

EXCESSIVE PRICING OF OFF-PATENT PHARMACEUTICALS: HATCH IT OR RATCHET?

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There is growing concern over the pharmaceutical industry's ability to set and raise drug prices as it sees fit. The price of a drug that has not been protected by a patent for decades can suddenly increase—or “ratchet”—as much as 10,000%. This Note identifies the problem of ratcheting drug prices and considers whether these abrupt changes in drug prices derive from a longstanding problem inherent in the United States' pharmaceutical regulatory regime. It then considers the most commonly suggested mechanism for countering high drug prices—stimulating competition in the pharmaceutical market—but ultimately concludes that focusing solely on increasing competition constructs an overly simplistic view of ratcheting drug prices. In order to find an effective solution to unexpected increases in drug prices, this Note evaluates a small subset of pharmaceuticals that have recently undergone a sudden price increase and separates the ratcheting events into two categories: (1) those that occur as a result of natural deviations in the market, and (2) those that occur due to business tactics that take advantage of vulnerabilities in the drug market. It concludes that under this categorization, antitrust law may provide an effective solution specifically directed at ratcheting events of the second category—those driven by anticompetitive behavior.

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INTRODUCTION

Imagine the following scenario: Your loved one suffers from an illness, but luckily can take a drug daily for effective treatment. The drug she takes is the only drug on the market with such curative effects and is by far the best treatment for her specific disease. Now imagine that the pharmaceutical company that produces this drug announces that it has suddenly increased the price by more than fifty times. Because the United States does not regulate drug prices with caps or controls and there is little leverage for consumers to stop buying the products, there is nothing stopping the companies from increasing the price. The only choice your loved one has is to pay the high drug prices.

Thousands of people in the United States taking Daraprim, a brand-name drug that treats the parasitic infection toxoplasmosis, found themselves in this exact situation in late September 2015.¹ In August 2015, Turing Pharmaceuticals (Turing) purchased the rights to Daraprim, which were sixty-two years old and no longer protected by patent, and soon thereafter raised—or “ratcheted”—the price from

¹ See Andrew Pollack, *Drug Goes From \$13.50 a Tablet to \$750, Overnight*, N.Y. TIMES (Sept. 21, 2015), <http://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html> (reporting Turing Pharmaceuticals’s price increase of Daraprim).

\$13.50 per tablet to \$750.² This overnight price hike gained Turing much notoriety.³ Raising the price of this drug may be the result of a new business strategy: acquire old and neglected drugs, often for rare diseases, and turn them into costly “specialty” drugs. Daraprim’s price hike is not an isolated instance; other drugs’ prices have similarly increased.⁴

To introduce a generic competitor to counteract price-ratcheting behavior, a company must develop an identical copy of the drug that satisfies federal testing requirements before the generic drug can enter the market. Currently, developing a generic drug involves analytical testing and modest pharmacokinetic testing to prove bioequivalence to an innovator drug.⁵ Developing a market-ready generic also requires substantial time and money.⁶ The long waiting period and

² *Id.*

³ See, e.g., Sarah Kliff, *Martin Shkreli Raised His Drug’s Price 5,500 Percent Because, in America, He Can*, VOX (Dec. 17, 2015, 12:26 PM), <http://www.vox.com/2015/9/22/9366721/daraprim-price-shkreli-turing>; Nadia Kounang & Azadeh Ansari, “*Outrageous Pill Prices Are Big Business as Usual*,” CNN (Sept. 23, 2015, 8:08 AM), <http://www.cnn.com/2015/09/23/health/pill-prices-are-big-business-as-usual/>; Laura Lorenzetti, *This 62-year-old Drug Just Got 5,000% More Expensive*, FORTUNE (Sept. 21, 2015, 2:24 PM), <http://fortune.com/2015/09/21/turing-pharmaceuticals-drug-prices-daraprim/>.

⁴ See HOUSE COMM. ON OVERSIGHT & GOV’T REFORM, RANKING MEMBER CUMMINGS AND CHAIRMAN SANDERS INVESTIGATE STAGGERING PRICE INCREASES FOR GENERIC DRUGS (2014), <https://democrats-oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/Table%20on%20Generic%20Drug%20Price%20Increases%20FINAL.pdf> (listing ten generic drugs with significant price increases from 2013 to 2014); Richard Blackwell, *Drugs Targeted in Valeant Pricing Controversy Acquired in February*, GLOBE & MAIL (Sept. 29, 2015), <http://www.theglobeandmail.com/report-on-business/drugs-targeted-in-valeant-pricing-controversy-acquired-in-february/article26590603/> (noting a pharmaceutical company’s purchase of two drugs and immediate “jack[] up” of their respective prices); see also Krishnadev Calamur, *What Mylan’s CEO Will Tell Congress About the Price of EpiPen*, ATLANTIC (Sept. 21, 2016), <http://www.theatlantic.com/liveblogs/2016/09/mylan-ceo-congressional-testimony/500924/> (describing the rising price of EpiPen in recent years). For an in-depth discussion of specific drugs that have been subject to dramatic price increases, see *infra* Section III.A.

⁵ In order to enter the market, a generic company must prove to the Food and Drug Administration (FDA) through pharmacokinetic testing, which studies the time course of drug absorption, distribution, metabolism, and excretion, that the drug is “bioequivalent,” or chemically equivalent to an innovator drug, which was initially marketed as a new chemical entity and already received FDA approval. See Mark J. Ratain & William K. Plunkett, Jr., *Pharmacology*, in 1 HOLLAND-FREI CANCER MEDICINE 695, 698–701 (Donald W. Kufe et al. eds., 6th ed. 2003) (explaining in depth the basic principles of pharmacokinetic testing); *infra* note 38 (describing standards for bioequivalence testing).

⁶ The Federal Trade Commission (FTC) calculated in 2011 that the cost of preparing a generic drug for Paragraph IV certification (which claims that the listed patents are either invalid or not infringed) ranges from approximately \$2 million to \$6 million. FED. TRADE COMM’N, AUTHORIZED GENERIC DRUGS: SHORT-TERM EFFECTS AND LONG-TERM IMPACT 111 (2011); see also Erwin A. Blackstone & Joseph P. Fuhr, Jr., *The Economics of Biosimilars*, 6 AM. HEALTH & DRUG BENEFITS 469, 470–71 (2013) (noting that the investment needed to develop and market a biosimilar would be more expensive than the

high costs for generic drug approval pose a serious deterrent to generic competition—given the cost and time to get a generic to market, the marginal likelihood of return on investment is not promising. For example, approximately 2000 people take Daraprim each year.⁷ The treatment course involves a single dosage for up to eight weeks.⁸ Thus, a maximum of 112,000 doses of Daraprim are needed each year. If it could cost as much as \$6 million to get a generic product to market,⁹ a generic substitute to a brand-name drug like Daraprim could need to retail at approximately \$55 per pill—nearly four times more than Daraprim’s cost prior to the hike—just for the competitor company to break even.¹⁰ Exacerbating the issue, the

\$1 million to \$4 million required in the generic market). Note that this range is assumed representative of most Abbreviated New Drug Application (ANDA) filings; generic companies typically certify by Paragraph IV since it is seen as the most financially beneficial to the company. See Michael S. Montgomery, Note, *Generics and Biosimilars: Mapping the Biosimilars Regulatory Approval Pathway Against the Hatch-Waxman Act and Projecting Future Effects on the Biologics Market and Patent Protection*, 75 U. PITT. L. REV. 387, 391 (“Of the four certifications, Paragraph IV certifications are the most common.”); see also ORAL CONTROLLED RELEASE FORMULATION DESIGN AND DRUG DELIVERY: THEORY TO PRACTICE 322 (Hong Wen & Kinam Park eds., John Wiley & Sons, Inc. 2010) (describing the benefits of Paragraph IV certification).

⁷ Robert Langreth & Drew Armstrong, *Clinton’s Tweet on High Drug Prices Sends Biotech Stocks Down*, BLOOMBERG (Sept. 21, 2015, 12:31 PM), <http://www.bloomberg.com/news/articles/2015-09-21/clinton-s-tweet-on-high-drug-prices-sends-biotech-stocks-down>. Note that these 2000 patients are most likely immune-compromised persons with toxoplasmosis, not acute malaria, which Daraprim also treats, as there are better treatments for malaria. See *Daraprim*, DRUGS.COM, <https://www.drugs.com/pro/daraprim.html> (last visited Aug. 30, 2017) (indicating that Daraprim is mostly used for the treatment of toxoplasmosis, and while sometimes prescribed for acute malaria and chemoprophylaxis of malaria, Daraprim is often not the preferred method of treatment for those ailments).

⁸ *FDA Package Inserts for Daraprim (Pyrimethamine)*, IODINE, <http://www.iodine.com/drug/daraprim/fda-package-insert> (last visited June 25, 2017) (“The adult starting dose is 50 to 75 mg of the drug daily . . . This dosage is ordinarily continued for 1 to 3 weeks . . . The dosage may then be reduced to about one half . . . for an additional 4 to 5 weeks.”).

⁹ See *supra* note 6 (describing the cost to bring a generic to market); see also FED. TRADE COMM’N, EMERGING HEALTH CARE ISSUES: FOLLOW-ON BIOLOGIC DRUG COMPETITION 14 (2009) [hereinafter FTC 2009 REPORT] (estimating that “small-molecule generic drugs product development costs range from approximately \$1 to \$5 million”); cf. Sumner La Croix & Ming Liu, *Patents and Access to Essential Medicines*, in 2 FRONTIERS OF ECONOMICS AND GLOBALIZATION: INTELLECTUAL PROPERTY, GROWTH AND TRADE 423, 426 (Keith E. Maskus ed. 2008) (providing a wider range for the cost of generic drug development as early as 1999 based on “[i]nterviews with FDA officials and several generic pharmaceutical managers [that] generated estimated costs of filing an [Abbreviated New Drug Application] of \$250,000 to \$20 million” (quoting Fiona M. Scott Morton, *Entry Decisions in the Generic Pharmaceutical Industry*, 30 RAND J. ECON. 421, 423 (1999))). These costs would likely be even higher for biologics.

¹⁰ Note that this pricing estimation would be based on achieving payoff after the first year. Perhaps a company would want to market the drug at a lower price, which means it would take even longer before the company would begin to see a return on its investment.

alternative would not likely reach the market for three to five years.¹¹ And when the generic does finally enter the market, the branded drug company could then attempt to lower its price back to the pre-hike price or below the new generic drug's market price, completely eviscerating the generic's potential for a return on investment. This could explain in large part why the industry is not investing in new generics in response to high drug prices like Daraprim's.

Some attribute the price hikes to a company's ability to target neglected drugs that treat rare diseases,¹² but prices of drugs that treat common diseases are also rising. For example, the price of Doxycycline, an antibiotic that treats many conditions, was ratcheted almost 10,000% between late 2013 and 2015,¹³ despite its wide use; over eleven million prescriptions of Doxycycline are filled each year.¹⁴ Similarly, the price of EpiPen, an emergency epinephrine injection treatment for anaphylaxis, was ratcheted almost 500% since 2009, notwithstanding that there were approximately 3.6 million EpiPen prescriptions filled in the United States in 2015.¹⁵ Thus, drugs that treat both common and rare diseases are ratcheting in price.

To solve the drug price-ratcheting problem, we must first address a fundamental underlying question: Why are the prices of certain drugs ratcheting at such an extreme level? There is currently no clear answer. This Note attempts to fill that gap.

This Note focuses on rising prices of both brand-name and generic pharmaceuticals not currently protected by a patent, or "off-patent" drugs, and the law's failure to regulate their prices.¹⁶ Many commentators contend that the problem of price ratcheting could be addressed by simply stimulating competition in the pharmaceutical

¹¹ See FTC 2009 REPORT, *supra* note 9, at iii (estimating small-molecule generic development of three to five years).

¹² See, e.g., Franklin Liu, Article, *Daraprim and the Pharmaceutical Pricing Paradox: A Broken System?*, B.C. INTELL. PROP. & TECH. F., Winter 2015–2016, at 127, 127 (noting that drug companies may realize a substantial upside by targeting old, neglected drugs, often used for treating rare diseases, and "refashioning them into high-priced specialty drugs").

¹³ See Elisabeth Rosenthal, *Officials Question the Rising Costs of Generic Drugs*, N.Y. TIMES (Oct. 7, 2014), <http://www.nytimes.com/2014/10/08/business/officials-question-the-rising-costs-of-generic-drugs.html> (reporting that from October 2013 to April 2014, the price of Doxycycline was ratcheted from \$20 per bottle to \$1849 per bottle).

¹⁴ *Drug Record: Doxycycline*, LIVERTOX, <http://livertox.nih.gov/Doxycycline.htm> (last visited June 26, 2017).

¹⁵ Kelly Tunney, *How Many People Use EpiPens in America? Mylan's Price Increase Is Taking Advantage of Its Users*, BUSTLE (Aug. 26, 2016), <https://www.bustle.com/articles/180800-how-many-people-use-epipens-in-america-mylans-price-increase-is-taking-advantage-of-its-users>.

¹⁶ See *infra* Sections I.A, I.B.

industry.¹⁷ This Note disproves that notion by examining drugs whose prices rose, faced increased competition, yet did not decrease in price, suggesting that price ratcheting implicates far more complex issues.¹⁸ It also highlights the failure of legal methods that increase competition to lower the hiked drug prices.¹⁹ To further understand the complexities that contribute to the price-ratcheting phenomenon, this Note compiles data on a wide set of pharmaceuticals that have recently been ratcheted in price,²⁰ and identifies two major categories of drugs subject to price ratcheting: (1) drugs whose prices have risen for natural reasons, such as shortages in raw materials, and (2) drugs whose prices have risen as a result of anticompetitive business practices.²¹ In light of this distinction, this Note maintains that a solution is unnecessary for the first category of drugs because it is healthy for a company to ratchet the price of its drug when warranted by temporary market deviations, and recommends that the government, specifically the Federal Trade Commission (FTC), should respond to the second category of drugs by charging certain pharmaceutical companies with engaging in unfair methods of competition.²²

I

THE RISE OF DRUG PRICES AND THE LAWS THAT REGULATE PRICING

Rising drug prices are common and widespread, affecting millions of people throughout the United States. A nationally representative telephone poll conducted by Consumer Reports Best Buy Drugs in March 2016 found that three in ten Americans, or approximately thirty-two million people, encountered price hikes within the previous twelve months on at least one of their routine medications and paid an average of \$63 more for the drug than in the year prior.²³ Section I.A demonstrates that there is indeed a significant problem posed by rising drug prices, and that research and development costs do not justify this problematic ratcheting behavior. Section I.B examines laws that govern pharmaceutical competition, including patent exclusivity and generic introduction, explaining our system's rationale for keeping the pharmaceutical industry unregulated. Section I.C then

¹⁷ See *infra* Section I.C.

¹⁸ See *infra* Section II.A.

¹⁹ See *infra* Sections II.B, II.C.

²⁰ See *infra* Section III.A.

²¹ See *infra* Section II.B.

²² See *infra* Section III.C.

²³ *Is There a Cure for High Drug Prices?*, CONSUMER REP. (July 29, 2016), <http://www.consumerreports.org/drugs/cure-for-high-drug-prices/>.

presents the commonly advanced idea that high drug prices can be lowered by bolstering competition in the relevant markets.

A. *Drugs Are So Expensive! But Is that a Problem?*

Over three-quarters of Americans think that pharmaceuticals cost too much, and that number is rising each year.²⁴ Further, the pharmaceutical industry has been criticized for decades for setting high drug prices.²⁵ But do high drug prices actually need to be addressed? Often, scholars and pharmaceutical companies argue that drug prices are not in fact excessive, contending that the high prices are justified by maintenance, research, and development costs,²⁶ or, alternatively, that drug prices are in fact *lower* now.²⁷ This Section argues that, despite contention that raising prices of pharmaceuticals is not problematic, drug prices are indeed excessive and should be brought down.

Companies under scrutiny often justify ratcheting the prices of their drugs, claiming that they need to increase pharmaceutical prices to pay for research, development, and manufacturing costs.²⁸ This may

²⁴ Ashley Kirzinger, Bryan Wu & Mollyann Brodie, *Kaiser Health Tracking Poll: September 2016*, KAISER FAM. FOUND. (Sept. 29, 2016), <http://kff.org/health-reform/report/kaiser-health-tracking-poll-september-2016/> (finding that 77% of Americans in 2016 said prescription drug costs are unreasonable, up from 72% in 2015).

²⁵ See P. Roy Vagelos, *Are Prescription Drug Prices High?*, 252 SCIENCE 1080, 1080 (1991) (noting that during the late 1980s through 1991, “pharmaceutical companies ha[d] come under mounting criticism for their prices”); see also S. REP. NO. 101-F, at iii (1990) (“There can be little doubt that we face a growing crisis in the United States due to rising prescription drug prices.”). The U.S. legal system may simply perpetuate high drug prices; such may be the nature of our pharmaceutical system, rather than any sort of abnormal ratcheting events. See Arthur Caplan, *Analysis: Shkreli Isn’t to Blame for High Drug Prices in U.S.*, NBC NEWS (Dec. 21, 2015, 1:17 PM), <http://www.nbcnews.com/health/health-care/analysis-shkreli-isnt-blame-high-drug-prices-u-s-n483861> (implying that it is not Turing’s fault that Daraprim’s price rose so high, but is rather due to faults in this nation’s health care system).

²⁶ See John LaMattina, *Martin Shkreli Has a Research Plan for Turing Pharmaceuticals—Is It Viable?*, FORBES (Dec. 15, 2015, 8:05 AM), <http://www.forbes.com/sites/johnlamattina/2015/12/15/martin-shkreli-has-a-research-plan-for-turing-pharmaceuticals-is-it-viable/> (noting Turing’s claim that it was justified in raising the price of Daraprim so that the company could use the money towards research and development).

²⁷ See, e.g., Alex Tabarrok, *Forget Shkreli: Generic Drugs Are Cheaper than Ever*, FOUND. FOR ECON. EDUC. (Feb. 24, 2016), <https://fee.org/articles/forget-shkreli-generic-drug-prices-are-falling/> (arguing that, as per three recent studies of generic drug prices, generic drug prices are falling, not rising). The studies that Professor Tabarrok cites, however, only show a decrease in prices of the “most commonly used” generic drugs and only until 2014, which does not account for the ratcheting prices of specialty drugs in recent years. *Id.*

²⁸ See Lydia Ramsey, *Pharma Companies’ No. 1 Justification for High Drug Prices Is Bogus*, BUS. INSIDER (Dec. 9, 2015, 12:53 PM), <http://www.businessinsider.com/research-and-development-costs-might-not-factor-into-drug-pricing-2015-12> (“Pharmaceutical companies often cite the cost of researching and developing new compounds as the reason

be true for companies selling brand-name drugs, especially those still under patent protection. Historically, the originator pharmaceutical companies that first discover the drug are the companies that continue to conduct research to discover new drugs,²⁹ and such companies maintain that they must charge high prices in order to have the capacity to discover the revolutionary, life-saving drugs that may one day cure or prevent cancer, heart disease, Alzheimer's disease, and other human maladies.³⁰ Recently, however, companies that sell off-patent drugs are spending on research and development (R&D), too.³¹ But for companies like Turing, justifying price ratcheting with R&D is simply distorting the truth.³² Although Turing purports that its "R&D investments began in February 2015" and that year "invested 60 percent of net revenues . . . in R&D,"³³ and claimed that the Daraprim price hike was aimed at "targeting investments that both improve on the current formulation and seek to develop new therapeutics with better clinical profiles [to] help eradicate [toxoplasmosis]."³⁴ As it turns out, Turing is investing in very little, if any, R&D. In a hearing by the Committee on Oversight & Government Reform on February 4, 2016, representatives noted that Turing's R&D

for their high drug prices."); *see also infra* notes 70–71 (discussing how Turing and Mylan are justifying their drugs' new high prices).

²⁹ See Charles R. Goulding et al., *The R&D Tax Aspects of Generic Drugs*, R&D TAX SAVERS, <http://www.rdtaxsavers.com/articles/Generic-Drugs> (last visited June 26, 2017) (noting that "the once well-established notion" was that "innovation was the domain of originator companies").

³⁰ See Richard A. Spinello, *Ethics, Pricing and the Pharmaceutical Industry*, 11 J. BUS. ETHICS 617 (1992), reprinted in PEG TITTLE, *ETHICAL ISSUES IN BUSINESS: INQUIRIES, CASES, AND READINGS* 443, 443–44 (2000) (describing a company's justification of its high price for AZT as "high research and development cost[s] and the threat of obsolescence" and maintaining that "in order to recoup its oppressively high research and development costs for this medication, it has no choice but to charge" an extremely high price).

³¹ See Goulding et al., *supra* note 29 ("In recent years, the distinction between innovators, or research-based originator companies, and generic copiers has become blurrier, as a growing number of generics manufacturers engage in important innovative efforts.").

³² A pharmaceutical company that only sells generic drugs should have very low overhead costs. See Pharmaguy, *R&D Cost for Generics Is Zero. Nothing. Nada. Nilch. So Why Are Their Prices Surging?*, PHARMA MARKETING BLOG (Nov. 21, 2014, 10:29 AM), <http://pharmamkting.blogspot.com/2014/11/r-cost-for-generics-is-zero-nothing.html> (arguing that the price of generics should be low considering how low marketing and R&D costs are for generic drugs). This would be similarly true for a pharmaceutical company that purchased a brand-name drug and never partook in any of the initial R&D. It thus seems highly counterfactual for a company like Turing to justify its high drug prices with R&D.

³³ *Research & Development*, TURING PHARMACEUTICALS, <https://www.turingpharma.com/research/> (last visited June 27, 2017).

³⁴ Laura Lorenzetti, *Here's Why Turing Pharmaceuticals Says 5,000% Price Bump Is Necessary*, FORTUNE (Sept. 21, 2015), <http://fortune.com/2015/09/21/turing-pharmaceuticals-martin-shkreli-response/>.

was equal to a very low percentage of its sales and that Turing has not brought a single drug from the conceptual stage all the way to market.³⁵ More specifically, Turing had revenues of \$98 million in 2015, with manufacturing costs of only \$1 million for Daraprim, but only reported spending \$22 million on R&D, which is 22.45% of its spending—a percentage far below the claimed 60%—and even those expenditures identified as R&D spending were questionable, appearing to go to “donations to unnamed entities,” “contributions to foundations,” and “other research and development costs.”³⁶ Lawmakers in several states, including New York, Pennsylvania, and Massachusetts, have introduced pharmaceutical cost transparency bills that would force pharmaceutical companies to report how much they spend on researching, making, and advertising their drugs.³⁷ If these bills pass, disclosures of a pharmaceutical company’s R&D spending, or a lack thereof, would likely expose falsities behind the rationalization of price ratcheting.

The idea that patented drug prices have price tags that increase because of their exclusive monopoly in the market but generic drugs remain inexpensive no longer holds true today. Nearly eight out of ten prescriptions filled in the United States are for generic drugs.³⁸ Considering that almost 70% of Americans take at least one prescription

³⁵ See, e.g., Oversight and reform, *Developments in the Prescription Drug Market: Oversight*, YOUTUBE 2:24:00–2:30:14 (Feb. 4, 2016), <https://www.youtube.com/watch?v=BPPerZLjp4M> (recording of Hearing by the Committee on Oversight & Government Reform) (statement of Congresswoman Brenda Lawrence) (noting that Valeant Pharmaceutical’s R&D was a very low percentage of sales between 2014 and 2015). Representative Elijah Cummings contended that expenditures “were just as much about PR as R&D,” stating that Turing’s actions were “like a Ponzi scheme,” where Turing may have been using revenues from Daraprim to “research” and identify the next drug it would acquire and ratchet in price. *Id.* at 16:44:00–17:08:00.

³⁶ *Id.* at 15:59:00–16:44:00 (statement of Representative Elijah Cummings).

³⁷ See, e.g., S. 5338A, 201st Leg., 238th Sess. (N.Y. 2016); S. 1048, 189th Gen. Court, Reg. Sess. (Mass. 2015); H.R. 1042, 199th Gen. Assemb., Reg. Sess. (Pa. 2015); cf. Tracy Seipel, *High-Cost Drugs: California Legislator Pulls Bill Seeking Cost ‘Transparency,’* MERCURY NEWS (Jan. 12, 2016), <http://www.mercurynews.com/2016/01/12/high-cost-drugs-california-legislator-pulls-bill-seeking-cost-transparency/> (reporting that California Assemblyman David Chiu pulled Assembly Bill 463 off of the Assembly Health Committee agenda).

³⁸ *Facts About Generic Drugs Infographic*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandGenericDrugs/ucm305896.htm> (last updated May 30, 2012). Because the FDA requires that generic drugs prove bioequivalence to and pass the same quality standards as the brand-name drug, generic drugs are expected to have the same performance as the brand-name drug, with negligible variation. *Id.* Since the average cost of a generic drug is 80–85% less than its brand-name counterpart, generic drugs are the most common treatment course for consumers. *Id.*

drug, and more than half take two,³⁹ the generic industry controls a large majority of the pharmaceutical market. But since 2013, the price of certain generic drugs has ratcheted out of normal range, often increasing over 650%, and close to 10,000% in extreme cases, when most generic drug prices typically increase only 10% per year on average.⁴⁰ Therefore, the price-ratcheting issue is affecting pharmaceuticals that are not protected by patents.

The rising prices of off-patent pharmaceuticals are indeed a significant problem. Not only is price hiking widespread,⁴¹ but in response to sudden and large increases in drug prices, people are “more likely to take unhealthy measures.”⁴² For example, in the poll conducted by Consumer Reports Best Buy Drugs, many consumers reported that the higher prices made it increasingly difficult for them to afford their medical bills, with 57% reporting that they cut back spending on other necessities in order to pay for their medicines.⁴³ Others turn to inadequate alternatives, take fewer doses than prescribed, or cease buying their medication at all.⁴⁴ In conclusion, ratcheting drug prices is posing a significant problem and is unjustifiable under the pretext of R&D. Because of the detrimental implications of recent price-hiking events, identifying and understanding any underlying causes of the upsurges will shed light on where the United

³⁹ *Nearly 7 in 10 Americans Take Prescription Drugs*, Mayo Clinic, *Olmsted Medical Center Find*, MAYO CLINIC (June 19, 2013), <http://newsnetwork.mayoclinic.org/discussion/nearly-7-in-10-americans-take-prescription-drugs-mayo-clinic-olmsted-medical-center-find/>.

⁴⁰ See Patrick A. Malone, *Why Has the Cost of Generic Drugs Gone Crazy?*, PATRICK MALONE & ASSOCIATES (Oct. 30, 2014), http://www.protectpatientsblog.com/2014/10/why_has_the_cost_of_generic_dr.html (noting that between 2013 and 2014, Simvastatin’s price increased more than 650% and Doxycycline’s price increased 9145%, while most generics increase in price by an average of 10% per year, according to the chief executive of a health information technology company that monitors prescription drug costs).

⁴¹ See *Is There a Cure for High Drug Prices?*, *supra* note 23 (estimating that thirty-two million people across the United States were “hit with price hikes” between 2015 and 2016).

⁴² *Id.*

⁴³ See *id.* (finding that those who experienced a price increase in their drugs in the last twelve months prior to March 2016 often spent less on entertainment and dining out, groceries, and their family, used their credit card more often, and postponed paying other bills and retiring in order to afford their medications); *Some Americans Take Risks with Needed Drugs Due to High Costs*, CONSUMER REP., <http://www.consumerreports.org/cro/2014/09/some-americans-take-risks-with-needed-drugs-due-to-high-costs/index.htm> (last updated Sept. 2014) (reporting on how adults took steps to curb high medication costs).

⁴⁴ See *Is There a Cure for High Drug Prices?*, *supra* note 23 (relaying accounts of a person who takes a single injection of insulin per day instead of multiple daily injections, and a person who altogether “stopped taking the drug” that treated her rheumatoid arthritis because the price of her drug skyrocketed).

States's legal regime is failing to regulate pharmaceuticals and how the law can be better implemented to halt abusive price ratcheting.

B. Brand-Name and Generic Drug Laws: The Rules that Regulate Pricing

The United States, unlike other countries, currently has no direct price controls on pharmaceuticals.⁴⁵ The patent system allows for pharmaceutical companies to gain substantial revenues as a reward for their innovations and an incentive to continue novel and useful research.⁴⁶ Although encouraging innovation and the introduction of new drugs is a good idea in theory, there is a trade-off between this benefit and the hardships of high costs for consumers. Some are afraid that a federal regulatory approach to drug prices that reduces pharmaceutical revenues may generate modest consumer savings at best, but would risk substantial costs, namely lowering life expectancy as a result of decreased pharmaceutical innovation.⁴⁷ This Section will discuss federal statutes and policies that regulate drug pricing, including patent laws and the Hatch-Waxman Act, and their failure to alleviate the price-ratcheting fiasco.

1. Drug Pricing in Patent Law and the Right to Exclude

In the United States, the fundamental purpose of patent law is “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”⁴⁸ Because of this purpose, it is important that a patent owner is given the opportunity to receive pecuniary rewards that stem from the patent right. The Federal Circuit explained:

[Courts] have long acknowledged the importance of the patent system in encouraging innovation. Indeed, “the encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude.” . . . Importantly,

⁴⁵ See 108 CONG. REC. 15,722 (2004) (statement of Sen. Kyl) (“The United States is virtually the only developed nation that does not regulate pharmaceutical prices.”).

⁴⁶ See U.S. PATENT & TRADEMARK OFFICE, INTELLECTUAL PROPERTY AND THE U.S. ECONOMY: 2016 UPDATE 1 (2016) (“Patents add to the incentive that inventors have to invest in costly research and development (R&D) by providing the opportunity to reap the rewards of their innovations.”).

⁴⁷ DANA P. GOLDMAN ET AL., RAND HEALTH, REGULATING DRUG PRICES: U.S. POLICY ALTERNATIVES IN A GLOBAL CONTEXT 1 (2008), http://www.rand.org/pubs/research_briefs/RB9412.html.

⁴⁸ U.S. CONST. art. I, § 8, cl. 8.

the patent system provides incentive to the innovative drug companies to continue costly development efforts.⁴⁹

In other words, the constitutional right to exclude serves to incentivize innovation and allow inventors and inventing companies to recoup on the high costs of R&D. Thus, a patent owner not only can, but has the right to set the price of her product as she sees fit. This is especially true in the pharmaceutical industry, where the average large pharmaceutical company spends about 19% of revenues on R&D.⁵⁰ Patent protection ensures a legal means for inventors and inventing companies to earn a reasonable return on their R&D investment: It prevents imitators from immediately entering the market with a copy of the drug, driving down the new drug's price before the innovator has had a chance to recover R&D costs.

Attempts to regulate the prices of patented drugs have not gained much momentum in the United States, despite severe price regulation in other countries.⁵¹ Notably, in *Biotechnology Industry Organization*

⁴⁹ *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006) (quoting *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 599 (Fed. Cir. 1985)).

⁵⁰ See PHARM. RESEARCH & MFRS. IN AM., 2016 BIOPHARMACEUTICAL RESEARCH INDUSTRY PROFILE 36 fig.13 (2016), <http://phrma-docs.phrma.org/sites/default/files/pdf/biopharmaceutical-industry-profile.pdf> (demonstrating that the biopharmaceutical sector invested 18.3% in R&D as a percentage of sales from 2000–2012); CONG. BUDGET OFFICE, RESEARCH AND DEVELOPMENT IN THE PHARMACEUTICAL INDUSTRY 9 (2006) (stating that since the 1980s, R&D spending has accounted for approximately 19% of sales). Smaller companies spend even more of their revenues on R&D, but were not included in the survey in which the Congressional Budget Office's study was based. See Courtney Rubin, *Small Companies Spend More on R&D*, INC. (May 27, 2010), <https://www.inc.com/news/articles/2010/05/small-companies-spend-more-on-innovation.html> (“Small companies spend proportionally more of their revenues on research and development than large ones . . .”); see also RAYMOND M. WOLFE, NAT'L SCI. FOUND., U.S. BUSINESSES REPORT 2008 WORLDWIDE R&D EXPENSE OF \$330 BILLION: FINDINGS FROM NEW NSF SURVEY 3 (2010), <https://wayback.archive-it.org/5902/20160210164334/http://www.nsf.gov/statistics/infbrief/nsf10322/nsf10322.pdf> (noting that the largest companies accounted for 42% of worldwide sales and 33% of total R&D expense, while small companies accounted for 11% of worldwide sales but 19% of R&D expense).

⁵¹ See, e.g., PATRICIA M. DANZON, PHARMACEUTICAL PRICE REGULATION 15–29 (1997) (describing how other countries regulate pharmaceutical prices). Some countries, including France, Italy, and Spain, engage in direct price regulation, requiring that prices of new products and price changes of existing products be approved if they are to be reimbursed by the social insurance system. See *id.* at 16. Canada has a Patented Medicines Prices Review Board that monitors the prices of new products to determine whether they are “reasonable.” *Id.* at 17. Some countries enforce a reference price reimbursement system. See *id.* at 19–21 (Germany, Netherlands, Denmark, New Zealand, and British Columbia). A country may also enforce a rate-of-return regulatory scheme. See *id.* at 21–24 (describing the U.K. Pharmaceutical Price Regulation Scheme, which regulates profits, not prices, where companies are free to set launch prices of new products, provided that the total rate of return on capital of their portfolio of products reimbursed by the National Health Service does not exceed a specified limit). Lastly, pharmaceutical prices can be regulated by enforcing a drug reimbursement system. See *id.* at 25–26 (describing

v. District of Columbia,⁵² the United States Court of Appeals for the Federal Circuit found that a state Prescription Drug Excessive Pricing Act, which allowed residents to sue a drug company if the wholesale price of a patented drug was 30% higher than the drug's price in Canada, Germany, Australia, or the United Kingdom, was preempted by the Patent Act.⁵³ Trying to penalize high prices of drugs under patent protection "is contrary to the goals established by Congress in the patent laws" because it "in effect diminish[es] the reward to patentees in order to provide greater benefit to District drug consumers."⁵⁴ But periods of exclusivity, and thus unfettered drug prices, are meant to only be for "limited [t]imes."⁵⁵ Once the patent expires, in a properly functioning market, others would enter the market with products based on the patent's teachings, creating competition that would bring down the patented product's elevated price.⁵⁶

2. *Generic Drug Entry Under the Hatch-Waxman Act*

Once a branded drug's patent term expires, generic drugs can enter the market and compete with the branded drug. The Food and Drug Administration (FDA) requires that generic drugs, like all other new drugs, be safe and effective.⁵⁷ Before the Hatch-Waxman Act of 1984,⁵⁸ makers of generic drugs had to apply for a New Drug Application (NDA) in accordance with 21 U.S.C. § 355(b)(1), and thereby prove safety and efficacy through extensive scientific studies in animal models and clinical trials. Since the passage of the Hatch-Waxman Act, a generic drug is no longer required to undergo tedious and expensive testing and now only needs to show bioavailability and bioequivalence to an already-approved drug.⁵⁹ Additionally, a drug

the Japanese system where the government sets the reimbursement price for each drug dispensed by the physician, so that drug manufacturers are incentivized to cut their prices below the reimbursement price to increase the physician's financial incentives to prescribe the manufacturer's drugs).

⁵² 496 F.3d 1362 (Fed. Cir. 2007).

⁵³ *Id.* at 1365–66, 1374.

⁵⁴ *Id.* at 1374.

⁵⁵ U.S. CONST. art. I, § 8, cl. 8.

⁵⁶ For a study that used information from the IMS Health National Sales Perspectives database and found that generic introductions lowered pricing of brand drugs, see *infra* note 62 and accompanying text.

⁵⁷ See 21 U.S.C. § 355(b)(1) (2012) (requiring patent applicants "to show whether or not [the] drug is safe for use and whether such drug is effective in use").

⁵⁸ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 (2012)).

⁵⁹ Bioavailability refers to the extent and rate at which a drug enters systemic circulation and is ultimately absorbed into the living system, or made available at the site of physiological activity. Jennifer Le, *Drug Bioavailability*, MERCK MANUAL, <https://www.merckmanuals.com/professional/clinical-pharmacology/pharmacokinetics/drug->

company need only apply for an Abbreviated New Drug Application (ANDA), which ultimately involves a much speedier and cost-effective application process in comparison to that of an NDA.⁶⁰ Through this streamlined process, a generic should be able to enter the market and offer price-competitive alternatives to the brand-name drug, making it less burdensome for the consumer to purchase the drug.⁶¹

Current U.S. law thus leaves drug prices unregulated because these prices are supposed to normalize in response to competitive market forces upon the expiration of the patent. Longitudinal studies on price trends after the Hatch-Waxman Act have confirmed that the availability of generic drugs has indeed saved purchasers tens of billions of dollars a year.⁶² Similarly, the FDA tracked prices of drugs between 1994 and 2005 and found a significant negative correlation between drug price per dose and the number of generic manufacturers of that drug.⁶³ Further, the National Bureau of Economic Research studied how generic introductions affected the prices of drugs that lost patent protection between 2001 and 2007. The study found that the

bioavailability (last updated Apr. 2016). For a description of bioequivalence testing and standards, see *supra* note 5 and accompanying text, and note 38.

⁶⁰ See *Abbreviated New Drug Application (ANDA): Generics*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/abbreviatednewdrugapplicationandgenerics/default.htm> (last updated Feb. 27, 2017) (describing the ANDA application process).

⁶¹ See *In re Barr Labs., Inc.*, 930 F.2d 72, 76 (D.C. Cir. 1991) (“[Through the Hatch-Waxman Act.] Congress sought to get generic drugs into the hands of patients at reasonable prices—fast.”); see also *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358 (Fed. Cir. 2003) (“The purpose of Title I of the [Hatch-Waxman Act] is to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962.” (quoting H.R. Rep. No. 98-857, pt. 1, at 14 (1984), as reprinted in 1984 U.S.C.C.A.N. 2647, 2647)).

⁶² See FED. TRADE COMM’N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 9* (2002) (stating that a Congressional Budget Office study “estimated that, in 1994, the availability of generic drugs saved consumers \$8 to \$10 billion”); IMS INST. FOR HEALTHCARE INFORMATICS, *PRICE DECLINES AFTER BRANDED MEDICINES LOSE EXCLUSIVITY IN THE U.S. 2* (2016) (“Generics that entered the market between 2002 and 2014 reduced the price of medicines by 51% in the first year and 57% in the second year following the loss of exclusivity.”). *But see* CONG. BUDGET OFFICE, *HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY 30* (1998) (collecting studies on how generic entry affects brand-name prices and concluding that generic competition does not typically have a large effect on brand-name prices); Rena Yoneyama, *The Determinants of the Reduction of Generic Drug Prices Relative to Brand Drug Prices in the U.S. Pharmaceutical Market 20–21* (Aug. 2007) (unpublished M.S. thesis, Cornell University) (on file with Cornell University Library system) (summarizing findings that generic competition was not associated with brand-name drug price trends).

⁶³ *Generic Competition and Drug Prices*, FDA, <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm> (last updated May 13, 2015); see also IMS INST. FOR HEALTHCARE INFORMATICS, *supra* note 62, at 2 (“Generic drugs greatly reduce the price of medicines.”).

average monthly price declined by 38% to 46.4% for formerly protected physician-administered drugs and 25% to 26% for formerly protected oral drugs following patent expiration.⁶⁴ Lipitor, the bestselling drug of all time,⁶⁵ is a quintessential example. Lipitor's patent expired on November 30, 2011.⁶⁶ Pharmaceutical company Pfizer, the maker of Lipitor, announced that profit declined 19% the following quarter, largely because of declines in Lipitor sales.⁶⁷ This classic example shows how the U.S. market self-regulates drug prices: A drug in high demand is priced by the pharmaceutical company, the drug brings in substantial revenue while protected by a patent, the patent expires and generic versions enter the market, the market becomes diluted, and the drug price drops.

The system under the Hatch-Waxman Act may preserve prices at a competitive level for bestselling drugs. But the system does not function properly for specialty drugs without competition, when shortages in raw materials occur, or when pharmaceutical companies consolidate. When drugs become more expensive for these (or other) reasons, our legal regime does nothing to regulate the drug prices, and consumers bear the ultimate burden of the higher costs. Even if insurance companies cover the overall high costs, consumers are charged much higher premiums,⁶⁸ and, even worse, the uninsured are charged the total cost.⁶⁹ Meanwhile, some pharmaceutical companies try to justify the price hikes, rather than acknowledging the faults in the generic market. For example, Martin Shkreli, Chief Executive Officer (CEO) of Turing, purports that Daraprim's price needed to increase

⁶⁴ Rena M. Conti & Ernst R. Berndt, *Specialty Drug Prices and Utilization After Loss of U.S. Patent Exclusivity, 2001-2007*, at 1 (Nat'l Bureau of Econ. Research, Working Paper No. 20016, 2014).

⁶⁵ *FirstWord Lists: The Best Selling Drugs of All Time - An Updated Analysis*, FIRSTWORD PHARMA (June 3, 2013), <http://www.firstwordpharma.com/node/1096220#axzz473dT8QGG>; Sean Williams, *The 19 Best-Selling Prescription Drugs of All Time*, MOTLEY FOOL (Mar. 13, 2017, 8:41 AM), <https://www.fool.com/investing/2017/03/13/the-19-best-selling-prescription-drugs-of-all-time.aspx>.

⁶⁶ *Lipitor Loses Patent, Goes Generic*, CNN, <http://www.cnn.com/2011/11/30/health/lipitor-generic/index.html> (last updated Nov. 30, 2011).

⁶⁷ Katie Thomas, *Pfizer Profit Declines 19% on Slumping Lipitor Sales*, N.Y. TIMES, May 2, 2012, at B1.

⁶⁸ See Stephen Barlas, *Are Specialty Drug Prices Destroying Insurers and Hurting Consumers?*, 39 PHARMACY & THERAPEUTICS 563, 563-64 (2014) (discussing the impact of high-priced drugs and explaining that "drug costs are a significant part of premiums"); *infra* note 83.

⁶⁹ See Ifrad Islam, *Rising Cost of Drugs: Where Do We Go from Here?*, HEALTHAFFAIRS BLOG (Aug. 31, 2015), <http://healthaffairs.org/blog/2015/08/31/rising-cost-of-drugs-where-do-we-go-from-here/> (explaining that higher drug prices shift costs to patients, where copayments go to their highest tiers).

to fund the company's R&D.⁷⁰ Similarly, Heather Bresch, CEO of Mylan Pharmaceuticals (Mylan), defends that EpiPen's price needed to increase for Mylan to earn some profit.⁷¹ Regardless of whether such price ratcheting is warranted, our laws do not regulate these prices. The normal generic competition process does not take effect here because it is expensive and takes significant time to receive approval for a generic copy.⁷² Therefore, there is an inherent failure in the current U.S. regulatory scheme because there is nothing that is providing generic companies adequate incentive to enter the market.

C. *The Commonly Advanced Solution: Increase Competition to Lower Drug Prices*

Those concerned over sudden price hikes typically highlight a reduction in or lack of competition as the determinative factor. With few or no companies vying to capture the consumer base of a particular drug, there are no external market constraints to prevent a pharmaceutical company from exercising its market power to raise the price of that drug exponentially. There is a strong sentiment amongst scholars,⁷³ politicians,⁷⁴ and federal agency leaders⁷⁵ that increasing

⁷⁰ LaMattina, *supra* note 26 (“Shkreli plans to plough back revenues from Daraprim sales into R&D, saying this will ensure long-term returns for his investors.”). At first, this argument seems to have merit. A primary goal of the Hatch-Waxman Act is to incentivize continued drug research and innovation. H.R. REP. NO. 98-857, pt. 1, at 15 (1984) (“The purpose of Title II of the bill is to create a new incentive for increased expenditures for research and development of certain products which are subject to premarket governmental approval.”). This argument, however, fails to explain why a company would arbitrarily raise the price of a drug that is already on the market. Rather, Congress intended in drafting the Hatch-Waxman Act to give patent holders some of the time lost in regulatory review to restore part of their patent term. Thus, claiming that an off-patent drug's price needs to be higher to provide funding for further R&D is not an applicable extension of the Hatch-Waxman Act and should not be an acceptable excuse for radical price hiking. In fact, it is likely that companies like Turing do not actually spend much money on R&D at all. *See supra* notes 32–37 and accompanying text.

⁷¹ *See* Calamur, *supra* note 4 (“Heather Bresch . . . defended [the increased price of EpiPen] to congressional lawmakers . . . ‘I think many people incorrectly assume we make \$600 off each EpiPen . . . [when] our profit is \$100, or approximately \$50 per pen.’”).

⁷² For further discussion of the lengthy FDA approval process, *see infra* notes 134–38 and accompanying text.

⁷³ *See, e.g.,* Peter Stein & Ernst Valery, *Competition: An Antidote to the High Price of Prescription Drugs*, 23 HEALTH AFF. 151 (2004) (calling competition the “antidote” to lowering drug prices).

⁷⁴ *See, e.g.,* Amy Klobuchar, *Let's Work with Trump to Reduce Drug Prices: Sen. Klobuchar*, USA TODAY (Dec. 13, 2016, 7:27 AM), <http://www.usatoday.com/story/opinion/2016/12/13/drug-prices-klobuchar-competition-column/95307768/> (indicating that Senator Amy Klobuchar and Senator John McCain desire to increase competition to incentivize pharmaceutical companies to lower their drug prices); *see also* April Short, *5 Ways Bernie Sanders Is Leading the Fight Against Big Pharma's Unconscionable Greed*, SALON (Mar. 2, 2016, 4:25 AM), http://www.salon.com/2016/03/02/5_ways_bernie_sanders_

competition in the drug market would bring current prices down to their market value and prevent future price ratcheting.⁷⁶

It is a current priority of the U.S. government to lower pharmaceutical prices and the executive and legislative branches are looking primarily at increasing competition to do so. President Donald Trump stated during a meeting with drug industry leaders that he wants to reduce drug prices by bolstering competition.⁷⁷ Correspondingly, Congress is looking for new ways to regulate high drug prices. Specifically, the House will consider a bill to pass the Lower Drug Costs Through Competition Act, which would require the FDA to review ANDA applications of any new generic versions of drugs with little or no competition in 180 days, and would offer those generic pharmaceutical companies a voucher for speedier review of another generic product.⁷⁸ Thus, policymakers are currently focused on how to increase drug competition when considering the drug price-ratcheting problem.

II

INCREASING COMPETITION AS A WAY TO BURY THE RATCHET

We currently face a clear⁷⁹ problem: Price surges are making the

is_leading_the_fight_against_big_pharmas_unconscionable_greed_partner/ (explaining that Senator Bernie Sanders advocates for increasing competition to lower prescription drug prices).

⁷⁵ See, e.g., Lev Facher, *Pressed on Drug Prices, Nominee to Head Medicare and Medicaid Praises Competition*, STAT (Feb. 16, 2017), <https://www.statnews.com/2017/02/16/medicare-drug-prices-2/> (describing praise by Seema Verma, President Trump's nominee to lead the Centers for Medicare and Medicaid, of increased competition as a solution for lowering drug prices).

⁷⁶ See Stein & Valery, *supra* note 73, at 153 (advocating for increased competition in the pharmaceutical marketplace to combat the high cost of prescription drugs); see also David Brodwin, *Competition Is the Cure*, U.S. NEWS (Oct. 5, 2015, 11:05 AM), <http://www.usnews.com/opinion/economic-intelligence/2015/10/05/a-smarter-way-to-lower-prescription-drug-prices> (“Frankly, the best solution to this problem is the simplest one: competition.”).

⁷⁷ See Anna Edney & Justin Sink, *Trump Calls Drug Pricing ‘Astronomical’ and Promises Changes*, BLOOMBERG (Jan. 31, 2017, 5:41 AM), <https://www.bloomberg.com/politics/articles/2017-01-31/trump-meets-with-drugmakers-as-industry-fears-price-controls> (noting that President Trump believes that increasing “[c]ompetition is key to lowering drug prices”).

⁷⁸ Harris Meyer, *House to Consider Bill to Cut Drug Prices Through More Generic Competition*, MODERN HEALTHCARE (Feb. 5, 2017), <http://www.modernhealthcare.com/article/20170205/NEWS/170209955>; see also H.R. 4784, 114th Cong. (2016) (proposing a bill to amend the Federal Food, Drug, and Cosmetic Act (FDCA) to expedite the approval process for generic drug applications in 2018 of drugs for which there is a shortage or that have not been recently introduced to the market by more than one manufacturer).

⁷⁹ There are, however, critics that do not see rising drug prices as problematic at all. See, e.g., Tyler Cowen, *Are Pharmaceutical Drug Prices Too High?*, MARGINAL

cost of some pharmaceuticals very expensive. Yet there is no obvious answer as to why this is happening. There are a plethora of factors that may be implicated in rising drug costs, including lack of market competition,⁸⁰ acquisition of rare drugs by pharmaceutical companies,⁸¹ drug shortages,⁸² the ability to shift costs to insurance companies rather than consumers,⁸³ industry consolidation,⁸⁴ overly low

REVOLUTION (Sept. 24, 2015, 1:36 AM), <http://marginalrevolution.com/marginalrevolution/2015/09/are-pharmaceutical-drug-prices-too-high.html> (arguing that high drug prices are good because they induce innovation). For a further discussion, see *supra* Section I.A.

⁸⁰ See Michael Hiltzik, *The FDA Can Single-Handedly Reduce Drug Price-Gouging. Why Is It Waiting?*, L.A. TIMES (Jan. 5, 2016, 12:31 PM), <http://www.latimes.com/business/hiltzik/la-fi-mh-the-fda-can-single-handedly-stop-20160105-column.html> (contending that generic drug prices are rising when manufacturers face little or no competition); see also *supra* notes 73–78 and accompanying text. See generally Stein & Valery, *supra* note 73 (calling competition the “antidote” to high drug prices).

⁸¹ See John972, *New Business Model, Buy Rights to Old Rare Drugs, Jack Up the Price from \$13.50 to \$750 per Pill!*, DAILY KOS (Sept. 21, 2015, 5:09 AM), <http://www.dailykos.com/story/2015/9/21/1423357/-New-Business-Model-buy-rights-to-old-rare-drugs-jack-up-the-price-from-13-50-to-750-per-pill> (discussing how pharmaceutical companies buy the rights to old, rare drugs and “sky rocket the price”).

⁸² See *Why Are Generic Drug Prices Shooting Up?*, FORBES (Feb. 27, 2015, 8:38 AM), <http://onforb.es/1DZ9NdY> (naming drug shortages as a factor that contributes to drug price risings). When a manufacturer runs short on inventory, demand outweighs supply and prices increase as a result. *Id.* Drug shortages are typically caused by issues in quality and manufacturing at the manufacturing company’s facility. *Id.* However, drug shortages have also occurred in direct response to stricter FDA regulations that require more quality control in manufacturing facilities. *Id.*; see also Anuradha Verma, *FDA Bans Another Ranbaxy Plant from Selling Products in the US*, VC CIRCLE (Jan. 24, 2014), <http://www.vccircle.com/news/pharmaceuticals/2014/01/24/fda-bans-another-ranbaxy-plant-selling-products-us> (describing an FDA banning of a facility from producing or distributing any drug ingredients for quality reasons, resulting in excessive delays to produce the generic heartburn drug).

⁸³ See Emma Court, *Here’s Why Daraprim Still Costs \$750 a Pill*, MARKETWATCH (Feb. 4, 2016, 3:33 PM), <http://www.marketwatch.com/story/heres-why-daraprim-still-costs-750-a-pill-2016-02-03> (noting that Turing has been trying to portray its price hike as costly only to insurance companies and not consumers); David Lazarus, *What’s Behind the Huge Price Jump for Some Generic Drugs?*, L.A. TIMES (Oct. 20, 2014, 6:14 PM), <http://www.latimes.com/business/la-fi-lazarus-20141021-column.html> (“[C]onsumers often are unaware of such high price hikes because they face only a copay when they buy meds at a drugstore.”). While insurance companies may end up bearing the high costs from an increase in drug price, insurance companies will subsequently raise people’s premiums to cover the greater expenses. *Id.* Thus, the ultimate cost is still on the consumer, and thus the argument that pharmaceutical companies can raise drug prices because the patient is not actually paying the full increased price is unconvincing.

⁸⁴ See Lazarus, *supra* note 83 (“Some of the biggest generic drug companies—Mylan, Actavis and Teva Pharmaceutical Industries—have been aggressively snapping up other manufacturers in recent years, reducing the number of players in the market.”); *Why Are Generic Drug Prices Shooting Up?*, *supra* note 82 (describing how the mergers and acquisitions by generic drug manufacturers that have occurred since 2009 have been a soft factor that contributes to the price hikes).

generic prices,⁸⁵ and unethical or unfair business practices.⁸⁶ Section II.A analyzes the commonly advanced theory that increasing competition⁸⁷ would normalize drug prices that have dramatically increased for any of the above reasons, and concludes that it would not.⁸⁸ Sections II.B and II.C then examine two approaches that attempt to stimulate competition: compounding drugs and prioritizing ANDA

⁸⁵ See Lazarus, *supra* note 83 (reporting that William Comanor, head of Pharmaceutical Economics and Policy studies at UCLA, believes that “the reality is that many generic drugs may be priced too low”). The argument here is that some pharmaceutical companies were setting a drug’s price too low to begin with, which prevented them from investing in stores of raw materials. Thus, when demand for the raw materials is heightened, the costs and therefore prices of the drugs will necessarily rise. *Id.*; see also *supra* note 82 and accompanying text.

⁸⁶ See Lazarus, *supra* note 83 (“[S]ome instances have skyrocketed because of unethical or unfair business practices . . .”). Since antitrust laws prohibit unfair business practices, such as price fixing or creating an illegal monopoly, see Federal Trade Commission Act, 15 U.S.C. §§ 41–45 (2012), it is tempting to make an antitrust case against drug price increases. However, such an approach is not as simple as it may seem. See discussion *infra* Section III.C.

⁸⁷ See *supra* Section I.C (explaining the commonly advanced theory that increasing competition is the solution to drug price ratcheting).

⁸⁸ Some commentators suggest that the United States could also increase competition by allowing either the sale or importation of any generic approved for sale abroad. See Alex Tabarrok, *Generic Drug Regulation and Pharmaceutical Price-Jacking*, MARGINALREVOLUTION (Sept. 24, 2015, 2:15 PM), <http://marginalrevolution.com/marginalrevolution/2015/09/generic-drug-regulation.html> (noting that buying generics from India and Europe would provide for cheap alternatives to drugs highly priced in the United States); see also Karthick Arvinth, *Daraprim: Generic Version of Drug Costs Less than £0.07 in India*, INT’L BUS. TIMES (Sept. 25, 2015), <http://www.ibtimes.co.uk/daraprim-like-drug-costs-less-0-07-india-1521144> (showing that pyrimethamine, the active ingredient in Daraprim, only costs pennies to produce in India). However, importing inexpensive generics from countries like India may pose dangerous issues regarding the quality of the drug. For a comparable issue of quality concern, see discussion *supra* Section II.B regarding quality concerns surrounding compounded drugs. But even allowing for the importation of more trusted generics such as those approved in Canada or Europe, which may resolve issues of safety, would likely cause new restrictions attached to discounted imports. See Rafi Mohammed, *Cheap Drugs from Canada Won’t Reduce U.S. Drug Prices*, HARV. BUS. REV. (Feb. 12, 2016), <https://hbr.org/2016/02/why-importing-cheap-pharmaceuticals-from-canada-wont-work> (“New restrictions will be attached to discounted [foreign pharmaceutical] deals. For example, exports will be banned, or quantities sold at a discount will be limited (enough to cover citizens), with amounts over the limit being charged full price.”). Further, a recent decision by the Supreme Court held that the authorized sale of a patented product exhausts the patent holder’s rights in that product. *Impression Prods., Inc. v. Lexmark Int’l, Inc.* 137 S. Ct. 1523, 1535 (2017). The decision potentially takes geographic price discrimination between U.S. and foreign markets off of the table, especially when a drug is under patent protection. International patent exhaustion now presents a likelihood that pharmaceutical companies will begin to refuse selling drugs at lower prices to lower-income countries because the companies would fear arbitrage. Moreover, even if this Note did consider the ability to introduce foreign drugs into the U.S. market, it would reach the same conclusions as set forth in Part III because increasing competition with imported drugs is a general approach that looks at all drugs as the same, rather than categorizing them into narrow groups. See *infra* Section III.B.

approval. These Sections contend that such approaches will fail to lower high drug prices.

A. *Assessing the Reduced Competition Theory*

To test the idea that reduced competition is at the heart of price ratcheting and thus that increasing competition will effectively bring down these prices, this Section considers the sudden escalations in the prices of Daraprim, EpiPen, and Doxycycline. The price of the first of these three drugs, Daraprim, was ratcheted from \$13.50 to \$750 per tablet in September 2015.⁸⁹ Turing acquired marketing rights to Daraprim only one month before its price was ratcheted.⁹⁰ Since Daraprim was not competing with viable alternatives,⁹¹ Turing was not constrained by market competition in setting its price and those who needed the pill effectively had no other choice but to continue purchasing Daraprim. Thus, it appears that a lack of competition was indeed a factor that allowed Daraprim's price to ratchet, but was not the sole consideration. Turing's acquisition of the drug seems to have also played a part; Turing specifically sought out a drug with little competition.

Shortly after Turing's price hike, another pharmaceutical company, Imprimis, began to offer a compounded drug as an alternative to Daraprim at less than \$1.⁹² Yet, over a year after Imprimis

⁸⁹ Pollack, *supra* note 1.

⁹⁰ See Turing Pharmaceuticals AG, *Turing Pharmaceuticals AG Acquires U.S. Marketing Rights to DARAPRIM® (Pyrimethamine)*, PR NEWswire (Aug. 10, 2015, 6:35 AM), <http://www.prnewswire.com/news-releases/turing-pharmaceuticals-ag-acquires-us-marketing-rights-to-daraprim-pyrimethamine-300125853.html> (announcing Turing's acquisition of the rights to market Daraprim on August 10, 2015). Communications between Turing's CEO and board members, hospital officials, and healthcare providers suggest that Turing purchased the rights to Daraprim with the "purpose of increasing the price dramatically and making hundreds of millions of dollars by exploiting its existing monopoly before any competitor could enter the market." Barbara Kollmeyer, *'\$1bn Here We Come.'*—Martin Shkreli Told Turing Board as Daraprim Buy Got Closer, MARKETWATCH (Feb. 3, 2016, 10:34 AM), <http://www.marketwatch.com/story/1bn-here-we-come-martin-shkreli-told-turing-board-as-daraprim-buy-got-closer-2016-02-03>.

⁹¹ Although alternatives to Daraprim may exist, see *Daraprim Alternatives*, TREATO, <https://treato.com/Daraprim,Alternatives/?a=S> (last visited June 24, 2017) (listing general alternatives to Daraprim), this Note does not consider any of them to be viable alternatives because such alternatives do not work as well to treat the parasitic ailment and/or have significant side effects. See Murat Hökelek, *Toxoplasmosis Medication*, MEDSCAPE, <http://emedicine.medscape.com/article/229969-medication> (last updated Oct. 24, 2016) ("The efficacy of azithromycin, clarithromycin, atovaquone, dapsone, and cotrimoxazole is unclear; therefore, they should be used only as alternatives in combination with pyrimethamine.").

⁹² Natalie Grover, *Imprimis Offers \$1 Alternative to Turing's \$750 Pill*, REUTERS (Oct. 22, 2015, 1:20 PM), <http://www.reuters.com/article/us-imprimis-daraprim-idUSKCN0SG29K20151022>.

announced its alternative, the price of Daraprim remains just as high.⁹³ While the initial lack of competition may have contributed in part to the sudden ratchet in Daraprim's price, the subsequent introduction of an alternative to the drug did not have the curative effect that would support the solution proposed by advocates of the reduced competition theory.⁹⁴

In contrast to Daraprim, EpiPen experienced a sudden price hike despite existing competition in the market. The price of EpiPen was ratcheted from \$103.50 for a two-pack of injectors in 2009 to \$608.61 in 2016.⁹⁵ At that time, EpiPen's generic competitor, Adrenaclick, provided a lower-cost alternative to the brand name.⁹⁶ Adrenaclick has been declared safe by the FDA, is sold in pharmacies nationwide, and is priced at a third of the cost of EpiPen.⁹⁷ While the injection device is built differently,⁹⁸ Adrenaclick contains the same exact dose of epinephrine as EpiPen.⁹⁹ Adrenaclick's earliest version became

⁹³ Court, *supra* note 83; see also Carolyn Y. Johnson, *What Happened to the \$750 Pill that Catapulted Martin Shkreli to Infamy*, WASH. POST (Aug. 1, 2017) ("That drug, called Daraprim, went from \$13.50 a pill to \$750 a pill in the summer of 2015. Now that the outrage over access to that lifesaving medicine has died, guess how much the pill costs? \$750."). Turing did halve the price of Daraprim for hospitals to \$375, see Court, *supra* note 83, but this was in response to public outrage, rather than increased competition. Shkreli also stated that he would readily raise drug prices again. Nikita Vladimirov, *Shkreli: 'Of Course' I'd Raise Drug Price Again*, HILL (Dec. 23, 2016, 12:20 PM), <http://thehill.com/policy/healthcare/311665-shkreli-reflects-on-his-decision-to-increase-drug-prices>.

⁹⁴ To understand why this may be the case, see *infra* text accompanying note 109 and Section II.B, discussing how compounded drug alternatives are not likely to successfully resolve problems of ratcheting drug prices. This is not to say that compounded drugs cannot or do not act as adequate competition for excessively priced drugs. See, e.g., Benjamin J. Barenberg, Taryn Smith & Mikio A. Nihira, *Compounded Estradiol Cream: A Cost Conscious Alternative*, 107(4) J. OKLA. ST. MED. ASS'N 155, 155–56 (2014) (finding that compounded estrogen is a cost effective alternative to branded versions of vaginal estrogen). Thus, under the basic premise of the reduced competition theory, compounded drug alternatives should bring high drug prices down. The fact that it did not in the case of Imprimis's alternative to Daraprim thereby suggests that this theory does not account for all of the complexities involved in the pricing and marketing of pharmaceuticals.

⁹⁵ Mylan CEO on EpiPen Drug Price Controversy: "I Get the Outrage," ONE WORLD NEWS SERVICE (Jan. 27, 2017), <http://oneworldnewsservice.com/mylan-ceo-on-epipen-drug-price-controversy-i-get-the-outrage/>.

⁹⁶ Katie Thomas, *Why the Lone EpiPen Competitor Hasn't Taken Off*, N.Y. TIMES (Nov. 1, 2016), <http://www.nytimes.com/2016/11/02/business/also-ran-to-epipen-reaches-for-a-closing-window-of-opportunity.html>.

⁹⁷ *Id.*

⁹⁸ Compared to the EpiPen injector, which has one cap to remove, *id.*, the Adrenaclick injector has two. *How to Use Adrenaclick (Epinephrine Injection, USP Auto-injector)*, ADRENACLICK, http://adrenaclick.com/how_to_use_adrenaclick_epinephrine_injection_USP_auto_injector.php (last visited June 24, 2017) (instructions for use).

⁹⁹ Both EpiPen and Adrenaclick contain 0.3 mg of epinephrine per dose, and offer an injector with a smaller dose of 0.15 mg for younger children. Sharon Orange, *EpiPen vs Adrenaclick: You Have Options*, GOODRX (Aug. 25, 2016, 10:45 AM), <https://www.goodrx.com/blog/epipen-vs-adrenaclick-you-have-options/>.

available in 2003,¹⁰⁰ and has competed with EpiPen in the market for epinephrine auto-injectors.¹⁰¹ Yet, notwithstanding the outrage over EpiPen's increased cost, few people have turned to Adrenaclick.¹⁰² Because existing competition did not stop the price hike in this case, the notion that simply introducing more competitors into the market would have any effect on the cost of EpiPen is speculative.

Lastly, Doxycycline—an off-patent drug that recently faced an exorbitant price increase—is a broad-spectrum antibacterial antibiotic that fills over eleven million prescriptions per year.¹⁰³ In October 2013, the cost of Doxycycline hyclate antibiotic was \$20 per bottle, but by April 2014, the price was ratcheted to \$1849 per bottle.¹⁰⁴ Similar to the ratcheting event in the EpiPen example, this price increase of more than 9000% was not caused by a lack of competition. While the major alternative to Doxycycline is Penicillin,¹⁰⁵ which is widely used and mass produced,¹⁰⁶ there are also many other alternatives specific to the condition that Doxycycline is being used to treat. For example, consumers using Doxycycline to treat acne may use Clindamycin, Tetracycline, Minocycline, Lymecycline, TMP-SMX, Erythromycin, and Azithromycin.¹⁰⁷ For pneumonia, consumers may alternatively use Azithromycin, Clarithromycin, Amoxicillin, or Erythromycin.¹⁰⁸ Considering the presence of these alternatives in the market, the sudden surge in the price of Doxycycline cannot be explained by a lack of competition. Merely increasing competition, then, would not provide an obvious solution to price ratcheting in this context.

These examples illustrate that a lack of competition is not the sole cause of ratcheted drug prices and, more importantly, proposals that regard increasing competition as a panacea to price ratcheting do not account for the more complex reality. Thus, while competition may

¹⁰⁰ See Thomas, *supra* note 96 (explaining that Adrenaclick was sold as Twinject starting in 2003).

¹⁰¹ Sam Wood, *A Cheaper Way to Get Epinephrine Pen, If You Know How*, PHILLY.COM, <http://www.philly.com/philly/health/Theres-a-cheaper-way-to-get-an-epinephrine-pen---but-you-have-to-know-how.html> (last updated Aug. 31, 2016, 1:30 PM).

¹⁰² Thomas, *supra* note 96; see also Wood, *supra* note 101 (noting that Adrenaclick's share of the market has only grown from 2% in 2013 to 8% after EpiPen's price increase).

¹⁰³ *Drug Record: Doxycycline*, *supra* note 14.

¹⁰⁴ Rosenthal, *supra* note 13.

¹⁰⁵ *Doxycycline*, DRUGS.COM, <http://www.drugs.com/pro/doxycycline.html> (last visited Aug. 2, 2017).

¹⁰⁶ See *Penicillin*, ANTIBIOTICS (Dec. 2, 2005), <http://antibioticinformation.blogspot.com/2005/12/penicillin.html> (“Approximately 50 million kilograms [of penicillin] is produced world wide [sic] each year.”).

¹⁰⁷ *Antibiotics for Acne*, EMEDEXPERT, <http://www.emedexpert.com/conditions/acne.shtml> (last updated Apr. 7, 2017).

¹⁰⁸ *Community Acquired Pneumonia Guidelines*, MPR (Mar. 10, 2015), <http://www.empr.com/clinical-charts/coommunity-acquired-pneumonia-guidelines/article/321826/>.

contribute to the ratcheting problem, it is important to look at all factors in order to find an adequate solution. The problem is more complex and often differs on a case-by-case basis. Sometimes high prices are due primarily to little or no existing competition, but frequently, ratcheting events are caused by shortages in raw materials, other market fluctuations, or a combination of multiple factors.¹⁰⁹ Further, increasing competition does not simply “cure” high prices;¹¹⁰ many other considerations are involved, such as the safety of the product, familiarity with and trust in the brand name (brand loyalty), willingness of doctors to prescribe alternatives, and even basic awareness on the part of pharmacists and consumers that an alternative exists. While competition clearly has a part to play in whether these ratcheting events occur, creating more competition as a blanket “be-all and end-all” solution fails to address the multifaceted nature of this problem.

B. Increasing Competition Through Compounded Drugs: Food and Drug Modernization Act Section 352 and the Compounding Quality Act of 2013

Pharmacy compounding is “a practice in which a licensed pharmacist combines, mixes, or alters ingredients in response to a prescription to create a medication tailored to the medical needs of an individual patient.”¹¹¹ Compounding has been around for as long as medicine has been made. In the 1990s, compounding had a resurgence of popularity, which prompted Congress to enact the Food and Drug Modernization Act (FDAMA) exempting compounded drugs from FDA approval, allowing such drugs to enter the market without going through the tedious and expensive approval process that generics typically undergo.¹¹² Pharmacists began selling compounded drugs, often

¹⁰⁹ See *supra* notes 80–86 and accompanying text (discussing the many factors that can affect the price of pharmaceuticals).

¹¹⁰ *Contra* Stein & Valery, *supra* note 73, at 151 (calling competition the “antidote” to the high prices of prescription drugs); Brodwin, *supra* note 76 (asserting that increasing competition by relaxing import restrictions on generic drugs is a cure for rising drug prices).

¹¹¹ *The Special Risks of Pharmacy Compounding*, U.S. FOOD & DRUG ADMIN. (Dec. 3, 2012), <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm107836.htm>.

¹¹² See Food and Drug Administration Modernization Act of 1997 (FDAMA), Pub. L. No. 105-115, 111 Stat. 2328 (codified as amended at 21 U.S.C. § 353a(a) (2012)) (exempting compounded drugs from the FDCA’s “new drug” requirements and other requirements if the drug satisfies various given restrictions). FDAMA’s conditional exemption reads in part: “Sections 501(a)(2)(B) [adulteration provision], 502(f)(1) [misbranding provision], and 505 [new drug approval provision] shall not apply to a drug product if the drug product is compounded for an identified individual patient . . . [and] approved by the prescribing practitioner . . . if the drug product meets the requirements of

promoting them as “more effective alternatives to commercially available drugs.”¹¹³ While the most common compounded products are gels, creams, suppositories, and oral suspensions,¹¹⁴ it might be a good idea to counter high drug prices by making a compounded tablet drug alternative. Compounding drugs would offer a quick and inexpensive solution to drug price ratcheting since the drug could get to market without undergoing the timely and costly procedures that the FDA requires of a generic drug.¹¹⁵ In fact, this idea has already materialized, which brings us back to Imprimis’s Daraprim alternative. Imprimis is taking the compound pyrimethamine from Daraprim and combining it with another compound, leucovorin.¹¹⁶ Accordingly, Imprimis’s compounded drug does not require FDA approval to enter the market.¹¹⁷ This also means that the quality of Imprimis’s drug does not ensure its safety or its efficacy in treating toxoplasmosis, unlike an FDA-approved drug like Daraprim.¹¹⁸

Further, the Supreme Court declared in *Thompson v. Western States Medical Center*¹¹⁹ that certain provisions of FDAMA were unconstitutional.¹²⁰ There is now a circuit split as to whether the unconstitutional provisions are severable from the residual compounding provisions of FDAMA, and thus whether FDAMA is still at

this section . . .” *Id.* (emphasis added). Courts typically look at this to mean that FDAMA creates a safe harbor for compounded drugs from FDA approval requirements. *See, e.g., Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 394, 405 (5th Cir. 2008) (applying the *Chevron* analysis and finding that the statutory scheme of FDAMA created an exemption for compounded drugs, on the basis that they are “new drugs” which do not need to undergo the approval requirements if they comply with the conditions set forth in section 353(a) of the Act). For a discussion on the generic approval process, see *supra* Section I.B.2, note 38 and accompanying text.

¹¹³ Jesse M. Boodoo, Note and Comment, *Compounding Problems and Compounding Confusion: Federal Regulation of Compounded Drug Products and the FDAMA Circuit Split*, 36 AM. J.L. & MED. 220, 222 (2010).

¹¹⁴ *Id.* at 223.

¹¹⁵ For a discussion of the FDA approval process for generic drugs, see *supra* Section I.B.2, note 38 and accompanying text.

¹¹⁶ *See* Nathan Bomey, *Drug Company Attempts \$1 Alternative to Daraprim*, USA TODAY (Oct. 23, 2015, 10:03 AM), <http://www.usatoday.com/story/money/2015/10/23/imprimis-pharmaceuticals-turing-pharmaceuticals-daraprim/74452030/> (“The Imprimis oral capsules . . . are customized formulations of its pyrimethamine and leucovorin treatments.”).

¹¹⁷ *See id.* (“To be sure, the FDA has not approved Imprimis’s compounded drug formulations as a recommended treatment for toxoplasmosis.”).

¹¹⁸ The FDA requires that all generic drugs, like all other new drugs, be safe and effective. 21 U.S.C. § 355(a) (2012). Accordingly, a drug that goes through the generic approval system has been heavily tested and has proven that it will have the desired result with a low likelihood of adverse effects. *See also supra* note 57.

¹¹⁹ 535 U.S. 357 (2002).

¹²⁰ *Id.* at 377.

least partially valid.¹²¹ For this reason, pharmacy compounding does not currently offer an appropriate solution to price ratcheting because it is unclear how the FDA will enforce compounding practices until Congress passes new legislation.

The fact that Imprimis's alternative is a compounded drug rather than an FDA-approved drug may explain why Turing has not responded to this competitor drug.¹²² First, compounded drugs are meant to act as an individualized treatment, not a general drug for all affected people alike.¹²³ Second, there have been a large number of instances where compounded drugs have endangered public health, which is possible with these drugs since they do not have to go through the rigorous safety testing that other new drugs do. Critics of compounded drugs call them "dangerous concoctions" that can cause a range of problems such as meningitis, eye infections, erectile dysfunction, priapism, and many other complications.¹²⁴ This is likely due to errors in mixing, calculation, and selection of ingredients when compounding, as well as contamination that can occur from insanitary mixing techniques.¹²⁵ Notably, the "FDA has identified insanitary conditions at many of the facilities that it has inspected," and yet the "FDA does not inspect the vast majority of compounding facilities in the United States" since most facilities do not register with the FDA unless they elect to become outsourcing facilities.¹²⁶ Assuming that facilities *not* subject to FDA inspection are also likely to compound drugs under insanitary conditions, the safety of compounded drugs is highly questionable. Thus, even if the public sees the value and importance of compounding, just as the majority did in *Western States Med-*

¹²¹ *Compare* Med. Ctr. Pharmacy v. Mukasey, 536 F.3d 383, 383 (5th Cir. 2008) (holding that the provisions found unconstitutional in *Western States Medical Center* are severable from the compounding provisions of FDAMA, and thus declaring that federal compounding laws are still alive and well), *with* W. States Med. Ctr. v. Shalala, 238 F.3d 1090, 1097–98 (9th Cir. 2001) (holding that the provisions found unconstitutional in *Western States Medical Center* are not severable from the compounding provisions of FDAMA, and thus declaring that federal compounding laws are invalid and dead).

¹²² See *supra* note 93 and accompanying text (explaining that Daraprim still costs \$750, even after Imprimis began offering a \$1 compounded drug alternative).

¹²³ See *The Special Risks of Pharmacy Compounding*, *supra* note 111, at 1 (explaining that pharmacy compounding is meant to create a medication tailored to the medical needs of an individual patient).

¹²⁴ See Rebecca Porter, *Compounded Drugs Are Dangerous Concoctions, Critics Say*, TRIAL, May 2007, at 14 ("By 2004, the FDA had collected at least 200 reports of adverse reactions to compounded drugs, and an agency study that year showed that one-third of compounded drugs failed to meet basic standards of quality.").

¹²⁵ *Id.*

¹²⁶ Insanitary Conditions at Compounding Facilities; Draft Guidance for Industry; Availability, 81 Fed. Reg. 51,449, 51,450 (Aug. 4, 2016).

ical Center,¹²⁷ the reality lies in accord with the dissenters' skepticism about the dangers of compounding practices.¹²⁸

The reason that the FDA currently allows compounding is that the FDA only has authority over pharmaceutical manufacturers, not pharmacies which simply combine drugs.¹²⁹ But many wrongful death and negligence claims have been filed across the country against compounding pharmacies.¹³⁰ Thus, doctors and consumers alike may be wary, and rightfully so, when faced with the option of turning to a compounded drug, and decide instead to stay loyal to the generic drug, despite its new outrageous cost.

In 2013, Congress passed the Compounding Quality Act,¹³¹ which requires that an outsourcing facility of compounded drugs comply with certain conditions and raises the standard of reporting information about the products it compounds and adverse events that occur in order to qualify for exemption from FDA approval. Congress is very concerned about "assur[ing] the safety of compounded drugs."¹³² Congress's concern with increasing the quality of compounded drugs

¹²⁷ See *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360–61, 376–77 (2002) (noting that compounding allows a doctor or pharmacist to tailor a medication to an individual patient's needs).

¹²⁸ See *id.* at 382–83 (Breyer, J., dissenting) ("[C]omounding is not necessarily a matter of changing a drug's flavor but rather it is a matter of combining different ingredients in new, untested ways," where "the risks associated with the untested combination of ingredients or the quicker absorption rate or the working conditions necessary to change an old drug into its new form can, for some patients, mean infection, serious side effects, or even death." (internal citations omitted)).

¹²⁹ See 21 U.S.C. § 353(a) (Supp. III 2015) (granting the FDA limited authority over pharmacy operations).

¹³⁰ See, e.g., *Batiste v. Am. Home Prods. Corp.*, 231 S.E.2d 269, 273–74 (N.C. Ct. App. 1977) (holding that a pharmacist has a duty to act with "due, ordinary, care and diligence" in compounding and selling drugs); Jess Bidgood & Sabrina Tavernise, *Pharmacy Executives Face Murder Charges in Meningitis Deaths*, N.Y. TIMES, Dec. 18, 2014, at A25 (describing charges against compounding pharmacy executives for killing sixty-four individuals and sickening hundreds after an outbreak of fungal meningitis linked to an injectable steroid medication in fall of 2012); Andrew Pollack, *Avastin Injections Are Reported to Cause Blindness*, N.Y. TIMES, Aug. 31, 2011, at B3 (describing a suit against compounding pharmacies responsible for repackaging injections of Avastin that caused serious eye infections and blindness in August 2011). Pharmacies that compound drugs face potential liability on multiple counts. For example, a plaintiff harmed by an adulterated compounded drug can pursue action based on a negligence theory, or may also proceed based on a warranty theory, since the pharmacy is the one best able to take measures to prevent its contamination. See 27 FLORIDA JURISPRUDENCE: FOODS, DRUGS, AND COSMETICS § 114 (2d ed. 2017) (explaining the duty of a pharmacy filling compounded drug prescriptions).

¹³¹ Pub. L. No. 113-54, 127 Stat. 587 (2013) (codified as amended at 21 U.S.C. § 353(a)-(b) (Supp. III 2015)).

¹³² *Id.* § 107(a).

is well-founded; unfortunately, problems with compounded drugs have not stopped since the passing of the Act.¹³³

Because of the serious concerns raised about the safety and efficacy of compounded drugs and given that pharmacy compounding provisions are entirely invalid in some circuits, compounding does not currently present a workable means of introducing alternatives into the market to bring down ratcheted drug prices. A consumer who trusts a drug she has been using for years to treat her serious health issues will probably bear the higher costs in order to ensure her safety, rather than save money on a drug that could do more harm than good. If pharmacies begin performing more tests on compounded drugs, then compounding could be a viable remedy to high drug prices because compounded drugs are easy to make and can enter the market quickly. Until then, compounded drugs are unlikely to succeed as alternatives to high-priced drugs.

C. *Increasing Competition Through Generic Drugs: FDA MAPP Prioritization of ANDAs*

If the FDA approves a new drug as safe and effective, the drug can enter the market as a generic, thereby increasing competition in the market for the branded drug.¹³⁴ Aside from the time that bioequivalence testing takes,¹³⁵ there is a long waiting period for approval chiefly due to internal FDA backlog.¹³⁶ The Office of Generic Drugs (OGD) reviews and assesses all ANDAs.¹³⁷ Because of the nature of

¹³³ See, e.g., *Cantrell Drug Company Issues Voluntary Recall of Select Sterile Drug Products Due to Lack of Sterility Assurance*, U.S. FOOD & DRUG ADMIN. (Nov. 18, 2016), <https://www.fda.gov/Safety/Recalls/ucm529776.htm> (“Cantrell Drug Company is voluntarily recalling certain unexpired sterile drug products due to lack of sterility assurance.”); *Compounded Products by Reliable Drug Pharmacy: Recall - Potential for Mislabeling and Lack of Quality Assurance*, U.S. FOOD & DRUG ADMIN. (Mar. 28, 2016), <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm492677.htm> (“Reliable Drug Pharmacy is recalling all unexpired lots of compounded products due to concern of lack of quality assurance and potential mislabeling.”); *Isomeric Pharmacy Solutions Issues Voluntary Nationwide Recall of All Sterile Compounded Products*, U.S. FOOD & DRUG ADMIN. (Apr. 6, 2017), <https://www.fda.gov/Safety/Recalls/ucm551281.htm> (“Isomeric Pharmacy Solutions . . . is voluntarily recalling all lots of sterile products compounded and packaged by Isomeric and that remain within expiry to the hospital/user level because of the US Food and Drug Administration’s concerns of a lack of sterility assurance.”).

¹³⁴ See *supra* Section I.B.2 (discussing generic drugs and the FDA approval process).

¹³⁵ For further background on bioequivalence testing and standards, see *supra* note 5 and accompanying text, note 38, and text accompanying note 59.

¹³⁶ See *infra* note 138 (describing the backlog of ANDAs over time at the OGD).

¹³⁷ *Office of Generic Drugs*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm119100.htm> (last updated Feb. 27, 2017).

the review process, there is an increasing backlog of ANDAs.¹³⁸ Generic entries thus face serious barriers, especially if the generic is meant to offset a sudden drug price increase. A company that wants to introduce a new competitor to an existing drug whose price increased yesterday has to evaluate whether it is practical when its competitor will only enter the market many years in the future.

On March 11, 2016, the FDA updated a Manual of Policies and Procedures (MAPP), announcing that it will begin prioritizing ANDAs for generic submissions where there is only one manufacturer. The FDA stated that it will prioritize review of ANDAs for drugs without competition:

Submissions for drug products for which there is only one approved drug product listed in the Prescription Drug Product List (the “active section”) of FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations* (the “Orange Book”) and for which there are no blocking patents or exclusivities may receive expedited review, except where the approved drug product was approved pursuant to a suitability petition under section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act.¹³⁹

The new policy thus has the potential to speed up the FDA’s review of “sole-source” generic drugs—drug products with only one approved drug equivalent of a brand-name drug listed in the Prescription Drug Product List of the Orange Book.¹⁴⁰ Affording sole-source drugs “expedited review” essentially means that the OGD will determine which ANDA submissions will receive heightened review priority, either following a request from the applicant or at the OGD’s initiative.¹⁴¹

This initiative has been generally applauded thus far.¹⁴² Some commentators hope that the expedited review will provide pharmaceutical companies incentives for developing a generic competitor ver-

¹³⁸ Between 1984, when ANDAs were first introduced, and November 2002, the OGD maintained the backlog at a consistent level, leaving less than 100 ANDAs pending at any time. Bob Pollock, *The Backlog at OGD – a Historical Look*, LACHMAN CONSULTANTS (July 16, 2015), <http://www.lachmanconsultants.com/2015/07/the-backlog-at-ogd-a-historical-look/>. However, after that point, the backlog grew steadily each year, with over 1300 ANDAs pending by the end of 2006, and nearly 3000 by the end of 2012. *Id.* In 2014, the OGD received 1473 ANDAs, the greatest number of ANDAs up until that date, but only approved 409 that year. *Id.* In 2014, the backlog stood at nearly 4000 ANDAs. *Id.*

¹³⁹ U.S. FOOD & DRUG ADMIN., MAPP 5240.3 REV. 2, MANUAL OF POLICIES AND PROCEDURES, PRIORITIZATION OF THE REVIEW OF ORIGINAL ANDAS, AMENDMENTS, AND SUPPLEMENTS 6 (2016) [hereinafter MAPP 5240.3 REV. 2].

¹⁴⁰ *Id.*

¹⁴¹ *Id.* at 2.

¹⁴² See, e.g., Jeff Lagasse, *Healthcare Supply Chain Association Lauds FDA Prioritization of ‘Sole Source’ Generic Drug Applications*, HEALTHCARE FIN. (Mar. 22, 2016), <http://www.healthcarefinancenews.com/news/healthcare-supply-chain-association->

sion of off-patent, one-source drugs.¹⁴³ Further, the FDA estimates that the prioritization change could expedite as many as 125 ANDA submissions.¹⁴⁴ And in theory, the policy would directly support the commonly advanced solution discussed in Section I.C, namely, to increase competition with FDA-approved, and therefore safe and effective, drugs. In actuality, however, this initiative is unlikely to be the miracle solution to high drug prices. Firstly, performing bioequivalence testing and applying for an ANDA will still cost the same amount, acting as the first barrier to enter the market—pharmaceutical companies that do not think that the overall return on investment will be economically justified will still be deterred from producing a competitor drug. Secondly, potential competitors are unlikely to actually manufacture a generic and submit the ANDA, even with prioritized review, because once their competitor drug enters the market, there is little stopping the original sole-source drug company from simply lowering prices right back down to market and destroying the competitor's return on investment. There is thus no real incentive to capture the market because the earlier drug will continue to occupy that space.

The FDA's new policy on sole-source drugs is not the first time that the FDA has updated its prioritization procedures in recent years. In August 2014, the FDA also prioritized review for certain ANDA submissions.¹⁴⁵ Despite these theoretically positive developments, drug prices of certain drugs remain high, and others continue to increase.¹⁴⁶ While the FDA's prioritization effort is a positive develop-

lauds-fda-prioritization-sole-source-generic-drug (describing praise of FDA's prioritization decision by the President and CEO of Healthcare Supply Chain Association).

¹⁴³ See Jiazhong Luo & Jordana A. Garellek, *Benefits of Expedited Review of Sole-Source Drug ANDAs*, LAW360 (Apr. 22, 2016, 9:43 AM), <https://www.law360.com/articles/787070/benefits-of-expedited-review-of-sole-source-drug-andas>.

¹⁴⁴ Anna Edney, *Shkreli's Strategy to Jack Up Drug Prices May Be Curbed by FDA*, BLOOMBERG (Mar. 14, 2016, 4:51 PM), <http://www.bloomberg.com/news/articles/2016-03-14/shkreli-s-strategy-to-jack-up-drug-prices-may-be-curbed-by-fda>.

¹⁴⁵ The FDA prioritized review for generics that are: (1) potential first generic products for which there are no blocking patents or exclusivities on the reference listed drug; (2) related to drug shortages; (3) subject to special review programs; (4) related to public health emergencies; (5) related to certain government purchasing programs, including expiration-date extensions on packaging changes usually requested by the government-wide quality assurance program; (6) subject to statutory mandates or other legal requirements; and (7) need expedited review due to public health reasons or if delay would impose an extraordinary hardship on the applicant. MAPP 5240.3 REV. 2, *supra* note 139, at 3–5.

¹⁴⁶ See also Katie Thomas, *Drug Prices Keep Rising Despite Intense Criticism*, N.Y. TIMES (Apr. 26, 2016), <https://www.nytimes.com/2016/04/27/business/drug-prices-keep-rising-despite-intense-criticism.html> (showing that the trend of increasing drug prices is continuing, despite legislative scrutiny and public criticism).

ment that hopefully will in fact incentivize at least some generic companies to produce competitor versions of off-patent, sole-source drugs, it is unlikely to solve price ratcheting entirely.

III

REFRAMING THE PROBLEM: WHAT'S ALL THIS RATCHET?

While reduced competition is seemingly implicated in many ratcheted drug pricing scenarios, focusing solely on competition constructs an overly broad and simplistic view of the problem. This Part compiles data on a small subset of drugs that have ratcheted in price in recent years in order to understand the competitive landscape for each of these drugs and explore other factors that affect price. The analysis of the data suggests that it would be more effective to classify ratcheting events into two categories: (1) those that occur as a result of natural deviations in the market, and (2) those that occur due to business tactics that take advantage of vulnerabilities in the market. It appears that increasing competition would not influence the drug prices in category (1), but a competition-based solution would be more effective in lowering current prices and deterring future ratcheting events in category (2)—situations where there is anticompetitive behavior.

A. *Data on Off-Patent Drugs and Price Ratcheting*

1. *Selection Criteria*

In order to construct a framework to illustrate the core of the ratcheting problem, this Section compiles data on a selection of off-patent drugs without market exclusivity that have undergone price increases of at least 200% since 2013 or later. Although this is not a comprehensive list of all drugs that have ratcheted in price during this timeframe,¹⁴⁷ it includes as a sample the following fourteen pharmaceuticals: Doxycycline, Tetracycline, Daraprim, Albuterol, Vasopressin, Clomipramine, Cuprimine, Cycloserine, Syprine, Dutoprol, Isuprel, Simvastatin, EpiPen, and Nitropress. These drugs were specifically selected because they are not protected by a living patent (either the patent expired or there was no patent protection in the first place) and have been subject to significant media attention,

¹⁴⁷ This is not an exhaustive list of all drugs that have increased by 200% or more since 2013, but is rather a select list of drugs with ample data to draw conclusions across columns. The drugs were derived from media sources that acknowledged recent hikes in the drugs' prices, but other drugs that did not gain any media attention or did not report the percentage increase and/or have any information surrounding the price-ratcheting event were excluded.

highlighted in news articles between 2013 and 2017. Drugs whose price increased by less than 200% were categorically excluded on the basis that the price increase was too low to make accurate predictions, though future studies may wish to include drugs such as Flucytosine, which faced an increase in price of 189%. Other drugs were excluded if accurate pricing information was difficult to obtain or verify. These include Glumetza (estimated increase of 1018%), Zonegran (estimated increase of 567%), and Nephrocaps (estimated increase of 521%).

2. Data Compilation

After narrowing the sample size to fourteen off-patent drugs, each drug was categorized as either a generic or brand-name drug, and assessed for general usage, current ownership of the drug, price before and after it was ratcheted, and the resulting percentage increase. The analysis also took into account what, if any, known events surrounded the price increase. Future research should gather data on a more comprehensive list of drugs that have ratcheted in price. The ability to distinguish amongst the subset of drugs subjected to price ratcheting will target a specific group of contentiously priced drugs, without swamping the system or focusing on broad categories that include a large number of drugs, as discussed in Section III.C.

TABLE 1. FOURTEEN OFF-PATENT PHARMACEUTICALS THAT WERE RECENTLY RATCHETED IN PRICE

Drug	Generic or Brand?	Use	Current Owner of Drug	Price Before Ratchet (\$/bottle)	Ratcheted Price (\$/bottle)	Percent Increase (%)	Events Surrounding Price Increase
Doxycycline	Generic	Antibiotic	Multiple	20	1849	9145	Shortages
Tetracycline	Generic	Antibiotic	Multiple	0.06	4.60	7567	Shortages; Reduced Competition
Daraprim	Brand	Toxoplasmosis	Turing	13.5	750	5456	Acquisition
Albuterol	Generic	Asthma	Multiple	11	434	3845	Reduced Competition
Vasopressin	Generic	Diabetes; Heart	Multiple	2.25	85.64	3706	Shortages; Consolidations
Clomipramine	Generic	Antidepressant	Mallinckrodt	0.22	8.32	3682	Shortages
Cuprimine	Brand	Wilson's disease; Cysturia; Severe Arthritis	Valeant	888	26,189	2849	Acquisition
Cycloserine	Generic	Tuberculosis	Rodelis	500	10,800	2060	Acquisition
Syprine	Brand	Wilson's disease	Valeant	1395	21,267	1425	Acquisition
Dutoprol	Brand	Heart	AstreZeneca	0.52	5.26	912	Acquisition
Isuprel	Brand	Heart	Valeant	4489	36,811	720	Acquisition
Simvastatin	Generic	Cholesterol	Merck & Co.	N/A	N/A	650+	Unknown
EpiPen	Brand	Allergies	Mylan	103.50	608.61	488	Acquisition
Nitropress	Brand	Heart	Valeant	257.8	805.61	212	Acquisition

3. *Data Summary and Analysis*

Although the sample size of the drugs evaluated is small, some basic findings were made based on the data at hand. Of the fourteen pharmaceuticals analyzed, seven were generic drugs and seven were brand-name drugs. None of the analyzed drugs were protected by a patent. This suggests that both generic and off-patent brand-name drugs can experience extreme price increases. Interestingly, the generic drugs in the sample account for the larger percentage increases of more than 2000% (aside from Simvastatin), and brand-name drugs show lower percentage increases of less than 3000% (aside from Daraprim). Of the drug prices that were ratcheted following drug shortages,¹⁴⁸ only two increased in price after events that reduced competition, such as company consolidations.¹⁴⁹ Eight of the drugs had price hikes following acquisition by their current owner. No information was found regarding Simvastatin's increase in price.

Inferences can be drawn when looking at the data in regards to the competitive landscape at the time of the price ratchet. For example, at the time that Doxycycline, Tetracycline, Vasopressin, and Clomipramine were ratcheted in price, viable alternatives were present for each of these drugs.¹⁵⁰ The existence of alternatives in these

¹⁴⁸ See *Doxycycline Shortage*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/std/treatment/drugnotices/doxycyclineshortage.htm> (last visited Aug. 30, 2017) (reporting a Doxycycline shortage from January to October 2013 and Tetracycline shortage from February 2013 to March 2014); *Tees, Esk and Wear Valleys*, NHS (Mar. 27, 2014), <http://www.valeofyorkccg.nhs.uk/rss/data/uploads/drugs-a-z/clomipramine-final.pdf> (warning of a Clomipramine shortage in the United Kingdom in March 2014); *Vasopressin Injection*, AM. SOC'Y HEALTH-SYS. PHARMACISTS (May 13, 2015) <https://www.ashp.org/drug-shortages/current-shortages/Drug-Shortage-Detail.aspx?id=795> (documenting a Vasopressin shortage in May 2015).

¹⁴⁹ Note that Tetracycline's price increase is attributed both to shortages and reduced competition and thus is counted twice in the analysis of this data.

¹⁵⁰ At the time that Doxycycline was ratcheted in price from \$20 for a bottle of 500 tablets in October 2013 to \$1849 per bottle by April 2014, Rosenthal, *supra* note 13, comparable medications used for similar purposes were widely available to the public, including Amoxicillin, Sulfamethoxazole, Ciprofloxacin, Clindamycin phosphate, Cephalexin, Levofloxacin, Penicillin and Azithromycin. *Vibramycin Alternatives*, IODINE, <http://www.iodine.com/drug/doxycycline/alternatives> (last visited Feb. 24, 2017). At the time that the 250-milligram pill of Tetracycline was ratcheted in price from 6¢ in 2013 to \$4.60 in 2015, Priyanka Dayal McCluskey, *As Competition Wanes, Prices for Generics Skyrocket*, BOS. GLOBE (Nov. 6, 2015), <https://www.bostonglobe.com/business/2015/11/06/generic-drug-price-increases-alarm-insurers-providers-and-consumers/H3iA9CSxAUyInCdGjLNKVN/story.html>, comparable medications used for similar purposes were widely available to the public, including Erythromycin, Amoxicillin, Benzoyl peroxide, Clindamycin, Minocycline, Doxycycline, Azithromycin, and Ciprofloxacin. *Acnecycline Alternatives*, IODINE, <http://www.iodine.com/drug/tetracycline/alternatives> (last visited Feb. 24, 2017). When Vasopressin's cost rose from \$2.25 to \$85.64 in 2015, Jennifer Parks, *Phoebe Putney Memorial Hospital Board Approves Fee Increase*, ALBANY HERALD (Aug. 4, 2015), <http://www.albanyherald.com/news/phoebe-putney-memorial-hospital-board->

cases suggests that the price hikes were caused purely by their shortages in raw materials at that time, not by a lack of competition. Albuterol is the only drug analyzed that was ratcheted in price following reduced competition, which was caused by the FDA ban on albuterol CFC-based inhalers, leaving albuterol HFA-based inhalers competition-free.¹⁵¹ Thus, reduced competition for this drug can be recharacterized as an effect of regulatory changes. For drugs that were acquired shortly before being ratcheted in price, in contrast, most of the drugs analyzed were branded drugs that did not compete with any generic substitutes, and market alternatives were unsuitable to supplant the brand.¹⁵² EpiPen and Dutoprol were exceptions in this case; both had viable alternatives available when their prices were ratcheted.¹⁵³ In sum, of the drugs analyzed, all four drugs that experienced

approves-fee-increase/article_88cf84ff-4aae-518b-ae43-8f4fde990b7b.html, the American Society of Health-System Pharmacists published a table listing alternatives in specific situations. See *Table 1. Alternatives to Vasopressin in Selected Situations*, AM. SOC'Y HEALTH-SYS. PHARMACISTS, <https://web.archive.org/web/20161021112238/http://www.ashp.org/DocLibrary/Policy/DrugShortages/VasopressinCurrentexpanded-posting060711.aspx> (last visited July 9, 2017). Additionally, Clomipramine is the generic equivalent to the branded antidepressant, Anafril, Lazarus, *supra* note 83, yet Clomipramine's price was ratcheted from 22¢ per pill to \$8.32. Jonathan D. Alpern et al., *High-Cost Generic Drugs: Implications for Patients and Policymakers*, 371 NEW ENGL. J. MED. 1859, 1860 (2014).

¹⁵¹ See Alexander Gaffney, *FDA Ban on CFCs in Asthma Inhalers Raised Costs for Patients, New Study Finds*, REG. AFF. PROF. SOC'Y (May 11, 2015), <http://www.raps.org/Regulatory-Focus/News/2015/05/11/22139/FDA-Ban-on-CFCs-in-Asthma-Inhalers-Raised-Costs-for-Patients-New-Study-Finds/> (explaining how the FDA ban on CFC-based inhalers paved the way for ratcheting the price of HFA-based inhalers).

¹⁵² There is no generic equivalent of Daraprim, and though the guidelines for toxoplasmosis treatment currently advise Trimethoprim-sulfamethoxazole as an alternative, *Guidelines for Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents*, NAT'L INST. HEALTH B-2 to B-3, https://aidsinfo.nih.gov/contentfiles/lvguidelines/adult_oi.pdf (last updated May 18, 2017), alternative therapies may not work as well. See Pollack, *supra* note 1 ("There are alternative treatments [to Daraprim], but there is less data supporting their efficacy."). Similarly, there are no generic substitutes for Isuprel, Nitropress, or Cuprimine. See *Is There a Cure for High Drug Prices?*, *supra* note 23 ("In all three cases, the drugs had no generic equivalents available . . ."); see also Carolyn Y. Johnson, *High Prices Make Once-Neglected 'Orphan' Drugs a Booming Business*, WASH. POST (Aug. 4, 2016), https://www.washingtonpost.com/business/economy/high-prices-make-once-neglected-orphan-drugs-a-booming-business/2016/08/04/539d0968-1e10-11e6-9c81-4be1c14fb8c8_story.html?utm_term=.30a6b7a4f041 (explaining that Syprine, a drug that treats a rare disease, is an "orphan" product affecting so few patients that it is not subject to the typical pressures that bring down prices). Cycloserine, the generic version of Seromycin, is used to treat multidrug-resistant tuberculosis; there are only about ninety new cases each year in the United States. Andrew Pollack, *Big Price Increase for Tuberculosis Drug Is Rescinded*, N.Y. TIMES (Sept. 21, 2015), <https://www.nytimes.com/2015/09/22/business/big-price-increase-for-tb-drug-is-rescinded.html>.

¹⁵³ While there is no generic equivalent to EpiPen, alternative injectors such as Adrenaclick work just as well. See notes 96–102 and accompanying text. There are also at least five generic alternatives to Dutoprol. See *Generic Alternatives in Class*, BLUE SHIELD

shortages in raw materials had considerable competition when their prices were ratcheted, one drug's price increased due to a new regulation that reduced competition, and six out of the eight that were acquired shortly before their prices were ratcheted were specialty drugs with little or no competition in the market.

B. Differentiating Between Market Needs and Unfair Business Tactics

The data in Section III.A suggest that recent increases in the prices of off-patent drugs pose a multifaceted problem. Contrary to the popular conception that lack of competition in the market is entirely responsible for sudden price hikes,¹⁵⁴ limited competition is not the only driving force for ratcheting drug prices in all cases. In order to address the varying causes of price ratcheting, it is useful to separate these events into two categories: (1) those resulting from naturally occurring deviations in market resources, and (2) those ensuing from conduct exploiting a lack of or reduction in competition. This Section addresses how the drugs analyzed fit into these two categories.

As illustrated by the sample of drugs surveyed above, some price surges appear to follow shortages of raw materials. A shortage occurs when demand for a product is higher than the available supply of that market. When there is a shortage of a raw material necessary to manufacture a certain drug, the price of that drug will rise because the inputs for production are higher and thus to maintain profit margins, the extra cost is passed onto consumers. Note, however, that shortages do not occur often.¹⁵⁵ When they do happen though, the shortages could be caused by a multitude of factors. A common reason production becomes limited is due to manufacturing and quality control issues.¹⁵⁶ Unfortunately, shortages of raw materials occur in any given market. In a normal-functioning market, a company should respond to shortages by increasing the price of its product so that it can expand the necessary supply and return to a state where it meets demand. It is

CAL., https://www.blueshieldca.com/bzca/pharmacy/formulary/generic-alternatives-in-class.sp?url=%2Fpharmacy%2Fformulary%2Fsearch-drug-class.sp&stype=D_class&drugId=159118&name=Dutoprol&conditionId=&letter=&search_text=beta-adrenergic+agents&firstItem=10&sortOrder=0 (last visited July 9, 2017) (listing generic alternatives in class for Dutoprol).

¹⁵⁴ See *supra* notes 73–77, 80 and accompanying text.

¹⁵⁵ See OFFICE OF THE ASSISTANT SEC'Y FOR PLANNING & EVALUATION, DEP'T OF HEALTH & HUMAN SERVS., *ECONOMIC ANALYSIS OF THE CAUSES OF DRUG SHORTAGES* 3 (2011) (“A very small minority of all drugs used in the United States (typically about 1/2 of 1%) experience a shortage in any given year.”).

¹⁵⁶ Nancy Ferrari, *How Drug Shortages Happen*, HARV. HEALTH BLOG (Feb. 17, 2012, 9:52 AM), <http://www.health.harvard.edu/blog/how-drug-shortages-happen-201202174276>.

thus healthy for a pharmaceutical company to ratchet the price of its drug in the face of temporary shortages, given that it brings the price back down in time.¹⁵⁷ Therefore, there is no additional solution—particularly one focused on increasing competition—necessary to address this first category of ratcheting.¹⁵⁸

Ratcheting events that fall into the second category, however, cannot be tied to normal market conditions. Interestingly, for more than half of the drugs analyzed, a new pharmaceutical company acquired the drug shortly before it increased in cost. Here, a lack of or reduction in competition for the existing drug plays a significant role in the ratcheting of these drugs' prices. It appears that pharmaceutical companies are specifically acquiring a pharmaceutical *because* it has little or no competition, or raising its drug's price because competition was reduced. These pharmaceutical companies seem to be using their position in the market to exploit consumers.

Conduct that exploits consumers must be controlled. Pharmaceutical mergers and acquisitions are becoming extremely popular.¹⁵⁹ A company often acquires a drug, or many drugs, in order to maintain sustainable growth, because a diversified drug portfolio expands a company's overall capabilities and growth.¹⁶⁰ But when a company acquires a drug with little or no competition and sharply raises its price, it exploits its monopoly power to force high prices on patients, many of whom can no longer afford their medications and are left without recourse. Potential solutions to sudden price ratcheting should thus focus on price hikes following a specialty drug's acquisition or sudden reduction in competition, which fall within the second category.

¹⁵⁷ Prices do typically decrease when the shortage abates. *See, e.g.*, Eric Palmer, *Hikma Profits Soften as Shortages of Doxycycline Are Resolved*, FIERCEPHARMA (Mar. 12, 2015, 10:13 AM), <http://www.fiercepharma.com/manufacturing/hikma-profits-soften-as-shortages-of-doxycycline-are-resolved> (documenting a decrease in Doxycycline's price when the shortage came to an end).

¹⁵⁸ Note that the FDA also attempts to help situations of shortages by expediting review of ANDA submissions where there is a drug shortage. *See supra* note 145 and accompanying text.

¹⁵⁹ *See* Michael Glasser, *New Acquisitions Show Pharmaceutical M&A Remaining Strong*, WESTLAW MERGERS & ACQUISITIONS DAILY BRIEFING, Jan. 13, 2015, 2015 WL 135188.

¹⁶⁰ *See* Matt Stroud, *Here's Why Mylan Is Spending \$9.9B on a Pharma Acquisition*, PITTSBURGH BUS. TIMES (Feb. 10, 2016, 6:44 PM), <http://www.bizjournals.com/pittsburgh/blog/the-pulse/2016/02/heres-why-mylan-spent-9-9b-on-a-pharma-acquisition.html> (explaining the philosophy that making acquisitions thereby expanding a company's portfolio of both branded and generic drugs creates significant opportunities for accelerated growth).

C. *Regulating Drug Prices with Antitrust Law: Sherman Act Section 2 and FTC Section 5*

This Note recommends that the federal government address price hikes of off-patent pharmaceuticals in the second category¹⁶¹ by using the antitrust laws, the principal goal of which is to “protect consumers against the charging of excessive prices.”¹⁶² The government could bring antitrust actions against offending pharmaceutical companies responsible for purposefully ratcheting prices of drugs. In the past, federal courts have been reluctant to address excessive pharmaceutical prices under antitrust law, drawing on the notion that “antitrust enforcement makes mistakes more often than it helps correct market failures,”¹⁶³ thus concluding that the market should correct itself and keep prices at competitive levels.¹⁶⁴ The presumption is that, when producers charge prices high above marginal cost, new competitors will enter the market with a lower cost alternative, forcing the incumbent producer to lower its price, thus improving the market’s efficiency. This fails, however, in situations where the market does not in fact attract newcomers and thereby never self-corrects. Thus, antitrust law may be newly appropriate in the pharmaceutical context in situations where competition is lacking.

One potential way that antitrust law may be applied is for the Department of Justice (DOJ) to review single-firm conduct of pharmaceutical companies for use of monopoly power. Under section 2 of the Sherman Act (Section 2), it is a felony to “monopolize, or attempt to monopolize . . . any part of the trade or commerce among the several States.”¹⁶⁵ Section 2 can apply to all forms of single-firm unilateral conduct, covering a vast range of activities. The Supreme Court set forth the longstanding two-prong test for monopolization in *United States v. Grinnell Corp.*: A company must (1) possess monopoly power in the relevant market, and (2) engage in an exclusionary act—“the

¹⁶¹ See *supra* Section III.B.

¹⁶² Frederick M. Abbott, *Excessive Pharmaceutical Prices and Competition Law: Doctrinal Development to Protect Public Health*, 6 U.C. IRVINE L. REV. 281, 283 (2016).

¹⁶³ DAVID BALTO, CTR. FOR AM. PROGRESS, RESTORING TRUST IN ANTITRUST ENFORCEMENT 1 (2009); see also *Verizon Commc’ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004) (“The mere possession of monopoly power, and the concomitant charging of monopoly prices, is not only not unlawful, it is an important element of the free-market system.”).

¹⁶⁴ See Richard A. Posner, *The Chicago School of Antitrust Analysis*, 127 U. PA. L. REV. 925, 925–28, 932 (1979) (analyzing the Chicago School of antitrust economics, which praises economic efficiency and theorizes that markets can take care of themselves without the need for heavy regulation); see also Abbott, *supra* note 162, at 285–86 (noting that this philosophical market approach has affected recent federal court decisions to apply antitrust law to decide fair prices of drugs).

¹⁶⁵ 15 U.S.C. § 2 (2012).

willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.”¹⁶⁶ As to the first element, courts and agencies have identified important indicators of monopoly power, including the defendant’s market share and barriers to enter the market.¹⁶⁷ As to the second element, monopolization case law is centered on the question of when conduct is, or is not, exclusionary and does not focus on willfulness or intent, under the conception that all firms willfully acquire or maintain monopoly power.¹⁶⁸ The Court has held that whether conduct is “exclusionary” depends on “its impact on consumers and whether it has impaired competition in an unnecessarily restrictive way.”¹⁶⁹ Thus, if the company impairs consumer welfare without legitimate business justifications, the conduct is illegal under Section 2.

Ratcheting events within the second category occur as a result of a company using its “power to control prices or exclude competition”¹⁷⁰ in a way that harms consumers. This type of price ratcheting results from anticompetitive behavior in violation of Section 2. Using Daraprim as an example, the DOJ would show that Turing exercised monopoly power by ratcheting the price of Daraprim both directly, with the simultaneous increase of Daraprim’s price and reduction of its output to hospitals in order to fix the price above competitive levels, and indirectly, with evidence of Turing’s 100% share of the relevant market.¹⁷¹ Meanwhile, the hiked price of Daraprim harms consumers¹⁷² and is without legitimate business justifications.¹⁷³ Thus,

¹⁶⁶ *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966).

¹⁶⁷ *See, e.g., U.S. Anchor Mfg., Inc. v. Rule Indus., Inc.*, 7 F.3d 986, 999 (11th Cir. 1993) (“The principal measure of actual monopoly power is market share”); *Movie 1 & 2 v. United Artists Comm’ns, Inc.*, 909 F.2d 1245, 1254 (9th Cir. 1990) (“[M]arket share is perhaps the most important factor to consider in determining the presence or absence of monopoly power.”); *Weiss v. York Hosp.*, 745 F.2d 786, 827 (3d Cir. 1984) (“A primary criterion used to assess the existence of monopoly power is the defendant’s market share.”); 1 *AM. BAR ASS’N, ANTITRUST LAW DEVELOPMENTS* 231 (6th ed. 2007) (“A market share in excess of 70 percent generally establishes a prima facie case of monopoly power, at least with evidence of substantial barriers to entry and evidence that existing competitors could not expand output.”).

¹⁶⁸ Timothy J. Muris, *The FTC and the Law of Monopolization*, 67 *ANTITRUST L.J.* 693, 695 (2000).

¹⁶⁹ *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 605 (1985).

¹⁷⁰ *United States v. E.I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956).

¹⁷¹ *See* Michael A. Carrier et al., *Using Antitrust Law to Challenge Turing’s Daraprim Price Increase*, 31 *BERKELEY TECH. L.J.* 1379, 1386–89 (2017) (identifying direct and indirect proof of Turing’s monopoly power).

¹⁷² *See supra* notes 41–44 and accompanying text (discussing the problems that consumers face after sudden hikes in their drugs’ prices).

¹⁷³ *See supra* notes 32–36 (contending that the business justifications Turing put forth are illegitimate).

firms that ratchet drug prices in the second category could be held criminally liable for monopolization pursuant to the Sherman Act.

It may be difficult to persuade a court to apply Section 2 to the actions of pharmaceutical companies given that “it is black letter law that high [drug] prices, in themselves, are not a Section 2 violation.”¹⁷⁴ Moreover, since the Supreme Court’s announcement in *American Needle, Inc. v. National Football League*¹⁷⁵ that antitrust law should be applied “without chilling vigorous competition through ordinary business operations,”¹⁷⁶ the Court has been reluctant to find a single firm’s conduct violative of Section 2.¹⁷⁷ Although applying antitrust law in these cases would not “chill competition” since these drugs are ratcheted in price specifically because of a lack of competition, Section 2 may only be applied to firms that acquire or maintain monopoly power through improper means.¹⁷⁸ Because pharmaceutical companies are lawfully acquiring the rights to the drugs, their exclusionary conduct is unlikely to provide a cause of action under Section 2.

If Section 2 does not apply to firms ratcheting pharmaceutical prices, perhaps a more favorable result would occur under section 5 of the Federal Trade Commission Act (Section 5). Section 5 enables the FTC to bring administrative proceedings challenging “[u]nfair methods of competition in or affecting commerce.”¹⁷⁹ “Unfair” practices are those that “cause [] or [are] likely to cause *substantial injury* to consumers which is *not reasonably avoidable* by consumers themselves and *not outweighed by countervailing benefits* to consumers or to competition.”¹⁸⁰ Section 5, standing alone—as opposed to by way of challenging conduct that violates the Sherman Act and other anti-trust laws—could thus be used against the practice of raising a drug’s price subsequent to certain events that take advantage of low market

¹⁷⁴ Harry First, *Unfair Drug Prices and Section 5*, at 3 (NYU Ctr. for Law, Econ. & Org., Working Paper No. 16-03, 2015), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2699843.

¹⁷⁵ 560 U.S. 183 (2010).

¹⁷⁶ *Id.* at 190.

¹⁷⁷ *See, e.g.,* *Weyerhaeuser Co. v. Ross-Simmons Hardwood Lumber Co.*, 549 U.S. 312, 325 (2007) (noting the “serious” risk of “chilling procompetitive behavior with too lax a liability standard” for predatory bidding); *Verizon Commc’ns, Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 408, 414 (2004) (noting that the Supreme Court has “been very cautious” in applying Section 2 to unilateral refusals to avoid chilling desirable investment); *Spectrum Sports, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993) (noting that the Court has avoided construing Section 2 in ways that “might chill competition, rather than foster it”).

¹⁷⁸ U.S. DEP’T OF JUSTICE, COMPETITION AND MONOPOLY: SINGLE-FIRM CONDUCT UNDER SECTION 2 OF THE SHERMAN ACT 5 (2008) (“[S]ection 2 makes it illegal to acquire or maintain monopoly power through improper means.”).

¹⁷⁹ 15 U.S.C. § 45(b) (2012).

¹⁸⁰ *Id.* § 45(n) (emphasis added).

competition, such as acquisitions, in order to exploit consumers.¹⁸¹ By targeting this business strategy, the FTC can bring administrative proceedings specifically against those companies that abuse their dominant position in the market to exploit consumers, but not against those that raise prices in response to normal market forces.

Section 5 proceedings against such pharmaceutical companies are especially feasible considering the FTC's recent scrutiny of companies that imposed high prices in industries lacking competition. The FTC was especially concerned with firms raising licensing rates for standard-essential patents (SEPs)¹⁸² simply because consumer organizations had no choice but to license the patents.¹⁸³ For example, in 2008, the FTC charged that Negotiated Data Solutions LLC (N-Data) violated Section 5 when, despite its predecessor's commitment to charge a one-time licensing royalty of \$1000 to manufacturers or sellers of products using the standard, N-Data demanded substantially higher royalties from users after it acquired patent rights for autonegotiation technology.¹⁸⁴ The FTC asserted that this price-ratcheting conduct, where "there were no commercially viable alternative[s]" in the marketplace, was an "unfair method[] of competition" in violation of Section 5.¹⁸⁵ In this same light, the FTC could bring charges against pharmaceutical companies that acquire drug monopolies and then

¹⁸¹ See also First, *supra* note 174 (suggesting that it would be interesting for the FTC to take up a standalone Section 5 case against a pharmaceutical company that is taking advantage of market opportunities).

¹⁸² SEPs are patents that, *ex ante*, are considered dispensable because technology variants do not rely on them, but are necessary to comply with a technical standard. Josh Lerner & Jean Tirole, *Standard-Essential Patents*, 123 J. POL. ECON. 547, 548 (2015). Thus, companies in that industry must obtain licenses to all patents essential to complying with the given standard.

¹⁸³ The FTC's scrutiny of such cases began with *In re Dell Computer Corp.*, 121 F.T.C. 616 (1996), concerned with Dell's manipulation of the standard-setting process when Dell failed to disclose to the standard-setting organization that it had a patent on the standard that the organization was about to approve. Subsequent cases have focused on the conduct of patentees that committed themselves to licensing their SEPs on fair terms. See, e.g., *Motorola Mobility LLC & Google Inc.*, 156 F.T.C. 147 (2013).

¹⁸⁴ Complaint para. 28, *Negotiated Data Solutions LLC*, FTC File No. 051-0094, No. C-4234 (F.T.C. Sept. 22, 2008), <https://www.ftc.gov/sites/default/files/documents/cases/2008/09/080923ndscomplaint.pdf>.

¹⁸⁵ *Id.* at paras. 19, 38. The FTC eventually settled with N-Data, prohibiting it from enforcing its patents unless it first offered the standard organizations the patent license for \$1000. See Press Release, Fed. Trade Comm'n, *FTC Challenges Patent Holders Refusal to Meet Commitment to License Patents Covering 'Ethernet' Standard Used in Virtually All Personal Computers in U.S.* (Jan. 23, 2008), <https://www.ftc.gov/news-events/press-releases/2008/01/ftc-challenges-patent-holders-refusal-meet-commitment-license>. If the company to which the offer was made allowed the offer to lapse, however, then N-Data could initiate litigation but would also need to offer to settle for a payment of \$35,000. Neal R. Stoll & Shepard Goldfein, *Standards Setting: Hold-up or Fair Play?*, N.Y.L.J., Feb. 19, 2008, at 3, 8.

ratchet their prices as unfair methods of competition in violation of Section 5.

Certain ambiguities will have to be clarified if the FTC begins to scrutinize ratcheted drug prices under Section 5. For instance, it is unclear when a price hike would have to be made in relation to an anticompetitive act, such as acquisition, to classify as an unfair practice. Does the pharmaceutical company have to raise the drug's price the same day as the act? The same month? Year? Yet clarifying a time frame could pose a new challenge: What is to stop a company from waiting for some set time after acquiring a drug with no competitors on the market and raising the price later on? Pharmaceutical companies could ratchet drug prices just as before, only doing so slightly later in time to go undiscovered by the government. Additionally, it is unclear whether the effects of suddenly ratcheting drug prices amounts to "substantial injury" for Section 5 purposes, which could lead to inconsistent results in different suits. There could also be other legitimate reasons that a company acquiring a drug might need to raise prices shortly after an acquisition (e.g. shortages, economic inflation), and focusing on post-acquisition price hikes would overlook other companies that harm consumers by ratcheting a drug's price for which they have long held the rights to that drug. These are all issues that legislatures, courts, and agencies should resolve by clearly defining Section 5's boundaries in this context.

In conclusion, using the antitrust laws to target anticompetitive behavior poses a reasonable and immediate solution to ratcheting events. Further, if such actions were taken against current price-ratcheting behavior in the second category, it would set a precedent likely to have deterrent effects in the future. While courts may still be unwilling to use the Sherman Act against high drug prices, Section 5 may provide a readily available mechanism for the regulation of ratcheted prices.

CONCLUSION

The United States does not regulate the prices of pharmaceuticals—in fact, drug prices are intended to be high so that a company can recoup on its investments in R&D. But recent instances in which drug prices have skyrocketed by percentages in the hundreds, and even thousands, present a real economic and social problem. While the prevailing theory suggests that a lack of competition is at the heart of recent price hikes and that increasing competition would solve the problem, the situation is far more complex. Because competition only sometimes plays a role, neither compounded drug alternatives nor pri-

oritized review of ANDAs for sole-source drugs to bring competitors to the market more quickly presents a holistic solution to the problem. Extreme ratcheting of pharmaceutical prices can be directly tied to two different types of events: natural market deviations and exploitative actions. Framing the problem in this way, an effective solution would aim only to address price ratcheting when a pharmaceutical company takes advantage of little or no competition in the relevant market, not when ratcheting results from natural market changes, such as raw material shortages. In light of the two-category approach advanced in this Note, antitrust litigation claiming unfair methods of competition is perhaps the best way to target companies that exploit consumers, while allowing the market to correct price hikes unrelated to anticompetitive behavior.