Entry and pricing with fighting brands: Evidence from the pharmaceutical industry*

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Abstract

In the pharmaceutical industry, branded drug manufacturers can compete with generics by releasing an Authorized Generic (AG), which is identical to the branded drug but without the brand label attached. This is used to price discriminate between consumers of different preferences, with the branded drug charging high price and AG charging low price to compete with generics. Such "fighting brand" strategies are common in various industries, and in this paper we study these in the context of the pharmaceutical industry. We analyze how the brand, AG and generics interact in a strategic setting using total drug sales and revenue data on US for 2004-2016. First, we estimate a random-coefficients discrete choice demand model and find significant heterogeneity in brand valuation and price sensitivity among consumers. Next, we build a structural model of generic entry, AG release, and pricing. Combined with calibrated cost parameters, this is used to conduct counterfactuals. First, we change key demand primitives to study responses by generics and AGs in these alternative environments. Second, we show that the decision to release an AG depends mostly on the difference in marginal and per-period operating cost between generics and the AG - the higher the AG's marginal cost and operating cost relative to generics, the less likely it is to

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enter. Third, we show that the AG's ability to enter immediately in contrast to generics that have to wait for FDA approval gives branded drug manufacturers an additional incentive to release an AG. Fourth, we show that a faster generic approval rate leads to greater generic entry, lower likelihood of AG being released, and lower prices. Finally, we study what happens to market outcomes if AGs are banned, as has been discussed in policy circles and argued for by generic firms. Conditional on AG and generics having the same marginal cost, we find that banning AG leads to higher market prices.

1 Introduction

Pharmaceutical products in US can be broadly classified into two categories: i) branded prescription drugs, which are pioneer molecules temporarily protected by patents and market exclusivities from competitors, and ii) generic prescription drugs that are bioequivalent to their branded counterparts. Branded prescription drugs initially enjoy monopoly power in the market and charge high prices. After loss of market exclusivity – including through patent expiration – generic prescription drugs enter the market and compete with each other and the branded product. This results in significant loss of market share for the branded prescription drug, corresponding increases in market share among generics and lower spending by payers. In some cases, the incumbent branded drug manufacturer responds to generic entry and competition by releasing a fighting brand, known in the pharmaceutical industry as 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. The motivation behind releasing an AG is that it allows the branded drug manufacturer to discriminate between consumers with different valuations of the brand label and its corresponding price. Pricing patterns in such markets are often that branded drug prices stay the same or even increase, while generics and the AG are priced very low.

Studying product entry and pricing decisions in pharmaceutical markets is important for several reasons. First, high prescription drug prices impede access to needed treatment among patients and results 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 entry after branded drugs lose market exclusivity. 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, incumbents can respond in several ways through price adjustment and product line expansion.

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. Note that the incumbent has to weigh business-stealing vs cannibalization incentives when deciding to release a fighting brand.[1] However, there is only a nascent empirical IO literature looking at this phenomenon.

Using national quarterly data on total quantity of sales and associated revenue on all prescription drugs sold in the US between 2004-2016, we build and estimate a structural model of the pharmaceutical industry in the US after the branded drug's loss of market exclusivity. Following previously published papers, the unit of analysis is the molecule-formulation pair (Yurukoglu et al. (2017), Conti and Berndt (2020)). We use this to study entry decisions by generics and AGs and their corresponding pricing strategies.

First, we set up a random-coefficients discrete-choice model of demand for pharmaceutical products. In our model, 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, etc. Rather than model them separately, our demand model predicts the outcome from the joint-decision making by all these agents together. Next, we set up a two-stage model of the supply side of the industry. 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 entry by the regulator (the United States Food and Drug Administration, FDA) and the branded drug manufacturer decides whether to release an AG.

The demand model is estimated using the method of Berry et al. (1995). 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.

The results from demand estimation show that there is significant heterogeneity in brand valuation and price sensitivity between consumers. We also impute marginal costs for different pharmaceutical products and types of firms using the Nash-Bertrand first-order conditions. The supply side has additional cost parameters (entry cost and per-period operating cost) which are calibrated. This is because - assuming that these costs vary by molecules,

[1]Fighting brands are commonly observed in the real world. Examples (from Bourreau et al 2021) include Intel had the Pentium series (brand) and Celeron (fighter brand) to compete with AMD; Lufthansa (brand) has a lower-cost subsidiary called Germanwings (fighter brand) to fight against low-cost carriers; Canadian telecom provider Rogers (brand) has a low-cost alternative (Chatr). Another example is Costco's release of Kirkland products, which have the same quality but lower brand value and price.

formulations, and types of firms, which is realistic to imagine - it is not possible to point-identify these parameters from the data. After calibration we perturb these cost parameters to see how they affect market outcomes.

The dynamic supply-side model is solved to conduct counterfactuals. First, we study how market outcomes change as we vary different demand parameters, thus clarifying the link between our demand system and the outcomes we observe. Second, we show that the decision to not release an AG can only be rationalized by the AG having a higher marginal or operating cost compared to generics. Third, we show that the AG's ability to enter immediately in contrast to generics that have to wait for FDA approval gives branded drug manufacturers an additional incentive to release an AG. Fourth, we show that a faster generic approval rate leads to greater generic entry and reduces the incentive to release the AG. Fifth, we impose a ban on AG release - a policy discussed by policymakers including the Federal Trade Commission (FTC) in the United States and generic manufacturers - and find that it leads to greater generic entry but also higher generic prices overall. This is mostly because the presence of AG provides competition immediately after loss of exclusivity. Without the AG, the random FDA approval means that the initial generics get to enjoy lower competition and higher generic prices.

Contributions and related literature First, we contribute to a very sparse Empirical IO literature on fighting brands. Furthermore, we are one of the very few papers to build and estimate a model of an incumbent releasing a fighting brand. There is an extensive theory literature on fighting brands, notably Johnson and Myatt (2003). An important empirical paper studying fighting brands is Bourreau et al. (2021). They show that in the French mobile telecommunications market, releasing fighting brands is due to a breakdown of collusion, and use a structural model of demand and supply to make their point.

Second, we also 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 possible feedback between AG and generic decisions when a key economic parameter is changed. 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 detailed information sources to lay out the decision to release the AG and generic manufacturers' reactions to it.

Third, we add to the literature on generic entry. While many papers have studied generic

entry in 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 to model learning dynamics. We adopt part of our entry model from this paper. Other notable papers are Morton (1999), Starc and Wollmann (2022), and Gallant et al. (2017).

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 important references include Arcidiacono et al. (2013), Bhattacharya and Vogt (2003), Bokhari and Fournier (2013), Bokhari et al. (2020), Dubois et al. (2022), Ellison and Ellison (2011), Frank and Salkever (1997), Reiffen and Ward (2005), Reiffen and Ward (2007), Olson and Wendling (2018), and Tenn and Wendling (2014). In particular, Berndt et al. (2017), Berndt et al. (2018), and Conti and Berndt (2020) provide important evidence about the aggregate dynamics and inner workings of the industry which we use to motivate our model.

2 Institutional Background

2.1 Pharmaceutical product life cycle

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

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".

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 product and correspondingly increased market share of the generic equivalents.

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", the pioneer molecule as the "branded drug" and manufacturer of the equivalent generic as the "generic drug manufacturer" and the generic equivalent molecule at the "generic drug".

2.2 Generic Drugs and FDA approval

After loss of exclusivity, bioequivalent products called generic drugs enter the market. Manufacturers of generic drugs need to prove to the FDA that their products are "bioequivalent" to the branded drug before selling their products. 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.[2] Generic manufacturers have to give further evidence that they can manufacture the drug accurately; this could involve setting up supply chains and equipment, giving factory tours, and creating a sample of the product. As a result, gaining FDA approval is costly to entrants in a given product market. It is important to note in the US 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.

To gain FDA approval, a generic manufacturer 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. Approval times of generics vary due to the amount of work involved in verifying the evidence submitted in support of the entrant's ANDA and the FDA's workload. In the past several 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. FDA approval times are also stochastic.

To meet ANDA requirements, the generic firm will reverse-engineer the branded drug, source inactive and active components, and build dedicated production facilities, labor and processes that ensure bioequivalence to the brand and scale. 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.

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

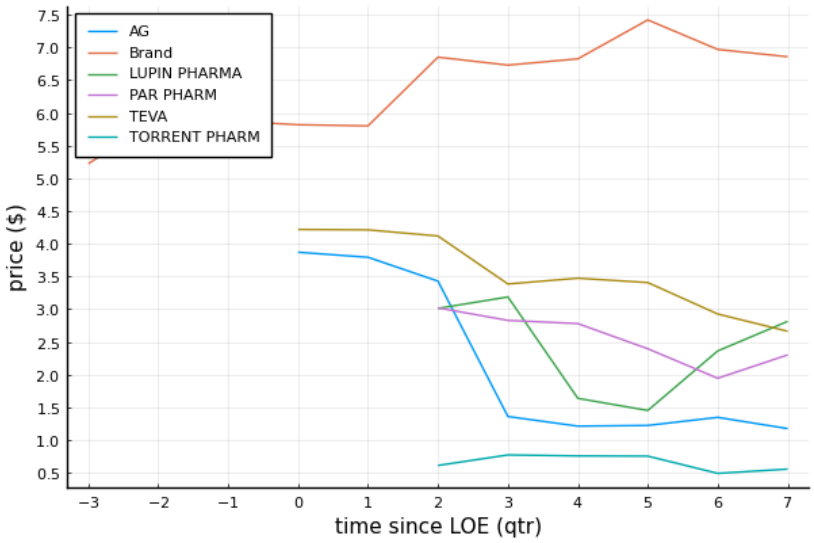

Figure 1: US-average prices by product for a representative molecule-formulation

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. 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.

The general pattern we see is 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 stays stable or increases. An Authorized Generic is sometimes released by a branded drug manufacturer (or by another form in contract with the branded manufacturer) in response to generic entry. Over time, the branded drug's share dramatically falls after generic entry begins. An example of this pattern can be seen in Figures 1 and 2.

3 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 (e.g., chain stores and food stores), 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), strength, and other information including therapeutic

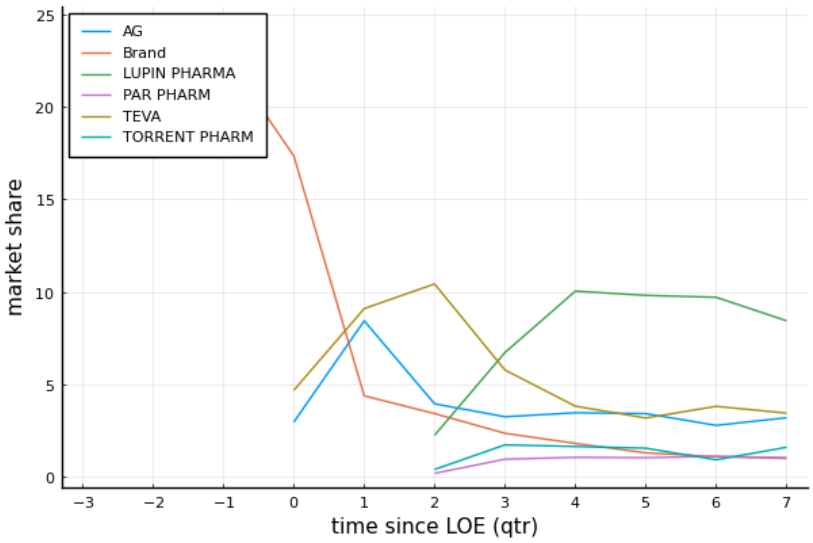

Figure 2: Market shares in US by product for representative molecule-formulation

class, product launch date, patent status, etc. Following previous literature (Conti and Berndt (2020), 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 example, lorazepam-injectable is a different drug from lorazepam-oral.

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. tablet, 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 not pay rebates, but branded drugs do, so this creates potential measurement error for branded drug prices.[3]

Furthermore, the NSP database reports volumes of each drug sold in "standard units". This allows us to compare volumes across different products in the same molecule-formulation.

Note that we only have quantity sales and revenue data at the US-quarter level. This stops us from analyzing finer details about the pharmaceutical industry, such as bargaining

[3]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).

across different agents and inclusion in insurance plans. Instead, we use this data to study aggregate industry dynamics such as average prices and entry decisions.

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.

In addition, data on Authorized Generics and Paragraph IV lawsuits were hand-collected. Authorized Generics 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.[4]

We define a market at the molecule-formulation level. After cleaning the data, we are left with 246 molecule-formulations. Of these, 110 markets see an AG released. 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). Note that each molecule-formulation has one branded drug and can have at most one AG.

This now 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, the fewer number of products allows us to capture substitution patterns between these bioequivalent products more accurately. Second, the branded drug's patent and generic approval holds at molecule-formulation level. Third, one drug can be in multiple therapeutic classes which makes modeling markets unclear. Fourth, 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 I'm studying. Fifth, this market definition has been used in various antitrust proceedings and empirical papers (Conti and Berndt (2020), Starc and Wollmann (2022), Yurukoglu et al. (2017)). Finally, we put in a molecule-formulation fixed effect in the demand function to account for attractiveness of other molecule-formulations in the same therapeutic class.

We now present some descriptive statistics of the data. Figure 3 shows when AGs are released relative to generic entry. For the 110 markets that see AG release, the histogram shows how many quarters after first-generic-entry is AG released. 58 markets see AG release

[4]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.

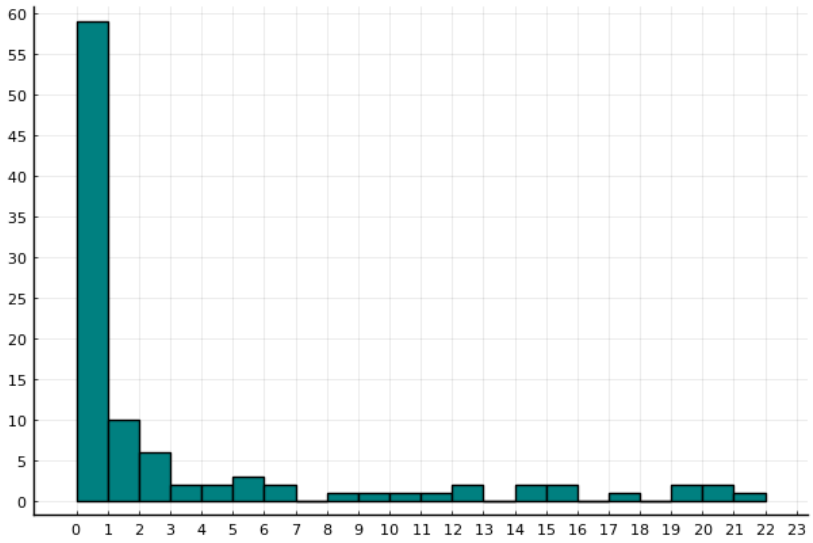

Figure 3: Histogram of time-difference between first generic entry and AG release period.

immediately with the first generic entry, 11 markets see AG release one quarter after the first generic entry, and so on.

Figure 4 is the histogram of number of generics present in a molecule-formulation-quarter. Figure 5 shows the histogram of total generics that enter into a molecule-formulation over time. This reveals that most markets have between 1-3 generic competitors.

4 Model

To study market dynamics after loss of exclusivity, we develop a structural model of the pharmaceutical industry. 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 random-coefficients discrete choice model of demand. 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, all the firms in a market engage in a pricing game.

4.1 Demand

The utility of consumer i for product j in time t is given by:

$$u_{ijt} = \gamma_{m(j)} + \alpha_i ln\, p_{jt} + \beta_i^{(1)} \cdot \text{non-brand}_j + \beta^{(2)} \cdot AG_j + \beta^{(3)} brand_j \cdot \text{time-since-loe} + \xi_{jt} + \epsilon_{ijt} \quad (1)$$

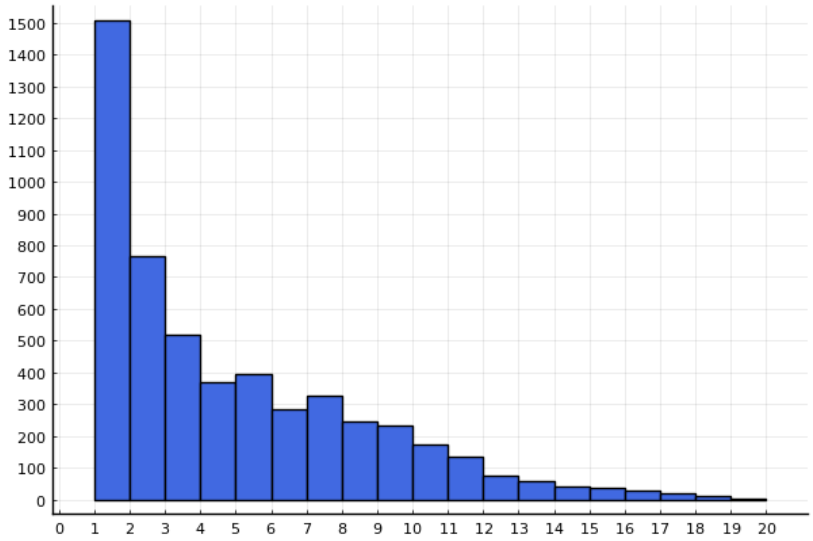

Figure 4: Histogram of count of generics present by molecule-formulation-quarter.

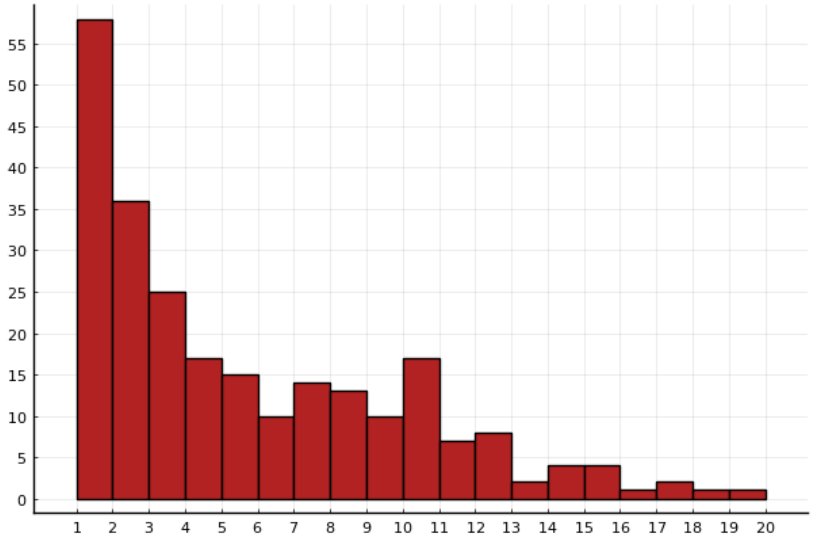

Figure 5: Histogram of total generic entry by molecule-formulation

where $m(j)$ is the molecule-formulation in product j, p_{jt} denotes price, "non-brand" is an indicator that turns 1 for generics and AGs, and ξ_{jt} allows for unobserved product-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. We also include a dummy for product j being an Authorized Generic AG_j. The random coefficients α_i and $\beta_i^{(1)}$ allow for heterogeneity in price sensitivity and non-brand valuation respectively. As is common in the empirical literature, we further assume $\alpha_i \sim \mathcal{N}(\alpha, \sigma_\alpha^2)$ and $\beta_i^{(1)} \sim \mathcal{N}(\beta^{(1)}, \sigma_1^2)$.

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 consumers jointly making a purchase decision. For instance, there's 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, 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).

4.2 Supply

We first present an overview of our supply model. The following subsections explain the components of the model, and Section 5 goes over the reasoning behind the modeling choices.

There are two stages to the supply side:

1. In the first stage, generic firms decide whether to enter a market (i.e. 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 introduced into the market. The branded drug manufacturer decides whether to release AG or not (the AG release decision is irreversible). Then, all the firms set prices and receive payoffs.

4.2.1 Per-period payoffs

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

$$\pi^b(s_t) = [P_t^b - MC_m^b]s_b(s_t)M_t - \phi_m^b + \mathbf{1}(AG_t = 1)\left[[P_t^{AG} - MC_m^{AG}]s_{AG}(s_t)M_t - \phi_m^{AG}\right] \quad (2)$$

where s_t denotes the market state variable vector, superscripts b and AG refer to the branded product and AG respectively, P denotes price, MC denotes marginal cost, $s(s_t)$ denotes market share, ϕ denotes the per-period operating cost, $M(t)$ 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's payoff is that it makes the first half of the payoff from the branded drug, and makes the second half of the payoff 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:

$$\pi^g(s_{l,t}) = (P_t^g - MC_m^g)s_g(s_{l,t})M_t - \phi^g \quad (3)$$

Generics and AGs compete on prices in a Nash-Bertrand setting. In the current draft, we fix branded drug's price to an average of the price observed in the data; this will be relaxed in a future draft.

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 discrete game begins from $t = 0$ and lasts T periods, where every period is a quarter. The value function for a branded drug manufacturer every period is given by:

$$V^b(s_t, \varepsilon_t) = \max_{AG_{t+1}\in\{0,1\}} \pi^b(s_t) - \mathbf{1}(AG_t = 0, AG_{t+1} = 1)\kappa_m^{AG} + \beta E[V^b(s_{t+1}, \varepsilon_{t+1})|s_t, \varepsilon_t] + \varepsilon_t(AG_{t+1}) \quad (4)$$

where $AG_{t+1} = 1$ means the AG is released. 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 choice-specific structural error $\varepsilon_t(AG_{t+1})$ follows a Type 1 Extreme Value distribution.

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

$$V^g(s_{l,t}) = \pi^g(s_{l,t}) + \beta E[V^g(s_{l,t+1})|s_{l,t}] \tag{5}$$

where $s_{l,t}$ includes whether generic l has been approved for production by the FDA.

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

$$V^b(s_T) = \sum_{\tau=T}^{\infty} \beta^\tau \pi^b(s_T) \tag{6}$$

Similarly, for generics the payoff is:

$$V^g(s_T) = \sum_{\tau=T}^{\infty} \beta^\tau \pi^g(s_T) \tag{7}$$

The branded drug manufacturer also has to form an expectation over generics' approval probabilities; recall that approval is given randomly to entrants over time. Suppose $n_e^* - m$ entrants have already received approval and started marketing. The probability that of the m remaining entrants, k will receive approval in this period is given by:

$$P_e(k, m, t) = \binom{m}{k} \lambda(t)^k (1 - \lambda(t))^{m-k} \tag{8}$$

Note that we assume the equilibrium number of generics that applied for ANDA n_e^* is known to the branded drug manufacturer from $t = 0$.

4.2.3 First-stage

In the first stage, an infinite number of generics decide if 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.

Intuitively, generics would 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:

$$V(s_0, n_e^*) \geq \kappa_m^g > V(s_0, n_e^* + 1) \tag{9}$$

where κ_m^g denotes the cost of entering molecule-formulation m. Note that we allow entry cost to vary across molecule-formulations.

5 Discussion

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

1. Pricing game: We model the price setting as a static Nash-Bertrand pricing game. This abstracts away from the sort of multilateral negotiation happening between many agents as well as pricing rules by the federal government. There are several reasons behind this. First, there isn't yet a pricing model that captures in a unified way exactly how each price is set in the pharmaceutical industry. Second, given that we are modeling aggregate industry dynamics, we need a tractable way of measuring per-period payoffs; Nash-Bertrand pricing has been used for exactly this in other papers such as Dubois et al. (2022) and Starc and Wollmann (2022). Third, our paper only looks at prescription drugs, which allows us to avoid further complexities surrounding physician-administered or over-the-counter drugs. Fourth, we only have aggregate data (total sales and total revenue in US), which limits us with regards to how finely we can model the pricing game.

   Note further that in the current draft, we fix branded drug prices at the level observed in the data and allow Nash-Bertrand pricing to occur between AG and generics. This gives more reasonable pricing patterns in our model simulations.[5] Several papers such as Ching (2010) and Bhattacharya and Vogt (2003) argue why branded drug's pricing decision is dynamic to explain the high brand prices. Our assumption can therefore be thought of as capturing such dynamic pricing incentives for the branded product in a simplified manner.

2. Generic entry as a static entry game: Most dynamic games model entry as a decision that potential entrants make every period and is implemented the next period. However for pharmaceuticals, the mean approval time for ANDA is about 40 months, so any decision to enter is implemented with significant delay. As a result, generic manufacturers often need 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

[5] We are also currently exploring alternatives for modeling brand pricing, to be incorporated in a future draft.

expiration, they do not know exactly when they will get FDA approval. In reality there are sometimes cases that 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. We try to allow for this by modeling generic entry rates as being higher in the initial periods after patent expiration; this should create the pattern that most approvals happen earlier in the dynamic game rather than latter. This approximates the industry patterns well.

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

4. Pay-for-delay and no-AG settlements: Generic manufacturers can file a Paragraph IV lawsuit to try and invalidate a branded drug's patent. In some cases, this results in the branded drug manufacturer agreeing to a pay-for-delay settlement, whereby it pays the generic firm a sum of money to delay entering the market. There are also no-AG 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 speak to either of these issues, partly because it is extremely difficult to identify which Paragraph IV lawsuits resulted in such settlements. Our demand model is not affected by such settlements, and our calibrated supply model applies to markets where such settlements have not occurred.

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 filed for ANDA to a molecule-formulation. 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. While our paper abstracts away from modeling the uncertainty regarding the number of entrants, it is quite likely that firms within the industry are well-connected to various

	Demand
ln(price)	-3.017
	(0.019)
Non-brand	-4.807
	(0.116)
AG	0.372
	(0.067)
Brand * time-since-LOE	-0.041
	(0.004)
σ_1	3.381
	(0.092)
σ_α	0.240
	(0.034)

Table 1: Results of demand estimation

personnel and become aware of ANDA filing relatively soon after it happens.

5.1 Estimation and Results

We estimate the demand model using the method of Berry et al. (1995). We use Gandhi-Houde instrumental variables and employ 2-step GMM. We also restrict our estimation to markets with 3 or fewer generics. The results are given in Table 1. Non-branded drugs are perceived more negatively on average relative to the branded product, but there is significant heterogeneity across consumers; that is, some consumers place a much higher value on the branded product compared to other consumers. There is also significant dispersion in price sensitivity across consumers. Authorized Generics are regarded more favorably than regular generics; this could be driven by patient-physician perception of the AG, or because AGs use the supply chains of branded drugs resulting in better distribution. Finally, the brand-specific time trend shows that the branded drug gets less attractive over time.

We now discuss estimation and calibration of the cost parameters in our model. The Nash-Bertrand first-order conditions allow us to impute the marginal cost parameters. The rest of the cost parameters in the supply model are calibrated for counterfactual analysis. We set T = 32, meaning that the dynamic game lasts 32 quarters. Generics and AGs are set to have an entry cost of \$2 million and \$1 million respectively. Generics have a per-period operating cost of \$20,000 compared to AG's operating cost of \$70,000. In our counterfactuals we will be mostly concerned with the *change* in market outcomes as we vary these cost parameters, so the resulting economic intuition should hold at different calibrated values.

The supply model is solved by backward induction. For a given guess of generic entrants, we solve for the conditional choice probabilities (CCPs) of releasing an AG at every state until T. This is used to recalculate generics' value function and compute the new number of generic entrants, which then leads back to recalculating the CCP of AG. This iteration between the two stages is done until convergence. This makes the information assumption that the AG knows the exact number of generics that have filed for application.

6 Counterfactuals

To understand our model and predict the impact of different policies, we solve the model by backward induction. In reporting our results, we take the model-predicted choice probabilities and run 3000 simulations, then report the average results from the simulations. Note that "AG release fraction" denotes the fraction of simulations where an Authorized Generic is released in the market.

Demand primitives: First, we see how the market outcomes change as we vary different key demand parameters. The takeaways are:

Nonbrand coef	Total generics	AG release fraction	AG price	Generic price	Per-Generic share	Brand share	AG share
-2.4	13.0	1.0	2.74	2.69	6.92	0.72	9.37
-2.88	11.0	1.0	2.76	2.71	8.02	0.95	10.83
-3.37	9.0	1.0	2.78	2.72	9.54	1.28	12.84
-3.85	7.0	1.0	2.82	2.75	11.79	1.79	15.71

Table 2: Market outcomes with changing non-brand coefficient.

1. More negative mean non-brand coefficient $\beta^{(1)}$ leads to fewer generics entering, higher AG and generic prices and market share, and higher market share for brands. Incentive to release AG remains unchanged at the estimated parameter values. See Table 2.

2. More negative mean price coefficient α leads to fewer generics entering, lower AG and generic prices, higher AG and generic market shares, and lower branded drug market shares. Incentive to release AG remains unchanged at the estimated parameter values. See Table 3.

Price coef	Total generics	AG release fraction	AG price	Generic price
-2.41	9.0	1.0	3.29	3.17
-2.72	6.0	1.0	3.04	2.94
-3.02	4.0	1.0	2.88	2.79

Per-Generic share	Brand share	AG share
8.87	8.41	11.75
12.88	5.62	17.11
18.13	3.67	23.82

Table 3: Market outcomes with changing price coefficient.

Nonbrand variance	Total generics	AG release fraction	AG price	Generic price
2.37	6.0	0.0	0.0	2.73
2.7	8.0	0.05	2.73	2.74
3.04	9.0	1.0	2.74	2.69
3.38	10.0	1.0	2.75	2.69
3.72	12.0	1.0	2.73	2.69

Per-Generic share	Brand share	AG share
15.77	5.41	0.0
10.48	3.16	13.0
9.39	2.72	12.8
8.6	2.29	11.71
7.34	1.9	10.01

Table 4: Market outcomes with changing variance on non-brand's random coefficient.

AG fixed cost	Total generics	AG release fraction	AG price	Generic price
100000.0	4.0	1.0	2.88	2.79
110000.0	4.0	1.0	2.88	2.79
120000.0	4.0	1.0	2.88	2.79
130000.0	4.0	1.0	2.88	2.79
140000.0	5.0	0.01	2.85	2.91
150000.0	5.0	0.0	0.0	2.91
160000.0	5.0	0.0	0.0	2.91

Per-Generic share	Brand share	AG share
18.13	3.67	23.82
18.13	3.67	23.82
18.13	3.67	23.82
18.13	3.67	23.82
15.68	3.06	18.56
19.25	3.75	0.0
19.25	3.75	0.0

Table 5: Market outcomes with changing operating cost of AG.

MC of AG (normalized)	Total generics	AG release fraction	AG price	Generic price
1	4.0	1.0	2.88	2.79
2	5.0	1.0	5.3	2.85
3	5.0	1.0	7.95	2.88

Per-Generic share	Brand share	AG share
18.13	3.67	23.82
18.42	3.6	4.3
18.98	3.69	1.41

Table 6: Market outcomes with marginal cost of AG.

3. Higher variance of the non-brand coefficient σ_1^2 leads to more generics entering, higher AG release probability, and lower prices and market share for generics and AG. See Table 4.

Cost primitives: Next, we see how the market outcomes change as we vary the cost parameters. The takeaways are:

1. Higher fixed cost for AG relative to generics leads to lower likelihood of AG release. Conditional on AG not being released, more generics enter and generic prices are on average higher. Branded drug's market share as well as each generic firm's market share are higher. See Table 5.

2. Higher marginal cost for AG relative to generics leads to higher AG and generic prices and greater generic entry. Price of Ag and generics increase. Market shares of generics and branded drug increase while that of AG declines. AG release is not affected even

Generic entry rate (normalized)	Total generics	AG release fraction
0.75	3.0	1.0
1.0	4.0	1.0
2.0	5.0	1.0
4.0	5.0	1.0
6.0	5.0	1.0

AG price	Generic price	Per-Generic share	Brand share	AG share
2.97	2.85	22.37	4.13	28.76
2.88	2.79	18.13	3.67	23.82
2.82	2.75	15.25	3.38	20.39
2.81	2.74	15.23	3.42	20.43
2.8	2.74	15.22	3.43	20.45

Table 7: Market outcomes with changing FDA approval rates.

after its marginal cost is three times that of generics', but simulations show that at higher marginal costs the AG no longer enters. See Table 6.

Note that over 50% of the markets in our dataset do not see AG released; our counterfactuals suggest that this is primarily because of cost differentials between AG and generics. That is, an AG is more likely to be released in a market where the operating and/or marginal cost disadvantage of the AG relative to the generic is not very large. The previous counterfactuals rule out that the absence of AG could be explained by variation in demand parameters across markets.

ANDA approval rates: As FDA approval rate increases, there is greater generic entry while AG release decision remains unchanged. Average prices of AG and generics drop (even after conditioning on number of total generic entrants). Market shares of AG, brand and individual generics decline. See Table 7.

Intuitively the greater generic entry happens because generics can enter the market earlier, and hence have more time to recoup their entry cost. At certain cost values for the AG, the increase in generic entry rate can stop the AG from entering; for instance, if the generics and AGs have identical costs and the generic approval is close to immediate, then an additional generic entrant not finding it profitable to enter also means the AG will not find it profitable to enter. That is, the generic firms being able to commit by making the first move can stop the AG from being released. This is an interesting implication that we plan to explore more carefully in a future draft.

Ban on Authorized Generic: When AG is banned, there is greater generic entry, and on average the generics charge higher prices. Each generic enjoys higher market share on average, as does the brand. See Table 8.

This result requires a deeper explanation. It turns out that the average price in simulations is higher without the AG than with the AG, even if the total number of nonbrand

Cases	Total generics	AG release fraction	AG price	Generic price	Per-Generic share	Brand share	AG share
Baseline	4	1.0	2.88	2.79	18.13	3.67	23.82
AG ban	5	0.0	0.0	2.91	19.25	3.75	0.0

Table 8: Market outcomes with and without AG ban.

products in both cases are the same. That is, the average price in simulations with 5 generics is higher than the average price in simulations with 4 generics and 1 AG. This happens because of the timing of AG release. Without an AG ban, the AG is released as soon as the first generic enters, so there is always an additional competitor in the market. Without the AG, the generics face lower competition in the initial periods as all the generics slowly gain approval. In both cases the industry price drops to the same level over time, but with the AG this price drops much faster.

7 Conclusion

We study market dynamics and aggregate pricing in the pharmaceutical industry after generic entry. 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 total drug sales and revenue data on US for 2004-2016, we estimate a structural model of drug entry and pricing. Our demand estimation shows that there is significant heterogeneity in price sensitivity and brand valuation among consumers. 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 market. 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. We use this to run counterfactuals. Our first set of counterfactuals involve changing key demand and cost parameters and studying the resulting market outcomes. We find that not releasing an AG is rationalized by the cost differential between the AG and generics being very large. Next, we show that a faster generic approval rate leads to greater generic entry, lower likelihood of Authorized Generic being released, and lower prices. Finally, we study what happens to market outcomes if Authorized Generics are banned, and find that such a ban leads to higher market prices.

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