

CAPTIVE GENERICS: THE WOLF IN SHEEP’S CLOTHING

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I. INTRODUCTION

Since the passage of the Hatch-Waxman Act (“Hatch-Waxman”) in 1984,¹ the introduction of generic drug competition has provided a crucial means of keeping prescription drug prices in check.² By creating incentives

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¹ Drug Price Competition and Patent Term Restoration (“Hatch-Waxman”) Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended in scattered sections of 21 U.S.C. and 35 U.S.C.) [hereinafter Hatch-Waxman].

² See generally ROBIN FELDMAN & EVAN FRONDORF, DRUG WARS: HOW BIG PHARMA RAISES PRICES AND KEEPS GENERICS OFF THE MARKET 26–33 (2017) (describing the terms and intent of the Hatch-Waxman Act). See also, e.g., Aaron S. Kesselheim & Jonathan J. Darrow, *Hatch-Waxman Act Turns 30: Do We Need a Re-Designed Approach for the Modern*

for generic companies to challenge brand patents and codifying a pathway for generic drugs to enter the market once patents and other exclusivities expire,³ Hatch-Waxman has enabled impressive generic market penetration. The Act even provides for a six-month period of exclusivity for the first generic company to file for approval under certain circumstances.⁴

On its face, the Hatch-Waxman Act has had an enormous impact on the pharmaceutical landscape. Approximately 80% of non-biologic drugs have a generic competitor,⁵ and nearly 90% of all prescribed non-biologic drugs are generics.⁶ The entry of a single generic produces a discount within months;⁷ several generic competitors can bring down the price of what a brand drug costs on its own by 90%.⁸ Consequently, one estimate pegged the total consumer savings of generic drugs at over \$1 trillion over the course of a decade.⁹

Despite these impressive gains, the pharmaceutical industry today is beset by staggering growth in prescription drug prices. Jaw-dropping list

Era?, 15 YALE J. HEALTH POL'Y, L., & ETHICS 293 (2015) (describing the history of the Hatch-Waxman Act); WENDY H. SCHACHT & JOHN R. THOMAS, CONG. RSCH. SERV., R41114, THE HATCH-WAXMAN ACT: A QUARTER CENTURY LATER (2012) (describing the impact of the Hatch-Waxman Act); JOHN E. DICKEN, U.S. GOV'T ACCOUNTABILITY OFF., GAO-12-371R, DRUG PRICING: RESEARCH ON SAVINGS FROM GENERIC DRUG USE (2012), <https://www.gao.gov/products/gao-12-371r> [<https://perma.cc/ER5G-WRAZ>] (describing the terms and intent of the Hatch-Waxman Act); *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 316 (D.R.I. 2017) (“The public relies on pharmaceutical companies to develop and bring to market the medical advances that keep us healthy . . .”); *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, 557 F.3d 1346, 1347 (Fed. Cir. 2009) (“The Hatch-Waxman Act strikes a balance between the sometimes-competing policy interests of inducing pioneering research and development of new drugs and enabling production of low-cost, generic copies of those drugs.”); FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY (2002), https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf [<https://perma.cc/MV6L-WGSV>] (“Beyond any doubt, Hatch-Waxman has increased generic drug entry.”).

³ 21 U.S.C. § 355(j); *see also* FELDMAN & FRONDORF, *supra* note 2; Kesselheim & Darrow, *supra* note 2; SCHACHT & THOMAS, *supra* note 2; DICKEN, *supra* note 2; FED. TRADE COMM'N, *supra* note 2.

⁴ 21 U.S.C. § 355(j)(5)(B)(iv). It is possible, under 2003 amendments to Hatch-Waxman, for a generic company to forfeit its right to the exclusivity period without losing its patent case. It is also possible for the brand-name drug company to choose not to bring litigation against the generic filer; the first filer retains its rights to the period in this case. *See* FELDMAN & FRONDORF, *supra* note 2, at 39–40.

⁵ *See* Ernst R. Berndt & Murray L. Aitken, *Brand Loyalty, Generic Entry and Price Competition in Pharmaceuticals in the Quarter Century after the 1984 Waxman-Hatch Legislation* 6 (Nat'l Bureau of Econ. Rsch., Working Paper No. 16431, 2010), www.nber.org/papers/w16431.pdf [<https://perma.cc/AU59-C2CT>].

⁶ *Implementation of the Generic Drug User Fee Amendments of 2012 (GDUFA): Hearing Before the H. Comm. on Oversight & Gov't Reform*, 114th Cong. 1 (chart 1) (2016) (statement of Janet Woodcock, Dir., Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin.); *see also* Evan Hoffman, *Competitive Dynamics of the Generic Drug Manufacturing Industry*, 52 BUS. ECON. 68, 68 (2017) (noting the growth in the generic market from 55% of all prescribed drugs in 2005 to 88.7% in 2015).

⁷ Berndt & Aitken, *supra* note 5, at 9–10.

⁸ *Id.*

⁹ Hoffman, *supra* note 6, at 69.

prices¹⁰ are joined by steady price hikes across the board. The author's prior analysis of Medicare patients found that the average dosage-unit price of common brand-name drugs increased by 313% between 2010 and 2017, even after accounting for rebates.¹¹

The harm extends beyond a strain on the government's Medicare budget. Even patients with insurance are saddled with higher out-of-pocket drug costs across time,¹² and the prices paid by the uninsured are far higher still. As a result, many who depend on life-saving medication are forced to skip or ration their dosages.¹³ Therein lies the puzzle. With the pathways for robust generic competition available, how are we to explain the steep climb of drug prices?

Prior academic literature has identified a number of obstacles to the realization of the goals of Hatch-Waxman. In particular, generics cannot reduce costs if they are prevented from entering the market. Various strategic behaviors that drug companies employ to delay or deter competitive entry play an important role in undermining Hatch-Waxman. From pay-for-delay¹⁴ to citizen petitions¹⁵ to product hopping,¹⁶ drug-makers throw everything but the kitchen sink into their efforts to keep generic competitors out of their yard as long as possible. These anticompetitive practices, as prior literature describes, have caused more than their fair share of lost savings for patients.¹⁷ This grab bag alone, however, cannot fully answer the question of why the storied Hatch-Waxman Act is failing to deliver on its promise.

¹⁰ See, e.g., Hannah McQueen, *The 20 Most Expensive Drugs in the US*, GOODRX (Sept. 7, 2021), <https://www.goodrx.com/blog/20-most-expensive-drugs-in-the-us/> [<https://perma.cc/5FZZ-JNHB>] (several drugs exceeded \$50,000 for a monthly supply).

¹¹ Robin Feldman, *The Devil in the Tiers*, 8 J.L. & BIOSCIENCES 1, 19 (2021) [hereinafter Feldman, *Devil*].

¹² See Nathan E. Wineinger, Yunyue Zhang & Eric J. Topol, *Trends in Prices of Popular Brand-Name Prescription Drugs in the United States*, 2 JAMA NETWORK OPEN 1, 1 (2019), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2734804> [<https://perma.cc/D4NM-LWMB>] (78% of the top-selling drugs have carried a 50% or greater increase in insurer and out-of-pocket costs since 2012).

¹³ See, e.g., COLO. DEP'T OF LAW, PRESCRIPTION INSULIN DRUG PRICING REPORT 2 (2020) (approximately 40% of Coloradans using insulin reported having to skip or ration doses at least once a year).

¹⁴ See, e.g., Robin Feldman, *The Pricetag of "Pay-for-Delay"*, 23 COLUM. SCI. & TECH. L. REV. 1 (2022) [hereinafter Feldman, *Price Tag*]; see generally Robin C. Feldman & Prianka Misra, *The Fatal Attraction of Pay-for-Delay*, 18 CHL-KENT J. INTEL. PROP. 249 (2019); C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U.L. REV. 1153 (2006) [hereinafter Hemphill, *Paying for Delay*]; Michael A. Carrier, *Payment After Actavis*, 100 IOWA L. REV. 7 (2013) [hereinafter Carrier, *Payment After Actavis*].

¹⁵ See generally Robin Feldman, Evan Frondorf, Andrew K. Cordova & Connie Wang, *Empirical Evidence of Drug Pricing Games—A Citizen's Pathway Gone Astray*, 20 STAN. TECH. L. REV. 39 (2017); Michael A. Carrier & Carl Minniti, *Citizen's Petitions: Long, Late-Filed, and At-Last Denied*, 66 AM. U.L. REV. 305 (2017).

¹⁶ See generally FELDMAN & FRONDORF, *supra* note 2, at 69–80; Jessie Cheng, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 COLUM. L. REV. 1471 (2008).

¹⁷ See, e.g., Feldman, *Price Tag*, *supra* note 14, at 4 (noting the cost of our findings).

Prior academic research has focused primarily on the strategic behaviors that brand companies engage in with their brand-name drugs. This article takes a different path. In a first-of-its-kind look at the generics industry, this article demonstrates that the industry itself is not what it appears. Quite simply, many generic drugs are not true competitors in the market, but, rather, are produced or licensed by the brand company.¹⁸ Although known in the industry as “authorized generics,” this article will refer to them as “captive generics,” given that these drugs are subject to the interests and direction of the brand drug company.¹⁹

At first glance, captive generics sound promising. Why should it matter whether a lower-priced version comes from the brand drug company or a new entrant? Lower prices are lower prices, and lower prices are good for consumers.²⁰ However, this Article demonstrates that, after twenty years of experience with captive generics, the opposite is true. Rather than acting as a gift to consumers, captive generics operate to elevate prices and reduce competition, undermining the entire structure of the Hatch-Waxman system.

Captive generics were not mentioned in the original Hatch-Waxman Act at all. They came to prominence almost two decades after Hatch-Waxman was signed into law, when two separate courts ruled that brand companies are not prohibited from marketing their own generic during the period in which the first-filing generic should have exclusive access to the market, much to the outrage of generic manufacturers.²¹ As of July 1, 2021, nearly 1,200 captive generics circulate on the market.²²

The limited research that exists on captive generics is more than a decade old, much of it dating back to the early 2000s.²³ The most extensive among this body is a 2011 Federal Trade Commission (“FTC”) report, which found that captive generics had “a substantial effect” on true generic revenues during the six-month period of marketing exclusivity the Hatch-Waxman Act guarantees the first generic company to file a patent chal-

¹⁸ For a primer on captive generics, see *FDA List of Authorized Generic Drugs*, U.S. FOOD & DRUG ADMIN., (Feb. 5, 2022, 4:00 PM), <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/fda-list-authorized-generic-drugs> [<https://perma.cc/S28B-7M47>].

¹⁹ The exception to this nomenclature will be in the section referencing complex litigation agreements in which brand companies agree not to launch some form of a captive generic in exchange for which a true generic agrees to stay off the market for a period of time. This Article will follow the convention of calling these “no-AG clauses.”

²⁰ See, e.g., IMS CONSULTING, REPORT TO PHRMA: ASSESSMENT OF AUTHORIZED GENERICS IN THE U.S. 2 (2006), http://208.106.226.207/downloads/IMSAuthorizedGenericsReport_6-22-06.pdf [<https://perma.cc/4P2J-P3VH>] (consulting firm report to industry as captive generics emerged on the scene arguing that “authorized generics” reduce prices for patients by providing another drug option on the market).

²¹ See *Teva Pharm. Indus. v. Crawford*, 410 F.3d 51, 52 (D.C. Cir. 2005); *Mylan Pharm., Inc. v. U.S. Food & Drug Admin.*, 454 F.3d 270, 271 (4th Cir. 2006). During the six-month exclusivity period, only the brand and the first-filing generic may be sold in the market; other generics must wait for the six-month clock to run before entering. See *Mylan*, 454 F.3d at 271.

²² U.S. FOOD & DRUG ADMIN., *supra* note 18.

²³ See sources cited *infra*, notes 56–59.

lenge.²⁴ The dearth of scholarship is remarkable given the continued entrenchment of captive generics in the realm of prescription drugs.²⁵ As this Article starkly demonstrates, captive generics significantly distort the market by artificially elevating drug prices and limiting competition. This impact is not limited to the initial six-month exclusivity period; rather, captive generics leave a significant mark on the industry across time and across multiple dimensions. They allow brand manufacturers to claw back some of the revenue lost when generic competition erodes a brand drug monopoly. In turn, the launch of a captive generic severely cuts back true generic profits and impacts generic market penetration. Moreover, captive generics are frequently deployed by brand manufacturers in anticompetitive side deals, formulary manipulations, and pay-for-delay schemes that directly obstruct other generic entry.

In support of these conclusions, this Article contains a detailed analysis of 373 different drug markets and finds that those hosting a captive generic share several alarming features.

- **Captive Generics Triple the Magnitude of Brand Price Increases:** The increase of brand net prices once generics entered the market was three-and-a-half times greater in drug markets with a captive generic (21%) compared to drug markets without one (6%).
- **Captive Generics Boost the Growth of True Generic Prices:** The presence of a captive generic caused the price of true generics to increase 11% more during their first year on the market.
- **Captive Generics Reduce True Generic Market Share:** True generics hold 22% less of the market if a captive generic enters.
- **Captive Generics Better Permeate Markets:** Compared to the average true generic, a captive generic is able to occupy a 6% larger market share.
- **Captive Generics Do Not Increase the Total Number of Generics:** One may assume that a captive generic constitutes an extra generic on the market, increasing the total number of generics available. This is not the case; rather, when a captive generic is present, there tends to be one fewer true generic option.
- **Captive Generics Contribute to Irrational Formulary Tier Placement of True Generics:** Given that brand drugs are so much more

²⁴ See FED. TRADE COMM'N, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACTS 58 (2011), <https://www.ftc.gov/sites/default/files/documents/reports/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission/authorized-generic-drugs-short-term-effects-and-long-term-impact-report-federal-trade-commission.pdf> [perma.cc/6YJG-CCN7] [hereinafter FTC AG REPORT] (examining the impact of such drugs on and after the six-month period of exclusivity over the years 2003–2008); see also Carrier, *Payment After Actavis*, *supra* note 14, at 42 (citing the 2011 FTC AG Report and exploring the impact of brand company promises *not to* launch captive generics in the context of pay-for-delay litigation settlements between brand and generic companies).

²⁵ The landmark FTC report, published in 2011, used data from 2003–2008. The report was preceded by numerous other pricing studies.

expensive than generics, it would be irrational to place the brand and generic version of a drug on the same health plan reimbursement tier. The proportion of true generics located in the same formulary tier as the brand drug averaged 12% higher where a captive generic was available than in markets where one was not available.

The Article proceeds as follows. Part I outlines the rise of captive generics and places them in the context of the Hatch-Waxman system, describing how they disrupt the incentive structure designed to promote generic entry. Part II explains how brand drug-makers use captive generics to induce delayed generic entry through pay-for-delay deals and other collusive arrangements. Part III offers an extensive analysis of 373 distinct drug markets to examine how the entrance of captive generics impacts prices and generic market share.

Part IV, responding to these findings, outlines prospective regulatory and legislative actions to check the harm of captive generics on patients and payors. These include requiring captive generics to join true generics in submitting Abbreviated New Drug Applications (“ANDAs”) for regulatory approval and preventing brand companies from double-dipping by marketing brand and generic products simultaneously. Furthermore, the FTC ought to consider a drug-maker’s captive generics in a more robust merger evaluation.

The findings in this Article provide strong evidence that regulators, legislators, and the courts should reconsider the rules of the game. Otherwise, what we call generic competition will continue to be the brand drug-maker winning in both uniforms.

II. HATCH-WAXMAN & THE RISE OF CAPTIVE GENERICS

The passage of the Hatch-Waxman Act in 1984 opened drug markets to generic competition with measures to facilitate generic entry as soon as drug patents expire. Potential generics can submit an ANDA relying on the brand drug’s safety and efficacy data. The generic can submit this application before expiration of the patent so that the Federal Drug Administration’s (“FDA”) approval process can be completed, and any intellectual property disputes resolved, in time for the generic to enter the market immediately upon brand patent expiration.²⁶ Compared to the New Drug Application required to enter as a new, patent-protected drug, ANDAs are much briefer and less expensive to complete, lowering the barrier of entry for prospective generics.

Hatch-Waxman also contains an incentive for generic companies to challenge patents that have been improperly granted or that the brand company is improperly applying to a particular drug before their expiration through a process known as Paragraph IV certification.²⁷ A Paragraph IV

²⁶ See FELDMAN & FRONDORF, *supra* note 2, at 21–22.

²⁷ 21 U.S.C. § 355(j)(5)(B)(iv); FELDMAN & FRONDORF, *supra* note 2, at 22.

certification operates as a paper form of infringement. By kicking off litigation between the brand and generic company, filing the certification offers generics a safer route for resolving disputes than launching the product and taking the risk of paying damages for market harm.²⁸ A successful Paragraph IV submission can also overturn problematic patents prior to their expiration, thereby giving patients earlier access to less-expensive generics.

In order to encourage generics to take on the costs of litigation, the first generic to file a Paragraph IV certification and win regulatory approval earns an exclusivity period of 180 days.²⁹ Before the advent of captive generics, only the brand drug and the first-filing generic competitor were permitted on the market during this “generic duopoly” period.³⁰ Given that the generic company is insulated from competition with other generics over this period, the six-month duopoly represents a lucrative reward. In fact, for many generic products, the exclusivity period can generate the large majority of their lifetime revenue.³¹ As a result, the exclusivity period is a powerful incentive for generics to challenge brand patents, making it key to Hatch-Waxman operating effectively.

The end-of-life for a patent on a blockbuster drug can be a bleak period of time for a brand-name company. When a patent’s exclusionary period ends, the company’s revenue stream can plummet dramatically as new entrants drive prices down to competitive levels. This is how the patent system is designed to operate, but no company wishes to give up its market dominance. As described below, rather than being an inevitable part of the Hatch-Waxman system’s design, captive generics are a shrewd response by brand drug-makers once their monopoly profits for a brand drug give way to encroaching generic competition.³²

On the whole, the Hatch-Waxman Act has worked better than any legislator at the time might have imagined. In 1984, only 35% of top-selling

²⁸ FELDMAN & FRONDORF, *supra* note 2, at 22. An “at-risk” launch describes when a generic manufacturer enters the market with a patent-protected brand drug present. Doing so exposes the generic to liability and damages if they lose the subsequent patent infringement suit—the Paragraph IV certification preempts this risky process.

²⁹ 21 U.S.C. § 355(j)(5)(B)(iv).

³⁰ The 2003 Medicare Modernization and Improvement Act clarified that multiple applicants may enjoy generic exclusivity if they submit Paragraph IV certifications on the same day. See JOHN THOMAS, CONG. RSCH. SERV., RL33605, AUTHORIZED GENERIC PHARMACEUTICALS: EFFECTS ON INNOVATION 7 (2006), <https://crsreports.congress.gov/product/pdf/RL/RL33605> [<https://perma.cc/PT2V-9C6Z>]. Moreover, the “generic duopoly” is a misnomer also because the possibility of a captive generic means that, in fact, a minimum of three distinct generics may exist on the market during this period of time.

³¹ C. Scott Hemphill & Mark A. Lemley, *Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act*, 77 ANTITRUST L.J. 947, 953 (2011) (stating that “[f]or many drugs, the exclusivity period offers the majority of the profits available to the generic firm,” and that once other generics enter, “the falloff in sales can be extreme”) (quoted in Carrier, *Payment After Actavis*, *supra* note 14, at 39).

³² See *infra* notes 40–45 and accompanying text.

brand-name drugs with expired patents had generic alternatives.³³ Following implementation of the Hatch-Waxman system, the proportion of all dispensed prescription drugs comprising generics increased to 43% in 1995, 72% in 2008, and finally 89% in 2016, suggesting that an overwhelming majority of the most commonly purchased brand-name drugs are now available generically.³⁴ Similarly, the share of total pharmaceutical revenue commanded by the sale of generic drugs grew from 19.8% in 2006 to 28.0% in 2016, and an estimated 29.6% or \$91.6 billion in 2022.³⁵

The growth of the generics industry over recent decades has come at the expense of brand companies' revenue. Recognizing that generics reduce the brand revenue stream to a narrow trickle, brand drug-makers have responded by undercutting generic competition through a number of strategic behaviors, which are well-documented and studied in the literature.³⁶ In addition to these strategies, however, brand companies have addressed the problem of true generics by following the old adage, "if you can't beat 'em, join 'em." The result is the emergence of captive generics.

As with true generics, captive generics are chemically identical versions of brand-name drugs. These versions, however, are licensed or produced by the brand-name drug company itself.³⁷ Crucially, neither an ANDA nor a separate New Drug Application ("NDA") is required when a brand decides to launch or license a captive generic. Rather than having to submit to these lengthy and expensive processes, a brand company wishing to release a captive generic can simply notify the FDA.³⁸ Moreover, the brand drug-maker is free to launch or license its captive generic at any point in time, including during the exclusivity period.³⁹

Captive generics first appeared on the scene in the 1990s, largely struggling at first before experiencing widespread success in the early 2000s as generic markets continued to expand. Although 119 captive generics were launched between 2001 and 2008, only 7 were released prior to 2003, before increasing to an average of 19–21 captive generic launches per year between

³³ Garth Boehm, Lixin Yao, Liang Han & Qiang Zhang, *Development of the Generic Drug Industry in the U.S. after the Hatch-Waxman Act of 1984*, 3 ACTA PHARMACEUTICA SINICA B 297, 298 (2013), <https://www.sciencedirect.com/science/article/pii/S2211383513000762?via%3Dihub> [https://perma.cc/8ZQC-AL4D].

³⁴ Marc-Andre Gagnon & Karena Volesky, *Merger Mania: Mergers and Acquisitions in the Generic Drug Sector, 1995 to 2016*, 13 GLOBALIZATION & HEALTH 62, 62 (2017), <https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-017-0285-x> [https://perma.cc/5YXQ-M3QN].

³⁵ Hoffman, *supra* note 6, at 71.

³⁶ See Feldman, *Devil*, *supra* note 11; Wineinger et al., *supra* note 12; COLO. DEP'T OF LAW, *supra* note 13.

³⁷ See U.S. FOOD & DRUG ADMIN., *supra* note 18.

³⁸ *Id.*

³⁹ For the judicial basis of captive generics' entry during the exclusivity period, see *infra* notes 44–54 and accompanying text.

2003 and 2006.⁴⁰ By 2018, captive generics were arriving at the frenetic rate of about one per week.⁴¹

One explanation for the growth of captive generics in the early 2000s is that during this period, pharmacies and physicians became quicker to pivot from brand to generic drugs once the generic entered the market.⁴² In addition, an increase in Paragraph IV challenges and improved litigation success rates in the early 2000s bolstered generic markets. In turn, this trend boosted the number of product markets for which captive generics made financial sense. Generics' growing strength in the marketplace and the courthouse gave brand drug-makers the incentive to stake their own claims in the generic market and, in doing so, deter would-be competitors.⁴³

The ascent of captive generics did not occur without challenge. In 2004, generic drug-makers Teva and Mylan filed petitions with the FDA, requesting that the Agency prohibit the distribution of captive generics during the 180-day exclusivity period.⁴⁴ Teva also requested that the FDA require brand companies holding NDAs to file supplemental NDAs ("sNDAs") in order to market and distribute captive generics.⁴⁵ In effect, Teva and Mylan's petitions advocated for requiring captive generics to play by the same Hatch-Waxman rules as true generics, as well as for fully excluding captive generics from the first-filer exclusivity period.

The FDA rejected the petitions, which prompted two legal challenges by the generic companies. In *Teva Pharmaceuticals Industries, Ltd. v. Crawford*, the D.C. Circuit agreed with the FDA that the Hatch-Waxman Act does not prohibit NDA holders from marketing captive generics during the exclusivity period.⁴⁶ Teva argued that Congress could not have anticipated captive generics and hence a "functional" interpretation was needed to preserve Hatch-Waxman's statutory purpose.⁴⁷ Otherwise, as Teva argued, "adhering to the 'literal' terms of the statute would lead to an absurd result, namely, that [the Hatch-Waxman Act] grants only a 'meaningless' exclusivity against subsequent ANDA filers rather than a 'commercially effective' ex-

⁴⁰ FTC AG REPORT, *supra* note 24, at 11.

⁴¹ Jay Hancock & Sydney Lupkin, *Drugmakers Master Rolling Out Their Own Generics To Stifle Competition*, KAISER HEALTH NEWS (Aug. 5, 2019), <https://khn.org/news/drugmakers-now-masters-at-rolling-out-their-own-generics-to-stifle-competition/> [<https://perma.cc/RM2U-VYN6>].

⁴² THOMAS, *supra* note 30, at 8.

⁴³ *See id.*; *see also* FTC AG REPORT, *supra* note 24, at 11–12.

⁴⁴ *See* Teva Pharm. Indus. Ltd. v. Crawford, 410 F.3d 51, 52 (D.C. Cir. 2005); Mylan Pharm., Inc. v. U.S. Food and Drug Admin., 454 F.3d 270, 273 (4th Cir. 2006); *see also* John M. Rebman, *Dr. Strange Drug, Or: How I Learned to Stop Worrying and Love Authorized Generics*, 12 DEPAUL J. HEALTH CARE L. 159, 169 (2009). The petitions were filed as part of the so-called "citizen petition" process. Designed in the 1970s to encourage ordinary citizens to participate in regulatory agency process, the citizen petitions at the FDA are frequently filed by drug manufacturing companies, rather than ordinary citizens. *See* Feldman et al., *supra* note 15, at 43; Carrier & Minniti, *supra* note 15, at 328.

⁴⁵ Rebman, *supra* note 44, at 169.

⁴⁶ Teva, 410 F.3d at 55.

⁴⁷ *Id.* at 53–54.

clusivity that runs against the NDA holder as well.”⁴⁸ In other words, the generic company argued that captive generics so undermined the incentive structure designed by Hatch-Waxman that they should be entirely prohibited from the market during the exclusivity period.

The court, however, was not swayed. In its ruling, the court chafed at Teva’s interpretation of the exclusivity period as an unlimited guarantee to generic companies.⁴⁹ The court also pointed out that the statutes do not suggest any authority to ban captive generics.⁵⁰ Indeed, reasoned the court, “nothing in the [Federal Food, Drug, and Cosmetic] Act prohibited the holder of an approved NDA from marketing a ‘brand-generic’ version of its drug,”⁵¹ and Hatch-Waxman neglects any mention of captive generics.⁵² Moreover, the ruling suggested that the possibility of captive generics did not sufficiently disrupt the incentives of Hatch-Waxman as written.⁵³

The court in *Mylan Pharmaceuticals, Inc. v. FDA* ruled similarly. In 2006, the Fourth Circuit affirmed that Hatch-Waxman does not empower the FDA to ban captive generics from the 180-day exclusivity period, however much it economically limits the generic first-filer.⁵⁴ In so doing, *Mylan* joined the *Teva* decision in validating the FDA’s stance in favor of captive generics.

With *Teva* and *Mylan* giving the green light, captive generics have become a fixture in the pharmaceutical industry.⁵⁵ As the validity of captive generics was weighed in court and as pharmacists increasingly dispensed captive generics, several studies sought to discern their effects on drug price—with conflicting outcomes. One group of researchers—funded by drug-maker giant Johnson & Johnson—found that captive generics lowered prices during the first filer’s six-month exclusivity period.⁵⁶ In contrast, a different study—authored by a consultant to Canada’s largest generic company—modeled and confirmed using empirical data from the Canadian drug market that the presence of a captive generic corresponded to higher brand prices as late as four years following generic entry.⁵⁷ Another pair of studies

⁴⁸ *Id.* at 54.

⁴⁹ *See id.* (“It does not follow, however, from the Congress having intended to create an incentive to challenge brand-drug patents—as it clearly did—that the incentive it created is without limitation.”).

⁵⁰ *See id.* (“Nothing . . . permits the agency to create a de facto type of exclusivity against the NDA holder’s brand-generic drug.”).

⁵¹ *Id.* at 53.

⁵² *See generally* Hatch-Waxman, *supra* note 1.

⁵³ *Teva*, 410 F.3d at 54 (“Nor, contra *Teva*, is the result of reading the Act as it is written to render ‘meaningless’ the ‘specific statutory incentive that Congress enacted.’ For 180 days the generic market is the exclusive preserve of two firms. . .”).

⁵⁴ *Mylan*, 454 F.3d at 271.

⁵⁵ *See supra* notes 36-39 and accompanying text.

⁵⁶ *See* Ernst R. Berndt, Richard Mortimer, Ashoke Bhattacharjya, Andrew Parece & Edward Tuttle, *Authorized Generic Drugs, Price Competition, and Consumers’ Welfare*, 26 HEALTH AFF. 790, 795-96 (2007).

⁵⁷ Aidan Hollis, *How Do Brands’ “Own Generics” Affect Pharmaceutical Prices?*, 27 REV. INDUS. ORG. 329, 344-48 (2005).

published in the same year reached mutually conflicting conclusions as to the effect of captive generics on prices despite the fact that the studies used the same dataset of drugs. Perhaps unsurprisingly, one study was funded by PhRMA, while the generic industry trade group sponsored the other.⁵⁸

Most notably, in 2011, the FTC published a comprehensive report examining how captive generics impact drug prices, generic entry, and instances of anticompetitive conduct such as pay-for-delay.⁵⁹ The report confirmed that brand companies deploy captive generics both to cushion profit losses following patent expiration and to discourage generic entry.⁶⁰ The report noted that small drug markets are especially vulnerable to the discouraging effects of a captive generic.⁶¹ The agency, studying price data from 2003–2008, did find captive generics to be associated with lower retail generic prices but only if the captive generic enters during the exclusivity period.⁶²

One could argue that lower prices during the exclusivity period are exactly the opposite of what Hatch-Waxman intended. The exclusivity period is a short-term concession to duopoly designed to incentivize generic entry and, by extension, long-term competition. Thus, although the immediate price reduction provides a short-term benefit to patients, the more significant harm is the deterrence of generic competition.

In particular, it is generic companies, not brands, that bear the consequences of the temporary price reduction reported by the FTC. The agency's study concluded that true generics lose between 40–52% of exclusivity period revenue, a proportion that increases to 53–62% in the first thirty months after exclusivity.⁶³ On the other hand, brand company revenue is not affected.⁶⁴ The FTC report explained that reduction in revenue from the brand is offset by revenue from the captive generic during this period, with the result that overall revenues to the brand company are not diminished.⁶⁵ The report failed to study the effects of captive generics on brand prices or market share.

⁵⁸ Compare IMS CONSULTING, *supra* note 20, with Aidan Hollis & Bryan A. Liang, *An Assessment of the Effects of Authorized Generics on Consumer Prices*, 12–18 (July 31, 2006); see also FTC AG REPORT, *supra* note 24, at 35 (documenting discord between prior studies of captive generics' pricing effects, especially with respect to whether wholesale or retail drug prices should be used).

⁵⁹ See FTC AG REPORT, *supra* note 24.

⁶⁰ *Id.* at iv.

⁶¹ *Id.* at iii.

⁶² *Id.* at ii, 101.

⁶³ *Id.* at iii.

⁶⁴ *Id.* at 63 (“Finally, while sales of brand-name products are lower when an AG is launched, revenue losses on brand-name products may be offset by revenues from AGs. The data do not suggest that brand-name firms’ overall revenues are diminished.”). The FTC report stopped short of saying that the data definitively show an increase in brand-name firms’ overall revenues, but it found no evidence that the data show a decrease. *Id.* at 61–62.

⁶⁵ *Id.* at 61–62.

In spite of the diminished revenue opportunity, the FTC report asserted that the rise of captive generics has not reduced the total number of Paragraph IV challenges. As a result, the report suggested that captive generics have not restricted generic entry on the whole. The report, however, conceded that other factors—such as the continued growth of the generics market—may be masking any detracting effect the presence of captive generics may be having on generics’ decision to attempt entry.⁶⁶

The FTC, moreover, hinted that because of captive generics, true generic companies require a larger market size and a greater expectation of winning a Paragraph IV patent suit across all drug markets in order to be sufficiently incentivized to challenge brand drug patents.⁶⁷ This could implicate other concerns. If the number of Paragraph IV challenges holds steady even though generic companies have less incentive to win them, perhaps generic companies are being motivated to file Paragraph IV certifications, not to follow them to conclusion, but to enter into collusive settlements that are not in society’s interests. In fact, as the next section will detail, the FTC report raised considerable alarm about the role of captive generics in collusive patent settlements that kept generic competition off the market.

III. ANTICOMPETITIVE APPLICATIONS, INCLUDING CONSUMER HARMS & BROADER SOCIETAL IMPLICATIONS

The case in favor of captive generics asserts that they serve generic competition by providing another price-lowering drug option to consumers.⁶⁸ As has been well-described in the literature,⁶⁹ however, captive generics

⁶⁶ See *id.* at 121 (“[I]t is possible that disincentives to patent challenges arising from the marketing of AGs during exclusivity might be masked by other factors that encouraged such challenges.”).

⁶⁷ *Id.* at 124 (“The sales-level data thus suggest that many low-sales drugs receive patent challenges, notwithstanding potential AG competition. This is not to say that patent-challenge incentives are adequate for all small-market drugs. Nor does it suggest that patent challenges are as likely for small-revenue drugs as for large-revenue drugs. Indeed, as a general matter, the reverse is true.”).

⁶⁸ See, e.g., IMS CONSULTING, *supra* note 20.

⁶⁹ See, e.g., Feldman, *Price Tag*, *supra* note 14; Feldman & Misra, *supra* note 14; Hemphill, *Paying for Delay*, *supra* note 14; Carrier, *Payment After Actavis*, *supra* note 14; FELDMAN & FRONDORF, *supra* note 2, at 34–48 (describing history of pay-for-delay settlements); C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629 (2009) (analyzing different types of pay-for-delay); Matthew Avery & Mary Nguyen, *The Roadblock for Generic Drugs: Declaratory Judgment Jurisdiction for Later Generic Challengers*, 15 N.C. J.L. & TECH. 1 (2013) (discussing how later generic filers have tried to contest consequences of pay-for-delay settlements between generic first-filers and brand drug company); FED. TRADE COMM’N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS (2010), <https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf> [<https://perma.cc/3TKZ-9J8Q>] (analyzing empirical costs to consumers of pay-for-delay settlements); Farasat A.S. Bokhari, Franco Mariuzzo & Arnold Polanski, *Entry Limiting Agreements: First-Mover Advantage, Authorized Generics, & Pay-for-Delay Deals*, 29 J. ECON. & MGMT. STRATEGY 516 (2020) (showing how limiting ability of brand drug companies to re-

have the potential to directly undermine generic competition through so-called pay-for-delay settlements. The presence, or the threat, of captive generic competition allows brand companies to deploy a variety of tactics that either tempt or threaten generics into agreeing to stay off the market for a period of time. As the following Section will explain, many of these variations—including so-called “no-AG clauses,” declining royalty structures, and acceleration clauses—have flourished in the decade since the FTC study was published. Equally troubling, but previously undescribed, is the role of captive generics in exacerbating brand companies’ abuses of the health insurance reimbursement system. Specifically, captive generics are displacing or distorting the proper location of true generics, squeezing additional profit out of a mechanism intended to save patients and health plans money.

A. *Pay-for-Delay*

Pay-for-delay deals unfold in the following manner: a prospective generic files a Paragraph IV challenge, alleging that a branded drug’s patents are “invalid or not infringed” by their generic product.⁷⁰ The brand company then sues the generic filer for patent infringement. As an alternative to costly patent litigation, a brand company can offer the generic filer a deal: if the generic agrees to postpone entry to a later date, the brand will drop the infringement suit and reward the generic with a payment. A payment may manifest as a simple cash transfer or as a number of other promises—such as the opportunity to avoid competing with a captive generic—that furnish the generic with extra revenue. A pay-for-delay settlement is a win-win for the brand and the generic. The brand company gets to maintain its monopoly position in the market longer than it would have if the patent had been overturned. The generic company receives some form of value in exchange for delaying market entry, and still enjoys six months as the only generic product when it eventually comes to market.

As numerous scholars and commentators have explained, the losers in the deal are patients, payors, and society.⁷¹ During the period in which monopoly pricing remains, those who pay the bills have to shoulder the burden of higher prices and reduced access. Society loses in the form of reduced competition during the period of delay.

Both brand and generic companies involved in these types of settlements have argued that the settlements are perfectly acceptable.⁷² They claim

lease captive generics also limits brand drug company incentives to enter into pay-for-delay settlements).

⁷⁰ See generally Feldman & Misra, *supra* note 14, at 253–54.

⁷¹ See Feldman, *Price Tag*, *supra* note 14; Feldman & Misra, *supra* note 14; Hemphill, *Paying for Delay*, *supra* note 14; Carrier, *Payment After Actavis*, *supra* note 14; FELDMAN & FRONDORF, *supra* note 2, at 69–80; Cheng, *supra* note 16.

⁷² See, e.g., Brief of Pharmaceutical Research & Manufacturers of America (“PhRMA”) as Amicus Curiae in Support of Respondent at 2–5, *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013) (No. 12-416); Brief of Generic Manufacturers Upsher-Smith Laboratories, Inc. et al. as Ami-

that settling a case is a rational reflection of the costs and risks of taking a case to trial, and that any settlement saves judicial resources.⁷³ In many of these settlements, moreover, the companies merely agree that the generic will stay out of the market until the time the patent would have expired anyway. How can that be a problem?

As Hemphill has noted, “Not all patents are created equal.”⁷⁴ Patent examiners have limited time to review patent applications. Most patents never generate any revenue for the patent holders and are largely irrelevant. Thus, the system relies on the courts to weed out improper patents that may become important in the market. Moreover, many patents involved in Hatch-Waxman litigation are weak, ancillary patents based on minor modifications to a drug’s dosage or delivery system.⁷⁵ These can be subject to challenge on the grounds that they would be obvious to one skilled in the relevant art.

Nor are all patents properly applied to a particular drug. Companies launch numerous weapons at potential competitors, not all of which are justified. For the brand company to win, the patent must be valid, and the generic must infringe that patent. And yet, experience shows that is frequently not the case in Hatch-Waxman litigation. Rather, the FTC found that when generics pursue Hatch-Waxman litigation to its conclusion, the generic wins three-quarters of the time.⁷⁶

Most important, Hatch-Waxman was designed to encourage generic companies to challenge weak patents. When brand companies pay generics to drop those challenges, the settlement undermines the intent of the Hatch-Waxman system. Even if the result is merely that the patent holder enjoys the full patent term, the appropriate length of time for an invalid patent—one that is invalidly applied—would be zero.

cus Curiae in Support of Respondents at 2–4, *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013) (No. 12-416).

⁷³ For a discussion of how pay-for-delay is economically irrational as a business deal outside the context of paying for an extended monopoly period, see FELDMAN & FRONDORF, *supra* note 2, at 51–52; Steve D. Shadowen, Keith B. Leffler & Joseph T. Lukens, *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 *RUTGERS L.J.* 1, 76 (2009) (“If a profit-maximizing firm engages in conduct that would not be economically rational (i.e., increase profits) absent a reduction in competition, then it can be inferred that the firm was aware of and motivated solely to achieve that reduction.”); Michael A. Carrier, *Sharing, Samples, & Generics: An Antitrust Framework*, 103 *CORNELL L. REV.* 1, 27 (2017) (“If a firm undertakes conduct that makes no economic sense, its ‘anticompetitive intent’ can be ‘unambiguous . . . inferred.’”).

⁷⁴ C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 *J. EMPIRICAL LEGAL STUD.* 613, 619 (2011).

⁷⁵ *See id.* at 621; *see also* KEVIN T. RICHARDS, KEVIN J. HICKEY & ERIN H. WARD, *CONG. RSCH. SERV.*, R46221, *DRUG PRICING AND PHARMACEUTICAL PATENTING PRACTICES* 17 (2020).

⁷⁶ *FED. TRADE COMM’N, supra* note 2, at 16. In light of this problem, the FDA established a separate database compiling patents associated with brand drugs that are in dispute. *See FED. TRADE COMM’N, ORANGE BOOK PATENT LISTING DISPUTE LIST* (2021), <https://www.fda.gov/drugs/drug-approvals-and-databases/orange-book-patent-listing-dispute-list> [<https://perma.cc/2LZE-8NTG>].

In 2013, the Supreme Court's *Actavis* decision opened pay-for-delay deals to antitrust scrutiny, finding that a sufficiently large reverse payment might indicate anticompetitive behavior.⁷⁷ Notably, the settlement at issue included a cash transfer,⁷⁸ a fact that further encouraged drug-makers to opt for more complex payment methods.⁷⁹

Captive generics provide a perfect vehicle for creating value. The absence of a captive generic can make the exclusivity period more lucrative for a first-filing generic. Thus, a promise by the brand company not to market a captive generic during the exclusivity period can represent a significant transfer of value to the generic company. In essence, such an agreement promises the generic company the full cut of its expected exclusivity revenue, effectively "paying" it the revenue that the generic company would lose if a captive generic were to enter.

As this author has noted in studying pay-for-delay deals, these agreements can constitute offers that generics cannot refuse:

The deal is a little like old movies portraying protectionist rackets, in which the neighborhood shakedown artist says, 'Nice front window you have there. Be a real shame if it got smashed in.' Here, a brand-name company can say the equivalent of, 'Nice 180-day exclusivity period. Be a real shame if you lost half of it. Tell you what, just stay off the market for a while, and it is all yours.'⁸⁰

Agreements in which brand companies agree not to launch some form of a captive generic as part of pay-for-delay deals are charmingly called "no-AG [authorized generic] clauses."⁸¹ The title, which is used throughout FTC reports on pay-for-delay agreements, is as hopelessly convoluted as the clauses themselves; this article will not even begin to try to improve it.

With no-AG clauses, many brand drug-makers have successfully prolonged their monopolies by promising not to market a captive generic during the first filer's exclusivity period. In fact, studying patent settlement agreements between 2004 and 2010, the FTC found that nearly a quarter of deals included captive generics in some form.⁸² In the majority of these, the brand promised to not compete with the first filer by releasing a captive generic.⁸³ In the seven-year period studied, these settlements postponed generic com-

⁷⁷ *FTC v. Actavis, Inc.*, 570 U.S. 136, 159 (2013) ("[T]he likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.").

⁷⁸ *Id.* at 145.

⁷⁹ See generally FELDMAN & FRONDORF, *supra* note 2, at 49–56.

⁸⁰ See Feldman, *Price Tag*, *supra* note 14, at 37.

⁸¹ Although the author prefers the term "captive generic" to the benign-sounding "authorized generic," the term "no-AG clause" is maintained here on account of its widespread use to refer to the practice in settlement agreements.

⁸² *FTC AG REPORT*, *supra* note 24, at 139.

⁸³ See *id.* at 144 (39 of 75 agreements involving captive generics included a promise by the brand to not use its captive generic to compete with the first-filer).

petition in drug markets worth more than \$23 billion.⁸⁴ The arrangement is a win-win for brand and generic companies' bottom line, at harm to payors and patients.⁸⁵

Promises not to compete with a captive generic can manifest in several ways. Commonly, a brand manufacturer grants the generic an exclusive license or exclusive supply of their captive generic for a set period of time, effectively excluding a captive generic from the market.⁸⁶ Rather than making an explicit promise not to compete using a captive generic, a brand can also promise not to license or distribute their captive generic to a third party.⁸⁷ If the brand manufacturer has a limited track record of launching captive generics, this agreement can have the same outcome as a no-AG clause.⁸⁸

Although courts initially failed to extend *Actavis* to pay-for-delay deals that used payments other than cash,⁸⁹ the judicial system eventually caught on to the practice, recognizing that a no-AG clause can work like a cash transfer in compensating generic companies to stay off the market.⁹⁰ As a

⁸⁴ *Id.* at 147.

⁸⁵ See Feldman, *Price Tag*, *supra* note 14, at 17–34.

⁸⁶ FTC AG REPORT, *supra* note 24, at 146; see, e.g., King Drug Co. of Florence v. Smithkline Beecham Corp., 791 F.3d 388, 406–08 (3d Cir. 2015) (describing the mechanics of an anticompetitive no-AG settlement).

⁸⁷ See, e.g., FED. TRADE COMM'N, OVERVIEW OF AGREEMENTS FILED IN FY 2017: A REPORT BY THE BUREAU OF COMPETITION 2 (2020) [hereinafter FTC FY 2017 REPORT].

⁸⁸ See Jamie Towey & Brad Alpert, *Then, Now, and Down the Road: Trends in Pharmaceutical Patent Settlements After FTC v. Actavis*, FED. TRADE COMM'N (May 28, 2019), <https://www.ftc.gov/news-events/blogs/competition-matters/2019/05/then-now-down-road-trends-pharmaceutical-patent> [<https://perma.cc/FDF2-RZWH>] (“[A]n agreement in which the brand company commits not to license any third party to sell an AG product for a period of time (a no-third-party-AG commitment) . . . could nonetheless replicate the adverse effect of a no-AG commitment, particularly if the brand company has little or no experience selling generic products in the United States.”).

⁸⁹ See, e.g., *In re Loestrin 24 Fe Antitrust Lit.*, 814 F.3d 538, 538 (1st Cir. 2016); *In re Lamictal Direct Purchaser Antitrust Litig.*, 18 F. Supp. 3d 560 (D.N.J. 2014), *vacated and remanded sub nom. King Drug*, 791 F.3d 388.

⁹⁰ See *Loestrin*, 814 F.3d at 549–50; *King Drug*, 791 F.3d at 403–06; *In re Aggrenox Antitrust Litig.*, 94 F. Supp. 3d 224, 243 (D. Conn. 2015) (“[R]everse payments . . . can bring [anticompetitive] effects regardless of the particular form the transfer of value takes and thus are not limited to cash payments.”); *United Food & Com. Workers Loc. 1776 v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1069–70 (N.D. Cal. 2014) (rejecting theory that *Actavis* applies only to cash reverse payments as “[t]here are many plausible methods by which plaintiffs may calculate the value of non-monetary terms.”); *In re Effexor XR Antitrust Litig.*, No. 11–5479 (PGS) (LHG), slip op. at 19 (D.N.J. Oct. 6, 2014) (“The common use of the term payment is described as something given to discharge a debt or obligation and does not require the payment to be in the form of money.”); *Time Ins. Co. v. Astrazeneca AB*, 52 F. Supp. 3d 705, 710 (E.D. Pa. 2014) (“In my opinion, reverse payments deemed anti-competitive pursuant to *Actavis* may take forms other than cash payments.”); *In re Lipitor Antitrust Litig.*, 46 F. Supp. 3d 523, 543 (D.N.J. 2014) (finding that *Actavis* covers situations where “the non-monetary payment must be converted to a reliable estimate of its monetary value.”); *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 751 (E.D. Pa. 2014) (“[T]he term ‘reverse payment’ is not limited to a cash payment.”); *In re Nexium (Esomeprazole) Antitrust Litig.*, 968 F. Supp.2d 367, 392 (D. Mass. 2013) (“This Court does not see fit to read into the opinion a strict limitation of its principles to monetary-based arrangements alone.”).

result, the FTC, in its most recent annual report on brand-generic settlements, celebrated zero instances of the no-AG clauses that were so prevalent a decade prior.⁹¹

But even as courts have successfully deterred no-AG clauses, drug-makers continue to devise other complex arrangements that leverage their captive generics. For instance, a “declining royalty structure” reduces the amount the generic company pays the brand for a license of their drug if the brand launches a competing captive generic.⁹² In this scenario, a brand settles its patent dispute by licensing the disputed drug to a generic company, for which the generic company owes the brand a royalty. The royalty amount, however, decreases if the brand launches a captive generic. Reducing the royalty amount the generic must pay the brand if a captive generic enters acts as an incentive for the brand to not launch a captive generic. In this way, a declining royalty structure can function like a no-AG clause.⁹³

The convoluted mechanics of declining royalty structures and the absence of an explicit promise not to compete, however, may explain the FTC’s hesitancy to label this scheme—several of which occur annually—as an example of anticompetitive conduct.⁹⁴ Moreover, the only material payment in a declining royalty structure occurs from generic to brand company, in contrast to the typical “reverse payment” from brand to generic.⁹⁵ Seeing past the smoke and mirrors, however, it is clear the declining royalty structure presents another way that a drug-maker can anticompetitively withhold its captive generic.⁹⁶

⁹¹ See Press Release, Fed. Trade Comm’n, *FTC Staff Issues FY 2017 Report on Branded Drug Firms’ Patent Settlements with Generic Competitors* (Dec. 3, 2020), <https://www.ftc.gov/news-events/press-releases/2020/12/ftc-staff-issues-fy-2017-report-branded-drug-firms-patent> [<https://perma.cc/369J-UA46>] (“[F]or the first time since [fiscal year] 2004, no agreement in [fiscal year] 2017 contains a no-AG commitment.”).

⁹² FTC FY 2017 REPORT, *supra* note 87, at 2.

⁹³ *Id.*

⁹⁴ See FTC FY 2017 REPORT, *supra* note 87, at 2 (recognizing that the declining royalty structure may achieve the same effect as an explicit no-AG clause); see also Feldman & Misra, *supra* note 14, at 265–66 (noting that FTC reports have become increasingly cognizant of the declining royalty structure as an anticompetitive tool, re-categorizing them from a form of unknown payment in 2010 to a form of possible compensation in 2013).

⁹⁵ Pay-for-delay cases are often termed “reverse payment settlements.” See FELDMAN & FRONDORF, *supra* note 2, at 24 (“‘Reverse payment’ refers to the odd nature of the arrangement—instead of a defendant paying a plaintiff to settle a suit, brand drug companies pay off the generic to end a patent infringement lawsuit.”).

⁹⁶ A recent complaint alleges a more complex and convoluted structure for a deal in which the generic agrees to enter only as a captive generic in exchange for a deal that reduces the incentive for the brand to produce a competing captive generic. See Complaint, *Molina Healthcare Inc. v. Jazz Pharms., Inc.*, No. 3:21-cv-07935 (N.D. Cal. Oct. 8, 2021). Specifically, *Jazz* involves a brand offering a potential generic competitor a six-month license with an escalating royalty agreement based on the number of generic bottles sold. The plaintiffs allege the royalty scheme disguises the value transfer from the brand to the generic because it gives the appearance of having the alleged generic infringer pay the brand. Nevertheless, if the brand authorized another generic, captive generic #2 would just reduce the number of bottles sold by captive generic #1, which would, in turn, reduce the flow of payments of captive generic #1 to

Brand drug-makers may also elect to license their captive generic to another manufacturer,⁹⁷ allowing the opportunities for captive generic games to multiply with the brand manufacturer's portfolio of drugs.⁹⁸ Given that captive generics are permitted during the 180-day exclusivity period, a license to a captive generic can serve as a considerable inducement for a generic company that is otherwise excluded from the 180-day exclusivity window.⁹⁹ In return, the generic may agree to delay its entry into a *different* drug market where it could compete with the brand drug-maker. In other words, in order to delay the generic entry of one drug, a brand manufacturer may offer the generic licenses to captive generics on *other drugs* marketed by the brand, even if the generic company did not even attempt to enter those other generic markets.

For example, in return for delaying the launch of a true generic version of the oral contraceptive Loestrin, the brand company, Warner Chilcott, compensated the challenging generic drug-maker with licenses to market captive generic versions of Femcon, another drug the brand company owned.¹⁰⁰ Such an agreement may not limit competition for Femcon, and, if the brand company would not have otherwise launched a captive generic, the deal may actually prove procompetitive in that drug market.¹⁰¹ Nevertheless, the anticompetitive harm caused by extending the Loestrin monopoly must also be scrutinized in order to determine whether the Femcon captive generic ultimately detracts from generic competition.¹⁰² As with declining royalty structures, introducing captive generics across several drug markets can help camouflage anticompetitive outcomes.

the brand. This structure, therefore, reduces the brand's incentive to authorize a second party to compete with the first generic, thereby providing value to the first generic.

⁹⁷ See, e.g., Jing Luo, John D. Seeger, Macarius Donneyong, Joshua J. Gagne, Jerry Avorn & Aaron S. Kesselheim, *Effect of Generic Competition on Atorvastatin Prescribing and Patients' Out-of-Pocket Spending*, 176 JAMA INTERN. MED. 1317, 1318 (2016) (noting that Pfizer licensed a captive generic version of its blockbuster Lipitor to Watson), reprinted in FELDMAN & FRONDORF, *supra* note 2, at 59.

⁹⁸ Other evidence of drug-makers' market power accruing over a portfolio of drugs can be seen in practices such as bundling, as drug-makers wield power in one drug market to secure preferential formulary tiering for its product in another market. Cf. ROBIN FELDMAN, DRUGS, MONEY, AND SECRET HANDSHAKES 22 (2019) [hereinafter FELDMAN, HANDSHAKES] (describing how drug-makers can utilize volume-based leverage to negotiate advantageous rebate positions with insurers and pharmacy benefit managers ("PBMs") across several different products, even excluding rivals from the market entirely).

⁹⁹ If the generic company is not the first to file an ANDA, then it may not market its generic during the exclusivity period.

¹⁰⁰ *In re Loestrin 24 Fe Antitrust Lit*, vacated and remanded, 814 F.3d 538, 547 (1st Cir. 2016).

¹⁰¹ See FTC AG REPORT, *supra* note 24, at 152.

¹⁰² This situation exemplifies why a holistic, broad scrutiny of settlements is required to accurately assess competitive harm. See Mark A. Lemley & Robin Feldman, *Atomistic Antitrust*, 63 WM. & MARY L. REV. (forthcoming 2022) (arguing that the narrow scope of current antitrust law has no answer for individually lawful acts that, taken together, create anticompetitive harm); see also *infra* Part V (advocating for updated and broadened regulatory review of mergers and other agreements).

Moreover, if a captive generic license works as a carrot, it can also be used as a stick. Brands may sign deals that license their captive generic to non-first-filer generic companies, specifying that the license will take effect only if the original filer—the generic engaged in Hatch-Waxman litigation—does not settle its patent suit with the brand or launch its generic product “at risk.”¹⁰³ The brand can then publicly release the details of its agreement with the non-first-filer generic companies through a press release or public earnings report to induce the first-filing generic to settle its patent litigation.¹⁰⁴ Basically, the brand coerces the first-filer into settling by hinting that if the first-filer doesn’t settle with the brand, a captive generic is ready to join the first-filer on the market and slash its revenue. Of course, any threat from the brand is merely implied, enabling brand companies to plead ignorance or otherwise disguise any anticompetitive intentions.

Such a settlement, especially if the brand would not have otherwise released a captive generic, may also appear procompetitive by increasing the number of drug options on the market. However, society may be ultimately harmed if a generic company is enticed to settle a patent infringement suit it was likely to win,¹⁰⁵ an outcome that would have opened the market to more competitors even sooner. In one agreement that relied on this scheme, the settlement postponed generic entry by more than three years—hardly a boon for competition.¹⁰⁶

Other captive generic schemes are trickier still. Given that captive generics are not barred from the exclusivity period, brand drug-makers can create a proto-exclusivity period for those generic companies that did not file the first ANDAs and therefore would not be able to market a drug during the first-filer’s exclusivity period. For example, despite not being the first to file, Teva received a license to market Takeda’s captive generic version of AC-TOS along with permission to enter with its own generic product after the first-filer’s exclusivity period ended.¹⁰⁷ The settlement Takeda and Teva entered into following Teva’s Paragraph IV challenge also ensured that Teva could enter the market with the captive generic earlier than the agreed-upon

¹⁰³ For an explanation of “at risk” launch see Michele B. Kaufman, “*At-Risk*” *Generic Launches Can Be Unpredictable*, MODERNMEDICINE NETWORK (May 1, 2010), <http://www.formularywatch.com/view/risk-generic-launches-can-be-unpredictable> [<https://perma.cc/3LXE-V7YE?type=image>] (“At-risk” generic launches refer to generic pharmaceuticals that are approved by FDA based on the review of an abbreviated new drug application (ANDA) and are subsequently launched while patent litigation is ongoing.”).

¹⁰⁴ *Id.* at 151–52.

¹⁰⁵ See C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCIENCE 1386, 1387 (2013) (showing that 89% of patents in settled litigation disputes are secondary patents, which courts usually—68% of the time—find invalid or not infringed); John R. Allison, Mark A. Lemley & David L. Schwartz, *Understanding the Realities of Modern Patent Litigation*, 92 TEX. L. REV. 1769, 1787 (2014) (a study of patent lawsuits filed between 2008–2009 in a federal district court found that accused infringers won 74% of the definitive merits rulings while patentees won only 26% of the time).

¹⁰⁶ FTC AG REPORT, *supra* note 24, at 151.

¹⁰⁷ *In re Actos End Payor Antitrust Litig.*, No. 13-CV-9244 RA, 2015 WL 5610752, at *6 (S.D.N.Y. Sept. 22, 2015), *aff’d in part, vacated in part*, 848 F.3d 89 (2d Cir. 2017).

date if another generic successfully challenged Takeda's patents—an assurance known as an acceleration clause.¹⁰⁸ The acceleration clause ensured Teva would still have a chance to beat other generics to the market. Per the agreement, Teva would pay Takeda 75% of any profits earned from marketing the captive generic.¹⁰⁹

In 2015, indirect purchasers of ACTOS brought a class action suit against Takeda, Teva, and three generic companies that won first-filer rights to the drug, alleging that the settlements Takeda had come to with each of the other companies constituted an antitrust violation. Although the district court declined to find the settlements problematic, Takeda's agreement with Teva may still exhibit a troubling application of the captive generic. In deeming the agreement permissible, the court noted that it "did not preclude Takeda from authorizing any other generic": that is, Takeda retained the right to grant licenses for marketing captive generic versions of ACTOS to the other first-filer generic companies during the 180-day exclusivity period and then to "any other manufacturer" following the period's end.¹¹⁰ By granting these additional licenses, Takeda would increase generic competition. The court also reasoned that the 75% royalty payments Teva would pay Takeda for the right to market as a captive generic were acceptable in contrast to the "reverse payments" scrutinized in *Actavis*.¹¹¹ Neither the FTC nor the Department of Justice took issue with the agreement.¹¹²

In fact, the acceleration clause within the agreement not only pressured the three generic first-filers into settling to avoid competing with Teva; it also deterred other prospective generics from challenging Takeda's patents by guaranteeing that their entrance would trigger the presence of competitors.¹¹³ In so discouraging generic competition, Takeda effectively guaranteed Teva what amounted to an exclusivity period—with partial royalties from sales of the captive generic—that the company would not have been able to access otherwise, given that it was not itself a first-filer. Of course, it is entirely possible that the 25% Teva could keep from its captive generic sales may not qualify as a sufficiently "large" payment under *Actavis*.¹¹⁴ Nevertheless, creating an artificial exclusivity period, as Takeda did for Teva

¹⁰⁸ *Id.* at *15; see also Carrier, *Payment After Actavis*, *supra* note 14, at 37–40 (using the term "poison-pill clauses" and noting that acceleration clauses can also effectively deter subsequent filers from litigating by negating the exclusivity period incentive).

¹⁰⁹ *In re Actos End Payor Antitrust Litig.*, 2015 WL 5610752, at *18.

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² *Id.* at *6.

¹¹³ Because captive generics cut into generic revenue during the generic's lucrative exclusivity period, a captive generic can disincentivize generic entry. See *supra* text accompanying notes 65–68.

¹¹⁴ See *FTC v. Actavis, Inc.*, 570 U.S. 136, 159 (2013) ("[T]he likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification.").

by licensing its captive generic with an acceleration clause, presents another potential abuse of the captive generic.

B. Health Plan Reimbursement

Until recently, brand drug-makers had also exploited their captive generics in contexts other than pay-for-delay. For example, brand drug-makers have used their captive generic sales in order to reduce the rebate amount they owe states for drugs covered by Medicaid.¹¹⁵ The scheme works in the following manner: The average manufacturing price that drug companies report to the government dictates the rebate amount that they owe per drug. Thus, reporting a lower average manufacturing price means the drug company owes less.¹¹⁶ As a result, many drug companies blend the lower cost of their captive generic with their brand drug to bring down their average manufacturing price and, hence, the rebate amount they owe.¹¹⁷ Closing this loophole, as Congress did in 2019,¹¹⁸ is estimated to save the government \$3.15 billion over the next decade.¹¹⁹

Captive generics can also abet brand drug-makers in their profiteering. After Mylan raised the price of its life-saving EpiPen product 600% in the decade after acquiring it in a merger, the company released a captive generic version—despite there being no generic competitors on the market—as a palliative optics measure.¹²⁰ The \$300 price tag on this new captive generic, however, was still 300% greater than what the branded version of EpiPen cost when Mylan first acquired it.¹²¹ Moreover, when the first true generic entered in 2019, it retailed for the same amount as Mylan’s captive generic.¹²² The voluntary launch of a captive generic did not grow out of a sudden altruistic impulse; rather, it helped the brand to continue to prop up its pricing scheme and served as a pricing floor, encouraging the true generic to set a high price, albeit one that was still below the brand price. In other words, a captive generic can act as a silent pricing signal to an entering

¹¹⁵ U.S. DEP’T HEALTH & HUM. SER., OFF. INSPECTOR GEN., REP. NO. A-06-18-04002, MEDICAID COULD SAVE HUNDREDS OF MILLIONS BY EXCLUDING AUTHORIZED GENERIC DRUG TRANSACTIONS TO SECONDARY MANUFACTURERS FROM BRAND NAME DRUGS’ AVERAGE MANUFACTURER PRICE CALCULATIONS 1 (2019).

¹¹⁶ *Id.*

¹¹⁷ *Id.* at 4.

¹¹⁸ H.R. 3276, 116th Cong. (2019).

¹¹⁹ CONG. BUDGET OFF., PROPOSALS AFFECTING HEALTH PROGRAMS IN BUDGET FUNCTION 550—CBO’S ESTIMATE OF THE PRESIDENT’S FISCAL YEAR 2020 BUDGET 2 (2020).

¹²⁰ See Zachary Brennan, *Authorized Generics: Why Mylan Would Compete with Itself in the EpiPen Market*, REGUL. FOCUS (Aug. 29, 2016), <https://www.raps.org/regulatory-focus/E2%84%A2/news-articles/2016/8/authorized-generics-why-mylan-would-compete-with-itself-in-the-epipen-market> [<https://perma.cc/V7WW-YQXV>].

¹²¹ Gina Kokosky, *Newly Approved Generic Version of EpiPen is Not Cheaper Than Available Option*, PHARMACY TIMES (Jan. 27, 2019), <https://www.pharmacytimes.com/view/newly-approved-generic-version-of-epipen-is-not-cheaper-than-available-option> [<https://perma.cc/R5RA-JTBD>].

¹²² *Id.*

generic. Without saying a word, the brand company can indicate: “No need for us to have a price war—here’s a price that lets both of us profit handsomely so long as we stick to it.”¹²³

Finally, a previously undocumented avenue of abuse using captive generics may exist in the health care reimbursement system. Health care plans use formulary tiers as a mechanism to designate how much and for which drugs a patient should be reimbursed.¹²⁴ This system is designed to save money for the health plans by rewarding patients for choosing cheaper drugs (such as generics) over more expensive ones (their branded counterparts).¹²⁵ It does so, in theory, by situating cheaper drugs on lower tiers, which have correspondingly lower copays and co-insurance costs.¹²⁶ A Tier 1 drug, therefore, costs the patient less than a Tier 2 drug, which costs the patient less than a Tier 3 drug. But the reality is not so straightforward. Pharmaceutical companies, working with pharmacy benefit managers (“PBMs”), use spread pricing,¹²⁷ volume rebates,¹²⁸ and rebates connected to other drugs in their portfolios¹²⁹ both to secure preferential tier placement

¹²³ See, e.g., STAFF OF H.R. COMM. ON OVERSIGHT & REFORM, 117TH CONG., DRUG PRICING INVESTIGATION: ABBVIE—HUMIRA & IMBRUVICA 33–35 (Comm. Print 2021) (describing how AbbVie and Amgen engage in “shadow pricing” of Humira and its competitor Enbrel by raising prices in lockstep). While Enbrel is neither a captive generic of Humira nor vice versa, the situation offers an analogous example of how drug companies may subvert the expectation that the presence of a competitor necessarily leads to more competitive pricing.

¹²⁴ See Feldman, *Devil*, *supra* note 11 (analyzing pharmaceutical companies’ exploitation of the formulary tiering system).

¹²⁵ *Id.* at 3–4.

¹²⁶ *Id.* at 10–11.

¹²⁷ PBMs essentially are paid by health plans based on the amount of the discount they can negotiate between the list price (wholesale price plus a markup) of a drug and its post-rebate price; the greater the discount, the higher their pay. While this method, known as spread pricing, should theoretically incentivize PBMs to negotiate for larger discounts that help to drive costs down for patients using that health plan, PBMs and drug companies work together to increase profits by doing the opposite. Drug companies often raise the list price of their drugs to increase the spread (rather than lowering the final price by increasing the rebate). Because patients pay the full list price in some circumstances, or have out-of-pocket payments based on a percentage of that list price, consumers end up bearing the burden of these agreements. See, e.g., Feldman, *Devil*, *supra* note 11, at 13–14; FELDMAN, HANDSHAKES, *supra* note 98, at 18–19.

¹²⁸ Drug-makers can offer rebates based on quantities of drugs purchased to entice PBMs to select their drugs over those of rival companies. This can enable entrenched market participants to keep out newer competitors, even if the competitors offer lower prices. For example, an entrenched drug-maker can offer a PBM a discount on drug X if the PBM buys 10,000 units of the drug. The deal effectively squeezes the competitor out of the market or prevents the competitor from gaining much traction. This is just one of multiple ways in which drug-makers can leverage volume for preferential treatment by PBMs. However, much depends on context. Volume strategies are not per se anticompetitive, and can be procompetitive in other industries and circumstances. See FELDMAN, HANDSHAKES, *supra* note 98, at 21–29 (describing different manifestations of volume rebating).

¹²⁹ More than leveraging volume with one drug, as described in note 128, drug-makers can leverage volume across a bundle of multiple drugs by offering PBMs steeper discounts if they purchase a certain quantity of each of, for example, three drugs. Not only does this make it even more difficult for another company to offer a competing package—even if a competitor can offer a competitive discount on a single drug, the competitor would have to reduce the price on its single drug enough to compensate for the rebates offered for all three drugs. If one

and to ensure more sales. Drug-makers' tactics are numerous and complex, but they typically boil down to the use of market power to secure favorable dealing from PBMs.¹³⁰ Captive generics may benefit from the same sales and marketing relationships and leveraging process to get a leg up on true generics in the formulary system. Not only does this inflate the captive generic's market share, it also exacerbates tier distortions, costing patients and payors alike while padding the brand company's bottom line.

In short, the unique position of the captive generic empowers drug-makers to choose from a veritable playbook of anticompetitive schemes. Although some obviously anticompetitive practices like no-AG clauses have been tamped down,¹³¹ more nebulous applications of the captive generic threaten to continue stalling generic entry. It is important to recognize, as brand drug-makers clearly do, that captive generics are more than merely another generic on the market.

IV. FINDINGS

In addition to their role as a bargaining chip in pay-for-delay or other drug-maker games, the legitimate presence of captive generics on the market raises its own set of concerns with respect to affordable medication access. To better understand the impact of captive generics on drug prices and market share, we undertook an empirical analysis of 373 unique drug markets between 2006 and 2018, using data from all of the Medicare Part D claims for a cohort of approximately one million patients. This approach compared 134 drug markets that included a captive generic with 239 other drug markets that did not include a captive generic.

of the three drugs is under patent protection and no generic equivalent exists, its inclusion in a package of drugs will make the package more persuasive, given that the PBM would not be able to buy that drug from anyone else, and no other company can throw in its own version of the drug as part of the package. The fact that PBMs are tasked with negotiation purchase of drugs that cover a range of ailments makes package offers containing such a range especially attractive. See FELDMAN, HANDSHAKES, *supra* note 98, at 26–29. See also Robin Feldman, *Defensive Leveraging in Antitrust*, 87 GEO. L.J. 2079 (1999), at 2103–05 (describing how Eli Lilly used bundled pricing in the cephalosporin market to target competition from SmithKline). Cf. *Cascade Health Sols. v. PeaceHealth*, 502 F.3d 895 (9th Cir. 2007) (arguing that bundled pricing does not by itself constitute an antitrust violation, placing a high burden of proof on plaintiffs to demonstrate its anticompetitive effects).

¹³⁰ See Feldman, *Devil*, *supra* note 11, at 11–12; see also FELDMAN, HANDSHAKES, *supra* note 98, at 21–31 (explaining how drug-makers leverage the size and breadth of their product lines to entrench their market shares and distort formularies).

¹³¹ The most recent FTC annual report (fiscal year 2017) found no instances of no-AG clauses. See Press Release, Fed. Trade Comm'n, *supra* note 91. Settlements with no-AG clauses enacted before 2017 continue to be litigated. See, e.g., *Impax Labs, Inc. v. FTC*, 994 F.3d 484 (5th Cir. 2021).

A. Summary of Findings

The analysis reveals that the presence of a captive generic predicts several troubling outcomes. Markets with captive generics feature both significantly greater increases in brand drug net prices and generic drug prices in the 3 years following the creation of a generic market for a given drug. (It is possible these effects persist beyond 3 years, but we did not analyze impact beyond this period.) The higher prices for true generics last for 2 years and then wane, and the higher prices for brand drugs are long-lasting. In short, captive generics keep prices higher, rather than bringing prices down.

At the same time, true generics suffer an average 21% reduction in market share when a brand drug manufacturer launches a captive generic. Moreover, if other true generics launch as the generic market grows, they will cut into other true generics' market shares, but the captive generic's share of the market will remain intact.

In addition, captive generics do not increase the total number of generics on the market. Rather, a market in which a captive generic is present has, on average, one fewer true generic option than a market in which no captive generic is present. Captive generics also affect the placement of true generics in the health insurance reimbursement system. Given that brand drugs are much more expensive than generics even after accounting for rebates, and health care reimbursement tiers are supposed to reflect the price of the drug, a brand drug and its generic version should not be in the same reimbursement tier. However, the analysis showed that the proportion of true generics irrationally located in the same tier as the brand drug is on average 12% higher in markets with a captive generic than in markets without a captive generic. In sum, the price, market share, and formulary placement findings here suggest that captive generics, unlike their true generic counterparts, inhibit affordable access to prescription drugs.

B. Methodology

The following section provides additional details on the study's methodology. In order to ascertain the effects of captive generics on drug markets, our analysis compiled a dataset of brand, true generic, and captive generic drugs from sources including Medicare Part D patient claims, the FDA, the National Library of Medicine, and Cerner Multum.¹³² In a given drug mar-

¹³² The data used for this study were derived from Research Identifiable Files, which are files that contain beneficiary level protected health information. See Lori Siedelman, *Differences between RIF, LDS, and PUF Data Files*, RSCH. DATA ASSISTANCE CTR. (Aug. 10, 2016), <https://www.resdac.org/articles/differences-between-rif-lds-and-puf-data-files> [https://perma.cc/Y9QL-B4YY]. The Institutional Review Board reviewed and approved the study according to the requirements of the Common Rule and the Health Insurance Portability and Accountability Act (HIPAA). Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, 110 Stat. 1936 (1996). The methodology is made available in accordance with the protocols outlined in Robin Feldman, Mark A. Lemley, Jonathan S. Masur & Arti K. Rai,

ket, a captive generic falls under the same New Drug Application as the drug-maker's brand version but is distributed as a generic. Independent generics, of which there are often many for a given brand drug, are therapeutically equivalent to the brand drug and hold an Abbreviated New Drug Application. The dataset included drugs for which a true generic first entered the market between 2006–2018.¹³³

Using this dataset, we compared two scenarios: (1) markets with a brand drug and one or more true generics only; and (2) markets with a brand drug, one or more true generics, and one or more captive generics.¹³⁴ In total, our dataset, spanning 2006–2018, included 239 drug markets with only a brand drug and true generics, in addition to 134 distinct drug markets that featured a captive generic along with the brand drug and true generics. We standardized price and market share data in order to accurately compare drug markets of vastly different sizes, compositions, and typical prices.

Patient claims from Medicare Part D between 2006–2018 provided data for prescription drug list prices and drug market share. Here, we updated past analyses of generic prices such as the aforementioned FTC study, which used pricing data from 2003–2008.¹³⁵ Our analysis also expanded the scope of captive generics' pricing effects by studying how the presence of a captive generic impacts brand price, too.¹³⁶ Furthermore, to better gauge what consumers actually pay for brand drugs, whose retail price is commonly discounted by a significant rebate,¹³⁷ we applied a standard Medicare rebate

Open Letter on Ethical Norms in Intellectual Property Scholarship, 29 HARV. J. L. & TECH. 339, 350–52 (2016) (with list of signatories). Detailed information on the data and methodology will be made available at U.C. Hastings Law Center for Innovation, <https://www.uchastings.edu/academics/centers/center-for-innovation/> [<https://perma.cc/5JPM-9RFA>].

¹³³ Specifically, we did not include drug markets in which the first true generic launched between January 1, 2006, and June 1, 2006, in order to have greater confidence that, for a given drug, its first true generic did not actually appear prior to 2006.

¹³⁴ Although classifying drugs as brand, captive generic, or true generic sounds like a straightforward enterprise, there is a non-negligible amount of variation in the categorization. For this study, the classification was based on three sources (in order of preference): the original CMS data, the National Library of Medicine's RxNorm database, and finally, Cerner Multum's commercial drug database. The National Library of Medicine is a medical library and an institute within the National Institutes of Health, operated by the federal government. *RxNorm*, NIH NAT'L LIBR. OF MED., <https://www.nlm.nih.gov/research/umls/rxnorm/index.html> [<https://perma.cc/6YJZ-BW46>]. The author also purchased access to a drug database managed by Cerner Multum, a medical information company. The author used Cerner Multum's database last to categorize drugs because it was not a governmental source. *Drug Database*, CERNER, <https://www.cerner.com/solutions/drug-database> [<https://perma.cc/6KV8-NR98>].

¹³⁵ See FTC AG REPORT, *supra* note 24.

¹³⁶ Hollis, *supra* note 57 (studying brand prices as well, but in the Canadian market).

¹³⁷ Rebates can exceed 50% of brand drug list prices and constituted 25% of Medicare prescription drug spending in 2018. See Steven M. Lieberman, Paul G. Ginsburg & Erin Trish, *Sharing Drug Rebates with Medicare Part D Patients: Why and How*, HEALTH AFF. BLOG (Sep. 14, 2020), <https://www.healthaffairs.org/doi/10.1377/forefront.20200911.841771/full/> [<https://perma.cc/MGW5-8C3W>]. In some remarkable cases, this can mean that the seemingly much pricier brand drug costs about the same as its captive generic after accounting for rebates. See, e.g., Hancock & Lupkin, *supra* note 41 (noting that the \$137 list price for the captive generic version of Eli Lilly's Humalog insulin is about the same as what the drug-

percentage to all brand prices.¹³⁸ Beginning when the first true generic option for a drug market appeared in Medicare patient claims data, we studied generic price, brand price, and market share quantities over the following 36 months in 373 unique drug markets.

C. Results

1. Market Share

Across the drug markets in our analysis, the presence of a captive generic reduced the combined market share of true generics by about 22% over the first 3 years following the entry of the first true generic. This finding indicates that the eroding effect of captive generics on true generic market share persists long past the six-month exclusivity period that the FTC report, for example, highlighted.¹³⁹

Furthermore, the deficit in market share for a true generic that occurs when a captive generic exists does not lessen as total generic market penetration increases. In other words, when a captive generic is present, true generics occupy on average about 20% less of the total market—whether generics as a whole comprise 70% or 90% of the total drug market (Figure 1a). This finding implies that, if other true generics launch as the generic market grows, they will cut into other true generics' market share, but the captive generic's share will remain intact.

Put simply, captive generics are better than true generics at staking out a share of the market and holding onto it, no matter how many competitors enter the field. Our analysis found that, on a per-drug basis, an individual captive generic succeeds in capturing a considerably larger portion of the market as compared to a single true generic. In the three years after a true generic enters a market that also contains a captive generic, the true generic can expect to obtain 6% less of the market than the captive generic.

This result indicates that captive generics are, by an obvious margin, better than true generics at penetrating generic markets. A number of factors may help to explain why. First, captive generics can be sold during the first-

maker nets for the \$275 brand version after rebates). Typically, this does not occur. In general, at an individual drug and class level, the higher costs of brand drugs, even after rebates, leave intact the conclusion as to irrational tiering. For rebates across each drug class in a representative year, see CTRS. FOR MEDICARE & MEDICAID SERVS., PART D REBATE SUMMARY FOR BRAND DRUGS (2014) (showing that for no class did rebates exceed 26.3% of cost). Again, this study discounts brand costs with rebates only so that its conclusions as to price better reflect what payors actually experience.

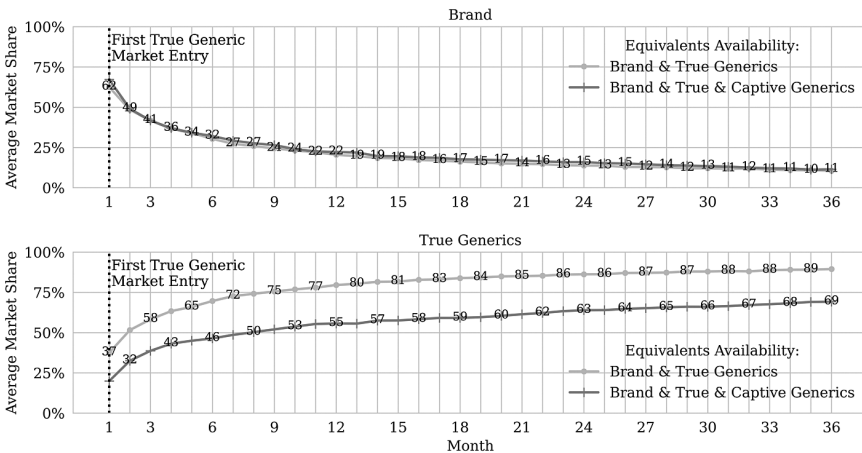
¹³⁸ The rebate percentage on total Medicare Part D spending came from annual Medicare Trustees' Reports. See, e.g., CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE TRUSTEES REPORT (2018). The rebate percentages are calculated for spending across all prescription drugs, brand and generic. However, because generic drugs typically do not carry manufacturer rebates, the analysis modified the rebate amounts in line with the proportion of spending for brand drugs only. See Feldman, *Devil*, *supra* note 11, at 53 for further detail.

¹³⁹ See FTC AG REPORT, *supra* note 24, at iii.

filer exclusivity period, enabling them to compete with the first true generic before anyone else and preventing the true generic from gaining the foothold that the exclusivity period is meant to guarantee. Second, captive generics sometimes precede true generics to market: our analysis discovered that captive generics enter the market before a true generic 22% of the time. In these cases, the captive generic, not the true generic, is the one that enjoys a period of exclusivity. Finally, brand drug-makers can leverage the sales and marketing relationships they have cultivated for their brand product on behalf of their captive generic. Given the prevalence of volume rebates in the industry, brand companies may be able to create incentives for health insurance plans, and the intermediaries who help develop those plans, to situate their generic more favorably within the formulary tiering system.¹⁴⁰ In these cases, the brand company uses its existing market power, earned through patents that have since expired, to provide preference and shelter for its captive generic. Whatever the cause, the clear result is that captive generics outperform their true generic counterparts.

In Figure 1a, the upper graph compares brand drug market share in drug markets with and without a captive generic. The lower graph compares true generic market share based on the presence of a captive generic. As the figure shows, the share of the brand drug remains steady, regardless of whether a captive generic enters. It is the market for generics that becomes distorted by the presence of a captive generic.

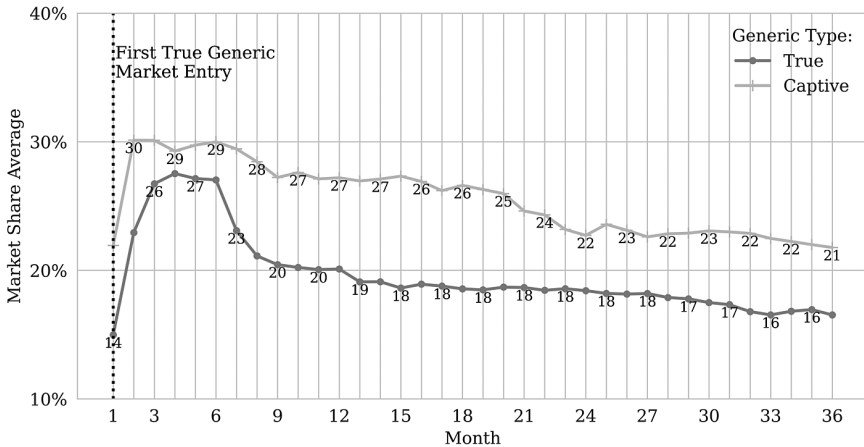
FIGURE 1A: COMPARING BRAND & TRUE GENERICS' MARKET SHARE BASED ON PRESENCE OF A CAPTIVE GENERIC



¹⁴⁰ See generally Feldman, *Devil*, *supra* note 11, at 22 (describing how PBM volume rebates can empower drug-makers across multiple drug markets). See also, *infra* text accompanying notes 144–46.

The presence of such a powerful player in the generic market has a profound adverse impact. As is detailed below, captive generics are associated with higher prices for both brand and generic drugs. On a more basic level, though, the distortion of the generic market (by which the brand’s market share is unaffected) is itself concerning. In essence, the captive generic carves out a part of the market and is then much less affected by new competitors than are true generics. Figure 1b illustrates that although captive generics’ average market share gradually declines from about 30% to about 21% over 3 years, it remains significantly higher than true generics’ average market share, which declines from about 27% to about 16%, throughout that period. Thus, with every new entrant, true generics compete more with one another than they do with the captive generic.

FIGURE 1B: COMPARING AVERAGE MARKET SHARE OF CAPTIVE AND TRUE GENERICS WHEN THEY ARE AVAILABLE ALONG WITH A BRAND DRUG



As a result, captive generics’ ability to cling to market share serves as a powerful deterrent to potential competitors whether or not a true generic is already available. If the market has a true generic, additional true generics looking to enter know that their potential slice of the pie is a limited piece of the total generic market. They can only nibble at the captive generic’s slice and bite at the existing true generics’ already smaller portions. Even when there are no true generics in the market, the presence of a captive generic reduces the incentive for the first true generic to enter, simply because the true generic knows that part of the generics market will always be less accessible. Thus, captive generics’ ability to insulate brands from the forces of competition has the persistent effect of scaring away potential competitors in the first place.

In short, the presence of a captive generic shrinks the size of the market available for the true generic, and, therefore, the magnitude of the incentive for the true generic to enter.

2. *Formulary Tiering*

Our analysis determined that the presence of a captive generic does in fact contribute to growing irrational formulary tier placement. If the objective of the formulary system is to locate cheaper drugs on lower tiers, as described above in Section II.B, true generics should logically be located on lower tiers than their brand-name counterparts. We therefore defined “irrational placement” as either: 1) the placement of the brand on the same tier as a generic; or 2) the placement of the generic on a higher (that is, more expensive) tier than the brand drug. As the graphs in Figure 2a display, incidences of both kinds of irrational tiering grew between 2010–2018 in markets both with and without captive generics. Nevertheless, irrational tiering was more common in markets with a captive generic than in those without. Our results suggest that, while drug companies and PBMs continue to game the formulary system even in the absence of captive generics, the presence of captive generics exacerbates abuses, enabling pharmaceutical industry players to extract even more from the system than they would otherwise.

Particularly noteworthy is the tier placement of true generics. We found that, between 2010–2018, when there is a captive generic, the true generic sits on the same tier as the brand 12% more often.¹⁴¹ Similarly, when there is a captive generic, the true generic sits in its proper place on a less-expensive tier than the brand 12% less often.¹⁴² That the percentages are nearly equivalent indicates that there may be a relationship between the presence of a captive generic and the rise in irrational formulary tiering. Put differently, the percentage by which one type of irrational tier placement of true generics increases is nearly equal to the percentage by which the rational tier placement of true generics decreases. While it is not possible to conclude that every true generic that was once properly placed on a rational tier was displaced onto an irrational tier due to the encroachment of a captive generic, the result does suggest that the presence of a captive generic is not incidental to the rise in formulary games.

As described throughout this paper, brand companies may integrate captive generics into the wider network of strategic behaviors they use to delay the entry of generics and to prevent generics from gaining much trac-

¹⁴¹ This figure is calculated as an average across the period.

¹⁴² In addition, when there is a captive generic, there is a slight increase in the frequency with which a true generic is placed on a more-expensive tier than the brand (as opposed to its proper place on a less-expensive tier or even on the same tier). In 2017, for example, the increase in frequency of this misplacement was 1%; in 2018, the increase in frequency was 2%.

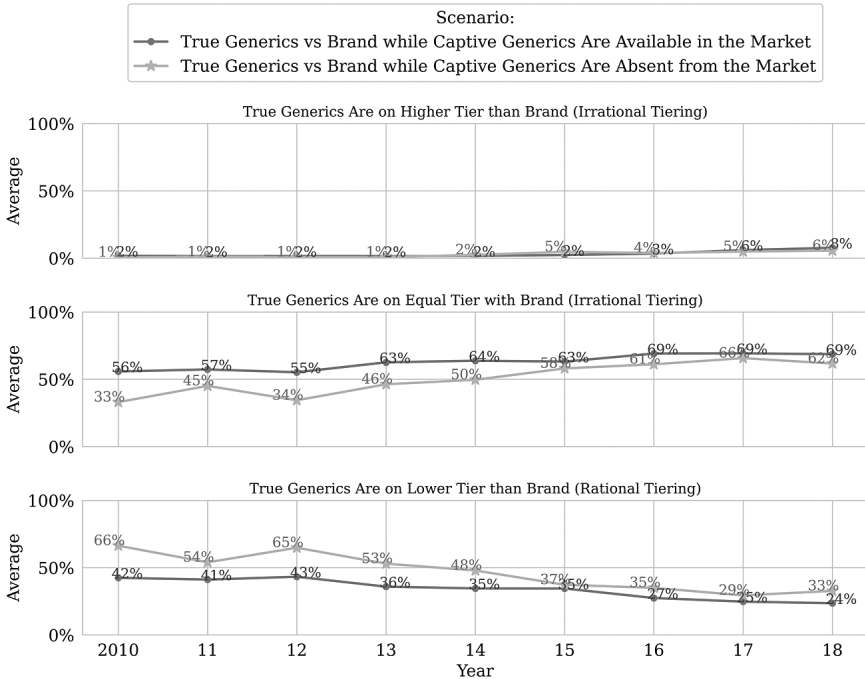
tion when they do make it to market.¹⁴³ When the brand company itself makes the captive generic, one could imagine that the brand may be able to offer a single deal on its brand and captive generic, reducing the transaction costs for the PBM or health plan, and even offering rebates on the brand conditioned on favorable placement of the captive generic.¹⁴⁴ The inclusion of a captive generic in a bundled package can also help rationalize more favorable treatment of a brand drug than its true generic. After all, the captive generic is available to the plan's consumers. Ostensibly, everyone wins. But recall that the money in this case is flowing from the captive generic to the brand drug-maker because the brand drug-maker is making both of them. Thus, from the brand's perspective, the key is whether at least one of the drugs on its team (the brand or the captive generic) is placed more favorably than the true generic. As long as one team member gets preferential treatment (and even better if both do), the brand wins. Indeed, as the graphs in Figure 2b show, while true and captive generics are located on the same tier 82% of the time when brand drugs are also available in the same market—a rational result given that both true and captive generics should fall under comparable price classes—true generics are located irrationally on a higher tier than captive generics 6% of the time. In those circumstances, patients bear the long-term burden of higher prices, while brand companies reap the profits.

¹⁴³ For in-depth discussions of this network of strategic behaviors, see generally Robin Feldman, *Perverse Incentives: Why Everyone Prefers High Drug Prices—Except For Those Who Pay the Bills*, 57 HARV. J. ON LEGIS. 303 (2019); Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. ON LEGIS. 500 (2016).

¹⁴⁴ See *supra* note 128 (describing the practice of volume rebating) and note 129 (describing the practice of bundled pricing).

FIGURE 2A: COMPARING THE FORMULARY TIER PLACEMENT OF TRUE GENERICS AND BRAND DRUGS BASED ON THE PRESENCE OF A CAPTIVE GENERIC¹⁴⁵

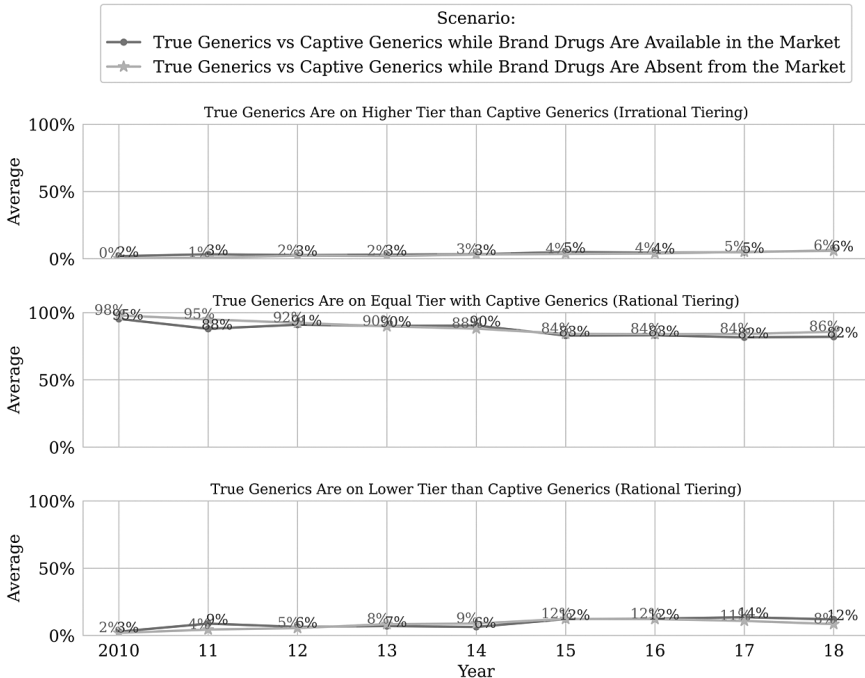
Comparing True Generics Formulary Tier Placement to Pharmaceutical Equivalent Brand Drugs Based on Captive Generics Availability



¹⁴⁵ The top graph compares the average percentages at which a true generic appears on a higher tier than the brand drug when a captive generic is and is not present. The middle graph compares the average percentages at which a true generic appears on the same tier as the brand drug when a captive generic is and is not present. The bottom graph compares the average percentages at which a true generic appears on a lower tier than the brand drug when a captive generic is and is not present. The top two graphs display the frequency of two kinds of irrational tiering; the bottom graph displays the frequency of rational tiering.

FIGURE 2B: COMPARING THE FORMULARY TIER PLACEMENT OF TRUE GENERICS AND CAPTIVE GENERICS BASED ON THE PRESENCE OF A BRAND DRUG¹⁴⁶

Comparing True Generics Formulary Tier Placement To Pharmaceutical Equivalent Captive Generics Based on Brand Drug Availability



3. Availability

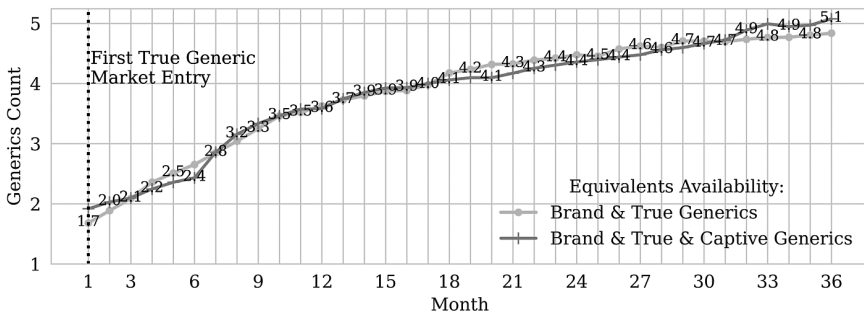
The fact of more generic varieties on the market does not translate to more total generic options. Our analysis reveals that, on the whole, drug markets with a captive generic tend to have the same number of total generic options. That is, rather than adding another generic product, the captive generic simply displaces one of the true generic competitors. We found this to be the case across the three years following first true generic entry, including during the six-month exclusivity period. Thus, our analysis implies that cap-

¹⁴⁶ The top graph compares the average percentages at which a true generic appears on a higher tier than the captive generic when a brand drug is and is not present. The middle graph compares the average percentages at which a true generic appears on the same tier as the captive generic when a brand drug is and is not present. The bottom graph compares the average percentages at which a true generic appears on a lower tier than the captive generic when a brand drug is and is not present. The top graph displays the frequency of irrational tiering; the bottom two graphs display the frequency of two kinds of rational tiering.

tive generics do little to boost generic competition in terms of the number of competitors, even during the six-month exclusivity period when they would intuitively seem to have the greatest impact.

FIGURE 3: COMPARING AVERAGE NUMBER OF GENERICS AVAILABLE IN A MARKET BASED ON PRESENCE OF A CAPTIVE GENERIC¹⁴⁷

Comparing Generic Drugs Count Regardless of Their Types Based on Equivalence Availability



In contrast to true generic drugs, we found that the market share of brand drugs over time was largely unaffected by the presence of a captive generic. To be precise, the brand drug market share was usually about 1% higher when a captive generic was also available. Once generic competition ensued, a brand drug’s market share declined precipitously in the first year before leveling off to hold approximately 10% of the market after three years of generic presence.¹⁴⁸ The study found the same result in both markets with and without a captive generic, suggesting that while a captive generic may be bad for the market shares of true generics, it does not appear to diminish the market share of the brand drug. Rather, a captive generic simply has the effect of giving the brand drug company a share of the generics market, along with more favorable positioning in the reimbursement system.

4. Price

Although the market share effects of captive generics may be largely invisible to consumers, who are not likely to know if they are prescribed a true or a captive generic, our analysis demonstrates that captive generics also have effects on drug prices. Comparing drug markets containing a captive generic with those that did not, the presence of a captive generic appears to increase both true generic and brand net prices in a given drug market. For

¹⁴⁷ The total number of generics includes captive and true generics.

¹⁴⁸ The generic market penetration found here is consistent with past studies. See, e.g., Berndt & Aitken, *supra* note 5, at 9–10.

true generic drugs, this inflationary effect was confined primarily to the two years following first true generic entry into a market.

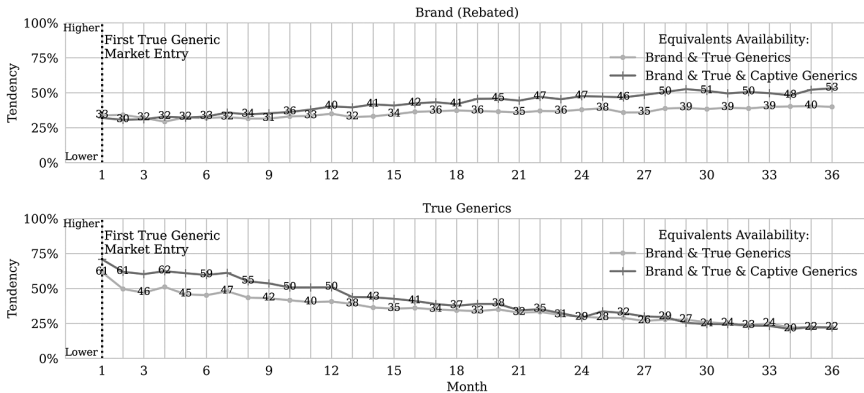
Brand drug net prices tend to increase over time,¹⁴⁹ whether or not a captive generic is present in the market, but our analysis reveals that captive generics magnify that effect significantly (Figure 4). In the three years following the first launch of a true generic in a market, the brand net price rose an average of 6% if a captive generic was not also present. This growth in brand net price soared to 21% if a captive generic was also competing on the market. In other words, the increase of brand net prices was three-and-a-half times greater in markets with a captive generic compared to markets without one. Moreover, because we measured net prices instead of list prices, this finding already accounts for any rebates that might otherwise mitigate the steep climb in brand prices observed here.

The presence of a captive generic also serves to inflate the prices of true generic competitors on the market, an effect that is most apparent during the first two to three years after the first true generic launches (Figure 4). In the first year, the presence of a captive generic caused the prices of true generics to increase 11% more than they would if a captive generic were not also available. This growth ebbs to about 4% in the second year before leveling off, presumably as the introduction of more true generic options exert a downward pressure on price. In short, consumers are faced with markedly more expensive drugs in the first two years, when one of their choices is a captive generic.

¹⁴⁹ See Inmaculada Hernandez, Alvaro San-Juan-Rodriguez, Chester B. Good & Walid F. Gellad, *Changes in List Prices, Net Prices, and Discounts for Branded Drugs in the US, 2007-2018*, 323 *JAMA* 854, 854 (2020) (finding substantial increases in brand drug net prices between 2007–2018).

FIGURE 4: COMPARING BRAND & TRUE GENERIC PRICE TENDENCY, BASED ON PRESENCE OF A CAPTIVE GENERIC¹⁵⁰

Comparing Drugs' Prices Tendency Based on Equivalent Availability



In addition to the finding that true generics cost more when there is a captive generic in the market than when there is no captive generic in the market, the analysis found that true generics are more expensive than captive generics during the first two years. Although our analysis cannot answer the question of why this occurs, the following are potential explanations. First, true generics may be more expensive than captive generics in the first two years because some of the overhead cost of a captive generic (especially when it is produced by the brand) is borne by the brand.¹⁵¹ When this is the case, what the data is reflecting is precisely the opposite of Hatch-Waxman’s intention: the brand undercutting the true generic. Alternatively, or perhaps additionally, the true generic’s revenue maximization may require higher pricing than otherwise necessary in order to compensate for the lower sales associated with the presence of a competitor, especially given that the competitor’s market share seems largely immune to market forces. Finally, true generics expect to make much of their profit during the six-month Hatch-Waxman duopoly period, during which other true generics are not permitted to enter. That profit is reduced by the presence of the captive generic during the six-month period, which reduces the true generic’s market share. This could possibly encourage a dynamic in which other true generics enter more

¹⁵⁰ The upper graph illustrates a comparison of net (rebated) brand price trends with and without a captive generic on the market. The lower graph shows the same comparison for true generic price trends.

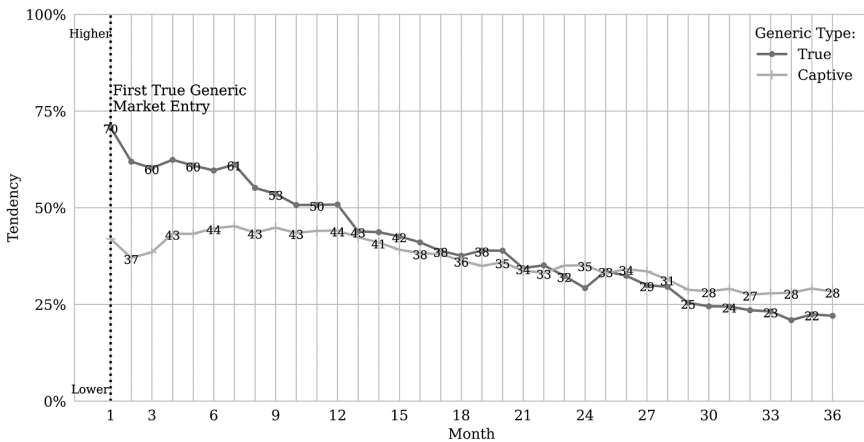
¹⁵¹ See FELDMAN & FRONDORF, *supra* note 2, at 59 (“[The] existence of authorized generics is an example of both how cheap the marginal cost of production can be once research and development are completed, and of how extensive the markup can be on branded pharmaceuticals. It demonstrates that a brand-name company can instantly reduce the price on its drug if it so wishes toward the end of its exclusivity life span.”).

slowly and the first true generic keeps its price high for a longer period of time to compensate for the lower market share.

The trend tended to reverse beginning in the third year (Figure 5). Specifically, true generics cost 21% more on average than the captive generic in the first six months and 15% more during the first year. The cost of true generics relative to the captive generic decreased until, in the third year, the captive generic cost 4% more than the true generic.

FIGURE 5: COMPARING TRUE GENERIC & CAPTIVE GENERIC PRICE TENDENCY

Comparing the Two Generic Drug Types' Price-Tendency When They Are Available Together Along With a Brand Drug



On the whole, a thorough comparison of drug markets, some with a captive generic and others without, reveals several concerning patterns. First, the findings here confirm what past research and intuition suggest: captive generics erode true generics' market share by a significant quantity. Brand drugs, by contrast, escape unscathed, even experiencing a slight boost in market share when a captive generic also inhabits the market. At the same time, our analysis suggests that captive generics create significantly greater cost for patients and payors—not only on a per-drug basis but at the level of the formulary system. This holds for consumers of brand and generic drugs alike.

Considering these results alongside the many games drug-makers play using their captive generics,¹⁵² it is clear that the captive generic is not an innocent competitor, entering to bring down the price of the drug. Rather, the captive generic is simply a wolf in sheep's clothing. Without adequate

¹⁵² See *supra* Part III.

measures to combat captive generics, patients and payors will continue to needlessly bear additional costs, while generics face the possibility of being squeezed out. As the next part details, however, there are many paths to greener pastures.

D. Limitations

While our findings have significant consequences for present understandings of captive generics, it is important to acknowledge the limitations of our results. First, our analysis did not take drug therapeutic class into account. It is possible that captive generics predominate among drugs that share certain therapeutic objectives or other characteristics that affect the size of their markets, their typical placement within formularies, their tendency to be subject to mis-tiering or folded into volume bargaining agreements, and/or their pricing over time. These characteristics may include small patient cohorts, targeting of patients of a particular age, classification as “orphan drugs,” and use for terminal illness, among others. Even if captive generics are not confined to drugs that share such characteristics, the inclusion in the analysis of drugs sharing such characteristics could have skewed our results.

Another element for which our analysis did not account is the effect of competition from other drugs. That is, our analysis focuses on the effects of competition between the brand drug and its pharmaceutically equivalent captive and true generics. But the brand drug and its equivalents may also see competition from other, pharmaceutically different drugs that have similar therapeutic objectives. With Lipitor, for example, not only are there other drugs that can be used to lower cholesterol, there are also other statins that can be used to lower cholesterol. The waxing and waning of competition between molecule types as new drugs are released or taken off the market can affect each of the four categories described above.

Finally, we did not look into which brand drug manufacturers release captive generics. It is possible that the practice of using captive generics to retain market share and/or recapture lost revenue is limited to certain manufacturers, rather than being widespread across the pharmaceutical industry. Not only would such a situation affect how captive generics should be regulated (the topic of the following section); it would also affect the suitability of comparisons between markets with and without captive generics: markets with captive generics would always be limited to the markets of particular brand companies, whereas markets without captive generics would not. Once again, this limitation would affect the accuracy of our analysis of the effects of captive generics on market share, formulary tiering, availability, and pricing.

Each of these limitations presents an opportunity for further research and analysis. Future explorations of these areas would help to enhance our

understanding of captive generics and refine our ability to assess and combat their implications for patients.

V. GREENER PASTURES: POTENTIAL SOLUTIONS

Captive generics are able to enjoy the best of all worlds. On the one hand, captive generics are therapeutically interchangeable with true generics, allowing them to compete as equivalent products.¹⁵³ Unlike true generics, however, captive generics neither have to file an ANDA nor abide by the six-month exclusivity period used to incentivize competition.¹⁵⁴ The inconsistent standing of captive generics prevents Hatch-Waxman from operating as intended, skewing incentives and providing brands with leverage to stifle true generics. In particular, the analysis in Part IV suggests that captive generics are creating unnecessary price increases for both brand and generic drugs, distorting competition in the generic drug market, and engaging abuse of the formulary system as a result of their privileged place within the Hatch-Waxman system. The following section outlines legislative, regulatory, and judicial actions that are available to remedy the higher prices and restricted access caused by captive generics in the marketplace.

A. Legislative Approaches

Although captive generics are not explicitly provided for in the Hatch-Waxman Act,¹⁵⁵ the Act could provide pathways for remedying the problems these products have created. A range of options are available, resulting in varying degrees of disruption to the generic industry structure. These would range from reserving the six-month exclusivity period for true generics to prohibiting brand drug-makers from competing in the generic space entirely.

A relatively simple measure to level the generic playing field would reserve the 180-day exclusivity period for true generics and the existing brand product. The mechanism to ensure this true exclusivity period could involve amending the Hatch-Waxman Act to require that in order to launch a captive generic, the brand must wait until a first-filer has entered and the exclusivity period has expired. This approach would overturn the *Teva* court's ruling that the current language of the Act does not mandate such an approach.¹⁵⁶ Restoring the exclusivity period would appropriately restore generic incentives.

¹⁵³ See U.S. FOOD & DRUG ADMIN., *supra* note 18.

¹⁵⁴ See *supra* text accompanying notes 37–39.

¹⁵⁵ See *supra* Part II.

¹⁵⁶ See *Teva Pharm. Indus. v. Crawford*, 410 F.3d 51, 52–53 (D.C. Cir. 2005) (upholding summary judgment in favor of the FDA and rejecting the generic company's suggestion to "prohibit the marketing and distribution of 'authorized generic' versions of brand name products until after the expiration of any '180-day exclusivity period' applicable to an [ANDA] for the drug product" or require, in the alternative, that the brand "submit a pre-approval supplemental new drug application . . . before marketing or distributing any version of [a name-

A more powerful approach would be to prohibit captive generics from entering the marketplace for a longer period than 180 days to promote cost-saving generic competition. As the analysis demonstrates, the inflationary price effects of having a captive generic in the market persist into the third year following first generic entry (Figures 4 and 5). Keeping captive generics off the market for this duration could also mitigate their erosion of true generic market share (Figure 1), enabling more generic options to enter the market and depress prices.

Once again, this restriction could be enacted through amendments to the Act. The New Drug Application could be amended to restrict generic distribution or licensing following patent expiration, for instance. A three-year prohibition is a recommendation based on our findings, although a more extensive ban on captive generics may be warranted in light of their other harmful effects.¹⁵⁷

The most drastic form of this approach would prevent brand drug-makers from competing in generic marketplaces at all: barring captive generics entirely. The logic would be that affordable and accessible medications depend on robust generic competition, and a serious conflict of interest exists when a company operates in both the generic and brand drug arenas, as is common in the industry.¹⁵⁸ For example, one academic study found that drug companies with a “mixed” brand-generic portfolio of drugs are less likely to challenge brand patents and more likely to settle patent disputes compared to pure generic companies.¹⁵⁹ In other words, drug-makers with a stake in both sides are less motivated to pursue the generic agenda on which Hatch-Waxman depends to keep drug prices low. Preventing brands from double-dipping in generic markets eliminates a conflict of interest and the opportunity for certain brand company games. When drug-makers stay in their own lane, it improves competition in the market and affordable access for consumers.

Trying to provide a permanent separation of activities may prove difficult. Although regulations of certain industries, such as banking, have required separation of activities at times in history, that level of market regulation is more extensive than the norm in this country. Thus, if banning brand drug-makers from generic production across the board is not optimal, amending Hatch-Waxman to postpone or prohibit captive generics could provide an important partial measure for clarifying generic incentives and invigorating competition. Legislative action limiting the presence of captive

brand drug] changed in any way such that the product purports to be, resembles, or could be confused with, a generic (unbranded) version of [the drug]”).

¹⁵⁷ See, e.g., *supra* text accompanying notes 115–117 (describing how brand drug-makers used captive generics to pay reduced rebate amounts to state Medicaid programs).

¹⁵⁸ See Michael A. Carrier, Mark A. Lemley & Shawn Miller, *Playing Both Sides? Branded Sales, Generic Drugs, and Antitrust Policy*, 71 HASTINGS L.J. 307, 310 (noting that many large drug-makers have opted for a “mixed” brand-generic business model).

¹⁵⁹ *Id.* at 307.

generics would safeguard generic incentives to challenge brand monopolies and help ensure competitors actually compete.

B. Regulatory Approaches

Captive generics also have consequences for antitrust and merger policy. Even if a captive generic is therapeutically the same as a true generic, their unique privilege within the pharmaceutical regulatory framework serves to empower the brand drug-maker. Regulators need to appreciate that brand companies can easily abuse their right to a captive generic in order to activate pay-for-delay schemes and other side deals.¹⁶⁰

To complement major legislative reform, regulators such as the FTC can take immediate action to mitigate the anticompetitive effects of captive generics. The FTC should adopt more robust pre- and post-merger review processes and include captive generics in an expanded assessment of how mergers impact competition. Such adoption and inclusion would give the FTC a clearer sense of how to distinguish between competitive and anticompetitive mergers when captive generics are in play. Moreover, regulators should articulate a clearer stance against complex usages of captive generics in patent settlements (e.g., declining royalty structures) while also releasing the details of patent settlements to improve deterrence. The following paragraphs elaborate on these proposals.

Merger policy needs to account for the presence of captive generics alongside brand products in a given drug market. The Clayton Act, as amended by the Hart-Scott-Rodino Act, empowers the FTC (or sometimes the DOJ or a state AG) to block mergers that it sees as potentially anticompetitive.¹⁶¹ Currently, the FTC relies primarily on quantitative measures like the Herfindahl-Hirschman Index to distinguish between acceptable and problematic mergers.¹⁶² These measures use market share and market concentration to assess whether a merger may constitute an antitrust violation; if a merger pushes a firm's market share above an established threshold level, further regulatory review is triggered.¹⁶³ Although the FTC has treated pharmaceutical mergers with a remarkably light touch in the past decade, despite the explosion of M&A activity in the industry,¹⁶⁴ the agency has announced

¹⁶⁰ See *supra* Part III.

¹⁶¹ 15 U.S.C. § 18a.

¹⁶² See U.S. DEP'T OF JUSTICE & FED. TRADE COMM'N, HORIZONTAL MERGER GUIDELINES 15–19 (2010), <https://www.justice.gov/sites/default/files/atr/legacy/2010/08/19/hmg-2010.pdf> [<https://perma.cc/MU6M-3X6E>].

¹⁶³ See *id.*

¹⁶⁴ See Robin Feldman, *Drug Companies Keep Merging. Why That's Bad for Consumers*, WASH. POST (Apr. 6, 2021), <https://www.washingtonpost.com/outlook/2021/04/06/drug-companies-keep-merging-why-thats-bad-consumers-innovation/> [<https://perma.cc/R8FV-6SEH>] [hereinafter Feldman, WASH. POST] (describing past merger waves in the pharmaceutical industry); see also Eleanor Tyler & Grace Maral Burnett, *Analysis: FTC Rethinks Pharma M&A After a Decade of Mega Deals*, BLOOMBERG LAW (Apr. 15, 2021), <https://news.bloomberglaw.com/bloomberglaw-analysis/analysis-ftc-rethinks-pharma-m-a-after-a-decade-of-mega-deals>

that it plans to bolster its merger review outlook.¹⁶⁵ This bodes well for new drug innovation¹⁶⁶ and a generics industry that can hardly afford to be further squeezed out.¹⁶⁷

As the FTC reviews its approach to pharmaceutical merger analysis, the agency would do well to consider factoring captive generics into its assessment of market power, such as by measuring captive generics in the same basket as branded drug assets. If a brand company produces or licenses a captive generic product in addition to their brand drug, for instance, then the true extent of the company's market power is understated by the sales of the brand drug alone.

Even the potential to launch a captive generic can dissuade generic competitors, particularly if that potential is presented as a threat.¹⁶⁸ Thus, the FTC should take into account the potential market power a brand company could maintain if the company chooses to launch a captive generic alongside its brand drug, even if the brand company does not presently have a captive generic competing in a market.

Moreover, because some drug companies are "mixed" brand and generic manufacturers,¹⁶⁹ a merger could mean that a company ends up controlling brand and generic (and captive generic) versions of the same product. Future merger review should evaluate whether a prospective merger would create potential conflicts of interest between brand and generic products. For the same reason, when two brand drug companies merge, the impact on relevant generic markets also must be weighed. Currently, the FTC can require companies to divest from certain drug pipeline products if they overlap with

[<https://perma.cc/X28R-QV7N>] (noting that the FTC has not blocked a single mega-merger in the past decade and has required divestitures or other conditions on less than a third).

¹⁶⁵ See, e.g., Press Release, Fed. Trade Comm'n, FTC Announces Multilateral Working Group to Build a New Approach to Pharmaceutical Mergers (Mar. 16, 2021), <https://www.ftc.gov/news-events/press-releases/2021/03/ftc-announces-multilateral-working-group-build-new-approach> [<https://perma.cc/P8W9-2BQL>] (describing the launch of a working group consisting of an international cohort of competition enforcement agencies that will work together to update their analysis of pharmaceutical mergers).

¹⁶⁶ See generally Feldman, WASH. POST, *supra* note 164; Tyler & Burnett, *supra* note 164.

¹⁶⁷ The generics industry enjoys lower profit margins compared to brand drug-makers. Compare Carolyn Y. Johnson, *The Generic Drug Industry Has Brought Huge Cost Savings. That May be Changing.*, WASH. POST (Aug. 1, 2017), https://www.washingtonpost.com/business/economy/the-generic-drug-industry-has-brought-huge-cost-savings-that-may-be-changing/2017/08/01/ee128d0a-68cf-11e7-8eb5-cbcc2e7bfbf_story.html [<https://perma.cc/8ZAC-5QJC>] (noting that the razor-thin profit margins of the generics industry has depleted available generic options in some drug industries) with Neeraj Sood, Tiffany Shih, Karen Van Nuys & Dana Goldman, *Flow of Money Through the Pharmaceutical Distribution System* 5 tbl.2 (Univ. S. Cal. Schaeffer Ctr. White Paper 2017) (the profit margin for branded drugs is 76% compared to generic drugs' 50%). Moreover, the generics industry is remarkably consolidated as it is, with four drug-makers responsible for more than 50% of all generic drugs sold in 2017. See Robert Coopman, *Generic Drug Industry's Rise*, CHAIN DRUG REV. (Sept. 25, 2017).

¹⁶⁸ Cf. FTC AG REPORT, *supra* note 24, at iii (noting that the entrance of a captive generic can reduce first-filer revenue by 40–52% in the exclusivity period).

¹⁶⁹ Carrier et al., *supra* note 158, at 310.

the acquirer's portfolio;¹⁷⁰ the FTC should also consider requiring brand companies to divest from or discontinue its generic products before approving a merger.

A post-merger review process may be the most effective means of addressing concerns raised by captive generics. Rather than trying to gaze into the crystal ball, regulators can benefit from evaluating mergers as they play out. In the case of captive generics and otherwise overlapping drug product portfolios, a post-merger review offers a safety net against unforeseen yet pernicious merger outcomes. Captive generics, of course, can be withheld or licensed at will, or used across different drug markets to inhibit competition. Assessing these complex market dynamics may be better suited by hindsight.

Finally, regulators can counteract the anticompetitive impact of captive generics, by cracking down on pay-for-delay deals. One proposal, currently under consideration in Congress, would declare that drug patent settlements bearing certain characteristics of pay-for-delay deals are presumptively anticompetitive, with opportunities to rebut that presumption.¹⁷¹ The FTC should also release more detailed patent settlement data.¹⁷² The mechanism for doing so is already in place: the 2003 Medicare Modernization Act stipulates that drug companies submit any patent settlement to the FTC for review.¹⁷³ The FTC, moreover, already compiles annual reports from this data, but limited resources prevent the agency from investigating individual cases. Instead, the reports, which are often years delayed, provide only annualized statistics and may understate the anticompetitive potential of strategies used by drug-makers.¹⁷⁴ For example, in the most recent report, the FTC merely deems declining royalty structures,¹⁷⁵ licensing a captive generic to subse-

¹⁷⁰ See, e.g., FED. TRADE COMM'N., FTC IMPOSES CONDITIONS ON ABBVIE INC.'S ACQUISITION OF ALLERGAN PLC (May 5, 2020), <https://www.ftc.gov/news-events/press-releases/2020/05/ftc-imposes-conditions-abbvie-incs-acquisition-allergan-plc> [<https://perma.cc/22PR-MNQR>] (the FTC required AbbVie and Allergan to transfer drug assets treating ulcerative colitis and Crohn's disease on the expectation that the merged holdings could create competitive harm in those drug markets).

¹⁷¹ Preserve Access to Affordable Generics and Biosimilars Act, H.R. 2891, 117th Cong. (2021). Similar legislation was proposed in Oregon. S.B. 764, 80th Leg. Assemb., 2019 Reg. Sess. (Or. 2019). California recently enacted a law to the same effect, but a federal judge enjoined it on Dormant Commerce Clause grounds. See *Ass'n. for Affordable Med. v. Bonta*, No. 2:20-cv-01708-TLN-DB (E.D. Cal. Dec. 9, 2021).

¹⁷² See Feldman, *Price Tag*, *supra* note 14, at 51.

¹⁷³ See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, §§ 1111-18, 117 Stat. 2066, 2461-64 (2003), reprinted in Laura Karas, Gerald F. Anderson & Robin Feldman, *Pharmaceutical "Pay-for-Delay" Reexamined: A Dwindling Practice or a Persistent Problem?*, 71 HASTINGS L.J. 959, 964 (2020).

¹⁷⁴ See Feldman & Misra, *supra* note 14, at 260-65 (describing the annual FTC reports and their limitations).

¹⁷⁵ See FTC FY 2017 REPORT, *supra* note 87, at 2 (recognizing that the declining royalty structure may achieve the same effect as an explicit no-AG clause); see also Feldman & Misra, *supra* note 14, at 265-66 (noting that FTC reports have become increasingly cognizant of the declining royalty structure as an anticompetitive tool, re-categorizing them from a form of unknown payment in 2010 to a form of possible compensation in 2013).

quent filers, and agreements not to license captive generics to third parties to be “possible forms of compensation.”¹⁷⁶

Although it would be untenable for the FTC to investigate and litigate every suspect patent settlement, a decision to make settlement information widely available would throw open the curtains for other investigators. Greater transparency would empower state attorney general offices, civil attorneys, and academic researchers to prosecute or articulate anticompetitive harm stemming from pay-for-delay.¹⁷⁷ The pending burden-shifting legislation, which sets out penalties for pay-for-delay and requires settling parties to demonstrate pro-competitive effects, would go a long way in deterring pay-for-delay deals and the corrosive captive generics to which they give rise. This is especially useful in the case of nebulous and complex arrangements that employ captive generics, such as those the FTC presently lacks the resources to analyze and outright condemn. The parallel reforms of better illuminating captive generic abuses and facilitating antitrust actions could serve to deter drug-makers from engaging in harmful practices, especially to the extent that transparency can enable judicial action.¹⁷⁸ Moreover, a fuller picture of captive generics will help catalyze further legislative reform in the area.

VI. CONCLUSION

The Hatch-Waxman system depends on a series of carefully designed incentives in order to encourage generic competition without scuttling brand drug-makers’ profit motive. As with a hanging mobile or carefully calibrated scale, however, introducing a new element threatens to bring the whole system crashing down.

At first glance, captive generics appear to be a gift to consumers. The brand company reduces prices in the market by introducing a less expensive version of a drug, sometimes even before any true generic drug-maker has the opportunity to do so. The minute the captive generic enters, a cheaper alternative exists, which should be a benefit to all. Why should society care who is providing competition in the market, as long as that competition exists?

After years of experience, however, it is clear that captive generics are not what they appear. Rather than driving down prices and enhancing competition, captive generics have the opposite effect. The proliferation of captive generics has chipped away at true generics’ revenue opportunities while

¹⁷⁶ See FTC FY 2017 REPORT, *supra* note 87, at 2. For certain brand companies that do not usually manufacture captive generics, an agreement to not license AGs to third parties can function as a no-AG clause.

¹⁷⁷ See Feldman, *Price Tag*, *supra* note 14, at 51–53.

¹⁷⁸ Prosecuting no-AG deals has successfully deterred this form of misconduct, according to the latest FTC report. See Press Release, Fed. Trade Comm’n, *supra* note 91 (suggesting that drug-makers are highly responsive to judicial decisions).

allowing brand companies to capture more than their fair share. Our analysis demonstrates that the presence of captive generics has, in turn, inflated prices of brand drugs and true generics alike for patients. Brand companies also regularly exploit their captive generic to discourage other generic competition entirely.

All of this should come as no surprise. The interests of the brand company lie in maximizing its price and market share potential. Society would be naïve to expect anything different.

Captive generics are neither a natural nor inevitable feature of the Hatch-Waxman landscape, and it is clearly time to reassess their presence altogether. New legislation should amend Hatch-Waxman to prohibit or restrict the entry of captive generics following the expiration of brand patents. As part of a more robust pharmaceutical merger review, regulators need to also account for the market power and potential brand-generic conflicts of interest conferred by captive generics. Generic competition cannot be optimized to its full price-lowering potential if brand drug-makers are allowed to field players on both sides. With this in mind, legislators, regulators, and the courts should understand that a captive generic is simply a wolf in sheep's clothing. It is time to ensure greener pastures.