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AMERICAN ECONOMIC LIBERTIES PROJECT

Executive Summary

The Costs of Pharma Cheating

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American Economic Liberties Project and Initiative for Medicines, Access, & Knowledge (I-MAK)

REPORT EXECUTIVE SUMMARY

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,[1] 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.[2] Voters consistently show anger about the high and rising cost of drugs in the United States.

New research from American Economic Liberties Project and I-MAK examines one central driver of this trend: the illegal and anticompetitive tactics used by the pharmaceutical industry to perpetuate monopolies—in the form of government-backed patents over brand drugs—and block competition from more affordable generic drugs. We estimate that the total cost to final payers for these antitrust violations was $40.07 billion in 2019 alone. This implies an average cost of about $120 in 2019 for every American, solely because of antitrust violations by the pharmaceutical industry.

Drug companies use many illegal tactics to prevent competition and keep drug prices high. The two major players in the pharmaceutical industry responsible for these antitrust violations are brand drug manufacturers, who make the drugs, and pharmacy benefit managers (PBMs). PBMs are hired by health insurance companies to negotiate with manufacturers over the cost of drugs covered by their insurance plans. Economic Liberties and I-MAK identified 10 overlapping strategies used by the pharmaceutical industry:

1. **Horizontal Collusion** – One of the most blatant antitrust violations, rivals or potential rivals agree to raise prices, restrict output, rig a bidding process, allocate market share, or impose high prices or low quality across an industry rather than competing.

   Example: Eli Lilly & Co., Novo Nordisk, and Sanofi-Aventis have allegedly engaged in horizontal collusion to maintain high prices for insulin.

2. **Pay-for-Delay or Reverse Payment** – Brand drug companies pay generic competitors to drop lawsuits challenging their drug patents, allowing the former to maintain their government-sanctioned monopolies.

   Example: Prior to 2019, Allergan entered into several pay-for-delay agreements to prevent and delay generic competition for Bystolic, a blood pressure medication.

3. **No-Generics Agreement** – A brand drug manufacturer signs an agreement with a potential

1 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.

2 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.

generic manufacturer on the condition that the latter does not launch a rival product.

4. **Patent Abuse** – Brand drug companies pursue sham patent litigation (going to court to defend a fraudulent patent) and engage in "patent thicketing" (creating a web of overlapping patents to exclude competitors) to extend their monopolies.

   Example: Among other practices, Celgene has maintained an anticompetitive patent thicket around the production of Revlimid, a blockbuster oncology drug first approved by the FDA in 2005.

5. **Product Hopping and Patent Evergreening** – A brand drug company slightly modifies an existing drug whose patent is about to expire and withdraws the existing drug before generic versions of the original drug become available. This forces all patients onto the new product, which has a newer patent, and prevents them from switching to an authorized generic.

   Example: Indivior pulled the original version of Suboxone, an opioid-addiction medication, from the market and shifted patients to a new version before any generic versions of the original drug were able to come to market.

6. **Sham Citizen Petition** – A brand drug company uses the U.S. Food and Drug Administration's (FDA's) citizen petition process to create fraudulent safety concerns about upcoming generic or biosimilar competitors in order to delay their regulatory approval and entry into the market.

   Example: Among other practices, Allergan has submitted sham citizen petitions to the FDA to create fake safety concerns and block potential competing versions of Restasis, an eyedrop medication for dry eyes.

7. **Sham Orange Book Listing** – A brand drug company illegally lists a patent, usually for a drug-device combination, in the FDA's official patent registry, called the Orange Book. This triggers the "30-month stay," during which the FDA is prohibited from approving generic competitors.

   Example: Boehringer Ing., GlaxoSmithKline, and Teva likely violated antitrust laws by

illegally maintaining exclusivity for several asthma inhalers by unlawfully listing device-only patents in the Orange Book.

8. **REMS Abuse** – Brand drug companies exploit the FDA's Risk Evaluation and Mitigation Strategy (REMS) program, which requires heightened precautions for dangerous drugs, to block generic and biosimilar competition.

   Example: Among other practices, Celgene has illegally listed sham REMS patents in the FDA Orange Book for Revlimid, its blockbuster oncology drug.

9. **Exclusionary Rebates** – Brand drug companies pay pharmacy benefit managers (PBMs) – who decide which medications are and are not covered under a health insurance plan – large rebates in exchange for the PBMs excluding cheaper or generic alternatives. Patients do not see the benefits, as co-pays and deductibles are determined as a percentage of gross drug price before rebates are applied.

   Example: The highly concentrated insulin market includes a series of manufacturer rebates to PBMs that direct patients toward expensive branded insulin products and away from generic insulins.

10. **Acquisition of Monopoly** – A brand drug company acquires a potential brand, generic, or biosimilar competitor to eliminate it from the market.

    Example: Mallinckrodt illegally maintained the price of Acthar at tens of thousands of dollars by acquiring the competitors most likely to come to market with cheaper generic versions.

Economic Liberties and I-MAK estimate the total costs of these antitrust violations by examining the 100 top-selling drugs for both Medicare Part D and Medicaid in 2019. We found that 25 of the top brand drugs for Medicare or Medicaid have faced a highly credible allegation of misconduct under one or more of America's antitrust laws: the Sherman Act, the Clayton Act, and the Robinson-Patman Act. Based on the type of drug and the type of violation, we estimate the degree of overcharge to payers that resulted from the drug manufacturers' anticompetitive conduct. The analysis indicates that the government programs spent nearly 12.88% more than necessary on these drugs, corresponding to excess payments of $20.5 billion for Part D and $2.95 billion for Medicaid. Extending this estimate to all pharmaceutical spending, if all U.S. net retail

spending on brand drugs was similarly impacted, the analysis estimates that the cost of antitrust violations by pharmaceutical companies for American patients and taxpayers was $40.07 billion in 2019.

Consumers, payers, and generic drug makers may challenge these illegal and anticompetitive tactics by pursuing antitrust claims under the antitrust laws. More proactive enforcement could result in great returns for patients and other payers. Economic Liberties and I-MAK recommend the following policy changes to improve antitrust enforcement:

1. Pay-for-delay agreements between brand and generic manufacturers should be completely prohibited. Legislation should subject such agreements to a complete *per se* ban.

2. FDA regulations should be reformed to prohibit drug manufacturers from listing device-only and REMS patents in the FDA Orange Book.

3. To prevent product-hopping, FDA procedures should be reformed to treat generics as substitutable equivalents to minimally adjusted versions of branded drugs.

4. Dramatically increase funding and resources to antitrust enforcers to tackle the problem of repeated pharmaceutical antitrust violations.

5. Restrict laws around pharmaceutical patent eligibility, including the Noerr-Pennington doctrine, to ensure that drug companies cannot use bad-faith patent strategies to perpetually extend monopolies without creating useful enhancements to existing drug products.

6. Develop sophisticated systems to identify likely antitrust violations from public data and intervene before patients and payers are harmed.

7. Increase penalties for corporations and individuals engaging in antitrust violations to better deter such conduct.

8. Empower the Justice Department and state attorneys general to recover damages on behalf of public health programs, such as by filing follow-on cases to private litigation.

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The American Economic Liberties Project is a new, independent organization fighting against concentrated corporate power to realize economic liberty for all, in support of a secure, inclusive democratic society.

The Initiative for Medicines, Access, and Knowledge (I-MAK) is a non-profit and non-partisan organization with a mission to build a more just and equitable medicines system, motivated by a multidimensional assessment of the patent system informed through input from stakeholders including members of affected communities and leaders from government, academia, and the private sector.

economicliberties.us

@econliberties

info@economicliberties.us