

Our Broken Drug Pricing and Patent System Diverts Resources Away from Innovation and into Mergers, Patent Gaming and Price Gouging



KEY POINTS

- » Instead of incentivizing innovation, the United States incentivizes gaming and abuse of drug patents and monopolistic price gouging.
- » The current drug development and pricing system is bad for consumers and bad for innovation.
- » Only Congress can stop pharmaceutical companies' exploitation.

It's Time for Congress to Act

In the American system of prescription drug manufacture and sales, investing in the development of an innovative drug is only one way to increase profit — and, perversely, it is by far the hardest. Instead of incentivizing the development of new and valuable treatments, our government incentivizes pharmaceutical manufacturers to extend patent protections on decades-old medications.¹

It is much easier for drug companies to make huge profits by gaming the system and gouging consumers through legal and market maneuvers than it is to develop and test a truly innovative new drug. When an effort to develop a drug with significant clinical benefit falls short, manufacturers are able to manipulate Medicare's lack of pricing leverage to charge high prices for products with marginal clinical benefit.² We let drug companies pay off potential competitors or manipulate the patent system to delay competition indefinitely and maintain monopolies.³ We prohibit Medicare from using tools to keep those companies from increasing prices on many drugs long after they were launched, even though these products were introduced at prices supposedly designed to offset the cost of research and development.⁴

Put simply, today's drug development and pricing system is bad for consumers and bad for innovation. The system fails to reward investments in research innovation and drug development and allows pharmaceutical companies to reap huge profits by exploiting the rules of the game. But drug companies will engage in these abusive and predatory practices as long as our government allows it. Only Congress has the power to stop them.

As Congress considers ways to reform drug pricing this year, it is, unsurprisingly, being met with heavy resistance from paid special interests, including pharmaceutical companies' lawyers and lobbyists

who claim that any attempt to rein in industry abuses will harm innovation. This is false. In fact, as laid out below, there is overwhelming evidence that our current system actually stifles innovation

Reforming our drug pricing system can and should aim to retain positive financial incentives for innovation while eliminating destructive incentives that steer tax and premium dollars to anti-competitive behavior.

The cost of prescription drugs is driven in large part by price increases for existing drugs, not the development of innovative new drugs.

- » MedPAC's June 2021 annual report found that Medicare spending on drugs that consumers purchased at the pharmacy grew by 26% for the same number of prescriptions filled. "Nearly all the growth in drug spending was due to higher prices and launches of new drugs rather than an increase in the number of prescriptions filled by beneficiaries"
- » Between 2006 and 2017, the net prices that the Medicare Part D program pays for drugs rose a stunning 313%.⁵

High and rising drug prices are too often unrelated to innovation.

- » A study of particularly high price increases in already high-spend drugs found seven of the 10 drugs not only had limited value but showed no additional clinical benefit relative to other available drugs.⁶
- » Biogen set the price of its unproven and potentially harmful Alzheimer's drug, Abucanumab, at \$56,000 — although experts overwhelmingly determined it to have no proven clinical benefit.⁷

Drug makers are pushing legal boundaries, not innovating drug development.

For decades, drug makers have systematically abused patent and market exclusivity rules to block competition. One common abuse is to make minor tweaks to existing drugs that typically confer no additional clinical benefit but allow for extended patent protections.

- » Marketers of the 12 best-selling drugs in the U.S. filed, on average, 125 patent applications per drug for the sole purpose of extending their monopolies and blocking competition for up to four decades. The top-selling drug globally, AbbVie's Humira, has a whopping 247 patent applications.⁸

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The pharmaceutical industry spends relatively little on research.

Drug companies often tout investment in research and development (R&D) as the primary driver of prices, and they blame price increases on rebates and discounts sought by purchasers and payers. Yet pharmaceutical companies' expenditures are much higher for marketing and payments to shareholders than on R&D. See Figure 1 for a breakdown of a single drug companies' spending over a 5-year period.^{9, 10}

- » A recent U.S. House Committee on Oversight and Reform report analyzing financial data from **large drug companies** found that they **spend significantly more on stock buybacks and dividends than on drug R&D**, and that a significant proportion of this recorded **R&D spending is actually for extending patents and otherwise suppressing generic and biosimilar competition.**¹¹
- » A WestHealth and Johns Hopkins Bloomberg School of Public Health study revealed that **brand-name drug manufacturing would still be the most profitable industry sector** — and manufacturers would be able to maintain the same research investments — **even if their sales were \$1 trillion lower.**¹²
- » And public investment in foundational research and development enables the pharmaceutical industry to generate enormous profits. Notably, U.S. taxpayer dollars funded the research that underlaid every drug developed from 2010 to 2019, totaling more than \$230 billion.¹³

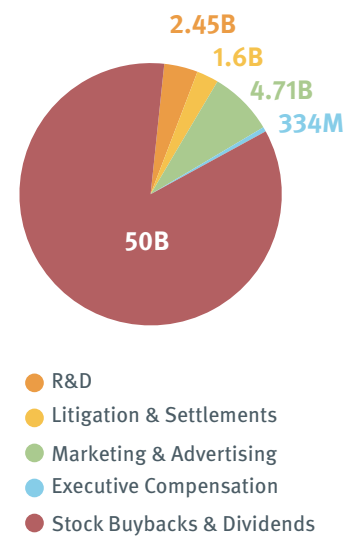
Price increases on established drugs are about gouging, not innovation.

Another tactic is to raise prices when opportunity strikes, regardless of the cost to public health. The most infamous example of this is former Turing Pharmaceuticals CEO Martin Shkreli's overnight price hike of a 60-year-old antiparasitic drug from \$13.50 to \$750 per pill. Such pricing strategies are routinely observed during public health crises. They are unrelated to innovation.

- » Patients for Affordable Drugs reports that three-quarters of the drugs with price increases in the first half of 2020 impacted COVID-19 risk, treatment, and recovery.¹⁴
- » Even the price of dexamethasone — a key therapeutic now considered a standard of care for COVID-19 and hailed for being inexpensive and accessible — increased by 137% in 2020 while on the Food and Drug Administration shortage list.¹⁵

Figure 1

Relative Spend on Research and Development (millions & Billions): AbbVie 2013-2018



- » In the midst of the opioid crisis, the price of lifesaving naloxone rose from \$1 to \$150 for a two-pack of nasal spray and a stunning \$4,500 for an auto-injected version.¹⁶
- » And during the worst public health and financial crisis in a century, which economically devastated so many families, a record-setting 900 drugs saw price increases.¹⁷

Congress has an historic opportunity to reduce drug costs for consumers and get the incentives right for industry.

Brand-name prescription drugs cost U.S. taxpayers almost 350% more than they do in 32 other countries,¹⁸ and poll after poll has shown that nearly nine in 10 voters say it is important that Congress and the president take action to lower prescription drug prices this year. **Congress has an opportunity to correct current market distortions that reward gaming over innovation and respond to the call of the vast majority of voters, especially seniors, to bring relief from high drug prices.**

Policy Recommendations

The following policies would help correct market distortions, close legal loopholes, and incentivize true innovation.

- » Eliminate the restriction on Medicare's authority to negotiate drug prices.
- » Protect all consumers from drug price increases above the rate of inflation.
- » End prescription drug patent abuses and drive competition.
- » Ensure fair prices for drugs developed using taxpayer dollars.

Endnotes

¹ <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Amgen%20Staff%20Report%2010-1-20.pdf> .

² <https://www.fiercepharma.com/pharma/we-have-serious-concerns-congressional-democrats-launch-probe-into-approval-pricing-for>.

³ <https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away>.

⁴ Rabah Kamal, Cynthia Cox, and Daniel McDermott, “What are the recent and forecasted trends in prescription drug spending?” Peterson-KFF Health System Tracker, February 20, 2019. <https://www.healthsystemtracker.org/chart-collection/recent-forecasted-trends-prescription-drug-spending/>.

⁵ Robin Feldman, “What Is the Price of a Prescription Drug?” ProMarket, February 4, 2021. <https://promarket.org/2021/02/04/transparency-price-list-prescription-drugs-pharma/>.

⁶ ICER. Unsupported price increases occurring in 2019. January 2021. <https://icer.org/assessment/unsupported-price-increase-2021/>

⁷ <https://www.statnews.com/pharmalot/2021/07/16/pharmalittle-icer-aduhelm-alzheimers-fda-fibrogen-anemia-drug/>.

⁸ I-MAK “Overpatented, Overpriced Special Edition: Humira, October 2020. <http://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf>.

⁹ <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/COR%20Staff%20Report%20-%20Pharmaceutical%20Industry%20Buybacks%20Dividends%20Compared%20to%20Research.pdf>; graphic by Representative Katie Porter.

¹⁰ <https://twitter.com/RepKatiePorter/status/1394724627566391297>.

¹¹ <https://oversight.house.gov/news/press-releases/chairwoman-maloney-releases-staff-report-showing-pharmaceutical-industry-spends>

¹² West Health, “New Analysis Finds Large Drugmakers Could Lose \$1 Trillion in Sales and Still Be the Most Profitable Industry” [Press Release], November 14, 2019. <https://www.westhealth.org/press-release/new-analysis-finds-large-drug-makers-could-lose-1-trillion-in-sales-and-still-be-the-most-profitable-industry/>

¹³ Fred Ledley, Ekaterina Cleary, and Matthew Jackson, “US Tax Dollars Funded Every New Pharmaceutical in the Last Decade,” Institute for New Economic Thinking, September 2, 2020. <https://www.ineteconomics.org/perspectives/blog/us-tax-dollars-funded-every-new-pharmaceutical-in-the-last-decade>.

¹⁴ Brianna Jones and Sarah Kaminer Bourland, “Drug Companies Keep Raising Prices in the Midst of a Pandemic” June 28, 2020. <https://patientsforaffordabledrugs.org/2020/06/28/covid-price-hikes-report/>.

¹⁵ Maia Anderson, “Dexamethasone Price Has Increased 137% in Recent Months,” Becker’s Hospital Review, October 7, 2020. <https://www.beckershospitalreview.com/pharmacy/dexamethasone-price-has-increased-137-in-recent-months.html>.

¹⁶ Kate Johnson, Sandra Wilkniss, and Hemi Tewarson, Public Health Crises and Pharmaceutical Interventions: Improving Access while Ensuring Fiscal Sustainability (Washington, D.C.: National Governors Association Center for Best Practices, 2018). <https://www.nga.org/wp-content/uploads/2018/08/Public-Health-Crises-and-Pharmaceutical-Interventions.pdf>.

¹⁷ 46brooklyn Research, “Drugmakers Break Record for Most January List Price Increases in a Decade,” 46brooklyn, January 29, 2021. <https://www.46brooklyn.com/news/1/29/2020/whats-happening-to-generic-drug-prices-jan-2021-nadac-survey-update-hmthw-yzgeb-db9lb-pkwcs-tw4ya-ashfh-rhlgc>.

¹⁸ Andrew W. Mulcahy et al., International Prescription Drug Price Comparison: Current Empirical Estimates and Comparisons with Previous Studies (Santa Monica, California: Rand Corporation, 2021). https://www.rand.org/pubs/research_reports/RR2956.html.

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