the campaign for
SUSTAINABLE Rx PRICING

SECOND OPINION: DEBUNKING BIG PHARMA'S BOGUS INNOVATION RHETORIC

Brand Name Drug Companies Claim Lowering Rx Prices Will Undercut R&D — The Facts Disagree

For far too long Big Pharma has used the excuse that research and development (R&D) costs justify out-of-control prescription drug prices and that solutions to lower prices threaten innovation into new breakthroughs. These tired arguments, which Big Pharma wields like a shield to protect the industry's anti-competitive and price-hiking practices, simply don't hold up to scrutiny.

PRICE HIKES UNCONNECTED TO CLINICAL IMPROVEMENTS

Multiple studies have found Big Pharma's price hikes have little to no connection to the cost of its development or improvements in drugs' efficacy. In other words, brand name drug companies set launch prices and hike prices to maximize profits — not because there is any connection to innovation.

- **"No Association" Between Drug Company's Prices and Investments In Research & Development.** A September 2022 paper in The Journal of American Medical Association (JAMA) Network Open examined a subset of 63 drugs approved by the U.S. Food and Drug Administration (FDA) between 2009 to 2018, representing around one-fifth of the drugs approved by the FDA during this time span. The researchers found that for this subset of drugs, "there was no association between estimated research and development investments and treatment costs based on list prices at the launch of the product or based on net prices a year after launch." ("Association of Research and Development Investments With Treatment Costs for New Drugs Approved From 2009 to 2018," JAMA Network Open, September 26, 2022)

- **No "Meaningful Association Between Cancer Drug Prices And The Magnitude Of Benefit For Any End Points."** An October 2022 study in JAMA Internal Medicine found a lack of correlation between the prices set by Big Pharma on cancer drugs and their effectiveness for patients. "We did not detect a meaningful association between cancer drug prices and the magnitude of benefit for any of the end points," the researchers wrote. "This suggests that cancer drugs are priced based predominantly on what the market will bear." In other words, Big Pharma sets prices to maximize profits, not based on clinical value or outcomes for patients. ("Association Between US Drug Price and Measures of Efficacy for Oncology Drugs Approved by the US Food and Drug Administration From 2015 to 2020," JAMA Internal Medicine, October 31, 2022)

- **"A Drug's Sunk R&D Costs Do Not Influence Its Price."** A 2021 report from the Congressional Budget Office (CBO) found that pharmaceutical R&D costs do not have a relationship to the prices drug companies set on their products. The report concluded, "Importantly, when drug companies set the prices of a new drug, they do so to maximize future revenues net of manufacturing and distribution costs. A drug's sunk R&D costs—that is, the costs already incurred in developing that drug—do not influence its price." ("Research And Development In The Pharmaceutical Industry," Congressional Budget Office, April 2021)

- **Big Pharma's Unjustified Price Hikes On Just Seven Popular Drugs Cost American Taxpayers $805 Million In Increased Costs.** An analysis conducted by the Institute for Clinical and Economic Review (ICER) found Big Pharma hiked prices on seven of the top 10 most popular drugs in 2021 with no accompanying increase in clinical value — increasing overall drug spending by $805 million. The price of the costliest drug, Horizon Therapeutics' gout treatment Krystexxa, increased by 12 percent, raising out-of-pocket spending by $3,210 on average per patient. The second and third most widely used drugs among Medicare Part B beneficiaries, Seagen's cancer drug

Adcetris and Ipsen's injection Somatuline Depot both increased costs by $1,000 per patient. ("ICER Identifies Most Significant 2021 US Drug-Price Hikes Unsupported by New Clinical Evidence," ICER, December 6, 2022)

- **Price Hikes On AbbVie's Blockbuster Drug Humira Were Not Supported By Clinical Evidence And Led To A More Than $1.8 Billion Increase In Unnecessary U.S. Drug Spending.** Price hikes on AbbVie's Humira were not supported by new clinical evidence and accounted for an unnecessary increase in U.S. drug spending of more than $1.8 billion from 2017-2018 according to ICER. ("AbbVie's Humira, Roche's Rituxan top ICER's list of worst price-hike offenders," FierceHealthcare, October 8, 2019)

In addition, a series of reports from the U.S. House Committee on Oversight and Reform found that Big Pharma's price hikes and pricing practices were tied to earnings targets and had little if nothing to do with clinical improvements.

- **"Internal Communications Show That Pricing Decisions By Amgen Executives—Including Executive Vice President Anthony Hooper—Were Driven Primarily By The Need To Meet Increasingly Aggressive Revenue Targets."** (Staff Report, "Drug Pricing Investigation: Amgen – Enbrel And Sensipar," U.S. House Committee On Oversight And Reform, 10/1/20)

- **"Documents Also Show How Companies Anticipating Generic Competition Executed More Frequent and Higher Price Increases to Maximize Revenues as their Drugs Faced Loss of Patent Protection or Market Exclusivity."** ("Drug Pricing Investigation: Industry Spending on Buybacks, Dividends, and Executive Compensation," U.S. House Committee On Oversight and Reform Staff Report, 7/8/21)

BIG PHARMA INCREASINGLY PURSUING SECONDARY PATENTS, NOT TRUE INNOVATION

Several recent analyses also demonstrate that Big Pharma is increasingly focused on developing new and more effective strategies to exploit loopholes and extend monopoly pricing on blockbuster products – instead of investing in true innovation.

- **Just Six Percent of Drug Patents in Infringement Suits Were for Active Ingredients or New Molecules.** An analysis conducted in Nature Biotechnology examined 21 patent infringements lawsuits pursued by pharmaceutical companies on biologic drugs under the Biologics Price Competition and Innovation Act (BPCIA), covering a total of 179 patents. Of the patent filings examined in the study, just six percent were for active ingredients or new molecules. The vast majority were for secondary uses – oftentimes for much less critical changes to the drugs or their manufacturing process, with little to no innovation involved that might improve clinical value for patients. ("The Characteristics of Patents Impacting Availability of Biosimilars," Nature Biotechnology, January 18, 2022)

- **There Has Been A "Whopping" 200 Percent Increase In The Number Of "Secondary" Patent Filings Pursued By Drug Makers Since 2000.** According to coverage from STAT News of an August 2023 analysis in JAMA, "there has been a whopping 200 percent increase in patents filed by companies that made few substantive changes to their drugs." According to STAT News, the analysis published in JAMA found that from 2000 to 2015, "The ratio of continuation patents increased from 0.6 for drugs that were approved in 2000 to 1.8 for drugs approved in 2015," or a 200 percent increase. Meanwhile, "the ratio of the number of original patents for each FDA approval increased by just 15 percent." ("More Drugmakers Are Filing Continuation Patents That Sideline Generic Competition," STAT News, August 8, 2023)

- **The Ratio Of The Number Of Patents For Each Drug In The FDA's Orange Book Increased By 68 Percent In 15 Years.** According to coverage from STAT News of the same August 2023 JAMA analysis, the ratio of the number of patents for each drug listed in the FDA's Orange Book "increased from 1.9 for those approved in 2000 to 3.2 for those approved in 2015." This amounts to a 68 percent increase in the number of patents on each drug, underscoring Big Pharma's increasing focus on pursuing patents to protect profits and block competition. ("More Drugmakers Are Filing Continuation Patents That Sideline Generic Competition," STAT News, August 8, 2023)

BIG PHARMA INVESTS BOLDLY IN ADVERTISING AND PROFITS — NOT R&D

In addition, contrary to the industry's insistence that out-of-control prices support costly investments in R&D, the facts show that brand name drug companies invest more boldly in advertising, profits and overhead than innovation and R&D.

- **$56 Billion:** A 2021 report from the House Oversight Committee found that over the last five years, the top 14 drug companies spent almost $577 billion on stock buybacks and dividends – $56 billion more than on research and development during that same time span. ("Drug Pricing Investigation: Industry Spending on Buybacks, Dividends, and Executive Compensation," U.S. House Committee On Oversight and Reform Staff Report, 7/8/21)

- **$8.1 Billion:** A report from Fierce Pharma in May found that Big Pharma spent $8.1 billion on direct-to-consumer (DTC) advertising pushing brand name prescription drugs in 2022. ("The Top 10 Pharma Drug Ad Spenders for 2022," Fierce Pharma, May 1, 2023)

- **$6.88 Billion:** Big Pharma companies spent $6.88 billion on TV ads in 2021, according to Kantar's media tracking data. (Beth Snyder Bulik, "Big Pharma Ad Spending Edges Toward $7B With Sanofi, Regeneron and Novo Nordisk Leading The Way," Endpoints News, March 22, 2022)

Big Pharma also used a windfall from the Tax Cuts and Jobs Act of 2017 to line shareholders' pockets rather than invest in innovation and R&D.

- **112 Percent:** From 2017 to 2018, dividends and share repurchases increased by 112 percent – more than double the previous year. ("Big Pharma Tax Windfall," The Campaign for Sustainable Rx Pricing, December 9, 2019)

- **17 Times:** The single-year increase in payouts to Wall Street and shareholding Big Pharma board members and executives was 17 times larger than the increase in R&D spending. ("Big Pharma Tax Windfall," The Campaign for Sustainable Rx Pricing, December 9, 2019)

TAXPAYERS CARRY A SUBSTANTIAL AMOUNT OF THE R&D LOAD

While Big Pharma tries to obfuscate their out-of-control list prices by invoking "innovation," the industry has gotten a huge boost in recent years from taxpayer dollars in the form of taxpayer-funded research at the National Institute of Health (NIH).

- "**The U.S. taxpayer has funded research for every single one of the 210 new drugs that the FDA approved between 2010-16.** Yet the companies that have access to this research are increasingly viewing pharmaceuticals in the same way that banks view their financial product — opportunities for short-term returns." (Mariana Mazzucato, "Big Pharma Is Hurting Drug Innovation," The Washington Post, 10/17/18)

- "**More than $100 billion in NIH funding went toward research** that contributed, either directly or indirectly, to the 210 drugs approved between 2010 and 2016. That's roughly 20 percent of NIH spending since 2000." (Megan Thielking, "NIH funding contributed to 210 approved drugs in recent years, study says," STAT News, 2/12/18)

One of the worst offenders is brand name drug maker Gilead, which has repeatedly acquired government-funded research breakthroughs for pennies on the dollar and turned them into blockbuster best-selling drugs.

- **Gilead Sciences Did Not Invent Its Blockbuster Hepatitis C Treatment Sovaldi, Rather It Acquired The Product From A Small Company, Much Of Whose Work Was Federally Funded.** "Gilead Sciences did not invent its blockbuster treatment for hepatitis C, sofosbuvir (Sovaldi), which it priced at $1,000 per pill. Rather, it acquired the product from a small company founded by the drug's inventor, a faculty member at Emory University, much of whose work on the usefulness of nucleoside viral inhibitors was federally funded. Gilead paid $11 billion in late 2011 for the rights to market Sovaldi, an amount it totally recouped in its first year of sales after approval of the drug in late 2013." ("The $2.6 Billion Pill – Methodological And Policy Considerations," New England Journal of Medicine, May 14, 2015)

- **Gilead Recouped Its Investment In Sovaldi In Its First Year On Market.** "Gilead paid $11 billion in late 2011 for the rights to market Sovaldi, an amount it totally recouped in its first year of sales after approval of the drug in late 2013." ("The $2.6 Billion Pill – Methodological And Policy Considerations," New England Journal of Medicine, May 14, 2015)

- **$84,000:** The cost of a single course of treatment for Gilead's blockbuster Hepatitis C Drug Sovaldi. ("Wyden-Grassley Sovaldi Investigation Finds Revenue-Driven Pricing Strategy Behind $84,000 Hepatitis Drug," U.S. Senate Committee on Finance Report, December 1, 2015)

- **Taxpayer Funded Research Also Contributed To Gilead's Blockbuster HIV Prevention Treatment Truvada.** "Thomas Folks spent years in his U.S. Centers for Disease Control and Prevention lab developing a treatment to block deadly HIV in monkeys. Then San Francisco AIDS researcher Robert Grant, using $50 million in federal grants, proved the treatment worked in people who engaged in risky sex. Their work — almost fully funded by U.S. taxpayers — created a new use for an older prescription drug called Truvada: preventing HIV infection. But the U.S. government, which patented the treatment in 2015, is not receiving a penny for that use of the drug from Gilead Sciences, -Truvada's maker, which earned $3 billion in Truvada sales last year." ("An HIV Treatment Cost Taxpayers Millions. The Government Patented It. But A Pharma Giant Is Making Billions," The Washington Post, March 26, 2019)

- **Taxpayer Dollars Funded "Much Of The Preclinical And Clinical Research" Behind Gilead's COVID-19 Treatment, Remdesivir.** "The research outlined below demonstrates how the U.S. Army, the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH)/National Institute Allergies and Infectious Diseases (NIAID) either conducted or funded much of the preclinical and clinical development of remdesivir. ("Role of the Federal Government in the Development of Remdesivir," Knowledge Ecology International, March 20, 2020)

- **Gilead Devised Egregious Patent Strategy to Extend Monopoly on HIV Treatment, By Delaying Access to "Less Toxic" Version.** In July 2023, The New York Times published an article exposing how brand name drug maker Gilead employed a greedy patent strategy around a pair of blockbuster HIV treatments to maximize profits while blocking access to newer versions of those treatments proven to be safer for patients. According to The Times, internal documents from Gilead showed executives and researchers at the company were aware that a

newer version of one of their HIV drugs, Truvada, "had the potential to be less toxic to patients' kidneys and bones than the earlier iteration." However, the company purposefully delayed the development of this "less toxic" treatment so that its eventual release would coincide with the loss of patent protection around Gilead's existing HIV treatments that were already on the market. ("How a Drugmaker Profited by Slow-Walking a Promising H.I.V. Therapy," The New York Times, July 22, 2023)

All this goes to show that Big Pharma's innovation rhetoric is bogus – and policymakers must see through the pharmaceutical industry's smoke and mirrors excuses and enact market-based solutions that hold brand name drug makers accountable and lower prescription drug prices.

Read more about Big Pharma's first round of price hikes to start out the year HERE.

Learn more about market-based solutions to hold Big Pharma accountable and lower prescription drug prices HERE.

About CSRxP: The Campaign for Sustainable Rx Pricing is a broad-based coalition of physicians, nurses, hospitals, consumers, health plans, pharmacy benefit managers, pharmacists, and businesses promoting bipartisan, market-based solutions to lower drug prices. Learn more: www.csrxp.org

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