



By Any Means Necessary

How Allergan Gamed the System to Raise Drug Prices and Flood the Country with Pills

Acknowledgments

This report was written by Zain Rizvi, law and policy researcher in Public Citizen's Access to Medicines Program. It was edited by Steve Knieval, advocate in the Access to Medicines Program, and Peter Maybarduk, director of the Access to Medicines Program.

About Public Citizen

Public Citizen is a national non-profit organization with more than 500,000 members and supporters. We represent consumer interests through lobbying, litigation, administrative advocacy, research, and public education on a broad range of issues including consumer rights in the marketplace, product safety, financial regulation, worker safety, safe and affordable health care, campaign finance reform and government ethics, fair trade, climate change, and corporate and government accountability.



1600 20th St N.W.
Washington, D.C. 20009
P: 202-588-1000
<https://citizen.org>

Contents

INTRODUCTION	4
BACKGROUND: GROWTH PHARMA	7
PAYING FOR DELAY	8
HOPPING ALL THE WAY TO THE BANK	10
PETITIONING FOR PROFITS.....	11
SPIKING LIKE SHKRELI	12
PRICING WITH NO LIMITS	15
FLOODING THE COUNTRY WITH PAIN PILLS.....	17
CONCLUSION	19
APPENDIX.....	20

Introduction

After Pharma Bro Martin Shkreli unleashed a public outcry by jacking up the price of HIV treatment Daraprim, Brent Saunders decided to publish a social contract. Saunders, the CEO of pharmaceutical giant Allergan, had once called Shkreli a “rising star” whose hedge funds had given him “phenomenal returns.”¹ Now Saunders condemned price-gouging, promising a more ethical course.² A flurry of headlines soon declared that Allergan was committed to a better way.

But a closer examination of the corporation’s record reveals a catalogue of abuses, showing just how deeply the pharmaceutical industry business model is broken.

The corporation now known as Allergan has repeatedly used dubious tactics to boost profits—from paying off its competitors, to gaming the patent system, to hiking the prices of old medicines. Last year, Allergan’s own shareholders shamed the corporation for its “embarrassing legal initiatives” and “stunningly excessive level of management compensation.”³

In the past three months, Allergan has entered settlements for a billion dollars over its anticompetitive conduct.⁴ The corporation is enmeshed in several other lawsuits, with possible legal exposure for billions more.⁵ Between 2006 to 2012, its former subsidiary sold 26 billion opioid pills, more than 80 for every American.⁶ Allergan has gone by three different names in the past decade.⁷ With every iteration, the corporation has largely shed its predecessor’s tarnished image and escaped sustained public scrutiny—until now.

¹ Renae Merle, Before becoming ‘Pharma Bro,’ Martin Shkreli was a sought-after Wall Street insider, testimony shows, THE WASHINGTON POST (June 30 2017), <https://tinyurl.com/yc7nxklc>.

² Brent Saunders, Our Social Contract with Patients, ALLERGAN, (Sept 6 2016), <https://tinyurl.com/uz86jdg>.

³ David Tepper on behalf of APPALOOSA LP, Letter to Allergan (Feb. 19 2019), <https://tinyurl.com/qwnvrmd>.

⁴ Both cases are documented below. ALLERGAN, Forest Resolves Antitrust Class Action Litigation with Direct Purchasers of Namenda (Oct. 28 2019), <https://tinyurl.com/v47tkpq> & ALLERGAN, Warner Chilcott and Watson Resolve Antitrust Class Action Litigation with Direct and Indirect Purchasers of Loestrin 24 FE and Minastrin 24 FE (Jan 6 2020), <https://tinyurl.com/vd2f4cy>.

⁵ Allergan’s September financial statement suggested that, after the Namenda settlement, Allergan had accrued loss contingencies of \$50 million. Since then, Allergan has entered into a \$300 million settlement over Loestrin and Minastrin. A class-action related to Restasis is expected to go to trial in April, in which experts allege damages in the billions. The opioid matters are also pending. ALLERGAN, Form 10-Q, SEC FILING, p.45, 50-52 (Sept 30 2019), <https://tinyurl.com/tpf6k2d>. See also In re Restasis Antitrust Litigation, 18-md-02819 (E.D.N.Y.), ECF 407-2. Declaration of Jeffrey Leitzinger (April 26 2019).

⁶ This refers to sales of oxycodone and hydrocodone. Scott Higham et al., 76 billion opioid pills: Newly released federal data unmask the epidemic, THE WASHINGTON POST (July 16 2019), <https://tinyurl.com/y6k5anst>. Allergan has since sold the Actavis generics business in an unusually well-timed sale. Teva has agreed to indemnify the corporation for generic drug liabilities. But Allergan could still be on the hook if Teva declares bankruptcy. Allergan is also not shielded for its brand-name products. See FLOODING THE COUNTRY WITH PAIN PILLS.

⁷ Watson Pharmaceuticals, Actavis and Allergan. The corporation also includes Warner Chilcott and Forest Laboratories. See BACKGROUND: GROWTH PHARMA.

The Federal Trade Commission should step in. Last summer AbbVie, a pharmaceutical corporation notorious for its anticompetitive patenting, announced a deal to acquire Allergan for \$63 billion.⁸ Allergan is attempting to shed its name yet again. Together, the companies would “create the fourth largest global biopharmaceutical company.”⁹ A coalition of labor and consumer groups including Public Citizen and collectively representing ten million people already have called for the FTC to investigate and “take all necessary action, including blocking the merger, to prevent further harm to consumers.”¹⁰ If FTC nevertheless proceeds, it should at a minimum order the companies to finally stop the anticompetitive practices detailed below and impose conditions intended to prevent such anticompetitive conduct from ever occurring again. Over the years, the FTC has taken more than a dozen actions related to Allergan and its subsidiaries, but their abuses have largely continued unabated.¹¹ A larger corporation is likely only to increase the harmful effects of these tactics. A new approach is needed.¹²

Table 1: Minimum suggested conditions for pharmaceutical mergers

Suggested Terms
<ol style="list-style-type: none"> 1. Explicitly prohibit anticompetitive conduct outlined below, like pay-for-delay deals, product hopping, citizen petition abuse, price hikes,¹³ patent monopoly abuse, and illegal marketing and influence. 2. Enforce non-compliance through meaningful penalties, like issuing compulsory licenses¹⁴ and imposing personal liability for management. 3. Impose regular reporting requirements and transparency. 4. Require divestiture of products, including candidates in early-stage clinical trials, in overlapping markets.

Congress should also act. Beyond Allergan, many pharmaceutical corporations routinely employ some of the tactics documented in this report at the expense of consumers. Compared to people living

⁸ Susannah Luthi, AbbVie sued over Humira 'patent thicket', MODERN HEALTHCARE (March 19 2019), <https://tinyurl.com/y68qj9jq> (noting AbbVie obtained 136 patents on Humira). Saunders is lined up to receive \$38.7 million in compensation if the merger is approved and he is let go. Carly Helfan, Pharma Allergan CEO Saunders lines up for \$39M parachute after AbbVie buy, FIERCEPHARMA (Aug. 14 2019), <https://tinyurl.com/uym6u4h>.

⁹ ABBVIE INC., CEO Rick Gonzalez on Acquisition of Allergan Conference Call Transcript (June 25 2019), <https://tinyurl.com/vsm7pdg>.

¹⁰ Letter by Consumer Groups Asking FTC to Investigate Merger (Sept 12. 2019), <https://tinyurl.com/usptqzz> (noting how merger could exacerbate anticompetitive conduct).

¹¹ See APPENDIX for list of FTC actions.

¹² See Commissioner Rohit Chopra, Dissenting Statement In the Matter of Bristol-Myers Squibb/Celgene, FEDERAL TRADE COMMISSION (Nov. 15 2019) (noting that he is “deeply skeptical that [the status quo] approach can unearth the complete set of harms to patients and innovation, based on the history of anticompetitive conduct of the firms seeking to merge and the characteristics of today’s pharmaceutical industry when it comes to innovation”).

¹³ See Commissioners Rohit Chopra & Rebecca Kelly Slaughter, Federal Trade Commission Report on the Use of Section 5 to Address Off-Patent Pharmaceutical Price Spikes, FEDERAL TRADE COMMISSION (June 24 2019).

¹⁴ James Love, Recent Examples of the Use of Compulsory Licenses on Patents (2007) <https://tinyurl.com/tqk9ttx> (documenting several cases where the FTC ordered compulsory licenses).

in other rich countries, Americans on average spend nearly twice as much on prescription drugs.¹⁵ This is why lowering prescription drug prices ranks among voters' top priorities.¹⁶ Illegal marketing and influence also place a significant burden on public health, having contributed to an opioid epidemic that kills 130 Americans every day.¹⁷

Using Allergan as a case study, this report describes six tactics pharmaceutical corporations use to boost profits and describes Congress' attempts to respond. In doing so, the report highlights the immense opportunity for the federal government to enact structural change. Members of Congress have developed several important bipartisan proposals. Congress can choose to pass these reforms this year and bring real relief to millions of people who struggle to access medicine, and finally start to hold pharmaceutical corporations accountable for illegal marketing and influence.

Table 2: Tactics used by drug corporations like Allergan to boost profits and legislative responses

Tactic	Description	Legislative Responses
Pay-for-Delay	Drug corporations pay off competitors to delay launching low-cost competing products.	Preserve Access to Affordable Generics and Biosimilars Act (S. 64, H.R. 2375)
Product Hopping	Drug corporations make superficial tweaks to old products and shift patients onto new products to undermine generic competition.	Affordable Prescriptions for Patients Through Promoting Competition Act (H.R. 5133) Affordable Prescriptions for Patients Act (S. 1416)
Citizen Petition Abuse	Drug corporations abuse the regulatory process by filing sham petitions to delay approval of generic competition.	Stop STALLING Act (S. 1224, H.R. 2374)
Price Hikes	Drug corporations increase the price of existing medicines, at least once a year.	Lower Drug Costs Now Act (H.R. 3) Prescription Drug Pricing Reduction Act (S. 2543) Stop Price Gouging Act (S.378, H.R. 1093)
Outrageous Prices	Drug corporations abuse their patent monopolies to set outrageous prices.	Lower Drug Costs Now Act (H.R. 3) Medicare Negotiation and Competitive Licensing Act of 2019 (S.377, H.R. 1046)

¹⁵ Irene Papanicolas et al., Health Care Spending in the United States and Other High-Income Countries, The Commonwealth Fund (Mar. 13 2018), <https://tinyurl.com/w8l96yy> (noting “the U.S. spends \$1,443 per person on pharmaceuticals, compared to the average of \$749.”).

¹⁶ Politico-Harvard Poll, American's Priorities for New Congress in 2019 (Dec. 2018), <https://tinyurl.com/y8z5gbof> (finding that 80 percent of Americans think taking action to lower prescription drug prices is “extremely important”).

¹⁷ CDC, Understanding the Epidemic (Dec. 2018), <https://tinyurl.com/h9qlzi9>.

		Prescription Drug Affordability and Access Act (S.3166) Prescription Drug Price Relief Act (S. 102, H.R. 465)
Illegal Marketing and Influence	Drug corporations aggressively and inappropriately promote their drugs and pay kickbacks to physicians.	Affordable Medications Act (S.1801, Section 304) Opioid Crisis Accountability Act (S.1584, H.R. 2917)

Today, the industry business model consistently rewards creative lawyering and financial engineering over medical innovation. Social contracts are not enough. Only the government can make sure pharmaceutical corporations follow a better way.

Background: Growth Pharma

When Actavis acquired Allergan in 2015 and took its name, Brent Saunders boasted that the combination created “a leader in a new industry model known as Growth Pharma.”¹⁸ The model prioritized acquiring products to generate growth, instead of investing in research and development.

Acquisitions had long been the strategy for Allergan, which now includes Watson, Actavis, Warner Chilcott and Forest Laboratories. The shapeshifting began in 2012 when Watson Pharmaceuticals acquired Actavis and took its name.¹⁹ The following year, as part of a maneuver to avoid taxes, Actavis acquired Warner Chilcott, moving its domicile to Ireland.²⁰ In 2014, Actavis acquired Forest Laboratories, where Saunders served as the CEO.²¹ In 2015, as part of another tax inversion, Actavis acquired Allergan Inc., changing the group’s name to Allergan plc.²² Together, the entities have a long legacy of engaging in suspect tactics. For clarity, this report refers to the different affiliated entities as “Allergan” unless specified otherwise.

From 2010 to 2015, Allergan and its subsidiaries spent \$105 billion on 22 deals, paying on average six times the revenue.²³ Scholars suggested the Growth Pharma approach “seemed closer to that of a deal-making company specialized in the pharmaceutical industry rather than that of a pharmaceutical company.”²⁴ But this is what the new pharmaceutical industry looked like. Corporations increasingly generate growth through buying products developed by others, often smaller biotechnology firms that benefit from publicly funded research at university labs.²⁵

¹⁸ ALLERGAN, Actavis Completes Allergan Acquisition (Mar. 17 2015), <https://tinyurl.com/s8nlgnn>.

¹⁹ ACTAVIS, Form 10-K, SEC FILING p.3 (Dec. 31 2012) <https://tinyurl.com/rnwht2d>.

²⁰ Michael Merced, Actavis to Buy Warner Chilcott in All-Stock Deal, NY TIMES (May 20 2013), <https://tinyurl.com/v947ldp>.

²¹ ACTAVIS, Form 10-K, SEC FILING p.5 (Dec. 31 2014), <https://tinyurl.com/woj8tcz>.

²² ACTAVIS, Form 10-K, SEC FILING p.3 (Dec. 31 2015), <https://tinyurl.com/wuw4t69>.

²³ Max Nisen, How Allergan Rose and Valeant Fell, BLOOMBERG (Mar. 24 2016), <https://tinyurl.com/s2ygvfh>.

²⁴ Marta Colomar Roig & Nicolas Julian, Understanding Growth Pharma: A Deep Dive Into the Actavis-Allergan Merger (2017), ACADEMIC RESEARCH PAPER AT HEC PARIS, p.49 <https://tinyurl.com/vx5vs922>.

²⁵ See PUBLIC CITIZEN, PHARMA 101 (Aug 6. 2019), <https://tinyurl.com/y3hs8hgw>.

Sometimes they acquire entire companies. The AbbVie acquisition of Allergan is based on this understanding.²⁶ One biotechnology investor notes "This is an example of a pharma company doing a financial transaction—it has nothing to do with science; it has 100 percent to do with financial engineering."²⁷

From 2009 to 2018, Allergan spent \$4 billion more on stock buybacks than research and development.²⁸ If the acquisition is approved, AbbVie announced it will cut Allergan's already limited spending on research and development by nearly half.²⁹ Even Wall Street analysts thought the figure was "surprisingly large."³⁰

For Allergan, the underbelly of the Growth Pharma model was the pressure to keep revenues high by any means necessary. Its continued failure to innovate only fueled more egregious tactics.³¹

This often took shape in attempts to extend its monopolies. The modern U.S. drug pricing system grants originator companies a time-limited monopoly and depends on the entry of generic competitors to make medicines affordable.³² Generic competition, the Food and Drug Administration (FDA) has found, can lead to price reductions of more than 95 percent.³³ But that reduction can be averted if the competition can be paid off.

Paying For Delay

There is perhaps nothing more emblematic of Allergan's corporate character than the fact that its two subsidiaries once entered into an anticompetitive deal with *each other*. Before being subsumed

²⁶ This is not the first time Allergan has been the subject of interest. In an attempted corporate tax inversion, Pfizer planned to acquire Allergan for \$160 billion dollars in 2016, one of the largest deals ever, until the Obama Administration pushed back and changed tax rules. Caroline Humer, Obama's inversion curbs kill Pfizer's \$160 billion Allergan deal, REUTERS (April 5 2016), <https://tinyurl.com/vrffwsct>.

²⁷ Sy Mukherjee, Protect at all costs: How the maker of the world's bestselling drug keeps prices sky-high, Fortune (July 18 2019), <https://fortune.com/longform/abbvie-humira-drug-costs-innovation/> (quoting Brad Loncar).

²⁸ William Lazonick et al., Financialization of the U.S. Pharmaceutical Industry, p. 4 (Dec. 2 2019), https://www.ineteconomics.org/uploads/papers/Lazonick_financialization.pdf.

²⁹ Matthew Herper, How Brent Saunders' Allergan experiment failed (June 26 2019), STAT, <https://tinyurl.com/y4p8u5nq> (quoting CEO plan to cut \$1 billion from Allergan's \$2.3 billion spending on R&D).

³⁰ *Id.*

³¹ Madeline Armstrong & Jonathan Gardner, Rapastinel flop leaves Allergan in a hole (March 7 2019), <https://tinyurl.com/s5ekl4z> (describing Allergan clinical failures and noting "thinness of Allergan's late-stage pipeline").

³² The Drug Price Competition and Patent Term Restoration Act (Public Law 98-417) (1984).

³³ FDA, Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices (Dec. 2019), <https://tinyurl.com/uxdc9>.

under Allergan, Watson and Warner Chilcot were on both sides of a 2009 deal to delay the launch of generic Loestrin 24, a contraceptive.³⁴

Years earlier, Warner Chilcott had filed a patent infringement lawsuit against Watson when Watson was trying to gain regulatory approval for its generic. Under the Hatch-Waxman Act, this automatically triggered a 30-month stay that prevented the FDA from approving Watson's new drug.

Typically, in a patent infringement settlement, the alleged *infringer* pays the patent holder. But pay-for-delay deals work just the opposite. Because of the lucrative nature of the monopoly, brand-name corporations that hold patents can make more money by paying the generic corporation to *stay off the market*. Pay-for-delay deals allow corporations to profit, while patients suffer.

Just as the stay was about to expire, allowing for the possibility of FDA approval, Warner Chilcott and Watson entered into a deal. Watson agreed to delay the launch of its generic.³⁵ In a series of side deals, Warner Chilcott then agreed not to market its own generic and offered a grab bag of other industry treats.³⁶ Plaintiffs who later sued the companies alleged the deals were cumulatively worth more than \$250 million.³⁷ This January, they settled with both companies for around \$300 million over two drugs.³⁸

Watson eventually became Actavis—infamous for its role in the foundational U.S. Supreme Court decision that held that a pay-for-delay deal could have “significant anticompetitive effects” and violate antitrust laws.³⁹ Actavis acquired Warner Chilcot. Now it's called Allergan. The corporation has settled multiple pay-for-delay cases.⁴⁰

Legislative Proposal

The Preserve Access to Affordable Generics and Biosimilars Act (S. 64, H.R. 2375), sponsored by Sen. Amy Klobuchar (D-MN) and Rep. Jerry Nadler (D-NY), could help prevent these kinds of anticompetitive pay-for-delay deals by establishing a presumption that they are unlawful. The bill passed the House Judiciary Committee and has bipartisan support in the Senate. The Congressional Budget Office (CBO) has estimated it would save the federal government more than \$600 million over ten years.

³⁴ *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307 (D.R.I. 2017). *See also* Michael Carrier, The US Court of Appeals for the First Circuit concludes that a reverse payment need not be in cash (Loestrin), E-COMPETITIONS (March 2016).

³⁵ *Id.*

³⁶ *Id.*

³⁷ *Id.*

³⁸ ALLERGAN, Warner Chilcott and Watson Resolve Antitrust Class Action Litigation with Direct and Indirect Purchasers of Loestrin 24 FE and Minastrin 24 FE (Jan 6 2020), <https://tinyurl.com/vd2f4cy>.

³⁹ *Federal Trade Commission v. Actavis*, 133 S. Ct. 2223.

⁴⁰ *See e.g.*, Nate Raymond, Allergan settles generic Asacol delay claims for nearly \$2.75 million, Reuters (Aug. 5 2019), <https://tinyurl.com/r2lmhun> & Markus Meier et al., OVERVIEW OF FTC ACTIONS IN PHARMACEUTICAL PRODUCTS AND DISTRIBUTION, FEDERAL TRADE COMMISSION (June 2019), <https://tinyurl.com/v3pvjzf> (describing Warner Chilcott's Ovcon settlement agreement and other FTC actions). *See also* Appendix.

Hopping All The Way To The Bank

As one of their best-selling treatments neared the end of its patent monopoly term, the executives at Allergan—at the time known as Forest Laboratories—began thinking about what to do next. Generic competition was fast approaching for Namenda IR. Taken twice a day, it was the first medicine approved for individuals suffering from moderate to severe Alzheimer's disease.⁴¹

Therein lay the key “discovery.” Namenda IR had to be taken twice a day. What if they could develop a new product that had to be taken only once a day?

The extended-release version, Namenda XR, received FDA approval in 2010. Namenda IR's patent monopoly was expected to expire in 2015. Namenda XR's patent monopoly was expected to expire in 2029—an additional 14 years.⁴² State laws typically allow pharmacists to automatically substitute brand-name prescriptions for low-cost generics if they are “therapeutically equivalent.”⁴³ IR and XR met some of the requirements: they both had the same active ingredient and the same clinical effect. But they did not have the same strengths and dosage regimens. If Allergan could convert patients to the new pill, pharmacists would not be able to automatically substitute generic IR drugs for XR.

So Allergan began spending “substantial sums of money” promoting XR to doctors, caregivers, patients, and pharmacists.⁴⁴ It also sold XR at a discounted rate, making it significantly less expensive than the IR tablets.⁴⁵ This was not enough. Their internal analysis showed that only 30 percent of IR users would voluntarily switch prior to the patent expiration date in 2015.⁴⁶ Five generics had tentative approval to enter the market on that date, meaning they could capture the majority of the market within months.

In February 2014, Allergan announced it would stop selling Namenda IR.⁴⁷

The move, had it been successfully executed, would have gutted the generic market, forcing patients to continue to pay high prices. But New York state filed a lawsuit alleging the conduct was anticompetitive, and the U.S. District Court for the Southern District of New York ordered Allergan to keep IR on the market, which allowed consumers to more widely benefit from the affordable generics.⁴⁸ The parties later settled.⁴⁹ A class-action lawsuit launched later settled for \$750 million.⁵⁰

⁴¹ New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638 (2d Cir. 2015).

⁴² *Id.*

⁴³ FDA, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations (2020).

⁴⁴ New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638 (2d Cir. 2015).

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ Ed Silverman, Allergan and New York settle suit over Alzheimer's drug switching (Dec. 1 2015), STAT, <https://tinyurl.com/sh2lxxa>.

⁵⁰ ALLERGAN, Forest Resolves Antitrust Class Action Litigation with Direct Purchasers of Namenda (Oct. 28 2019), <https://tinyurl.com/v47tkpq>.

Inconsistent judicial rulings—and consistently cunning legal strategies—mean that product hops are still ubiquitous. Companies continue to obstruct generic competition by making superficial tweaks to products.

Allergan has been accused of multiple product hops.⁵¹ One product hop to a bigger capsule was so bold-faced that when patients cut the new capsule open, the original tablet fell out.⁵² It's never been a secret. When Allergan was acquiring another company, its executives even praised the skill of a colleague at keeping generic competition out, noting “We have been extremely impressed with how Roger and his team have built out, I think, the ever-greening line extension strategy behind the scenes.”⁵³

Legislative Proposal

The Affordable Prescriptions for Patients Act (S. 1416) and the Affordable Prescriptions for Patients Through Promoting Competition Act (H.R. 5133), sponsored by Sen. John Cornyn (R-TX) and Rep. David Cicilline (D-RI), respectively, and passed by both the Senate and House Judiciary Committees could help end to this practice. The Act deems product hops an unfair method of competition and provides the Federal Trade Commission with enforcement authority. The CBO has estimated the Senate version of this legislation would lower federal spending by more than half a billion dollars over ten years.

Petitioning For Profits

Restasis is among Allergan's most prized medicines. In 2013, the FDA issued recommendations for companies seeking approval to launch generic versions of the treatment for dry eye. So began the arduous—and still unfinished—process of approving a competitor. Contributing to the delay has been the barrage of Allergan citizen petitions.

Citizen petitions allow any person to request the FDA take or refrain from taking administrative action.⁵⁴ Some require a response within 150 days of receipt. The petitions are complex, containing “detailed analysis and precise scientific documentation” and requiring review by “multiple disciplines” within the FDA.⁵⁵ This takes time and resources, often redirected from other areas of

⁵¹ See e.g., *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307 (D.R.I. 2017) (Loestrin), *Federal Trade Commission v. Warner Chilcott Corporation*, Civil Action No. 1:05-CV2179-CKK (D.D.C) (Ovcon), *In re Asacol Antitrust Litig.*, 233 F. Supp. 3d 247 (D. Mass. 2017) (Asacol).

⁵² Plaintiff's Consolidated Complaint, *In re Asacol Antitrust Litig* Civil Action No. 1:15-cv-12730, p.41. See also DELZICOL: HOW NEW IS IT? (July 27 2013), <https://www.youtube.com/watch?v=eNtahEEyGHI> (video of woman opening new capsule to find original tablet).

⁵³ Seeking Alpha, Actavis' CEO Hosts Acquisition of Warner Chilcott Conference, (May 20 2013), <https://tinyurl.com/r2tbyy7>.

⁵⁴ 21 C.F.R. § 10.25(a)(2).

⁵⁵ *The Generic Drug Maze: Speeding Access to Affordable Life-Saving Drugs: Hearing Before the S. Spec. Comm. on Aging*, 109th Cong. 6 (2006) (statement of Gary Buehler, Director, Office of Generic Drugs, FDA).

work.⁵⁶ Brand-name drug corporations sometimes abuse the process to delay FDA approval of generic competitors—a problem long acknowledged by the FDA.⁵⁷

Allergan filed its first petition in January 2014—later withdrawing it and replacing it with another petition filed in February. The petition cited to submissions made by doctors who had been previously paid by Allergan, without disclosing that conflict of interest.⁵⁸ It was denied.

Later that year, Allergan tried again. This time, the corporation supplemented the petition four times. In 2016, the FDA denied the petition saying Allergan “should not be surprised” by its response.⁵⁹ By the time the FDA denied Allergan’s third petition in 2018, the agency noted that it “repeats many of the assertions” of earlier petitions that had been rejected.⁶⁰

What is particularly revealing is that Allergan chose not to appeal any of the denials to federal court, as permitted by federal law.⁶¹ This would allow the FDA to devote renewed attention to other matters. Instead, the corporation chose to file successive petitions, with amendments, that clogged up FDA resources. The year Allergan’s latest petition was denied, Restasis, unimpeded by generic competition, brought in more than a billion dollars.⁶² Mobilizing the army of lawyers had paid off.

Legislative Proposal

The Stop STALLING Act (S. 1224, H.R. 2374), sponsored by Sen. Amy Klobuchar (D-MN) and Rep. Hakeem Jeffries (D-NY), and passed by the Senate and House Judiciary Committees, could help stop brand-name drug corporations like Allergan from abusing the citizen petition process. The Act deems submitting a petition or series of petitions that are a sham an unfair method of competition and provides the Federal Trade Commission with enforcement authority. The CBO has estimated this legislation would save the federal government more than \$100 million over ten years.

Spiking Like Shkreli

When Brent Saunders released a social contract in 2016, his promise to limit price spikes made headlines:⁶³

⁵⁶ FEDERAL TRADE COMMISSION, Comment on the FDA’s Revised Draft Guidance on Citizen Petitions (2019).

⁵⁷ See Michael A. Carrier & Carl J. Minniti III, Citizen Petitions: Long, Late-Filed, and At-Last Denied, 66 Am. U. L. Rev. 305, 308 (2016) (finding that the FDA denies 92 percent of petitions targeting pending generics). Robin Feldman, A Citizen’s Pathway Gone Astray – Delaying Competition from Generic Drugs, 376 New Eng. J. Med. 1499 (2017).

⁵⁸ Class Action Complaint, In re Restasis Antitrust Litigation, Case 2:18-cv-00012, p. 40 (E.D.N.Y. 2018) (describing several doctors who had filed petitions and previously received payments from Allergan).

⁵⁹ Petition Denial Response Letter from FDA CDER to (Allergan, Inc) and Physical Pharmaceutica, LLC (Feb 10 2016), <https://tinyurl.com/qkdrn7>.

⁶⁰ Petition Denial Letter from FDA CDER to Allergan, Inc (Jan 2 2018), <https://tinyurl.com/tmtzfw>.

⁶¹ 5 U.S.C. § 702. Opinion and Order on Motion to Dismiss, In re Restasis Antitrust Litigation, 333 F.Supp.3d 135 (E.D.N.Y. 2018) (“No other inference is offered by defendant as to why it did not appeal the denials.”).

⁶² ALLERGAN, Form 10-K, SEC FILING p.55 (Dec. 31 2018), <https://tinyurl.com/sb6wha6>.

⁶³ Brent Saunders, Our Social Contract with Patients, ALLERGAN, (Sept 6 2016), <https://tinyurl.com/uz86jdg>.

Where we increase price on our branded therapeutic medicines, we will take price increases no more than once per year and, when we do, they will be limited to single-digit percentage increases.

Saunders' forward-looking message managed to largely conceal his corporation's past record. In the years prior, Allergan had profited handsomely from arbitrarily spiking the price of older drugs. Between 2012 and 2015, Allergan was ranked among the specialty pharmaceutical companies with the worst-track record for price increases.⁶⁴ From 2014 to 2015, for example, Allergan increased the list price of a topical cream for a skin disease by 185 percent.⁶⁵ And, in a ten-year period, Allergan more than doubled the price of its best-selling eyedrop, Restasis.⁶⁶ The social contract made no mention about *restoring* original prices. But there was a display of restraint, which was widely applauded.

In the years since, Allergan has continued to increase prices, typically falling just under its pledged 10 percent limit. In 2019, The Wall Street Journal reported that Allergan was "setting the pace with increases."⁶⁷ That year, Allergan had raised the price of 51 products—27 by around 9 percent, and 24 by about 4.9 percent. Among the companies analyzed, Allergan had the most increases of more than 9 percent.

Pressed to reconcile his pricing strategy with his social contract, Saunders blamed the supply chain and said the company had "absolutely lived up to well beyond the spirit and heart of our social contract."⁶⁸ Still, likely wary of the 2019 headlines, Allergan has somewhat moderated its price increases in 2020. It raised prices in January at only *double* the rate of inflation. Within the first week, it had raised the price of 33 products.⁶⁹

⁶⁴ Max Nisen, Massive, unexpected drug price increases are happening all the time, QUARTZ (Oct 1 2015), <https://tinyurl.com/sar92u4>.

⁶⁵ Max Nisen, How Allergan Rose and Valeant Fell, BLOOMBERG (Mar. 24 2016), <https://tinyurl.com/s2ygfvh>

⁶⁶ David Crow, Allergan deal with Mohawk tribe casts patent shadow, FINANCIAL TIMES (Sept. 27 2017), <https://tinyurl.com/wzmo4wa> ("The average wholesale price of a 30-dose pack of Restasis has more than doubled from \$117 in 2008 to almost \$280 today.").

⁶⁷ Jared Hopkins, Drugmakers Raise Prices on Hundreds of Medicines, THE WALL STREET JOURNAL (Jan. 1 2019), <https://tinyurl.com/y8bo6nh8>.

⁶⁸ Ed Silverman and Matthew Herper, Allergan CEO: We stuck to the spirit of our social contract with recent price hikes, STAT (Jan. 8 2019), <https://tinyurl.com/tdwyelx>.

⁶⁹ PATIENTS FOR AFFORDABLE DRUGS, January 2020 Price Hikes: Data Set (Jan. 8 2020), <https://tinyurl.com/uxj9z4u>.

Table 3: Names of Allergan products with price spikes⁷⁰

Product Name	Price Spike
Aczone	8.22%
Alphagan P	5%
Armour Thyroid	5%
Azelex	5%
Blephamide	5%
Bystolic	5%
Carafate	5%
Combigan	5%
Dalvance	3%
Fetizma	5%
FML	5%
FML Forte	5%
Infed	5%
Lexapro	5%
Liletta	5%
Linzess	5%
Lo Loestrin Fe	5%
Lumigan	5%
Monurol	5%
Namzaric	5%
Pred Forte	5%
Pred Mild	5%
Pred-G	5%
Restasis	5%
Restasis Multidose	5%
Savella	5%
Taytulla	5%
Tazorac	5%
Teflaro	5%
Viberzi	5%
Viiibryd	5%
Vraylar	2%
Zenpep	5%

While single-digit price increases can seem relatively less harmful, they can still lead to a dizzying upward spiral over time.

⁷⁰ *Id.*

Table 4: Hypothetical impact of price spikes over time

Annual Price Spike	Cumulative Price Spike after 5 years	Cumulative Price Spike after 10 years
3%	16%	34%
5%	28%	63%
9.5%	57%	248%

Arbitrary price spikes can lead to hundreds of millions of dollars in additional spending. Take Bystolic, for example, a blood pressure medication sold by Allergan. In 2013, before rebates, Medicare was spending \$108 per prescription.⁷¹ Within five years, it was spending twice as much—at \$233 per prescription. Despite reimbursing fewer prescriptions, Medicare spent nearly \$200 million more on the drug by 2018 than 2015.

Legislative Proposal

The House-passed Elijah E. Cummings Lower Drug Costs Now Act (H.R. 3), sponsored by Rep. Frank Pallone (D-NJ), could address this issue. The bill, in part, would require prescription drug companies to pay rebates when they raise drug prices covered under Medicare Part B and Part D beyond the level of inflation. The bill also includes price spike protections for people covered by group health plans and insurance coverage. This would limit Allergan’s ability to increase revenues by continually raising prices.

The Prescription Drug Pricing Reduction Act (S. 2543), sponsored by Sen. Chuck Grassley (R-IA) and passed by the Senate Finance Committee, could also partially address this issue. The bill, in part, would similarly require prescription drug companies to pay rebates to the federal government when they raise prices of drugs covered under Medicare Part B and Part D beyond the level of inflation. But its protections, unlike H.R. 3, are limited to Medicare beneficiaries.

The Stop Price Gouging Act (S.378, H.R. 1096), sponsored by Sen. Sherrod Brown (D-OH) and Rep. Mark Pocan (D-WI), would take the strongest approach. The bill would penalize drug companies that unjustifiably increase prices at a rate that exceeds the level of inflation by imposing financial penalties proportionate to the price spike. Revenues collected through the bill would fund research and development at the National Institutes of Health.

Pricing With No Limits

The thought of losing her eyesight terrifies Saunta Anderson.⁷²

Restasis helps keep her eyes healthy. But, despite having private insurance, the medicine manufactured by Allergan is still nearly out of reach. “Without a special coupon the drug is typically \$300 each month. The coupon is unreliable and I don’t always get it,” Anderson told Patients for

⁷¹ CENTER FOR MEDICARE AND MEDICAID SERVICES, Medicare Part D Spending Database, <https://tinyurl.com/wlhua7p>.

⁷² PATIENTS FOR AFFORDABLE DRUGS, Saunta Anderson, <https://tinyurl.com/s7qr7gy>.

Affordable Drugs. “That’s an astronomical cost for me. I’m constantly worried that I won’t be able to get the coupon that reduces the price of my drug.”

Joseph Landi has had to stop taking other medicines he needs to pay for Restasis.⁷³

What the arcane legal arguments and complex financial models attempt to conceal is this simple reality. Pharmaceutical corporations wield enormous power over sick patients. They set the price for getting better, for living a longer life. By pricing essential goods like they are commodities, pharmaceutical corporations can force people to make impossible choices.

The government confers this power through patents and a complex layer of regulatory exclusivities. It does not regulate or by and large even negotiate for the monopoly price. Pharmaceutical corporations vigorously protect the ability to extract as much wealth as possible from sick people, and if they are lucky enough to have good medical coverage, their insurance.

For example, when its Restasis patents were challenged at the Patent Office, Allergan sought to avoid review by transferring its patents to a Native American tribe in an attempt to take advantage of tribal immunity.⁷⁴ The move failed. The Patent Trial and Appeal Board rejected the gimmick, a decision the Federal Circuit affirmed.⁷⁵

What was particularly galling—and far less widely reported—were the patents subject to the maneuver. Just as Restasis’ primary patents were about to expire, Allergan gained a second wave of patents starting in 2014. In a decision invalidating some of these patents, the U.S. District Court for the Eastern District of Texas held that Allergan “persuaded the examiner to issue the patent by way of a presentation that was more advocacy than science.”⁷⁶ Plaintiffs in a class-action lawsuit go further and now allege fraud.⁷⁷

Last January, Allergan’s chief executive Saunders admitted the tribe deal “clearly eroded trust.” But Allergan’s lawyers nonetheless still marched forward to ask the Supreme Court to recognize the maneuver.⁷⁸ Saunders had also previously defended the move in a Wall Street Journal opinion piece, saying that the “social contract has come under stress recently” due to a procedure used to challenge its patents.⁷⁹ Allergan could not support the “unfair burden.” Nobody asked Saunta Anderson about hers.

⁷³ PATIENTS FOR AFFORDABLE DRUGS, Joseph Landi, <https://tinyurl.com/w78lbbk>.

⁷⁴ Katie Thomas, Patents for Restasis Are Invalidated, Opening Door to Generics, NY TIMES (Oct. 16 2017), <https://tinyurl.com/yxqk5qrh>.

⁷⁵ Saint Regis Mohawk Tribe v. Mylan Pharm., Inc., No. 18-1638 (Fed. Cir. 2018).

⁷⁶ Allergan Inc., v Teva Pharm. Inc, Case No. 2:15-cv-1455-WCB (E.D. TX 2018), p. 133.

⁷⁷ Class Action Complaint, In re Restasis Antitrust Litigation, Case 2:18-cv-00012, p. 1 (E.D.N.Y 2018) (alleging that Allergan misrepresented data which formed the basis for granting the patent).

⁷⁸ Ed Silverman, Allergan and a Mohawk tribe ask the Supreme Court to review their controversial patent deal, STAT (Jan 15. 2019) <https://tinyurl.com/wv2j3ym>.

⁷⁹ Brent Saunders, Reverse Patent Trolls Are Harming Drug Innovation—and Patients, THE WALL STREET JOURNAL (Oct. 8 2017) <https://tinyurl.com/y9f69a4q>.

Legislative Proposal

The House-passed Elijah E. Cummings Lower Drug Costs Now Act (H.R. 3), sponsored by Rep. Frank Pallone (D-NJ), could help address corporations' unchecked ability to set prices. The bill, in part, would empower Medicare to negotiate directly for the price for select drugs, imposing a tax penalty if the negotiations failed.⁸⁰ The negotiated price could be applied to people with private plans. If Restasis were chosen for negotiation, H.R.3 could help significantly drive down its price.

The Medicare Negotiation and Competitive Licensing Act of 2019 (S.377, H.R. 1046) introduced by Sen. Sherrod Brown (D-OH) and Rep. Lloyd Doggett (D-TX) would target the monopoly itself, which is the root of price abuse. It would authorize generic competition if Medicare negotiations failed. The Prescription Drug Affordability and Access Act (S. 3166), sponsored by Sen. Cory Booker (D-NJ), builds on this idea. The bill would create a new agency—the Bureau of Prescription Drug Affordability and Access—to review and determine prices. Failure to comply with the price would allow the government to break the monopoly and authorize generic production. The Prescription Drug Price Relief Act (S. 102, H.R. 465), sponsored by Sen. Bernie Sanders (D-VT) and Rep. Ro Khanna (D-CA), also targets the monopoly when drug companies charge excessive prices. It would authorize generic competition if the U.S. price exceeds the median price in five other large, wealthy countries, or if the price of a drug is otherwise found to be excessive.

Flooding The Country With Pain Pills

The executives did not want opioid prescriptions to slow. At one sales training in 2011, Allergan—then known as Actavis—reportedly pressed its employees: “To meet and exceed our quota, we must continue to get [opioid] scripts from our loyalists. MCOs [Managed Care Organizations] will continue to manage the pain products more closely. We MUST have new patient starts or we will fall back into ‘the big leak’. We need to fill the bucket faster than it leaks.”⁸¹

This, in part, forms the complaint against the corporation for misrepresenting the addiction risk posed by its product and targeting the biggest prescribers of opioids for marketing.⁸² Between 2006 and 2012, Actavis sold more opioids than almost anyone else.⁸³ It was responsible for almost 35 percent of pills on the market.⁸⁴ At 26 billion pills, Actavis peddled more than 80 for every American. In 2012, Actavis refused the Drug Enforcement Administration's request to slash production.⁸⁵

⁸⁰ The bill would also implement price spike protections and set an out-of-pocket cap for Medicare beneficiaries.

⁸¹ Second Amended Complaint by Cabell County Commission, Ohio, In re: National Prescription Opiate Litigation Northern District of Ohio, ohnd-1:2017-md-02804 (2018).

⁸² *Id.*

⁸³ Scott Higham et al., 76 billion opioid pills: Newly released federal data unmask the epidemic, THE WASHINGTON POST (July 16 2019), <https://tinyurl.com/y6k5anst>.

⁸⁴ Aaron C. Davis et al., Little-known makers of generic drugs played central role in opioid crisis, records show, THE WASHINGTON POST (July 27 2019), <https://tinyurl.com/yxtqhnwq>.

⁸⁵ *Id.* (“Florida was having, on average, 11 fatal overdoses a day. . . Actavis had sent nearly 240 million pills to Florida during the previous 30 months — more oxycodone than the manufacturer had sent to almost all other

Allergan has since sold the Actavis generics business in an unusually well-timed sale for over \$40 billion, seemingly rewarded for flooding the country with pills. Teva has agreed to indemnify the corporation for generic drug liabilities.⁸⁶

But Allergan could still be on the hook if Teva declares bankruptcy.⁸⁷ Indeed, after Teva settled with the state of Oklahoma for \$85 million, Allergan's shares fell by 17 percent, suggesting the risk felt by investors.⁸⁸ Allergan is also not shielded for its brand-name products, which constituted 6 percent of the branded opioid market in 2009.⁸⁹

Allergan has been named as a defendant in over 2,000 lawsuits relating to the promotion and sale of opioids.⁹⁰ In 2019, Allergan settled with two Ohio counties and agreed to pay \$5 million to resolve allegations that its aggressive marketing practices fueled the opioid epidemic.⁹¹ Announcing the settlement, Allergan emphasized that the corporation has “a history of supporting—and continues to support—the safe, responsible use of prescription medications.”

The press release omitted some inconvenient facts. In 2015, Allergan paid \$125 million to resolve claims that its subsidiary illegally marketed drugs.⁹² The subsidiary also pled guilty to paying kickbacks to physicians. The CEO of the subsidiary was criminally charged. In 2010, Allergan similarly pled guilty for illegally promoting its product for unapproved uses, paying a \$375 million criminal fine.⁹³ It also reached a settlement for \$225 million to resolve claims that it paid kickbacks to physicians and taught doctors how to fraudulently charge government programs.

Legislative Proposal

The Affordable Medications Act (S. 1801), sponsored by Sen. Tina Smith (D-MN), includes provisions in Section 304 that could partially help address this issue. The bill would impose new penalties for misbranding, fraud, and illegal marketing, including by terminating lucrative marketing exclusivities.⁹⁴

states combined. . . Michael R. Clarke, the company's vice president for ethics and compliance, testified in a deposition that it felt like DEA officials were treating Actavis like “street dealers.”).

⁸⁶ Meg Tirrell, One opioid drugmaker's solution to billions of potential liabilities: spin them out into new company, CNBC (July 23 2019), <https://tinyurl.com/y4u9n65c>. See also Allergan, Investor FAQ (June 14 2019).

⁸⁷ Allergan, Investor FAQ (June 14 2019), <https://tinyurl.com/qn4lrer>.

⁸⁸ Michael Gibney, Allergan could split divisions amid 'sense of urgency' to restore investor value, S&P GLOBAL (June 20 2019), <https://tinyurl.com/twrqmdp>.

⁸⁹ *Id.*

⁹⁰ ALLERGAN, Form 10-Q, SEC FILING, p.52 (Sept 30 2019), <https://tinyurl.com/tpf6k2d>.

⁹¹ ALLERGAN, Allergan Announces Settlement with Two Ohio Plaintiffs in Federal Opioid Litigation (Aug. 30 2019), <https://tinyurl.com/wohb6pr>.

⁹² DEP'T OF JUSTICE, Warner Chilcott Agrees to Plead Guilty to Felony Health Care Fraud Scheme and Pay \$125 Million to Resolve Criminal Liability and False Claims Act Allegations (Oct. 29 2015), <https://tinyurl.com/ql9htcs>.

⁹³ DEP'T OF JUSTICE, Allergan Agrees to Plead Guilty and Pay \$600 Million to Resolve Allegations of Off-Label Promotion of Botox® (Sept. 1 2010), <https://tinyurl.com/zq7sxn>.

⁹⁴ The bill could be strengthened by allowing the government to terminate exclusivities held by other products if the drug subject to the violation was not protected by exclusivity, by expanding the remedy to

The Opioid Crisis Accountability Act (S. 1584, H.R. 2917), sponsored by Sen. Bernie Sanders (D-VT) and Rep. Tulsi Gabbard (D-HI), would prohibit the dubious marketing and excessive distribution of opioids, create criminal liability for pharmaceutical executives and penalize drug companies that have engaged in such practices. It would also require drug companies to reimburse the country for the negative economic impact of their products and create a fund to help combat the opioid addiction crisis. Finally, the bill would reduce exclusivity periods of, and restrict granting of new exclusivity periods to, companies that violate its terms.

Conclusion

The story of Allergan shows how corporate power harms public health. It shows the harm produced by incentives in a monopoly-based business model. And, most fundamentally, it shows the harm that the federal government has largely failed to prevent in the institutions it has structured.

Allergan reflects the deep dysfunction of the pharmaceutical industry. With immense popular demand and bipartisan support, there is now an unprecedented opportunity to make medicines affordable and hold pharmaceutical corporations accountable. Bringing real relief for millions of Americans is within reach. Congress and the Federal Trade Commission should rein in giant pharmaceutical corporations like Allergan. People deserve better.

include patent licensing, and by setting significant minimum monetary penalties for companies with no products protected by patents or exclusivities.

Appendix

Table 5: FTC actions against Allergan and its subsidiaries⁹⁵

FTC Enforcement Actions		
Cases Filed	Alleged conduct	Year
Federal Trade Commission v. Allergan PLC, et al., Case No. 17-cv-00312 (N.D. Cal.).	Pay-for-delay	2017
Federal Trade Commission v. Actavis, 133 S. Ct. 2223. Federal Trade Commission, et al. v. Watson Pharmaceuticals, Inc., et al., (Generic Androgel), Case No. CV-09-00598 (C.D. Cal.).	Pay-for-delay	2009
Federal Trade Commission v. Warner Chilcott Corporation, Civil Action No. 1:05-CV2179-CKK (D.D.C)	Pay-for-delay and product hop	2005
Amicus Briefs Filed	Alleged conduct	Year
Mylan Pharmaceuticals, Inc., et al., v. Warner Chilcott Public Limited Company, et al., Federal Trade Commission as Amicus, Civil Action No. 12-3824 (E.D. Pa. November 21, 2012); Brief for Amicus Curiae Federal Trade Commission Supporting Plaintiff-Appellant, No. 12-3824-PD (3d. Cir. September 30, 2015).	Product hop	2012, 2015
In re: Ciprofloxacin Hydrochloride Antitrust Litigation (Arkansas Carpenters Health and Welfare Fund v. Bayer AG, Bayer Corp.), Brief of Amicus Curiae Federal Trade Commission, In Support of Appellants and Urging Reversal, No. 2008-1097 (Fed. Cir. January 25, 2008); Brief Amicus Curiae of Federal Trade Commission In Support of Rehearing En Banc, Docket No.'s 05-2851-cv (L) and 05-2852-cv (CON 2d. Cir. May 20, 2010)	Pay-for-delay	2008, 2010
Mergers	Order	Year
Teva Pharmaceutical Industries Ltd./Allergan PLC	Divestiture, supply requirement	2016
Actavis PLC/Forest Laboratories, Inc.	Divestiture	2014
Actavis, Inc./Warner Chilcott plc	Divestiture, supply requirement, and requiring company to relinquish claim to first filer marketing exclusivity	2013
Watson Pharmaceuticals Inc./Actavis, Inc.	Divestiture	2012
Watson Pharmaceuticals, Inc./Robin Hood Holdings (Arrow)	Divestiture	2010
Actavis Group/Abrika Pharmaceuticals, Inc.	Divestiture	2007
Allergan Inc./Inamed Corp.	Divestiture, confidential business information requirement	2006

⁹⁵ Markus Meier et al., OVERVIEW OF FTC ACTIONS IN PHARMACEUTICAL PRODUCTS AND DISTRIBUTION, FEDERAL TRADE COMMISSION (June 2019), <https://tinyurl.com/v3pvjzf>.

Watson Pharmaceuticals Inc./Andrx Corp	Divestiture, supply requirement and termination of marketing agreement	2006
--	--	------