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

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*Preliminary and Incomplete*

(Link to latest version)

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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. We analyze how 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 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

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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 drugs, which are pioneer molecules protected by patent for 15+ years, ii) generic drugs that are bioequivalent to their branded counterparts. Before patent expiration branded drugs enjoy monopoly power in the market and charge high prices; after its patent expires, generics enter the market and increase competition, leading to lower drug prices. In some cases, branded drug manufacturer responds by releasing a fighting brand, known as an Authorized Generic (AG). AGs are identical to the branded drug but without brand name attached. The motivation behind releasing an AG is that it allows the branded drug manufacturer to price discriminate between consumers with different valuations of the brand label and price level. The pricing patterns that emerge in such markets is often that branded drug prices stay roughly the same, while generics and AGs are priced very low and close to their marginal cost.

Studying such product entry and pricing decisions in pharmaceutical markets is important for several reasons. First, high drug prices have been a source of great controversy in US for many years, and the largest decline in drug prices occur once a branded drug's patent expires. By studying market dynamics after loss of exclusivity, we can better understand the economic incentives in the pharmaceutical industry and craft more targeted policies. 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 with low brand value/low quality and low prices, 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 such fighting brand strategy, the incumbent releases a low brand-value/low quality 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

[1]These fighting brands are commonly observed in the real world. Examples (from Bourreau et al 2021)

only a nascent empirical IO literature looking at this phenomenon.

Using quarterly data on total sales and revenue of pharmaceutical products in US for 2004-2016, we build and estimate a structural model of the pharmaceutical industry in US after the branded drug's loss of market exclusivity. we use this to study entry decisions by generics and Authorized Generics and pricing by all pharmaceutical products.

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 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, 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 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. Second, 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. Third, we show that a faster generic approval rate leads to greater generic entry, but at estimated demand and cost parameters does not lower AG's total payoff sufficiently to discourage its entry. Fourth, we

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).

impose a ban on AG release - a policy discussed by the FTC and generic manufacturers - and find that it leads to greater generic entry but also higher drug prices.

**Related literature and contributions:** 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 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 Authorized Generics 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 any sort of 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 an Authorized Generic. A few other papers have used reduced-form evidence to study AG. Notably, Appelt (2015) uses a recursive bivariate probit regression to show that AG entry does not impact generic entry in Germany.

Third, we add to the literature on generic entry. While many papers have studied generic entry in US, few use structural methods to endogenize 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), and Tenn and Wendling (2014). A nice review of the workings of this industry can be found in Lakdawalla (2018).

# 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. Our discussion borrows from Lakdawalla (2018). A pharmaceutical product can be thought of as going through three stages (insert right citation)

1. Research and Development: A pharmaceutical manufacturer (henceforth branded drug 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. Marketing of branded drug: Once approved, 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. Generic competition: After patent expiration, bio-equivalent 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.

Throughout we refer to the manufacturer that pioneered the molecule as the "branded drug manufacturer" and the pioneer molecule as the "branded drug".

Note that for the pharmaceutical industry, the importance of patent to stop generic entry is more critical than other applications. This is because pharmaceutical products are easy to reverse-engineer and manufacture, and generic firms tend to specialize in doing so. Patents prevent copycat drugs from flooding the market after R$D, allowing monopoly profits to persist and therefore incentivizing R&D in the first place.

## 2.2 Generics and FDA approval

After patent expiration, bioequivalent products called generic drugs enter the market. However, these generic manufacturers need to prove to the FDA that their product is "bioequivalent", which is defined as "product has the same active ingredient, dosage form, strength, route of administration and conditions of use as the listed drug."[2] Generic firms have to give further evidence that they can manufacture the drug properly; this could involve setting up

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

supply chains and equipment, giving factory tours, and creating a sample of the product. As a result, gaining FDA approval is costly.

To gain FDA approval, a generic firm 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 due to the amount of work involved in verifying the evidence as well as because the FDA has a significant backlog of pending ANDA applications. Repeated discussions have happened around giving the FDA more resources to speed up generic approval rates since generic competition directly lowers drug prices. The approval time is also highly stochastic. This is also partly due to the ANDA backlog, and partly because there is back-and-forth between the FDA and generic firm about flaws with the ANDA application and how to correct them. The takeaway is that it is generally very hard for a generic firm to predict when its ANDA will be approved.

Since the branded drug is protected by a patent, and so generic firms do not know exactly how the branded drug is manufactured. Thus, to apply for ANDA, a generic firm needs to reverse-engineer the branded drug and figure out its components, then set up production. Estimates of the cost of ANDA application range from $2 million to $20 million. Starc and Wollmann (2022) estimates this cost for a subset of molecules to be $3.2 million.

In some cases, the generic firm can outsource the exact production of the drug to a Contract Manufacturing Organization (CMO). The generic firm still has to file for and receive an ANDA in this setting. Little is known within the Economics literature about CMOs and their industry structure.

## 2.3 Authorized Generics

In response to generic entry, the branded drug manufacturer can release an Authorized Generic (henceforth referred to as AG). An AG is 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 approval. This is because they are riding on the branded drug's approval from the FDA. The AG is identical to the branded drug in terms of molecule structure and formulation, but does not have the brand label attached.

The general pattern we see is in the data is as follows. After loss of exclusivity, generics enter the market and undercut the brand's price. The branded drug's price does not change much or even increases. In response, an AG is sometimes released 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.

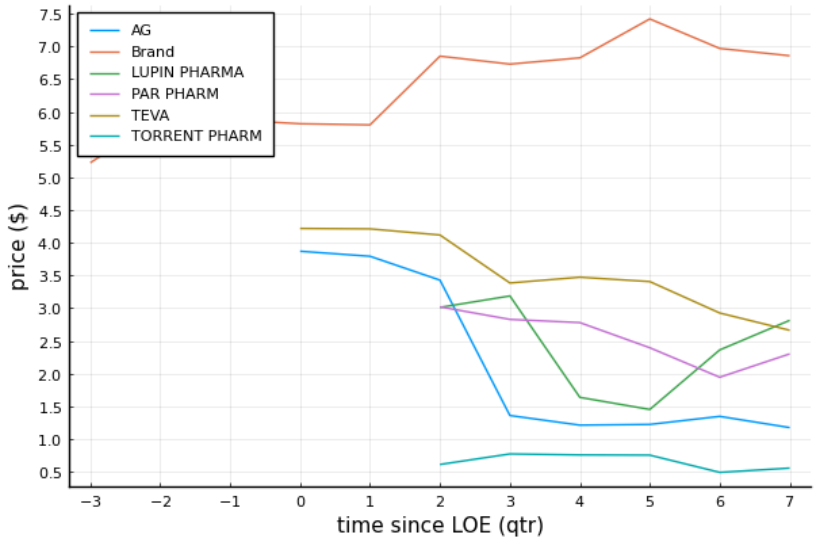


Figure 1: US-average prices for amlodipine-hydrochlorothiazide-valsartan (oral)

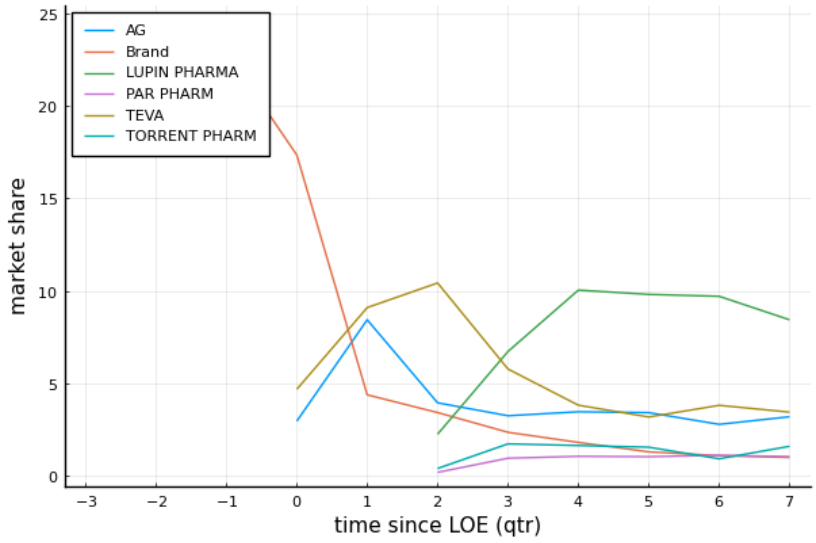


Figure 2: Market shares for amlodipine-hydrochlorothiazide-valsartan (oral)

### 2.4 Additional details

The branded drug's market exclusivity can be over before patent expiration through patent lawsuits by generic manufacturers. In US these lawsuits are called Paragraph IV certifications, and they aim to invalidate a branded drug's patent. A successful Paragraph IV litigation allows the generic manufacturer filing the lawsuit to immediately enter the market, and other generics to also enter after 180 days. Such Paragraph IV litigations sometimes result in pay-for-delay (the branded drug manufacturer pays the generic firm a sum of money to delay entry) or a no-AG settlement (the generic firm delays entry but receives assurance that an AG won't be released in the future). Our paper does not shed light on markets where these Paragraph IV lawsuits and settlements are going on.

## 3 Data

The data for this paper comes from IQVIA and covers drug sales in US for 2004-2016.To fix some notation, a drug's *therapeutic class* describes what broad diagnoses it targets; a drug's *molecule* structure describes the active ingredients present (can be thought of as subset of therapeutic class); and a drug's *formulation* is its method of delivery, e.g. tablet, injectable, etc. For each drug product we see the quarterly sales in US, the revenue generated, the formulation of the product (oral, injectable, or other), and therapeutic class (ATC3). Data on Authorized Generics and Paragraph IV Exclusivity was hand-collected. Sales for a drug-molecule-formulation are aggregated by dosage and strength.

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

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 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 market at 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

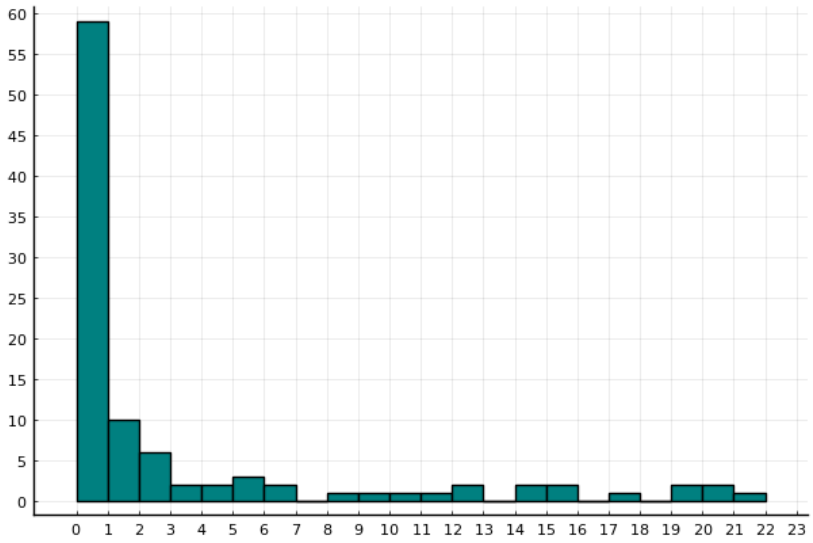


Figure 3: Histogram of time-difference between first generic entry and AG release period.

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. In my data I only look at periods after generic entry, so unlikely that people are switching away from the molecule-formulation I'm studying. Finally, I put in a molecule-formulation fixed effect in my 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 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.

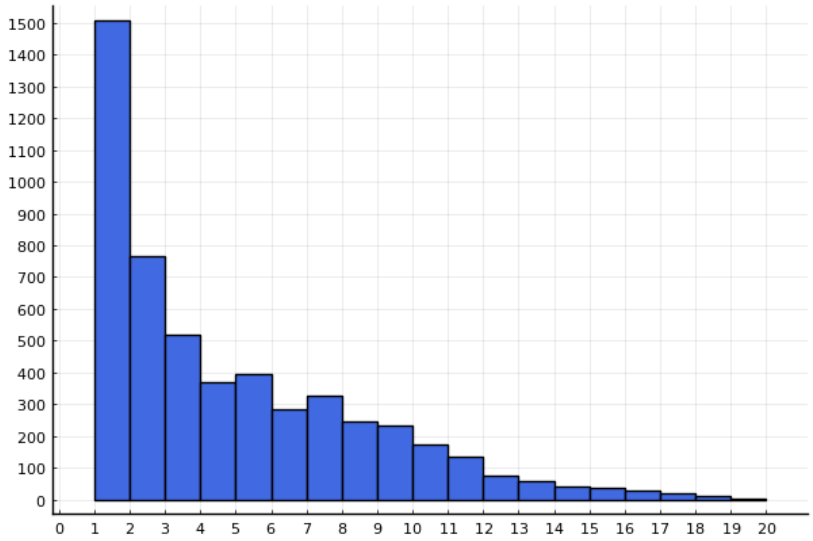


Figure 4: Histogram of count of generics present by molecule-formulation-quarter.

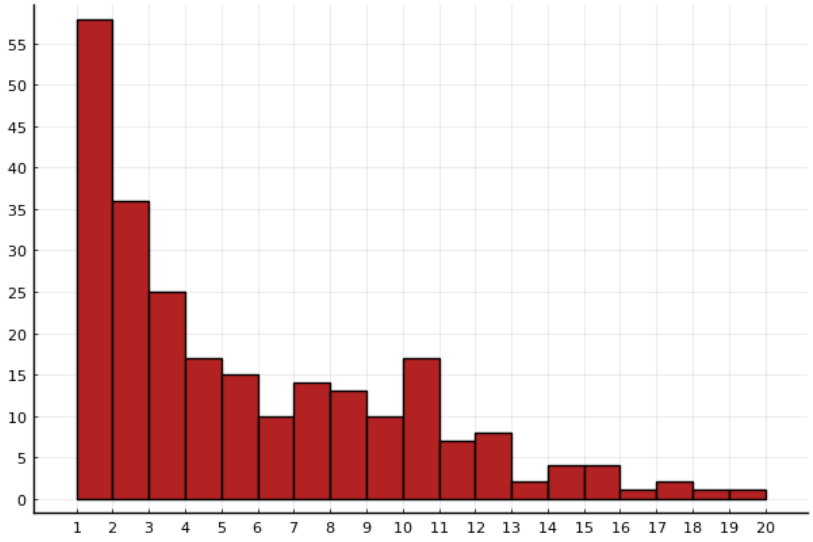


Figure 5: Histogram of total generic entry by molecule-formulation

# 4 Model

## 4.1 Demand

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

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

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 $\xi_{jt}$ allows for unobserved product-specific quality. The variable time-since-loe measures the number of quarters since generic entry, 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 $\alpha_i$ 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 4.3 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). Finally, all the firms set prices and receive payoffs.

### 4.2.1 Per-period payoffs

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

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

where 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, $\phi$ 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 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 patent 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 $\xi_{jt}$ 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 $\kappa_m^g$ denotes the cost of entering molecule-formulation $m$. Note that we allow entry

cost to vary across molecule-formulations.

## 4.3 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 points to 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.[3] The reason is that at the estimated demand parameters the extremely high brand prices cannot be rationalized without also estimating a high marginal cost for the brand relative to the generic. This is a well-known problem with the IQVIA dataset, as has been documented in Arcidiacono et al. (2013).

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.

   Another simplification I 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 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

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

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 should approximate the industry patterns well.

3. Authorized Generic entry as a dynamic game: In our data, while we see that most AGs are released immediately with generic entry, some are released over a year after generic entry begins. This could be happening for several reasons. There could be an economic reason to delay AG release. Alternatively, there could be production delays, or a surprise patent expiration due to lawsuits or unforeseen circumstances.

4. 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. On the supply side,

5. Pay-for-delay and Pay-for-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 pay-for-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.

## 4.4 Estimation and Results

We estimate this using the method of Berry et al. (1995). We use Gandhi-Houde IVs and estimate it using 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

| | 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) |
| RC: Non-brand | 3.381 |
| | (0.092) |
| RC: Price | 0.240 |
| | (0.034) |

Table 1: Results of demand estimation

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 placement in the supply chain. Finally, the brand-specific time trend shows that the brand gets less attractive over time.

The Nash-Bertrand first-order conditions allow us to impute the marginal cost parameters. The rest of the cost parameters are calibrated for the counterfactuals. We set T = 32, meaning that the dynamic game lasts 32 quarters. Generics and AGs 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 counterfactual 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.

| Nonbrand coef | Total generics | AG release fraction | AG price | Generic price |
|---|---|---|---|---|
| -2.4 | 13.0 | 1.0 | 2.74 | 2.69 |
| -2.88 | 11.0 | 1.0 | 2.76 | 2.71 |
| -3.37 | 9.0 | 1.0 | 2.78 | 2.72 |
| -3.85 | 7.0 | 1.0 | 2.82 | 2.75 |

| Per-Generic share | Brand share | AG share |
|---|---|---|
| 6.92 | 0.72 | 9.37 |
| 8.02 | 0.95 | 10.83 |
| 9.54 | 1.28 | 12.84 |
| 11.79 | 1.79 | 15.71 |

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

| 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.

# 5 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:

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 $\alpha$ 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.

| 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.

3. Higher variance of the non-brand coefficient $\sigma_1^2$ 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

| MC of AG (normalized) | Total generics | AG release fraction | AG price | Generic price | Per-Generic share | Brand share | AG share |
|---|---|---|---|---|---|---|---|
| 1 | 4.0 | 1.0 | 2.88 | 2.79 | 18.13 | 3.67 | 23.82 |
| 2 | 5.0 | 1.0 | 5.3 | 2.85 | 18.42 | 3.6 | 4.3 |
| 3 | 5.0 | 1.0 | 7.95 | 2.88 | 18.98 | 3.69 | 1.41 |

Table 6: Market outcomes with marginal cost of AG.

and branded drug increase while that of AG declines. AG release is not affected even 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.

**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 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

| 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.

| Cases | Total generics | AG release fraction | AG price | Generic price |
|---|---|---|---|---|
| Baseline | 4 | 1.0 | 2.88 | 2.79 |
| AG ban | 5 | 0.0 | 0.0 | 2.91 |

| Per-Generic share | Brand share | AG share |
|---|---|---|
| 18.13 | 3.67 | 23.82 |
| 19.25 | 3.75 | 0.0 |

Table 8: Market outcomes with and without AG ban.

AG, the generics face lower competition in the initial periods as the 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.

# 6 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

sets 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.

# References


Appelt, Silvia (2015) "Authorized Generic Entry prior to Patent Expiry: Reassessing Incentives for Independent Generic Entry," *The Review of Economics and Statistics*, 97, 654–666, DOI: 10.1162/REST_A_00488.

Arcidiacono, Peter, Paul B. Ellickson, Peter Landry, and David B. Ridley (2013) "Pharmaceutical followers," *International Journal of Industrial Organization*, 31, 538–553, DOI: 10.1016/J.IJINDORG.2013.10.005.

Berry, Steven, James Levinsohn, and Ariel Pakes (1995) "Automobile Prices in Market Equilibrium," *Econometrica*, 63, 841, DOI: 10.2307/2171802.

Bhattacharya, Jayanta and William B. Vogt (2003) "A simple model of pharmaceutical price dynamics," *Journal of Law and Economics*, 46, 599–626, DOI: 10.1086/378575.

Bokhari, Farasat A.S. and Gary M. Fournier (2013) "ENTRY IN THE ADHD DRUGS MARKET: WELFARE IMPACT OF GENERICS AND ME-TOO'S," *The Journal of industrial economics*, 61, 339–392, DOI: 10.1111/JOIE.12017.

Bokhari, Farasat A.S., Franco Mariuzzo, and Arnold Polanski (2020) "Entry limiting agreements: First-mover advantage, authorized generics, and pay-for-delay deals," *Journal of Economics and Management Strategy*, 29, 516–542, DOI: 10.1111/JEMS.12351.

Bourreau, Marc, Yutec Sun, and Frank Verboven (2021) "Market Entry, Fighting Brands, and Tacit Collusion: Evidence from the French Mobile Telecommunications Market," *American Economic Review*, 111, 3459–99, DOI: 10.1257/AER.20190540.

Ching, Andrew T. (2010) "A dynamic oligopoly structural model for the prescription drug market after patent expiration," *International Economic Review*, 51, 1175–1207, DOI: 10.1111/j.1468-2354.2010.00615.x.

Dubois, Pierre, Ashvin Gandhi, and Shoshana Vasserman (2022) "Bargaining and International Reference Pricing in the Pharmaceutical Industry," 2020, DOI: 10.3386/W30053.

Ellison, Glenn and Sara Fisher Ellison (2011) "Strategic Entry Deterrence and the Behavior of Pharmaceutical Incumbents Prior to Patent Expiration," *American Economic Journal: Microeconomics*, 3, 1–36, DOI: 10.1257/MIC.3.1.1.

Frank, Richard G. and David S. Salkever (1992) "Pricing, Patent Loss and the Market for Pharmaceuticals," *Southern Economic Journal*, 59, 165, DOI: 10.2307/1060523.

Frank, Richard G. and David S. Salkever (1997) "Generic Entry and the Pricing of Pharmaceuticals," *Journal of Economics and Management Strategy*, 6, 75–90, DOI: 10.1111/J.1430-9134.1997.00075.X.

Gallant, A. Ronald, Han Hong, and Ahmed Khwaja (2017) "The Dynamic Spillovers of Entry: An Application to the Generic Drug Industry," *https://doi.org/10.1287/mnsc.2016.2648*, 64, 1189–1211, DOI: 10.1287/MNSC.2016.2648.

Johnson, Justin P. and David P. Myatt (2003) "Multiproduct Quality Competition: Fighting Brands and Product Line Pruning," *American Economic Review*, 93, 748–774, DOI: 10.1257/000282803322157070.

Lakdawalla, Darius N. (2018) "Economics of the Pharmaceutical Industry," *Journal of Economic Literature*, 56, 397–449, DOI: 10.1257/JEL.20161327.

Morton, Fiona M. Scott (1999) "Entry Decisions in the Generic Pharmaceutical Industry," *The RAND Journal of Economics*, 30, 421, DOI: 10.2307/2556056.

Reiffen, David and Michael R. Ward (2005) "Generic drug industry dynamics," *Review of Economics and Statistics*, 87, 37–49, DOI: 10.1162/0034653053327694.

Reiffen, David and Michael R. Ward (2007) "Branded generics' as a strategy to limit cannibalization of pharmaceutical markets," *Managerial and Decision Economics*, 28, 251–265, DOI: 10.1002/MDE.1339.

Starc, Amanda and Thomas Wollmann (2022) "Does Entry Remedy Collusion? Evidence from the Generic Prescription Drug Cartel," *SSRN Electronic Journal*, DOI: 10.2139/SSRN.4076263.

Tenn, Steven and Brett W. Wendling (2014) "Entry threats and pricing in the generic drug industry," *Review of Economics and Statistics*, 96, 214–228, DOI: 10.1162/REST_a_00382.