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

Based on ongoing project by Rubaiyat Alam and Rena Conti

Summary written by Rubaiyat Alam

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Pharmaceutical products in US can be broadly classified into two categories: i) branded drugs, which are pioneer molecules temporarily protected by patents and market exclusivities from competitors, ii) generic drugs that are bioequivalent to ther branded counterparts. Branded drugs initially enjoy monopoly power in the market and charge high prices. After loss of market exclusivity – usually through patent expiration – generics enter the market and compete with each other and the branded product. This results in loss of market share for the branded drug and lower prices for payers. In some cases, the incumbent branded drug manufacturer responds to generic competition by releasing a fighting brand, known in the pharmaceutical industry as an Authorized Generic (AG). AGs are chemically identical to the branded drug but without the brand name attached. 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. Pricing patterns in such markets are often that branded drug prices stay the same or even increase, while generics and the AG are priced very low.

Studying 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 the US for many years, and the largest decline in pharmaceutical spending by payers occur once a branded drug loses market exclusivity. By studying market dynamics after loss of exclusivity, we can better understand the economic incentives in the pharmaceutical industry and craft more targeted policies. Second, the release of AG is quite similar to strategies undertaken

by incumbents when faced with rival entry in other industries as well. When facing new entrants, incumbents can respond in several ways through price adjustment and product line expansion. One commonly observed strategy is price discrimination through release of "fighting brands". In a fighting brand strategy, the incumbent releases a low brand-value version of its existing product, called a fighting brand. The high brand-value product charges high price and the fighting brand charges low price. This segments the market, with fighting brand competing with new entrants and original product serving the higher end of the market. Note that the incumbent has to weigh business-stealing vs cannibalization incentives when deciding to release a fighting brand.[1] However, there is only a nascent empirical IO literature looking at this phenomenon.

Using quarterly data on total quantity sales and revenue of pharmaceutical products in the US for 2004-2016, we build and estimate a structural model of the pharmaceutical industry in the US after the branded drug's loss of market exclusivity. The unit of analysis is the molecule-formulation pair. We use this to study entry decisions by generics and Authorized Generics and their pricing strategies.

First, we set up a random-coefficients discrete-choice model of demand for pharmaceutical products. In our model a consumer is an aggregation of the individual patient and all the other intermediaries who influence her decision, e.g. physicians, pharmacies, insurers, PBMs, wholesalers, etc. Rather than model them separately, our demand model predicts the outcome from the joint-decision making by all these agents together. Next, we set up a two-stage model of the supply side of the industry. In the first stage, generic manufacturers make a static entry decision on whether to enter a molecule-formulation market. In the second stage a dynamic game begins where every period, generics who decided to enter are randomly approved for entry by the 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

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

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

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 a fighting brand. There is an extensive theory literature on fighting brands, notably Johnson and Myatt (2003). An important empirical paper studying fighting brands is Bourreau et al. (2021). They show that in the French mobile telecommunications market, releasing fighting brands is due to a breakdown of collusion, and use a structural model of demand and supply to make their point.

Second, we also contribute to a small literature on Authorized Generics. We are the first to study the impact of 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 the AG. A few papers have used reduced-form evidence to study Authorized Generics. Notably, Appelt (2015) uses a recursive bivariate probit regression to show that AG entry does not impact generic entry in Germany. An important source for us is a report from the Federal Trade Commission (FTC (2011)) that leveraged many detailed information sources to lay out the decision to release the AG and generic manufacturers' reactions to it.

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

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

Finally, our paper relates to a large literature on pharmaceuticals. A vast amount of work has been done on the theoretical and empirical side of this industry. Frank and Salkever (1992) was the first to lay out a theoretical model for why branded drug prices often stayed above generic prices. A non-exhaustive list of important references include Arcidiacono et al. (2013), Bhattacharya and Vogt (2003), Bokhari and Fournier (2013), Bokhari et al. (2020), Dubois et al. (2022), Ellison and Ellison (2011), Frank and Salkever (1997), Reiffen and Ward (2005), Reiffen and Ward (2007), Olson and Wendling (2018), and Tenn and Wendling (2014). In particular, Berndt et al. (2017), Berndt et al. (2018), and Conti and Berndt (2019) provide important evidence about the aggregate dynamics and inner workings of the industry which we use to motivate our model.

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