The Cost of Brand Drug Product Hopping

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EXECUTIVE SUMMARY

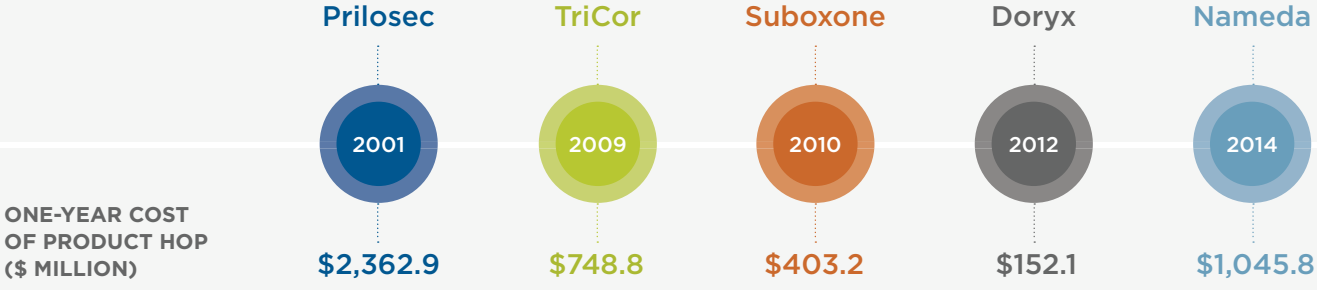
Brand drug manufacturers in the United States have developed strategies to thwart generic competition and preserve monopoly profits longer than policymakers intended. In doing so, they cost US patients and healthcare payors billions of dollars. This report focuses on one strategy known as product hopping that brand drug companies use to prevent generic competition and extend their monopoly prices. The analysis presented in this paper finds that just five instances of specific product hops cost the US healthcare system $4.7 billion annually.

Product hopping describes when a brand drug company with a product nearing the end of its monopolistic life works to move patients to a reformulation of the drug that has longer exclusivity. It is a lifecycle management tactic that creates quantifiable burdens on patients and the healthcare system, as generic savings cannot be realized if patients have been moved to a protected drug before generic competitors can enter the market.

This report looks at just five examples of this tactic over the last 20 years – for the brand drugs Prilosec, TriCor, Suboxone, Doryx, and Namenda – and estimates that these five product hops carried a total cost of $4.7 billion annually.

Proposals to address product hopping include encouraging the Food and Drug Administration to use suitability petitions to approve a generic drug with small differences from the reference product and authorizing the Federal Trade Commission to sue brand companies for product hopping. Ending this type of gamesmanship would facilitate substantially greater generic drug savings and reduce patients' out-of-pocket costs.

5 PRODUCT HOPS Cost US Healthcare System $4.7 BILLION ANNUALLY



Introduction

In the US prescription pharmaceutical market, new brand drugs are shielded from generic competition for a period of time to allow the innovator company to recoup its substantial research and development costs. After brand drugs' patent protection and market exclusivity expire (or patents are successfully challenged), generic drug manufacturers can enter the market. The ensuing competition results in lower drug prices, which translate to savings for patients and the healthcare system. This pattern of brand drug exclusivity followed by generic competition was the creation of the Drug Price Competition and Patent Term Restoration Act of 1984 (known as the Hatch-Waxman Act after its sponsors), which sought to balance the benefits to society of drug innovation and competition.

Over the years, brand drug manufacturers have developed strategies to thwart generic competition and preserve monopoly profits longer than Hatch-Waxman intended. These include patent and exclusivity strategies, market ploys, regulatory maneuvering, and litigation tactics. One result of this gamesmanship is that, between 1995 and 2014, generic entry for brand drugs with sales greater than $250 million was delayed an additional 2.2 years on average, from 10.3 to 12.5 years (*Grabowski et al., 2016*). In a previous report, I estimated that accelerating generic entry by 2.2 years would save the US healthcare system $31.7 billion (*Brill, 2019*). This present report focuses on one market-related strategy that brand drug companies use to thwart generic competition: product hopping. In this report, I offer five examples of this tactic and present an original analysis of the cost to the healthcare system of the associated delay in generic savings.

Product Hopping

Brand drug manufacturers are known to pursue strategies to extend the patent life of their products without making clinically significant changes to the products. A recent study of prescription drugs on the market between 2005 and 2015 found that "78% of the drugs associated with new patents in the FDA's records were not new drugs coming on the market, but existing drugs" (*Feldman, 2018*). Another study found evidence of "deliberate attempts by branded firms to lengthen their monopoly for more lucrative drugs" through secondary patents with no chemical compound claim (*Kapczynski et al., 2012*).

Product hopping is one of the tactics brand companies use. It describes when a brand drug company with a product nearing the end of its monopolistic life works to move patients to a reformulation of the drug that has longer exclusivity. For example, a brand drug firm with a tablet nearing patent expiration might introduce the same drug in capsule form with years of patent protection remaining. In an effort to shift patients from the tablet to the capsule, the brand company might actually withdraw the tablet from the market (known as a "hard switch") or push physicians to prescribe the capsule instead of the tablet (known as a "soft switch"). As drug competition experts have explained, "The brand-name drug company takes advantage of its market power to shift pharmacists, doctors, and consumers to new versions of drugs before a generic for the 'old' version is able to reach the market" (*Feldman and Frondorf, 2016*).

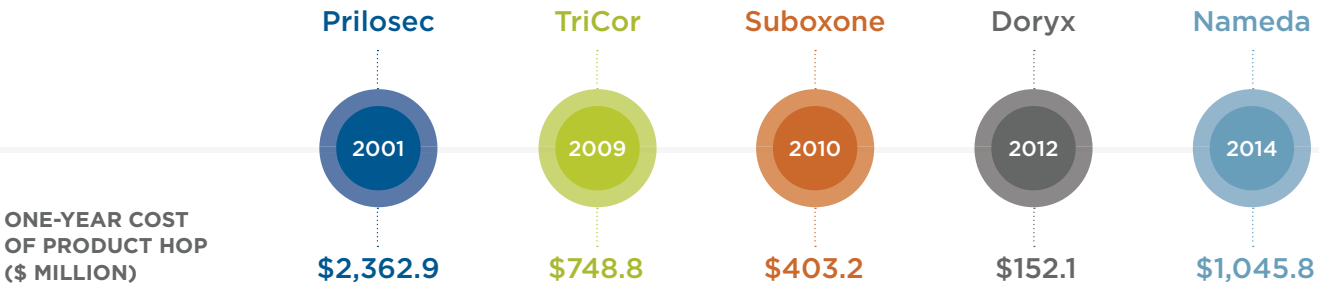
This is remarkably effective in the prescription drug market because generic drugs achieve the market share and healthcare savings they are known for through near-universal automatic substitution policies. Generic substitution and savings are thwarted if patients have been moved to a protected drug before generic competitors can enter the market. For example, generics of a drug described below (TriCor) achieved only 2 percent of the brand product's prior market share following the brand's product hop (*Carrier and Shadowen, 2017*). While there are ways that a reformulation of an existing drug *can* bring real benefit to patients, reformulations often are used only as a tactic to thwart competition. As a result, patients and payors, including government health programs, end up missing out on generic savings. And in Medicaid, additional costs can arise from brand companies avoiding paying bigger rebates on established products.

Product Hopping Case Studies

To illustrate the negative impact of product hopping on the healthcare system, I estimate the annual cost of product hopping associated with five brand drugs: Prilosec, TriCor, Suboxone, Doryx, and Namenda. This is not an exhaustive list of all instances of product hopping, but rather illustrates the strategies employed in certain high-profile cases that have been widely reported and discussed by other experts. A brief description of each case appears below.

By my estimation, these five product hops carry a total cost of $4.7 billion annually. **Figure 1** presents the annual cost associated with each product hop, ranging from roughly $150 million to $2.4 billion. (See the following section for the methodology used in this analysis.)

FIGURE 1. 5 PRODUCT HOPS **Cost US Healthcare System** $4.7 BILLION ANNUALLY



1

Prilosec

The anti-ulcer drug Prilosec was, at one time, the top drug by sales in the United States. In 2000, before its scheduled patent expiration the following year, Prilosec sales reached $4.1 billion (*NIHCM Foundation, 2001*). In anticipation of generic competition for its blockbuster product, AstraZeneca, Prilosec's manufacturer, introduced and pushed doctors to prescribe its new anti-ulcer drug, Nexium, which was only slightly chemically different from Prilosec but had 13 years of patent protection left. A lawsuit alleging that AstraZeneca engaged in anticompetitive behavior with Prilosec and Nexium was dismissed in early 2008 when a district court found that AstraZeneca "did not eliminate consumer choice" (*Callan, 2015*). But antitrust experts have pointed out that the court's reasoning ignores "the realities of drug markets," where a prescription for a single-source brand drug removes the option of a generic version (*Carrier and Shadowen, 2016*).

PRILOSEC® (OMEPRAZOLE)

2

TriCor

Beginning in the early 2000s, Abbott Laboratories executed several product hops for its cholesterol medicine TriCor by slightly reformulating the drug — for example, moving from capsules to tablets with slight differences in dose. As health scholars have described, "As soon as direct generic competition seemed likely with the latest formulation, where substitution would be allowed, Abbott would launch another reformulation, and the cycle would repeat" (*Downing et al., 2012*). Abbott further ensured the success of the product hops by removing the previous TriCor version from the market when launching a new formulation. Largely for this reason, the Delaware district court in 2006 refused to dismiss a lawsuit against Abbott alleging anticompetitive behavior (*Carrier and Shadowen, 2016*). By TriCor's third reformulation — to a version called Trilipix, which was approved in late 2008 — Abbott's annual US sales for the product had reached nearly $1.4 billion (*Downing et al., 2012*).

3

Suboxone

The Department of Justice (DOJ), the Federal Trade Commission (FTC), and state attorneys general went after manufacturer Reckitt Benckiser for its schemes — including a product hop — to illegally profit off the opioid addiction treatment Suboxone. With exclusivity expiring for Suboxone tablets in 2009 — and more than $700 million in annual US sales at stake — Reckitt Benckiser introduced Suboxone sublingual film (*FTC, 2019*). Though the film and tablet formulations of the drug both dissolve orally, Reckitt aggressively tried to undermine its tablets:

> Reckitt allegedly promoted Suboxone film to physicians, disparaged Suboxone tablets, warned of false safety concerns, publicly announced the removal of tablets for these fabricated safety reasons but did not remove the tablets until six months later, and raised the price of tablets. (*Carrier and Shadowen, 2016*)

In 2019, Reckitt agreed to a settlement "to resolve its potential criminal and civil liability" related to Suboxone, including the FTC's allegations of anticompetitive behavior (*DOJ, 2019*).

4

Doryx

Like TriCor, the acne drug Doryx was also reformulated three times to dodge generic competition (*Mylan, 2015*). In its first product hop, Warner Chilcott, Doryx's manufacturer, "stopped selling the original capsule versions of its drug, removed capsules from its website, and bought back and destroyed capsules while introducing a reformulated version in tablet form" (*Carrier and Shadowen, 2017*). By the fourth formulation of the drug, in 2011, US sales of Doryx totaled $264.1 million (*Leuty, 2012*).

Unlike TriCor, Doryx litigation brought by generic manufacturer Mylan was dismissed. When Mylan requested rehearing en banc, the FTC filed an amicus brief in support of the rehearing, noting, among other concerns, that "the panel improperly focused on the effect of product hopping on Mylan rather than its overall effect on competition" (*FTC, 2016*).

5

Namenda

In anticipation of generic competition for the Alzheimer's drug Namenda IR, Forest Laboratories in 2013 launched an extended-release version, Namenda XR, and in 2014 removed Namenda IR from the market (*Rai and Richman, 2018*). The difference between the products amounted to Namenda IR needing to be taken twice a day, and Namenda XR once, but Namenda XR had years of patent protection left. The product hop would have allowed Forest to preserve Namenda IR sales, which totaled $1.8 billion in the United States in 2013 (*Drugs.com, 2014*). However, the New York State Attorney General sued to compel Forest to keep manufacturing Namenda IR. In 2015, the Second Circuit Court of Appeals ruled that Namenda IR had to remain on the market for 30 days after generic market entry (*Rai and Richman, 2018*).

Methodology

To estimate the cost of product hopping in the five examples described above, I begin with the peak brand sales before the product hop. If a brand company executed multiple hops for the same product, I include only the last hop in the analysis. Without the product hop, generics in a steady state of competition achieve, on average, 90 percent market share (*AAM, 2019*) at a price discount of 80–85 percent (*FDA, 2018*). For this analysis, I assume the more conservative price discount of 80 percent. Brand drug firms' efforts to move market share to a new product have varying degrees of success. As mentioned above, generics achieved only 2 percent market share after the TriCor product hop. In the case of the Prilosec-to-Nexium hop, generics achieved 30 percent market share (*Callan, 2015*). For this analysis, I assume that the average product hop moves 80 percent of patients to the new product while generics obtain 18 percent market share of the original product market and the brand preserves 2 percent.

The annual cost, or lost savings, associated with product hopping is therefore:

$$GS_1 - GS_2 =$$

$$(B * 0.9 * 0.8) - (B * 0.9 * 0.8 * 0.2) =$$

$$B * 0.576$$

where GS_1 = generic savings absent the product hop, GS_2 = generic savings despite the product hop, and B = brand original sales.

As noted above, the one-year cost of product hopping for all five cases presented above totals $4.7 billion. It should be noted that this estimate does not constitute an estimate of the full scope of the cost of product hopping as a strategy employed repeatedly by manufacturers, as it encompasses only five case studies. It also does not include the potential for increasing sales of a brand drug after the product hop (as was the case with Suboxone, for example) or the cost of previous product hops for the same drug (for example, TriCor and Doryx).

It should also be noted that the cost of product hopping would be lower during the first six months of generic competition, given the 180 days of market exclusivity typically awarded to the first generic competitor and the less aggressive generic discounting that occurs during that initial period. The annual costs presented here assume a mature and competitive generic market, which generally occurs rapidly for markets large enough to warrant product hops. In addition, the cost of product hopping should not be considered to persist in perpetuity, as the market for drugs eventually shifts as new products are developed. Nevertheless, the ability to largely avoid the lost brand sales associated with generic entry by hopping patients to a new formulation can extend the revenue stream for a brand drug by many years.

Policy Options to Address Product Hopping

As some of the legal decisions noted above demonstrate, the courts are not necessarily the best corrective to the tactic of product hopping. Legal scholars recently argued that the FDA could step in to address product hopping:

> Antitrust suits are expensive and time-consuming, and any remedy they provide typically emerges many years after the fact. . . . In contrast to judges and juries, the FDA is in an exceptionally good position to determine when product hops lack evidence of genuine innovation and to allow generic competition in that circumstance. (*Rai and Richman, 2018*)

The authors argue that the FDA could use suitability petitions, allowed by the Hatch-Waxman Act, to approve a generic drug with small differences from the reference product. In other words, the FDA, where appropriate, could deem a generic to be substitutable for both the original product and the post-hop product.

A legislative proposal to address product hopping was included in S. 1416, the Affordable Prescriptions for Patients Act, which was introduced in 2019 by Senators John Cornyn (R-TX) and Richard Blumenthal (D-CT). The bill would codify a definition of product hopping in the FTC Act, which "would empower the FTC to challenge [product hopping] as anti-competitive and enable the FTC to bring antitrust suits against companies who attempt to capitalize on their abuse of the system" (*Offices of Cornyn and Blumenthal, 2019*). With 13 cosponsors – seven Republicans, five Democrats, and one independent – this bipartisan proposal was reported favorably by the Senate Judiciary Committee in June 2019.

Finally, a new proposed rule from the Centers for Medicare & Medicaid Services (CMS) offers a promising reform in Medicaid. As mentioned above, product hopping can allow brand drug firms to circumvent Medicaid rebates on established products. The CMS rule, if finalized, would address these attempts to avoid paying Medicaid rebates on line extensions (*CMS, 2020*).

Conclusion

Product hopping is a tactic of brand drug companies that creates quantifiable burdens on patients and the healthcare system. This report looks at just five examples over the last 20 years and finds that these five product hops carried a total cost of $4.7 billion annually. Patients and the healthcare system stand to save billions if policymakers end product hopping gamesmanship.

SOURCES

Association for Accessible Medicines (AAM). 2019. *The Case for Competition 2019 Generic Drug & Biosimilars Access & Savings in the U.S. Report.*

Brill, Alex. 2019. "Gamesmanship and Other Barriers to Drug Competition." July. www.getmga.com/wp-content/uploads/2019/07/Brand_Gamesmanship_July_2019.pdf.

Callan, Nicole. 2015. "Antitrust Liability for 'Product Hopping': A Look at Recent Decisions." Intellectual Property Committee, ABA Section of Antitrust Law. Spring.

Carrier, Michael A. and Steve D. Shadowen. 2016. "Product Hopping: A New Framework," *Notre Dame Law Review* 92, no. 1: 167–230.

Carrier, Michael A., and Steve Shadowen. 2017. "Pharmaceutical Product Hopping: A Proposed Framework for Antitrust Analysis." Health Affairs Blog. June 1.

Centers for Medicare & Medicaid Services (CMS). 2020. "Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements," *Federal Register* 85, no. 119 (June 19): 37286–37322.

Department of Justice. 2019. "Justice Department Obtains $1.4 Billion from Reckitt Benckiser Group in Largest Recovery in a Case Concerning an Opioid Drug in United States History." News release. July 11.

Downing, Nicholas S., Joseph S. Ross, Cynthia A. Jackevicius, and Harlan M. Krumholz. 2012. "Avoidance of Generic Competition by Abbott Laboratories' Fenofibrate Franchise," *Archives of Internal Medicine* 172, no. 9 (May 14): 724–30.

Drugs.com. 2014. Namenda Sales Data. February.

Federal Trade Commission (FTC). 2016. Brief for Amicus Curiae Federal Trade Commission in Support of Plaintiff-Appellant Mylan Pharmaceuticals Inc.'s Petition for Rehearing and Rehearing *en Banc. Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd. Co*. Case No. 15-2236. Document No. 003112439683. Third Circuit Court of Appeals. October 19.

Federal Trade Commission v. Reckitt Benckiser Group PLC. 2019. Case No. 1:2019cv00028. Complaint. July 11.

Feldman, Robin and Evan Frondorf. 2016. "Drug Wars: A New Generation of Generic Pharmaceutical Delay," *Harvard Journal on Legislation* 53, no. 2: 499–561.

Feldman, Robin. 2018. "May Your Drug Price Be Evergreen." *Journal of Law and the Biosciences* 5 (3): 590–647.

Food and Drug Administration (FDA). 2018. "Generic Drugs: Questions & Answers." June 1.

Grabowski, Henry, Genia Long, Richard Mortimer, and Ani Boyo. 2016. "Updated Trends in US Brand-Name and Generic Drug Competition." *Journal of Medical Economics* 19, no. 9: 836–44.

Kapczynski, Amy, Chan Park, and Bhaven Sampat. 2012. "Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of 'Secondary' Pharmaceutical Patents," *PLOS ONE* 7, no. 12 (December).

Leuty, Ron. 2012. "FDA Pulls Impax Antibiotic Dose as It Approves Mylan Version." *San Francisco Business Times*. February 9.

Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd. Co. 2015. Civ. No. 12-3824 (E.D. Pa. Apr. 16).

National Institute for Health Care Management (NIHCM) Foundation. 2001. "Prescription Drug Expenditures in 2000: The Upward Trend Continues." May.

Offices of John Cornyn and Richard Blumenthal. 2019. "Cornyn, Blumenthal Introduce Bill to Prevent Drug Companies from Abusing Patent System." News Release. May 9.

Rai, Arti K. and Barak D. Richman. 2018. "A Preferable Path for Thwarting Pharmaceutical Product Hopping." Health Affairs Blog. May 22.

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