RESEARCH BRIEF • MAY 2022

Does Entry Remedy Collusion? Evidence From the Generic Prescription Drug Cartel

Based on BFI Working Paper 2022-49, "Does Entry Remedy Collusion? Evidence From the Generic Prescription Drug Cartel," by Amanda Starc, Northwestern University; and Thomas G. Wollmann, Chicago Booth

KEY TAKEAWAYS

- ✓ Over 18 months in 2013 and 2014, prices on over 100 generic drugs saw price increases averaging 50 percent, prompting a criminal complaint against drug manufacturers for collusive pricing.
- ✓ Economic theory suggests that such price increases should increase entry into the market by new manufacturers, and the resultant competition will drive prices down.
- ✓ This paper investigates this "entry effect" on the generic drug market to find that collusion does induce competitive entry and that prices likewise fall.
- ✓ Importantly, though, this work also finds that regulatory delays restrict timely entrance and thus keep prices higher than they otherwise would be.

In April 2013, Teva Pharmaceuticals, a large generic drug manufacturer, hired a marketing executive with strong connections throughout the industry with the goal of exploring opportunities to increase profits. Or, in that marketing executive's own words, to enact "price increase implementation."

Just three months later, Teva, in alleged collusion with key competitors, began an 18-month price hike spree on over 100 generic drugs costing governments, insurers, and patients billions of dollars.

Those prices, for drugs treating everything from cancer to bacterial infections, arthritis pain, high blood pressure, and many other ailments, caught the attention of enterprising reporters and, soon after, Connecticut's Attorney General's office, resulting in a 2019 complaint led by Connecticut and 48 states and US territories vs. about three dozen defendants.[1]

The case brought into focus key questions about collusive (or cartel) pricing that have long interested economists and that were described in a foundational paper by UChicago's George Stigler in 1964, namely: How can cartels prevent cheating, and to what degree would entry into markets challenge a cartel's pricing power?[2]

[1]See portal.ct.gov/AG/Press-Releases/2019-Press-Releases/DRUG-PRICE-FIXING-COMPLAINT-UNSEALED; see page 50ff for discussion of price hikes.

[2]G. J. Stigler. A theory of oligopoly. The Journal of Political Economy, 72(1):44–61, 1964.

Becker Friedman Institute
FOR ECONOMICS AT UCHICAGO

5757 S. University Ave.
Chicago, IL 60637
Main: 773.702.5599
bfi.uchicago.edu

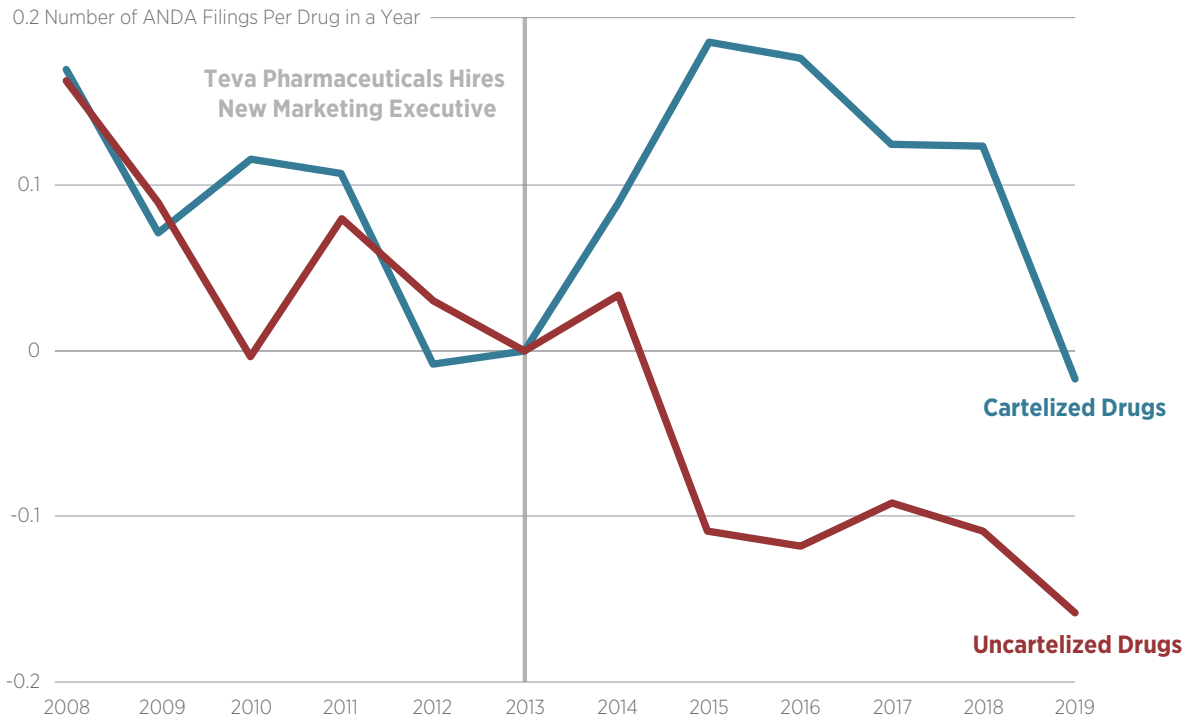
This second question—the policing power of competition on attempts to collude over price—is the motivating query behind "Does Entry Remedy Collusion? Evidence From the Generic Prescription Drug Cartel," by Amanda Starc and Thomas G. Wollmann. The good news is that collusion does, indeed, induce competitive entry in this case, which reduces prices. The bad news is that regulations delay entry by competitors, at great cost to consumers. For policymakers, especially those inclined toward price controls or other rules-based solutions, these are salient findings.

Competition works when it's allowed to work

As many readers likely know from personal experience, generic drugs are a competition success story. Following passage of the Hatch-Waxman Act of 1984, which encouraged the manufacture of generic drugs post-patent and established new regulations, drug prices fell dramatically. Since then—at least until 2013—the first generic entrant would typically price its product slightly lower than the branded drug, and the second generic entrant would reduce the price to approximately 50 percent of the branded drug price, with the price tumbling to around 20 percent of the branded counterpart as more firms entered. Such is competition at work.

However, what happens when firms allegedly collude on price? To investigate this phenomenon, the authors measure the effect of price fixing on market entry, estimate a structural model of generic drug competition, and then use those estimates to assess counterfactual policies that would reduce regulatory costs and delays. The authors employ information from the court filing, which includes a rich collection of internal documents, private communications, lists of drugs, price-fixing dates, among much else. In addition, the authors use data from IQVIA, a private healthcare analytics firm, and Medicaid, to measure point-of-sale price in dollars per prescription. Finally, regarding regulation, before manufacturing a drug, firms must file an Abbreviated New Drug Application (ANDA)

Figure 1 · Entry Into Generic Drug Markets in Calendar Time



Notes: This figure plots the number of Abbreviated New Drug Application (ANDA) filings per drug-year on the y-axis against calendar time on the x-axis. The solid and dashed lines correspond to uncartelized and cartelized drugs, respectively. The vertical line at 2013 corresponds to when Teva hired its new marketing director. Prior to that point, average ANDA filings for cartelized and uncartelized drugs evolved similarly, and uncartelized drugs trend smoothly, but the two groups diverge sharply in 2013. In other words, cartel formation induces substantial entry. ANDA filings are normalized to zero in 2013.

and have it approved by the Food and Drug Administration (FDA); ANDA filings closely correspond to market entry by competitors.

Combining information from the complaint with regulatory filings and market outcomes, the authors find the following:

- Collusion leads to abrupt price increases, which average 40 to 50 percent. In this case, cartel-induced price increases occurred within a narrow window. Most occurred within months of April 2013, when Teva hired its new marketing director, and all were completed within 18 months of that event.

- The cartel induces significant entry. Following collusion, firms file 30 to 40 percent more ANDAs. As the accompanying Figure illustrates, prior to April 2013, average ANDA filings for cartelized and uncartelized drugs evolved similarly, but the two groups diverge sharply when Teva brings its new marketing director on board.

- Regulation delays competition from newly filed ANDAs for years. On average it takes several years to receive an approval so, for example, a firm filing an ANDA in 2013 might not enter before 2017. Given that entrants exert downward pressure on prices, these delays are potentially very costly.

- Entry precipitates price declines. Up until April 2013, "small market" and "large market" drugs trend similarly, but after that the prices of drugs in both groups rise sharply, especially relative to uncartelized drugs. By mid-2014, high prices of "small market" drugs persist, whereas the prices of "large market" drugs fall consistently. Within a few years, below-median cartelized drug prices are 50% higher than those in the uncartelized group, while above-median cartelized drug prices have converged to within 10% of it. These findings strongly support the idea that entrants drive down prices.

As for their model and their counterfactual experiments on lower entry costs and the potential effect of fewer regulatory delays, the authors begin with estimated sunk entry costs averaging $3.2 million per ANDA for the drugs

Regulation delays competition from newly filed applications for years. On average it takes several years to receive an approval so, for example, a firm filing in 2013 might not enter before 2017. Given that entrants exert downward pressure on prices, these delays are potentially very costly.

in their sample. For their first experiment, they reduce the upfront costs of entering a drug market by $400,000-$800,000, approximately one-eighth to one-quarter of the average expense required to do so. In this case, the authors find that market entry increases, saving consumers between $142-374 million. Their second experiment studies the effect of reducing regulatory delays by one to two years. Here they find a similar effect on entry but a much greater benefit for consumers, with savings from $596 million to $1.5 billion.

Caveat: The authors stress that these results do not suggest that the time and expense associated with generic drug evaluations are wasteful, only that limiting fees and hastening approvals generates significant surplus for buyers when incumbent firms are playing cooperatively. Delays, for example, may persist because the FDA is understaffed, which is a problem with an obvious remedy.

Conclusion

Cartels thwart competition, and the cost is high. The US Department of Justice has prosecuted price fixing by all three major canned tuna brands, 70 auto parts suppliers, 15 global financial institutions trading foreign currency, over 100 real estate investors bidding in foreclosure auctions, and many others in the last few years alone. However, cartels do not operate in a vacuum. As prices and profits rise, they attract new entrants happy to undercut cartel prices. Hence, these newcomers serve as safeguards against collusion.

At least in theory. In practice, entry can be a slow and expensive process, inhibiting the beneficial effects that competition would otherwise bring. This novel research investigates alleged collusive pricing in the generic drug market to reveal that new entrants into a cartelized market result in lower prices, but that such entrance is stymied by costly and slow regulatory evaluations.

While specific policy proposals are beyond the scope of this research, the results suggest that policymakers can likely impact at least some of the costs and delays in the generic drug market. On that note, reducing time-to-market by a year and reducing sunk costs by 35% have approximately the same impact. And why not attempt both? Bottom line: This new work provides guidance to policymakers considering optimal regulation of this important industry, and the lessons apply to other industries as well.

CLOSING TAKEAWAY

The authors stress that their results do not suggest that the time and expense associated with generic drug evaluations are wasteful, only that limiting fees and hastening approvals generates significant surplus for buyers. Delays, for example, may persist because the FDA is understaffed, which is a problem with an obvious remedy.

READ THE WORKING PAPER

NO. 2022-49 · MAY 2022

Does Entry Remedy Collusion? Evidence From the Generic Prescription Drug Cartel

bfi.uchicago.edu/working-paper/202249

ABOUT OUR SCHOLAR

Thomas G. Wollmann
Associate Professor, Chicago Booth
chicagobooth.edu/faculty/directory/w/thomas-wollmann

CHICAGO BOOTH
The University of Chicago Booth School of Business

Written by David Fettig, BFI Senior Writer and Editor