


1-1-2017

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Recommended Citation

Kieran Meagher, *Abuse of the Hatch-Waxman Act: Mylan's Ability to Monopolize Reflects Weaknesses*, 11 Brook. J. Corp. Fin. & Com. L. 589 (2017).

Available at: <https://brooklynworks.brooklaw.edu/bjcfcl/vol11/iss2/12>

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ABUSE OF THE HATCH-WAXMAN ACT: MYLAN'S ABILITY TO MONOPOLIZE REFLECTS MAJOR WEAKNESSES

ABSTRACT

The Drug Price Competition and Patent Term Restoration Act of 1984, better known as the Hatch-Waxman Act, is intended to lower the average price paid by consumers for prescription drugs. The Hatch-Waxman Act attempts to do so by simplifying the application process for generic drug manufacturers, allowing generic drug applications to circumvent the lengthy FDA testing and approval process that brand-name manufacturers must undergo. Though the Hatch-Waxman Act has successfully created a clear path to the market for generic drugs, it contains loopholes that allow brand name and generic companies to engage in practices aimed at maximizing monopoly profits, effectively depriving consumers of a generic option. Some of these practices include: reverse payments, citizen petitions, product hopping, and the misclassification of drugs. This Note argues that pharmaceutical companies have engaged in some of these practices and that the Hatch-Waxman Act must be amended to prevent these companies from continuing to circumvent the true intention of the Act.

INTRODUCTION

Mylan Pharmaceuticals, founded in 1961, is one of the “largest generics and specialty pharmaceutical companies in the world, manufacturing and marketing more than 2,700 different products to retail, wholesale, governments and institutional customers.”¹ Mylan is most well known for its life-saving epinephrine auto-injectors, EpiPen and EpiPen Jr.—two emergency medical devices that work to halt the deadly result of anaphylaxis suffered by millions of patients throughout the United States.² Currently, the EpiPen, with a list price of over \$600, is one of only two products on the market available to these patients—patients whose medical coverage, co-pays, deductibles, and income vary greatly.³ Mylan makes billions of dollars every year by selling drugs and medical devices throughout the country.⁴ But, Mylan uses the law to prevent generic anaphylaxis products from reaching

1. *A History of Doing What's Right*, MYLAN PHARMACEUTICALS, <http://www.mylan.com/en/company> (last visited Feb. 20, 2017).

2. See *Highlights of Prescribing Information Reference ID: 3932500*, U.S. FOOD & DRUG ADMIN. (Oct. 20, 2016) [hereinafter *Highlights of Prescribing Information*], http://www.accessdata.fda.gov/drugsatfda_docs/label/2016/019430s061lbl.pdf; see also Cynthia Koons, Michael Keller & Robert Langreth, *How the EpiPen's Price Rose and Fell*, BLOOMBERG (Sept. 1, 2016), <https://www.bloomberg.com/graphics/2016-epipen-pricing/>.

3. See, e.g., Koons, Keller & Langreth, *supra* note 2.

4. See *Annual Financials for Mylan N.V.*, MARKETWATCH, <http://www.marketwatch.com/investing/stock/myl/financials> (last visited Feb. 20, 2017).

the market, leaving consumers with an increasingly expensive option,⁵ albeit a necessary one to save millions of American lives.⁶

In the past, the government has attempted to combat the lack of market competition within the pharmaceutical industry, by passing laws attempting to remove the potential for monopolization. In 1984, President Ronald Reagan signed into law the Drug Price Competition and Patent Term Restoration Act of 1984, better known as the Hatch-Waxman Amendments (Hatch-Waxman or the Act).⁷ The intention of the Act was to make it easier for generic drugs to enter the market.⁸ It attempted to do this by streamlining and simplifying the application and approval process for generics, allowing generic companies to circumvent the lengthy and expensive testing that brand-name pharmaceuticals are subject to.⁹ In addition, the Act allows generic manufacturers to challenge the patents of brand-name pharmaceutical companies.¹⁰ Hatch-Waxman has done wonders for consumers and the generic drug industry, generating more than \$1.2 trillion in savings to the health care system and creating a clear pathway to market for generic drugs.¹¹

Although Hatch-Waxman has provided greater consumer access to low-cost, quality medication, the FDA still faces enormous challenges in ensuring access to affordable and quality generic drugs.¹² This is because Hatch-Waxman contains loopholes that allow brand-name pharmaceutical companies, such as Mylan, to prevent generic drugs from reaching the market and to do so legally. The meager safety net, if one would even call it that, is the FDA's power to approve generic drugs and to help maintain a fluid, operating, and competitive market. However, the FDA has been immensely backlogged with generic drug applications for new generic products.¹³ Aside from the Generic Drug User Fee Amendments of 2012 (GDUFA), which "requires [the] industry to pay user fees to supplement the cost of reviewing generic drug applications," and "enables the Agency to reduce current backlog of pending applications," there is little standing law helping the FDA

5. See, e.g., Reuters, *Mylan's EpiPen Price Hikes Reportedly Add Millions to Pentagon Costs*, FORTUNE (Oct. 26, 2016), <http://fortune.com/2016/10/28/mylan-epipen-price-hikes-pentagon/>.

6. See Facts and Statistics, FARE FOOD ALLERGY RES. & EDUC., <https://www.foodallergy.org/facts-and-stats> (last visited Feb. 20, 2017).

7. See, e.g., Margaret A. Hamburg, M.D., *Celebrating 30 Years of Easier Access to Cost Saving Generic Drugs*, U.S. FOOD & DRUG ADMIN. (Sept. 24, 2014), <http://blogs.fda.gov/fdavoices/index.php/tag/drug-price-competition-and-patent-term-restoration-act-of-1984/>; see also *Scherling-Plough Corp. v. FTC*, 402 F.3d 1056, 1059 n.2 (11th Cir. 2005).

8. See Hamburg, *supra* note 7.

9. See e.g., KENNETH GLAZER & JENÉE DESMOND-HARRIS, *ANTITRUST HEALTHCARE HANDBOOK, REVERSE PAYMENTS: HARD CASES EVEN UNDER GOOD LAW* 15 (2010).

10. See, e.g., *id.*

11. See Hamburg, *supra* note 7 (noting that about eighty-five percent of all prescriptions filled are generic versions).

12. *Id.*

13. See, e.g., Sydney Lupkin, *EpiPen Controversy Fuels Concern Over Generic Drug Approval Backlog*, KAISER HEALTH NEWS (Sept. 6, 2016), <http://khn.org/news/epipen-controversy-fuels-concerns-over-generic-drug-approval-backlog/>.

get generics to market.¹⁴ Hatch-Waxman fails to prevent or penalize brand-name companies from depriving consumers of an affordable generic product, while the FDA is resigned to its slow, complex process of approving other affordable drugs.

For example, Mylan, acting completely within the confines of Hatch-Waxman, has created a monopoly with its EpiPen and cleared the field of any generic competition. This Note argues that the lack of regulation under Hatch-Waxman enables pharmaceutical companies to drain the market of generic competition, and thus requires drastic amendments. Part I of this Note discusses the interrelation between Hatch-Waxman and the Sherman Antitrust Act and explains how these statutes work together to regulate pharmaceutical market activity, as well as Mylan's current position in that market. Part II introduces strategies pharmaceutical companies use to work around Hatch-Waxman and facilitate monopolization of the pharmaceutical industry. Part III considers the effect these practices have on consumers. Lastly, Part IV discusses potential solutions to these problems, including the creation of internal oversight committees on drug pricing and amendments to Hatch-Waxman to ban reverse payments and bad faith citizen petitions.

I. REGULATING THE PHARMACEUTICAL MARKET

A. NEW DRUG APPLICATION (NDA): BRAND-NAME DRUG APPLICATION PROCESS

Pharmaceutical companies, in the business of creating powerful and potentially dangerous products, are subject to the rigorous FDA application processes involved in getting a drug to the market.¹⁵ The FDA's process varies by whether a pharmaceutical company is seeking to introduce a brand-name drug or a generic version of a brand-name drug.¹⁶ According to the Hatch-Waxman, when a manufacturer seeks to bring a new brand-name drug to the market it must submit a New Drug Application (NDA) containing evidence that the drug is safe and effective.¹⁷ Whether the company has been issued a patent for this drug or not, the FDA grants the brand-name pharmaceutical company an "exclusivity" window, which prevents the

14. *Generic Drug User Fee Amendments of 2012*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/default.htm> (last updated Feb. 10, 2017).

15. *See, e.g., How Drugs Are Developed and Approved*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/> (last updated Aug. 18, 2015).

16. *See, e.g., CTR. FOR DRUG EVALUATION & RESEARCH SMALL BUS. & INDUS. ASSISTANCE CHRONICLES, PATENTS AND EXCLUSIVITY 1* (2015), <https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/UCM447307.pdf> [hereinafter *PATENTS AND EXCLUSIVITY*].

17. *See Drug Price Competition and Patent Term Restoration Act of 1984*, 21 U.S.C. § 355(b) (2012).

submission or approval of similar generic drugs for a period of time.¹⁸ This provides the brand-name company an exclusive market right to sell the product free of competition from any other drug, brand name or generic, during the exclusivity period.¹⁹

The length of exclusivity granted to a new drug varies by the type of drug and type of exclusivity granted. There are four types of exclusivity granted to an NDA, which range from six months to seven years: Orphan Drug Exclusivity (7 years), New Chemical Exclusivity (5 years), Pediatric Exclusivity (6 months added to existing patents/exclusivity), and Other (3 years).²⁰

B. ABBREVIATED NEW DRUG APPLICATION (ANDA): STREAMLINING THE GENERIC APPLICATION PROCESS

Hatch-Waxman was designed to encourage new drug innovation and “promote the availability of generic drugs, while still allowing for legitimate patent claims and maintaining financial incentives for research and development of new pharmaceuticals.”²¹ The Act attempts to encourage new drug innovation by providing an alternate application process and exclusivity period for generic drugs, called the Abbreviated New Drug Application (ANDA).²² A company looking to apply for generic drug approval files an ANDA, which allows the generic company to supplement another company’s NDA, an already approved brand-name application, with studies showing that the generic company’s drug is the “bioequivalent to that of the brand-name.”²³ Though the generic must contain the same active ingredients as the brand name, it may differ in terms of the drug’s *inactive* ingredients.²⁴ This streamlined process allows generic manufacturers to circumvent the lengthy

18. See, e.g., PATENTS AND EXCLUSIVITY, *supra* note 16, at 1.

19. *Id.*

20. *Id.* at 2–3 (Orphan Drug Exclusivity is “granted to drugs designated and approved to treat diseases or conditions affecting fewer than 200,000 [people] in the United States.” New Chemical Exclusivity is “granted to drugs that contain no active moiety that has been approved by the FDA under section 505(b).” Pediatric Exclusivity “grants an additional six months of market protection at the end of listed patents and/or exclusivity for sponsor’s drug products containing active moiety, when the sponsor has conducted and submitted pediatric studies on the active moiety in response to a Written Request from the FDA.” “Other” Exclusivity is “granted to drugs when [the] application or supplement contains reports of new clinical investigations conducted or sponsored by applicant and essential for approval.”); see also 21 C.F.R. §§ 316.31, 314.108 (2016); FOOD AND DRUG ADMINISTRATION MODERNIZATION ACT OF 1997, S. 830-10, 105th Cong. § 505A (1997).

21. GLAZER & DESMOND-HARRIS, *supra* note 9, at 14.

22. 21 U.S.C. § 355(j).

23. *Id.* § 355(j)(8)(b)(i–ii) (both drugs deliver the same amount of the same active ingredient content into a patient’s blood stream over the same amount of time). Generic manufacturers filing ANDAs are required to submit the “Paragraph IV certification,” demonstrating that with respect to each patent belonging to the brand-name drug that (1) no patent was listed to the drug, (2) the patent has expired, (3) the ANDA drug will not be marketed until the patent expires, and (4) the patent is invalid or would not be infringed by the generic version. See *id.* § 355 (b)(2)(A).

24. See *id.* § 355(j)(2).

and comprehensive application process that a brand-name drug must undergo.

The first company, or “first flier,” to submit an ANDA has the exclusive right to market the generic drug for 180 days.²⁵ However, “a branded drug manufacturer is permitted to market an authorized generic version of its own brand product at any time, including during the 180 days after the first generic competitor enters the market.”²⁶ So, although the exclusivity period is very valuable and gives “generic manufactures strong incentives to challenge the patented products of the branded drug manufacturer,”²⁷ there is yet another challenge facing generic drugs, in that they are not awarded true exclusivity. Instead, they must compete with the brand-name company’s generic drugs, since the approved brand-name company is not excluded from entering the market during the 180-day period.²⁸

The brand-name drug company is thus incentivized to produce a generic version of its own drug and apply for generic drug approval, since they will not be banned from the exclusivity period and will reap the profits of both drugs. According to the FDA, when generic products enter the market they do so with a slow decrease in product price.²⁹ This gradual decrease in product price is initiated by the first generic competitor, which markets its product cheaper, but very close to that of the brand-name product. The second generic manufacturer then continues to reduce the price to nearly half the brand-name drug.³⁰ Products that are in high demand can attract a larger number of generic manufacturers and drop the price to twenty percent below the brand-name price.³¹

As a result of generics’ somewhat “fast-track” to market by way of the Hatch-Waxman, brand-name companies are interested in delaying or preventing competing generics from hitting the market with a lower-priced

25. See, e.g., PATENTS AND EXCLUSIVITY, *supra* note 16, at 3.

26. *FTC Sues Endo Pharmaceuticals Inc. and Others for Illegally Blocking Lower-Cost Generic Versions of the Branded Drugs Opana ER and Lidoderm*, FED. TRADE COMM’N (Mar. 31, 2016) [hereinafter *FTC Sues Endo Pharmaceuticals*], <https://www.ftc.gov/news-events/press-releases/2016/03/ftc-sues-endo-pharmaceuticals-inc-others-illegally-blocking-lower>.

27. GLAZER & DESMOND-HARRIS, *supra* note 9 at 15.

28. See *FTC Sues Endo Pharmaceuticals*, *supra* note 26.

29. See, e.g., CONG. BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED THE PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY xii (1998) [hereinafter *INCREASED COMPETITION*].

30. See, e.g., *Generic Competition and Drug Prices*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/CDER/ucm129385.htm> (last updated May 13, 2015); see also *INCREASED COMPETITION*, *supra* note 29 (stating that the CBO suggests a slightly different impact on prices, reporting that when a brand name loses its patent, the first generic competitor to enter the market typically enters at a price point 25% lower than the brand-name and additional generics on the market lower the price by as much as 60% of the brand-name price).

31. See, e.g., *Generic Competition and Drug Prices*, *supra* note 30; see also *INCREASED COMPETITION*, *supra* note 29.

product and causing the brand-name companies to lose a percentage of their market share.

C. SHERMAN ACT & FEDERAL TRADE COMMISSION ACT

Once approved to sell a drug on the market, pharmaceutical companies must abide by two core federal antitrust laws, which “have had the same basic objective: to protect the process of competition for the benefit of consumers, making sure there are strong incentives for businesses to operate efficiently, keep prices down, and keep quality up.”³² The Sherman Antitrust Act, enacted in 1890, outlaws “every contract, combination in the form of trust or otherwise, or conspiracy in restraint of trade,” and monopolization, attempted monopolization, or conspiracy or combination to monopolize.³³ The Sherman Act does not, however, actually prohibit every restraint of trade, at least according to the courts that have interpreted it, but rather only those restraints that are unreasonable.³⁴ Violators of the Sherman Act are potentially subject to both civil actions and Department of Justice criminal prosecution.³⁵

The second law, the Federal Trade Commission Act (FTCA), bans “unfair methods of competition” and “unfair or deceptive acts or practices,” and allows the Federal Trade Commission (FTC) to bring actions for similar kinds of activities that violate the Sherman Act.³⁶ In addition to these federal statutes, most states have additional antitrust laws.³⁷ Pharmaceutical companies such as Mylan, however, have managed to shield themselves from these federal statutes by slipping through the gaps that the Hatch-Waxman has left open.

D. MYLAN’S MARKET

Mylan’s EpiPen devices are intended for immediate administration and are used in the “emergency treatment of allergic reactions.”³⁸ These devices are used to combat anaphylactic reactions to stinging insects, biting insects, foods, drugs, diagnostic testing substances, and other allergens, as well as idiopathic anaphylaxis and exercise-induced anaphylaxis.³⁹ Studies show that

32. *Antitrust Laws*, FED. TRADE COMM’N, <https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/antitrust-laws> (last visited Feb. 20, 2017).

33. *See* Sherman Act, 15 U.S.C. §§ 1–2 (2012).

34. *See, e.g., Antitrust Laws*, *supra* note 32.

35. *Id.* (“The Sherman Act imposes criminal penalties up to \$100 million for a corporation and \$1 million for an individual, along with up to 10 years in prison. Under federal law, the maximum fine may be increased to twice the amount the conspirators gained from the illegal acts or twice the money lost by the victims of the crime, if either of those amounts is over \$100 million.”).

36. *Id.* (“The Supreme Court has said that all violations of the Sherman Act also violate the FTC Act.”); Federal Trade Commission Act, 15 U.S.C. §§ 45 (a)(1), (a)(4)(B).

37. *Id.*

38. *Highlights of Prescribing Information*, *supra* note 2.

39. *See id.* (Anaphylaxis is a severe and potentially deadly allergic reaction.).

anaphylaxis—a severe, life-threatening reaction—is very common and occurs in at least one in fifty adults, more likely closer to one in twenty.⁴⁰

It is not preposterous to assume that with the prevalence of this dangerous allergic reaction that medical studies, experts, and pharmaceutical companies would be working to supply consumers with reasonable, effective, and life-saving devices to combat this condition. Oddly enough, there are only two treatments: Mylan's EpiPen and Amedra Pharmaceuticals' Adrenaclick.⁴¹ The FDA approved both Mylan's EpiPen and EpiPen Jr. on December 22, 1987, and both products have patent expiration dates of September 11, 2025.⁴² It is estimated that in 2015, 3.6 million Americans received an EpiPen prescription.⁴³ The FDA approved Amedra Pharmaceuticals' Adrenaclick on November 25, 2009.⁴⁴

The next questions, naturally, are: why are there only two such life-saving medical devices, and how has Mylan been able to raise the price of the EpiPen 548% since it began selling the product in 2007?⁴⁵ Consumers without insurance or with a high-deductible plan end up paying the full list price for a two-pack, the only way either EpiPen is currently sold.⁴⁶ As a result, "EpiPen is Mylan's top-selling product, generating more than \$1 billion of the company's \$9.5 billion [in] total revenue last year."⁴⁷ Mylan receives hardly any competition from Adrenaclick and essentially dominates the market; "[i]n fact, Mylan has about an [eighty-nine percent] market share currently."⁴⁸

40. See, e.g., Dr. Robert Wood et al., *Anaphylaxis in America: The Prevalence and Characteristics of Anaphylaxis in the United States*, 133 J. ALLERGY & CLINICAL IMMUNOLOGY 461, 462 (2014); see also Press Release, Asthma & Allergy Found. of Am., New Study Shows Nearly 1-In-50 At-Risk For Severe Allergic Reactions (Oct. 21, 2013), <http://www.aafa.org/media/Anaphylaxis-in-America-Press-Release-2014.pdf>.

41. See *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, U.S. FOOD & DRUG ADMIN., http://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm (last visited Mar. 24, 2017); see also Ciara Linnane, *CVS Takes on Mylan's EpiPen with Much Cheaper Version of an Alternative*, MARKETWATCH (Jan. 15, 2017, 12:01 PM), <http://www.marketwatch.com/story/cvs-takes-on-mylans-epipen-with-much-cheaper-version-of-an-alternative-2017-01-12>.

42. See *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, EpiPen*, U.S. FOOD & DRUG ADMIN. [hereinafter *EpiPen Evaluation*], http://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=019430 (last visited Feb. 20, 2017).

43. See Jonathan D. Rockoff, *Mylan Faces Scrutiny Over EpiPen Price Increases*, WALL ST. J. (Aug. 24, 2016, 5:40 PM), <http://www.wsj.com/articles/mylan-faces-scrutiny-over-epipen-price-increases-1472074823>.

44. See *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, Adrenaclick*, U.S. FOOD & DRUG ADMIN., http://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=020800 (last visited Feb. 20, 2017).

45. See, e.g., Rockoff, *supra* note 43.

46. See, e.g., Koons, Keller & Langreth, *supra* note 2.

47. Rockoff, *supra* note 43.

48. Ed Silverman, *How Mylan Tried to Keep Teva from Selling a Generic EpiPen*, STAT (Aug. 31, 2016), <https://www.statnews.com/pharmalot/2016/08/31/mylan-teva-generic-epipen/>.

Mylan's continued success and financial gain from its EpiPen sales are due, in part, to the lack of generic competition. Mylan has been able to monopolize this area of the pharmaceutical drug industry using tactics to delay generic market entry or by convincing generic manufacturers to abandon their market entry altogether.⁴⁹

II. STRATEGIC DERAILEMENT OF THE HATCH-WAXMAN ACT

Mylan and other pharmaceutical companies have the ability to derail Hatch-Waxman because there is no federal regulation capping drug pricing in the United States, and the Act, the one statute designed to increase the flow of generic market entry, fails to fill that void. The Act has led to many unforeseen situations as the industry has developed. The looming expiration of a patent, together with the approaching 180-day generic exclusivity period, has incentivized brand-name companies to creatively and legally come up with a host of ways to cement their market shares, while making and saving as much money as possible.

A. REVERSE PAYMENTS

As a result of the 180-day exclusivity period, "more generic filers are seeking to enter the market sooner."⁵⁰ Although the intent behind the exclusivity period is to encourage this generic competition, the 180-day exclusivity period has "ultimately created an incentive for the brand and generic companies to limit competition with each other."⁵¹ Since generic manufacturers typically gain an average of 44% of sales of branded drugs within the first year they are allowed to go to market, brand-name companies want to keep these threatening generics out of the hands of the public for at least those 180 days.⁵² As a result, instead of generics competing for the first flier position, they are now competing to be the first company paid off by the brand-name companies not to enter the market.⁵³

49. See U.S. FOOD & DRUG ADMIN., Division of Dockets Management, Mylan-Citizen Petition, Jan. 16, 2015 [hereinafter Mylan-Citizen Petition]; see also Press Release, Mylan, Inc., Mylan and Pfizer Announce Epinephrine Auto-injector Settlement Agreement With Teva, (Oct. 6, 2012, 4:00 PM) [hereinafter *Epinephrine Auto-Injector Settlement*], <http://newsroom.mylan.com/press-releases?item=123144>; see also Wyden, Pallone Confirm EpiPen Makers Overcharged Medicaid for Two Decades, U.S. SENATE COMM. ON FIN. (Sept. 28, 2016) [hereinafter *EpiPen Makers Overcharged Medicaid*], <http://www.finance.senate.gov/ranking-members-news/wyden-pallone-confirm-epipen-makers-overcharged-medicaid-for-two-decades>.

50. Alyssa L. Brown, *Modest Proposals for a Complex Problem: Patent Misuse and Incremental Changes to the Hatch-Waxman Act as Solutions to the Problem of Reverse Payment Settlements*, 41 U. BALT. L. REV. 583, 588 (2012).

51. GLAZER & DESMOND-HARRIS, *supra* note 9, at 15.

52. See, e.g., GLAZER & DESMOND-HARRIS, *supra* note 9, at 15.

53. See, e.g., JON LEIBOWITZ, CHAIRMAN, FED. TRADE COMM'N, CENTER FOR AM. PROGRESS, PAY FOR DELAY SETTLEMENTS IN THE PHARMACEUTICAL INDUSTRY: HOW CONGRESS CAN STOP ANTICOMPETITIVE CONDUCT, PROTECT CONSUMERS' WALLETS, AND HELP PAY FOR HEALTH CARE REFORM (THE \$35 BILLION SOLUTION) 1, 5 (June 23, 2009).

One major, controversial strategy pharmaceutical companies use to halt generic entry is known as “reverse payment,” or “pay-for-delay.”⁵⁴ Reverse payments are essentially arrangements in which the brand manufacturer sues the generic manufacturer for patent infringement, arising from invalidity of the required Paragraph IV certification of the ANDA,⁵⁵ whether or not there actually is patent infringement.⁵⁶ These cases quickly settle with the brand-name manufacturer paying the generic manufacturer in exchange for the generic’s delay in launching its product.⁵⁷ These settlements make sense for both companies since, from the outset, the generic stands to make less profit than the brand name stands to lose from its entry.⁵⁸ As former FTC Chairman Jon Leibowitz explained in 2009:

So if it is legal for a brand to pay the generic to ‘sit it out,’ why wouldn’t it? And if the generic drug company is allowed to make more money by not competing than by going to market, isn’t that a good business deal for the company and its shareholders? Of course it is.⁵⁹

The payment from the brand name to the generic company typically accounts for the amount of money that consumers would have saved if the generic drug actually went to the market.⁶⁰ Instead, both companies share the “pool of money” that the Act actually intended to save consumers.⁶¹ In fact, reverse payment settlements actually “cost American consumers anywhere between \$0.6 billion and \$7.5 billion each year, or \$3.5 billion each year on average.”⁶²

It is likely that Mylan dipped its feet in the reverse payment pool in 2012 when they filed a patent infringement suit against Israeli pharmaceutical company Teva Pharmaceutical Industries Ltd., which sought permission from the FDA to manufacture, market, and sell a generic version of the EpiPen.⁶³ Mylan quietly announced an agreement wherein Teva would not launch a generic epinephrine auto-injector until 2015, subject to FDA

54. FED. TRADE COMM’N, PAY FOR DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 1 (2010) [hereinafter DRUG COMPANY PAY-OFFS].

55. *See* Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j)(8)(b)(i–ii) (2012).

56. *See, e.g.*, DRUG COMPANY PAY-OFFS, *supra* note 54, at 8–9.

57. *See, e.g.*, GLAZER & DESMOND-HARRIS, *supra* note 9, at 15.

58. *See* GLAZER & DESMOND-HARRIS, *supra* note 9 (noting that generic competitor drugs normally enter the market at prices between twenty and thirty percent lower than prices of brand-name counterparts. Some enter the market as much as eighty percent or more below that of a brand-name drug).

59. LEIBOWITZ, *supra* note 53, at 4.

60. *See id.*

61. GLAZER & DESMOND-HARRIS, *supra* note 9, at 15.

62. Brown, *supra* note 50, at 590 (“As such, the FTC asserts that banning these agreements outright has the potential to save consumers \$35 billion over the course of a decade.”); *see also* DRUG COMPANY PAY-OFFS, *supra* note 54, at 8–10.

63. *See Epinephrine Auto-Injector Settlement*, *supra* note 49.

approval of its ANDA.⁶⁴ After waiting three years per the terms of the settlement, Teva's launch was again delayed due to a lengthy citizen petition Mylan threw its way in 2015. Eventually, the FDA rejected Teva's ANDA in the spring of 2016.⁶⁵ Mylan quickly took advantage of this continued exclusivity period and raised the price of its EpiPen two-pack to \$609.⁶⁶

Although it has not been officially reported that Teva and Mylan engaged in a reverse payment settlement, the holes in the Hatch-Waxman allow Mylan to lawfully pay off a generic manufacturer such as Teva and implement major price increases. It is difficult to imagine Teva agreeing to refrain from market entry and giving up its spot as the only company with a generic epinephrine injector on the market without hefty consideration from the billion-dollar brand-name company. Other drug companies have also circumvented the statute by entering into these reverse payment settlements.⁶⁷ The Act, however, does not account for these reverse payments that thwart the consumer benefits of generic competition. Such failure has resulted in judicial uncertainty and Circuit splits concerning reverse payments.

In *FTC v. Actavis*, the Supreme Court ruled that brand-name and generic pharmaceutical companies are subject to antitrust scrutiny for engaging in reverse payment settlements, since these payments deter generic entry and contribute to rising health care costs that consumers and governments are struggling to keep up with.⁶⁸ The Supreme Court rejected a common defense used by pharmaceutical companies that claim to be acting within the "scope of the patent," in paying off generics to delay market entry.⁶⁹ The Court applied the "rule of reason" antitrust analysis and outlined some considerations to justify its decision to subject reverse payment settlements to antitrust scrutiny.⁷⁰ Though a somewhat successful ruling for the FTC, *Actavis* failed to fill the gaping holes in Hatch-Waxman that allow for this type of activity.

64. *Id.*

65. See, e.g., Anna Edney & Cynthia Koons, *Plastic Cap is the Crux of Mylan Argument Against Teva's EpiPen*, BLOOMBERG MKTS. (Aug. 31, 2016, 4:04 PM), <http://www.bloomberg.com/news/articles/2016-08-31/plastic-cap-is-crux-of-mylan-argument-against-competing-epipen>; see generally Mylan-Citizen Petition, *supra* note 49.

66. See, e.g., Andrew Pollack, *Mylan Raised EpiPen's Price Before the Expected Arrival of a Generic*, N.Y. TIMES, Aug. 24, 2016, at B1.

67. See, e.g., LEIBOWITZ, *supra* note 53, at 4.

68. See Remarks of Joshua D. Wright, Comm'r, Fed. Trade Comm'n, *FTC v. Actavis and the Future of Reverse Payment Cases 1, 3* (Sept. 26, 2013) [hereinafter Wright Remarks]; see also *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2227 (2013).

69. See, e.g., Wright Remarks, *supra* note 68, at 1, 3.

70. See *Actavis*, 133 S. Ct. at 2237–38; see also Kenneth R. O'Rourke, Jon Sallet & Katrina Robinson, *FTC v. Actavis: Reconciling Conflicts in Rule of Reasons*, LAW360 (July 2, 2013, 5:55 PM), <http://www.law360.com/articles/453428/ftc-v-actavis-reconciling-conflicts-in-rule-of-reason> ("The problem with the rule of reason is that it can be expensive and burdensome In rejecting the FTC's quick-look analysis, the court has hastened to add that a full-scale rule of reason analysis is not always necessary. Rather . . . the Actavis court endorsed a 'sliding scale in appraising reasonableness.'").

The latest pay-for-delay suit accused Endo Pharmaceuticals Inc. of paying Watson Pharmaceuticals Inc. to delay its launch of a generic version of the lidocaine pain patch.⁷¹ In January 2017, Endo and the FTC settled the claim that Endo violated Section 5 of the FTCA by entering into a reverse-payment settlement agreement with Watson, resolving all litigation between Endo and the FTC.⁷² Though Endo “denies that it engaged in any illegal conduct under the deal,” the settlement “prohibits the company from entering into the same type of reverse payment patent infringement settlement for [ten] years, including agreements that involve promises by branded drug makers not to market competing authorized generics.”⁷³ Although the FTC’s commitment to stopping reverse payments continues, the fact remains that reverse payments are an attractive and, if done strategically in light of these rulings, legal practice that works to favor corporations to the detriment of consumers.

In an attempt to combat the derailment of Hatch-Waxman via reverse settlements, Congress passed the Medicare Prescription Drug Improvement and Modernization Act of 2003, which required such settlements to be filed with the FTC within ten days of being agreed upon.⁷⁴ Congress sought to stop companies from quickly settling through a reverse payment without the FTC hovering over quiet payouts.⁷⁵ One brand-name company, following an industry pattern of circumventing the law, attempted to get around this requirement by lying to the FTC about the true nature of the settlement.⁷⁶

In regard to the settlement between Mylan and Teva,⁷⁷ consumers are left to foot the bill without any explanation of why this generic is not on the market. This is because there is no disclosure requirement for these patent infringement settlements. Hatch-Waxman has the foundational purpose and potential to combat this abuse of the market. These reverse payments can be outlawed and phased out as a *legal* tool for cementing a brand-name company’s position in the market.

71. See, e.g., *FTC Sues Endo Pharmaceuticals*, *supra* note 26.

72. See, e.g., Kelly Knaub, *Endo Settles Pay-For-Delay Suit As FTC Renews Watson Case*, LAW 360 (Jan. 23, 2017, 11:07 PM), <https://www.law360.com/articles/883817?scroll=1>.

73. *Id.*

74. See, e.g., GLAZER & DESMOND-HARRIS, *supra* note 9, at 16.

75. *Id.*

76. See LEIBOWITZ, *supra* note 53, at 2 (“Bristol-Meyers was the subject of an FTC order stemming from charges that, among other things, it paid a competitor to drop a patent challenge. So when it decided to settle a patent case with a company planning to sell a generic version of Plavix . . . Bristol-Meyers had a problem In an attempt to evade FTC review, Bristol-Meyers lied about a secret deal, in which it agreed to provide substantial payments to a generic competitor to stay out of the market. Both Dr. Bodner and his former employer subsequently pleaded guilty to criminal charges of making false statements.”).

77. See *Epinephrine Auto-Injector*, *supra* note 49.

B. CITIZENS' PETITIONS

The citizen petition is another tactic that brand name companies use to impede competitors' efforts to enter the market. According to the Administrative Procedure Act (APA), the FDA must provide the public with a right to petition an agency rule.⁷⁸ A citizen petition is a means through which the FDA allows the public to invoke their right to petition for the issuance, amendment, or revocation of a rule, or to petition the FTC "to take or refrain from taking any other form of administrative action."⁷⁹ The citizen petition must contain, amongst other things, the factual and legal grounds for the petition.⁸⁰ In theory, the right to petition a government agency allows for an "important route of dialogue" that provides the public "with an invaluable tool for getting good scientific arguments in front of the FDA."⁸¹ In addition, the citizen petition is intended to raise valid medical and safety issues that the FDA considers, addresses, and reports on to the filing pharmaceutical company. In practice, however, brand-name companies have been able to morph this right of the people into a clever business tactic to delay FDA approval of competing generic drugs, without facing any legal or regulatory penalty for doing so.

Brand-name pharmaceutical companies can ask the FDA to take a particular action against a pending ANDA through the use of a 505(q) citizen petition, the petition that brand names "are most likely to file to delay generic entry."⁸² The FDA is mandated to take final action on these petitions no later than 150 days after the petition's filing date, unless a delay would be necessary to protect the public health.⁸³ Though the FDA must respond to the citizen petition within 150 days, it does not have to do so before it rules on the ANDA.⁸⁴ Current FDA policy is to assess the citizen petition prior to approving the ANDA, but the FDA often waits to release the response to the citizen petition alongside releasing the ruling on the accompanying ANDA.⁸⁵ Since the FDA often responds to the citizen petition and ANDA simultaneously, it is not difficult to imagine a situation wherein an ANDA is weeks from being approved or the brand-name drug's patent is nearing expiration, and the brand name files a 505(q) petition at this time. This tactic effectively pushes back the approval of the ANDA by taking advantage of

78. See 5 U.S.C. § 553(e) (2012).

79. 21 C.F.R. §§ 10.25, 10.30 (2017).

80. See *id.* § 10.30(b)(3).

81. Scott Gottlieb, Deputy Comm'r, Med. & Sci. Affairs, Remarks Before Annual Generic Drug Forum (Apr. 7, 2006), <http://www.fda.gov/NewsEvents/Speeches/ucm051966.htm>.

82. Michael A. Carrier & Carl Minniti, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 AM. U. L. REV. 305, 327 (2016).

83. See Food and Drug Administration Safety and Innovation Act (FDASIA), Pub. L. No. 112-144, 126 Stat. 993, 1123 (2012) (codified as amended at 21 U.S.C. § 355 (2012)).

84. See, e.g., Darren S. Tucker, *FDA Citizen Petitions: A New Means of Delaying Generic Entry*, 20 ANTITRUST HEALTH CARE CHRONICLE 10 (2016).

85. *Id.*

the FDA's well-reasoned policy of thoroughly vetting the citizen petition before approving the ANDA. These petitions are known as "eleventh hour" petitions because companies would file them "on the eve of drug approval for the purpose of delay."⁸⁶

Brand-name manufacturers continue to file long and complex eleventh hour 505(q) petitions that push back the generic approval clock up to 150 days. Despite the 505(q) petition requirement that petitioners to certify that they did not delay in filing the petition, these eleventh hour petitions are extremely common in the pharmaceutical industry.⁸⁷ "Evidence that citizen petitions are used to delay generic entry can be inferred from the vast number of petitions that the FDA denies."⁸⁸ Specifically, the FDA denied 94% of citizen petitions challenging the approval of ANDAs in 2013, 95% in 2014, and 100% in 2015.⁸⁹ This tactic serves to delay the approval process of a generic drug, which the amended application process Hatch-Waxman purposely accelerated.

1. Mylan's Citizen Petition

In a 2006 press release, future Mylan CEO Heather Bresch called for an end to the abuse of citizen petitions being used by brand-name companies to delay access to affordable drugs:

The brand industry is misusing the citizen petition process to improperly delay generic competition. . . . [W]hen the process is abused, a citizen petition can become a tool for the brand industry to delay timely entry for safe and effective generic drugs.⁹⁰

Around the time this press release was written, Mylan was experiencing their own delay in generic approval because the brand-name company Ortho McNeil Pharmaceuticals filed a citizen petition against Mylan.⁹¹ Bresch expressed her distrust of frivolous citizen petitions that "give brand companies an undeserved patent extension, at no cost and with no

86. See, e.g., Michael A. Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 CARDOZO L. REV. 249, 264 (2012).

87. See Carrier & Minniti, *supra* note 82 at 328; 21 U.S.C. § 355(q)(1)(H) (2012).

88. Carrier & Minniti, *supra* note 82, at 330.

89. *Id.* at 333 (In 2013, only two of thirty-three petitions were granted; in 2014, only one of twenty-one petitions were granted; and in 2015, all thirteen petitions were denied.).

90. *Mylan Calls for an End to Abusive Practice That Delay Access to Affordable Pharmaceuticals*, MYLAN PHARMACEUTICALS, <http://newsroom.mylan.com/press-releases?item=122607> (last visited Feb. 20, 2017).

91. See *id.* ("Mylan's generic version of the drug had already been tentatively approved by the FDA, meaning the lawsuit was the only thing standing in the way of our ability to launch our product. On the eve of a decision from the district court invalidating the patent, Ortho McNeil Pharmaceuticals filed a citizen petition requesting that the FDA re-think its standards for approving generic versions on the drug. The petition raised no new information . . . and certainly appears to have been timed to delay final approval of our generic drug. Ten months later, the patent stands invalid but we are still unable to obtain final approval from the FDA.").

consequences.”⁹² Nine years later, on January 15, 2015, Mylan filed one of these “frivolous citizen petitions,” in an attempt to grant itself an “undeserved patent extension,” previously denounced by the company’s now CEO.⁹³

As previously discussed,⁹⁴ Israeli pharmaceutical company Teva settled a lawsuit with Mylan in 2012, in which “Teva agreed to delay the launch of its generic epinephrine auto-injector for more than three years, until June 2015.”⁹⁵ After waiting three years, however, Mylan submitted a 505(q) citizen petition just six months before Teva was allowed to launch, asking the FDA to reject Teva’s product.⁹⁶ Four months after the submission of this petition, and one month before the expiration of the FDA’s 150-day deadline to respond, Mylan submitted a forty-eight-page supplement to its petition, ultimately requiring the FDA to take more time to thoroughly consider whether any valid safety and health concerns existed in the 505(q) citizen petition.⁹⁷

The petition included a study, paid for by Mylan, which claimed that Teva’s product would have a 93% failure rate.⁹⁸ The study, however, had no control group and the participants did not actually manipulate the device or perform the injection.⁹⁹ Mylan, in conducting a study without a control group and without manipulating the device itself, failed to show any effort to produce a valid, scientific study concerned with addressing the safety of Teva’s medical device.¹⁰⁰ In addition, Teva had been in the process of developing its product for six years.¹⁰¹ Mylan’s failure to disclose alleged medical hazards in a reasonably timely manner prior to the release date of Teva’s product is the exact behavior Hatch-Waxman sought to prevent. This eleventh hour seventy-six-page submission was ultimately dismissed by the FDA for failure to include valid scientific results.¹⁰² The submission, however, mirrors a common pattern found by Rutgers Law Professor Michael Carrier, in that more than two thirds of citizen petitions come from brand-

92. *Id.*

93. *See generally* Mylan-Citizen Petition, *supra* note 49.

94. *See supra* Part IIA.

95. Carrier & Minniti, *supra* note 82, at 350; *Epinephrine Auto-injector Settlement*, *supra* note 49.

96. *See* Mylan-Citizen Petition, *supra* note 49.

97. *See* Michael A. Carrier & Carl J. Minniti III, *The Untold EpiPen Story: How Mylan Hiked Prices by Blocking Rivals*, 102 CORNELL L. REV. ONLINE 53, 64 (2017) (citing Supplement from Mylan Specialty, L.P., Docket No. FDA-2015-P-0181-0007 at *10 (posted May 28, 2015)).

98. *See* Chris Glorioso & Evan Stulberger, *I-Team: Company Behind EpiPen Fought to Keep Cheaper Generic Off the Market*, NBC4 N.Y. (Aug. 31, 2016, 7:17 AM), <http://www.nbcnewyork.com/news/local/EpiPen-Cheap-Generic-Teva-Product-Mylan-Investigation-Drug-Cost-391758871.html>; *see also* Mylan-Citizen Petition, *supra* note 49.

99. *See, e.g.*, Glorioso & Stulberger, *supra* note 98.

100. *See* Carrier & Minniti, *supra* note 82, at 351.

101. *Id.*

102. *See, e.g.*, Carly Helfand, *FDA Swats Down Teva’s EpiPen Copy, Putting Mylan in Cruise Control*, FIERCE PHARMA (Mar. 1, 2016, 10:39 AM), <http://www.fiercepharma.com/sales-and-marketing/fda-swats-down-teva-s-epipen-copy-putting-mylan-cruise-control>.

name companies seeking to block cheaper generics from hitting the market.¹⁰³ Carrier explained: “Every day that [brand-name companies] can delay generic entry could be millions of dollars lining its pockets Brand name companies often strategically time the filing of their citizen petitions to coordinate with patent infringement lawsuits—which also work to slow down generics seeking FDA approval.”¹⁰⁴

In theory, the longer the petition the more legitimate scientific issues it addresses; however, the petitions that are longer than average actually show a reduced likelihood of success.¹⁰⁵ In 2015, the average length of citizen petitions filed was thirty-two pages.¹⁰⁶ Mylan’s seventy-six-page total length does little to hide its classification as an eleventh hour petition. Instead, it makes clear that these “long petitions seem geared not to raising legitimate safety concerns but to bogging down the FDA and delaying generic entry.”¹⁰⁷

Though the FDA rejected Teva’s ANDA in the spring of 2016, such rejection was not a consequence of Mylan’s 505(q) petition.¹⁰⁸ The only consequence of Mylan’s petition was a further delay in the FDA’s ruling on the product. As Mylan’s own CEO previously stated, “[t]hese extensions provide anywhere from a few months to over a year of additional monopoly.”¹⁰⁹ Mylan’s involvement with competing generic drug company Teva is a prime example of how Mylan, through its probable use of reverse payments and use of the citizen petition, is able to legally and intentionally delay generic entry to the market.

There are reasonable, sound purposes for use of the citizen petition. It is not the general citizen petition that needs change, but the calculated nature of eleventh hour petitions to delay generic entry that needs attention.

C. DRUG MISCLASSIFICATION

Mylan is currently one of two brand-name companies with an available anaphylaxis product on the market,¹¹⁰ and is therefore enjoying the exclusivity for the time being.¹¹¹ However, Mylan has recently come under much public scrutiny for wrongly classifying its brand name EpiPen as a

103. See Glorioso & Stulberger, *supra* note 98.

104. *Id.*

105. See Carrier & Minniti, *supra* note 82, at 336–37 (“In 2013, when the average page length was 21, the two granted petitions were 13 and 15 pages long. And in 2014, when the average page length was 26, the only granted petition was 15 pages long.”).

106. *Id.*

107. *Id.*

108. See, e.g., Helfand, *supra* note 102 (In this rejection, regulators from the FDA flagged deficiencies with Teva’s product.).

109. Mylan Calls for an End to Abusive Practice That Delay Access to Affordable Pharmaceuticals, MYLAN PHARMACEUTICALS, <http://newsroom.mylan.com/press-releases?item=122607> (last visited Feb. 20, 2017).

110. See, e.g., Adrenaclick, AMEDRA PHARMACEUTICALS LLC, <http://adrenaclick.com/> (last visited Feb. 20, 2017).

111. See *Epipen Evaluation*, *supra* note 42.

generic drug to the Medicaid Drug Rebate Program (the Medicaid Program).¹¹² The Medicaid Program, which helps to “offset the Federal and State costs of most outpatient prescription drugs dispensed to Medicaid patients,” requires drug companies to enter into a rebate agreement with the Secretary of the Department of Health and Human Services.¹¹³ If a drug manufacturer hopes to be covered under Medicaid, this agreement requires that the drug manufacturer submit product and pricing data to the Centers for Medicare and Medicaid Services (CMS), and requires the manufacturer to pay a quarterly rebate to states for the drug payments they make under state plans.¹¹⁴ These payments are then shared between states and the federal government “to offset the overall cost of prescription drugs under the Medicaid Program.”¹¹⁵ The amount of rebate the manufacturer is required to pay is based on statutory formulas and determined by the data the manufacturer provides.¹¹⁶

According to the Administrator of CMS, “innovator drugs,” or brand-name products, pay a rebate of 23% under the Medicaid Program, and “non-innovator drugs,” or generic products, pay a 13% rebate.¹¹⁷ Despite having reaped the exclusive financial benefits of its brand-name EpiPen monopolizing the market, Mylan misclassified the drug to the Medicaid Drug Rebate Program as “generic” from 1997 to 2016, and has saved millions of dollars each year by paying half the quarterly required rebate amount.¹¹⁸

Though this activity has not directly prevented generics from reaching the market, it works to conceal information from government entities and the general public that the market lacks a generic epinephrine injector. The Medicaid Drug Rebate Program, under the impression that there was a generic version available to consumers, failed to expose Mylan for its purposeful monopolization of the market for almost twenty years. In addition, the misclassification of the drug actually cost consumers and state governments millions of dollars.¹¹⁹ Since “states and the federal government

112. See generally *EpiPen Makers Overcharged Medicaid*, *supra* note 49.

113. *Medicaid Drug Rebate Program*, MEDICAID.GOV, <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html> (last visited Mar. 11, 2017).

114. See *id.*

115. *Id.*

116. See *id.*

117. *EpiPen Makers Overcharged Medicaid*, *supra* note 49.

118. See *id.*; see also *Medicaid Drug Rebate Program*, MEDICAID.GOV, <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html> (last visited Mar. 11, 2017).

119. See Ed Silverman, *Fed Slams Mylan for Misclassifying EpiPen, with “Financial Consequences” to Medicaid*, STAT (Sept. 29, 2016), <https://www.statnews.com/pharmalot/2016/09/29/cms-slams-mylan-epipen-medicaid/> (“Minnesota officials believe the misclassification may have cost the state about \$4 million. ‘If this is true and indicative of the relative costs at other states, we believe the misclassification could be sizable for Mylan, as Minnesota represents less than 2 percent of the US population,’ Wells Fargo analyst David Maris wrote in an investor note Thursday.”).

use the rebates from drug makers to offset the cost of covering medicines,” Mylan’s misclassification became the taxpayers’ issue.¹²⁰

Not only has this misclassification kept government entities in the dark about the true nature of the epinephrine market, but it has also kept other manufacturers in the dark as well. Potential competitors are dis-incentivized from producing a generic product when research indicates that Mylan’s EpiPen allegedly already has both the brand name and generic market covered. This “no room for other” mentality propagated by Mylan, and perhaps other brand-name drug manufacturers as well, indirectly furthers Mylan’s monopoly power.

D. PRODUCT HOPPING

Another hole in Hatch-Waxman has allowed companies to engage in “forced-switch schemes,” or “product hopping.”¹²¹ The forced-switch scheme is a strategy used by pharmaceutical companies in which a brand-name company has an NDA drug on the market, but whose patent exclusivity period is almost expired, allowing for a generic version to soon enter and compete.¹²² Instead of using a reverse-payment strategy or filing citizen petitions against the generic company, brand-name companies have completely withdrawn their own drugs from the market and quickly introduced their own generic versions as a substitute.¹²³ Although another generic may come to the market after the forced-switch scheme, the court in *Actavis*, for example, found it unlikely that a patient with Alzheimer’s disease would choose to switch to the competitor’s generic after being forced to already switch to the brand-name company’s generic version.¹²⁴ This pattern of behavior may be mimicked when it concerns a drug that is in high demand, such as the EpiPen. This scheme essentially coerces patients to switch from the company’s brand-name product to the same company’s generic product, all the while maintaining their effective monopoly in the drug market.¹²⁵

This strategy grew in popularity until the Second Circuit became the first appellate court to finally address “product hopping” in *Actavis*.¹²⁶ The Second Circuit held that a scheme to *coerce* patients to switch from an old product to a new one, by withdrawing from the market with an intent to affect generic competition, violated antitrust laws.¹²⁷ The court indicated, though,

120. *Id.*

121. *New York v. Actavis*, 787 F.3d 638, 643 (2d Cir. 2015).

122. *See, e.g., Jonathan Lapook, Forced Switch? Drug Cos. Develop Maneuvers to Hinder Generic Competition*, CBS NEWS (Aug. 28, 2014, 8:40 PM), <http://www.cbsnews.com/news/drug-companies-develop-maneuvers-to-hinder-generic-competition/>.

123. *See Actavis*, 787 F.3d at 642.

124. *Id.* at 642–43.

125. *Id.* at 654.

126. *Id.* at 643.

127. *See id.* at 652–654.

that efforts to *persuade* patients to make the switch, while keeping the old product available, would be permissible.¹²⁸

As a result of public scrutiny of Mylan for the rising price of the EpiPen, the company announced it would release its own generic version of the EpiPen for half the price.¹²⁹ If Mylan were to do so, the removal of the brand-name EpiPen from the market immediately followed by the introduction of the generic version would be prohibited, as per the Second Circuit decision.¹³⁰ This forced “hard switch” would be the exact mechanism used to maintain the relevant market monopoly that the *Actavis* court wished to prevent.¹³¹ By contrast, the introduction of its own generic while keeping the brand name EpiPen on the market, also known as the “soft switch” is permissible.¹³²

Although the Second Circuit’s reliance on antitrust laws worked to outlaw this strategy, it was a result of gaping holes in the Hatch-Waxman Act that allowed Actavis to create a monopoly of its relevant market in the first place.¹³³ The Act has been ineffective at proactively combating these strategies because the Act does not itself forbid these tactics. Mylan and other companies are not technically violating the Act, but reap the benefits for years until the strategies are challenged in court.¹³⁴ Thus, without strict amendments to the Act that would work to further protect both generic applicants and approved generics, Mylan and other brand-name companies will continue to game the patent system to protect their monopolies. In addition, since these practices are prohibited by judicial precedent¹³⁵ and not by a legislative enactment, there is no telling if or when a court may decide to overturn such a ruling.

III. EFFECT ON CONSUMERS

A. INSURED CONSUMERS

Consumers’ interaction and involvement with Hatch-Waxman is limited, in that consumers are only aware of the enormous out-of-pocket price they are forced to pay every year for the two-pack of EpiPens. There is one area of the market with abundant price competition wherein consumers actually

128. *See id.* at 654.

129. *See Mylan to Launch First Generic to EpiPen Auto Injector at a List Price of \$300 per Two-Pack Carton, a More than 50% Discount to the Brand Product*, MYLAN INC. (Aug. 29, 2016) [hereinafter *First Generic*], <http://newsroom.mylan.com/2016-08-29-Mylan-to-Launch-First-Generic-to-EpiPen-Auto-Injector-at-a-List-Price-of-300-per-Two-Pack-Carton-a-More-than-50-Discount-to-the-Brand-Product>.

130. *See Actavis*, 787 F.3d at 651.

131. *Id.* at 661.

132. *Id.* at 654.

133. *Id.* at 649.

134. *Id.*

135. *See id.* at 659.

reap the benefits of consistent EpiPen prices.¹³⁶ This area consists of giant companies, known as pharmacy benefit managers (PBMs), which manage the drugs patients need and pit drug companies against each other to lower prices.¹³⁷ PBMs also offer these drugs at discounted prices.¹³⁸ For example, PBMs have fought for discounts and rebates on the EpiPen by playing competitors off each other, excluding certain companies like Auvi-Q from its list of preferred drugs, and holding the cost steady for certain insured consumers.¹³⁹ In fact, the co-payments for commercially insured consumers rose only forty-five cents from 2015 to 2016, even though the price of the EpiPen 2-pak rose by 51%.¹⁴⁰

The problem today, however, is that not all consumers have the luxury of just a co-pay on their prescriptions, as many are also faced with high-deductibles as a result of certain employer provided health insurance plans and the Patient Protection and Affordable Care Act.¹⁴¹ Those with high out of pocket costs and high deductibles still have to pay \$300 for a set of two.¹⁴² For these consumers, the discounts PBMs are fighting for are not particularly helpful, until they hit the high deductible.

B. MYLAN'S EPIPEN SAVINGS CARD

Mylan has attempted to soften the hefty bill its consumers face by offering the "My EpiPen Savings Card," which can allegedly be used to reduce the amount of out-of-pocket expenses up to a maximum of \$300 per EpiPen 2-Pak.¹⁴³ However, not everyone is eligible for these discounts. It is clear, from the eligibility requirements, that those who will benefit the most from these coupons are those who are commercially insured. Those with state or federally funded plans through a government employer, or those enrolled in Medicare, Medicaid, TriCare, or other military plans are ineligible for the co-pay discount.¹⁴⁴ One might wonder why Mylan did not just list those whom the coupons are valid for, considering the list of those eligible is much shorter.

136. See, e.g., Matthew Herper, *The Insurance Rip-Off at the Heart of the EpiPen Scandal*, FORBES (Aug. 30, 2016, 8:43 AM), <http://www.forbes.com/sites/matthewherper/2016/08/30/the-consumer-rip-off-at-the-heart-of-the-epipen-scandal/2/#5115d8a77187> (Express Scripts and CVS Caremark have market capitalizations of \$46 billion and \$99 billion respectively.).

137. *Id.*

138. *Id.*

139. *Id.*

140. *See id.*

141. *See, e.g., id.*

142. *See, e.g., Reality Checking Mylan CEO's Testimony on EpiPen Prices*, PUBLIC CITIZEN (Sept. 21, 2016), <http://www.citizen.org/documents/public-citizen-reality-check-on-mylan-2016.pdf> ("A problem made worse by the facts that many families purchase multiple sets of EpiPens and that EpiPens must be replaced every year.").

143. *See My EpiPen Savings Card Terms and Conditions*, EPIPEN, <https://www.epipen.com/copay-offer/> (last visited Feb. 20, 2017).

144. *Id.*

Mylan's CEO, testifying before the U.S. House Committee on Oversight and Government Reform, explained Mylan's efforts to help consumers with the use of these coupons: "We increased our My EpiPen Savings Card program benefit for the brand product from \$100 to \$300 . . . we doubled the eligibility of patients receiving free pens from \$48,600 to \$97,200 for a family of four."¹⁴⁵ Still, when attempting to use these coupons, a large percentage of Americans will face one of three problems. First, Mylan has explicitly excluded patients with certain health plans from participating in its savings card program. Second, the release of these coupons "trigger[s] insurance companies to raise prices on consumers in other ways—for example, in the form of higher premiums for everyone covered by the plan."¹⁴⁶ Third, Mylan's coupon program may only be temporary, as Mylan planned to re-evaluate the program as of December 31, 2016.¹⁴⁷ Thus, Mylan may discontinue these benefits even for those who have private health insurance and reaped the benefits of the coupon in 2016.

In sum, consumers are exposed to the high prices of the EpiPen product even though Mylan has attempted to provide rebates to third-party plans to make up for the lack of a cheaper, generic option.¹⁴⁸ Mylan's My Savings Card coupons are only a "short-term answer" to its rising drug price.¹⁴⁹

C. FED UP CONSUMERS

On August 23, 2016, a group of consumers who purchased the two-pack of EpiPens for \$600 filed a class action suit in the U.S. District Court for the Eastern District of Michigan, because Mylan discontinued selling the product individually.¹⁵⁰ The complaint claims that the company violated multiple state unfair trade practices and consumer protection statutes by forcing people to buy the two-pack at \$600 and not providing the opportunity to buy just one.¹⁵¹ The plaintiffs also claim that Mylan used deceptive and/or misleading representations, unconscionable commercial practices, deception, and false pretenses regarding the purchase of the two-pack—which prevented

145. *Reviewing the Price of EpiPens Hearing Before the United States H. of Rep. Comm. on Oversight & Government Reform* (2016) (testimony of Heather Bresch, CEO of Mylan Pharmaceuticals), <https://oversight.house.gov/wp-content/uploads/2016/09/2016-09-21-Mylan-CEO-Bresch-Testimony.pdf>.

146. Ginger Skinner, *EpiPen Coupons Might Save You Money, If Your Insurance Accepts Them*, CONSUMER REPORTS (Sept. 2, 2016), <http://www.consumerreports.org/drugs/epipen-coupons-might-save-you-money-if-your-insurance-accepts-them/>.

147. *See, e.g., id.*

148. *See, e.g., Herper, supra* note 136.

149. *See Skinner, supra* note 146.

150. *See, e.g., Ike Swetlitz, Mylan Faces Two Potential Class Action Lawsuits Over EpiPen Pricing*, STAT (Sept. 6, 2016), <https://www.statnews.com/2016/09/06/epipen-mylan-lawsuits/>; Class Action Complaint and Demand for Jury Trial at 9, *Johnson, et. Al. v. Mylan Specialty L.P. and Mylan Pharmaceuticals Inc.*, 2-16-cv-13060-NGE-SDD (Aug. 23, 2016).

151. *See Class Action Complaint and Demand for Jury Trial at 14–15, Johnson, et. Al. v. Mylan Specialty L.P. and Mylan Pharmaceuticals Inc.*, 2-16-cv-13060-NGE-SDD (Aug. 23, 2016).

patients and purchasers from being fully informed on the necessity, or lack thereof, of purchasing two EpiPens.¹⁵²

Another lawsuit was filed against the company in September of 2016 by a Cincinnati resident, Linda Bates, in the Court of Common Pleas for Hamilton County, Ohio.¹⁵³ Bates claims that the company's unconscionable price hikes violate the state's consumer protection law.¹⁵⁴

IV. POTENTIAL SOLUTIONS TO THE HATCH-WAXMAN PROBLEM

Legal precedent, class action lawsuits, and hefty settlements are effective in bringing the weakness of the Act to light, but in order to prevent drug manufacturers from continuing to monopolize the drug market, the Act must be amended. New legislative committees are required to oversee the enormous price hikes, and disingenuous tactics used by both brand-name and generic manufacturers should be cautiously approached, if not forbidden. The true purpose behind the Act is to benefit consumers, not pharmaceutical drug companies. Though the Act looks to benefit consumers by streamlining the generic drug application process, it nevertheless is and has always been about providing consumers with safe and affordable health care options.

A. CREATION OF AN OVERSIGHT COMMITTEE

The creation of a federal oversight committee empowered to specifically oversee drug price increases every year after an NDA is approved for the market could work to combat inflated pharmaceutical prices. This committee may set a cap on specific price hikes per year according to consumer needs, Medicaid coverage, insurance costs, and the number of competing products on the market. For example, if a situation arises, such as the one Mylan is in currently, wherein there is the only one company with a brand-name and generic product on the market, such committee may have prevented the price hike, by limiting Mylan's price increases over a yearly determined cap.¹⁵⁵

The creation of such committee should be done within the confines of the FDA's regulation and rulemaking procedures,¹⁵⁶ but would be most efficient if contracted out to independent economic experts, drug innovators, and medical experts working together to determine consumer need and product availability within the pharmaceutical industry. This solution, however, has one major flaw. Though the committee would work to lower the cost of drugs, the costs of creating such committee, hiring experts, and

152. *See id.* at 15.

153. *See, e.g.,* Swetlitz, *supra* note 150.

154. *See, e.g., id.*

155. *See, e.g.,* Pollack, *supra* note 66.

156. Such as under the Administrative Procedure Act, 5 U.S.C. § 553 (2012).

paying the salaries of committee members, would likely offset any savings gained as a result of the lowering of drug prices.

An alternative, and perhaps a more cost-effective option for consumers, would be if drug companies were required to set up their own independent committees, in lieu of a government-run committee. Such a committee's main tasks within the company would be to study market fluctuations, gauge the company's price increases, and ensure that the company is in line with the federal drug pricing oversight committee, if one were created. The board of directors would select the committee members, and give the committee specific quarterly tasks and proper procedures to fulfill such tasks.¹⁵⁷ The determinations and recommendations made by these committees may be subject to the business judgment rule (varying by state),¹⁵⁸ similar to that of special litigation committees, which are set up by corporations in an attempt to provide the company and its shareholders with a disinterested, independent opinion on business decisions.¹⁵⁹ This committee would work to sidestep the consumer cost of creating a federal oversight committee and instead force the companies to provide the public with accurate, up-to-date, and understandable information about the prices of their drugs.

Corporate directors and officers owe fiduciary duties to their shareholders, specifically the duty of loyalty and duty of care.¹⁶⁰ Directors are liable for acting contrary to these fiduciary duties and can be subject to a derivative or direct suit brought by the company's shareholders.¹⁶¹ Of course, private entities, unlike the government, were not created by the people and for the people and, in turn, owe little to the public. But pharmaceutical companies, whose main purpose is to provide the public with effective and affordable drugs, should be held accountable, as a matter of public policy, when this purpose is actually a smokescreen for corporate greed.

Though these fiduciary duties serve to protect the corporation's interests, there is little incentive for corporations to protect consumers' interests. To force companies to take consumer needs and interests into account, in addition to their own corporate interests, the proposed mandated internal oversight committee's duties should not be to the shareholders, but rather to pharmaceutical drug consumers, specifically in the form of a duty of loyalty. The members of the committee could be found liable for violating the newly crafted FDA regulations on drug prices, acting in bad faith, or acting in breach of their duty of loyalty to consumers. In theory, the creation of this private right of action, similar to that of a derivative or direct suit, could be

157. See MELVIN EISENBERG & JAMES COX, BUSINESS ORGANIZATIONS: CASES AND MATERIALS 232 (2014).

158. See generally Mary A. Lopatto, *Hasan v. CleveTrust Realty Investors: The Business Judgement Rule and Procedural Review of the Special Litigation Committee*, 34 CATHOLIC UNIV. L. REV. 791 (1985).

159. See, e.g., EISENBERG & COX, *supra* note 157, at 232.

160. See *id.* at 603–713.

161. *Id.*

invoked if it were found that the corporation unduly influenced the committee or acted in a self-interested way that hurt consumers.

An additional advantage of an internal oversight committee within pharmaceutical drug companies, over a government regulatory system, is that consumers would not bear these costs. Instead, companies would bear the burden of proving their prices are reasonable, affordable, and legal, in light of relevant economic factors, guidelines by the federal oversight committee, and amendments to the Hatch-Waxman. Although this suggestion proposes strict regulation of an enormous, free-market industry, the pharmaceutical industry is in need of some limits on a company's ability to manipulate the market and continue to reap billions each year through rapid price increases of their products without affording the consumers an alternative. If the United States does not begin, or even attempt, to regulate drug pricing, consumers will continue to foot the bill for any drugs that are in high demand.

B. AMENDING GENERIC EXCLUSIVITY PERIOD

The 180-day exclusivity period under Hatch-Waxman aids generic "first fliers" in increasing profitability for a period of time.¹⁶² However, this exclusivity period is not actually entirely exclusive. It does not exclude the brand-name company's generic drug from also being on the market during the 180 days.¹⁶³ Although the Act's "primary purpose was to decrease the high cost of prescription drugs by increasing the availability of cheaper generic versions while still encouraging new drug development," this gap in the Act undermines that purpose.¹⁶⁴ This loophole adds another tool to the brand name companies' arsenal and creates a further hurdle for generics to jump through.

The Act's 180-day exclusivity period should be amended to exclude the brand-name company from filing a generic ANDA or getting approval for a previously filed ANDA during that time.¹⁶⁵ Essentially, once the first flier is approved, *all* other applications should be frozen in time for 180 days. Mylan, which announced the launch of a generic EpiPen,¹⁶⁶ is legally taking advantage of this loophole and planning to bring in the profits from both the brand-name EpiPen and the generic version, while the "only competing device, Adrenaclick, has sold poorly. . . and many are unfamiliar with the way Adrenaclick works."¹⁶⁷ This period should be exclusive of *all* generic competition. In doing so, the market would not be dominated by the same

162. See, e.g., Henry Grabowski, Genia Long & Richard Mortimer, *Recent Trends in Brand-Name and Generic Drug Competition*, 17 J. MED. ECON. 2 (2013).

163. See, e.g., *FTC Sues Endo Pharmaceuticals*, *supra* note 26; Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) (2012).

164. Brian Urevig, *Hatch Waxman- Thoughtful Planning or Just Piling On: A Consideration of the Federal Trade Commission's Proposed Changes*, 4 MINN. INTELL. PROP. REV. 386, 391 (2003).

165. See 21 U.S.C. § 355(j).

166. See *First Generic*, *supra* note 129.

167. Silverman, *supra* note 48.

price-controlling company, but rather would allow the approved generic drug true exclusivity for 180 days.

C. REVERSE PAYMENT PENALTY

In 2006, the FTC stated that, “[n]o matter what you call them, eliminating these [reverse payment] deals is one of the Federal Trade Commission’s highest priorities.”¹⁶⁸ Aside from judicial holdings, however, no law has been implemented or amended to outlaw these practices since the FTC made those statements more than ten years ago. Since the “scope of the patent” test was rejected in *Actavis*,¹⁶⁹ there is no longer a concern that outlawing these settlements would infringe on a patent holder’s right to protect its patent.

With specific regard to agreements such as Mylan and Teva’s settlement in 2012, the Hatch-Waxman should be amended to require disclosure of certain information.¹⁷⁰ Though the agreements may contain confidential information for both parties and the FTC is required to review such agreements,¹⁷¹ information that is not pertinent to the companies’ businesses should be disclosed. Such information should include the terms of the agreement, the settlement amount, and the length of time, if any, the generic company agrees to delay the launch of its product. If such information is challenged as confidential, the FDA should be required to publish a press release informing the public of the reasons for the settlement and the current status of other pending drug applications with regard to the drug at issue. The purpose behind this proposed disclosure rule is not to gain access to pharmaceutical companies’ private records and business information, but rather to have access to closed-door settlement information that works to deprive consumers of cheaper drugs. The FDA, along with the FTC, should be required to disclose detailed information, as permissible, regarding such settlements to the public.

The Act should be amended to penalize reverse payments and disincentivize any interference with the application process of a generic product or the implementation of the 180-day exclusivity period for a generic product.

D. NEW REQUIREMENT FOR 505(Q) CITIZEN PETITIONS

Mylan’s submission of an eleventh hour citizen petition seems highly suspect since it was potentially in competition with Teva at the time.¹⁷² However, if pharmaceutical companies were prevented from submitting their own medical studies to the FDA while the FDA is in the process of approving or rejecting products, it would place a heavy burden on the FDA to actually

168. LEIBOWITZ, *supra* note 53, at 1.

169. Fed. Trade Comm’n. v. *Actavis, Inc.*, et. al., 133 S. Ct. 2223 (2013).

170. See *Epinephrine Auto-Injector Settlement*, *supra* note 49.

171. See 42 U.S.C. § 1396r-8(b)(3)(D) (2012).

172. See generally *Mylan-Citizen Petition*, *supra* note 49.

conduct these studies themselves.¹⁷³ In addition, the APA requires that the public, including competing pharmaceutical companies, be granted the opportunity to bring legitimate concerns about a drug before the FDA.¹⁷⁴ However, allowing a singular company to test and reject a drug is essentially granting them the powers that Congress has delegated to the FDA. Statistical information shows that these petitions are rarely, if ever, actually granted by the FDA.¹⁷⁵ Instead, it simply delays the FDA's process of reviewing a drug by forcing the FDA to review and reject a likely invalid and scientifically flawed 505(q) citizen petition, before it approves or rejects a competing generic's ANDA.¹⁷⁶

To prevent the submission of 505(q) citizen petitions for the sole purpose of delaying the FDA's review process, the petitioning brand-name company should be required to send the citizen petition to the generic company that filed the ANDA *before* submission to the FDA, and notify the FDA of the date on which this petition process was initiated. Generic companies then have the opportunity to reply to the petition and/or conduct an alternate study to invalidate the petition, which would then be sent back to the brand-name company. The supplemented 505(q) citizen petition would then be sent to the FDA. Though on its face, this presents the FDA with more paperwork to review, forcing both companies to produce a more thorough, scientific analysis can prevent the filing of eleventh hour petitions and provide the FDA with more comprehensive information with which to evaluate the NDA.

To avoid abuse of this pre-petition rule and prevent companies from forcing discussion to delay implementation, the Act should limit these petitions to 20-pages and implement temporal limits within which to review and respond to the citizen petition. Since the FDA would no longer be the first entity to probe the lengthy document (for under the new rule, both companies would have reviewed and responded to the petition prior to the FDA assessing it) the FDA's role during the pre-petition process would be to monitor such activity and ensure that the petition is filed in accordance with the page and temporal restrictions.

Lastly, the filing of bad faith eleventh hour petitions should be penalized. In 2015, the FDA denied 100% of 505(q) citizen petitions filed within six months of the expiration of brand-name patents.¹⁷⁷ If the vast majority of eleventh hour citizen petitions are being dismissed for lack of validity and credibility,¹⁷⁸ then why are these petitioners not penalized for their bad faith filing? Hatch-Waxman should completely outlaw any attempt by a

173. See, e.g., Sydney Lupkin, *FDA Fees on Industry Haven't Fixed Delays In Generic Drug Approvals*, NPR (Sep. 1, 2016, 2:04 PM), <http://www.npr.org/sections/health-shots/2016/09/01/492235796/fda-fees-on-industry-havent-fixed-delays-in-generic-drug-approvals>.

174. See 5 U.S.C. § 553(e).

175. See Carrier & Minniti, *supra* note 82, at 336.

176. *Id.* at 351.

177. See *id.* at 333.

178. *Id.* at 341.

competing company to purposely delay the FDA's ANDA review process. In turn, the Act should grant a private right of action to any company that was hindered or harmed by a bad faith petition, in addition to granting the FDA the discretion to prosecute as it sees fit.

E. CLASSIFICATION OF DRUGS

The importance of valid drug classification is now apparent to Mylan, after its recent \$465 million settlement for misclassifying the EpiPen as a generic drug to the Medicaid Program.¹⁷⁹ The Hatch-Waxman Act, intended to get more generic drugs to the market at a faster rate, can prevent this misclassification by requiring the FDA to notify the Medicaid Program and other government entities involved in the food and drug industry of the proper classification of drugs. The opportunity to "misclassify" seemed too appealing to Mylan and will continue to allow companies to dupe government entities throughout the country.

CONCLUSION

There should be no room for drug companies to mislead the government, other pharmaceutical manufacturers, or consumers, for, as we have seen, drug companies will soon find new, creative, and legal strategy to cement their monopolization over the relevant market. Some pharmaceutical companies, such as Mylan, have been able to dominate their market and increase the price of their product, all within the confines of the Hatch-Waxman Act. To tighten its hold on the market, Mylan has filed eleventh hour citizen petitions with the FDA, engaged in pay-for-delay settlements with generic manufacturers, and misclassified its drug to the Medicaid Program. Other drug manufacturers have also engaged in product hopping, which essentially coerces patients to continue to use the brand-name company's products. Without any oversight, these practices will continue to deny consumers affordable options for medication.

This Note calls for amendments to the Hatch-Waxman Act, such as mandatory reverse payment settlement disclosures, a well-regulated citizen petition process, and the handing over of drug classification responsibilities from drug companies to the FDA. These proposed amendments are fully within the spirit of what the Act was truly meant to do: provide consumers with greater consumer access to low-cost, quality medication.

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179. See, e.g., Jared S. Hopkins, *Mylan Settlement with DOJ, Not Enough*, BLOOMBERG (Oct. 19, 2016, 4:40 PM), <https://www.bloomberg.com/news/articles/2016-10-19/blumenthal-says-mylan-s-settlement-with-doj-a-sweetheart-deal>.

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