Six Ways Big Drug Companies Game the System to Keep Prices High

Drug companies alone set the prices of prescription drugs, and for years those high prices have put medicine out of reach for the patients who need them. Drug companies preserve their monopoly pricing power by manipulating the patent and regulatory processes to block lower-cost competition, often from generics and biosimilars, from reaching the market.

Here are six ways they do it:

Breaking Down Their Playbook to Keep Competition Low and Prices High

1 PAY-FOR-DELAY
KEEPING GENERICS OUT OF THE MARKET

Brand drug manufacturers delay low-cost alternatives from reaching the market by engaging in anticompetitive patent settlements with potential generic competitors so they can continue to set prices unilaterally.

These abusive pay-for-delay approaches by drug companies cost consumers and taxpayers a combined

$3.5B

IN HIGHER DRUG COSTS EACH YEAR[1]

2 REMS ABUSE
RESTRICTING ACCESS TO BRAND DRUG SAMPLES

Brand drug manufacturers exploit the FDA program known as Risk Evaluation and Mitigation Strategies (REMS) to prevent generic drug makers from accessing the samples they need to prove bioequivalence, a requisite to introducing a generic to the market.

The abuse of the REMS program by drug companies protects higher-priced brand name drugs from generic competition and results in lost savings of

$13.4B

EACH YEAR[2]

3 EVERGREENING
PROTECTING PATENTS TO LIMIT COMPETITION

Brand drug manufacturers prevent lower-cost alternatives from reaching patients by seeking additional patents on minor variations of the original drug to extend the patent period; by introducing an "extended release" version, for example. While these tweaks often do not convey enhanced clinical benefits to the customer, they do extend the time period during which drug manufacturers can continue to control pricing by preventing competition.

Humira, currently the best-selling drug in the world, is protected by over

247

PATENTS FILED

with the aim of delaying competition for 39 years. This extended monopoly is estimated to cost American payers and taxpayers an excess of $14.4 billion.[3]

4 EXTENDING MONOPOLY PRICING THROUGH AUTHORIZED GENERICS

Once the patent of a brand name drug expires, the manufacturer of that drug will often introduce the exact same product under a generic name to extend its ability to maintain high prices, creating a false competitor. The first generic drug to the market is often able to benefit from its own period of exclusivity for 180 days.

Mylan increased the list price of a two-pack EpiPen by **500% between 2009 and 2016.** In December 2016, it launched its own "authorized generic" for

$300

PER TWO-PACK[4]

5 MANIPULATING THE CITIZEN PETITION PROCESS

Citizen petitions are meant to be a way for the public to bring their concerns forward to the Food and Drug Administration. Instead, drug companies choke the system and use "citizen petitions" to delay generics from being approved by asking the FDA to delay action on a pending generic drug application.

Over six years, ViroPharma filed

43 CITIZEN PETITIONS WITH THE FDA TO DELAY THE APPROVAL

of generic versions of Vancocin, an antibiotic that was first approved in 1986.[5]

6 ABUSE OF ORPHAN DRUG STATUS
EXPLOITING POLICIES MEANT TO HELP PATIENTS

In order to entice drug manufacturers to help treat rare diseases, the government provides tax breaks and exclusivity incentives for drug manufacturers to develop "orphan drugs" —medicines targeting diseases that afflict fewer than 200,000 people. While the policy is intended to help develop new treatments for people with rare diseases, many orphan drugs are also approved to treat more common conditions, allowing drug companies to reap tax and exclusivity benefits while selling drugs to a broader set of people and keeping their prices high. Ultimately this behavior harms all patients, whether they're dealing with rare or common diseases.

11 drugs to treat rare seizure conditions have received orphan drug designation.

NONE OF THEM WERE NEW DRUGS; rather compounds that were already approved to treat other conditions, like epilepsy, or new ways to administer the medication.[6]

1. Federal Trade Commission: "Pay-for-Delay": How Drug Company Pay-Offs Cost Consumers Billions. January 2010.
2. Alex Brill, Matrix Global Advisors: Unrealized Savings from the Misuse of REMS and Non-REMS Barriers." September 2018.
3. I-MAK: "Overpatented, Overpriced: Special Humira Edition." 18 September 2018.
4. Business Insider, "The $300 Generic EpiPen is Here," December 16, 2016.
5. Federal Trade Commission Comment on the Food and Drug Administrations Revised Draft Guidance on Citizen Petitions. December 3, 2018.
6. Kaiser Health News: "Government Investigation Finds Flaws In the FDA's Orphan Drug Program." November 30, 2018.

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