A Peek at Big Pharma's Playbook That Leaves Many Americans Unable to Afford Their Drugs

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America's pharmaceutical giants are suing this summer to block the federal government's first effort at drug price regulation.

Last year's Inflation Reduction Act included what on its face seems a modest proposal: The federal government would for the first time be empowered to negotiate prices Medicare pays for drugs — but only for 10 very expensive medicines beginning in 2026 (an additional 15 in 2027 and 2028, with more added in later years). Another provision would require manufacturers to pay rebates to Medicare for drug prices that increased faster than inflation.

Those provisions alone could reduce the federal deficit by $237 billion over 10 years, the Congressional Budget Office has calculated. That enormous savings would come from tamping down drug prices, which are costing an average of 3.44 times — sometimes 10 times — what the same brand-name drugs cost in other developed countries, where governments already negotiate prices.

These small steps were an attempt to rein in the only significant type of Medicare health spending — the cost of prescription drugs — that has not been controlled or limited by the government. But they were a call to arms for the pharmaceutical industry in a battle it assumed it had won: When Congress passed the Medicare prescription drug coverage benefit (Part D) in 2003, intense industry lobbying resulted in a last-minute insertion prohibiting Medicare from negotiating those prices.

Without any guardrails, prices for some existing drugs have soared, even as they have fallen sharply in other countries. New drugs — some with minimal benefit — have enormous price tags, buttressed by lobbying and marketing.

AZT, the first drug to successfully treat HIV/AIDS, was labeled "the most expensive drug in history" in the late 1980s. Its $8,000-a-year cost was derided as "inhuman" in a New York Times op-

ed. Now, scores of drugs, many with less benefit, cost more than $50,000 a year. Ten drugs, mostly used to treat rare diseases, cost over $700,000 annually.

Pharmaceutical manufacturers say high U.S. prices support research and development and point out that Americans tend to get new treatments first. But recent research has shown that the price of a drug is related neither to the amount of research and development required to bring it to market nor its therapeutic value.

And selling drugs first in the U.S. is a good business strategy. By introducing a drug in a developed country with limited scrutiny on price, manufacturers can set the bar high for negotiating with other nations.

Here are just a few of the many examples of drug pricing practices that have driven consumers to demand change.

Exhibit A is Humira, the best-selling drug in history, earning AbbVie $200 billion over two decades. Effective in the treatment of various autoimmune diseases, its core patent — the one on the biologic itself — expired in 2016. But for business purposes, the "controlling patent," the last to expire, is far more important since it allows an ongoing monopoly.

AbbVie blanketed Humira with 165 peripheral patents, covering things like a manufacturing step or slightly new formulation, creating a so-called patent thicket, making it challenging for generics makers to make lower-cost copycats. (When they threatened to do so, AbbVie often offered them valuable deals not to enter the market.) Meanwhile, it continued to raise the price of the drug, most recently to $88,000 a year. This year, Humira-like generics (called biosimilars for its type of molecule) are entering the U.S. market; they have been available for a fraction of the price in Europe for five years.

Or take Revlimid, a drug by Celgene (now part of Bristol Myers Squibb), which treats multiple myeloma. It won FDA approval to treat that previously deadly disease in 2006 at about $4,500 a month; today it retails at triple that. Why? The company's CEO explained price hikes were simply a "legitimate opportunity" to improve financial "performance."

Since it must be taken for life to keep that cancer in check, patients who want to live (or their insurers) have had no choice but to pay. Though Revlimid's patent protection ran out in 2022, Celgene avoided meaningful price-cutting competition by offering generic competitors "volume-limited licenses" to its patents so long as they agreed to initially produce a small share of the drug's $12 billion monopoly market.

Par Pharmaceutical, another drugmaker, maneuvered to create a blockbuster market out of a centuries-old drug, isoproterenol, through a well-meaning FDA program that gave companies a three-year monopoly in exchange for performing formal testing on drugs in use before the agency was formed.

During those three years, Par wrapped its branded product, Vasostrict, used to maintain blood

pressure in critically ill patients, with patents — including one on the compound's pH level — extending its monopoly eight additional years. Par raised the price by 5,400% between 2010 and 2020. When the COVID-19 pandemic filled intensive care units with severely ill patients, that hike cost Americans $600 million to $900 million in the first year.

And then there is AZT and its successors, which offer a full life to HIV-positive people. Pills today contain a combination of two or three medicines, the vast majority including one similar to AZT, tenofovir, made by Gilead Sciences. The individual medicines are old, off-patent. Why then do these combination pills, taken for life, sometimes cost $4,000 monthly?

It's partly because many manufacturers of the combination pills have agreements with Gilead that they will use its expensive branded version of tenofovir in exchange for various business favors. Peter Staley, an activist with HIV, has been spearheading a class-action suit against Gilead, alleging "collusion." The negotiated price for these pills is hundreds of dollars a month in the United Kingdom, not the thousands charged in the U.S.

Faced with such tactics, 8 in 10 Americans now support drug price negotiation, giving Congress and the Biden administration the impetus to act and to resist Big Pharma's legal challenges, which many legal experts view as a desperate attempt to stave off the inevitable.

"I don't think they have a good legal case," said Aaron Kesselheim, who studies drug pricing at Harvard Medical School. "But it can delay things if they can find a judge to issue an injunction." And even a year's delay could translate into big money.

Yes, American patients are lucky to have first access to innovative drugs. And, sadly, patients in countries that refuse to pay up once in a while go without the latest treatment. But more sadly, polling shows, large numbers of Americans are forgoing prescribed medicines because they can't afford them.

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