Entry Delays and Fighting Brands: Evidence from Generics and Authorized Generics

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Introduction

Prescription drugs in the US can be:

1. Branded drugs: New molecules, protected by market exclusivities (e.g. patents).
2. Generic drugs: Bioequivalent to the branded drug.

After loss of market exclusivity (LOE) of branded drug:

- Generics enter.
- Key driver of lower drug prices and spending.

Generic entry faces two hurdles (among others):

1. Regulatory delays
2. Competition from Authorized Generic

Introduction: Entry delays

Generics cannot exactly control entry timing.

- Need FDA approval for product launch.
- Approval time = lengthy + stochastic.
- Entry delays blamed for high drug prices post-LOE.
- FDA has sped up the approval process, more mixed results recently.
- **Impact of faster approval rates on market outcomes?**

Introduction: Authorized Generics

Brand drug maker releases second product = "Authorized Generic" (AG).

- Chemically identical to branded drug
- Without brand label attached
- Priced lower than brand drug.
- Does not need FDA approval, can be launched anytime.
- "Fighting brand strategy"

Impact of AGs on market outcomes and deterring generic entry?

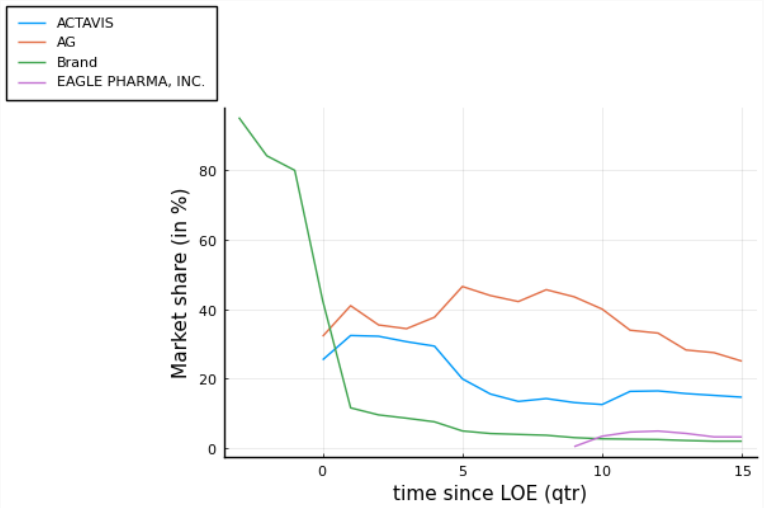
- FTC report in 2011.
- Generics advocated for AG ban, claiming entry deterrence.

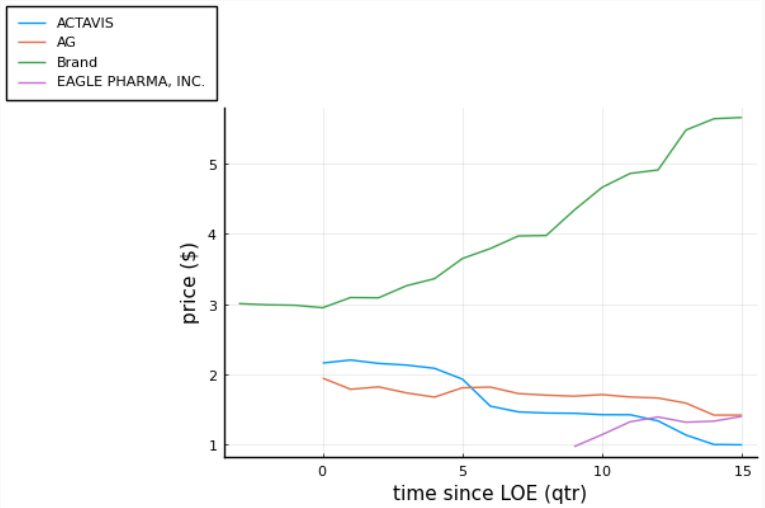
Dynamics

Pricing pattern:

- Brand price: high
- AG and generic price: low
- Continuing generic entry $\rightarrow$ lower prices.

Figure 1: Market shares and prices for Diclofenac-Misoprostol-oral.





Research questions

We study:

- Entry deterrence in this setting.
- Reduced generic entry delays $\rightarrow$ market outcomes.
- AGs $\rightarrow$ short/long-term market outcomes.

Method:

- Structural model of generic entry and AG release:
  - Simple model capturing key mechanisms.
- Simulate impact of entry delays and AG presence.

Contributions

Contributions:

1. Literature on modeling generic entry decisions: Ching (2010), Starc and Wollmann (2023), etc.
   - Tractable easy-to-solve model of generic entry.
   - Can be used to study generic entry deterrence via post-LOE actions of brand drug maker (e.g. product line extensions).
2. Small literature on Authorized Generics: Appelt (2015), FTC (2011), Fowler et al (2023).
   - First to build structural model of entry and competition between generics and AG.
3. Nascent empirical IO literature on fighting brands: Bourreau et al (2021)

Data

Data from IQVIA for 2004-2016 on the US.

- Quarterly sales of each drug in US
- Revenue of each drug (gives us average price)
- Formulation of product (oral, injectable, etc.)
- Active ingredients/molecule composition

Data on Authorized Generics hand-collected.

Descriptive statistics

Define markets at the molecule-formulation (molform) level.

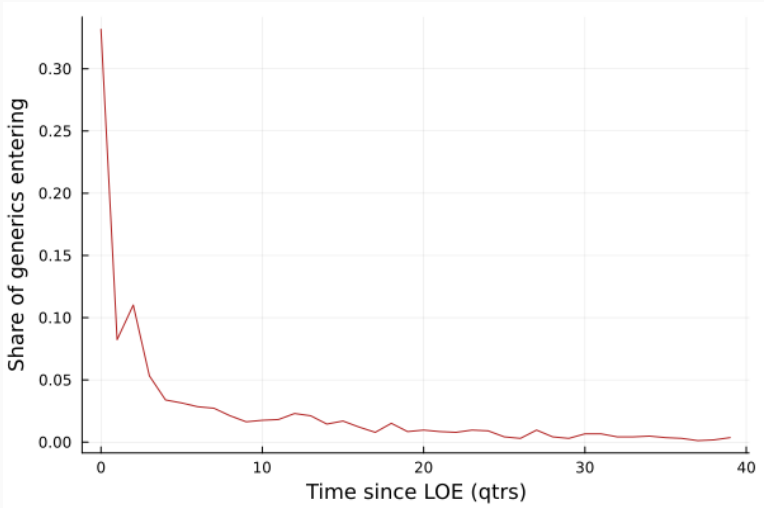
After data-cleaning:

- Prescription drugs.
- 241 molforms.
- 109 molforms see AG released.
- 53% of AGs released within one quarter of first generic entrant.
- Most markets have 1-11 generics, with a maximum of 19.

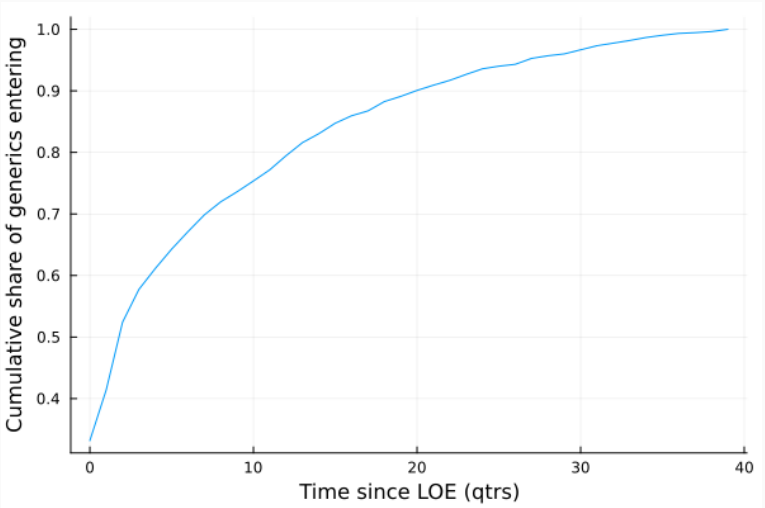
Each molform has one brand and can have at most one AG.

Loss-of-Exclusivity (LOE) for a molform: earliest quarter with generic presence in that molform.

Generic entry rates



(a) Fraction of total generics launching in every quarter since LOE.

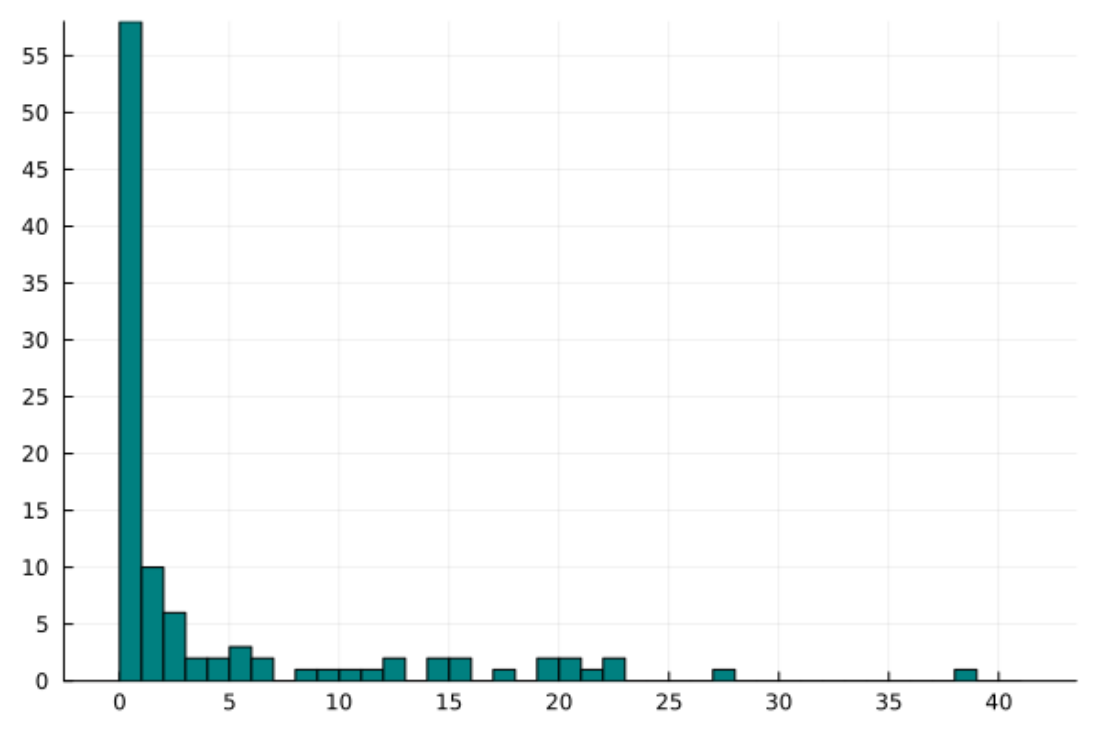


(b) Cumulative fraction of total generics launching in every quarter since LOE.

- Over 30% enter on LOE (anticipation + defn of LOE).
- However, majority of generic entry after LOE.
- By LOE + 20 qtrs, about 93% generics have entered.

AG release timing

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



Structural model: Demand

Stage 1: Consumer chooses a group – brand, nonbrand, or outside option.

The utility of consumer i for group g in molecule-formulation m at time t is given by:

$$u_{igmt} = \gamma_m^{(1)} + \lambda_t^{(1)} + \alpha_i^{(1)} ln\, p_{gt} + \beta_{1i}^{(1)} \text{brand}_g + \beta_2^{(1)} brand_g \cdot \text{time-since-loe}_t + \xi_{gt}^{(1)} + \epsilon_{igt}$$

where $\alpha_i^{(1)} \sim \mathcal{N}(\alpha^{(1)}, \sigma_\alpha^2)$ and $\beta_i^{(1)} \sim \mathcal{N}(\beta_1^{(1)}, \sigma_1^2)$

Structural model: Demand

If consumer chose nonbrand group in Stage 1, next chooses from all the nonbrand drugs available.

Stage 2: The consumer chooses a specific non-brand product.

The utility of consumer i choosing non-brand product j in market m at time t is given by:

$$u_{ijt} = \gamma^{(2)}_{m(j)} + \alpha^{(2)} ln\, p_{jt} + \beta^{(2)}_1 \mathrm{AG}_j + \xi^{(2)}_{jt} + \epsilon_{ijt}$$

Given our assumptions, the market share of a single good can be expressed as:

$$s_j = s_{g(j)} s_{j|g(j)}$$

Structural model: Supply

Model with two stages:

1. First stage: Generic firms decide whether to apply for entry into a molecule-formulation.
    - Static game of entry application, uncertain entry timing.
2. Second stage: LOE happens, then every period:
    - Stochastic number of generics gain FDA approval.
    - Brand drug maker decides whether to release AG.
    - Price competition between brand, generics and AG.
    - AG release: Single-agent dynamic timing decision.

Supply: Second stage

Branded drug maker's per-period profit:

$$\pi^b(s_{mt}) = [P^b_{mt} - MC^b_m]s_b(s_{mt})M_m + \mathbf{1}(AG_{mt} = 1)\left[[P^{AG}_{mt} - MC^{AG}_m]s_{AG}(s_{mt})M_m\right]$$

Generic firm l's per-period profit:

$$\pi^g(s_{lmt}) = (P^g_{mt} - MC^g_m)s_g(s_{lmt})M_m$$

Per-period price competition:

- This paper: Regression predicting prices in different states.
- Reasons: US-quarter average price data; Nash-Bertand likely an inaccurate approximation of complex multilateral bargaining.

Supply: Second stage

n_{em} = total generics that applied for FDA approval in market m.

- Determined in First Stage.
- Assumption: n_{em} is known to everyone in $t = 1$.

At $t = 2$, LOE happens.

For every $t \leq T$:

- Stochastic number of generics gain FDA approval.
- AG enters (irreversible) or stays out.

We set $T = 32$ quarters.

Supply: Second stage

Value function for branded drug maker:

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

Value function for generic l:

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

After period T, per-period profits $= 0$.

Supply: Second stage

Suppose by period t in market m, $\mathcal{N}_{mt}$ generics have already received approval.

The probability that of the $n_{em} - \mathcal{N}_{mt}$ remaining entrants, k will receive approval in period t is given by:

$$P_e(k, n_{em}, \mathcal{N}_{mt}, t; \lambda) = \binom{n_{em} - \mathcal{N}_{mt}}{k} \lambda(t)^k (1 - \lambda(t))^{n_{em} - \mathcal{N}_{mt} - k}$$

where $\lambda(t)$ is estimated from data.

$\lambda(t)$ measures regulatory frictions slowing down generic entry.

Supply: First stage

In the First Stage, generic makers decide if they want to apply for FDA approval.

For computational simplification, assume generic firms are ex-ante identical.

Equilibrium generic entrants n_{em} determined by:

$$V^g(s_{gm0}, n_{em}) \geq \kappa_m^g > V^g(s_{gm0}, n_{em} + 1)$$

where κ_m^g is generic's entry cost.

Estimation

Demand: Berry et al (1995) and Maggio et al (2022)

Full supply-side model is solved by backward induction + checking generic entry condition.

Generic entry costs: calibrated from publicly reported cost ranges. ($3m-$15m)

Marginal cost:

- Set $MC_m = \vartheta \bar{p}_{gm}$, where $\bar{p}_{gm}$ is the avg generic prices in m
- Estimate ϑ to match observed generic numbers.
- $\vartheta \uparrow \implies$ profits $\downarrow \implies$ generic entry $\downarrow$

Estimation

AG parameters:

- Logit scaling parameter: Maximum likelihood.
- AG entry cost: calibrated to 0, robust to sensitivity analysis.

Demand:

- Demand increases with: price $\downarrow$, brand, AG, brand x time-since-LOE $\downarrow$
- RC variance ≈ 0.0 (true for a wide variety of specs)

Supply: $\vartheta \in$ [0.54 to 0.65], Logit scaling parameter $=$ 586497.139

Demand: Stage 1 Demand: Stage 2 Price prediction regression

Counterfactuals

Counterfactuals:

1. Reduced generic entry delays.
2. Ban on AG.

Method: Solve model for AG policy function and n_{em}, simulate, report average outcomes.

Profitability in post-LOE lifecycle:

- Early quarters after LOE most profitable.
- Few firms in the market $\rightarrow$ high markups and profits.
- With time, more generics enter, markups and profits $\downarrow$.

Counterfactuals: Reduced entry delays

"Reduced entry delays" = Faster generic approval rates

Two opposing forces on a generic's entry decision:

1. Launch earlier $\rightarrow$ more time to make profits.
2. Greater rival presence upon entry $\rightarrow$ prices $\downarrow$ $\rightarrow$ profits $\downarrow$.

In simulations: (2) dominates.

- Faster generic approval $\rightarrow$ weakly less generic entrants.
- Yet, prices lower in early periods.
- Prices may be higher in later periods.

Faster generic approval $\rightarrow$ weakly less AG entry.

- (1) not present for AG, only (2).

Counterfactuals: AG ban

AG generally released soon after LOE. If AG banned:

1. One fewer competitor in early stages of market.
2. Greater generic entry.

Effect on prices due to AG ban:

- Early periods: Prices higher since AG no longer competing.
- Later periods: Ambiguous, could be lower if AG deters multiple generics.

Why can AG ban incentivize > 1 additional generic?

- Less competition in most profitable stages of market.

Conclusion

Study interactions between generics and AG using a structural model of entry timing.

Model may be used to study generic entry deterrence for a wider variety of post-LOE actions by brand drug maker:

- Product line extensions/pruning
- Late-stage lifecycle indications
- Settlements, etc.

Results: Price prediction regression

Patient-facing: Channels where patient + insurer + physician make product choice.

Non-patient-facing: Channels where the patient does not generally get a say in the product being chosen.

Results: Price prediction regression

	Patient-facing	Non-patient-facing
formulation: Injectable	2.118	–
	(0.136)	(–)
formulation: Oral	-1.308	–
	(0.112)	(–)
No. of nonbrand drugs	-0.269	-0.298
	(0.009)	(0.016)
No. of nonbrand drugs squared	0.008	0.010
	(4.843e-04)	(0.001)
Brand	0.123	-0.076
	(0.031)	(0.041)
Brand * time-since-generic-entry	0.017	-0.005
	(0.001)	(0.002)
Brand * No. of nonbrand drugs	0.232	0.231
	(0.004)	(0.008)
Brand * Authorized generic present	0.041	0.774
	(0.031)	(0.064)

Results

Results from demand estimation

Results

	Patient-facing	Non-patient-facing
ln(price)	-1.004	-2.781
	(0.033)	(0.244)
Brand	0.799	1.033
	(0.069)	(0.250)
Brand * time-since-generic-entry	-0.095	-0.008
	(0.007)	(0.014)
RC std: Brand	-5.946e-07	-1.812e-07
	(6.120)	(6.598)
RC std: Price	3.434e-07	-2.025e-07
	(4.778)	(11.838)

Table 1: Results of demand estimation for Stage 1.

Results from demand estimation

	Patient-facing	Non-patient-facing
Authorized Generic	0.857	0.067
	(0.077)	(0.186)
ln(price)	-0.647	-1.286
	(0.023)	(0.068)

Table 2: Results of demand estimation for Stage 2.

Estimation of generic entry rates

Results

- For each molecule-formulation and quarter-since-LOE, calculate the number of generics waiting to enter, i.e. final number of generics observed in that molecule-formulation minus the current number of generics present in the molecule-formulation.
- Sum this number across all molecule-formulations at a given quarter-since-LOE to get the remaining entrants for every quarter since loss-of-exclusivity in our dataset.
- Find the total generic entry that happens in every each molecule-formulation and quarter since loss-of-exclusivity.

Estimation of generic entry rates

Results

- Sum this number across all molecule-formulations at a given quarter-since-LOE to get the total generic entry for every quarter-since-LOE in our dataset.
- Taking the ratio of total generic entry by remaining entrants at every quarter-since-LOE gives us the average generic launch rates at every quarter-since-LOE.
- In our calculation of generic entry rates, we limit the generic entries to those happening on or before 17 quarters.
- Given how we calculate generic entry rates, this mechanically imposes that as a market moves very close to 17 quarters, the generic entry rate rises up to 1.0.
- For instance, in the 17th quarter, the total generic entry must equal the total remaining generics.