



AMERICAN
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LIBERTIES
PROJECT

The Costs of Pharma Cheating

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American Economic Liberties Project
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& Knowledge (I-MAK)

INTRODUCTION

Drugs prices are high in the United States, and many are getting more expensive. Out of 1,216 drugs whose price increases surpassed inflation from July 2021 to July 2022, the average price increase was 31.6 percent,² and a 2021 poll by Gallup found that 18 million Americans – 7 percent of adults – were unable to pay for medications prescribed to them by a doctor.³ Voters consistently show anger about the high and rising cost of drugs in the United States.⁴

This report examines one of the drivers of these high costs: violations of antitrust law by drug manufacturers aiming to avoid competition and keep prices high. The analysis reviews the 100 top-selling drug products in Medicare Part D (Part D) and Medicaid in 2019 to estimate the prevalence and financial impact of antitrust violations on the U.S. pharmaceutical industry. From this review, Economic Liberties and I-MAK estimate that antitrust violations increased Part D gross spending by 14.15 percent, or \$14.82 billion, and increased Medicaid gross drug spending by 9.05 percent, or \$3.15 billion, in 2019 for the top 100 drugs in each. Extrapolating based on the assumption that all U.S. retail brand drug spending was similarly impacted, Economic Liberties and I-MAK estimate that U.S. patients and payers spent an additional \$40.07 billion on pharmaceuticals in 2019 as a result of antitrust violations by the pharmaceutical industry. With a 2019 U.S. population of approximately 328.2 million, this equates to an average cost of approximately \$120 per year for every American man, woman, and child, solely because of antitrust violations by the pharmaceutical industry.

There are multiple implications for policymakers seeking to understand and fix pharmaceutical markets. One, the cost of branded drugs is significantly elevated above any reasonable market price. Two, given the significant fraction of revenues in the industry that accrue purely because of unlawful actions, firms are likely responding to this incentive, investing in legal innovations to unlawfully maintain monopolies instead of investing in the research and development of newer and better medicines. Eliminating this waste would reorient incentives back towards genuine innovation.

We make several specific recommendations. First, policymakers should dramatically increase funding and resources to antitrust enforcement to tackle the unlawful monopolies in this sector. Second, lawmakers should tighten the rules around pharmaceutical patent eligibility, including the Noerr-Pennington doctrine. Third, antitrust enforcement agencies should be more proactive

1 We would like to thank Professor Robin Feldman and Professor Michael A. Carrier for helpful comments on earlier versions of this paper.

2 Arielle Bosworth et al., “Price Increases for Prescription Drugs, 2016-2022,” Health and Human Services Office of Assistant Secretary for Planning and Evaluation, September 30, 2022, <https://aspe.hhs.gov/reports/prescription-drug-price-increases>.

3 Dan Witters, “In U.S., an Estimated 18 Million Can’t Pay for Needed Drugs,” Gallup, September 21, 2021, <https://news.gallup.com/poll/354833/estimated-million-pay-needed-drugs.aspx>.

4 Arnold Ventures, “Prescription Drug Prices: The Voters Speak,” May 2019, https://craftmediabucket.s3.amazonaws.com/uploads/AV-Summary-of-Polling-Project_052119_FINAL.pdf.

about identifying and stopping anticompetitive schemes before patients are harmed through high costs or a lack of treatment for inability to pay. Fourth, settlements by the antitrust agencies going forward should punish corporations and individuals more harshly to deter illegal behavior. Fifth, the Department of Justice and state attorneys general should actively seek to recover funds lost through overpayment through Medicare Part D and Medicaid, as they are the only actors who can recover damages for the 45 percent of U.S. drug spending represented by those programs, and the failure to do so leaves an enormous gap in potential deterrence.

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I. THE IMPORTANCE OF GENERIC AND BIOSIMILAR COMPETITION IN THE U.S. PHARMACEUTICAL INDUSTRY

The U.S. prescription drug industry is designed around laws that provide temporary patent and regulatory monopolies to companies that introduce proprietary “brand” drug products. These government-granted monopolies are intended to compensate companies for their upfront investment in researching, developing, and commercializing new drugs. However, these patent and regulatory monopolies are meant to be temporary. Under the structure created by the Hatch-Waxman Act of 1984,⁵ once drug patents and exclusivities expire, equivalent generic (and now biosimilar) drugs should enter and introduce price competition to lower drug costs. The Hatch-Waxman framework seeks a balance between maintaining incentives for research and development while ensuring that low-cost, equivalent generics can then come to market. Supplementing Hatch-Waxman, the 2009 Biologics Price Competition and Innovation Act (BPCIA) governs biologic drugs and the pathway for biosimilars to gain U.S. Food and Drug Administration (FDA) approval, including clearing any patent rights.

In addition to the Hatch-Waxman framework, state pharmacy laws also encourage the use of low-cost generic drugs or permit the substitution of an originator biologic to an interchangeable biosimilar. Specifically, state pharmacy laws permit and often mandate that pharmacists fill brand prescriptions with low-cost generic alternatives whenever possible. As a result, generics are dispensed 97 percent of the time when available.⁶

⁵ Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. §355 and 35 U.S.C. §156, 271 and 282).

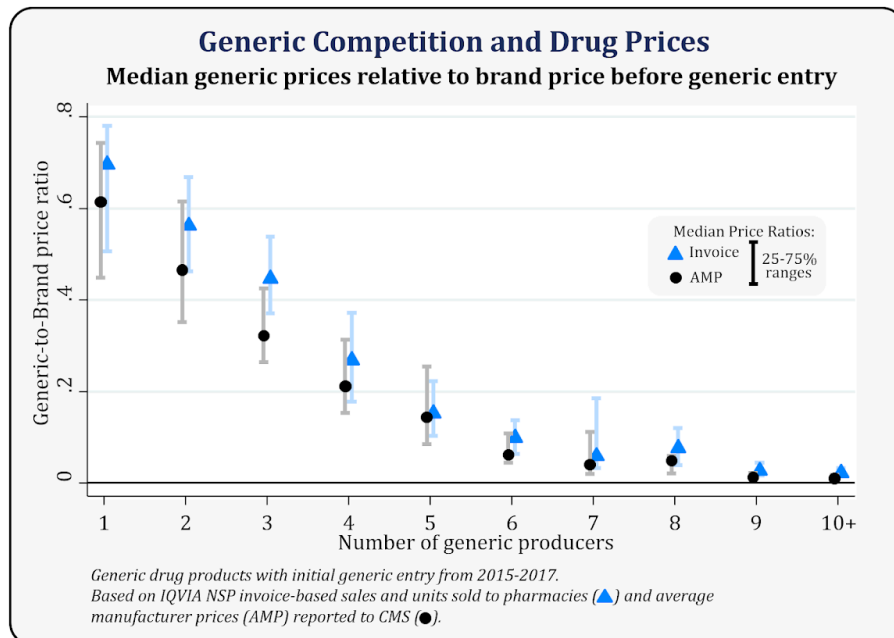
⁶ IQVIA Institute, *The Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025*, at 38 (May 2021), <https://www.iqvia.com/en/insights/the-iqvia-institute/reports/the-use-of-medicines-in-the-US>.

Unfortunately, over the last few decades, pharmaceutical manufacturers and pharmacy benefit managers (PBMs) have developed an entire menu of anticompetitive strategies to thwart the Hatch-Waxman Act and state substitution laws to delay or prevent generic and biosimilar competition. These strategies, including “pay-for-delay,” “product hopping,” and “sham citizen petitions,” as detailed here, frequently violate state and federal antitrust laws to deny patients and payers access to low-cost alternatives.

A. THE INTRODUCTION OF MULTIPLE GENERIC COMPETITORS DRAMATICALLY REDUCES PRICES AND OVERALL SPENDING IN IMPACTED MARKETS

Traditional generic drugs, particularly those sold as pills (oral solid dosage form), usually cost a fraction of the cost of equivalent brand drugs, particularly once multiple generic competitors have come to market. As shown in Figure 1 below, the FDA recently studied all first-time generic launches between 2015 and 2017 and concluded that the average manufacturer price (AMP) of generics was 39 percent less than the brand after a single generic came to market, 54 percent less after two generics came to market, 79 percent less after four generics came to market, and more than 95 percent less when there are six or more generic competitors.⁷

Figure 1 - Median Generic Prices Relative to Brand Price Before Generic Entry



⁷ FDA, *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices* (2019), <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices>.

When a brand faces multiple generic competitors for the first time, prices decline so dramatically that this is referred to as “the patent cliff” in the pharmaceutical industry because the prices in the impacted market appear to fall off a cliff once the patent expires and generics are allowed to compete on equal terms.⁸

Crestor offers an illustrative example. Crestor was a “blockbuster” cholesterol drug in the 2000s and early 2010s. The key Crestor patent finally expired in 2016, which allowed multiple generic versions of Crestor to come to market around that time.⁹ As shown in Table 1 below, average Medicare Part D spending per claim on brand and generic Crestor rapidly decreased from \$331 in 2015 to \$54 in 2018 as the market rapidly switched from the expensive brand to low-cost generics. This ultimately decreased spending on brand and generic Crestor by 79 percent, while the number of brand and generic claims increased from 8.71 million in 2015 to 11.06 million in 2018.

Table 1 - Part D Gross Spending on Brand and Generic Crestor 2015-18¹⁰

	2015			2016			2017			2018		
	No. Claims	Avg. Price	Spend	No. Claims	Avg. Price	Spend	No. Claims	Avg. Price	Spend	No. Claims	Avg. Price	Spend
Crestor (Brand)	8.71 m	\$331	\$2.88 b	6.01 b	\$386	\$2.32 b	0.76 m	\$403	\$308 m	0.17 m	\$443	\$77 m
Rosuvastatin (Generic)				1.59 m	\$87	\$137 m	7.67 m	\$63	\$486 m	10.89 m	\$48	\$518 m
Combined Total	8.71 m	\$331	\$2.88 b	7.60 m	\$324	\$2.46 b	8.44 m	\$94	\$794 m	11.06 m	\$54	\$596 m
Decline Since 2015						15%			72%			79%

B. RECENT BIOSIMILAR LAUNCHES HAVE RAPIDLY CAPTURED MARKET SHARE AND SIGNIFICANTLY REDUCED SPENDING ON IMPACTED BIOLOGICS

Biosimilars are low-cost, generic-like versions of biologic drugs that also significantly reduce prices and overall drug spending, but to a lesser degree than traditional generics. According to one recent IQVIA report, biosimilar prices have historically been an average of 30 percent less than equivalent brand biologics on an ASP basis.¹¹ Biosimilars also tend to gain market share

⁸ See e.g., Fierce Pharma, The Top 15 Blockbuster Patent Expirations Coming this Decade (July 12, 2021), <https://www.fiercepharma.com/special-report/top-15-blockbuster-patent-expirations-coming-decade> (“some of the biggest drugs in the industry will tumble off the patent cliff”).

⁹ See e.g., FDA, FDA Approves First Generic Crestor (April 26, 2016), <https://www.fda.gov/news-events/press-announcements/fda-approves-first-generic-crestor>.

¹⁰ Centers for Medicare & Medicaid Services (CMS), Medicare Part D Drug Spending Dashboard and Data, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD>.

¹¹ IQVIA Institute, Biosimilars in the United States 2020-24: Competition, Savings, and Sustainability, at 15 (Oct. 2020), <https://www.iqvia.com/insights/the-iqvia-institute/reports/biosimilars-in-the-united-states-2020-2024>.

more slowly than traditional generics, with the most successful biosimilar launches estimated to capture 55 percent market share within two years of coming to market.¹²

However, the rate of biosimilar price declines and the ability to grab market share appear to be increasing in just the last couple years as the market has come to understand and demand biosimilar alternatives. One biosimilar manufacturer, Amgen, recently reported that biosimilar prices are now decreasing by 9 to 19 percent per year.¹³ Additionally, biosimilars that launched before 2019 captured an average of 13 percent market share within two years, while biosimilars that launched since 2019 have captured an average of 64 percent market share over the same period.¹⁴ Combined, these trends establish that demand for low-cost biosimilars has increased in recent years and that U.S. patients have missed significant savings when biosimilars are delayed by anticompetitive schemes.

II. ESTIMATING THE PREVALENCE OF PHARMACEUTICAL ANTITRUST VIOLATIONS

A. METHODOLOGY

To estimate the prevalence or frequency of antitrust violations across the pharmaceutical industry, Economic Liberties and I-MAK first collected gross drug spending data for the top 100 drug products¹⁵ in Part D and Medicaid in 2019, many of which appear on both lists. We then searched for and reviewed documents from public and private antitrust litigation, government reports, credible industry sources, and academic research to determine whether spending on each drug was likely inflated because of a violation of the antitrust laws in 2019.

Brand drugs were classified as likely impacted by an antitrust violation in 2019 in three circumstances: (1) the drug did not face generic or biosimilar competition because of an antitrust violation; (2) the drug faced significantly less generic or biosimilar competition because of an antitrust violation; or (3) the drug was a direct successor to an older brand drug that would have already lost market share but for an antitrust violation.

For the purposes of this report, an “antitrust violation” is defined as a highly credible allegation of misconduct of the type that has been found to violate the antitrust statutes, but not necessarily regarding the drug at issue. Critically, this analysis considered both traditional antitrust claims

¹² Id.

¹³ Amgen Biosimilars, 2021 Biosimilar Trends Report, at 13 (2021), https://www.amgenbiosimilars.com/commitment/-/media/Themes/Amgen/amgenbiosimilars-com/Amgenbiosimilars-com/pdf/USA-CBU-80962_Amgen-2021-Biosimilar-Trends-Report.pdf.

¹⁴ Id at 14.

¹⁵ As used here, “drug product” refers to individual products while “brand drug” includes all drug products sold under the same brand name, which ordinarily contain the same active ingredients. For example, Novolog and Novolog Flexpen are two distinct drug products within the Novolog brand franchise.

under the Sherman Act as well as claims under the oft-forgotten Clayton Act and Robinson-Patman Act, which prohibit exclusionary dealing, commercial bribery, and acquisition of monopoly.¹⁶

Apparent violations were included independently from the outcome of cited antitrust lawsuits because private antitrust cases, which make up most antitrust lawsuits, usually settle before they address the merits of plaintiffs' claims or fail for plaintiff-specific reasons and therefore do not ultimately determine whether the defendant violated the antitrust laws. For example, a district court recently rejected a Robinson-Patman commercial bribery claim on the basis that payers and patients were potentially injured by the conduct more than the wholesalers who brought the claim.¹⁷ Accordingly, this case law supports the existence of a claim for commercial bribery under the Robinson-Patman Act even though it rejects the wholesaler plaintiff's claim.

Conduct was generally classified as an antitrust violation if there was some significant precedent supporting the existence of an antitrust claim for similar conduct, even if courts had previously rejected similar claims. Theories of potential antitrust liability taken from existing antitrust lawsuits were generally classified as likely antitrust violations unless the theory had been expressly rejected in the underlying case in a way that establishes the legality of the defendant's conduct as to all potential public and private claimants and all potential antitrust claims.

B. TYPES OF PHARMACEUTICAL ANTITRUST VIOLATIONS

In the review of the top 100 drug products, Economic Liberties and I-MAK identified 10 distinct types of anticompetitive schemes in the pharmaceutical industry that appear to violate existing antitrust laws.

Horizontal Collusion – This refers to the strategy of competitors or potential competitors agreeing to raise prices, restrict output, rig a bidding process, allocate market share, or otherwise impose high prices or low quality across an industry instead of competing on quality and prices. Horizontal collusion constitutes a per se violation of the Sherman Act.

Pay-for-Delay or Reverse Payment – This is when brand drug companies compensate generic competitors (often via complicated commercial transactions) to drop their patent challenges so that both companies can instead split the brand drug's continued windfall monopoly profits. The Supreme Court recognized that “large and unjustified” payments to generic competitors

¹⁶ See 15 U.S.C. § 14 (prohibiting exclusive dealing that tends to lessen competition or create a monopoly); 15 U.S.C. § 13(c) (prohibiting commercial bribery).

¹⁷ In re Direct Purchaser Insulin Pricing Litigation, 3:20-cv-3426 (BRM) (LHG), at *1 (D.N.J. July 9, 2021) (“Competitors of the PBM Defendants and the Manufacturer Defendants, as well as the health benefit plan clients and their insured, make up these potential victims, not wholesalers like Plaintiffs.”).

violate the Sherman Act regardless of the merits of the underlying patents in *FTC v. Actavis*, 133 S. Ct. 2223 (2013). As used here, “pay-for-delay” includes instances in which a brand company compensated a generic challenger by allowing generic entry in one market in exchange for dropping a patent challenge in another market, which is a form of horizontal collusion.

No-Generics Agreement – This refers to the practice of a brand company entering an agreement with a potential competitor on the condition that the potential competitor not launch their own competing product. This is a form of horizontal collusion and/or horizontal market allocation that appears to violate Sherman Act, § 1. No-generics agreements are distinct from pay-for-delay because they occur between two brand drug companies in the context of drug development agreements, unlike pay-for-delay agreements, which occur in drug patent settlements between brand and generic companies.

Patent Abuse – This includes several related practices, including submitting false statements to the United States Patent and Trademark Office (USPTO), pursuing sham patent litigation, and “patent thicketing”—all of which allow brand drug companies to obtain or extend brand drug monopolies by defrauding and abusing the U.S. patent system.¹⁸ Sham patent litigation is when a brand manufacturer sues a generic manufacturer for patent infringement, but where the patent in question is not valid. Patent thicketing refers to a situation in which the brand manufacturer uses many overlapping, and often low-quality, patents such that potential competing manufacturers are blocked for need of separate licenses for all the corresponding patents.

Product Hopping and Patent Evergreening – Product hopping and evergreening represent a distinct variety of patent abuse. They refer to when a brand company launches a new, slightly modified version of an existing drug whose patent is about to expire and then withdraws the existing drug (or uses another form of coercion), which then forces all patients onto the new drug before generic versions of the original drug come to market.¹⁹ Product hopping thwarts the generic equivalency at the core of the Hatch-Waxman Act and state generic substitution laws, which contemplate the brand drug staying on the market until equivalent generics have entered.

Sham Citizen Petition – This is when a brand drug company uses the FDA’s citizen petition process—which is intended to allow the public to warn the FDA about pressing safety issues—to create fraudulent safety and efficacy concerns about impending generic or biosimilar competitors to trick the FDA into delaying or rejecting meaningful competition.²⁰

18 *In re Lipitor Antitrust Litig. Rite Aid Corp.*, 868 F.3d 231, 266 (3d Cir. 2017) (“Fraudulent procurement of a patent or the enforcement of a patent obtained by fraud ... can provide the basis for antitrust liability.”).

19 *New York ex rel. Schneiderman v. Actavis PLC*, 787 F.3d 638, 660 (2d Cir. 2015) (“it is the combination of Defendants’ withdrawal of IR and introduction of XR in the context of generic substitution laws that places their conduct beyond the scope of their patent rights for IR or XR individually.”).

20 Robin Feldman, et al., *Empirical Evidence of Drug Pricing Games—A Citizen’s Pathway Gone Astray*, 20 *Stan. Tech. L. Rev.* 39 (2017), available at <https://law.stanford.edu/wp-content/uploads/2017/10/Empirical-Evidence-of-Drug-Pricing-Games%E2%80%94A-Citizens-Pathway-Gone-Astray-.pdf>; Michael A. Carrier & Carl Minniti, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 *American University Law Review* (2016), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2832319 (finding that brand firms file 92 percent of citizen petitions, but the FDA grants only 8 percent, indicating that they are frequently used to delay generic entry).

Sham Orange Book Listing – This is when a brand company lists a patent, often a drug-device combination patent, in the FDA’s official patent registry, known as the FDA Orange Book, when doing so is prohibited by statute and FDA regulation. Illegally listing patents in the Orange Book allows brand drug companies to unlawfully trigger the “30-month stay,” a period in which the FDA is statutorily prohibited from approving generic competitors. The First Circuit Court of Appeals recently held that patents that do not claim the final drug product, including many drug-device combination patents, should not be listed in the Orange Book and that doing so may violate the Sherman Act.²¹

REMS Abuse – REMS refers to the FDA’s Risk Evaluation and Mitigation Strategy program, which requires heightened safety procedures up and down the supply chain for drugs that are thought to be particularly dangerous.²² Unfortunately, REMS programs have frequently been used by brand drug companies to block generic and biosimilar competition in recent years, often by intentionally blocking competitors’ access to the samples needed to create an equivalent product.²³

Exclusionary Rebates – As used here, this refers to the practice of brand drug companies paying pharmacy benefit managers (“PBMs”) large rebates, known as “PBM rebates,” in exchange for PBMs excluding significantly cheaper alternatives from patients’ formularies. The formularies maintained by PBMs determine which drugs are covered by health insurance, so by excluding alternatives from the formulary, the brand drug avoids competition. In certain situations, PBM rebates are indistinguishable from bribes or kickbacks in that PBMs extract larger profits by driving patients to more expensive drugs. Crucially, patients’ co-pays and deductibles are determined as a percentage of gross drug price before any PBM rebates are deducted. This means patients never benefit from the PBM rebates supposedly negotiated to lower drug prices on their behalf.

Exclusionary PBM rebates appear to constitute commercial bribery in violation of the Robinson-Patman Act, 15 U.S.C. § 13(c), which prohibits corrupt payments to agents working on behalf of the opposing side in a transaction,²⁴ as is the case when drug manufacturers pay PBMs secret rebates to drive patients to more expensive drugs. The U.S. District Court for New Jersey recently addressed a Robinson-Patman commercial bribery claim for PBM rebate practices and suggested that health plans and patients may have viable antitrust claims under the statute.²⁵

21 *César Castillo, Inc. v. Sanofi-Aventis U.S., LLC (In re Lantus Direct Purchaser Antitrust Litig.)*, 950 F.3d 1 (1st Cir. 2020).

22 FDA, Risk Evaluation and Mitigation Strategies, <https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems>.

23 Michael A. Carrier & Carl J. Minniti, *Biologics: The New Antitrust Frontier*, Univ. Ill. L. Rev. 1, 46-49 (2018), available at <https://scholarship.libraries.rutgers.edu/esploro/outputs/journalArticle/Biologics-The-New-Antitrust-Frontier/991031549895104646> (analyzing abuse of the REMS system).

24 *In re Direct Purchaser Insulin Pricing Litigation*, 3:20-cv-3426, at *1 (D. N.J. July 9, 2021) (“[C]ommercial bribery is also actionable under Section 2(c).”).

25 *Id.* at *1 (“Competitors of the PBM Defendants and the Manufacturer Defendants, as well as the health benefit plan clients and their insured, make up these potential victims, not wholesalers like Plaintiffs.”).

The payment of PBM rebates to protect a dominant brand drug from a nascent competitor also likely violates Clayton Act, § 3, which makes it unlawful to sell goods, or determine prices or rebates, on the condition that the purchaser does not deal with a competitor when doing so may substantially lessen competition or tend to create a monopoly.²⁶ Finally, exclusionary rebates that bundled dominant products and nondominant products have also been found to violate Sherman Act, § 2, specifically in the pharmaceutical industry.²⁷

Acquisition of Monopoly – This refers to the strategy of a brand drug company merging, acquiring, or acquiring assets from a potential brand, generic, or biosimilar competitor for the purpose of eliminating potential competition and therefore maintaining or creating a brand drug monopoly. Intentionally acquiring a monopoly may violate Sherman Act, § 2 and Clayton Act, § 7.²⁸

C. PREVALENCE OF ANTITRUST VIOLATIONS

The results from Economic Liberties and I-MAK’s review of the top 100 drugs in Part D and Medicaid in 2019 are summarized in Table 2 below. As shown, we identified 20 of the top brand drugs, inclusive of 25 drug products, as likely impacted in 2019 by anticompetitive schemes that violated the antitrust laws.

Table 2 – Top 100 Part D and Medicaid Drugs Likely Impacted by Antitrust Violations in 2019

Drug Company	Brand Name	Source	Scheme Type
AbbVie/Allergan	Botox	<i>In Matter of Allergan and Inamed</i> , FTC No. 061-0031 (2006); <i>Tawfilis v. Allergan</i> , 15-cv-00307 (S.D. Cal.)	Acquisition of Monopoly; Pay-for-Delay
AbbVie/Allergan	Bystolic	<i>In re Bystolic Antitrust Litigation</i> , Case No. 20-cv-5538, 7352, 5735,7110, 5837, 5813, 7492, 5826, 7309, 5735, 5813, 5901, 5826, 6769, 7177, 6647, 7296, 7304 (S.D.N.Y.)	Pay-for-Delay
AbbVie/Allergan	Restasis	<i>In re Restasis Antitrust Litigation</i> , 18-md-02819 (E.D.N.Y.); FDA Orange Book	Sham Orange Book Listing; Patent Abuse; Sham Citizen Petition
Boehringer Ing.	Combivent Respimat	Beall, et al., <i>Is Patent “Evergreening” Restricting Access to Medicine/Device Combination Products</i> , PLoS ONE 11(2) (2016).	Sham Orange Book Listing
Boehringer Ing.	Spiriva	Beall, et al., <i>Is Patent “Evergreening” Restricting Access to Medicine/Device Combination Products</i> , PLoS ONE 11(2) (2016).	Sham Orange Book Listing
Celgene	Revlimid	<i>In re Thalomid and Revlimid Antitrust Litigation</i> , 2:14-cv-06997 (D. N.J.).	Sham Orange Book Listing; Patent Abuse; REMS Abuse
Eli Lilly & Co.	Basaglar	<i>In re Direct Purchaser Insulin Pricing Litigation</i> , 3:20-cv-03426 (D. N.J.); Adam J. Fein, Drug Channels, <i>Why PBMs and Payers Are Embracing Insulin Biosimilars with Higher Prices—And What That Means for Humira</i> (Nov. 9, 2021).	Exclusionary Rebates; Horizontal Collusion ²⁹

26 15 U.S.C. § 14 (Sale, etc., on agreement not to use goods of competitor); *Tampa Electric Co. v. Nashville Co.*, 365 U.S. 320, 327 (1961) (“In practical application, even though a contract is found to be an exclusive-dealing arrangement, it does not violate the section unless the court believes it probable that performance of the contract will foreclose competition in a substantial share of the line of commerce affected.”).

27 E.g., *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056 (3d Cir. 1978).

28 15 U.S.C. § 18 (acquisition by one corporation of stock of another).

29 The court in *In re Direct Purchaser Insulin Pricing Litigation* has recognized a potential RICO violation for conduct that essentially amounts to commercial bribery via rebates between insulin manufacturers. 3:20-cv-3426 (BRM) (LHG) (D.N.J. July 9, 2021).

Drug Company	Brand Name	Source	Scheme Type
Gilead Sciences	Epclusa	Adam J. Fein, Drug Channels, <i>Why Part D Plans Prefer High List Prices That Raise Costs for Seniors</i> , (Jan. 22, 2020).	Exclusionary Rebates
Gilead Sciences	Harvoni	Adam J. Fein, Drug Channels, <i>Why Part D Plans Prefer High List Prices That Raise Costs for Seniors</i> , (Jan. 22, 2020).	Exclusionary Rebates
GlaxoSmithKline	Advair Diskus	Beall, et al., <i>Is Patent “Evergreening” Restricting Access to Medicine/Device Combination Products</i> , PLoS ONE 11(2) (2016).	Sham Orange Book Listing
GlaxoSmithKline	Flovent HFA	Beall, et al., <i>Is Patent “Evergreening” Restricting Access to Medicine/Device Combination Products</i> , PLoS ONE 11(2) (2016).	Sham Orange Book Listing
GlaxoSmithKline	Ventolin HFA	Beall, et al., <i>Is Patent “Evergreening” Restricting Access to Medicine/Device Combination Products</i> , PLoS ONE 11(2) (2016).	Sham Orange Book Listing
Indivior Inc.	Suboxone	<i>In re Suboxone Antitrust Litigation</i> , 13-md-2445 (E.D. Pa.); <i>FTC v. Indivior Inc.</i> , 20-cv-00036 (W.D. Vir. 2020).	Product Hopping; Sham Citizen Petition
Janssen Biotech	Remicade	<i>In re Remicade Antitrust Litigation</i> , 2:17-cv-04326 (E.D.P.A.).	Exclusionary Rebates
Janssen Biotech	Zytiga	<i>United States v. Janssen Biotech, Inc.</i> , Civ. 19-12107 (D.N.J.); <i>In re Zytiga Antitrust Litigation (KPH Healthcare Services, Inc. v. Janssen Biotech, Inc.)</i> , 2:20-cv-05901 (D.N.J.).	Patent Abuse
Mallinckrodt	Acthar	<i>In re Acthar Antitrust Litigation (MSP Recovery Claims LLC v. Mallinckrodt)</i> , 2:17-cv-07928 (N.D. Cal.); <i>FTC et al. v. Mallinckrodt plc</i> , 1:17-cv-00120 (D. D.C.).	Acquisition of Monopoly
Novo Nordisk	Levemir	<i>In re Direct Purchaser Insulin Pricing Litigation</i> , 3:20-cv-03426 (D. N.J.).	Exclusionary Rebates; Horizontal Collusion
Novo Nordisk	Novolog	<i>In re Direct Purchaser Insulin Pricing Litigation</i> , 3:20-cv-03426 (D. N.J.); Beall, et al., <i>Is Patent “Evergreening” Restricting Access to Medicine/Device Combination Products</i> , PLoS ONE 11(2) (2016).	Sham Orange Book Listing; Exclusionary Rebates; Horizontal Collusion
Sanofi-Aventis	Admelog Solostar	<i>In re Direct Purchaser Insulin Pricing Litigation</i> , 3:20-cv-03426 (D. N.J.); Adam J. Fein, Drug Channels, <i>Why PBMs and Payers Are Embracing Insulin Biosimilars with Higher Prices—And What That Means for Humira</i> (Nov. 9, 2021).	Exclusionary Rebates; Horizontal Collusion
Sanofi-Aventis	Lantus	<i>In re Direct Purchaser Insulin Pricing Litigation</i> , 3:20-cv-03426 (D. N.J.); <i>In Re Lantus Direct Purchaser Antitrust Litigation</i> , 1:16-cv-12652 (D. Mass.)	Sham Orange Book Listing; Exclusionary Rebates; Horizontal Collusion
Teva	Copaxone	46Brooklyn, <i>The Flawed Design of Medicare Part D: A Copaxone Case Study</i> (Aug. 12, 2020); House Committee on Oversight and Reform, <i>Drug Pricing Investigation: Teva-Copaxone</i> (Sept. 2020).	Exclusionary Rebates
Teva	Proair HFA	Beall, et al., <i>Is Patent “Evergreening” Restricting Access to Medicine/Device Combination Products</i> , PLoS ONE 11(2) (2016).	Sham Orange Book Listing

III. ESTIMATING THE FINANCIAL IMPACT OF PHARMACEUTICAL ANTITRUST VIOLATIONS

While Table 2 above addresses the prevalence of antitrust violations among the top 100 drug products, the next step is to estimate the extent to which that conduct increased Part D and Medicaid spending in 2019. We make a series of assumptions depending on the type of violation and the type of drug in question.

For violations that delayed generic or biosimilar competition (e.g., product hopping or pay-for-delay), Economic Liberties and I-MAK estimated the rate of overspending by starting with the

default price and market share assumptions for brands versus generics and biosimilars, and circumstantially altering those assumptions where more precise comparisons are possible. Because the violations in question here maintained the temporary patent monopoly and thus the drug price mostly reflects monopoly profits rather than the cost of producing the drug, we assume that branded, blockbuster drugs that delayed generic competition experienced an overcharge rate of 90 percent, meaning that 90 percent of the sale price of the drug reflected an overcharge from an illegally extended monopoly.³⁰ Where generic or cheaper alternatives were blocked because of device patents, where costs often reflect a genuinely higher production cost, we assume a more conservative overcharge rate of 60 percent.

For antitrust violations that reduced the impact of brand-versus-brand or brand-versus-generic competition that did come to market (e.g., exclusionary PBM rebates), Economic Liberties and I-MAK estimated the rate of overspending as the difference between the price of the brand and the cheaper alternative (brand, authorized generic, or generic) that patients would have purchased but for the antitrust violation at issue. In other words, we assumed that all patients would have purchased the significantly cheaper drug if given the opportunity.³¹

Overall, this analysis is intended to be a general estimate of overspending as the result of antitrust violations in the pharmaceutical industry. It is based on the simplistic assumption that all the drug products of a particular brand (e.g., Novolog and Novolog Flexpen) were impacted by the antitrust violation equally, even though there's almost certainly some product-by-product variation in generic uptake. Similarly, this analysis assumes a flat, average rate of overspending across 2019 even though prices and generic uptake may have changed over the course of the year in the but-for world. This analysis is not intended to be a comprehensive expert damages report regarding every drug product at issue, which typically costs several million dollars and requires multiple specialized professionals including accountants, economists, FDA regulatory officials and experts, academic physicians, insurance professionals, and frequently, pharmaceutical scientists, depending on the scheme at issue. There are ultimately unlimited ways to quibble with any proposed estimates of anticompetitive conduct.

Regardless, the introduction of generic and biosimilar competition significantly reduces drug prices and spending in affected markets, and the delay of generic and biosimilar competition does the opposite. This undeniable fact is precisely why brand drug companies spend enormous sums on lawyers and invent, then fiercely defend, well-known anticompetitive schemes like product hopping. Drug companies spend hundreds of millions of dollars advancing these schemes because they have calculated that doing so is significantly more profitable than

30 This generalization is based on a recent FDA study showing that traditional generic drugs reduce prices by up to 95 percent, as well as particularly notable cases such as Truvada, which experienced a 99 percent price drop in 2020, as soon as the last of its patents expired. FDA, *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices* (2019), <https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices>.

31 This assumes 100 percent conversion to the cheaper alternative for simplicity; however, manufacturers often use a variety of tactics, including advertising and deceptive marketing to physicians, to prevent this from happening.

competing with generics and biosimilars based on price and quality.

Now we review each of the drugs, category by category, to explain the antitrust violations for which the manufacturers have been credibly accused and how the antitrust violations have likely led to substantially higher prices for the drug in 2019.

A. COPD/ASTHMA INHALERS

Three manufacturers likely violated the antitrust laws by illegally maintaining exclusivity for several COPD/asthma inhalers by unlawfully listing inhaler device patents in the Orange Book and therefore engaging in sham patent listing. The fact that several inhaler companies engaged in this practice cannot be disputed.³² As recently recognized by the First Circuit, these types of device-only patents cannot lawfully be listed in the Orange Book because they do not claim the final drug product and are therefore ineligible for inclusion under FDA statute and regulation.³³

Because these violations are based on delaying entry via a device patent, we estimate that Part D and Medicaid would have spent 60 percent less on the following inhaler products in 2019 if their sponsors had not unlawfully blocked generic competition by listing impermissible inhaler device patents in the FDA Orange Book to illegally maintain exclusivity in 2019. Even though these inhalers contain traditional, small-molecule drug substances, relatively few companies make inhaler products, which means these brand inhalers would have likely drawn fewer generic competitors than traditional, oral solid drugs and prices would have accordingly declined less rapidly.

Drug Co.	Brand Name	Antitrust Violation	Est. Antitrust Overspend %
Boehringer Ing.	Combivent Respimat	Sham Orange Book Listing	60%
Boehringer Ing.	Spiriva	Sham Orange Book Listing	60%
GlaxoSmithKline	Advair Diskus	Sham Orange Book Listing	60%
GlaxoSmithKline	Flovent HFA	Sham Orange Book Listing	60%
GlaxoSmithKline	Ventolin HFA	Sham Orange Book Listing	60%
Teva	Proair HFA	Sham Orange Book Listing	60%

B. INSULIN

The insulin market has been distorted by multiple overlapping anticompetitive schemes in recent years, including illegally listing injector device patents in the Orange Book,³⁴ horizontal

³² Beall, et al., Is Patent “Evergreening” Restricting Access to Medicine/Device Combination Products?, PLoS ONE 11(2) (2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4766186/> (explaining how several manufacturers of inhaler and injector drug products maintained exclusivity in part by listing device patents in the Orange Book beyond the length of the underlying drug substance patents).

³³ See *César Castillo, Inc. v. Sanofi-Aventis U.S., LLC (In re Lantus Direct Purchaser Antitrust Litig.)*, 950 F.3d 1, 10 (1st Cir. 2020) (“The statute and regulations clearly require that only patents that claim the drug for which the NDA is submitted should be listed in the Orange Book.”).

³⁴ *César Castillo, Inc. v. Sanofi-Aventis U.S., LLC (In re Lantus Direct Purchaser Antitrust Litig.)*, 950 F.3d 1 (1st Cir. 2020).

³⁵ *In re Direct Purchaser Insulin Pricing Litigation*, 3:20-cv-3426 (BRM) (LHG), at *37 (D.N.J. July 9, 2021) (“the Court finds Plaintiffs have plausibly alleged claims for RICO and RICO conspiracy”); *In re Insulin Pricing Litig.*, 2:17-cv-00699 (BRM) (ESK), at *33 (D.N.J. Dec. 17, 2021).

collusion among the top three manufacturers and PBMs in a way that constitutes a RICO violation,³⁵ and exclusionary rebates to drive patients toward brand products and away from substantially cheaper authorized generic versions.³⁶

Economic Liberties and I-MAK estimate that Part D and Medicaid would have spent approximately 50 percent less on three of the four major insulin brands (Levemir, Novolog, Lantus) in 2019 but for the anticompetitive strategies used by the major insulin manufacturers. This estimate is based on the approximate price difference between these major insulin brands and the low-cost authorized generic and biosimilars that patients would have received if not for exclusionary PBM rebates. Economic Liberties and I-MAK estimate that spending on the two generic-like insulins (Basaglar and Admelog) would have been at least 25 percent less in a fully competitive market, as indicated by substantially lower insulin prices in other countries.³⁷

Drug Co.	Brand Name	Antitrust Violation	Est. Antitrust Overspend %
Eli Lilly & Co.	Basaglar Kwikpen	Exclusionary Rebates; Horizontal Collusion	25%
Novo Nordisk	Levemir	Horizontal Collusion; Exclusionary Rebates	50%
Novo Nordisk	Novolog	Horizontal Collusion; Exclusionary Rebates	50%
Sanofi-Aventis	Admelog Solostar	Exclusionary Rebates; Horizontal Collusion	25%
Sanofi-Aventis	Lantus	Horizontal Collusion; Exclusionary Rebates; Sham Orange Book Listing	50%

C. ABBVIE AND ALLERGAN PRODUCTS

AbbVie, along with Allergan, which it recently acquired, has engaged in a sustained, consistent pattern of illegally blocking generic and biosimilar competition in violation of the antitrust laws.

Botox – Botox is an old, injectable biologic drug product that is used to both hide wrinkles and treat medical conditions such as migraines. Allergan appears to have illegally maintained its Botox monopoly by compensating a potential competitor from South Korea not to enter the U.S. market.³⁸ Economic Liberties and I-MAK estimate that Part D and Medicaid would have spent approximately 40 percent less on Botox in 2019 if Allergan had not previously delayed and blocked competition, based on the fact that the competing drug from Medytox was selling for 30-

36 Senate Finance Committee Staff Report, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* (Jan. 14, 2021), [https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20\(FINAL%201\).pdf](https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf) (“PBM contracting practices did little to discourage higher list prices for insulin.”); Adam J. Fein, *Drug Channels, Why PBMs and Payers Are Embracing Insulin Biosimilars with Higher Prices—And What That Means for Humira* (Nov. 9, 2021), <https://www.drugchannels.net/2021/11/why-pbms-and-payers-are-embracing.html> (explaining how major PBMs have excluded the generic-like insulin products in exchange for rebates).

37 Rand Corporation, *Comparing Insulin Prices in the United States to Other Countries* (2020), https://www.rand.org/content/dam/rand/pubs/research_reports/RR4700/RR4788-1/RAND_RRA788-1.pdf, at pg. 10 (noting the average price for a standard unit of insulin was \$98.70 in the U.S. compared to \$14.40 in Japan, \$12 in Canada, \$11 in Germany, \$9.08 in France, and \$7.52 in the U.K.). There are multiple reasons why insulin is more expensive in the United States, but the existence of significantly cheaper insulins in other countries indicates that all U.S. manufacturers sell insulin well above the cost of production.

38 *Tawfilis v. Allergan, Inc.*, No. 8:15-cv-00307 (filed Feb. 24, 2015) (denying motion to dismiss claims that Botox licensing arrangement was a pretext for market allocation).

50 percent less than Botox in South Korea, where it was a direct competitor.³⁹

Bystolic – Bystolic is a small-molecule blood pressure medicine. Allergan entered illegal pay-for-delay agreements to prevent and delay generic competition for Bystolic before 2019.⁴⁰ Because it is a traditional, small-molecule drug, Economic Liberties and I-MAK estimate that Part D and Medicaid would have spent 90 percent less on Bystolic and generic equivalents in 2019 in the absence of antitrust violations.

Restasis – Restasis is a nontraditional, small-molecule eyedrop medication for the treatment of dry eyes. Allergan has illegally protected its Restasis monopoly by committing fraud on the patent office, submitting sham citizen petitions to the FDA, and illegally listing eyedropper bottle patents in the FDA’s Orange Book on its next generation Restasis Multidose product.⁴¹ While eyedrop medications are a slightly unique market, Restasis has drawn several major potential generic challengers in recent years, which suggests substantial competition for this product. Economic Liberties and I-MAK estimate that Part D and Medicaid would have spent approximately 60 percent less on Restasis in 2019 in the absence of illegal anticompetitive conduct.

Drug Co.	Brand Name	Antitrust Violation	Est. Antitrust Overspend %
Allergan Inc.	Botox	Pay-for-Delay	40%
Allergan Inc.	Bystolic	Pay-for-Delay	90%
Allergan Inc.	Restasis	Patent Abuse; Sham Citizen Petition; Sham Orange Book Listing	60%

D. ONCOLOGY DRUGS

Expensive, blockbuster oncology drugs have also been the subject of anticompetitive schemes in recent years.

Revlimid – Revlimid is a small-molecule, former blockbuster oncology drug that received FDA approval in 2005. Celgene appears to have engaged in multiple schemes to illegally block generic versions of Revlimid from entering the market, including abusing the FDA’s REMS system, listing sham REMS patents in the FDA’s Orange Book, and relying on its patent thicket and evergreening strategy.⁴² Economic Liberties and I-MAK estimate that Part D and Medicaid would have spent approximately 90 percent less on Revlimid and equivalents in 2019 if Celgene had not illegally blocked competition.

³⁹ *Tawfilis v. Allergan, Inc.*, No. 8:15-cv-00307 (filed Feb. 24, 2015).

⁴⁰ See End-Payor Plaintiffs’ Consolidated Class Action Complaint, *In re Bystolic Antitrust Litigation*, 20-cv-05735 (S.D.N.Y. Sept. 21, 2021), available at <https://www.cohenmilstein.com/sites/default/files/Bystolic%20-%20Consolidated%20Complaint%2009212021.pdf> (alleging defendants entered seven illegal pay-for-delay settlements regarding Bystolic).

⁴¹ See *Allergan, Inc. v. Teva Pharm. USA, Inc.*, No. 2:15-CV-1455-WCB, 2017 WL 4619790 (E.D. Tex. Oct. 16, 2017). See also *In Re: Restasis Antitrust Litigation*, MDL No. 2819 (E.D.N.Y.).

⁴² *In re Thalomid and Revlimid Antitrust Litigation*, 2:14-cv-06997 (D. N.J.); *Cigna v. Celgene*, No. 2:21-cv-11686 (D.N.J.) <https://www.hbsslaw.com/sites/default/files/case-downloads/revlimid/2022-05-27-amended-complaint.pdf>.

Zytiga – Zytiga is a small-molecule oncology drug used to treat prostate cancer. Janssen appears to have engaged in patent fraud to protect its Zytiga franchise.⁴³ Economic Liberties and I-MAK estimate that Part D and Medicaid would have spent 90 percent less on Zytiga and equivalents in 2019 but for Janssen’s anticompetitive scheme to delay generic competition.

Drug Co.	Brand Name	Antitrust Violation	Est. Antitrust Overspend %
Celgene	Revlimid	Sham Orange Book Listing; Patent Abuse; REMS Abuse	90%
Janssen Pharm.	Zytiga	Patent Abuse	90%

E. OTHER BRAND DRUGS

Spending on the following top-100 drugs was also impacted by antitrust violations in 2019:

Remicade – Remicade is an injectable biologic drug used to treat inflammatory conditions including Crohn’s disease. Janssen appears to have used exclusionary rebates to protect Remicade from biosimilar competition in 2019. Because Remicade is a biologic injectable, Economic Liberties and I-MAK estimate that Part D and Medicaid spending on Remicade and equivalents would have been 25 percent less in the absence of exclusionary PBM rebates.⁴⁴

Suboxone – Suboxone is a small-molecule opioid addiction treatment that was previously sold in a slightly different form. As alleged in multiple complaints, Indivior carried out a product hopping scheme when it pulled the original version of Suboxone from the market, which forced all patients onto the new version before generic versions of the original product came to market.⁴⁵ Indivior also submitted sham citizen petitions to the FDA to create fake safety concerns about potential generic versions of its original product. Economic Liberties and I-MAK estimate that Part D and Medicaid would have spent 80 percent less on Suboxone in 2019 in the absence of antitrust violations.

Acthar – Acthar is an old injectable drug used to treat rare conditions including infantile spasms. The manufacturer of Acthar, Mallinckrodt, illegally maintained the price of the drug at tens of thousands of dollars while simultaneously acquiring the generic competitors most likely to come to market.⁴⁶ As a traditional, non-biologic drug, Economic Liberties and I-MAK estimates that Part D and Medicaid would have spent 90 percent less on Acthar and equivalents in 2019 but for Mallinckrodt’s anticompetitive conduct.

⁴³ See *United States v. Janssen Biotech, Inc.*, Civ. 19-12107 (KM) (ESK) (D.N.J. Dec. 17, 2021) (denying motion to dismiss False Claims Act claim based on patent fraud regarding Zytiga).

⁴⁴ Twenty-five percent is a slightly conservative approximation. Biosimilar prices have historically been an average of 30 percent less than equivalent brand biologics on an ASP basis. See IQVIA Institute, *Biosimilars in the United States 2020-24: Competition, Savings, and Sustainability*, at 15 (Oct. 2020), <https://www.iqvia.com/insights/the-iqvia-institute/reports/biosimilars-in-the-united-states-2020-2024>.

⁴⁵ *FTC v. Indivior Inc.*, No. 20-cv-00036 (W.D. Vir.), Complaint (June 24, 2020), available at <https://www.ftc.gov/enforcement/cases-proceedings/1310036/indivior-inc>.

⁴⁶ *FTC v. Mallinckrodt*, No. 1:17 cv-00120 (D.D.C.), Complaint (Jan. 25, 2017), available at www.ftc.gov/system/files/documents/cases/170118mallinckrodt_complaint_public.pdf.

Copaxone – Copaxone is an expensive small-molecule drug for the treatment of multiple sclerosis. Teva, which makes Copaxone, has illegally maintained sales of its brand Copaxone product after generic entry by offering large PBM rebates in exchange for PBMs and plans driving patients away from the low-cost generic competition.⁴⁷ Economic Liberties and I-MAK estimate that Part D and Medicaid would have spent 80 percent less on Copaxone in 2019 but for these antitrust violations.⁴⁸

Drug Co.	Brand Name	Antitrust Violation	Est. Antitrust Overspend %
Janssen Biotech	Remicade	Exclusionary Rebates	25%
Indivior Inc.	Suboxone	Product Hopping; Sham Citizen Petition	80%
Mallinckrodt	Acthar	Acquisition of Monopoly	90%
Teva	Copaxone	Exclusionary Rebates	80%

IV. TOTALS

Table 3 - Estimated Impact of Antitrust Violations on Top 100 Part D Drug Products 2019

Manufacturer	Brand Name	FDA Approval	Part D Spending	Est. Antitrust Overspend %	Est. Antitrust Overspend
Mallinckrodt	Acthar	1952	\$669 m	90%	\$602 m
GlaxoSmithKline	Advair Diskus	2000	\$1.45 b	60%	\$870 m
Eli Lilly & Co.	Basaglar Kwipen	2015	\$636 m	25%	\$159 m
Allergan Inc.	Bystolic	2007	\$454 m	90%	\$409 m
Boehringer Ing.	Combivent Respimat	2011	\$508 m	60%	\$305 m
Teva	Copaxone	1996	\$837 m	80%	\$670 m
GlaxoSmithKline	Flovent HFA	2004	\$423 m	60%	\$254 m
Sanofi-Aventis	Lantus (2 products)	2000	\$3.66 b	50%	\$1,827 m
Novo Nordisk	Levemir (2 products)	2005	\$2.14 b	50%	\$1,070 m
Novo Nordisk	Novolog (3 products)	2000	\$2.97 b	50%	\$1,484 m
Allergan Inc.	Restasis	2003	\$1.36 b	60%	\$813 m
Celgene	Revlimid	2005	\$4.67 b	90%	\$4,206 m
Boehringer Ing.	Spiriva (2 products)	2004	\$1.95 b	60%	\$1,168 m
GlaxoSmithKline	Ventolin HFA	2001	\$500 m	60%	\$300 m
Janssen Biotech	Zytiga	2011	\$760 m	90%	\$684 m
					\$14.821 b

47 Fierce Pharma, Mylan Sues Generic Rival Teva Over Sophisticated Scheme to Block Copaxone Copycats (July 1, 2021); 46Brooklyn, The Flawed Design of Medicare Part D: A Copaxone Case Study (Aug. 12, 2020), <https://www.46brooklyn.com/research/2020/8/12/copaxone>.

48 Because this is a traditional, small-molecule drug, we adjusted the overcharge estimate to 80 percent rather than 90 percent because there was some successful generic entry despite Teva's antitrust violations.

Table 4 - Estimated Impact of Antitrust Violations on Top 100 Medicaid Drug Products 2019

Manufacturer	Brand Name	FDA Approval	Medicaid Spending	Est. Antitrust Overspend %	Est. Antitrust Overspend
Sanofi-Aventis	Admelog Solostar	2017	\$226.99 m	25%	\$56.75 m
GlaxoSmithKline	Advair Diskus	2000	\$228.86 m	60%	\$137.32 m
Eli Lilly & Co.	Basaglar Kwikpen U-100	2015	\$670.80 m	25%	\$167.70 m
Allergan Inc.	Botox	1991	\$166.87 m	40%	\$66.75 m
GlaxoSmithKline	Flovent HFA	2004	\$684.12 m	60%	\$410.47 m
Sanofi-Aventis	Lantus (2 products)	2000	\$752.27 m	50%	\$376.13 m
Novo Nordisk	Levemir Flextouch	2005	\$184.68 m	50%	\$92.34 m
Novo Nordisk	Novolog (2 products)	2000	\$587.56 m	50%	\$293.78 m
Teva	Proair HFA	2004	\$357.26 m	60%	\$214.35 m
Janssen Biotech	Remicade	1998	\$218.66 m	25%	\$54.66 m
Celgene	Revlimid	2005	\$317.46 m	90%	\$285.71 m
Boehringer Ing.	Spiriva (2 products)	2004	\$442.44 m	60%	\$265.46 m
Indivior Inc.	Suboxone	2002	\$787.19 m	80%	\$629.76 m
GlaxoSmithKline	Ventolin HFA	2001	\$163.99 m	60%	\$98.39 m
					\$3.150 b

V. EXTRAPOLATING RESULTS ACROSS ALL U.S. DRUG SPENDING

While the analysis and results above calculate overspending as a percent of the top 100 drugs in Part D and Medicaid, these results can also be used to roughly estimate the scale and impact of antitrust violations across the entire pharmaceutical industry.

Table 5 - Summary of Impact of Antitrust Violations on Top 100 Part D and Medicaid Drug Products 2019

Part D Top 100 Antitrust Violations	
Top 100 Gross Spending	\$104,765 m
Top 100 Est. Antitrust Overspend	\$14,821 m
Overspend % of Top 100	14.15%
No. of Top 100 Brands Impacted	15
No. of Top 100 Products Impacted	20

Medicaid Top 100 Antitrust Violations	
Top 100 Gross Spending	\$34,801 m
Top 100 Est. Antitrust Overspend	\$3,150 m
Overspend % of Top 100	9.05%
No. of Top 100 Brands Impacted	14
No. of Top 100 Products Impacted	17

Combined Top 100 Antitrust Violations	
Combined Top 100 Gross Spending	\$139,566 m
Combined Top 100 Est. Antitrust Overspend	\$17,971 m
Combined Overspend % of Top 100	12.88%
Combined No. of Top 100 Products Impacted	25

To estimate the impact on overall drug spending, Economic Liberties and I-MAK then multiplied the combined rate of overspending from the top 100 drugs in both federal programs (12.88 percent) by the total amount of U.S. retail pharmaceutical spending on branded drugs in 2019 (\$311.2 billion) to estimate that U.S. payers and patients would have spent \$40.07 billion less on pharmaceuticals in 2019 but for antitrust violations, as summarized in Table 6.⁴⁹ Said differently, if we assume that all \$311.2 billion in U.S. net branded drug spending in 2019 was impacted similarly to gross spending on the top 100 drugs, then U.S. patients and payers spent an additional \$40.07 billion on pharmaceuticals as the result of drug companies and PBMs violating antitrust laws.

Table 6 - Estimated Impact of Antitrust Violations on All U.S. Net Pharmaceutical Spending in 2019

	Spending	No. Brands Impacted	No. Products Impacted	Est. % Overspend	Est. Overspend
Part D Top 100 (Gross)	\$104,765 m	15	20	14.15%	\$14.821 bn
Part D All Drugs (Net)	\$145,000 m	-		14.15%	\$20.513 bn
Medicaid Top 100 (Gross)	\$34,801 m	14	17	9.05%	\$3.150 bn
Medicaid All Drugs (Net) ⁵⁰	\$32,575 m	-		9.05%	\$2.948 bn
All U.S. Retail Pharmaceutical (Net) ⁵¹	\$369,700 m	-		12.88%	\$40.071 bn

This simple model provides a reasonable method to estimate the scale of the problem of antitrust violations in the pharmaceutical industry. However, there are obviously significant differences between estimates based on spending on the top 100 drugs in Part D and Medicaid and estimates of the total spending across all U.S. pharmaceuticals. For one, misconduct may be significantly more common among top brand drugs that have more to lose from generic or biosimilar competition than the average drug. Additionally, the impact of violations may be significantly different before and after PBM and other rebates have been deducted.

First, there are many well-known antitrust cases regarding drugs that have never been in the top 100 drug products, including Martin Shkreli's infamous scheme to hike up the price and then monopolize the market for Daraprim,⁵² as well as the nationwide illegal price-fixing scheme that increased the prices of dozens and potentially hundreds of generic medicines for several years.⁵³

Second, there are reasons to think antitrust violations may impact drug spending similarly on a gross or net basis because some anticompetitive schemes encourage larger rebates and an increased gross-to-net spread (e.g., exclusionary PBM rebates), while other schemes tend to discourage rebates and a large gross-to-net spread by eliminating competition altogether (e.g., product hopping) and therefore eliminating the need to entice PBMs and payers away from competing products with large rebates.

Third, the \$40.07 billion figure for overspending as the result of all antitrust violations comports with other estimates. Professor Robin Feldman recently estimated that pay-for-delay schemes alone may increase drug spending by up to \$36 billion per year.⁵⁴ Similarly, Professor Michael Carrier has previously estimated the impact of product hopping in individual drug markets and concluded that patients overpaid by \$1.7 billion per year for Namenda, \$200 million per year for Effexor, and \$700 million per year for TriCor.⁵⁵ Accordingly, Americans have tens of billions of dollars at stake in pharmaceutical antitrust issues every year.

49 We limit this to spending on branded drugs, rather than the entire pharmaceutical market, because the antitrust violations in question are anticompetitive extensions or abuses of patent claims that would only apply to branded drugs and not to generics. According to HHS, total retail pharmaceutical spending in 2019 was \$389 billion, 80 percent of which was spending on branded pharmaceuticals. See Department of Health and Human Services, Assistant Secretary for Planning and Evaluation, "Trends in Prescription Drug Spending, 2016-2021," September 2022, <https://aspe.hhs.gov/sites/default/files/documents/88c547c976e915fc31fe2c6903ac0bc9/sdp-trends-prescription-drug-spending.pdf>. This results in the estimate of \$311.2 billion for spending on branded drugs.

50 MACPAC, MACStats: Medicaid and CHIP Data Book, Exhibit 28, <https://www.macpac.gov/wp-content/uploads/2015/11/EXHIBIT-28.-Medicaid-Gross-Spending-and-Rebates-for-Drugs-by-Delivery-System-FY-2020-millions.pdf> (reporting FY 2020 Medicaid gross spending as \$71,817.1 billion reduced by Medicaid rebates of \$39,242 billion for Medicaid net drug spending of \$32,575 billion).

51 CMS, CMS Office of the Actuary Releases 2019 National Health Expenditures (Dec. 16, 2020), <https://www.cms.gov/newsroom/press-releases/cms-office-actuary-releases-2019-national-health-expenditures> (estimating retail prescription drug spending at \$369.7 billion in 2019).

52 *FTC et. al. v. Shkreli*, No. 1:20-cv-00706-DLC (S.D.N.Y. Jan. 14, 2022), available at https://www.ftc.gov/system/files/documents/cases/865_2022.01.14_opinion_and_order.pdf.

53 DOJ, Pharmaceutical Companies Pay Over \$400 Million to Resolve Alleged False Claims Act Liability for Price-Fixing of Generic Drugs (Oct. 1, 2021), <https://www.justice.gov/opa/pr/pharmaceutical-companies-pay-over-400-million-resolve-alleged-false-claims-act-liability>.

VI. CONCLUSIONS AND POLICY RECOMMENDATIONS

The frequency and impact of the violations discussed in this report should establish beyond any doubt that anticompetitive conduct is a major unaddressed problem and a significant factor in high U.S. drug prices and spending. These figures also establish that enforcement efforts to date have failed to meaningfully deter violations, which frequently reward the worst antitrust violators with billions in anticompetitive profits. While enhanced antitrust action would limit the negative effects of some of these practices, some of these strategies should be outright prohibited through legislative or regulatory changes to obviate the need for antitrust enforcement in the first place. Accordingly, policymakers and enforcers should pursue the following policies to address constant antitrust misconduct.

First, pay-for-delay agreements should be per se prohibited by new legislation. These sorts of agreements are some of the costliest antitrust violations—costing an estimated \$6.2 billion to \$37.1 billion per year⁵⁶—and enforcers must litigate individual cases against pharmaceutical companies to recover losses. Likewise, while the 2013 Actavis decision found direct-pay-for-delay agreements to be illegal,⁵⁷ pharmaceutical companies have found ways to compensate generics in indirect ways to stay out of the market. For example, the brand manufacturer might allow the generic to enter into one market in exchange for continued exclusivity in another, as AbbVie did to settle litigation over its blockbuster Humira.⁵⁸ A ban on pay-for-delay should require that the only acceptable terms of a settlement to resolve pharmaceutical patent litigation is a global date for generic entry at some time between the present and the expiration of the patent or market exclusivity.

Second, drug manufacturers should be prohibited from listing inappropriate types of patents in the FDA Orange Book, which they use to take advantage of an automatic 30-month stay on new approval should a generic competitor seek to enter the market. Device patents that do not correspond to any active ingredient, Risk Evaluation Mitigation Strategies (REMS) patents, and method of use patents should be prohibited in the FDA Orange Book, and the FDA should review all current Orange Book listings to remove any such patents already listed.

54 Robin Feldman, *The Price Tag of Pay-for-Delay* (forthcoming) (last revised Aug. 27, 2021), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3846484.

55 Michael A. Carrier, *Statement to House Energy & Commerce Committee (Subcommittee on Consumer Protection and Commerce)* (Sept. 19, 2019), available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3464850.

56 Robin C. Feldman, “The Price Tag of ‘Pay-for-Delay,’” *The Columbia Science and Technology Review*, Fall 2021, available at: https://repository.uchastings.edu/cgi/viewcontent.cgi?article=2867&context=faculty_scholarship.

57 *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013)

58 Center for Biosimilars, “Pfizer Becomes Latest to Settle With AbbVie Over Humira,” December 3, 2018, <https://www.centerforbiosimilars.com/view/pfizer-becomes-latest-to-settle-with-abbvie-over-humira>.

Third, the FDA should review some of its own procedures for generic approval in order to limit or eliminate the practice of product hopping. In particular, the FDA could reform its procedures to deem generics to be substitutable for both the original drug and any minimally altered form of the drug to which the branded company might be attempting to product hop. Changes in dosage, strength, or method of administration should not require separate approval, or provide renewed market exclusivities, for the originally approved drug.

Fourth, turning to antitrust enforcement, policymakers should dramatically increase funding and resources to antitrust enforcers to tackle the problem of repeated pharmaceutical antitrust violations. The FDA has about 14,000 employees to ensure Americans' drugs are safe and effective. By comparison, antitrust enforcement agencies only have a few dozen employees to make sure that patients can afford their prescription drugs. Given that 25 percent of Americans cannot afford their prescriptions,⁵⁹ policymakers should dedicate dramatically more resources to enforcing the antitrust laws against the pharmaceutical industry, which has the incentive to spend up to tens of billions of dollars to preserve its flow of illegal, anticompetitive profits.

Fifth, policymakers should consider tightening laws around pharmaceutical patent eligibility, including laws around the Noerr-Pennington doctrine, to ensure that drug companies cannot use bad-faith patent strategies such as patent thicketing to perpetually extend their monopolies without creating useful, obvious improvements to existing drug products. Similarly, enforcers should harshly punish all known instances of patent fraud in the pharmaceutical industry, including the individuals responsible, to reaffirm that attorneys and others have a duty of disclosure, candor, and good faith with respect to patent submissions.

Sixth, antitrust enforcement agencies should be more proactive about identifying and stopping anticompetitive schemes before patients are harmed. Nearly all the antitrust cases cited above were brought based on publicly available information. FDA drug approvals, drug patent litigation, and FDA Orange Book listings are matters of public record. Additionally, the DOJ and FTC have copies of every potential pay-for-delay agreement within 30 days of filing. The agencies should develop sophisticated systems to identify likely antitrust violations from public data and intervene before patients and payers are harmed.

Seventh, antitrust agencies should recognize that existing settlement practices, both by government enforcers and private claimants, have failed to deter illegal conduct in the industry, and settlements going forward should therefore punish corporations and individuals more harshly. As explained above, delaying generic competition and other illegal strategies are extremely profitable. This means that perpetrators have huge incentives to violate the antitrust laws and will not be deterred by relatively small settlements at the corporate level.

59 Kaiser Family Foundation, Poll: Nearly 1 in 4 Americans Taking Prescription Drugs Say It's Difficult to Afford Their Medicines (Mar. 1, 2019), <https://www.kff.org/health-costs/press-release/poll-nearly-1-in-4-americans-taking-prescription-drugs-say-its-difficult-to-afford-medicines-including-larger-shares-with-low-incomes/>.

Eighth, the DOJ and state attorneys should recognize that there are now more than a dozen ongoing pharmaceutical antitrust cases for conduct that injured Part D and Medicaid, and that they are the only authorities who can recover on behalf of the public health programs, which make up almost 45 percent of all U.S. prescription drug spending.⁶⁰ In other words, those agencies are the only ones who can recover damages for 45 percent of U.S. drug spending, and the failure to do so leaves an enormous gap in potential deterrence. Accordingly, DOJ and state attorneys should recognize their duty to protect the public from known antitrust violations and develop new methods to recover on behalf of the public as efficiently as possible by filing follow-on cases to private litigation, especially in those cases where courts have already determined that the defendant violated the antitrust laws.⁶¹ Additionally, these agencies should recognize that horizontal collusion makes up a small fraction of known pharmaceutical antitrust violations and that these agencies' singular focus on horizontal collusion leaves Part D and Medicaid without recovery for tens of billions of dollars of overspending each year.

⁶⁰ IQVIA, *Medicine Spending and Affordability in the United States*, at 33 (August 2020), available at <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-spending-and-affordability-in-the-united-states.pdf>.

⁶¹ See e.g., *In re Asacol Antitrust Litig.*, 323 F.R.D. 451 (D. Mass. 2017) (denying defendants' motion for summary judgment on product hopping claims), rev'd on other grounds, *United Food & Commercial Workers Unions & Emp'rs Midwest Health Benefits Fund v. Warner Chilcott Ltd. (In re Asacol Antitrust Litig.)*, 907 F.3d 42 (1st Cir. 2018).

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