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Drug Pricing Investigation

Majority Staff Report

Committee on Oversight and Reform
U.S. House of Representatives
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Dear Committee Members:

Today, I am releasing the final majority staff report in the Committee on Oversight and Reform's nearly three-year investigation of the pharmaceutical industry. In January 2019, under the leadership of our former Chairman, the late Elijah E. Cummings, the Committee launched a sweeping investigation into pricing and business practices in the pharmaceutical industry. The Committee focused on companies selling brand-name drugs that are especially costly to Medicare—which is currently prohibited by law from negotiating for lower prices. The goal of the investigation was to understand why drug companies have consistently raised prices, the strategies they use to protect their market power and keep prices high, and how Congress can reform the industry to make prescriptions more affordable for patients and taxpayers.

I have been honored to lead this investigation since becoming Chairwoman of the Committee in October 2019. The Committee has obtained more than 1.5 million pages of internal company documents, held five hearings, and released eight interim staff reports. The investigation has provided a rare glimpse into the decision-making of many of the world's most profitable drug companies.

What the Committee has learned should be troubling to lawmakers, taxpayers, and any American who has ever struggled to afford their prescriptions. Drug companies have raised prices relentlessly for decades while manipulating the patent system and other laws to delay competition from lower-priced generics. These companies have specifically targeted the U.S. market for higher prices, even while cutting prices in other countries, because weaknesses in our health care system have allowed them to get away with outrageous prices and anticompetitive conduct.

The drugs in our Committee's investigation ranged from cancer therapies to insulin to treatments for chronic conditions and rare diseases. Although the markets for these products differ, the Committee uncovered common practices that cut across the industry.

First, drug companies have raised prices with abandon, especially when they succeed in delaying or blocking competition. Internal documents reveal that companies have raised prices to meet ever-increasing revenue targets, which in some cases were tied to higher pay for executives.

Second, companies have manipulated the patent system and marketing exclusivities granted by the Food and Drug Administration to extend their monopolies far longer than lawmakers envisioned when they created these systems.

Third, all the companies the Committee investigated have employed anticompetitive strategies to suppress generic competition. Several companies have also used patient assistance programs and donations to third-party organizations—which were ostensibly intended to help patients afford expensive drugs—as tools to garner positive public relations, increase sales, and raise revenue.

These practices persist because the highly complex U.S. pharmaceutical market creates perverse incentives to raise prices, and unlike in other countries, drug companies can do so without limitation. Consumers will pay whatever they can afford—and often what they cannot—for lifesaving drugs.

Prescription drugs are increasingly unaffordable for Americans. The Committee heard firsthand accounts from patients who have been forced to make impossible sacrifices to afford their medications. High drug prices are also draining our federal health care programs. The Committee's analysis found that from 2014 to 2018, taxpayers lost $25 billion in savings on just seven drugs because Medicare could not negotiate to lower prices. The Medicare Trust Fund is expected to run out in 2026.

The pharmaceutical industry plays an essential role in developing and producing lifesaving drugs. But the Committee's investigation found that sky-high drug prices are not justified by the need to innovate. The largest drug companies spend more on payouts for investors and executives than on research and development. And many blockbuster drugs rely on scientific discoveries from research funded by taxpayers, while drug companies' R&D spending often focuses on minor changes to extend patent protection and block lower-priced competitors.

This staff report is intended to help Congress, regulatory agencies, and the public understand rising drug prices and pursue effective reforms to make prescription drugs more affordable. The evidence overwhelmingly supports the need to pass the Build Back Better Act, which will empower Medicare to negotiate for lower prices, restrain price increases, and cap out-of-pocket patient costs for insulin and other drugs. Reforms are also needed to make pharmaceutical R&D spending more transparent and prevent anti-competitive practices that suppress generic competition and keep prices high.

I would like to extend my heartfelt gratitude to the majority staff of the Oversight Committee for their dedication and persistence in pursuing this investigation, despite many challenges. Their diligent efforts have helped shed light on the inner workings of an opaque industry and will be crucial to Congress's pursuit of meaningful reforms to help Americans afford their prescription drugs.

Sincerely,

Carolyn B. Maloney

Carolyn B. Maloney
Chairwoman

EXECUTIVE SUMMARY

As Congress considers provisions in the Build Back Better Act to lower prescription drug prices in the United States, this report presents the findings of the Oversight Committee's nearly three-year investigation into pricing and business practices for branded prescription drugs. For years, prescription drug companies have aggressively raised prices on existing drugs and set higher launch prices for new drugs, all while reaping vast profits from American patients and taxpayers. In the five-year period from 2016 to 2020, pharmaceutical companies raised the prices of branded prescription drugs by 36%—almost four times the rate of inflation during that period.[1] From 2012 to 2017, drug companies raised prices for the 20 most commonly prescribed brand-name drugs in the Medicare Part D program, which provides prescription drug benefits to seniors, by more than 12% annually—approximately ten times the average annual rate of inflation during those years.[2] Patients in the United States pay more than twice as much for their prescription drugs as patients in 32 other developed nations.[3]

The pricing practices uncovered by the Committee's investigation are unsustainable, unjustified, and unfair to patients and taxpayers. In addition to straining the United States health care system, drug companies' pricing practices have left millions of Americans unable to afford lifesaving medications. According to data from the Kaiser Family Foundation from October 2021, approximately one-quarter of Americans reported having difficulty affording their medications and three in ten American adults reported not taking their medicines as prescribed at some point in the previous year due to cost.[4] Americans rely on the lifesaving drugs produced by pharmaceutical companies, but the Committee's investigation shows that the industry's excessive prices and anticompetitive practices are not justified by the need for innovation and have been used to enrich company executives and shareholders.

On January 14, 2019, at the direction of the late Chairman Elijah E. Cummings, the Committee on Oversight and Reform launched a comprehensive investigation into pharmaceutical pricing and business practices. The Committee's investigation focused on ten companies that sell 12 drugs that are among the costliest to the Medicare program.[5] The

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[1] *4 Recommendations to Guide the FDA in Its Analysis of the U.S. Patent System*, Medium: I-MAK (July 30, 2021) (online at https://i-makglobal.medium.com/4-recommendations-to-guide-the-fda-in-its-analysis-of-the-u-s-patent-system-6f212b6d9d82).

[2] Democratic Staff, Senate Committee on Homeland Security and Governmental Affairs, *Manufactured Crisis: How Devastating Drug Price Increases Are Harming America's Seniors* (Mar. 26, 2018) (online at www.hsgac.senate.gov/imo/media/doc/Manufactured%20Crisis%20-%20How%20Devastating%20Drug%20Price%20Increases%20Are%20Harming%20America's%20Seniors%20-%20Report.pdf). Medicare Part D is the Medicare prescription drug benefit.

[3] RAND Corporation, *International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies* (2021) (online at www.rand.org/pubs/research_reports/RR2956.html).

[4] Kaiser Family Foundation, *Public Opinion on Prescription Drugs and Their Prices* (Oct. 18, 2021) (online at www.kff.org/slideshow/public-opinion-on-prescription-drugs-and-their-prices/).

[5] This report focuses on the practices of the following ten companies: AbbVie Inc. (Humira and Imbruvica); Amgen Inc. (Enbrel and Sensipar); Celgene Corporation (Revlimid); Eli Lilly and Company (Humalog products); Mallinckrodt Pharmaceuticals (H.P. Acthar Gel); Novartis Pharmaceuticals Corporation (Gleevec); Novo

Committee examined the justifications drug companies provide for raising prices in the United States, the tactics drug companies use to keep prices high and suppress competition, and the impact that high drug prices have on American patients and federal health care programs.

Over the course of the investigation, Committee staff reviewed more than 1.5 million pages of documents—including internal strategy documents, communications among top executives, board materials, and non-public pricing data. These internal company documents provide significant new insights into the tactics drug companies use to raise prices and keep them high by suppressing competition.

As part of this investigation, the Committee held five hearings with drug company executives, patients, policy experts, and stakeholders. The Committee also released six staff reports detailing the pricing and business practices of AbbVie, Amgen, Celgene, Mallinckrodt, Novartis, and Teva. In July 2021, the Committee released an analysis showing that the 14 largest drug companies in the world have spent more to enrich investors and executives than on research and development. In September 2021, the Committee released a report detailing the billions of dollars in lost taxpayer savings due to the prohibition on Medicare from negotiating for lower drug prices.

This final report builds on the Committee's earlier reports and also presents new findings from the Committee's investigation of insulin products manufactured by Eli Lilly, Novo Nordisk, and Sanofi. These three companies collectively control approximately 90% of the global insulin market. Over the past 20 years, they have repeatedly and dramatically raised the list prices of their rapid-acting and long-acting insulins and reaped billions of dollars in revenues. New documents reveal:

- **The three insulin companies targeted the United States for price increases, and Medicare lost out on more than $16 billion in savings.** For years, these companies provided private Medicare Part D plans with significantly smaller rebates than those secured by other federal health care programs that are allowed to negotiate directly with drug companies. Information obtained by the Committee reveals that if Medicare Part D plans had secured the same discounts as other federal health care programs for three frequently used insulin products—Humalog, Lantus, and NovoLog—Medicare could have saved more than $16.7 billion from 2011 through 2017.

Nordisk Inc. (NovoLog products); Pfizer Inc. (Lyrica); Sanofi (Lantus products); and Teva Pharmaceutical Industries Ltd. (Copaxone). This report also examines the role of two other companies: Johnson & Johnson, which jointly markets the cancer drug Imbruvica with AbbVie, and Bristol Myers Squibb, which acquired Celgene as a subsidiary in 2019 and now markets Revlimid. According to publicly available information at the time the investigation was launched, these drugs were among the costliest per Medicare beneficiary, resulted in the highest aggregate spending by the Medicare Part D program, or had the largest price increases. *See* Centers for Medicare and Medicaid Services, *Medicare Part D Drug Spending Dashboard & Data* (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD) (accessed Nov. 9, 2021).

- **The three insulin companies have engaged in strategies to maintain monopoly pricing and defend against competition from biosimilars.** These strategies include manipulating the patent system and the marketing exclusivities granted by the Food and Drug Administration (FDA), pursuing tactics to switch patients to new formulations of their products before losing exclusivity, and engaging in "shadow pricing"—raising prices in lockstep with competitors—which keeps prices high.

This report also presents new findings from the Committee's investigation of Pfizer's pain-management drug Lyrica. Internal documents obtained by the Committee reveal:

- **Pfizer targeted the U.S. market for price increases.** A draft internal Pfizer presentation from 2016 explicitly linked Pfizer's global profitability to its ability to raise prices in the United States, noting that growth was driven by "price increases in the U.S."

- **Pfizer used patent protections, market exclusivities, and other tactics to delay generic competition and keep prices high.** Pfizer filed for dozens of patents on Lyrica and obtained an FDA pediatric marketing exclusivity period that the company estimated would generate an additional $1.6 billion in revenue. Pfizer also sought to shift patients to a new controlled-release formulation of the drug before the old formulation faced generic competition, and aggressively marketed to patients and physicians to extend the Lyrica franchise and drive sales.

The Committee's review of all ten companies' practices confirms that the pharmaceutical industry has targeted the United States for price increases for many years while maintaining or cutting prices in the rest of the world. This strategy has been driven in large part by the prohibition on Medicare negotiation, which would be lifted for certain drugs with the passage of the Build Back Better Act.[6] The Committee's investigation has also uncovered new evidence about pricing decisions, marketing strategies, patient assistance programs, and pharmaceutical companies' spending on research and marketing.

The Committee's three-year investigation revealed the following findings:

A. Drug Companies Aggressively Raise Prices to Meet Revenue Targets

Over the past several years, drug companies have repeatedly raised prices on existing drugs, while setting higher launch prices for new drugs. The companies in the Committee's investigation collectively raised prices more than 250 times on the 12 drugs examined. The drugs in the Committee's investigation are now priced at a median of almost 500% higher than when they were brought to market. Some far exceed this—Mallinckrodt's drug H.P. Acthar Gel (Acthar) is priced 100,000% higher than it was at launch.

[6] H.R. 5376 § 139001.

Figure 1: Price Increases and Revenue

Drug	Price Today	No. of Price Increases*	Price Increase Since Launch	2019 U.S. Net Revenue
Copaxone (Teva)	$85,400/year	25+	825%	$950 Million
Enbrel (Amgen)	$72,200/year	25+	486%	$5.05 Billion
Gleevec (Novartis)	$123,000/year	20+	395%	$330 Million
H.P. Acthar (Mallinckrodt)	$39,864/vial	5	> 100,000%	$953 Million
Humalog (Eli Lilly)	$274.70/vial	30+	1219%	$1.67 Billion
Humira (AbbVie)	$71,600/year	25+	471%	$14.9 Billion
Imbruvica (AbbVie)	$181,500–$242,000/year	5+	82%	$3.83 Billion
Lantus (Sanofi)	$283.56/vial	20+	715%	$1.14 Billion
Lyrica (Pfizer)	$1,200/year	20+	420%	$2.01 Billion
NovoLog (Novo Nordisk)	$289.36/vial	25+	627%	$1.18 Billion
Revlimid (Celgene/BMS)	$192,000/year	20+	255%	$6.27 Billion
Sensipar (Amgen)	$9,800/year	20+	232%	$252 Million

** Number of price increases since launch or acquisition*

Internal data obtained by the Committee reveals that the net prices—the prices manufacturers collect after accounting for rebates, price concessions, and other discounts—of nearly all of the drugs in the investigation increased year over year.[7] Net prices for all of the drugs examined are significantly higher today than at launch. This data, which has never before been shared with the public, undermines industry claims that price increases are primarily due to increasing rebates and discounts paid to pharmacy benefit managers (PBMs).

These price increases have fueled large corporate revenues. The ten companies in the Committee's investigation generated a combined $38.5 billion in U.S. net revenues from the sales of just 12 drugs in 2019 alone.[8] The Committee's investigation revealed evidence that

[7] In the insulin market, net prices increased steadily from when the drugs entered the market (1996 for Humalog and 2000 for NovoLog and Lantus) until the mid-2010s. Since the mid-2010s, competition over formulary placement has led to increasing pharmacy benefit manager rebates and stabilized net price growth.

[8] AbbVie Inc., *2019 Form 10-K* (Feb. 21, 2020) (online at https://investors.abbvie.com/sec-filings/sec-filing/10-k/0001551152-20-000007); Pfizer Inc., *2019 Form 10-K* (Feb. 27, 2020) (online at https://investors.pfizer.com/financials/sec-filings/sec-filings-details/default.aspx?FilingId=13958533); Eli Lilly and Company, *2019 Form 10-K* (Feb. 19, 2020) (online at https://investor.lilly.com/static-files/34d71960-241f-4160-bd20-86fb85df4def); Novartis Pharmaceuticals Corporation, *2019 Form 20-F* (Jan. 29, 2020) (online at www.sec.gov/edgar/browse/?CIK=0001114448&owner=include); Mallinckrodt Pharmaceuticals, *2019 Form 10-K* (Feb. 26, 2020) (online at www.mallinckrodt.com/investors/sec-filings/); Bristol Myers Squibb, *2019 Form 10-K* (Feb. 24, 2020) (online at https://d18rn0p25nwr6d.cloudfront.net/CIK-0000014272/468bfaba-6810-4cec-80b5-94aa4c7a5a23.pdf); Sanofi, *2019 Form 20-F* (Mar. 5, 2020) (online at www.sanofi.com/en/investors/reports-and-publications/financial-and-csr-reports); Novo Nordisk Inc., *2019 Form 20-F* (Feb. 5, 2020) (online at www.sec.gov/edgar/browse/?CIK=0000353278); Amgen Inc., *2019 Form 10-K* (Feb. 12, 2020) (online at

company executives made pricing decisions to meet revenue targets and earnings goals, including executing more aggressive price increases than previously planned to reach ever increasing revenue goals. 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.

B. Executive Compensation Provides Incentives to Raise Prices

The ten companies in the Committee's investigation paid their top executives more than $2.2 billion from 2016 to 2020, including $797 million in chief executive officer (CEO) compensation. All ten companies have compensation structures that tie incentive payments to revenue and other financial targets, and several companies directly tied incentive compensation to drug-specific revenue targets. The investigation showed that for at least two companies, the company would have missed its revenue targets and the executives would not have received bonuses had they not raised drug prices. Former Celgene CEO Mark Alles received more than $500,000 in bonus payments in 2016 and 2017 solely attributable to the company's price increases for the cancer drug Revlimid.

Figure 2: Executive Committee Compensation, 2016–2020

Company	Total
AbbVie	$ 347,697,413
Amgen	$ 240,436,746
Celgene/BMS*	$ 260,140,942
Eli Lilly	$ 234,015,759
Mallinckrodt	$ 160,784,443
Novartis	$ 320,585,194
NovoNordisk	$ 124,812,234
Pfizer	$ 287,751,046
Sanofi	$ 60,467,284
Teva	$ 195,881,480
Total	**$ 2,232,572,540**

** Reflects data from Celgene for 2016, 2017, and 2018 and data from Bristol Myers Squibb for 2019 and 2020. Bristol Myers Squibb acquired Celgene in 2019. Calculated using exchange rates from December 31, 2020.*

C. Drug Companies Target the U.S. Market for Higher Prices and Use the Medicare Program to Boost Revenue

The Committee's investigation uncovered new evidence showing how the pharmaceutical industry has exploited the federal law that prohibits the Secretary of the Department of Health and Human Services (HHS) from engaging in direct negotiation with drug companies to lower

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https://investors.amgen.com/financials/sec-filings); Teva Pharmaceutical Industries Ltd., *2019 Form 10-K* (Feb. 21, 2020) (online at https://ir.tevapharm.com/financials/sec-filings/default.aspx). To calculate these figures for companies using foreign currencies, Committee staff used exchange rates current as of December 31, 2020.

drug prices in the Medicare Part D program. Internal strategy documents show that drug companies targeted the U.S. market for price increases—while maintaining or lowering prices in the rest of the world—in part because Medicare cannot negotiate directly. A draft internal Pfizer presentation from 2016 explicitly linked Pfizer's profitability across the globe to its ability to raise prices in the United States, noting that growth was driven by "price increases in the U.S." In a 2016 strategy presentation, executives from Teva, which sells the multiple sclerosis drug Copaxone, described one of the company's key strengths as its ability to "increase prices successfully," which was "influenced heavily by US [Teva's U.S. Business] being allowed to hike prices." A presentation prepared for Celgene's pricing committee noted that a key strategy for Celgene to "win" in its cancer franchise Revlimid was to "[p]rotect free-market competition-based pricing for Medicare and commercial insurance" in the United States.

The Committee obtained non-public pricing data revealing how the Medicare program has lost out on savings because Medicare Part D plans have failed to secure the same generous rebates or discounts as other federal health care programs that negotiate directly with drug companies. The Committee's analysis found that taxpayers could have saved more than $25 billion over a five-year period for just seven of the drugs investigated—Humira, Imbruvica, Sensipar, Enbrel, Lantus, NovoLog, and Lyrica—if private Medicare Part D plans had obtained the same discounts as other federal health programs that are empowered to negotiate.[9] If Medicare Part D plans had received the same discounts as other federal health care programs for the three frequently used insulin products investigated by the Committee—Humalog, Lantus, and NovoLog—Medicare could have saved more than $16.7 billion in the period from 2011 through 2017.[10]

Figure 3: Lost Medicare Savings for Seven Drugs, 2014–2018

Drug	Medicare Part D Spending[11]	Lost Medicare Savings
Lantus	$ 11,583,098,197	$ 9,246,511,550
Humira	$ 10,907,732,233	$ 6,136,305,246
NovoLog	$ 3,627,264,339	$ 2,946,198,492
Enbrel	$ 6,160,200,000	$ 2,353,170,600
Lyrica	$ 7,254,607,375	$ 1,816,950,556
Imbruvica	$ 5,071,975,613	$ 1,695,126,731
Sensipar	$ 3,664,400,000	$ 948,124,100
Total	**$ 48,269,277,757**	**$ 25,142,387,275**

[9] These figures include comparisons of rebate data between Medicare and the Department of Defense (DOD) and the Department of Veterans Affairs (VA). For some drugs, including Imbruvica, Gleevec, and Lyrica, these figures represent the average rebates or discounts offered to both DOD and the VA. For other drugs, these figures include only rebates or discounts offered to one agency. For an in-depth analysis, see Chapter 3.

[10] Data from Novo Nordisk was provided for the "federal channel," which primarily reflects sales to the VA but also includes sales to DOD, the Indian Health Service, the Bureau of Prisons, and state homes for veterans.

[11] For three drugs—Lantus, NovoLog, and Lyrica—this figure represents net Medicare Part D expenditures. For the other drugs—Humira, Enbrel, Imbruvica, and Sensipar—this figure represents gross Medicare Part D expenditures.

Documents obtained by the Committee show that several of the companies in the Committee's investigation targeted Medicare to boost revenues. An internal Novo Nordisk slide deck from October 2013 emphasized, "Part D is the most profitable market for the Novo Nordisk insulin portfolio," and noted that insulin volume for the Part D market was growing three times faster than for the commercial market. A 2016 presentation prepared for Novartis by an outside consultant emphasized, "Medicare is critical to brand success, CMS spent ~$1 billion on Gleevec in 2014."

D. Drug Companies Abuse the Patent System and FDA Market Exclusivity to Suppress Competition

Evidence uncovered by the Committee shows that companies use patent protections and market exclusivities granted by FDA to suppress generic competition and keep prices high. Collectively, the companies in the Committee's investigation have obtained over 600 patents on the 12 drugs examined, which could potentially extend their monopoly periods to a combined total of nearly 300 years. For just six of the drugs in the Committee's investigation, the companies were issued almost 500 patents, collectively providing more than 200 years of potential market monopolies.

Figure 4: Patents and Extended Monopoly Periods

Company	Drug	Number of Patents Issued	Potential Years Blocking Competition
AbbVie	Humira	130	39
AbbVie	Imbruvica	88	29
Amgen	Enbrel	39	47.5
Celgene	Revlimid	109	40
Pfizer	Lyrica	69	32
Sanofi	Lantus	49	37
	Total:	**484**	**224.5**

The Committee's investigation has uncovered new details about patent settlement agreements that delay competition from would-be generic competitors. AbbVie entered into settlement agreements with nine competitors—including six companies that have FDA approval for Humira biosimilars—maintaining monopoly pricing for Humira until January 2023. AbbVie estimated internally that, had lower-priced biosimilars entered the market in the first quarter of 2017, AbbVie's U.S. net revenue would have decreased by $1.5 billion in 2017. According to this internal analysis, biosimilar competition would have forced a reduction in the price of Humira that would have saved the U.S. health care system at least $19 billion from 2016 to 2023.

2014 LRP Biosimilar Erosion											
	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Total HUMIRA Var	$0	$0	$0	($77)	($1,562)	($2,808)	($3,695)	($4,535)	($4,966)	($5,365)	($5,744)
% Var	0%	0%	0%	-1%	-20%	-34%	-42%	-50%	-52%	-55%	-57%
Price Var	$0	$0	$0	($8)	($1,259)	($1,968)	($2,399)	($3,044)	($3,289)	($3,537)	($3,797)
Vol Var	$0	$0	$0	($69)	($303)	($840)	($1,296)	($1,490)	($1,676)	($1,828)	($1,947)

Documents show that other companies abused market exclusivities granted by FDA to secure further market monopolies for widely used and commercially successful drugs. This included abuse of the Orphan Drug Act, which is intended to incentivize the development of drugs that treat rare diseases, and of FDA's pediatric exclusivity period, which grants a six-month extension of market exclusivity and is intended to incentivize manufacturers to conduct studies of drugs in children.

For example, Mallinckrodt aimed to leverage its orphan drug designation for Acthar as a justification for the drug's high price and then aggressively expand sales to non-orphan indications at the same high price, with the objective of bringing in "top-level shareholder returns."

AbbVie has obtained orphan drug protections for Humira, even though Humira is one of the best-selling drugs in the world. Today, AbbVie holds eight orphan designations and approvals for Humira.

Figure 5: Humira Orphan Designations and Approvals

Designation Date	Orphan Designation	Approved Labeled Indication	Marketing Approval Date	Orphan Exclusivity End Date
3/21/2005	Juvenile Rheumatoid Arthritis	Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients **4 years of age and older**	2/21/2008	2/21/2015
3/21/2005	Juvenile Rheumatoid Arthritis	Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients **2 years of age and older**	9/30/2014	9/30/2021
10/19/2006	Pediatric Crohn's Disease	Reducing signs and symptoms and inducing and maintaining clinical remission in patients **6 years of age and older** with moderately to severely active Crohn's disease who have had an inadequate response to corticosteroids or immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate	9/23/2014	9/23/2021
5/13/2014	Non-infectious Intermediate, Posterior, or Panuveitis, or Chronic Non-Infectious Anterior Uveitis	Indicated for the treatment of non-infectious intermediate, posterior, and panuveitis in **adult** patients	6/30/2016	6/30/2023
5/13/2014	Non-infectious Intermediate, Posterior, or Panuveitis, or Chronic Non-Infectious Anterior Uveitis	Treatment of non-infectious intermediate, posterior, and panuveitis in adults and **pediatric patients 2 years of age and older**	9/28/2018	9/28/2025
5/13/2015	Treatment of moderate to severe hidradenitis suppurativa	Treatment of moderate to severe hidradenitis suppurativa	9/9/2015	9/9/2022
5/13/2015	Treatment of moderate to severe hidradenitis suppurativa	Treatment of moderate to severe hidradenitis suppurativa in patients **12 years of age and older**	10/16/2018	10/16/2025
5/11/2011	Treatment of pediatric patients with ulcerative colitis	Treatment of moderately to severely active ulcerative colitis in pediatric patients 5 years of age and older.	2/24/2021	2/24/2028

Internal documents show that Pfizer viewed the six-month pediatric exclusivity granted by FDA to extend Lyrica's market monopoly as a key component of Lyrica's so-called life-cycle-management strategy. A 2015 internal presentation noted: "Pediatric Epilepsy Program for +6 months US Exclusivity Is the Most Valuable Remaining Lifecycle Deliverable." A 2018 Lyrica operating plan estimated that pediatric exclusivity would generate significant financial returns: "Pediatric Program Success Results in ~ $1.6B."

E. Companies Use Strategies to Suppress Competition and Maintain Monopoly Pricing

Every company in the Committee's investigation engaged in one or more strategies to suppress competition from generics or biosimilars, and keep prices high. These include what are often described as "life-cycle management" or "loss of exclusivity" strategies: (1) shifting patients to new products or formulations of a drug just before facing generic competition for the old formula (known as "product hopping" or "evergreening"); (2) pursuing contracts with PBMs and insurers that condition rebates and discounts on excluding competitor products; and (3) aggressively marketing directly to patients and physicians to drive sales, especially as drugs faced generic competition. These strategies are aimed at staving off generic competition and minimizing loss of revenue as older drugs lose their market protections. The Committee's investigation also uncovered new evidence of "shadow pricing," a practice in which would-be competitor companies follow each other's price increases.

Teva, AbbVie, Sanofi, and Pfizer all engaged in product hopping and evergreening. Independent experts estimate that Teva's product-hopping strategy cost the U.S. health care system between $4.3 billion and $5.6 billion in additional health care expenditures from 2015 to 2017 due to delayed generic competition. In 2018, Pfizer launched a controlled-release version of its blockbuster pain management drug Lyrica. Although Pfizer asserted publicly that the controlled-release version was more convenient for patients than the prior formulation, internal company documents obtained by the Committee described it as an "anchor" to the company's life-cycle management for Lyrica.

Novartis and Teva engaged in exclusionary tactics to block generics, using their market power to obtain contract terms with payers or PBMs that limited or blocked generic competitors from being covered on a drug formulary.

Companies targeted doctors and patients to drive sales. In the aggregate, AbbVie, Amgen, Novo Nordisk, and Pfizer spent more than $2.6 billion in direct-to-consumer advertising from 2015 to 2018 on just four drugs. AbbVie reported to the Committee that it spent over $1.5 billion in direct-to-consumer advertising for Humira over that period, and Pfizer disclosed over $750 million in marketing expenditures for Lyrica. Several companies also pursued "dispense as written" campaigns to encourage patients and physicians to request their brand-name drug and prevent lower-cost generic substitution.

Companies also kept prices high by engaging in shadow pricing with would-be competitors. Internal documents show that the three largest insulin manufacturers raised their prices in lockstep in order to maintain "pricing parity," and that senior executives encouraged this practice. Eli Lilly and Novo Nordisk have raised prices in lockstep on their rapid-acting insulin products, Humalog and NovoLog, while Sanofi and Novo Nordisk have raised prices in lockstep on their long-acting insulin products, Lantus and Levemir. In a discussion among Novo Nordisk employees about an Eli Lilly price increase for a different diabetes product on December 24, 2015, a Novo Nordisk pricing analyst remarked, "[M]aybe Sanofi will wait until tomorrow morning to announce their price increase ... that's all I want for Christmas."

Figure 6: Comparison of Rapid-Acting-Insulin Price Increases—Humalog (Eli Lilly) and Novolog (Novo Nordisk), 1996–2018

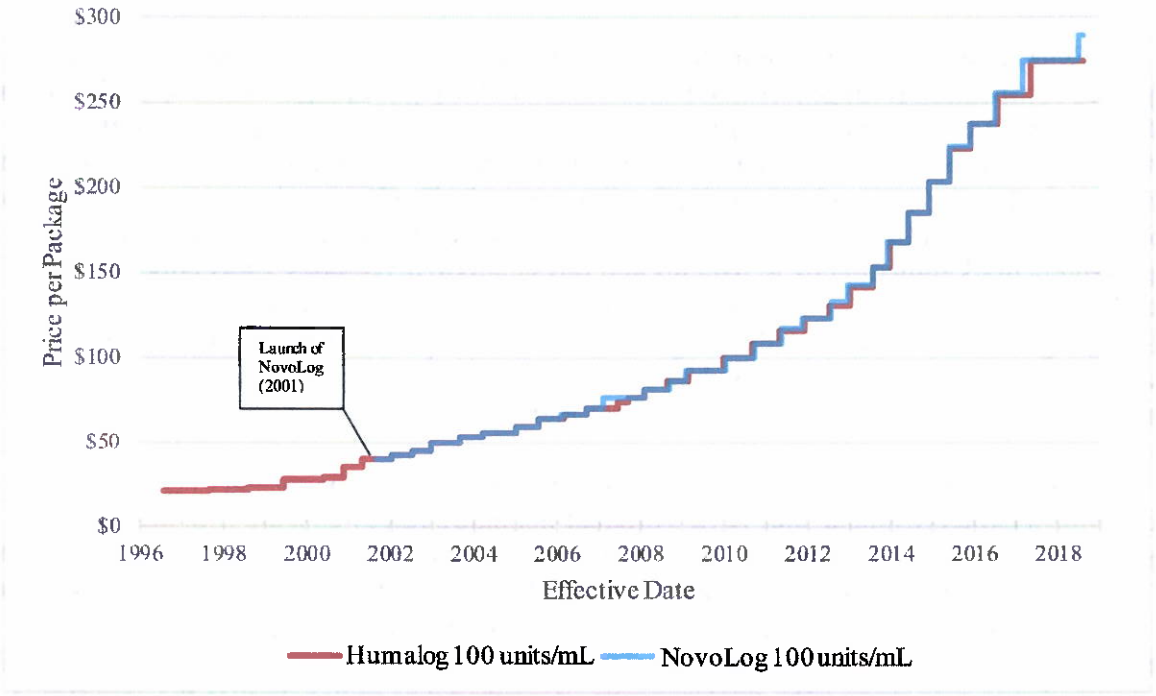
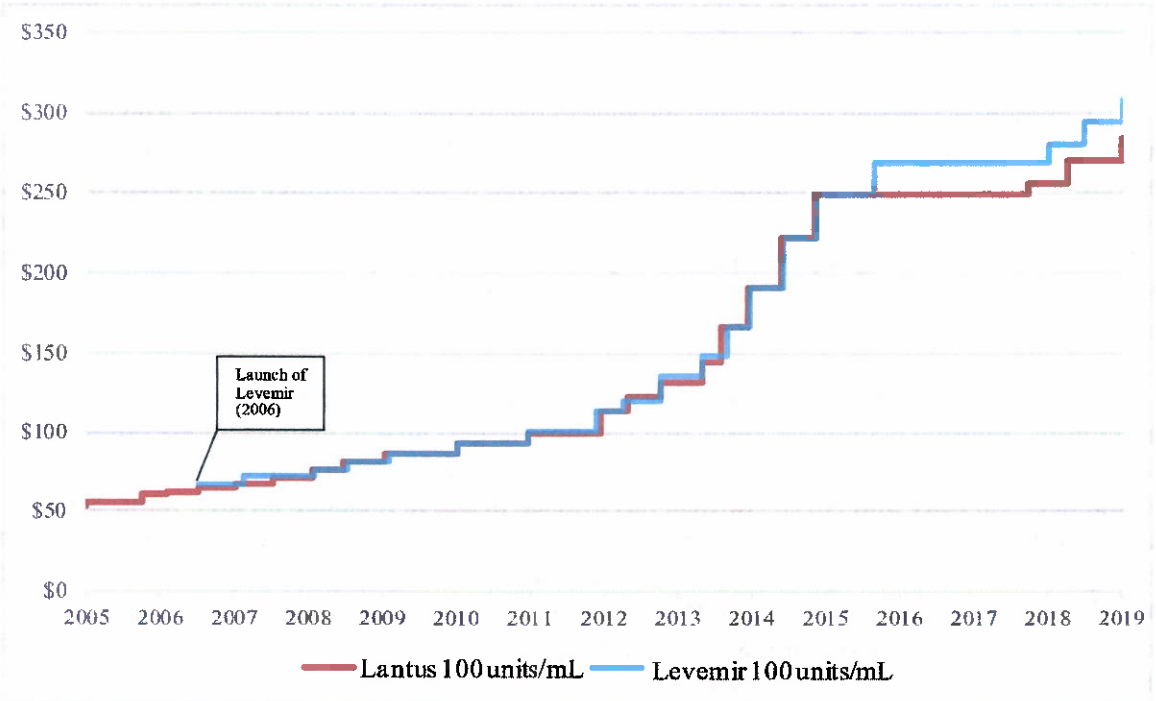
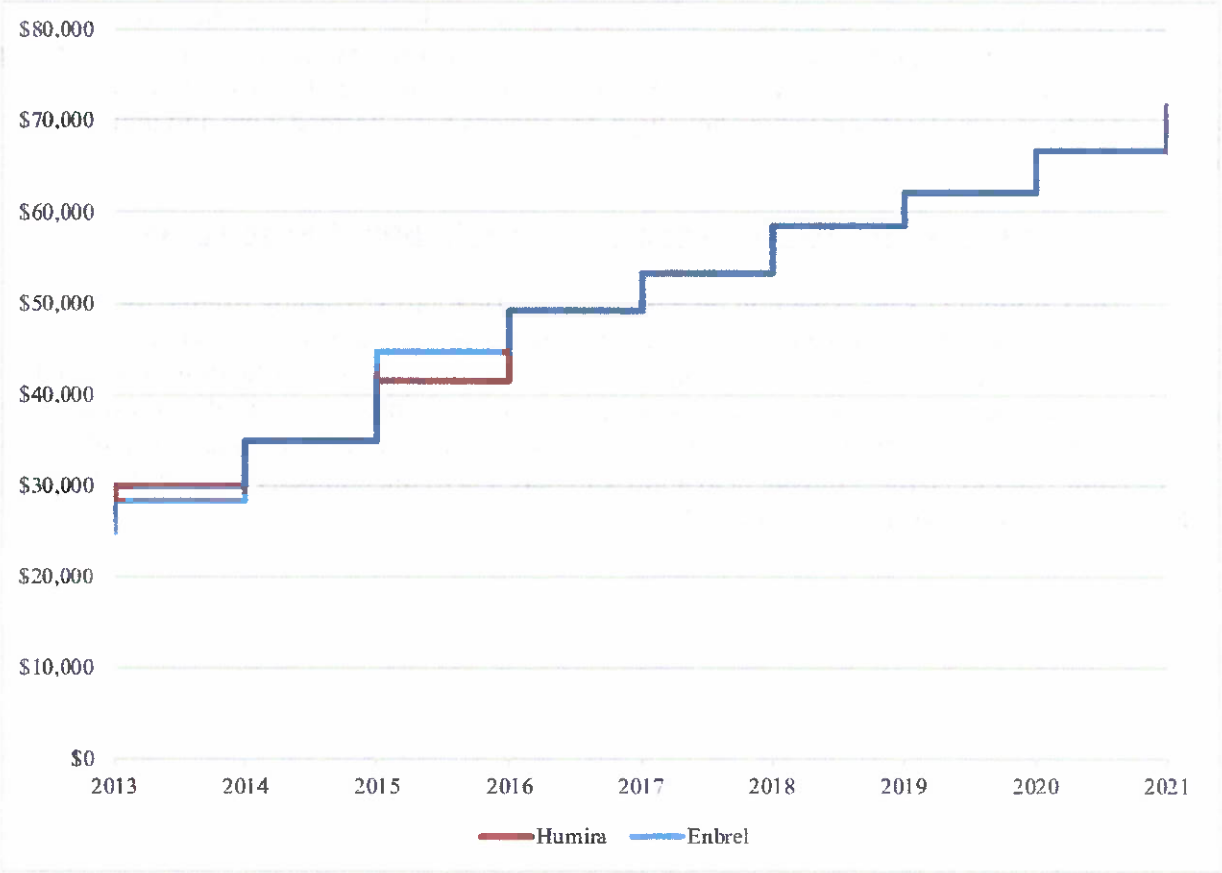


Figure 7: Comparison of Long-Acting-Insulin Price Increases—Lantus (Sanofi) and Levemir (Novo Nordisk), 2005–2019



AbbVie and Amgen also engaged in shadow pricing for their products Humira and Enbrel. One Amgen pricing committee presentation prepared in May 2016 described Amgen's pricing strategy for Enbrel: "Price increase strategy is to follow AbbVie's price increases." In December 2017, while approving a planned 4.9% Enbrel price increase for the end of the year, Amgen's then-Executive Vice President and Head of Global Commercial Operations told his team, "[Y]ou have authorization to proceed with a competitive price increase for Enbrel—should Humira pull the trigger at any point."

Figure 8: Comparison of Humira and Enbrel Prices for Annual Course of Treatment, 2013–2021



F. Companies Use Patient Assistance Programs as a Public Relations Tool to Boost Sales

In responding to criticism of their pricing practices, drug companies often highlight the generosity of their patient assistance programs. However, the Committee's investigation uncovered new evidence that companies emphasized the significant returns on investment from these programs in the form of increased sales, particularly for drugs approaching loss of exclusivity. The Committee obtained internal discussions and strategy documents in which companies, including Teva and Novartis, emphasized the rates of return of their copayment assistance programs for commercial patients. Internal Pfizer documents emphasized that its copayment program encouraged patients to stay on branded Lyrica even after the entry of generic

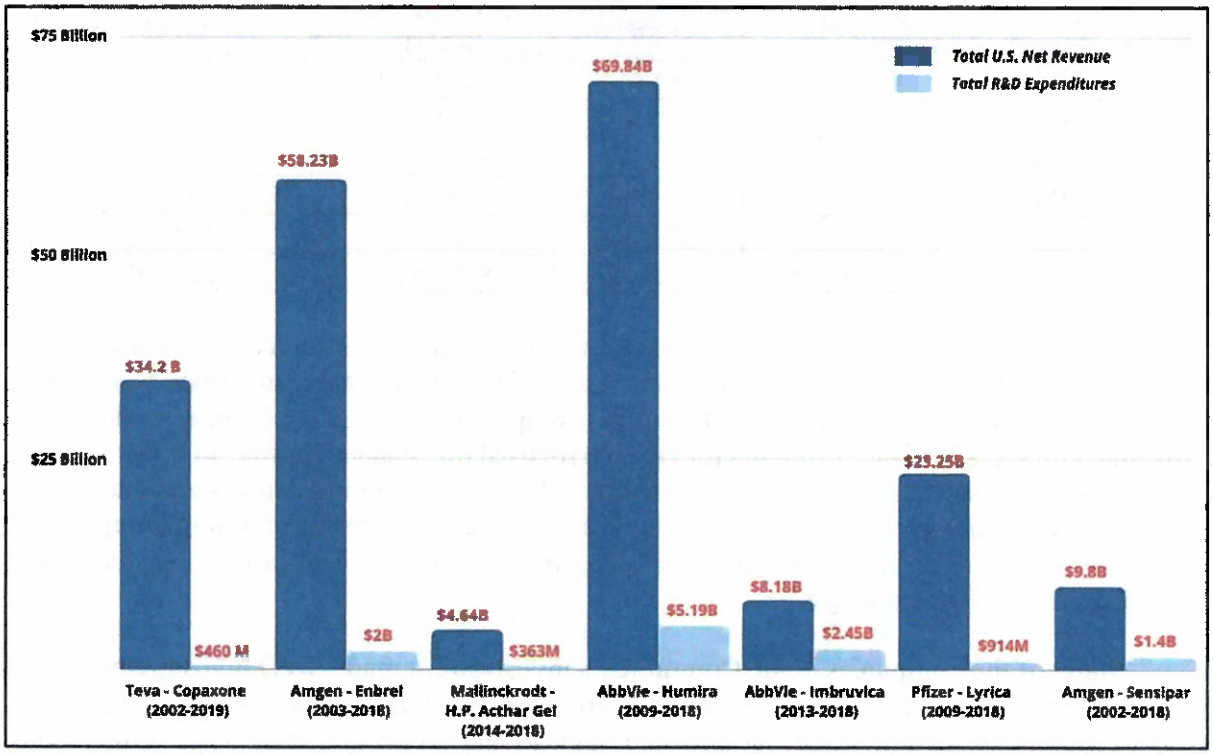
competition. Internal documents suggest that companies also used donations to third-party foundations that subsidize copayment and other cost-sharing obligations for Medicare Part D patients as a way to generate sales. For example, internal documents from both Teva and AbbVie indicate that these donations were intended to drive sales or attract patients who otherwise might not have used the companies' drugs.

Although internal documents show that companies view these programs as an important public relations tool, internal data obtained by the Committee confirms that companies' spending on patient assistance programs is minimal compared to the enormous amount of revenue brought in by these drugs. For example, the total cost of Pfizer's patient assistance program expenditures related to Lyrica from 2015 to 2017 was equivalent to less than one-tenth of one percent of Pfizer's net U.S. revenue from Lyrica over the same period. These programs often do not provide sustainable support for patients and do not address the burden that the company's pricing practices have placed on the U.S. health care system. The Committee obtained hundreds of pages of patient complaints describing how high drug prices have harmed them and their loved ones.

G. Research and Manufacturing Costs Do Not Justify Price Increases

The Committee's investigation revealed that justifications frequently offered by the pharmaceutical industry for raising prices—including research and development (R&D), manufacturing, and other costs—are not supported. The Committee's investigation found that companies' investments in R&D are far outpaced by revenue gains. For example, in response to the Committee's request, Pfizer identified a total of $914 million in R&D expenditures related to Lyrica from 2009 to 2018—equivalent to approximately 4% of the company's $23 billion in net U.S. revenue from the drug for that period.

Figure 9: Comparison of Net Revenue and R&D Expenditures for Seven Drugs



The Committee's investigation also found that even if the pharmaceutical industry collected less revenue due to pricing reforms, drug companies could maintain or even exceed their current R&D expenditures if they reduced spending on stock buybacks and dividends. From 2016 to 2020, the 14 leading drug companies spent $577 billion on stock buybacks and dividends—$56 billion more than they spent on R&D over the same period.[12]

[12] Data was compiled based on information from annual reports, proxy statements, and other documents from AbbVie, Amgen, AstraZeneca, Bristol Myers Squibb, Eli Lilly, Gilead, GlaxoSmithKline, Johnson & Johnson, Merck, Novartis, Novo Nordisk, Pfizer, Roche, and Sanofi. These 14 companies were the largest pharmaceutical companies by market capitalization in Q1 2021. *Q1 2021: A Look at Biopharma's Top 25 Companies by Market Cap*, BioSpace (May 3, 2021) (online at www.biospace.com/article/q1-2021-an-in-depth-look-at-biopharma-s-top-25-/).

Figure 10: Buybacks, Dividends, and R&D Expenditures for 14 Drug Companies, 2016–2020

	Buybacks ($M)	Dividends ($M)	Total Buybacks & Dividends ($M)	R&D Expenditures ($M)
2016	$45,193	$67,614	$112,806	$92,034
2017	$34,401	$67,338	$101,740	$96,392
2018	$70,162	$70,918	$141,080	$104,585
2019	$50,168	$73,533	$123,721	$107,573
2020	$19,104	$79,463	$98,567	$121,233
Total (2016–2020)	**$219,028**	**$358,886**	**$577,914**	**$521,817**

The Committee's investigation also found that companies dedicated a significant portion of their R&D expenditures to research that was intended to extend market monopolies, support the companies' marketing strategies, and suppress competition. For example, internal documents show that AbbVie's R&D investments for Humira focused on "enhancements" to the drug that would protect against biosimilar competition. One internal presentation emphasized that an objective of the "enhancement" strategy was to "raise barriers to competitor ability to replicate." Another presentation to the board of directors described investments in Humira "enhancement" as a biosimilar "defense strategy."

Many of the companies in the Committee's investigation made R&D investments in their drugs after other research demonstrated the potential for significant financial returns. Amgen, AbbVie, Mallinckrodt, and Sanofi acquired the rights to market Enbrel, Imbruvica, Acthar, and Lantus, respectively, after the drugs had demonstrated financial success. Pfizer, Celgene, and Novartis relied heavily on taxpayer-funded research to develop Lyrica, Revlimid, and Gleevec, respectively. For example, an internal Celgene "Strategic Rationale" memorandum from April 2009 shows that Celgene relied on previous federally funded research to justify investing in a larger study on its cancer drug Revlimid. The memorandum emphasized the "Financial Opportunity" of the investment, describing the newly diagnosed patient population as "the largest commercial opportunity for the multiple myeloma franchise." The memorandum estimated the net present value of the investment at "nearly $1.5 billion" with an "internal rate of return on investment of 114%." The memorandum concluded, "No other current or planned Celgene program approaches the financial value represented by realizing the assumptions in our current newly diagnosed multiple myeloma global sales forecast."

Internal data obtained by the Committee also confirms that companies' price increases are not justified by manufacturing costs. For some drugs, such as Humira and Lyrica, manufacturing costs increased at a rate significantly lower than the rate of price increases. For other drugs, such as Copaxone and Enbrel, manufacturing costs actually declined as the company raised prices. For all of the companies, manufacturing costs for their drugs were equivalent to only a fraction of annual revenues from these drugs.

* * *

The Committee's investigation highlights the need for structural reform of the pharmaceutical industry. This report calls on Congress to take the following actions to achieve this reform:

- **Allow Medicare Negotiation, Restrain Price Increases, and Cap Out-of-Pocket Costs:** Congress should enact reforms, like those in the Build Back Better Act, to enable Medicare to negotiate lower list prices, restrain excessive price increases through inflation rebates, and limit out-of-pocket costs for insulin and other drugs so American seniors and taxpayers are not exploited for pharmaceutical profits.

- **Address Anticompetitive Practices That Keep Prices High:** The Committee's investigation highlights the need for reforms that address anticompetitive practices, including product hopping and targeting doctors to prescribe branded drugs instead of lower-cost generics through dispense-as-written campaigns. Congress should pass legislation that targets these practices, such as the Affordable Prescriptions for Patients Through Promoting Competition Act.

- **Address Anticompetitive Settlement Agreements:** In light of the Committee's finding that companies engage in anticompetitive tactics to maintain monopoly pricing, including entering into settlement agreements that delay access to generics, Congress should consider reforms that address these issues, such as the Preserve Access to Affordable Generics and Biosimilars Act.

- **Ensure Transparency of Research and Development Costs and Support Innovative Research:** Congress should consider reforms to increase transparency around pharmaceutical investment in R&D. Cost transparency would provide valuable data about companies' investments in innovation and their claims that high costs of R&D justify the skyrocketing prices of their drugs. Transparency would also inform policies to help the government fund its own trials and incentivize innovation. Congress could also consider reforms to encourage innovative research by ensuring that eligible researchers have access to drugs at a discounted price.