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

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# Disclaimer

1. Slides made by Rubaiyat Alam.
2. Based on ongoing research project with Rena Conti.
3. Very preliminary results, subject to change.

# Industry

Pharmaceuticals in US can be broadly classified into two categories:

1. Branded drugs: New molecules, protected by market exclusivities (e.g. patents). Enjoy monopoly in that market and charge monopoly price.
2. Generic drugs: Drugs which are bioequivalent to and cheaper than their branded counterparts.

# Entry and pricing with AG

After loss of market exclusivity of original branded drug (usually patent expiration), generics start entering.

- Brand drug manufacturer often responds by releasing a fighting brand, known as an "Authorized Generic" (AG).
- AGs are identical to the branded drug but without brand name attached.

Pricing patterns generally are:

- Brand drug price stays the same/rises.
- Generic and AG price stays low and falls over time.

# Generic and AG entry

Generic approval time is lengthy and highly stochastic:

- Lengthy: Mean time is around 40 months.
- Stochastic: Hard to predict when approval will happen.

AGs can be introduced anytime and without approval, since they are riding on the original brand's approval.

# Example

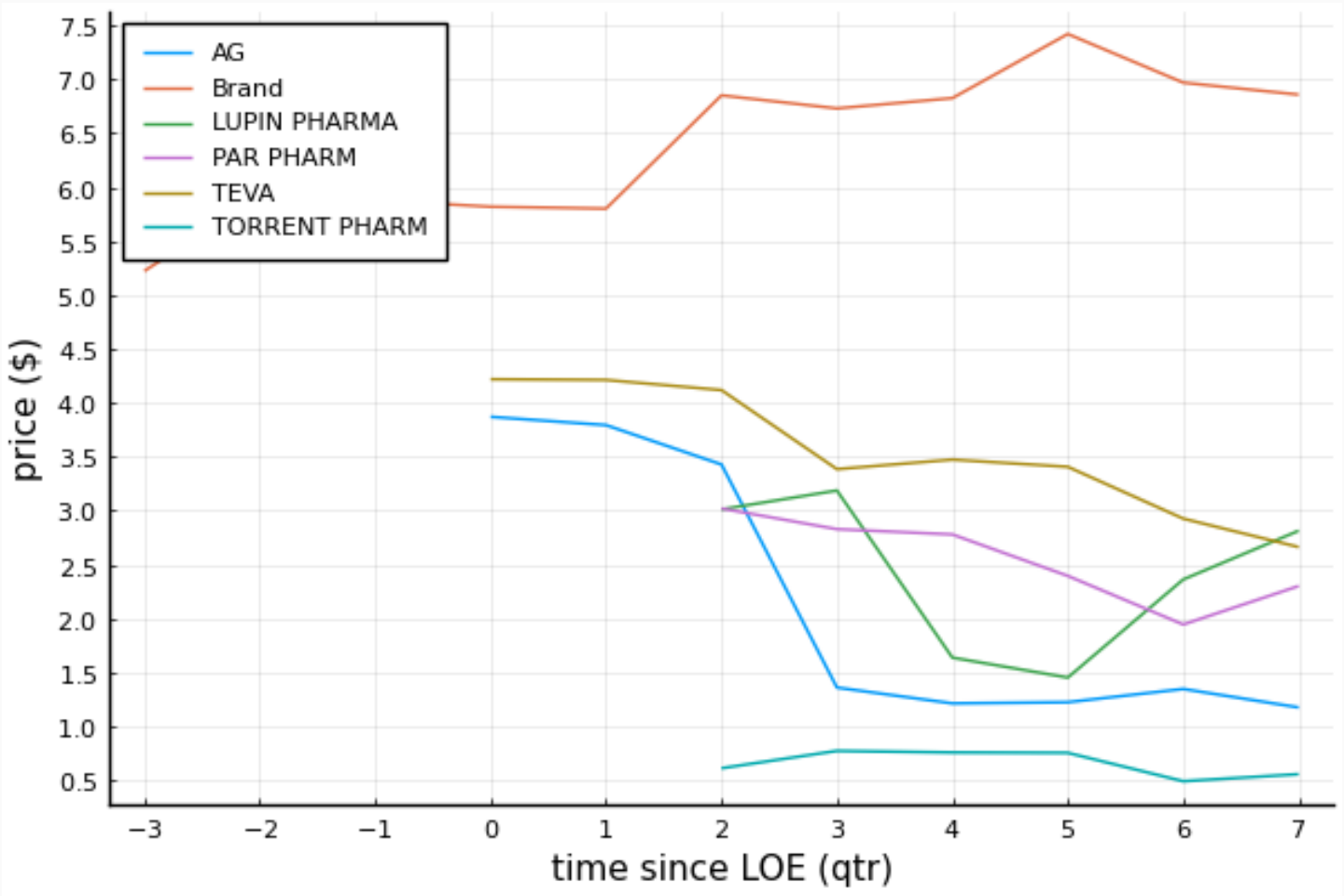


**Figure 1:** US-average prices for amlodipine-hydrochlorothiazide-valsartan (oral)

# Example

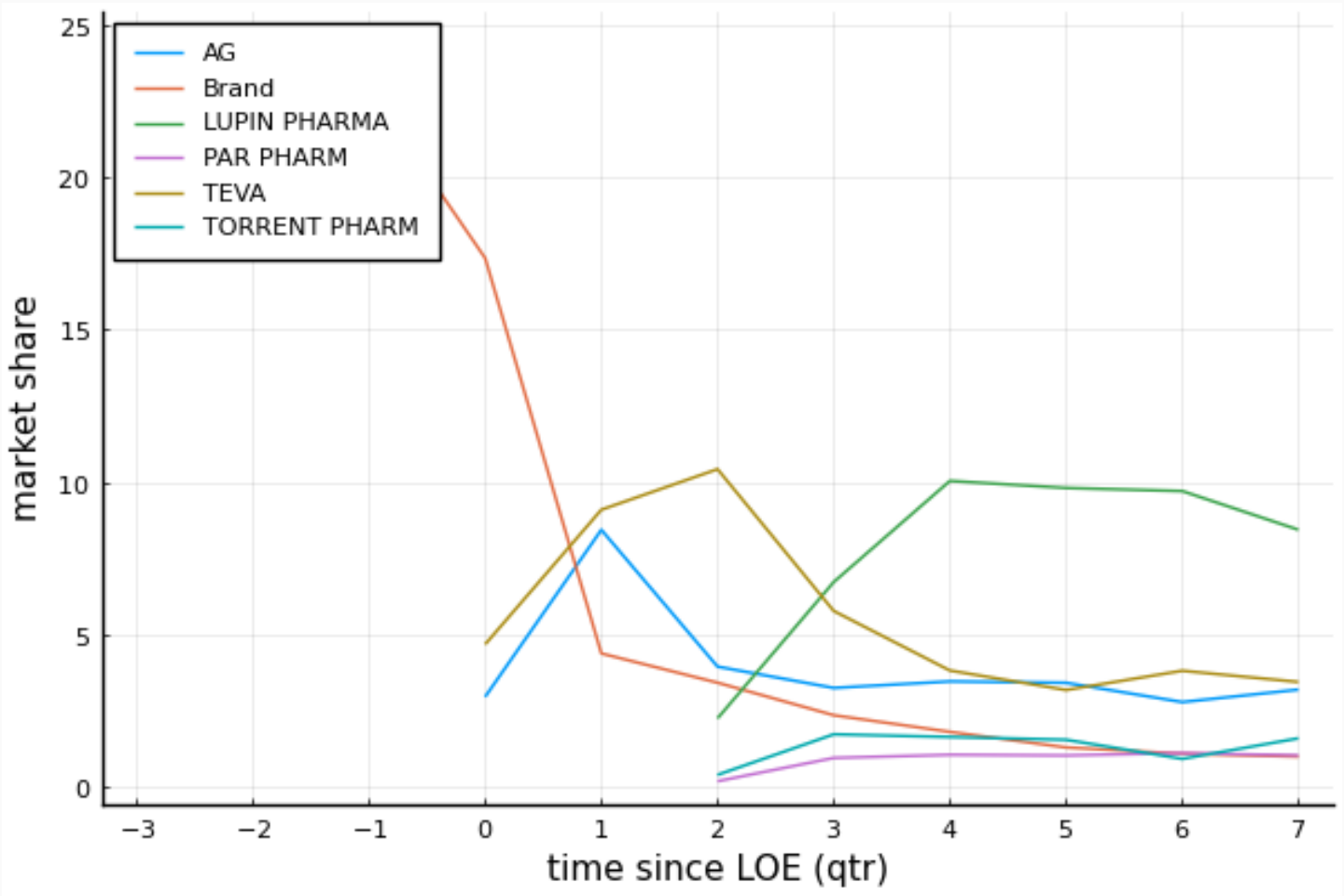


**Figure 2:** Market shares for amlodipine-hydrochlorothiazide-valsartan (oral)

# Entry and pricing with AG

What rationalizes this pricing and product line response by the incumbent?

- Heterogeneity in brand-valuation and price-sensitivity among consumers.
- Only consumers with high brand-valuation and low price-sensitivity buy the brand, and so brand can charge them high prices without losing them.
- Consumers with low brand-valuation and high price-sensitivity buy generics, so releasing fighting brands allows the incumbent to capture some of the profit from this segment of the market too.

# Research question

Build a structural model of demand, pricing and entry of pharmaceuticals after loss of patent protection.

Questions to answer:

- Quantifying level of heterogeneity in brand valuation and price sensitivity in demand for pharmaceuticals.
- Do AGs get a "quality" premium in the demand function?
- How pricing and entry decisions by incumbent and generics depend on demand primitives.
- Effect of AG on generic entry and pricing decisions (e.g. "chilling effect").
- Effect of speeding up generic approval rate.

# Motivation

Why is this useful?

- Policy discussion regarding high drug prices.
  - Major price declines happen after generic entry.
  - Studying this can help us understand market dynamics and craft better policy.
- Contribute to papers on Authorized Generics.
  - First to build a rational expectations framework that embeds generics and AG predicting each others' choices when making decision.
  - Lets us trace out feedback effects between AG and generics in counterfactual.
- Policy discussion surrounding banning Authorized Generics.

# Motivation

- Contribute to nascent empirical IO literature on **fighting brands**.
  - Incumbent releases low brand-value/low quality version of its existing product, called a fighting brand.
  - Price discrimination: high brand-value product charges high price, fighting brand charges low price.
  - Segments market: fighting brand vs new entrants, original product serving higher end of market.
  - Business-stealing vs cannibalization incentives.
  - Commonly observed in the real world.

  However, very small Empirical IO literature on this topic.

# Preview

(Preliminary) Findings:

1. Demand estimation: significant heterogeneity in price sensitivity and brand valuation; AG premium present.
2. Counterfactuals:
    - Changing key demand parameters $\implies$ market outcomes.
    - Not releasing an AG is rationalized by the cost differential between the AG and generics being very large.
    - Faster generic approval rate leads to greater generic entry, lower likelihood of Authorized Generic being released, and lower prices.
    - AG ban $\implies$ higher market prices.

# Data

Data from IQVIA for 2004-2016 on USA. Sales are aggregated to US, e.g. how many units of Lipitor tablet was sold in US in 2009Q1.

- Quarterly sales of each drug in US
- Revenue of each drug (gives me price)
- Formulation of product (oral, injectable, etc.)
- Therapeutic class
- Active ingredients

Data on Authorized Generics and Paragraph IV Exclusivity hand-collected.

# Data

To set expectations for the rest of the seminar:

- We only have sales data at US-quarter level.
- We use this to study *aggregate* industry dynamics like average price in US, entry decision, etc.
- We cannot look at finer variation like pricing and inclusion across insurance plans.
- The demand side of the paper is thus a mix of pharmaceutical intermediaries and consumers jointly making a purchase decision. We do not try to distinguish them or their individual payoffs; only their joint demand is modeled.

# Market definition

I define markets at the molecule-formulation (molform) level.

After data-cleaning,

- 246 molforms, each followed for many quarters before and after LOE.
- 110 molforms see AG released.

Each molform has one brand and can have at most one AG.

# AG release

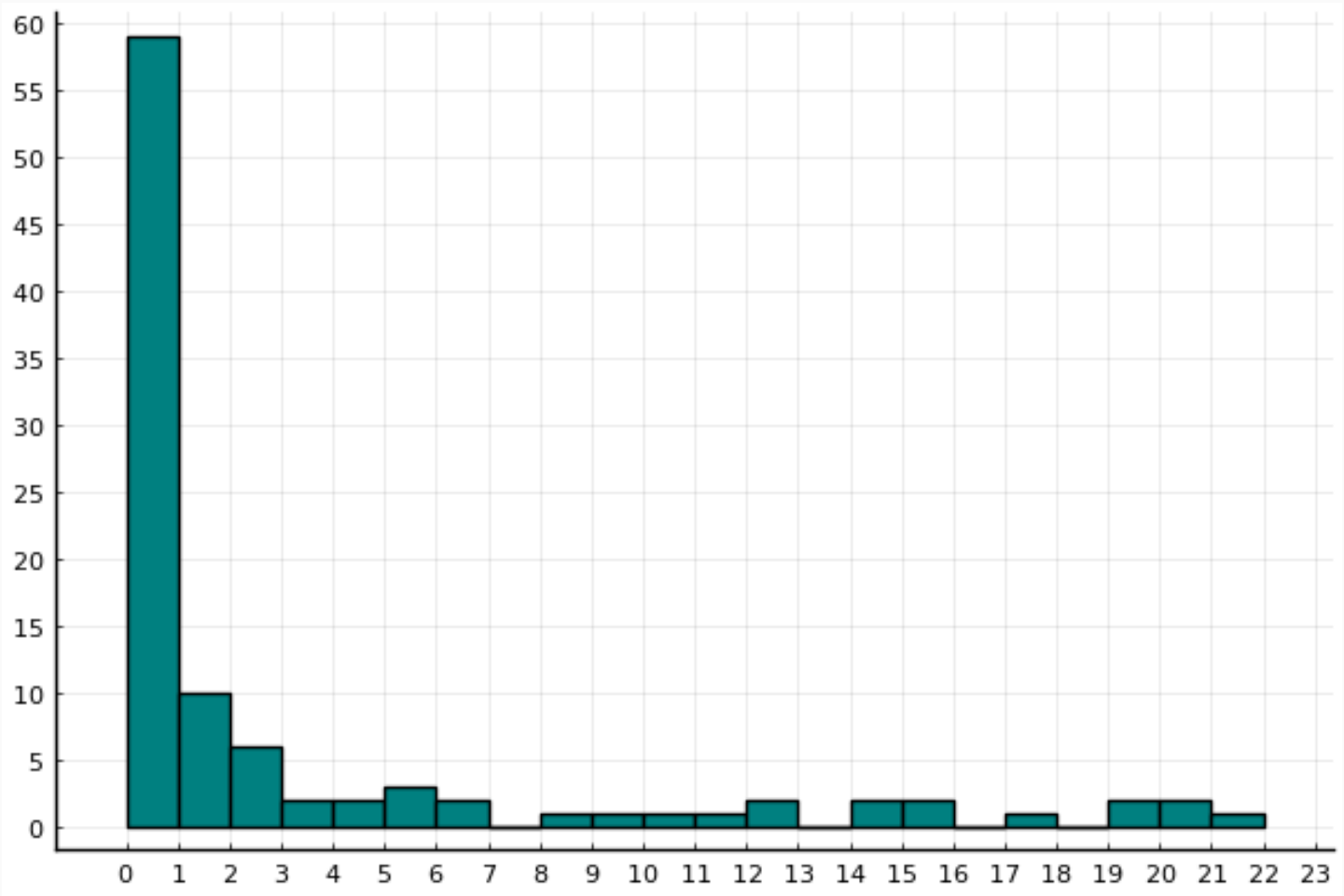


**Figure 3:** Time-difference between first generic entry and AG release period (in quarters).

# Competition

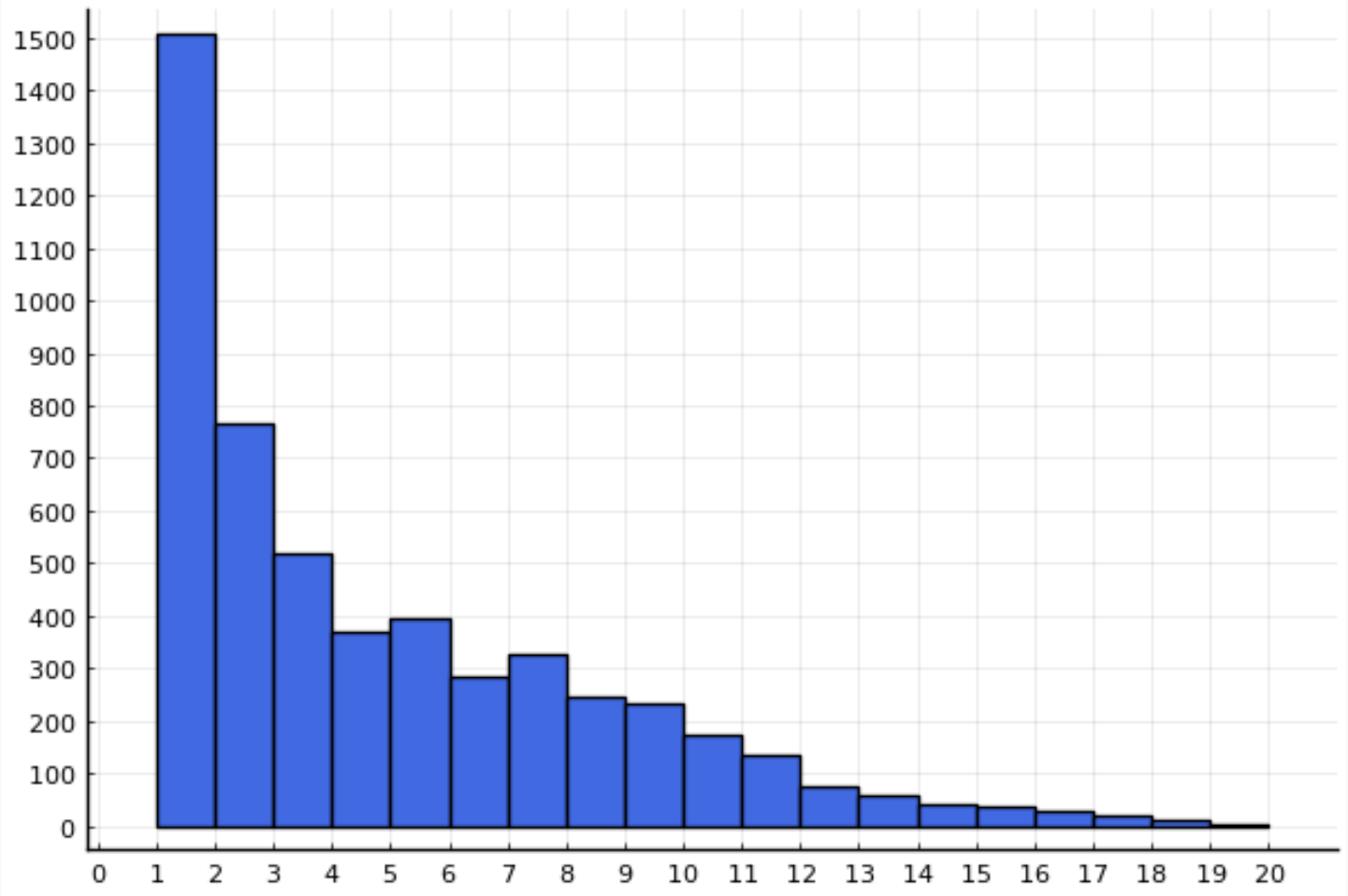


**Figure 4:** Count of generics present by molecule-formulation-quarter.

# Competition

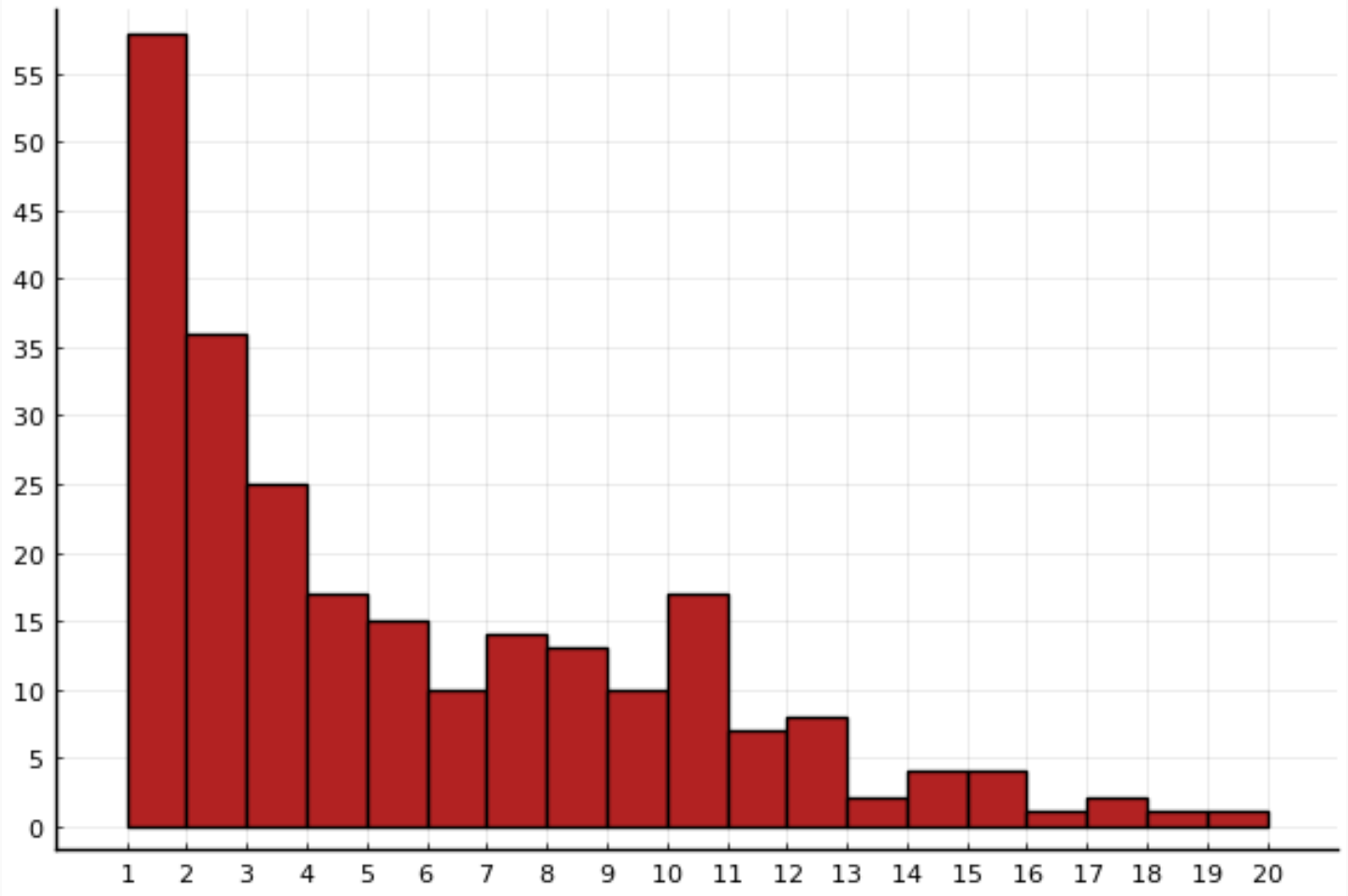


**Figure 5:** Total generic entry by molecule-formulation

# Structural model: Demand

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

where $\alpha_i \sim \mathcal{N}(\alpha, \sigma_\alpha^2)$, and $\beta_i^{(1)} \sim \mathcal{N}(\beta^{(1)}, \sigma_1^2)$

We estimate this using the method of Berry-Levinsohn-Pakes (1995):

- Gandhi-Houde IVs
- 2-step GMM

# Structural model: Supply

A model with two stages:

1. First stage: From a pool of potential entrants, generic firms decide whether to enter a market or not.
    - Static entry game.
    - Entry decision is implemented randomly with median time of 40 months.
2. Second stage: Loss-of-exclusivity happens and dynamic game begins. Every period,
    - A random number of the generic firms which chose to enter are introduced into the market.
    - Brand manufacturer chooses price of its branded product (static effect) and decides whether to release AG or not (dynamic, irreversible).
    - Price competition between brand, generic and AG.

# Structural model: Supply

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

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

The generic firm $l$'s per-period payoff is:

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

Nash-Bertrand pricing between generics and AGs.

Price fixed at observed level for brand.

# Structural model: Supply

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.

# Structural model: Supply

The value function for a branded drug manufacturer every period is given by:

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

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

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

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

# Structural model: Supply

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

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

Similarly, for generics the payoff is:

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

# Structural model: Supply

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

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

# Structural model: Supply

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.

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

# Results from demand estimation

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

where $\alpha_i \sim \mathcal{N}(\alpha, \sigma_\alpha^2)$, and $\beta_i^{(1)} \sim \mathcal{N}(\beta^{(1)}, \sigma_1^2)$

# Results from demand estimation

| | 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

# Supply

Cost parameters:

- Nash-Bertrand FOC gives marginal cost for each product.
- Remaining cost parameters calibrated:
  - Generics entry cost = \$2 million, AG entry cost = \$1 million.
  - Generics operating cost = \$20,000, AG operating cost = \$70,000.

Counterfactuals mostly concerned with comparative statics of cost parameters.

Thus, resulting economic intuition should hold at different calibrated values.

# Supply

Supply model solved by backward induction ($T = 32$).

Assumptions

- Generics ex-ante identical, do not draw private shocks, cannot forecast $\xi_{jt}$.
- AG knows the exact number of generics that have filed for application.
- Generics know number of applications.

# Counterfactuals

We explore four sets of counterfactuals:

1. Effect of changing demand parameters.
2. Effect of changing cost parameters
3. Faster FDA approval rates.
4. Ban on AG.

# Counterfactuals

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

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

# Counterfactuals

| 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 3:** Market outcomes with changing variance on non-brand's random coefficient.

# Counterfactuals

| Price coef | Total generics | AG release fraction | AG price | Generic price | Per-Generic share | Brand share | AG share |
|---|---|---|---|---|---|---|---|
| -2.41 | 9.0 | 1.0 | 3.29 | 3.17 | 8.87 | 8.41 | 11.75 |
| -2.72 | 6.0 | 1.0 | 3.04 | 2.94 | 12.88 | 5.62 | 17.11 |
| -3.02 | 4.0 | 1.0 | 2.88 | 2.79 | 18.13 | 3.67 | 23.82 |

**Table 4:** Market outcomes with changing price coefficient.

# Summary

1. More negative mean non-brand coefficient $\beta^{(1)} \implies$ fewer generics, higher AG and generic prices and market share, higher market share for brands. Incentive to release AG remains unchanged at the estimated parameter values.
2. More negative mean price coefficient $\alpha \implies$ fewer generics, lower AG and generic prices, higher AG and generic market shares, lower branded drug market shares. Incentive to release AG remains unchanged at the estimated parameter values.
3. Higher variance of the non-brand coefficient $\sigma_1^2 \implies$ more generics, higher AG release probability, lower prices and market share for generics and AG.

# Counterfactuals

We explore four sets of counterfactuals:

1. Effect of changing demand parameters.
2. Effect of changing cost parameters
3. Faster FDA approval rates.
4. Ban on AG.

# Counterfactuals

| AG fixed cost | Total generics | AG release fraction | AG price | Generic price | Per-Generic share | Brand share | AG share |
|---|---|---|---|---|---|---|---|
| 100000.0 | 4.0 | 1.0 | 2.88 | 2.79 | 18.13 | 3.67 | 23.82 |
| 110000.0 | 4.0 | 1.0 | 2.88 | 2.79 | 18.13 | 3.67 | 23.82 |
| 120000.0 | 4.0 | 1.0 | 2.88 | 2.79 | 18.13 | 3.67 | 23.82 |
| 130000.0 | 4.0 | 1.0 | 2.88 | 2.79 | 18.13 | 3.67 | 23.82 |
| 140000.0 | 5.0 | 0.01 | 2.85 | 2.91 | 15.68 | 3.06 | 18.56 |
| 150000.0 | 5.0 | 0.0 | 0.0 | 2.91 | 19.25 | 3.75 | 0.0 |
| 160000.0 | 5.0 | 0.0 | 0.0 | 2.91 | 19.25 | 3.75 | 0.0 |

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

# Counterfactuals

| MC of AG (normd) | 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 changing marginal cost of AG.

# Summary

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.
2. Higher marginal cost for AG relative to generics leads to higher AG and generic prices and greater generic entry.
   Price of Ag and generics increase. Market shares of generics and branded drug increase while that of AG declines. AG release is not affected even after its marginal cost is three times that of generics', but simulations show that at higher marginal costs the AG no longer enters.

# Summary

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.

# Counterfactuals

We explore four sets of counterfactuals:

1. Effect of changing demand parameters.
2. Effect of changing cost parameters
3. Faster FDA approval rates.
4. Ban on AG.

# Counterfactuals

| 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.

# Counterfactuals

We explore four sets of counterfactuals:

1. Effect of changing demand parameters.
2. Effect of changing cost parameters
3. Faster FDA approval rates.
4. Ban on AG.

# Counterfactuals

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

**Table 8:** Market outcomes with and without AG ban.

# Discussion

- Pricing game: Static Nash-Bertrand pricing game. Similar to Dubois et al (2022) and Starc and Wollmann (2022).
- Generic entry as a static entry game: mean approval time for ANDA is about 40 months, highly stochastic.
- Product hopping: brand-specific time trend in demand.
- Pay-for-delay and Pay-for-no-AG settlements: demand model not affected by such settlements, our calibrated supply model applies to markets where such settlements have not occurred.
- Information assumptions
- Generic heterogeneity assumptions

# Conclusion

Analyze pricing and product line response by brand incumbents in pharmaceuticals facing entry by competitively-priced generics.

(Preliminary) Findings:

1. Demand estimation: significant heterogeneity in price sensitivity and brand valuation; AG premium present.
2. Counterfactuals:
    - Changing key demand parameters $\implies$ market outcomes.
    - Not releasing an AG is rationalized by the cost differential between the AG and generics being very large.
    - Faster generic approval rate leads to greater generic entry, lower likelihood of Authorized Generic being released, and lower prices.
    - AG ban $\implies$ higher market prices.