molecule-formulation fixed effect in the demand function to account for presence of other molecule-formulations in the same therapeutic class. Second, similar market definitions have been used in various antitrust proceedings and empirical papers (Conti and Berndt (2020), Starc and Wollmann (2022), Wang et al. (2022), Yurukoglu et al. (2017)). Third, the fewer number

[7] While rebates could be significant before loss of exclusivity, the size of the branded drug's rebate *after* loss of exclusivity is unknown. A lot of the theoretical and empirical literature on pharmaceuticals state that even after controlling for rebates, branded drug prices are significantly higher than generic prices. This fact is also used to explain the release of the AG as stated in FTC (2011).

[8] The FDA list on AGs can be found here: https://www.fda.gov/media/77725/download.
The online source by AG producers can be found here: https://www.authorizedgenerics.com/product-finder/
The FDA list on Paragraph IV lawsuits can be found here: https://www.fda.gov/media/133240/download.

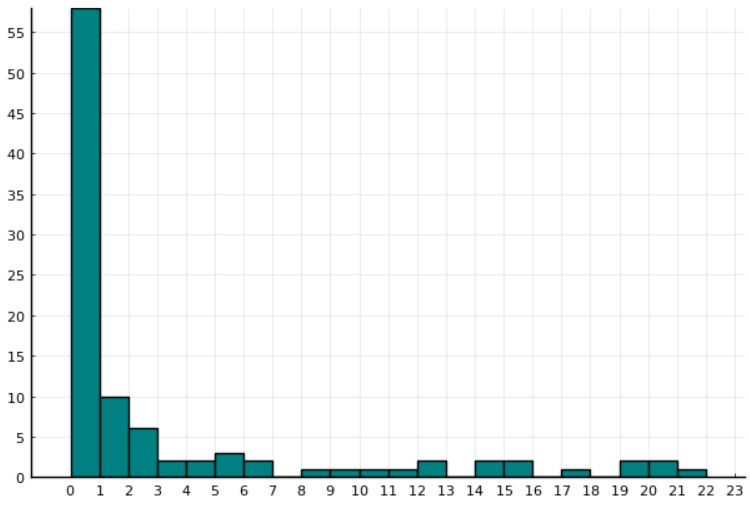


Figure 2: Histogram of time-difference between first generic entry and AG release period. This figure is limited to 22 quarters, while in the dataset 4 authorized generics get released later than 22 quarters. See the Appendix for the exact distribution.

of products allows us to capture substitution patterns between these bioequivalent products more accurately. Fourth, the branded drug's patent and generic approval holds at molecule-formulation level. Fifth, one drug can be in multiple therapeutic classes which makes modeling therapeutic classes as markets unclear. Finally, there is evidence suggesting that while there can be substitution across molecule-formulations within the same therapeutic class, usually the substitution is from a molecule-formulation without a generic to a molecule-formulation with one (Arcidiacono et al. (2013)). In this data we only look at periods after generic entry, so it is unlikely that people are switching away from the molecule-formulation we are studying.

3.2 Descriptive Statistics

While our dataset has comprehensive coverage across all prescription drugs sold in US, we look at a smaller subset of drugs for our project. We select molecule-formulations that lost exclusivity after 2004, for which we can identify presence or absence of AG with certainty, and those that are not surrounded by strong external circumstances (e.g. media outrage, serious or repeated lawsuits). This leaves us with 241 molecule-

	No. of molecule-formulations
Total	241
AG released	109
Formulation: Oral	162
Formulation: Injectable	58
Formulation: All Others	21
Faced Paragraph IV lawsuit	62

Table 1: Descriptive statistics

formulations. Of these 241 molecule-formulations, 109 see an AG released. Note that each molecule-formulation has one branded drug and can have at most one AG. Table 1 shows descriptive statistics about our selected molecule-formulations: of the 241 molecule-formulations, about 45% see an authorized generic released, and over 67% are oral formulations.

While Table 1 describes how many markets saw an AG released, Figure 2 shows *when* the AGs were released in these markets relative to generic entry. More specifically, Figure 2 is a histogram that shows how many quarters after first-generic-entry is AG released. 58 markets see AG release immediately with the first generic entry, 10 markets see AG release one quarter after the first generic entry, and 6 markets see AG released two quarters later. AGs continue being released sporadically afterh the third quarter, with the latest release happening 41 quarters after loss-of-exclusivity.

Next we look at the competitive landscape in our selected markets, specifically regarding generic presence. Figure 3 shows the histogram of total generics that enter into a molecule-formulation over time. This reveals that most markets have between 1-6 generic competitors.

4 Model

To study market dynamics after loss of exclusivity, we develop a structural model of entry and price competition between authorized generics and generics. The aim is to develop a stylized model that is tractable enough for estimation but captures the important economic mechanisms. On the demand side, we set up a discrete choice

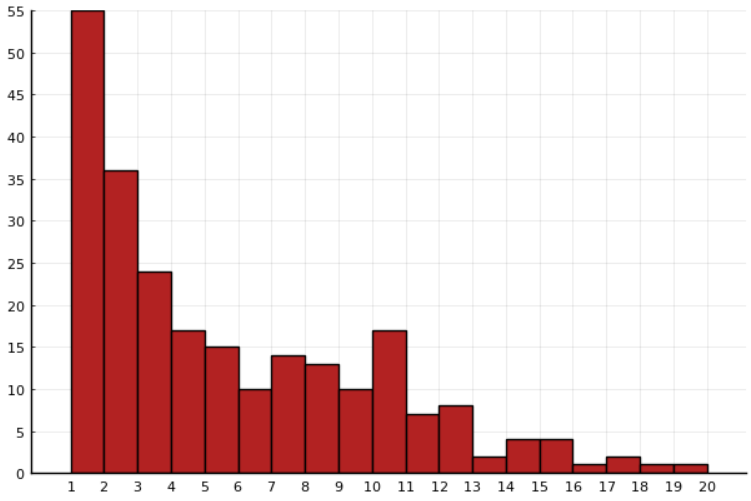


Figure 3: Histogram of total generic entry by molecule-formulation

model of demand, where the consumer first chooses a group (brand, nonbrand, or outside option) then chooses a product within the group. On the supply side, we construct a two-stage model. The first stage is a static game of generic entry. The second stage is a dynamic game of Authorized Generic release decision. Every period, generics who decided to enter are randomly approved for product launch by the Food and Drug Administration (FDA), the branded drug manufacturer decides whether to release an AG, and the market participants compete in prices.

4.1 Demand

We model consumer demand as proceeding in two stages. In Stage 1, for a given molecule-formulation, each consumer chooses a group – brand, nonbrand, or outside option (forgoing medication entirely, switching to another molecule, etc.). The non-brand group includes both generics and AG (if present). In Stage 2, each consumer picks a product from the group chosen in Stage 1. Consumer choice is driven by the characteristics and prices of each product.

Stage 1: For molecule-formulation m, let g denote a group. Thus:

$$g \in \{\text{brand}, \text{non-brand}, \text{outside option}\}$$

The utility of consumer i for group g in market m at time t is given by:

$$u_{igmt} = \gamma_m^{(1)} + \lambda_t^{(1)} + \alpha_i^{(1)} ln\, p_{gt} + \beta_{1i}^{(1)} \text{brand}_g + \beta_2^{(1)} brand_g \cdot \text{time-since-loe}_t + \xi_{gt}^{(1)} + \epsilon_{igt} \quad (1)$$

where $ln\, p_{gt}$ denotes the average of log prices within the group, "brand" is an indicator for the brand group, and $\xi_{gt}^{(1)}$ allows for unobserved group-specific quality. The variable "time-since-loe" measures the number of quarters since generic entry (loss of exclusivity), and this is used to form a brand-specific time trend. The random coefficients $\alpha_i^{(1)}$ and $\beta_i^{(1)}$ allow for heterogeneity in price sensitivity and brand valuation respectively. As is common in the empirical literature, we further assume $\alpha_i^{(1)} \sim \mathcal{N}(\alpha^{(1)}, \sigma_\alpha^2)$ and $\beta_i^{(1)} \sim \mathcal{N}(\beta_1^{(1)}, \sigma_1^2)$.

Note that the brand group has a single product, while the non-brand group can have multiple products. Thus $ln\, p_{gt}$ is the branded drug's price for the brand group, and is the *mean* of all non-branded drugs' prices for the non-brand group. The price of the outside option is normalized to zero as is standard in the discrete-choice estimation literature.

Stage 2: If the consumer chose the non-brand group in Stage 1, and there are multiple non-brand drugs available for the molecule formulation m at time t, then the consumer has to choose from among these products. The utility of consumer i choosing non-brand product j in market m at time t is given by:

$$u_{ijt} = \gamma_{m(j)}^{(2)} + \alpha^{(2)} ln\, p_{jt} + \beta_1^{(2)} \text{AG}_j + \xi_{jt}^{(2)} + \epsilon_{ijt} \quad (2)$$

where $ln\, p_{jt}$ denotes the log price of product j, AG_j is a dummy for product j being an Authorized Generic, and $\xi_{jt}^{(2)}$ allows for unobserved product-specific quality.

4.1.1 Derivation of Product-Level Market Share

We now derive the expression for product-level market share. We follow the notation of Conlon and Gortmaker (2020). Our derivation follows similar derivations in Berry et al. (1995), Conlon and Gortmaker (2020), Nevo (2000), and other related papers. Throughout the derivation, the time subscript is suppressed for clarity.

We can rewrite Stage 1 in terms of mean utilities and match values following Berry

et al. (1995).

$$\begin{aligned} u_{ig} &= \gamma_m^{(1)} + \lambda_t^{(1)} + \alpha_i^{(1)} ln\, p_g + \beta_{1i}^{(1)} \text{brand}_g + \beta_2^{(1)} brand_g \cdot \text{time-since-loe} + \xi_g^{(1)} + \epsilon_{ig} \\ &= \gamma_m^{(1)} + \lambda_t^{(1)} + \alpha^{(1)} ln\, p_{gt} + \beta_{1i}^{(1)} \text{brand}_g + \beta_2^{(1)} brand_g \cdot \text{time-since-loe} + \xi_g^{(1)} + \\ &\qquad \sigma_\alpha \nu_{\alpha,i} ln\, p_g + \sigma_\beta \nu_{\beta,i} \text{brand}_g + \epsilon_{ig} \\ &= \delta_g^{(1)} + \mu_{ig} + \epsilon_{ig} \end{aligned}$$

where the mean utility of group g, $\delta_g^{(1)}$, is given by:

$$\delta_g^{(1)} = \gamma_m^{(1)} + \lambda_t^{(1)} + \alpha^{(1)} ln\, p_g + \beta_1^{(1)} \text{brand}_g + \beta_2^{(1)} brand_g \cdot \text{time-since-loe} + \xi_g^{(1)}$$

and the match value of individual i with group g, μ_{ig}, is given by:

$$\mu_{ig} = \sigma_\alpha \nu_{\alpha,i} ln\, p_g + \sigma_\beta \nu_{\beta,i} \text{brand}_g$$

Let the idiosyncratic shocks ϵ_{ig} and ϵ_{ij} follow a Type-1 Extreme Value distribution. Then the probability of consumer i choosing group g is given as:

$$s_{ig} = \frac{e^{\delta_g^{(1)} + \mu_{ig}}}{\sum_l e^{\delta_l^{(1)} + \mu_{il}}}$$

For individual i, let μ_i be the vector of her match-values for all groups in the market, i.e. if both brand and nonbrand drugs are in market, μ_i is 3×1. Similarly, let δ_i be the vector of her mean-values for all products in the market. Since there are many consumers with heterogeneous preferences (reflected in the random coefficients $\alpha_i^{(1)}$ and $\beta_i^{(1)}$), the market share of group g is given by integrating over the distribution of random coefficients:

$$s_g = \int \frac{e^{\delta_g^{(1)} + \mu_{ig}}}{\sum_l e^{\delta_l^{(1)} + \mu_{il}}} f(\mu_i | \tilde{\theta}_2) d\mu_i \tag{3}$$

where $\theta_2 = (\sigma_\alpha, \sigma_\beta)$

Conditional on choosing nonbrand group, the probability of a consumer choosing

product j from nonbrand group is given by:

$$s_{j|g} = \frac{e^{\delta_j^{(2)}}}{\sum_k e^{\delta_k^{(2)}}} \tag{4}$$

where $\delta_k^{(2)} = \gamma_{m(k)}^{(2)} + \beta^{(2)}\text{AG}_k + \alpha^{(2)} ln(p_k) + \xi_k^{(2)}$.

Stage 1 gives the expression for the market share of a group, while Stage 2 gives the expression for the market share of a product conditional on a group. Therefore, we can express the market share of a single good in terms of group market share and market share of good conditional on choice of group:

$$s_j = s_{g(j)} s_{j|g(j)} \tag{5}$$

See the Appendix for the derivation of Equation 5. Therefore, estimating the parameters in Stage 1 allows us to predict $s_{g(j)}$, and estimating the parameters in Stage 2 allows us to predict $s_{j|g(j)}$. This allows us to study counterfactual scenarios and how they affect market shares of all products.

4.1.2 Discussion on demand model

This raises the question of what we mean by a "consumer" in our model. The demand side of the paper is a mix of pharmaceutical intermediaries and patients jointly making a purchase decision. For instance, there is the doctor who writes the prescription, the pharmacy which stocks the drugs, the insurer who decides which drugs to cover and to what degree, the pharmaceutical benefit managers who negotiate on behalf of several parties, the healthcare providers who procure for their institutions, etc. We do not try to distinguish these agents or their individual payoffs; only their joint demand is modeled. In other words, we think of a consumer i as being an aggregation of the patient and all intermediaries who participate in the decision process. This follows Dubois et al. (2022) and Starc and Wollmann (2022).

Next we discuss why we choose the two-stage demand setup instead of other demand setups. Generally, papers estimating demand systems follow the setup of Berry et al. (1995), where each consumer chooses from a set of products. When trying to account for correlated preferences within a group, some papers use a random-

coefficients or nested logit setup . In contrast, in our setting, a consumer chooses a group, then chooses a product within a group. The reasoning for this is that we found, after experimenting with different specifications, that this matched the empirical patterns of prices and market share best. In our data we see that the price difference between the brand and non-brand group leads to substantial switching from branded drug to non-branded drugs, which implies high price elasticity of consumers. However, within non-brand products, we see very little switching based on specific prices of non-brand drugs. That is, a higher-priced generic has only slightly lower market share than a lower-priced generic. This then suggests consumers are not price elastic. When all products are estimated together in a single discrete choice setting like Berry et al. (1995), we end up finding very low price-elasticity overall for the market. When we do counterfactuals, this low price-elasticity leads to unrealistic predictions such as low substitution between brand and generics after loss-of-exclusivity (which is at odds with what we see in the data).

Our specification gets around this by capturing the right substitution patterns in the data. Stage 1 captures the fact that the price gap between brand and nonbrand leads to a large substitution towards the cheaper nonbrand products. Stage 2 picks up the mild price elasticity between generics, while also helping explain why average prices decline as more generics enter the market. While our demand model is somewhat different from other discete-choice settings, note that our aim for the project is to study entry decisions; as long as we correctly predict prices and per-period profits, our central arguments work.

In our demand estimation, we also let parameters vary based on whether the molecule-formulation is mostly sold in "patient-facing channels" or "non-patient-facing channels", i.e. sold in channels where the individual patient (with her physician and insurer) chooses the product, versus other settings. See Section 5.2 for a more detailed description of our estimation strategy and specification.

4.2 Supply

We first present an overview of our supply model. The following subsections explain the components of the model, and Section 6 goes over the reasoning behind the

modeling choices.

Recall that generic manufacturers have to wait for FDA approval before they launch for approval; as a result, they enter (apply for ANDA approval) well in advance. In contrast, authorized generics can be released at any time. This motivates our model setup below.

There are two stages to the supply side:

1. In the first stage, generic firms decide whether to enter a market (i.e. apply for ANDA to molecule-formulation) or not. This stage is modeled as a game of sequential entry between identical firms, i.e. firms apply for ANDA sequentially until the value of entering no longer exceeds the entry cost.

2. In the second stage, loss of exclusivity happens and a dynamic game begins. The dynamic game lasts T periods. Every period, a random number of the generic firms which applied for ANDA are approved and introduced into the market. The branded drug manufacturer decides whether to release AG or not (where the AG release decision is irreversible). Then, all the firms set prices and receive payoffs.

We now explain the model in reverse, starting from payoffs in the second stage. Throughout we suppress the market subscript m unless necessary for exposition.

4.2.1 Per-period payoffs

The branded drug manufacturer's per-period payoff is:

$$\pi^b(s_t) = [P_t^b - MC^b]s_b(s_t)M_t + \mathbf{1}(AG_t = 1)\Big[[P_t^{AG} - MC^{AG}]s_{AG}(s_t)M_t\Big] \qquad (6)$$

where s_t denotes the market state variable vector, superscripts and subscripts b and AG refer to the branded product and AG respectively, P denotes price, MC denotes marginal cost, $s(s_t)$ denotes market share, and M_t denotes market size in period t. The indicator variable $\mathbf{1}(AG_t = 1)$ denotes whether an AG has been released onto the market. The intuition behind the branded drug manufacturer's payoff is that it

makes the first half of the payoff from the branded drug, and the second half from the AG conditional on releasing the AG.

Similarly, the generic firm l's per-period payoff with the firm-specific state variable vector $s_{l,t}$ is:

$$\pi^g(s_{l,t}) = (P_t^g - MC^g)s_g(s_{l,t})M_t \tag{7}$$

The branded drug, generics and AG compete on prices. We use a reduced-form price prediction regression to predict prices in different states and markets; see Section 5.1.

4.2.2 Second-stage

Let n_e^* be the number of generic firms that have applied for an ANDA (which is determined in the first stage). In period $t = 0$ the branded drug's market exclusivity expires, and every period a random number of generic firms gain FDA approval and enter the market.

A dynamic game begins from $t = 0$ and lasts T periods, where every period is a quarter. Since AG release is a dynamic decision, the branded drug manufacturer's choice problem can be written in terms of value functions. Thus, the value function for a branded drug manufacturer every period is given by:

$$V^b(s_t, \varepsilon_t) = \max_{AG_{t+1}\in\{0,1\}} \pi^b(s_t) - \mathbf{1}(AG_t = 0, AG_{t+1} = 1)\kappa_m^{AG} + \beta E[V^b(s_{t+1}, \varepsilon_{t+1})|s_t, \varepsilon_t] + \varepsilon_t(AG_{t+1}) \tag{8}$$

where $AG_{t+1} = 1$ means the AG is in the market in period $t + 1$. AG entry cost in molecule-formulation m is denoted as κ_m^{AG}. The AG entry decision is irreversible, i.e. $AG_t = 1$ implies $AG_{t+k} = 1\ \forall k > 0$. Also note that AG entry is implemented with a one-period delay.

The timing of AG release could be influenced by factors observed to the manufacturer but unobserved to the econometrician. To account for such factors, the model (following the existing literature on dynamic games) includes choice-specific payoff shocks $\varepsilon_t(AG_{t+1})$. These shocks follow a Type 1 Extreme Value distribution. Henceforth, we refer to these choice-specific shocks as "AG timing shocks", since they

primarily affect when the AG gets released in the market. A more detailed discussion is given in Section 4.3.

Similarly, the value function for generic l is given by:

$$V^g(s_{l,t}) = \pi^g(s_{l,t}) + \beta E[V^g(s_{l,t+1})|s_{l,t}] \tag{9}$$

where $s_{l,t}$ includes whether generic l has been approved for production by the FDA. While the generic manufacturers do not face a dynamic decision in the second stage, they use the value function to make entry decision in the first stage.

After period T, the market state is set at s_T, and the manufacturer receives the corresponding payoff for infinite periods:

$$V^b(s_T) = \sum_{\tau=T}^{\infty} \beta^\tau \pi^b(s_T) \tag{10}$$

Similarly for generics:

$$V^g(s_T) = \sum_{\tau=T}^{\infty} \beta^\tau \pi^g(s_T) \tag{11}$$

The manufacturers have to form expectations over generics' approval probabilities; recall that approval is given randomly to entrants over time. To express the value functions, we need to pin down how state transitions happen regarding generic approval. Thus, we model the FDA approval rate as a binomial process. This follows Ching (2010).

Suppose $n_e^* - m$ entrants have already received approval and launched their products. The probability that of the m remaining entrants, k will receive approval in this period is given by:

$$P_e(k, m, t) = \binom{m}{k} \lambda(t)^k (1 - \lambda(t))^{m-k} \tag{12}$$

where $\lambda(t)$ - the probability of a single generic receiving approval - is estimated from the data. Note that we assume the equilibrium number of generics that applied for ANDA, n_e^*, is known to the branded drug manufacturer from $t = 0$.

For a molecule-formulation m, the incumbent brand manufacturer draws the AG

entry cost κ_m^{AG} from the following distribution:

$$\kappa_m^{AG} = \begin{cases} \bar{\kappa}, & \text{w.p. } p & \text{“trade shock”} \\ \infty, & \text{w.p. } 1-p & \text{“no-trade shock”} \end{cases} \tag{13}$$

That is, with probability p releasing an AG costs $\bar{\kappa}$, and with probability $1-p$, releasing an AG is prohibitively expensive. For simplicity we refer to the former as the AG drawing a “trade shock” and the latter as a “no-trade shock” from the entry cost distribution. In Section 4.3 we discuss this modeling choice.

4.2.3 First-stage

In the first stage, an infinite number of generics decide whether they want to enter. We assume all generic firms are ex-ante identical, do not receive private error draws for entering and staying out, and do not know their draws of ξ_{jt} conditional on entry.

Generics keep entering until the value from entering no longer exceeds the cost of entry. More precisely, the equilibrium number of generic entrants is n_e^*, determined by the following inequality:

$$V^g(s_0, n_e^*) \geq \kappa_m^g > V^g(s_0, n_e^* + 1) \tag{14}$$

where κ_m^g denotes the generic manufacturer's entry cost for molecule-formulation m. Intuitively, the value function of entry is declining in the number of entrants - more entrants mean more competition in the market and lower per-period profits. At the equilibrium n_e^*, current entrants can cover their entry cost, but an additional entrant would stop that from happening. This follows Igami (2018).

4.3 Discussion

Economic interpretation of AG timing shocks and their variance: Recall that the authorized generic release decision faces “AG timing shocks”, which are choice-specific payoff shocks $\varepsilon_t(AG_{t+1})$ that follow a Type 1 Extreme Value distribution. These logit shocks have a logit scaling parameter σ_ϵ that governs the variance of these shocks. The higher the σ_ϵ, the greater the variance of choice-specific logit

shocks, so the greater the authorized generic release decision will deviate randomly from the optimal release decision. Intuitively, this is used to account for payoff shocks observed to the agent but unobserved to the econometrician. During estimation, it is used to reconcile why we observe firms in similar states of the world make different choices.[9]

In our model, the logit scaling parameter chiefly explains why authorized generic launch is delayed by some brand manufacturers far past the loss-of-exclusivity period (see Table 6 for a numerical illustration). In general, the most profitable quarters for a non-brand product are those right after loss-of-exclusivity, because there are few competitors. Over time, more generics gain FDA approval and enter, moving prices closer and closer to marginal cost. While authorized generic release also accounts for the knock-on effect on branded drug revenue, it is generally optimal for the authorized generic to be released early; yet, in the data, we see that a large fraction of authorized generics get released several quarters after loss-of-exclusivity. The logit scaling parameter rationalizes this behavior by ascribing the delay to unobserved payoff shocks not observed to the econometrician.[10]

So what could be plausible explanations behind such delays or unobserved payoff shocks? First, this could be driven by manufacturing delays in setting up production lines. Second, branded manufacturers may outsource authorized generic production to other firms (such as Prasco and Greenstone), and there could be contracting frictions and bargaining between these parties. Third, there could be organizational friction within the branded manufacturer that slows down the decision-making process. Fourth, it could be that the loss-of-exclusivity was unanticipated or there was uncertainty surrounding it, which meant that the branded manufacturer was unprepared for the loss-of-exclusivity when it happens. Finally, there could be policy uncertainty such as how the FDA would approve or regulate the new generic entrants, or how a lawsuit might be resolved, that may add further uncertainty to the release decision.

[9]This is a common methodology used in dynamic discrete choice models with dollar-valued payoffs. See Igami (2018) and Alam (2023). Papers which have unitless payoff functions instead normalize the logit scaling parameter to 1.0 and estimate all other structural parameters relative to it, as in Rust (1987).

[10]To be exact, the logit shocks also help explain why AG enters in unprofitable markets, as well as why an AG enters early when it should enter later. However, in our setting, we find that the logit shocks chiefly serve to delay entry into markets where the AG is profitable.

Motivation behind no-trade shock: We now discuss why we model authorized generic's entry cost as a bimodal distribution, i.e. a "trade shock" and a "no-trade shock".[11] Intuitively, the no-trade shock tries to subsume a variety of factors (unobserved to us) specific to the manufacturer or the market that makes it untenable to release an authorized generic. Below we give some examples of such events. What are the factors that can cause the brand manufacturer to draw a "no-trade shock" when it comes to releasing an authorized generic?

First, the branded drug manufacturer may not have any generic subsidiaries. This makes it very difficult to release an authorized generic, because marketing a non-branded drug versus a branded drug entail very different skillsets. The marketing of a branded drug focuses on advertising and detailing, negotiating formulary positions by insurer, etc. The marketing of a generic drug focuses on extreme cost efficiency, winning pharmacy auctions (Cuddy (2020)), etc. These are very different skillsets, and for a branded drug, it may not be worth the hassle of getting into the generics business just to release an authorized generic. It could instead outsource its production to another generic firm (for instance, Prasco and Greenstone specialize in bringing authorized generics for other firms into the market) but that involves negotiation cost and profit-sharing.

Second, the brand manufacturer could be facing capital or labor constraints, such that putting resources into releasing an authorized generic detracts it from other parts of its operation. For instance, a brand manufacturer could find it more worthwhile to put its limited resources into creating a new blockbuster drug rather than generate some revenue through launching an authorized generic.

Third, the brand manufacturer may choose to withhold an authorized generic due to a no-authorized-generic-settlement. See Section 8.5 for a brief discussion on no-AG settlements, as well as FTC (2011) for a more detailed analysis. Such a no-authorized-generic-settlement could be related to a Paragraph IV settlement regarding the same molecule-formulation, or a settlement involving a different molecule-formulation but involving the same firms. Unfortunately we do not have data on whether a no-authorized-generic-settlement deal was reached, and so it would be subsumed by the

[11] We have also done some preliminary work with a lognormal distribution instead of bimodal distribution, and found similar results.

"no-trade shock" in our model.

5 Estimation

We use a reduced-form price regression to predict prices, and estimate generic approval rates from the data. Demand is estimated using methods from Berry et al. (1995) and Maggio et al. (2022). The supply model is solved via backward induction, and AG cost parameters are estimated via simulated method of moments. We end with a heuristic discussion on identification.

5.1 Pricing and generic approval rates

Instead of assuming a pricing conduct (such as Nash-Bertrand or Nash-in-Nash bargaining), we choose to be agnostic about the price-setting behavior and instead predict prices using market-specific observables. That is, we regress observed prices on covariates such as molecule fixed effects, formulation fixed effects, number of generics, presence of branded drugs, etc. This regression is then used to predict prices in different states of the world. See Section 6 for a detailed discussion on why we do this instead of making a pricing conduct assumption such as Nash-Bertrand. The price prediction regression gives expected results - nonbrands charge lower prices as more nonbrand products enter, brands raise prices when facing generic entry, brands charge higher prices than nonbrands, and injectables are more expensive than oral formulation drugs.

We set the marginal cost for a molecule-formulation to be the minimum observed price in our data. We also assume that all non-brand drugs charge the same price in a market-by-quarter.We combine this price prediction equation and marginal costs with our estimated market share equation (Equation (5)) to generate per-period profits in different states of the world.

To operationalize Equation (12) we also estimate the per-quarter generic approval rates $\lambda(t)$, where t denotes quarters since loss-of-exclusivity (and not calendar time). We estimate the average generic launch rates at every quarter since loss-of-exclusivity, then use a best-fit line through the estimated rates. These predicted rates are used

	Patient-facing	Non-patient-facing
formulation: Injectable	2.118	–
	(0.136)	(–)
formulation: Oral	-1.308	–
	(0.112)	(–)
No. of nonbrand drugs	-0.269	-0.298
	(0.009)	(0.016)
No. of nonbrand drugs squared	0.008	0.010
	(4.843e-04)	(0.001)
Brand	0.123	-0.076
	(0.031)	(0.041)
Brand * time-since-generic-entry	0.017	-0.005
	(0.001)	(0.002)
Brand * No. of nonbrand drugs	0.232	0.231
	(0.004)	(0.008)
Brand * Authorized generic present	0.041	0.774
	(0.031)	(0.064)

Table 2: Price prediction regressions

in our main estimation.[12]

Note that the estimated generic launch rates comprise not just the FDA's approval rate but also generics applying early in an effort to get FDA approval close to the loss-of-exclusivity. In particular, some generics apply early so that they can be in the market as soon as loss-of-exclusivity happens, while others try to be there at least soon after loss-of-exclusivity. We estimate generic launch rates to be highest at the beginning of loss-of-exclusivity, and declining over time; this reflects the idea of anticipating loss-of-exclusivity described above. As the FDA speeds up its approval

[12]This is done as follows. For each molecule-formulation and quarter since loss-of-exclusivity, we calculate the number of generics waiting to enter, i.e. final number of generics observed in that molecule-formulation minus the current number of generics present in the molecule-formulation. We sum this number across all molecule-formulations at a given quarter since LOE to get the remaining entrants for every quarter since loss-of-exclusivity in our dataset. Then we find the net generic entry that happens in every each molecule-formulation and quarter since loss-of-exclusivity. We sum this number across all molecule-formulations at a given quarter since LOE to get the total net generic entry for every quarter since loss-of-exclusivity in our dataset. Taking the ratio of total net generic entry by remaining entrants at every quarter since loss-of-exclusivity gives us the average generic launch rates at every quarter since loss-of-exclusivity.

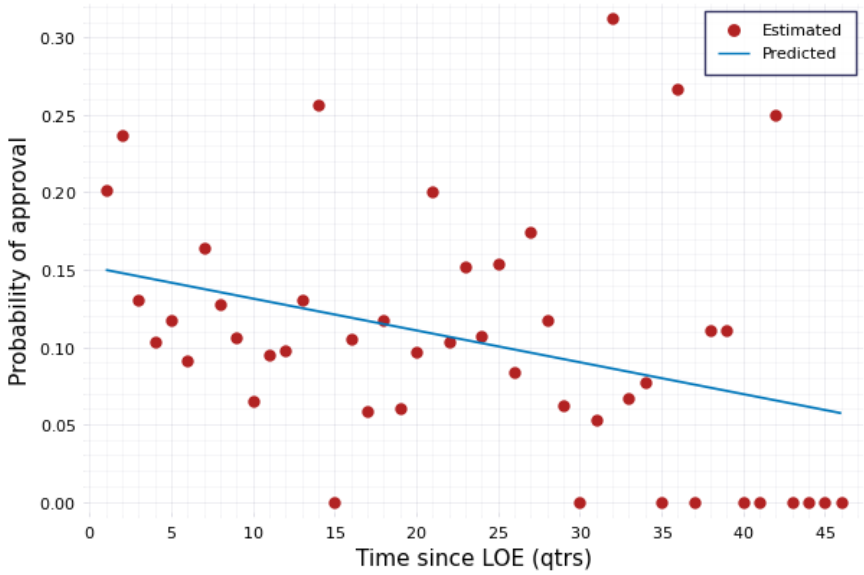


Figure 4: Generic entry rate

rates, it should lead to the estimated entry rates shifting up for every quarter after loss-of-exclusivity.

5.2 Demand estimation

We estimate each stage of the demand model separately. Stage 1 of the demand model is a standard random-coefficients discrete choice model, so we use the method of Berry et al. (1995) (see Conlon and Gortmaker (2020) and Nevo (2000) for detailed discussions on implementation). We use Gandhi-Houde instrumental variables (Gandhi and Houde (2019)) and employ two-step GMM.

Stage 2 of the demand model is a multinomial logit demand model but without an outside option. Given that idiosyncratic errors follow Type-1 Extreme Value distribution, we can write market share of generic drug j conditional on nonbrand group being chosen in Stage 1, as:

$$s_{jt|g} = \frac{e^{\delta_{jt}^{(2)}}}{\sum_k e^{\delta_{kt}^{(2)}}}$$

where $\delta_{kt}^{(2)} = \gamma_{m(k)}^{(2)} + \beta^{(2)} \text{AG}_k + \alpha^{(2)} ln(p_{kt}) + \xi_{kt}^{(2)}$. Using the transformation from Berry

(1994):

$$ln(s_{jt|g}) = -ln(\sum_k e^{\delta_{kt}^{(2)}}) + \delta_{jt}^{(2)}$$

Plugging in the formula for $\delta_{jt}^{(2)}$ gives us the estimating equation:

$$ln(s_{jt|g}) = -ln(\sum_k e^{\delta_{kt}^{(2)}}) + \gamma_{m(j)}^{(2)} + \beta^{(2)}\text{AG}_j + \alpha_2 ln(p_{jt}) + \xi_{jt}^{(2)} \tag{15}$$

Following Maggio et al. (2022) this can be estimated using a linear regression of logs of market share on market-by-quarter fixed effects and other covariates. That is, the first term on the right hand side varies at the market-by-quarter level, so including market-by-quarter fixed effects absorbs it. The remaining coefficients can just be estimated through a linear regression with fixed effects ($\xi_{jt}^{(2)}$ becomes the econometric error in the regression).[13]

We take advantage of this by allowing our demand parameters to coarsely vary based on the channel presence of a molecule-formulation. Our dataset contains a breakdown of drug sales by the channels were the sale happened. These channels are clinics, drugstores, federal facilities, food-stores, long term care hospital, HMO, home health care, mail services, and non-federal facilities (Berndt et al. (2017), Dubois and Majewska (2022)). In our estimation we classify all molecule-formulation into one of two types: patient-facing or non-patient-facing. "Patient-facing" molecule-formulations are ones mostly sold in channels where the patient makes the choice with input from a physician and her insurer (retail pharmacies, mail pharmacies, and food stores). "Non-patient-facing" molecule-formulations are ones mostly sold in channels where the patient does not generally get a say in the product being chosen. Note that generally most molecule-formulations get sold in most channels, and this categorization is done using the fraction of sales in either type of channels.

We can expect demand parameters to vary between these two categories because of the intermediaries and bargaining processes involved. In patient-facing channels,

[13]By contrast, in Berry (1994) the authors use the outside good's market share to net out the term $ln(\sum_k e^{\delta_{kt}})$. In our case this cannot be done because there is no outside option in Stage 2; conditional on choosing the non-brand group in Stage 1, the consumer has to choose from one of the non-brand products in Stage 2.

the insurer, patient, physician, and PBM together determine the product choice and prices; by contrast, non-patient-facing channels involve the provider negotiating with the wholesaler or manufacturer and determining product choice. In our data, we classify 183 molecule-formulations as patient-facing and 58 molecule-formulations as non-patient-facing.

5.3 Supply estimation

On the supply side, we estimate the logit scaling parameter of the authorized generics' choice-specific shocks σ_ϵ and the probability of drawing a trade shock p. We calibrate $\bar{\kappa}$ to be \$1.5 million. We also set T = 32, meaning that the dynamic game lasts 32 quarters. The parameters are estimated via simulated method of moments (SMM).

An overview of our estimation procedure is as follows. We follow Coen and Coen (2022) in setting up our objective function, and we adopt their notation and explanation in what follows. For a trial parameter vector $\psi = \{p, \sigma_\epsilon\}$, we solve the model, simulate data, and match the simulated moments with observed data moments. The estimated parameter vector $\hat{\psi}$ minimizes the sum of squared percentage differences between the theoretical and empirical moments:

$$\hat{\psi} = \arg\min_{\psi} \left(m(\psi) - m_0\right)' \Omega^{-1} \left(m(\psi) - m_0\right)$$

where $\Omega = m_0 m_0'$. We use two sets of trimmed moments for our SMM estimation:

1. Moments about *whether* to release an authorized generic: Our first set of moments captures the variation in decision to release authorized generic versus not across markets. Specifically, the moments are fraction of molecule-formulations that saw AG released, fraction of patient-facing molecule-formulations that saw AG released, fraction of non-patient-facing molecule-formulations that saw AG released, and covariance of authorized generic release decision with market size

2. Moments about *when* to release the authorized generic: Our second set of moments captures the variation in the timing of authorized generic release. For each molecule-formulation that saw an authorized generic release, we calculate

the "authorized generic release delay", i.e. how long after the first generic entrant was the authorized generic released. We use moments of the distribution of authorized generic release delay, specifically its mean, variance, skewness, and kurtosis.

The cost estimation proceeds as follows. For a given value of parameters:

1. We solve for conditional choice probabilities (CCPs) of authorized generic by backward induction from terminal period T. The CCP gives the probability of AG being released in every state of the world from $t = 1$ to T. Recall that the authorized generic knows the exact number of generics released in $t = 1$ (i.e. immediately after loss of exclusivity) as well as the total number of generics that will enter over the lifespan of the molecule-formulation, but can only form probabilistic beliefs about future generic entry.

2. The estimated CCPs are used to run S simulations for each molecule-formulation. In each simulation, generics are randomly released in the market based on Equation (12) and estimated generic approval rate. The authorized generic is released based on the estimated CCP.

3. We calculate moments of the simulated data. These include summary statistics of how often the authorized generic is released and delay after loss of exclusivity.

4. The simulated moments are used to calculate the objective function. Intuitively, the objective function gives a scalar measurement of how far the simulated moments are from the data moments.

This process is repeated for different trial values of parameters until the objective function is minimized.

The standard errors are estimated via block-bootstrapping, similar to Alam (2023) and Wang (2022). In what follows we closely adopt the explanation from Alam (2023). We sample molecule-formulations from the data with replacement until we match the total number of molecule-formulations in our full dataset. Then we re-estimate the model parameters for each bootstrap sample. This is used to construct the sampling distribution of each parameter.

5.4 Heuristic Discussion on Identification

We now present a brief non-technical discussion on what variation in the data help pin down different parameters. Note that from a technical standpoint, every parameter is identified off of every moment in the data, but certain variations in the data play a bigger role in informing certain parameters.

On the demand side, the price coefficient for Stage 1 (outside option versus brand versus non-brand) is pinned down by how much market share switches from the expensive brand to the cheap non-brand products. That is, the price coefficient captures the correlation between market share gap between brand and nonbrand, and price gap between brand and nonbrand groups. For Stage 2 (within-non-brand competition), the price coefficient is pinned down by how much higher market share is for cheaper non-brand drugs than more expensive non-brand drugs. This setup allows us to have different price sensitivies for the brand-to-nonbrand choice and within-nonbrand choice.

On the supply side, the probability of a trade-shock is pinned down by the variation in authorized generic release decisions across molecule-formulations, i.e. the first set of moments in the SMM estimation. The higher the fraction of molecule-formulations that see authorized generic launch, the higher the probability of the trade-shock. The logit scaling parameter is pinned down by the temporal variation in authorized generic release, i.e. the second set of moments in the SMM estimation. The greater the delay of authorized generic launch after loss-of-exclusivity, the greater the logit scaling parameter.

6 Discussion on Modeling Choices

To capture the aggregate dynamics of a highly complicated US pharmaceutical industry in a stylized and tractable model, we make several simplifications. In this section we discuss some of these modeling choices.

Price prediction equation: Instead of assuming a pricing conduct such as Nash-Bertrand or Nash-in-Nash bargaining, we use a price prediction regression to predict prices charged by different firms in different markets. We now discuss our reasoning

for this approach and the trade-offs involved.

One pricing conduct assumption we could have made is Nash-Bertrand pricing, which however implies that all bargaining power is upstream with the pharmaceutical manufacturer. This is unlikely to be true in reality, since there are many intermediaries - Pharmacy Benefit Managers (PBMs), wholesalers, pharmacies, providers, etc. - that negotiate drug prices with substantial bargaining leverage. This is also borne up by the estimated price elasticities in our paper - we find most price elasticities to be less than 1, which aligns with a model of split bargaining power between upstream and downstream firms rather than a take-it-or-leave-it offer (TIOLI) from upstream firms. Since we have aggregate data instead of detailed plan-level or PBM-level data, we cannot explicity model the pricing game between manufacturers and all the intermediaries.[14] The advantage is that our predicted per-period profits are not susceptible to misspecifications about the pricing conduct assumption.[15]

Note that in our counterfactuals, we do not change any primitives that would affect the static pricing game. Otherwise, the price prediction equation estimated from the observed data would no longer be a good predictor, as a change in demand primitives

[14]Other papers which study pharmaceuticals with aggregate data and make a pricing conduct assumption include Arcidiacono et al. (2013), Dubois et al. (2022), and Starc and Wollmann (2022). Unlike these papers there are major differences in our analysis that precludes us from doing the same. Arcidiacono et al. (2013) focus on a small number of molecules, which allows them to leverage additional data and impute rebates. In contrast, our paper considers well over 200 molecule-formulations. Dubois et al. (2022) restrict their attention to sales in the hospital channel for drug sales, while we consider all channels. They assume Nash-Bertrand, which is a more reasonable assumption in their setting because hospitals are not covered by large intermediaries such as PBMs, and price elasticities exhibited in these non-patient-facing channels are much larger. Starc and Wollmann (2022) consider the pharmacy channel and use different datasets compared to this paper.

[15]A regression of prices on level of competition may suffer from endogeneity issues from demand shocks. This is less of an issue than in other settings, because generics cannot simply respond to a demand shock and enter the market - they need to wait years to get FDA approval for marketing. Furthermore, we also add in molecule and formulation fixed effects.

We also cannot impute marginal cost rigorously from observed prices, as is done in Dubois et al. (2022) and Starc and Wollmann (2022). (Recall that we set the marginal cost of a molecule-formulation to be the minimum observed price for that molecule-formulation in our dataset.) However, if our pricing conduct assumption is incorrect, the imputed marginal costs would have been incorrect as well. There is some precedence in the recent IO-pharmaceuticals literature on using minimum observed prices to inform costs. Other approaches by authors who do not impute marginal cost by assuming a pricing conduct such as Nash-Bertrand include Tunçel (2022) (who uses the minimum observed price to construct moment inequalities about non-negative costs) and Grennan et al. (2021) (who set marginal cost as 0.17 times generic price).

should change the underlying pricing patterns. Instead, we limit our counterfactuals to changing parameters that affect dynamic incentives (such as entry restrictions or faster approval rates).

Our price prediction equation is also similar in spirit to the price-setting equation in Maini and Pammolli (2023). In their paper, the authors try to predict prices across different European countries with different bargaining policies and unknown objective functions. Instead of taking a strong stand on either, the authors opt for an agnostic approach to predicting prices and use a flexible control function. Our motivation is similar in that we want to be agnostic about how different intermediaries interact across the supply chain. In both our paper and Maini and Pammolli (2023), the main focus is on entry instead of the static pricing game, which means being able to accurately predict per-period payoffs is sufficient for our analysis.

Another issue is that during this period, some generic manufacturers may have been engaging in price-fixing (Cuddy (2020), Starc and Wollmann (2022)). This occurred from late 2013 onwards; our dataset's coverage is from 2004-2016. As a result, we rerun the price prediction regression by dropping years 2013 onwards, and obtain very similar results.

Generic entry as a static entry game: Recall that we model the entry decision by generics to be a static entry game that happens before loss-of-exclusivity (following Ching (2010)). We choose to model generic entry as a static game instead of a dynamic entry game for the following reasons. In the pharmaceuticals industry during our sample period of 2004-2016, the mean approval time for ANDA was about 40 months, so any decision to enter was implemented with significant delay. As a result, generic manufacturers needed to file for ANDA well in advance of patent expiration. Note that the AG does not need FDA approval as it is riding on the branded drug's original approval. As a result, we model AG entry as a dynamic decision being made every period.

Another simplification we make is that while generics apply well in advance of patent expiration, they do not know exactly when they will get FDA approval. In reality there are sometimes cases where a generic firm applies for and gains ANDA approval well in advance of patent expiration, and so can start production in the same quarter when patent expires. Our estimation of generic launch rates partly accounts

for that; see Section 5.1 for a detailed explanation.

Brand-specific time trend in demand function: Branded drug manufacturers can sometimes take actions that slow down generic adoption. This involves things like product hopping, getting approval for new therapeutic uses, gaining orphan drug designation, etc. These moves stop consumers and pharmacists from switching over to generic drugs and get around automatic substitution laws. While our model does not specifically account for such actions, our demand specification contains a brand-specific time trend that aims to capture the idea that the branded drug loses its appeal over time as the manufacturer runs out of such tactics. As would be expected, we find that the branded drug becomes less attractive over time, possibly because such tactics become less effective over time.

No-AG settlements: "No-AG settlements" are settlements where the generic firm agrees to not enter immediately in exchange for assurance that an Authorized Generic will not be released. This paper does not model No-AG settlements explicitly, partly because it is extremely difficult to identify which Paragraph IV lawsuits resulted in such settlements. Our demand model is not affected by No-AG settlements, the no-trade shock for AG subsumes No-AG settlements, and our counterfactuals apply to markets where such settlements have not occurred. We include a brief discussion on No-AG settlements through the lens of our model in Section 8.5.

Information assumptions: To simplify computation, we make two assumptions on information regarding the number of generic entrants. First, we assume that all generic manufacturers know how many others have already filed for ANDA to a molecule-formulation when it is their turn to decide whether to file an ANDA or not (i.e. sequential entry). Second, we assume that the AG knows how many generics have filed for ANDA to its molecule-formulation. In reality, the information on ANDA application by a generic manufacturer becomes public only after it wins ANDA approval from the FDA (although generic manufacuterers may have private information sources that could alert them to ANDA filings by rivals). This is a simplifying assumption that improves the tractability of our model. We also assume that the authorized generic correctly predicts the number of generic launches in the quarter when loss-of-exclusivity happens; this is realistic as the FDA would have announced before loss-of-exclusivity which ANDAs have been approved by then.

	Patient-facing	Non-patient-facing
ln(price)	-1.004	-2.781
	(0.033)	(0.244)
Brand	0.799	1.033
	(0.069)	(0.250)
Brand * time-since-generic-entry	-0.095	-0.008
	(0.007)	(0.014)
RC std: Brand	-5.946e-07	-1.812e-07
	(6.120)	(6.598)
RC std: Price	3.434e-07	-2.025e-07
	(4.778)	(11.838)

Table 3: Results of demand estimation for Stage 1. The demand model is estimated using 2-step nonlinear GMM. Robust standard errors are reported in parentheses. "RC std: Brand" and "RC std: Price" refer to σ_1 and σ_α respectively. Market and quarter fixed effects are suppressed.

	Patient-facing	Non-patient-facing
Authorized Generic	0.857	0.067
	(0.077)	(0.186)
ln(price)	-0.647	-1.286
	(0.023)	(0.068)

Table 4: Results of demand estimation for Stage 2. The demand model is estimated using a fixed-effects regression following Maggio et al. (2022). Robust standard errors are reported in parentheses.

7 Results

Tables 3 and 4 show the results of the demand estimation. From Table 3 we see that price has a negative impact on demand, and that the price-sensitivity is stronger for non-patient-facing molecule-formulations than patient-facing molecule-formulations. We also estimate the random coefficients to have statistically insignificant variance, meaning that any heterogeneity on the demand side is sufficiently picked up by the logit shocks. Table 4 shows that non-brand drugs also face negative price elasticity within the group. Moving to the supply side estimation, we find that brand manufacturers draw a trade-shock 62% of the time.

	Cost estimation
σ_ϵ	5.848×10^6
	(2.552×10^6)
p	0.620
	(0.044)

Table 5: Results of cost estimation. The entry cost for a trade shock, $\bar{\kappa}$, is set at \$1.5 million. Estimated using simulated method of moments. Bootstrapped standard errors are reported in parentheses.

8 Counterfactuals

In this section we explain how the supply model is solved; highlight key model dynamics that provide intuition for our subsequent results; and discuss the results of our counterfactuals.

8.1 Solving the full model

To understand our model and predict the impact of different policies, we solve the model by backward induction. For cost-estimation, we took the number of generic entrants as given and solved for the Conditional Choice Probability (CCP) of the authorized generic.[16] For the counterfactuals, we solve for both the number of generic entrants and CCP of authorized generic. The solution method is as follows:

1. For a given number of equilibrium generic entrants $\bar{n}$:

   (a) We solve for CCP of authorized generics conditional on n generics entering the market over the molecule-formulation's lifespan.

   (b) We use the CCP, (12) and estimated generic approval rate to calculate the state transition matrices for generics.

   (c) These state transition matrices are combined with per-period profits to construct value functions of generics using (14). This gives the expected discounted sum of profits that a generic expects to make if it enters the

[16] Recall that the CCP is gives the probability of AG being released in every state of the world from $t = 1$ to T.

market, conditional on a total of $\bar{n}$ generics entering. Thus this value function is *decreasing* in $\bar{n}$. Let us denote this value function as $V(\bar{n})$, suppressing other notation and arguments.

2. Repeat this step for $\bar{n} = 1, \ldots N$ where N is a large integer.

3. The equilibrium number of generics n^* is such that $V(n^*) \geq \kappa_m^g$ and $V(n^*+1) < \kappa_m^g$.

4. For this n^* re-solve the model to get the equilibrium CCP of authorized generics conditional on n^*.

In reporting our results, we take the model-predicted choice probabilities and run 500 simulations, then report the average results from the simulations. For computational ease, a simplification we make for our counterfactuals is that we assume one generic entrant is launched in the period of loss-of-exclusivity, and this is known by the generics. Any improvement in FDA approval rates leads to faster entry from one quarter after loss-of-exclusivity.[17] Finally, we calibrate generic entry costs to \$10 million; industry estimates show that generic entry costs range between \$2 million to \$20 million (Starc and Wollmann (2022)).

We now explain the terminology used in reporting the simulation results. "AG release fraction" denotes the fraction of simulations where an Authorized Generic is released in the market. Mean price (and share) is calculated by averaging over all observed prices (and market shares) in every period of every simulation path.

8.2 Discussion on key model dynamics

Profitability and phases of molecule-formulation: The early quarters of a molecule-formulation after loss-of-exclusivity are the most profitable for firms. During these periods, there are few firms in the market, resulting in high markups and high economic profits. As time goes by, more generics get FDA approval and enter

[17] This can be relaxed at the cost of greater computational time. It would require the generics to form probabilistic beliefs about all possible number of generics that may be present in the period of loss-of-exclusivity, calculate the AG release CCP for every such combination, then weight those AG CCPs by the probabilistic beliefs to form the generic value functions. We believe the qualitative results of this paper will hold in this scenario too.

the market, resulting in markups being driven close to zero and low economic profits. This provides another reason why generics want to launch earlier - the earlier phase of the market yield the highest profits and so contribute most towards covering the entry cost.

Commitment versus early launch: Both the independent generics and authorized generic can deter each other's entry, but in different ways. An independent generic can effectively commit to entering early. This is because a generic incurs its fixed cost in the first stage, before the authorized generic. Given that it has incurred the entry cost by the time the authorized generic makes its decision, this means that upon FDA approval, this independent generic can start marketing its product without additional fixed costs. This ability to commit earlier means that the generic can deter an authorized generic from entering. Note that the authorized generic having a substantially lower entry cost than independent generics (conditional on drawing a trade shock) means that this entry deterrence effect is light. On the other hand, an authorized generic can deter the independent generic's entry through the fact that it can control its launch timing. More specifically, the authorized generic can launch its product early – during the more profitable phase of the market – which has a strong entry deterrence effect on the independent generic.

Later entrants cannot cover entry cost: Generics which are approved later in the market usually cannot cover their entry costs. Later approval means that the product launch happens in the later phase of the market when the markups are close to zero, so in the remaining periods the firms make little to no economic profit.

This would be avoided if there were fewer generics to apply for entry. That way, even when the last generic launches, there would be fewer generics competing, the resulting markup would be higher, leading to more profits over the rest of the market's lifetime and allowing the last entrant to still cover its entry cost. Since this is the case, why are there more entrants?

This is because when deciding to enter, a potential entrant balances *expected profits* against entry cost. While a later approval leads to low profits, a lucky early approval leads to very large profits in the initial periods. So when making the entry decision, they are balancing the risk of a late approval and being unable to cover their entry costs with the possibility of an early approval and making windfall profits in the

early phase of the market. In other words, the realized profit could be significantly different from the expected profit. [18]

With faster generic approval rate, it is less likely that an entrant cannot cover their entry costs. This is because nearly all the generic entrants get approval in the early phase of the market, and so they can more accurately predict when they'll enter and how much competition they will face upon entry. The realized profit is therefore much closer to the expected profit.

This shows another advantage of increasing FDA approval rates, apart from lower prices for consumers earlier in the market. By allowing firms to accurately predict when they will enter the market, it reduces or outright prevents ex-post regret. Thus there are few firms that wastefully incur entry cost, leading to lower social costs.[19]

Impact of variance of AG timing shocks: The variance of the AG timing shocks dictates how accurately the brand manufacturer can control the authorized generic launch timing around the optimal release. Table 6 shows how authorized generic release delay gets lower as the logit scaling parameter (σ_ϵ) gets smaller.

Furthermore, lower σ_ϵ means the authorized generic is a stronger deterrent to generic entry because it is launched earlier during the most profitable phase of the market. This is illustrated in Table 7, where we see that lower σ_ϵ leads to fewer generics entering.

8.3 Generic approval rates

Our first set of counterfactuals involves studying the effects of faster ANDA (generic) approval rates by the FDA. In this scenario, we scale up the probability of ANDA being approved in every quarter after loss of exclusivity, and study the impact on market outcomes.

The core impact is on the number of generic entrants in equilibrium. Under faster

[18] In a way, there is ex-post regret associated with entry, and is similar to the sort studied in Seim (2006). However in Seim (2006) the ex-post regret came from incomplete information about rivals' entry decisions; in our model, it comes from uncertainty about when the FDA will approve a generic manufacturer's application.

[19] Interestingly, such excess entry could also lead to lower prices faced by consumers in the long run. From a policymaker's perspective, it is thus possible to prefer such excess entry since it lowers prices.

σ_ϵ	**AG release time**
10^{10}	9.76
10^9	9.17
10^8	6.26
10^7	1.49
10^6	1.0
10^5	1.0

Table 6: Effect of changing the logit scaling parameter σ_ϵ on authorized generic release timing. Simulation conducted for market with molecule-formulation fixed effect of 0.109 (80th percentile), marginal cost of \$6.47, market size of 38 million.

Cases	**Total generics**	**AG release fraction**	**Mean AG price**	**Mean Generic price**
High σ_ϵ	7.0	1.0	0.28	0.36
Low σ_ϵ	5.0	1.0	0.4	0.4

Table 7: Effect of changing the logit scaling parameter σ_ϵ on generic entry decisions. Simulation conducted for market with molecule-formulation fixed effect of -1.94 (30th percentile), marginal cost of \$0.006, market size of 26 million. High σ_ϵ equals 10^{10}, while low σ_ϵ equals 10^3.

FDA approval rates, there are opposing forces on a generic's entry decision. On the one hand, faster approval rates means the generic can market their drug earlier, and so has a longer time (till the terminal period) to make profits and cover their entry cost. This force would incentivize more generics to enter. On the other hand, faster approval rate means that when a generic does enter the market, more of its competitors are already in the market, so it will face greater competition and smaller profits upon entry.

So which of these forces dominate? This is an open question we can study by simulating the market under faster ANDA approval rates. For the first group of counterfactuals we assume an authorized generic has drawn a "no-trade shock" and so is not present in the market. The results are shown in Table 8. We see that as ANDA approval rates increase, there are fewer generic entrants. This means that the entry disincentive from earlier competition dominates the entry incentive from longer operation time in the industry. To see why, we can look at the per-period prices

(and profits) in the industry. The earliest periods are the most profitable, because there are few nonbrand products in the market, resulting in high markups. As more generics enter, these markups are driven down to zero, so that in the long run price is nearly equal to marginal cost. This means that after a certain number of periods, generic firms no longer make economic profit that can go towards covering their entry cost. With faster ANDA approval rates, price drops to marginal cost much faster, meaning that there are far fewer quarters when generics can make economic profit, because there will be more competitors in the market right from the beginning. Thus, while it is true that generics can operate in the market longer due to being approved earlier, most of that time is going to be spent making zero economic profit.

Next we rerun the counterfactuals but assume that the authorized generic has drawn a "trade shock", meaning it can be released by the incumbent manufacturer. The results are shown in Table 9.

Note that faster approval rates weakly reduces number of generics and weakly deters authorized generic entry. Under certain demand and cost primitives, it is possible that faster rates has no impact on generic entry and does not reduce authorized generic profit sufficiently to deter entry. An example of this are shown in Table 13, where increasing generic approval rate leads to no change in generic entry and AG release decision.

8.4 Ban on Authorized Generic

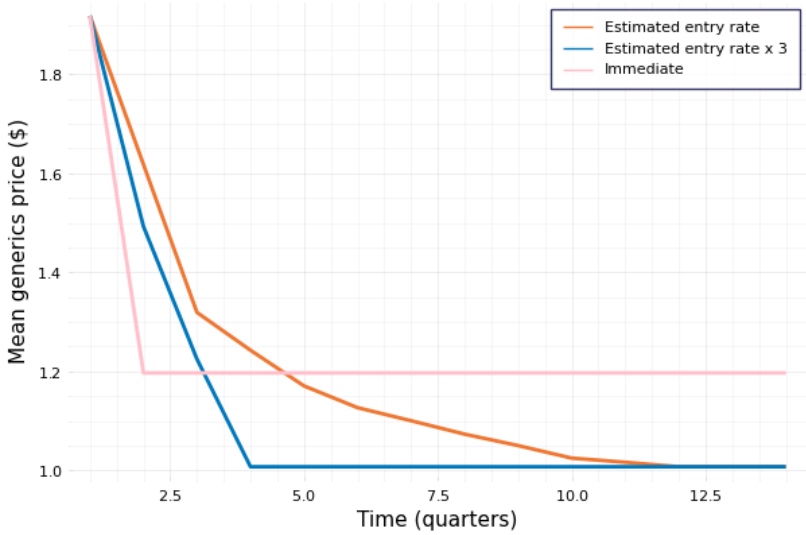
We find that a ban on AGs leads to weakly more generic entrants but has an ambiguous effect on overall prices. We also show that the impact of an AG ban depends on whether the AG in question is expected to avoid production delays and launch earlier. For this section, we assume that the AG would have drawn a "trade shock" had it not been banned, meaning it can be released by the incumbent manufacturer.

We first explain the impact from an AG ban on generic entrants. There are two opposing forces operating on different phases of the market's timeline after loss-of-exclusivity:

1. Early AG launch: Without an AG ban, the AG is released early in the market, so there is always an additional competitor in the market from the early quarters.

Cases	Total generics	AG release fraction	Mean AG price	Mean Generic price
Estimated	7.0	0.0	0.0	1.12
Estimated x 2	5.0	0.0	0.0	1.09
Estimated x 3	4.0	0.0	0.0	1.09
Immediate	3.0	0.0	0.0	1.24

(a) Market outcomes under different FDA approval rates.



(b) Generic price evolution under different FDA approval rates.

Table 8: Market outcomes and prices with different FDA approval rates. Simulation conducted for market with molecule-formulation fixed effect of -1.18 (50th percentile), marginal cost of $1.0, market size of 186 million. "Estimated" refers to the estimated product launch rates. The AG is assumed to have drawn a no-trade shock and therefore cannot enter the market.

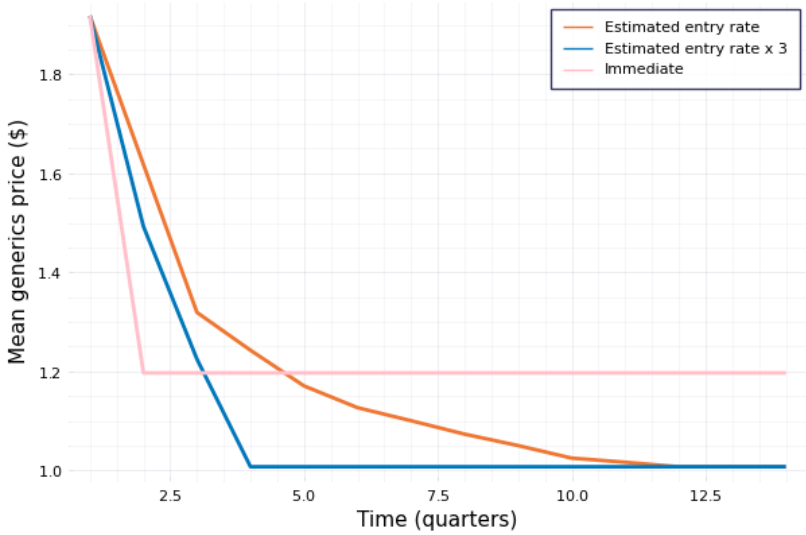
Without the AG, the generics face lower competition in the initial periods as all the generics slowly gain approval. Therefore, under an AG ban, prices are generally higher in the early phase of the market.

2. Greater generic entry: An AG ban leads to greater number of generic entrants. More generic manufacturers in the market drive prices down in the later phase of market.

The exact effect on mean prices depends on the demand and supply parameters.

Cases	Total generics	AG release fraction	Mean AG price	Mean Generic price
Estimated	7.0	0.81	1.01	1.12
Estimated x 2	5.0	0.62	1.01	1.09
Estimated x 3	4.0	0.51	1.01	1.09
Immediate	3.0	0.48	1.01	1.24

(a) Market outcomes under different FDA approval rates.



(b) Generic price evolution under different FDA approval rates.

Table 9: Market outcomes and prices with different FDA approval rates. Simulation conducted for market with molecule-formulation fixed effect of -1.18 (50th percentile), marginal cost of $1.0, market size of 186 million. "Estimated" refers to the estimated product launch rates. The AG is assumed to have drawn a trade shock and therefore can enter the market.

Among other things, it depends on how many generics are deterred by the presence of an authorized generic. If an authorized generic ban leads to multiple new generics entering, then the drop in price in the later phase of the market may result in lower mean prices.

Why can an AG ban lead to more than one new generic entering? This is because the AG is a more potent competitor than independent generics as a result of being released earlier in the market. Since the AG is released early, it has a negative impact

on every generic and particularly during the most profitable early periods of the market. If the AG is banned, not only is there one fewer competitor, but it is also one less competitor in the most profitable periods in the market. This results in a significant increase in expected generic profits compared to one fewer independent generic. In turn, this can incentivize multiple new generics to enter than if an AG had been present.

How many independent generics are deterred by the presence of an authorized generic depends on market-specific factors, particularly generic entry costs. In our simulations we generally found that the ban led to one or more than one new generic entrant, but a few simulations showed the ban leading to no new generic entrants. In the latter cases, while the AG ban makes the market more profitable, an additional generic still may not anticipate enough expected profit to cover its cost. Note that, conditional on receiving a trade shock, an AG has lower entry cost than an independent generic. This means that just because an AG found it profitable to enter a market does not mean that an independent generic would also have entered that market.

We can see the result of different simulations in Table 10. In Case 10a, an AG ban leads to an increase in generic entry by 1 and an increase in mean generic prices; for Case 10b, an AG ban leads to an increase in generic entry by 2 and a decrease in mean generic prices; for Case 10c, an AG ban leads to an increase in generic entry by 1 and an increase in mean generic prices. The reason behind cases 10a and 10b leading to opposite effects on price is because of which opposing force from above dominates. Compared to 10a, in 10b the number of additional generics due to the ban is sufficiently large that it more than negates the higher prices in the initial periods.

This illustrates how the number of generics deterred by the authorized generic plays a key role in understanding the impact of the AG ban. Another way to test this idea by changing the logit scaling parameter (variance) of the AG timing shocks. Recall that the AG timing shocks govern how close to the optimal time an incumbent can release an authorized generic. The smaller the variance of the AG timing shocks, the earlier the authorized generic can be released. This means that we can exogenously vary how "competitive" an AG is to generics by varying the logit scaling parameter -

Cases	Total generics	AG release fraction	Mean AG price	Mean Generic price
Baseline	4.0	1.0	1.1	1.2
AG ban	5.0	0.0	0.0	1.27

(a) Case 1. Simulation conducted for market with molecule-formulation fixed effect of -1.54 (40th percentile), marginal cost of $0.67, market size of 19 million.

Cases	Total generics	AG release fraction	Mean AG price	Mean Generic price
Baseline	7.0	1.0	1.3	1.45
AG ban	9.0	0.0	0.0	1.37

(b) Case 2. Simulation conducted for market with molecule-formulation fixed effect of -0.93 (60th percentile), marginal cost of $0.28, market size of 11 million.

Cases	Total generics	AG release fraction	Mean AG price	Mean Generic price
Baseline	2.0	1.0	6.97	7.41
AG ban	3.0	0.0	0.0	7.64

(c) Case 3. Simulation conducted for market with molecule-formulation fixed effect of -0.62 (85th percentile), marginal cost of $3.92, market size of 1.95 million.

Table 10: Market outcomes with and without AG ban for three different cases.

an incumbent with high variance will release its AG late and such an AG is less of a deterrent to potential entrants, while an incumbent with low variance will release its AG early and deter more potential entrants.

We illustrate this in Table 11. As predicted, banning an AG with low logit scaling parameter (σ_ϵ) leads to a large jump in generic entry, because the AG was such a strong deterrent through its early launch. However, banning an AG with a high logit scaling parameter has a much smaller effect on generic entry, because it entered much late and so had a small impact on generic profits.

This last counterfactual is not just of theoretical interest, but also has potential practical implications. While our estimated σ_ϵ is used to match overall industry patterns, it is possible that different brand manufacturers could have different values of σ_ϵ depending on firm-specific characteristics. A brand manufacturer with a generic subsidiary, or one which has more experience regarding AGs, may have a smaller σ_ϵ. Such an AG will deter more generics from entering, and so banning this AG will lead

Cases	Total generics	AG release fraction	Mean AG price	Mean Generic price
Baseline	6.0	1.0	1.48	1.48
AG ban	9.0	0.0	0.0	1.37

(a) Low logit scaling parameter ($\sigma_\epsilon = 10^3$)

Cases	Total generics	AG release fraction	Mean AG price	Mean Generic price
Baseline	8.0	1.0	1.05	1.41
AG ban	9.0	0.0	0.0	1.37

(b) High logit scaling parameter ($\sigma_\epsilon = 10^{10}$)

Table 11: Market outcomes with and without AG ban, and under different values of logit scaling parameter (σ_ϵ). Simulation conducted for market with molecule-formulation fixed effect of -0.93 (60th percentile), marginal cost of \$0.28, market size of 11 million.

to a significant increase in generic entry. On the other hand, a brand manufacturer expected to face delays in its AG launch is not deterring many generics anyways, so a ban in this case will have a small impact on generic entry. Therefore, this highlights how the impact of an AG ban turns on whether the AG in question is expected to avoid production delays and launch earlier.

8.5 Discussion on No-AG settlements

No-AG settlement are struck by the brand manufacturer to delay the first generic entrant, resulting in the exclusivity period lasting longer and consumers paying high prices over this extended time. See FTC (2011) for an in-depth discussion.[20] Due to lack of data, we do not seek to model no-AG settlements and their welfare implications. Instead, we offer a brief discussion on the implications of no-AG settlements through the lens of our model.

First, no-AG settlement means less competition at the beginning of loss-of-exclusivity – the generics entering in the first few quarters do not face an additional competitor

[20]The FTC also filed an amicus brief regarding no-AG settlements, see https://www.ftc.gov/legal-library/browse/amicus-briefs/re-effexor-xr-antitrust-litigation-0

in the authorized generic, resulting in higher prices. This therefore has a negative impact on consumer welfare.

Second, note that the negative effects of a no-AG settlement can be partially negated by higher generic entry – no AG means one less competitor in the market, leading to more generics deciding to enter the molecule-formulation. However, the impact of a no-AG settlement on generic entry can depend on how early the generic manufacturers find out that such a deal is in place.

As we have seen in our counterfactuals, a ban on authorized generic leads to weakly greater generic entry, but a ban implies that potential generic entrants are aware from the outset that there will not be an authorized generic in the market. Thus, if a no-AG settlement is struck, it implies one less competitor in the market, which incentivizes greater generic entry.

The exact effect of a no-AG settlement on generic entry depends on how early the generic manufacturers find out that such a deal is in place. Let us suppose that the market conditions were favorable for an authorized generic to be released in the absence of a no-AG settlement. If generics were expecting an authorized generic to enter, then some of them would not apply for ANDA to that market. However if then a no-AG deal is struck, there will be fewer generics, at least in the short term. Potential entrants realize an authorized generic will not in fact be released and file for ANDA approval, resulting in delayed generic entry than otherwise. If generics realize no-AG settlement has been struck early enough, then they can apply for ANDA earlier, resulting in earlier product launch.

The above discussion highlights the interesting dynamics behind no-AG settlement and their welfare discussions. Furthermore, no-AG settlement may be more complex than described above; see Bokhari et al. (2020) for a discussion. In short, this is potentially an exciting avenue for future research with important antitrust implications.

9 Conclusion

In the pharmaceutical industry, branded drug manufacturers can compete with generics by releasing an Authorized Generic, which is identical to the branded drug but

without the brand label attached. Using quarterly drug sales and revenue data on US for 2004-2016, we estimate a structural model of pharmaceutical demand, generic entry, AG release and pricing. We use this model to simulate the impact of two policy counterfactuals: faster generic approval rate, which has been a focus of the FDA in recent year; and a ban on AG, which aims to analyze the validity of concerns regarding the impact of AG on market outcomes.

We first set up a discrete choice model of demand where the consumer first chooses a group (brand, nonbrand, or outside option) then chooses a product within the group. We estimate this model (using the methods of Berry et al. (1995) and Maggio et al. (2022)) to recover price coefficients and general preferences for nonbrand drugs.

Next we build a two-stage supply model. In the first stage, generic manufacturers make a static entry decision on whether to enter a molecule-formulation. In the second stage a dynamic game begins where every period, generics who decided to enter are randomly approved for entry by the FDA and the branded drug manufacturer decides whether to release an Authorized Generic. This two-stage model setup is because unlike generics, AGs do not need FDA approval to launch. We estimate this model using simulated method of moments to recover the AG entry cost distribution.

We use this to run two counterfactuals. First, we study the impact of faster generic approval rates by the FDA. We find that a faster approval rate leads to weakly fewer generic entrants, strictly lower prices in the early periods of the market, and ambiguous effect on prices in later periods of the market. An authorized generic is less likely to be released, and entering generics are more likely to fully recoup their entry cost. The intuition behind our result on weakly fewer generic entrants is as follows. Faster approval rate means the generic accrues more revenue from operating on the market longer. However, faster approval rate also means that rival generics launch earlier as well. This means that the generic faces greater price competition and lower profits upon launch. Greater competition upon launch offsets the advantage from an early launch, and so weakly reduces generic entry. It also means that, while prices are lower in the early periods of the market, the reduction in generic entry leads to ambiguous effects on prices in later periods of the market.

Second, we show that a ban on authorized generics leads to weakly more generic entrants and ambiguous effect on overall prices. The latter happens because while

there is increased price competition from weakly more generic entrants in the later stages of the market, it is counteracted by lack of an additional competitor through the AG in the early stages of the market. We also highlight how the impact of an AG ban turns on whether the AG in question is expected to avoid production delays and launch earlier. We conclude with a brief discussion on no-AG settlements through the lens of our model and highlight that it is an exciting area for future research.

A Derivation of product-level market share equation

$$d_{ij} = \begin{cases} 1 & \text{if } U_{ij} > U_{ik} \text{ for all } k \neq j, \\ 0 & \text{otherwise.} \end{cases}$$

Therefore we can express the market share of a single good in terms of group market share and market share of good conditional on choice of group:

$$\begin{aligned} s_j =& \int d_{ij}(\delta + \mu_i) d\mu_i d\epsilon_i \\ =& \int \frac{e^{\delta_g + \mu_{ig}}}{\sum_l e^{\delta_l + \mu_{il}}} \frac{e^{\delta_j + \mu_{ij}}}{\sum_k e^{\delta_k + \mu_{ik}}} f(\mu_i | \tilde{\theta_2}) d\mu_i \\ =& \int \frac{e^{\delta_g + \mu_{ig}}}{\sum_l e^{\delta_l + \mu_{il}}} \frac{e^{\delta_j}}{\sum_k e^{\delta_k}} f(\mu_i | \tilde{\theta_2}) d\mu_i \\ =& \left[\int \frac{e^{\delta_g + \mu_{ig}}}{\sum_k e^{\delta_l + \mu_{il}}} f(\mu_i | \tilde{\theta_2}) d\mu_i \right] \frac{e^{\delta_j}}{\sum_k e^{\delta_k}} \\ =& s_{g(j)} s_{j|g(j)} \end{aligned}$$

B Additional summary statistics

Delay	Count
0.0	58
1.0	10
2.0	6
3.0	2
4.0	2
5.0	3
6.0	2
8.0	1
9.0	1
10.0	1
11.0	1
12.0	2
14.0	2
15.0	2
17.0	1
19.0	2
20.0	2
21.0	1
22.0	2
27.0	1
38.0	1
41.0	1

Table 12: AG Delay table. This shows, of the 110 AGs released, how many quarters after loss-of-exclusivity they were released. "Delay" is the number of quarters after loss-of-exclusivity. "Count" is the number of AGs released for the corresponding quarters since loss-of-exclusivity.

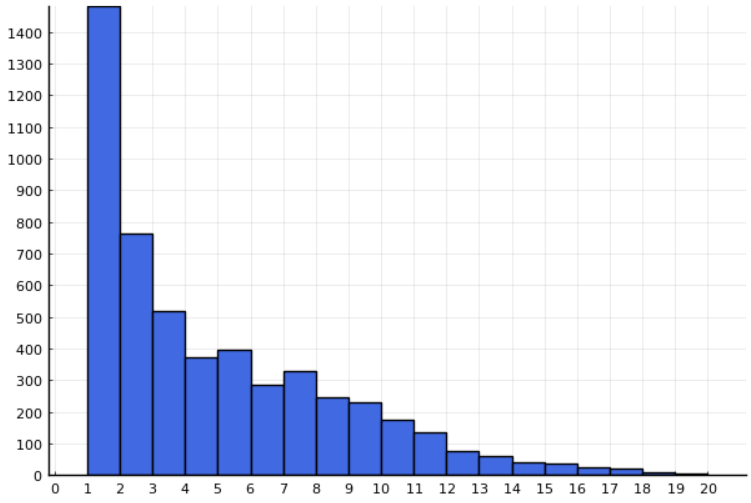
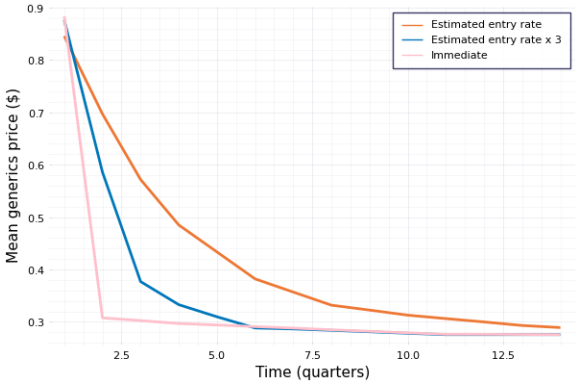


Figure 5: Histogram of count of generics present by molecule-formulation-quarter.

C Generic approval rate: additional results

Cases	Total generics	AG release fraction	Mean AG price	Mean Generic price
Estimated	6.0	1.0	0.33	0.36
Estimated x 2	6.0	1.0	0.29	0.34
Estimated x 3	6.0	1.0	0.29	0.33
Immediate	6.0	1.0	0.28	0.32

(a) New caption



(b) Market outcomes with changing FDA approval rates.

Table 13: New caption

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