Estimating Competitive Effects in Firm Entry with Applications in the Generic Pharmaceutical Industry

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Abstract

Rising health care costs are of significant public concern. A sizable portion of these costs stems from the prescription drug industry, which accounted for 12% of US health care spending ($234 billion) in 2008. Price competition between generic pharmaceutical companies should, in theory, reduce costs, but insufficient market entry by generic firms may keep drug prices high. Thus, I seek to understand the factors that influence generic entry decisions; specifically, I examine how firms make entry decisions based on expectations of competitor entry. I demonstrate that a simple logistic regression fails to properly identify this competitive effect because entry decisions between players are simultaneously determined. Instead, I model entry as a static game of incomplete information. This results in a negative coefficient on competitor entry that lowers a firm's equilibrium entry probability by 10% on average for each additional competitor. I apply the resulting structural model to predict the effect of a direct subsidy (or tax) on firm entry and show that firm entry is relatively inelastic to subsidies and taxes, compared to predictions from the logit model.

1 Introduction

Rising health care costs are of significant public concern. The costs associated with the prescription drug industry are especially salient for policymakers, as prescription drugs accounted for 12% of US health care spending in 2008 [Berndt and Newhouse 2010].

In theory, an increase in the use of generic drugs (cheaper copies of brand-name prescription drugs) should help to reduce overall drug expenditures. However, drug expenditures have grown significantly, from $25 billion in 1970 to over $234 billion in 2008[1], despite simultaneous growth in the use of generics (from 19% of prescriptions in 1984 to 67% in 2007) [Huckfeldt and Knittel 2011].

Understanding how pharmaceutical markets behave is thus integral to addressing the issue of rising health care costs. One potential explanation for these rising costs may stem from lack of price competition between the generic firms themselves. This, in turn, may be a result of insufficient entry by these firms into certain drug markets. A potential deterrent to entry could be expected competition with other firms. This "competitive effect" may be of interest to policymakers as it describes an important factor of entry decisions. These decisions in turn determine the level of competition, (and thus prices and expenditures), in a drug market. However, competitive effects are challenging to identify, since markets with many firms (and therefore more competition) are usually profitable for a myriad reasons unobservable to the econometrician.

I study the factors that affect a generic firm's entry decisions. I first estimate a simple linear regression that highlights the importance of market size on entry. Then, I model firm entry as a static discrete-choice game of incomplete information; from this, I estimate a structural parameter Δ that describes the effect of expected competition in a market. I determine that the expectation of one additional competitor reduces the probability of entry by 10% on average, which is comparable to a $540 million decrease in market size. I show that market size remains important, with an average marginal effect of 18.4% per $1 billion in additional market revenue. Firm size, measured

[1] (both figures in 2008 dollars)

as annual revenue, plays a somewhat muted role in entry.

Lastly, I conduct a counterfactual analysis using the structural model to predict how firm entry reacts to government subsidies (or taxes) on entry, applied over all firms. I find that subsidies increase the expected total entry in a drug market (on average), but by a smaller amount than predicted by a less-sophisticated model (in this case, a naïve logistic regression that treats competitor entry as exogenous).

The following sections introduce the generic pharmaceutical industry (section 2), prior study on generic entry (section 3), motivate the empirical approach and specify the discrete game models (sections 4 & 5), describe the data (section 6), and discuss results (section 7). I conclude by applying the estimated model to predict the effects of a policy change (section 8).

2 Background on the Generic Pharmaceutical Industry

The pharmaceutical industry is uniquely complex from a regulatory and intellectual property perspective. The traditional model of a brand name pharmaceutical company is as follows: the company invests capital into research and development for a new drug, which includes developing the drug itself, performing clinical trials, and (in the United States) receiving approval of a "new drug application" (NDA) from the Food and Drug Administration (FDA). The total cost of bringing a new medical entity to market has been estimated to be above $1 billion (in 2007) [Danzon and Nicholson 2012].

However, once a drug has been invented and approved, it typically costs very little to produce it on a large scale. Thus, the pharmaceutical industry is characterized by high, one-time innovation costs and low marginal costs. In this regime, intellectual property protection, in the form of patents, is important for incentivizing innovation, as it allows innovating firms to recoup their development costs.

Patents provide an opportunity for the innovator firm to monopolize a drug market for a defined period of time. Although this allows the firm to recoup its costs, the government has an

interest in allowing competition to decrease prices when patents expire. This competition takes the form of "generic" firms who enter drug markets with a copy of the branded drug at a lower price.

The modern regulatory environment for approving generic versions of branded drugs came into existence with the 1984 Hatch-Waxman Act. This act allows drug companies to submit "abbreviated new drug applications" (ANDAs) instead of NDAs to produce generic versions of off-patent drugs. It abolished the need to perform clinical trials for ANDAs; instead, generic versions must be shown to be "bioequivalent" (have the same effect in patients) to the branded drug [FDA 2012]. The ANDA is a simplified approval pathway that reduces the entry cost greatly — down to $2-5 million for typical small molecule drugs [Berndt and Newhouse 2010].

Generic entry has the potential to generate welfare gains in the form of reduced prices for drugs. In a basic sense, as drug patents expire, generic companies can begin to produce drugs alongside the brand name (or innovator) drug. This competition will, in theory, push prices down and reduce the acquisition cost of medicines. Empirical studies support this — drug markets with more generic entrants have lower prices [Berndt and Newhouse 2010]. In these markets, generic prices may be 80-85% lower than branded versions [FDA 2012].

Under ideal conditions, firms will be incentivized to innovate and develop new drugs, while older drugs become cheap and accessible due to generic entry. In practice, however, drug markets may see few generic entrants and prices may remain high. I seek to examine the factors that determine the set of generic firms that initially enter drug markets, a mechanism that determines the initial competitive landscape of off-patent drugs.

3 Prior Work on Generic Entry and Entry Games

The decision of whether to enter the market for a particular drug is complex and strategic, and the factors that influence firms' entry decisions are not fully understood.

Early work on estimating simultaneous entry games and the role of competition includes the 1991 paper on discrete games by Bresnahan and Reiss. This paper discusses the problem of

multiple equilibria when estimating entry games, and resolves it by transforming the model to predict the total number of entrants rather than the entry decisions of each individual firm. But although information on total entry is desirable, many of these models assume that competing firms are identical, which is unlikely to be true for most markets [Scott Morton 1999].

Berry 1992 studies entry in the airline industry and models both total entry as well as the identity of the entrants in a particular market. However, the Berry model assumes a sequential entry pattern, where firms enter one after another. In contrast, entry in the generic pharmaceutical industry is better described as a one-shot simultaneous game, for reasons that I discuss further alongside my model in Section 4.

In the generic pharmaceutical industry, larger markets have been documented to support more generic entrants [Scott Morton 1999; Olson and Wendling 2013]. Moreover, Scott Morton 1999 provides an examination of how heterogeneity between potential entrants can be used to identify which firms are likely to enter a particular market. She finds that firms tend to enter markets for drugs that are similar to those for which they have previous experience. This idea of specialization is explored further by Hong, Khwaja, and Gallant 2010, who estimate a dynamic model of complete information that demonstrates that experience in a drug market can reduce a firm's cost of entering a similar market in the future by 7% on average.

This body of prior work supports an interpretation that specialization allows firms to mitigate the risk of over entry (a phenomenon where multiple firms enter the same market and all make reduced profits). This is consistent with firms that form expectations on rival entry when making their own entry decisions.

My approach models generic entry as a discrete-choice, static game of incomplete information. It builds upon the substantial literature on theory and estimation of discrete choice games [Bresnahan and Reiss 1991; Tamer 2003; Aradillas-Lopez 2010; Sweeting 2009; Su and Judd 2012]. Like Scott Morton 1999, my model is static and allows for firm heterogeneity (albeit a more basic measure that only accounts for differences in firm revenue), includes market size as an important regressor, and assumes that entry decisions are made simultaneously across firms in a one-shot

game for each market. However, Scott Morton uses a probit model that does not include other firms' entry decisions, and focuses on studying the firm characteristics that determine selection into markets. In contrast, I explicitly estimate the competitive effect in a discrete game model, and focus less on firm heterogeneity.

Unlike Hong, Khwaja, and Gallant 2010, I assume that firms only have incomplete information about their competitors. This assumption not only simplifies the estimation procedure [Magnolfi 2016], but is reasonable in the context of the generic pharmaceutical industry, where firms may have limited information about the internal profit shocks of their competitors. My model is also static rather than dynamic.

In short, I picture generic firms making independent entry decisions for each market, based on imperfect expectations of their opponents' actions in that market. A substantial literature exists on the estimation of these games [Su and Judd 2012; Su 2014; Vitorino 2011].

By modeling entry decisions endogenously, I am able to estimate a structural parameter that represents the effect of competitive entry on a firm's profits, based on the method described in Su 2014 and similar to empirical work carried out in Vitorino 2011. This allows me to establish the importance of competition relative to other factors such as market size. To my knowledge, no previous papers have applied this model and estimation technique to compute competitive effects in the generic pharmaceutical industry.

4 Empirical Approach and Model Motivation

In this section, I outline my empirical approach and the institutional motivation for my final discrete game model. First, I seek to establish a reduced-form relationship between a market size proxy (branded revenue in the year preceding generic entry) and total entry in a drug market (section 4.1). This treats all firms as identical, and simply seeks to demonstrate that market size is an important determinant of total generic entry.

Next, I model generic entry as a static game of incomplete information played between firms

(section 4.2), where the entry decision of one firm depends on the equilibrium entry decisions of its competitors. I estimate the structural parameter (Δ) on the expected entry of a competitor, which I interpret as a "competitive effect": the effect of expected competition on a firm's entry decision.

4.1 Market-level Entry with Identical Firms - Linear Regression

I first estimate the following reduced-form linear regression model of total entry that depends only on market size and controls.

For M independent markets, I estimate:

$$Y_m = \beta_0 + \beta_1 log(sumSales_m) + \mu$$

where Y_m is a measure of total entry in market m for $m = 1, ...M$. I examine two definitions for entry: Y_m = total number of ANDAs approved within the first two years of generic entry (tot_entry) and Y_m = total number of drug products (numproducts) that are approved as a result of these ANDAs.

For the purposes of this regression, I treat all firms as identical, an assumption that I will relax for the discrete game model to follow. To measure market size, I use the log revenue of the branded version of a drug prior to generic entry, in USD billions (lsumSales_bil). As discussed in Scott Morton 1999, measures of market size are the most important predictors of total entry, and a significant positive relationship between market size and total entrants would be consistent with the notion that competitive effects are important in determining which firms enter in equilibrium. Put another way, if market size is an important determinant of total entry, then markets may be limited in how many firms they can accommodate, implying a competitive landscape.

4.1.1 Identification of the Market Size effect

I make the common assumption that revenue for the brand-name drug in the year before generic entry (lsumSales) is exogenous [Scott Morton 1999]. Brand-name drug revenue measured after entry is clearly endogenous, since generic entry greatly reduces the market share of the branded

drug. However, we may more plausibly assume that generic firms treat branded revenue before the first entrant (before patent expiration) as given.

4.2 Firm-Market Entry with Heterogeneous Firms - Discrete Game

In the generic pharmaceutical industry, strategic entry is crucial to firms, and is characterized by competition in the context of limited information, heterogeneous firms, and simultaneous actions. This segment outlines the theoretical basis for representing entry as a static game of incomplete information. I then formulate the model mathematically in Section 5.

Each additional competitor results in both lower (generic) prices as well as reduced market share for each firm [Frank and Salkever 1995; Huckfeldt and Knittel 2011; Olson and Wendling 2013], assuming that market sizes do not expand greatly due to generic entry. Thus, firms must strategize against competitors' expected actions. Moreover, if firms do not have complete information on their opponents' types (which could include costs or profitability information in a particular market), then the entry decision carries a risk of "over entry," where the entrant realizes negative profits, or "ex-post regret."

The existence of ex-post regret is a critical consequence of the incomplete-information framework, because it follows from the probabilistic determination of firm strategies. I believe the existence of ex-post regret is plausible as market entry strategies (and the associated research and development required) are typically private information. Anecdotes from working industry professionals reveal that, for example, a merger between two firms may uncover hidden plans for entry into the same market (which, post-merger, implies much wasted effort). This private information should result from profit determinants that are unknown to both competing firms and the econometrician. For example, elements of managerial vision and ability is often unknown to both other firms as well as the researcher.

In the real-world, pharmaceutical companies are not identical, and heterogeneity is an important determinant of which firms enter a particular drug market. I model heterogeneity by including a revenue measure of firm size (firm_revenue) in the model.

Due to the nature of FDA applications, the entry game is static. This is because the FDA does not release information on pending applications to anyone. Thus, firms must choose their actions without knowing what their competitors have decided. Because the process of ANDA approval requires a considerable amount of time, firms that wish to begin marketing right after patent expiration must begin applying (and paying the associated fixed cost) up to three years prior to patent expiration [Scott Morton 1999]. Firms either enter or not, so the action set of the game is discrete.

Given these institutional characteristics, the entry decision that a generic firm faces can be reasonably modeled as a static, discrete-choice game of incomplete information.

4.2.1 Identification of Competitive Effects & a Naïve Logit Regression

We cannot directly include other firms' entry decisions (other_entry) as an explanatory variable because it is endogenously determined. If we were to treat this endogenous variable as exogenous, we would simply recover a correlation between other firms' entry and favorable (large) markets. This effect can be seen in a naïve logit specification, formulated below for P players and M markets and estimated for comparison purposes in the Results section.[2]

$$\Pr(y_i^m = 1) = \Pr(\beta X_i^m + \Delta \times \sum_{j \in P | j \neq i} y_j^m) \qquad \text{for } i \in P \text{ and } m \in M$$

Where X_i^m is a vector of observed information about firm i in market m.

I avoid the problem of endogenous determination by modeling entry decisions in an equilibrium between players, as in the following section, where the model is simplified to two players. This results in a well-studied model of entry akin to those presented in Tamer 2003; Su and Judd 2012; Vitorino 2011; Su 2014.

[2]Firms do not observe the realized decisions of competitors when they decide whether to enter, so the naïve logit results I present are not realistic, but instead serve as a case of what the econometrician should avoid.

5 Model

We consider the following setup for the entry game, simplified to two players (the set of players $P = \{1, 2\}$) in one market. We denote the firms' entry decisions (action set) as y_1 and y_2, such that:

$$y_i = \begin{cases} 1 \text{ if firm } i \text{ enters,} \\ 0 \text{ otherwise.} \end{cases} \quad \text{for } i = 1, 2$$

I assume that a firm has deterministically zero profit if chooses not to enter. Thus, the *ex-post* payoffs (profit functions) of firms 1 and 2 have the following form:

$$\begin{aligned} y_1^* &= \beta X_1 + y_2 \Delta + \epsilon_1 \\ y_2^* &= \beta X_2 + y_1 \Delta + \epsilon_2 \end{aligned} \tag{1}$$

Where X_1 is a vector of observed information about firm 1 in the market and ϵ_1 is firm 1's unobserved information (X_2, ϵ_2 defined similarly). This specification of profits is consistent (though not equivalent to) a model of Cournot post-entry competition; entering firms determine quantity by capturing market share, and price tends to fall steadily with each additional firm (despite homogeneous products) rather than reach competitive pricing, as a Bertrand model might predict [Scott Morton 1999; Frank and Salkever 1995]. Across my specifications, I include variables for firm size (firm revenue) and market size (market revenue) in the $X_i's$, along with a constant (bias term). The unobserved information ϵ_i may consist, for example, of shocks to investment or private information on corporate strategy. We wish to estimate the structural parameters β, a vector of coefficients on X_i, and Δ, the effect of a competitors' entry on profits.

Note that a firm's profit from entry depends on the entry decision of its competitors. We assume that X_1 and X_2 are common knowledge among firms and observed by the econometrician, but that ϵ_1 and ϵ_2 are private information and i.i.d. Additionally, we assume that firm 1 knows the distribution of ϵ_2 and vice-versa. Thus, each firm forms a probabilistic belief about what its competitor will do. We denote firm 1's belief of firm b's probability of entry as $p_2 \in [0, 1]$. We can

then rewrite firm 1's *expected* profit as:

$$
\begin{aligned}
U_1(y_1, X_1, \epsilon_1) &= \begin{cases} p_2(\beta X_1 + \Delta + \epsilon_1) + (1 - p_2)(\beta X_1 + \epsilon_1) & \text{, if } y_1 = 1, \\ 0 & \text{, otherwise.} \end{cases} \\
&= \begin{cases} \beta X_1 + p_2 \Delta + \epsilon_1 & \text{, if } y_1 = 1, \\ 0 & \text{, otherwise.} \end{cases}
\end{aligned} \tag{2}
$$

We see that firm 1 will enter if and only if:

$$\beta X_1 + p_2 \Delta + \epsilon_1 > 0$$

We make the additional assumption that the errors ϵ_1 and ϵ_2 each follow a logistic distribution, such that the cumulative density function $F(\epsilon) = \frac{\exp(\epsilon)}{1+\exp(\epsilon)}$. This allows us to write the probability that firm 1 enters in terms of p_2:

$$
\begin{aligned}
p_1 &= \Pr(y_1 = 1) \\
&= \Pr(\beta X_1 + p_2 \Delta + \epsilon_1 > 0) \\
&= \Pr(\epsilon_1 > -\beta X_1 - p_2 \Delta) \\
&= \Pr(\epsilon_1 \leq \beta X_1 + p_2 \Delta) \qquad \text{by symmetry of the logistic pdf} \\
&= \frac{\exp[\beta X_1 + p_2 \Delta]}{1 + \exp[\beta X_1 + p_2 \Delta]} \\
&= \frac{1}{1 + \exp[-\beta X_1 - p_2 \Delta]} \equiv \Psi_1(p_1, p_2, X_1; \beta, \Delta)
\end{aligned} \tag{3}
$$

Here, $p_1 = \Psi_1(p_1, p_2, X_1; \beta, \Delta)$ is interpreted as the *best response function* of firm 1 given its belief p_2. The pair of beliefs (p_1^*, p_2^*) that are the *mutual* best responses of firms 1 and 2 will then form a *Bayes-Nash equilibrium*, which is determined by the following nonlinear set of equations:

$$
\begin{aligned}
p_1^* &= \frac{1}{1 + \exp[-\beta X_1 - p_2^* \Delta]} = \Psi_1(p_1^*, p_2^*, X_1; \beta, \Delta) \\
p_2^* &= \frac{1}{1 + \exp[-\beta X_2 - p_1^* \Delta]} = \Psi_2(p_1^*, p_2^*, X_1; \beta, \Delta)
\end{aligned} \tag{4}
$$

We assume that the data are generated by this type of equilibrium, which in turn must

satisfy the two *BNE constraints* above. We note that multiple solutions (pairs of p_1^* and p_2^*) may satisfy (4). An example of multiple equilibria in the simple case above can be found in [Su 2014].

5.1 Final Static-game Model with M Markets and P Firms

Because our data include many markets and firms, we would like to generalize the above model to accommodate M markets and P firms (for our empirical estimation, M=102 and P=14). As in Su 2014, two markets are different if they are associated with different observed types. For example, (X_1^m, X_2^m) represent the observed types of firm 1 and 2 in market m for $m = 1, ...M$. In our analysis, the observed firm information is 2014 revenue, and the observed market information is market size as defined in Section 4.1.1 (Identification of the Market Size Effect).

The vector of structural parameters (β, Δ) remains the same throughout markets, and we assume that firm decisions are independent across markets. Different observed types can thus not only lead to different equilibria, but may support different numbers of equilibria for each market [Su and Judd 2012; Su 2014].

Assuming that each additional competitor contributes a constant Δ to the ex-post profit of a firm, we can rewrite the ex-post profit of firm i in market m as:

$$y_i^{m*} = \beta X_i^m + \Delta \times \sum_{j \in P | j \neq i} y_i^m + \epsilon_i^m \tag{5}$$

Modifying the above two-firm example from Su 2014, we can see that each market has a set of P BNE constraints with the following form:

$$p_i^m* = \frac{1}{1 + \exp[-\beta X_1 - \Delta \sum_{j \neq i} y_i^{m*}]} = \Psi_i^m(p_i^*, p_{(j \neq i)}^*, X_i; \beta, \Delta) \quad \text{for } i = 1, ..., P \tag{6}$$

If the observed decisions y_i^m of firm i in market m were generated by solutions to the BNE constraints above, then we can formulate the log-likelihood function for observing these decisions in terms of the equilibrium entry probabilities p_i^{m*}. Equation 7 below gives the overall likelihood of observing the data for all M markets and P firms in the data at the parameters $\theta = (\beta, \Delta)$,

modified from Su 2014.

$$L(\text{data};\theta) = \sum_{m=1}^{M}\sum_{i=1}^{P}\left[y_i^m \times \log(p_i^{m*}(\theta)) + (1-y_i^m)\times\log(1-p_i^{m*}(\theta))\right] \tag{7}$$

5.2 Identification and Multiple Equilibria

With reference to the parallel discussion in Vitorino 2011, the conditions for nonparametric identification of the structural parameters of my model are as follows.

5.2.1 Conditions for identification

For identification of the expected profit functions, I **assume that the error terms in the profit functions are distributed i.i.d. Type-I extreme value across both actions and players.**[3] The assumption of independence of errors between players is a limitation of this model, as we can imagine unobserved market characteristics that affect all players considering entry into that market. In addition, I normalize the deterministic part of no-entry profits to zero [Bajari et al. 2010]. Successful identification of the profit function parameters also requires exclusion restrictions, which I satisfy by including a firm-specific profit shifter (firm size measured by annual firm revenue) [Vitorino 2011].

5.2.2 Assumption regarding multiple equilibria

Because each market may support multiple Bayes-Nash equilibria, I **assume that only one equilibrium is played in the data** for each market, although firms may play different equilibria across markets. This assumption is common in the literature; see, for example, Vitorino 2011; Su 2014; Bajari et al. 2010.

[3]Note that in equation 2, the error terms for each firm, ϵ_i, are distributed i.i.d. standard logistic, which is equivalent to including separate Type-1 extreme value error terms for both entry and non-entry, since the difference between two i.i.d. Type-1 extreme value random variables is distributed standard logistic [Train 2002].

5.3 Estimation Procedure

I use the constrained-optimization procedure described in [Su 2014] to estimate the structural parameters (β, Δ) by maximum-likelihood (ML). This optimization method expresses the log likelihood function as a continuous objective function of the equilibrium p's, coupled with the set of BNE constraints. In most cases, this method bears favorable finite-sample properties compared to other estimators including the two-step pseudo maximum-likelihood estimator, two-step least squares, and the nested pseudo-likelihood estimator; an in-depth discussion of these properties can be found in Su 2014. I modify code from Su 2014 to express the desired optimization problem in AMPL and call the solver KNITRO to solve the resulting nonlinear optimization problem, using the publicly-available NEOS server ["The NEOS Server"; Dolan 2001; Gropp, W. and Moré 1997]. I run the program for >100 sets of initial parameter values, and select the set of estimated parameters to which the program most frequently converges.

Standard errors are estimated by the bootstrap method as described in [Efron and Tibshirani 1986]. I run the estimation procedure on 500 re-sampled datasets, under the assumption that our original sample of 102 markets is representative of the population distribution. This may not be true, as the markets I observe are biased toward drugs with high revenue. However, because I also limit the universe of firms to the top 14 firms by entry in these markets, it becomes reasonable to assume that my data is representative of the population distribution of markets that the most productive firms consider entering.

6 Data

I conduct my analyses on generic entry and revenue data for ANDAs approved between 2004 and 2014 for high-revenue drugs. I incorporate data from three sources: entry data from the FDA publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the Orange Book; market revenue data from the *Top 100 Drugs* list from Drugs.com (which reproduces these statistics from the IMS health (Midas) database; and firm revenue data for a

subset of generic pharmaceutical companies from various sources that I document in Appendix C.

The Orange Book contains information on all FDA-approved drugs in the United States, including active ingredient(s), dosage form, route of administration, trade name, applicant firm, strength, application type (NDA or ANDA), and approval date. Using this dataset, I track each instance of generic entry. Because the Orange Book does not track patent expiration dates, I use the approval date of the first generic entrant (first_generic_date) as a proxy for the patent expiration date, under the assumption that the first generic entrant is approved very shortly after expiration. (I manually confirm this for a few prominent cases.)

The data from Drugs.com provide revenue figures for the top 100 (or 200, in some years) drugs by sales for each year from 2003 to 2013. I use these data to define a measure of market size (sumSales_bil, described in Section 4.1.1).

6.1 Constructing the Market-level Dataset for Linear Regression

For the purposes of estimating the linear regression in Section 4, I construct a dataset at the drug market level that contains measures of total entry (the realized number of entrants in each market), and market size, summarized in Table 1.

I define a generic drug market at the level of its active ingredient. This is a relatively coarse definition compared to the legal definition of a generic drug, which considers a unique drug to be a combination of active ingredient, dosage form, route of administration, and strength. This coarser definition is required because I can only access market revenue data at the ingredient level. Defining a drug market by its active ingredient is a natural simplifying assumption, since we would like to consider innovation in terms of novel compounds rather than producing different formulations. Appendix A gives examples of entry profiles at the ingredient level.

I construct this dataset as follows. The Orange Book dataset is first merged with the revenue dataset based on the drug's trade name. This identifies the ingredients for which I have any revenue information (285 unique markets). The dataset is then collapsed to the application level; each ANDA or NDA is given alongside its approval date, allowing me to pinpoint the first

Table 1: Summary of Linear Regression Dataset and Variables

Number of markets with any revenue data				285
. .Markets with no entrants				74
. .Markets with at least one entrant				211
. . . .Markets with revenue data in the year preceding generic entry*				114
Market Variables	mean	sd	min	max
rank	80.494	56.355	2	200
sumSales (billions USD)	1.022	1.063	0.134	5.502
log sumSales (billions USD)	-0.426	0.960	-2.013	1.705
year first generic entered	2008.281	2.952	2004	2014
Dependent Variables				
total generic entry	8.991	9.071	1	58
total generic products	22.289	25.293	1	125
log total generic entry	1.676	1.102	0	4.060
log total generic products	2.410	1.267	0	4.828

N = 114 for all variables

*Only markets with generic entry starting between Jan 1, 2004 and Jan 1, 2015 are considered.

Total generic entry: ANDAs approved within 2 years of the first generic entrant.

Total generic products: the number of drug products accounted for by the approved ANDAs (each ANDA may cover multiple products).

case of generic entry in each ingredient/market. This returns 211 markets with at least one generic entrant, and 74 without generic entry. Because I cannot observe pre-generic-entry revenue for these 74 markets, I must drop them, a potential source of selection bias that I discuss in Appendix B.

This dataset is then merged with the revenue data, this time by ingredient, to finalize the working dataset. Because some drugs are only in the top 100 or 200 for a subset of the years from 2003 to 2013, some of the 156 markets are missing revenue data. Thus, the final dataset includes the 114 drug markets with revenue data and at least one generic entrant. I summarize this dataset in Table 1.[4]

[4]In cases where two or more trade names map to the same ingredient (i.e. when two different branded drugs, with minor differences in formulation, appear individually in the revenue data), I calculate the mean, max, and sum of the revenues for these trade names and choose one for analysis. My results are robust to this choice, so I will report analyses in terms of the sum (or total) revenue per ingredient.

6.2 Constructing the Firm-Market-level Discrete Game Dataset

Next, I construct a dataset at the firm-market level, limiting the dataset to the top 14 firms by generic entry. These firms represent the set P of potential entrants in each market. At least one of these firms enters each of 102 out of the 114 markets included in the market-level dataset. Table 2 summarizes the relevant variables in the entry-game dataset.

Table 2: Summary of Static Entry Game Dataset and Variables

Number of markets				102
Number of firms				14
Total entry opportunities				1428
Market Variables	mean	sd	min	max
rank	72.709	52.654	2	194
sumSales (billions USD)	1.110	1.085	0.1336	5.502204
year first generic entered	2008.363	2.997	2004	2014
Dependent and Firm Variables				
entry in a firm-market	0.353	0.478	0	1
total entry in a market	4.941	3.428	1	14
firm revenue	3.217	2.757	0.65	9.1

N = 1428 for all variables

The top 14 firms by generic entry are assumed to have entry opportunities in every market for which there is at least one top-firm entrant.

Table 2 summarizes the dataset that is used to estimate the discrete game. The set of 1428 entry opportunities is the Cartesian product between the set of 102 markets and 14 players. We see that the average probability of entry in a firm-market is 35%, and the total number of generic firms that enter a market is about 5 on average, though this ranges from 1 to 14. We see that market sizes range from $134 million to $5.50 billion USD.

I use a natural break in the number of markets entered per firm to decide the set of players (all 14 of my selected firms enter at least 20 markets each, accounting for 62.8% of the total entry in my sample, and the next most productive firm only enters 15 markets).

Although I am unable to examine a broad set of firm characteristics, I do differentiate firms by their size (firm revenue), which may have implications for a firm's capacity for investment, manufacturing, and distribution [see Appendix C for more details].[5]

[5]I do not include all 105 firms in my data (firms that enter at least one market) because smaller firms may not be plausible potential entrants for all 102 markets, and are unlikely to factor into the entry decisions of much larger firms. On the other hand, these omitted firms do account for 47.2% of entry, so one might consider lumping them together as one entity. This is reasonable yet also problematic, since this entity would become the largest firm, even

7 Results

7.1 Linear Regression Results (market level)

Results from the linear regression of total entry on market size (described in Section 4.1) are presented in Table 3.

Table 3: Linear regression results: total entry vs. market size

	(1)	(2)	(3)	(4)
VARIABLES	tot_entry	numproducts	tot_entry	numproducts
log_sumSales_bil	2.956***	11.35***	3.568***	13.15***
	(0.848)	(2.247)	(0.870)	(2.301)
first_generic_year			-0.759***	-2.102***
			(0.286)	(0.756)
later_NDA			0.115	-1.914
			(1.706)	(4.514)
Constant	10.25***	27.12***	1,535***	4,251***
	(0.887)	(2.351)	(574.0)	(1,519)
Observations	114	114	114	114
R-squared	0.098	0.185	0.155	0.239

Standard errors in parentheses
*** p<0.01, ** p<0.05, * p<0.1

a. The dependent variables tot_entry and numproducts are defined as the total number of ANDAs and drug products (respectively) approved within two years of the first entrant in a particular drug market. A drug market is defined by a unique ingredient, whereas products may vary in strength, dosage form, route of administration, or may include other ingredients. One ANDA may cover multiple products.
b. first_generic_year is the year of the first approved ANDA (a measure of patent expiration date), and later_NDA is an indicator that equals one if an NDA was approved after the first generic entrant (this may be the case if an extended-release or reformulated version of the molecule was later approved under an NDA).

The market-level regression shows that market size (log_sumSales_bil) is positively associated with more entry (measured as tot_entry, numproducts). This effect is strong and robust to the inclusion of controls for the "age" of the market (first_generic_year) and later NDA approvals. Columns 1 and 2 show that a 1% increase in sales predicts a significant increase of about 3 entrants (ANDAs), or equivalently, 11 drug products. Columns 3 and 4 show that this effect is robust to

though its component firms would not be coordinating entry decisions.

controls. By abstracting away from individual firm decisions and considering generic entry at the drug market level, I establish that market size is an important predictor of entry in my data.

7.2 Discrete Game Results (firm-market level)

Table 4 reports results from the naïve logit regression, as well as various specifications of the discrete game estimated using constrained maximum likelihood.

Table 4 demonstrates that firm size (measured as firm revenue), market revenue, and expected competition (other entry) are important factors in a firm's decision for whether to enter a generic drug market. Moreover, precise estimation of more than a few (> 3) structural parameters is challenging given data limitations.

7.3 Results from the Naïve Logit

As expected, the naïve logit (Column 1 of Table 4) does not identify the correct effect of competition on entry. The significant positive coefficient on other entry corresponds to an average marginal effect (AME) of 0.053 ± 0.003 on the probability of entry per additional competitor, compared to a 0.045 $\pm$ 0.003 AME of an additional \$1billion increase in firm revenue. The effect of one additional competitor on entry is thus estimated to be comparable (in sign and magnitude) to a \$1 billion *increase* in firm revenue. In contrast, the coefficient on market size is small and non-significant (with an AME of 0.015 ± 0.010).

We don't expect that market size is unimportant to entry, nor do we expect competition to promote entry. Rather, other entry (as specified in the naïve logit) captures the effect of market size. Market size and other_entry are highly co-linear, such that this naïve logit implies that competition encourages a firm to enter the market. This only makes sense if we realize that here, this result only tells us that markets with a lot of entry are desirable to enter (because they tend to be large, and perhaps correlate with unobserved components of the error). This highlights the endogenous determination of firm entry and the necessity of the discrete game model.

Table 4: Naïve Logit and Discrete Game Estimation Results

Dependent Variable: Entry in a firm-market	(1) naïve logit	(2) game-Eff$_c$	(3) game-Eff$_c$, intercept	(4) game-Eff$_{lin}$
firm revenue	0.259***	0.183***	0.172	0.166***
	(0.023)	(0.016)	(0.145)	(0.043)
market revenue	0.089	0.904***	1.148	2.635
	(0.060)	(0.307)	(3.494)	(3.205)
other entry	0.307***	-0.491***	-0.721	-0.611*
	(0.023)	(0.102)	(3.175)	(0.357)
other entry * mkt revenue	–	–	–	-0.204
	–	–	–	(0.327)
constant	-3.094***	–	0.813	–
	(0.172)	–	(11.122)	–
Pseudo R^2	0.198	0.105	0.105	0.107

N = 1428 (firm-markets) for col 1 (logit); N = 102 (markets) for cols 2-4 (game model).
Specification [entry-Eff$_{lin}$, intercept] not shown because no stable equilibria found
Pseudo R2's: logit-McFadden's, STATA default; others are Efron's, treating firm-market observations as independent.
Standard errors in parentheses, generated using 500 bootstrap samples
*** p<0.01, ** p<0.05, * p<0.1

Column 1 presents naïve logit estimates; Columns 2-4 present discrete game estimates.
a. The dependent variable in all columns is an indicator for entry in a firm-market.
b. Estimates are reported for firm revenue (in USD billions) and market revenue (sumSales_bil).
c. "Other entry" is defined as realized entry in the naïve logit (column 1), and BN equilibrium expected entry in Columns 2-4.
- Column 2 gives the ML estimates where the competitive effect is a constant Δ, (hence, "Eff$_c$").
- Column 3 is equivalent to Column 2, but also estimates a coefficient on a constant (intercept).
- Column 4 estimates the competitive effect as an affine function $\Delta + \kappa \times$ (market revenue), where κ describes how the competitive effect depends on market size, (hence, "Eff$_{lin}$")

7.4 Results from the Discrete Game & Constrained ML Estimation

Modeling entry as a discrete game (Columns 2-4 of Table 4) recovers large, negative competitive effects (as coefficients on other entry), demonstrating that expected competition affects the entry decisions of the top 14 firms in the data.

Column 2 reports significant coefficients on firm revenue, market revenue, and equilibrium expected entry, where the effect of expecting an additional competitor is similar to a $540 million decrease in market revenues of the branded product, given average marginal effects of 0.037, 0.184,

and -0.100 for firm revenue, market revenue, and other entry respectively.[6] Thus, by the specification in Column 2, expecting one additional competitor lowers a firm's probability of entry by 10% on average, while each $1 billion increase in market revenue increases a firm's probability of entry by 18.4% on average. Overall, Column 2 demonstrates that constrained-ML estimation of the sparsest set of parameters gives meaningful point estimates of the competitive effects between firms, with tight standard errors. However, the Column 2 specification does not estimate a parameter for a constant term in the observed information (X_i^m) vector, so I estimate Column 3 for comparison.[7]

Column 3 reflects the same specification in Column 2, but estimates a coefficient on a constant term (intercept) in the observed information vector. It maintains similar point estimates in our parameters of interest (compared to Column 2); the average marginal effects for firm size, market size, and competition on entry are 3.5%, 23.4%, and -14.7% respectively. However, we observe that adding an additional parameter in the context of limited data (N = 102 markets) results in large standard errors. Bootstrap samples used in computing the standard errors of the ML parameters are sampled with replacement. This generates samples more homogeneous than the original data, leading to less-precise convergence of the optimization procedure. Because the signs and magnitudes of the point estimates in Column 3 largely match those in Column 2, I conclude that the large standard errors are due to data limitations, rather than model misspecification.

7.5 Interactions Between Competition and Market Size

Column 4 repeats the specification in Column 2 but includes an interaction term between expected other entry and market size in the form of the profit function. This specification estimates the effect of competition on entry probability as a constant (coefficient on other_entry) plus an effect that varies based on market revenue (coefficient on other_entry*mkt_size).

[6] Average marginal effects (AMEs) are calculated for the logit regression using the STATA margins command, and for the discrete game model by computing the derivative of the BNE constraints (at the estimated structural parameters) for each firm-market data point and taking the sample mean. Calculations of AME standard errors for the discrete game model are quite troublesome, and do not change significance thresholds, so I choose to omit these.

[7] Although Su 2014 omits the constant term in his simple example on simulated data, omitting the constant imposes an undesirable restriction on the functional form of the profit function (that profits are a purely linear, rather than affine, function of firm size, market size, and expected competition).

Although this specification, like Column 3, suffers from data limitations, the point estimates are consistent in sign and magnitude with Columns 2 and 3. The negative estimate on the interaction term implies that an additional competitor in a large market deters entry *more* than another competitor in a small market. This may be surprising, as we might expect smaller markets to be more sensitive to competitive entry due to a "smaller pie" of total revenue to distribute among firms. The negative sign on the interaction term (other_entry*market_revenue) could point to unobserved characteristics in the type of firm that enters larger markets. Or alternatively, it could correlate with potential entry from smaller firms outside of the 14 that I have included in the model. That said, I am hesitant to draw definitive conclusions due to the imprecision of the estimation.

7.6 Firm Size and Investments in Entry

The effect of firm size (measured as firm revenue in 2014) has a consistent, muted effect across all specifications. An additional $1 billion in annual firm revenues only increases the probability of entry by <4% on average. This smaller effect for firm revenue could indicate that revenue figures from one point in time are poor indicators of a firm's ability to invest in entering new markets. It could also mean that large firms do not necessarily invest in a large number of products, but instead invest in other efforts such as capturing market shares in drugs they already produce. I speculate, from prior literature, that a richer dataset incorporating firm variables such as "prior experience with a drug type" would account for more firm-specific variation in entry.

8 Counterfactual Analysis: Subsidizing Firm Entry

A major benefit of structural models (such as the discrete game) is the ability to conduct counterfactual analyses. Often, we would like to assess the effect of a tax or subsidy on market characteristics, such as entry. In generic drug markets, one might consider a policy that would subsidize firm entry. This might take the form of a monetary prize to be awarded to entrants of certain drug markets. Indeed, a policy of this nature already exists as a type of generic entry: paragraph IV certification.

8.1 Paragraph IV Entry as a Subsidy on Patent Challenges

Paragraph IV certification is one way to file an ANDA that potentially rewards a generic firm for attempting to enter a patent-protected drug market. The Hatch-Waxman Act allows generic firms to enter a market in one of four ways. These "paragraphs" describe different entry situations (certifications). Paragraph I certification applies when the innovator firm has not filed a patent for its branded product. Paragraph II refers to cases where the branded product has already lost patent protection and market exclusivity. Paragraph III applies when generic firms apply to enter only after the date of patent expiration. Lastly, Paragraph IV certification applies when the generic firm either argues that (1) the prospective generic drug does not actually infringe the innovator firm's patents or (2) that the original innovator firm's patents are invalid. Upon submission of a Paragraph IV ANDA, the generic firm notifies the incumbent firm, which usually results in extensive litigation. (If the incumbent chooses not to sue, then the FDA may simply approve the ANDA). If the generic firm is successful in court, then the FDA is allowed to approve the ANDA. In addition, the generic firm is granted 180 days of market exclusivity.

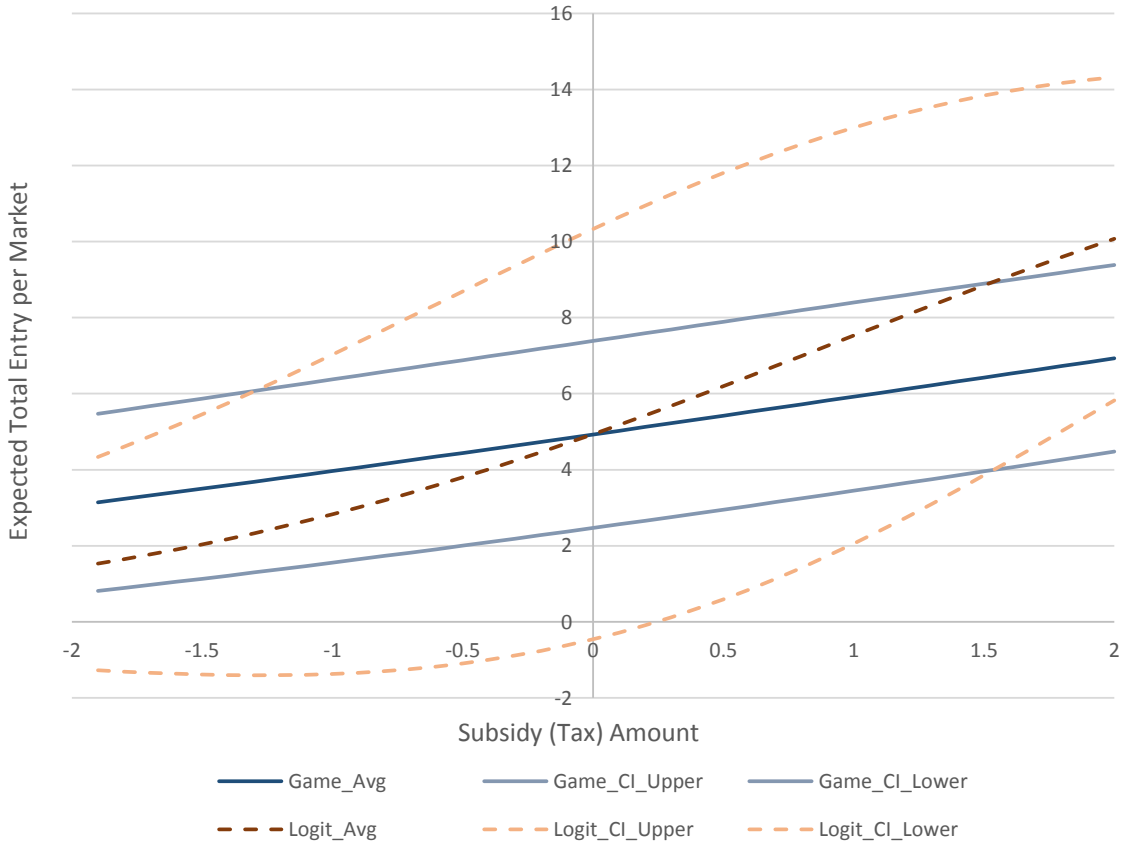
The 180-day period of exclusivity carries significant financial incentive, as it allows the generic to temporarily operate as a duopoly with the incumbent [Branstetter, Chatterjee, and Higgins 2011]. Consequently, there is no shortage of firms seeking Paragraph IV entry. To illustrate this, I defer to a 2003 FDA report on the topic, which notes that "[r]ecently, there have been a number of cases in which multiple ANDA applicants or their representatives have sought to be the first to submit a patent challenge by lining up outside, and literally camping out adjacent to, an FDA building for periods ranging from 1 day to more than 3 weeks." [Center for Drug Evaluation and Research 2003]

Thus, Paragraph IV certification operates much like a subsidy on submitting patent challenges, which gives firms both the incentive and the means to accelerate the approval of generic products. However, other potential subsidies could be construed, such as a subsidy for entry into markets with few competitors. If we also consider applications for novel drugs, we could imagine

subsidies for less-profitable markets that have a large effect on welfare, such as the market for new antibiotics.

8.2 Computing the Effect of a Direct Subsidy on Entry

Figure 1: Response of Firm Entry to Subsidies and Taxes: Naïve Logit vs. Discrete Game Models



- Expected total entry in a market is computed by summing the equilibrium probabilities of entry for all 14 firms in that market.
- These equilibrium probabilities are calculated by adding the subsidy to the post-entry profits of all firms in all markets, and numerically solving for a solution that satisfies the BNE constraints.
- The average and 95% confidence intervals are computed over the 102 markets in the sample. Subsidies (or taxes) between -2 and 2 are considered.

I demonstrate the importance of considering competitive effects when predicting the effect of a subsidy or tax. I do this by examining the average response of total entry per market over different amounts of the subsidy[8] on entry. I compare predictions generated by the naïve logit

[8]The same observations hold true for taxes as well

specification in Section 4.2.1 with the discrete game model (constructed using the parameter point estimates from Column 3 of Table 4). As shown in Figure 1, the response of total entry per market, as predicted by the discrete game, is affected much less by a direct subsidy than the logit model would imply.

One limitation to this approach is that the actual determinants of profits (other than competition) are not explicitly modeled, so the units of a subsidy (for example, a "subsidy of 1.5") are difficult to determine. In addition, although the logit and discrete game models are not fully comparable, their shared basis on the standard logistic distribution implies that the profit functions are scaled by similar magnitudes, making this comparison between the two models somewhat more reasonable.

We observe that the logit model predicts a more drastic change to average entry decisions as a result of the subsidy. The discrete game model, on the other hand, accounts for the increased competition that would result from a subsidy to all firms. With a subsidy, all firms have more incentive to enter, but they also realize that the equilibrium probability of competitor entry has also increased, which tapers the overall effect of the subsidy. Future analyses might examine the effect of only giving subsidies to particular firms, either randomly or based on firm characteristics. This could predict how firms behave in markets where a competitor might have a known governmental or political advantage.

On the other hand, the discrete game model suggests that a fixed tax on entry may also do less to decrease entry than expected. This makes sense as a tax would reduce entry across all firms, which in turn reduces competition (encouraging entry). The countervailing force of reduced competition partially offsets the negative effects of the tax. This implies that a tax on entry (for example, application fees) could be a more feasible revenue-generating tool than a logit model would suggest.

8.3 Limitations and Future Work

My model and empirical approach could be extended and improved, both by access to finer-resolution data and by reassessment of some of my model's assumptions. For instance, using revenue data that adopts a finer definition of drug markets would allow me to consider firm specialization or prior experience in certain types of drugs and examine differences between drug classes. In addition, my assumption of only including the top 14 firms is somewhat ad-hoc; future work might address various ways of accounting for smaller firms. Indeed, many industries are characterized by large sets of heterogeneous firms.

Due to data constraints, I am also forced to ignore interesting and salient firm dynamics, such as firm exits as well as mergers and acquisitions (M&A) among generic and branded firms. In particular, M&A is an increasingly common and important phenomenon in the pharmaceutical industry, evidenced by the fact that several firms in my sample had merged within the time frame of my data (see Section C). Moreover, some branded firms may forgo in-house research to acquire promising projects, or merge with generic firms to increase market share and preemptively absorb the competition. Phenomena such as these may form an interesting basis for future work.

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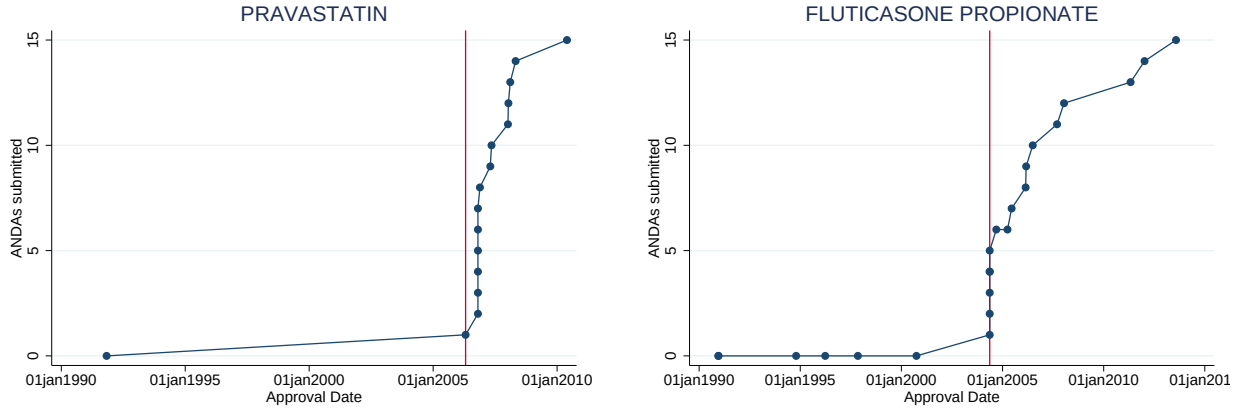
Appendix

A Entry Data Examples

Figure 2: Entry profiles for two example drug markets



- Figure A shows entry patterns for two drug markets (defined by their active ingredient).
- Each dot represents either an NDA or ANDA that was approved; while the y-axis measures the total number of ANDAs (generic versions) approved.
- The vertical line marks the date of the first generic approval.
- Pravastatin is a statin drug that treats high cholesterol. Its patent expiration in 2006 initiated a rapid sequence of generic entry. Because much of the variation in approval time for these initial drugs were likely due to FDA time lines, I consider all approvals within a 2-year window of the first approval as "simultaneous."
- Fluticasone Propionate treats nasal allergies and has a slower entry pattern. Dots that do not change the level of the graph indicate NDAs were submitted for this ingredient, perhaps for different forms or combinations of ingredients.

B Omission of Markets With No Generic Entrants

Because I rely on actual entry to establish pre-generic-entry revenue, I must omit 74 (of 285) drug markets with no generic entrants from my dataset. This is a potential source of selection bias, as I am forced to consider only markets that realize at least one generic entrant. However, the actual bias from this data limitation may be small under the following assumptions. First, these 74 drug markets correspond to more recently approved drugs that likely do not have generic versions because their patents have not yet expired (the average NDA approval date of these 74 markets is Jan. 2005, compared to Mar. 1999 for markets with at least one entrant).

Second, I can only consider drugs whose first generic entrant enters between Jan. 1, 2004 and Jan. 1, 2015, since I only have revenue data from 2003 through 2013 (156 out of 211 markets satisfy this). Patents for many of these other 74 drugs are unlikely to have expired before 2015 (the average time between NDA approval and the first generic entrant is 11.7 years in my data set, which would eliminate 43 out of these 74 as unexpired patents). This leaves a potential 31 markets with zero entrants (about 16.5% of a total sample of 156 + 31 markets for which I have revenue data).

C Firm Revenue Data and Sources

Table 5: Characteristics of Potential Entrants in the Discrete Game

Firm	Markets entered	2014 Revenue (billions USD)	Citation / Notes
Teva	86	9.1	FP
Mylan	70	6.5	FP
Sandoz	50	8.5	FP, as a subsidiary of Novartis
Apotex	49	1.7	FP
Sun	47	4.5	FP
Dr. Reddy's	44	1.8	FP
Aurobindo	37	1.6	FP
Watson	30	3.4	2011 pre-merger (with Actavis) global generics revenue. Information from [Watson Pharmaceuticals 2011]
Roxane	28	0.65	Private company. I use the company's expected 2015 revenue from Hikma acquisition proceedings [Bray 2016]
Zydus	25	1.2	FP
Lupin	25	2	FP
Actavis	20	2.5	Private company prior to acquisition in 2012 by Watson. I use Actavis's revenue in 2011, according to a pre-acquisition press release [Actavis Group 2012]
Torrent	20	0.776	2014 revenue from annual report [Torrent Pharmaceuticals 2014]. Conversion from Rupees to USD assumes 60 rupees to 1 dollar in 2014, from [X-Rates 2016]
Wockhardt	20	0.805	2014 revenue from annual report [Wockhardt Ltd. 2014]

Entries marked FP are from: Helfand 2015

Note: I measure firm size indirectly by 2014 global revenue from generic drugs. This data is unavailable to me in 3 out of 14 cases: two cases due to mergers (so I estimate revenue from the year prior to the merger), one case because the company is private (I use expected 2015 revenue). It would be ideal to use revenue in the year preceding generic entry in each market (as with my market size variable). Since I am unable to do so, I assume that the relative differences in firm revenue are preserved through the period of entry I consider (Jan 1, 2004 - Jan 1, 2015).