Drug Pricing Investigation

Lost Savings: How Prohibiting Medicare Negotiation Has Cost Taxpayers

Staff Report
Committee on Oversight and Reform
U.S. House of Representatives
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EXECUTIVE SUMMARY

On January 14, 2019, the Committee on Oversight and Reform launched a comprehensive investigation into pharmaceutical pricing and business practices. The Committee's investigation has focused on ten companies that sell 12 drugs that are among the costliest to the Medicare program.[1] The investigation has examined the tactics drug companies use to keep prices high and suppress competition and the impact that high drug prices have on U.S. patients and federal health care programs. Some of the drugs in the Committee's investigation have been on the market without competition for many years—far exceeding their intended market monopolies—and have collected billions in profits.

The Committee has released seven previous staff reports describing the findings of this investigation. The July 2021 report found that financial data from the largest drug companies contradicted claims that reducing U.S. prescription drug prices will harm innovation. That analysis indicated that even if the pharmaceutical industry collected less revenue due to pricing reforms, drug companies could maintain or even exceed their current research and development spending if they reduced spending on buybacks and dividends.[2]

This staff report, the Committee's eighth, reveals new information about the billions of dollars taxpayers have lost because Medicare is prohibited from negotiating directly with pharmaceutical companies to lower drug prices on behalf of Medicare Part D beneficiaries. This report also provides new evidence about the extent to which drug companies target 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. The lost savings presented in this report are likely a fraction of Medicare's total lost savings across all Part D drugs.

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[1] This report focuses on the practices of the following 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 International AG (Gleevec); Novo Nordisk (Novolog products); Pfizer (Lyrica); Sanofi (Lantus products); and Teva Pharmaceuticals (Copaxone). The Committee's investigation also covered the conduct of Johnson & Johnson, which jointly markets the cancer drug Imbruvica with AbbVie, Inc., 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).

[2] Majority Staff, Committee on Oversight and Reform, *Drug Pricing Investigation: Industry Spending on Buybacks, Dividends, and Executive Compensation* (July 2021) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/COR%20Staff%20Report%20-%20Pharmaceutical%20Industry%20Buybacks%20Dividends%20Compared%20to%20Research.pdf).

Specifically, the Committee's investigation found:

- **<u>The Prohibition on Medicare Negotiation Cost U.S. Taxpayers Billions.</u>**

  - Company pricing data obtained by the Committee shows that taxpayers could have saved more than $25 billion between 2014 and 2018 for just *seven* of the drugs investigated by the Committee—if Medicare Part D plans had secured the same discounts as other federal health care programs empowered to negotiate.

Drug	Lost Medicare Savings
Lantus	$ 9.2 billion
Humira	$ 6.1 billion
NovoLog	$ 2.9 billion
Enbrel	$ 2.3 billion
Lyrica	$ 1.8 billion
Imbruvica	$ 1.6 billion
Sensipar	$ 948 million
Total	**$ 25.1 billion**[3]

  - If Medicare plans had secured the same discounts as other federal health care programs for three frequently-used insulin products investigated by the Committee—Humalog, NovoLog, and Lantus—the Medicare program could have saved more than $16.7 billion from 2011 through 2017.

- **<u>Medicare Sales Drove Revenues and Profits.</u>** Internal documents obtained by the Committee reveal that drug companies relied on Medicare sales to drive revenues and profits. For example:

  - A Novo Nordisk Medicare Part D presentation from 2013 emphasized that "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.

  - An internal Pfizer presentation from 2018 showed that sales to Medicare accounted for 35% of Pfizer's gross sales of Lyrica in 2017 and were projected to account for 42% by 2019.

  - A 2016 presentation prepared for Novartis by an outside consultant emphasized the importance of Medicare for its cancer drug Gleevec, finding: "Medicare is critical to brand success, CMS spent ~$1 billion on

[3] Figures may not sum due to rounding.

Gleevec in 2014."

- **Pharmaceutical Companies Targeted the U.S. Market for Higher Prices.** Internal company documents show that pharmaceutical executives targeted the United States for price increases while maintaining or lowering prices in the rest of the world—in large part because of Medicare's inability to negotiate. For example:

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

  - An internal Novo Nordisk presentation highlighted the unconstrained pricing environment in the United States, noting, "Despite increased scrutiny and pressure, the US pricing environment still remains favourable," and, "Despite increased US rebates, payer scrutiny and pricing pressure, net sales has continued to increase."

  - Teva executives discussed the importance of keeping the prohibition on Medicare negotiation intact. In one presentation, executives identified Medicare drug price negotiation as a "Main Risk Event" with the largest potential impact on the company's future revenue.

The Committee's findings demonstrate the need for legislative reform, like the Build Back Better Act, to empower Medicare to negotiate directly with drug companies to rein in unreasonable price increases, save taxpayer dollars, and ensure that patients in the United States can afford lifesaving medications.

I. FINDINGS

In 2020, more than 47 million Americans enrolled to receive prescription drug coverage through Medicare Part D plans.[4] Unlike in other federal health care programs, the Secretary of the Department of Health and Human Services (HHS) is expressly prohibited from negotiating directly with drug companies on behalf of Medicare Part D beneficiaries.[5] Instead, drug prices are negotiated by the private insurers and pharmacy benefit managers (PBMs) that administer Part D plans.[6] Because Medicare provides prescription drug benefits in accordance with federal requirements, Medicare plans are further constrained in their ability to negotiate for lower prices through coverage restrictions.[7]

A. Lost Medicare Savings

Internal pricing data obtained by the Committee reveal that over the period examined, the ten drug companies in the Committee's investigation provided higher rebates and discounts to federal health care programs that are empowered to negotiate directly with drug manufacturers than to Medicare Part D plans.[8]

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[4] Centers for Medicare and Medicaid Services, *CMS Fast Facts* (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Fast-Facts) (accessed Sept. 21, 2021).

[5] Federal law states that the HHS Secretary "(1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP [prescription drug plan] sponsors; and (2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs." 42 U.S.C. § 1395w-111(i).

[6] Beneficiaries may also obtain prescription drug coverage through Medicare Advantage plans, which offer prescription drug benefits as part of broader managed care plans. Kaiser Family Foundation, *An Overview of the Medicare Part D Prescription Drug Benefit* (Oct. 14, 2020) (online at www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/).

[7] *See* 42 C.F.R. § 423 (2011). For example, plan sponsors are required to include on their formularies all or substantially all drugs in six categories or classes: (1) antidepressants; (2) antipsychotics; (3) anticonvulsants; (4) immunosuppressants; (5) antiretrovirals; and (6) antineoplastics, except in limited circumstances. *See* Centers for Medicare and Medicaid Services, *Fact Sheet: Medicare Advantage and Part D Drug Pricing Final Rule (CMS-4180-F)* (May 16, 2019) (online at www.cms.gov/newsroom/fact-sheets/medicare-advantage-and-part-d-drug-pricing-final-rule-cms-4180-f); Congressional Research Service, *Negotiation of Drug Prices in Medicare Part D* (Oct. 31, 2019) (online at https://crsreports.congress.gov/product/pdf/IF/IF11318).

[8] The federal health care programs examined in this report include that of the Department of Defense (DOD), that of the Department of Veterans Affairs (the VA), and other federal programs that purchase drugs directly from wholesalers and distributors, such as those of the Public Health Service, the Coast Guard, and the Bureau of Prisons. The prices paid by these programs are based in part on prices set in the Federal Supply Schedule. The prices paid by the largest direct purchasers (known as the "Big Four")—DOD, the VA, the Public Health Service (including the Indian Health Service), and the Coast Guard—are statutorily capped, but these programs are empowered to negotiate directly with drug manufacturers for even deeper discounts. The VA and DOD use national drug lists that provide preferred access to certain drugs and restrict access to others. These so-called closed formularies increase agencies' negotiating leverage. A Congressional Budget Office comparison of prices paid across federal programs found that the average price paid by DOD and the VA for top-selling drugs was approximately 55% of the average net price paid by Medicare. Congressional Budget Office, *A Comparison of Brand-Name Drug Prices Among Selected Federal Programs* (Feb. 2021) (online at www.cbo.gov/system/files/2021-02/56978-Drug-Prices.pdf).

According to the Committee's analysis of data from 2009 to 2018, taxpayers could have saved billions of dollars if Medicare Part D plans had secured rebates comparable to those secured by other federal health care programs.[9] For example, between 2014 and 2018, taxpayers could have saved approximately $25.1 billion on just seven drugs—Humira, Imbruvica, Sensipar, Enbrel, NovoLog, Lantus, and Lyrica—if Medicare plans had achieved rebates and discounts comparable to those negotiated with other federal agencies. Taxpayers could have saved more than $5.6 billion in 2017 alone. Figure 1 shows Medicare's lost savings for these seven drugs.

Figure 1: Lost Medicare Savings for Seven Drugs, 2014–2018

Drug	Medicare Part D Spending[10]	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**

The Committee's investigation examined three insulin products: Lantus, which is sold by Sanofi; NovoLog, which is sold by Novo Nordisk; and Humalog, which is sold by Eli Lilly. The Committee's analysis shows that if Medicare plans had secured the same discounts as other federal health care programs for these products, taxpayers could have saved approximately $16.7 billion from 2011 through 2017. Figure 2 shows Medicare's lost savings for these insulin products.

[9] According to a Government Accountability Office report, PBMs pass nearly all rebates on to Medicare Part D plans, retaining approximately 0.4% of total direct and indirect remuneration. Government Accountability Office, *Medicare Part D: Use of Pharmacy Benefit Managers and Efforts to Manage Drug Expenditures and Utilization* (July 15, 2019) (online at www.gao.gov/products/gao-19-498). Since the Committee did not account for this difference, the Committee's calculations may slightly underestimate Medicare Part D spending and potential savings.

[10] 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.

Figure 2: Lost Medicare Savings for Insulin Products, 2011–2017

Drug	Net Medicare Part D Spending	Lost Medicare Savings
Lantus	$ 15,293,263,635	$ 12,046,199,222
NovoLog	$ 4,569,176,125	$ 3,709,011,061
Humalog	$ 2,538,590,200	$ 949,020,500
Total	**$ 22,401,029,960**	**$ 16,704,230,783**

Lantus and NovoLog have been approved for use in the United States since 2000. Humalog was approved in 1996.[11] Data obtained by the Committee show that from 2009 to 2013, Sanofi, Novo Nordisk, and Eli Lilly drastically raised the prices of these drugs, with corresponding increases in net price—the amount a manufacturer receives after all rebates, discounts, and other price concessions.[12] Plans and PBMs have been able to use their negotiating power to secure higher rebates from insulin manufacturers in exchange for preferred placement on a covered drug list, or formulary.[13] Data show that, beginning in 2013, insulin manufacturers began providing higher rebates to PBMs in the Medicare and commercial sales channels, leading to a corresponding reduction in net price.[14] Nevertheless, in the years that these rebates began to increase, taxpayers lost out on billions of dollars in potential savings that were provided to other federal care programs but not to Medicare.

Despite these competitive dynamics, net prices across sales channels of the three insulin products examined are still higher than they were when they came to market. For example, according to an internal document, in 2016 the net price for Lantus was $87.48—88% higher

[11] Food and Drug Administration, *Drug Approval Package: Lantus (Insulin Glargine [rDNA Origin]) Injection* (Apr. 20, 2000) (online at www.accessdata.fda.gov/drugsatfda_docs/nda/2000/21081_lantus.cfm); Food and Drug Administration, *Drug Approval Package: NovoLog (Insulin Aspart [rDNA Origin] Injection)* (June 7, 2000) (online at www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20-986_NovoLog.cfm); Food and Drug Administration, *Drug Approval Package: Humalog (Insulin Lispro [rDNA Origin] Injection)* (June 14, 1996) (online at www.accessdata.fda.gov/drugsatfda_docs/nda/pre96/020563Orig1s000rev.pdf)

[12] *See, e.g.*, SANOFI_COR_00093935, at Slide 10 (an internal Sanofi document showing Lantus's net price increasing by 98.4% from 2007 to 2014); COR-BOX-00024053, at Page 2 (an internal Eli Lilly document showing the net price of Humalog at $36.59 in 2001 and steadily increasing each year until 2013, when the net price peaked at $80.46).

[13] Majority and Minority Staffs, Senate Committee on Finance, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* (Jan. 2021) (online at www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf).

[14] PBMs have been successful in moderating price increases through the use of contractual price protection clauses, which provide additional rebates when manufacturers raise a drug's wholesale acquisition cost, or list price, above a certain percentage over a set period of time. *See* Majority and Minority Staffs, Senate Committee on Finance, *Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug* (Jan. 2021) (online at www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf); *Insulin Prices Soar While Drugmakers' Share Stays Flat,* Wall Street Journal (Oct. 7, 2016) (online at www.wsj.com/articles/insulin-prices-soar-while-drugmakers-share-stays-flat-1475876764).

than the 2005 net price of $46.52.[15] Similarly, another internal Eli Lilly document identified the net price for Humalog as $70.30 in 2016—92% higher than the launch price of $36.59 in 2001.[16]

i. Sanofi—Lantus

According to internal pricing data obtained by the Committee, Sanofi collected more than $17 billion in net revenues from Medicare for its long-acting insulin, Lantus, between 2009 and 2018, even after accounting for rebates and discounts. Sanofi collected more than $2 billion in net revenues for each year between 2013 and 2017.[17]

In 2009, Medicare Part D plans secured an average rebate of 7% on Lantus, as compared to the 69% rebate secured by the Department of Veterans Affairs (VA).[18] In 2010, Medicare Part D plans received an average rebate of 8% on Lantus, while the VA received a 72% discount.[19] From 2009 to 2018, Medicare Part D plans secured an average rebate of 34% as compared to an average of 85% for the VA. If Medicare plans had secured the same rebates as the VA during this period, taxpayers could have saved approximately $13.9 billion on Lantus alone.[20] Figure 3 below highlights the differences in these discounts and the potential savings.[21]

[15] SANOFI_COR_00093935, at Slide 10. Since 2014, the net price for Lantus has decreased, even as list prices have increased. According to Sanofi's annual pricing report, the net price of Lantus decreased 53% from 2012 to 2020 while the list price increased by 141%. The decline in net price corresponds with an 82% increase in out-of-pocket costs by Lantus users over the same period, according to this report. Though Sanofi suggests that out-of-pocket costs increased because rebates are not passed on to patients due to "the way health benefit plans are often designed," many insured patients—including some Medicare Part D beneficiaries—maintain out-of-pocket spending obligations based on a drug's list price. Sanofi, *Prescription Medicine Pricing: Our Principles and Perspectives* (Feb. 2021) (online at www.sanofi.us/-/media/Project/One-Sanofi-Web/Websites/North-America/Sanofi-US/Home/corporateresponsibility/Sanofi_2021_Pricing_Principles_Report.pdf?la=en); Chien-Wen Tseng et al., *Impact of Higher Insulin Prices on Out-of-Pocket Costs in Medicare Part D*, Diabetes Care (Apr. 2020) (online at https://care.diabetesjournals.org/content/43/4/e50).

[16] COR-BOX-00024053, at Page 2.

[17] SANOFI_COR_00479237 to 00479241; SANOFI_COR-00493774 to 00493778; Centers for Medicare and Medicaid Services, *Medicare Part D Drug Spending Dashboard and Historical Data* (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Historical_Data) (accessed Sept. 21, 2021).

[18] SANOFI_COR_00493774.

[19] SANOFI_COR_00493775.

[20] SANOFI_COR_00479237 to 00479241; SANOFI_COR-00493774 to 00493778.

[21] SANOFI_COR_00479237 to 00479241; SANOFI_COR_00493774 to 00493778 (providing average discounts offered to Medicare Part D and the VA for each year). To arrive at this calculation, Committee staff also relied on gross sales data published by the Centers for Medicare and Medicaid Services. *See* Centers for Medicare and Medicaid Services, *Medicare Part D Drug Spending Dashboard and Historical Data* (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Historical_Data) (accessed Sept. 21, 2021).

Figure 3: Lost Medicare Part D Savings for Lantus

Lantus						
Year	Gross Medicare Part D Sales	Part D Discount %	Net Part D Expenditures	VA Discount %	Net Part D Expenditures if VA Discount	Lost Part D Savings
2010	$ 1,177,849,283	8.0%	$ 1,083,621,340	72.0%	$ 329,797,799	$ 753,823,541
2011	$ 1,467,024,268	10.0%	$ 1,320,321,841	74.0%	$ 381,426,310	$ 938,895,532
2012	$ 1,945,151,504	12.0%	$ 1,711,733,324	79.0%	$ 408,481,816	$ 1,303,251,508
2013	$ 2,683,090,322	18.0%	$ 2,200,134,064	82.0%	$ 482,956,258	$ 1,717,177,806
2014	$ 3,742,568,385	28.0%	$ 2,694,649,237	87.0%	$ 486,533,890	$ 2,208,115,347
2015	$ 4,359,504,167	38.0%	$ 2,702,892,584	89.0%	$ 479,545,458	$ 2,223,347,125
2016	$ 4,214,423,314	41.0%	$ 2,486,509,755	88.0%	$ 505,730,798	$ 1,980,778,957
2017	$ 4,186,582,366	48.0%	$ 2,177,022,830	88.0%	$ 502,389,884	$ 1,674,632,946
2018	$ 3,623,866,169	58.0%	$ 1,522,023,791	90.0%	$ 362,386,617	$ 1,159,637,174
Total	**$ 27,400,059,778**	**34.7%**	**$ 17,898,908,766**	**85.6%**	**$ 3,939,248,830**	**$ 13,959,659,937**

ii. Novo Nordisk—Novolog

In the six years from 2013 to 2018, Medicare spent more than $4.3 billion on Novo Nordisk's rapid-acting form of insulin, the NovoLog vial and the NovoLog FlexPen, after rebates and discounts.[22] In internal documents obtained by the Committee, Novo Nordisk executives noted that rebates were lower for Medicare Part D than for other federal health care programs, including the VA, the Department of Defense (DOD), the Indian Health Service, and the Bureau of Prisons.[23]

If Medicare Part D plans had secured the same discounts that Novo Nordisk offered to other federal health care programs for two of the highest-grossing NovoLog formulations—NovoLog vial and NovoLog FlexPen—taxpayers could have saved more than $4.2 billion between 2011 and 2018.[24] Figure 4 below shows Medicare's lost savings over this period.

[22] Centers for Medicare and Medicaid Services, *Medicare Part D Drug Spending Dashboard and Historical Data* (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Historical_Data) (accessed Sept. 21, 2021). Committee staff calculated net Part D expenditures by multiplying the amount of gross spending on each product for each year, as reported by CMS, by the average rebate percent offered to Medicare Part D, as reported to the Committee by Novo Nordisk for these years, and subtracting this net rebate amount from the gross spending total. NNI-ERR_0083951.

[23] *See* Letter from Akin Gump, on behalf of Novo Nordisk, to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Jan. 27, 2021); NNI-ERR_0083344, at Page 35; NNI-ERR_0083951; NNI-ERR_0083953; NNI-ERR_0083955.

[24] NNI-ERR_0083951; NNI-ERR_0083955 (providing average Part D discount for each year); NNI-ERR_0083953 (providing average "federal channel" discount for each year). According to Novo Nordisk, data on federal channel rebates "primarily reflect sales to the Department of Veterans Affairs" and also include sales to DOD, the Indian Health Service, the Bureau of Prisons, and state homes for veterans. Letter from Akin Gump, on behalf of Novo Nordisk, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Mar. 19, 2019). To arrive at this calculation, Committee staff also relied on gross sales data published by the Centers for Medicare and Medicaid Services. *See* Centers for Medicare and Medicaid Services, *Medicare Part D Drug Spending Dashboard and Historical Data* (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Historical_Data) (accessed Sept. 21, 2021).

Figure 4: Lost Medicare Part D Savings for NovoLog

Novolog Vial						
Year	Gross Medicare Part D Sales	Part D Discount %	Net Part D Expenditures	Federal Channel Discount %	Net Part D Expenditures if Federal Channel Discount	Lost Part D Savings
2011	$ 299,577,585	24.3%	$ 226,780,232	82.0%	$ 53,923,965	$ 172,856,267
2012	$ 368,664,418	35.3%	$ 238,525,879	84.0%	$ 58,986,307	$ 179,539,572
2013	$ 438,613,356	35.9%	$ 281,151,161	86.0%	$ 61,405,870	$ 219,745,291
2014	$ 514,411,128	40.8%	$ 304,531,388	88.0%	$ 61,729,335	$ 242,802,053
2015	$ 596,621,211	49.9%	$ 298,907,227	91.0%	$ 53,695,909	$ 245,211,318
2016	$ 579,747,934	60.0%	$ 231,899,173	92.0%	$ 46,379,835	$ 185,519,339
2017	$ 702,066,516	71.3%	$ 201,493,090	92.0%	$ 56,165,321	$ 145,327,769
2018	$ 694,913,262	72.8%	$ 189,016,407	93.0%	$ 48,643,928	$ 140,372,479
Total	**$ 4,194,615,410**	**53.0%**	**$ 1,972,304,557**	**89.5%**	**$ 440,930,471**	**$ 1,531,374,086**
Novolog FlexPen						
Year	Gross Medicare Part D Sales	Part D Discount %	Net Part D Expenditures	Federal Channel Discount %	Net Part D Expenditures if Federal Channel Discount	Lost Part D Savings
2011	$ 249,442,068	24.3%	$ 188,827,645	86.0%	$ 34,921,890	$ 153,905,756
2012	$ 408,455,852	35.3%	$ 264,270,936	87.0%	$ 53,099,261	$ 211,171,676
2013	$ 619,666,076	35.9%	$ 397,205,955	89.0%	$ 68,163,268	$ 329,042,687
2014	$ 817,956,972	40.8%	$ 484,230,527	91.0%	$ 73,616,127	$ 410,614,400
2015	$ 1,089,595,668	49.9%	$ 545,887,430	93.0%	$ 76,271,697	$ 469,615,733
2016	$ 1,163,647,229	60.0%	$ 465,458,891	94.0%	$ 69,818,834	$ 395,640,058
2017	$ 1,533,124,007	71.3%	$ 440,006,590	94.0%	$ 91,987,440	$ 348,019,150
2018	$ 1,712,623,585	72.8%	$ 465,833,615	94.0%	$ 102,757,415	$ 363,076,200
Total	**$ 7,594,511,458**	**57.2%**	**$ 3,251,721,591**	**92.49%**	**$ 570,635,932**	**$ 2,681,085,658**

iii. Eli Lilly—Humalog

Between 2009 and 2017, Medicare spent more than $3 billion on the Humalog family of rapid-acting insulin products, after rebates and discounts.[25]

Internal pricing data reviewed by the Committee indicate that from 2009 to 2013, Medicare paid significantly more for Humalog than other payers. Even taking into account higher Medicare rebates in more recent years, if Medicare Part D plans had secured the same rebates as the VA from 2009 to 2017, taxpayers could have saved nearly $1.2 billion on Humalog products.[26] Figure 5 below highlights the differences in these discounts and the potential savings.

[25] LLY-ORCOM-00000001. The Committee calculated these amounts by taking the gross sales provided for each year and deducting the dollar value of the rebates. The average percent reduction includes rebates, 340(b) discounts, and channel costs, defined by the company as:

> the costs associated with shipping and managing inventory through the physical supply chain such as wholesaler prompt pay discounts (pro-rated by segment volume), wholesaler services fees (pro-rated by segment volume) and, [*sic*] product returns (pro-rated by segment volume).

[26] LLY-ORCOM-00000001 (providing the average discount offered to Medicare Part D and the VA for each year, and gross Medicare Part D sales by year).

Figure 5: Lost Medicare Part D Savings for Humalog

Humalog						
Year	Gross Medicare Part D Sales	Part D Discount %	Net Part D Expenditures	VA Discount %	Net Part D Expenditures if VA Discount	Lost Part D Savings
2009	$ 336,400,000	24.1%	$ 255,327,600	55.6%	$ 149,361,600	$ 105,966,000
2010	$ 367,500,000	23.9%	$ 279,667,500	61.8%	$ 140,385,000	$ 139,282,500
2011	$ 480,400,000	39.4%	$ 291,122,400	65.9%	$ 163,816,400	$ 127,306,000
2012	$ 546,900,000	45.0%	$ 300,795,000	68.4%	$ 172,820,400	$ 127,974,600
2013	$ 766,700,000	54.0%	$ 352,682,000	72.0%	$ 214,676,000	$ 138,006,000
2014	$ 1,111,300,000	63.0%	$ 411,181,000	79.0%	$ 233,373,000	$ 177,808,000
2015	$ 1,360,400,000	68.8%	$ 424,444,800	82.9%	$ 232,628,400	$ 191,816,400
2016	$ 2,047,000,000	78.9%	$ 431,917,000	85.5%	$ 296,815,000	$ 135,102,000
2017	$ 2,040,300,000	84.0%	$ 326,448,000	86.5%	$ 275,440,500	$ 51,007,500
Total	**$ 9,056,900,000**	**66.1%**	**$ 3,073,585,300**	**79.2%**	**$ 1,879,316,300**	**$ 1,194,269,000**

iv. Pfizer—Lyrica

Between 2011 and 2018, Medicare spent nearly $9.1 billion on Lyrica, after accounting for rebates and discounts.[27] Pfizer offered Medicare plans an average rebate of approximately 29% on Lyrica during the period from 2011 to 2018 while the rebates offered to DOD and the VA averaged almost 50%. If Medicare Part D plans had secured the same rebates as DOD and the VA during this period, taxpayers could have saved more than $2.3 billion.[28] Figure 6 shows lost Medicare savings over this period.

[27] Centers for Medicare and Medicaid Services, *Medicare Part D Spending Dashboard and Historical Data* (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Historical_Data) (accessed Sept. 21, 2021); Letter from King & Spalding, on behalf of Pfizer Inc., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (June 6, 2019), Attachment A, at Page 3 (providing average discount percentages offered to Medicare Part D for each year).

[28] SRR_PFIZHCOR_00027153, at Pages 1-3 (providing, for each of DOD and the VA, quarterly gross sales according to the wholesale acquisition cost and the amount paid by each agency). The Committee calculated a blended VA/DOD rebate percentage from Pfizer's reported wholesale acquisition cost sales for Lyrica for each agency by year, and the amount paid to Pfizer by each agency by year. Letter from King & Spalding, on behalf of Pfizer Inc., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (June 6, 2019), Attachment A, at Page 3 (providing average discount percentages offered to Medicare Part D for each year). To arrive at this calculation, Committee staff also relied on gross sales data published by the Centers for Medicare and Medicaid Services. *See* Centers for Medicare and Medicaid Services, *Medicare Part D Drug Spending Dashboard and Historical Data* (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Historical_Data) (accessed Sept. 21, 2021).

Figure 6: Lost Medicare Part D Savings for Lyrica

Lyrica						
Year	Gross Medicare Part D Sales	Average Part D Discount %	Net Part D Expenditures	Average DOD/VA Discount %	Net Part D Expenditures if VA/DOD Discount	Lost Part D Savings
2011	$ 627,132,584	24.8%	$ 471,854,556	44.2%	$ 350,253,548	$ 121,601,008
2012	$ 767,435,442	25.4%	$ 572,199,865	45.0%	$ 422,089,493	$ 150,110,372
2013	$ 1,073,704,899	26.2%	$ 792,931,068	53.6%	$ 497,984,332	$ 294,946,736
2014	$ 1,404,488,160	27.8%	$ 1,013,478,656	53.1%	$ 658,424,049	$ 355,054,607
2015	$ 1,766,473,720	32.2%	$ 1,197,139,240	53.3%	$ 825,296,522	$ 371,842,718
2016	$ 2,099,262,044	28.9%	$ 1,491,735,609	51.5%	$ 1,018,352,018	$ 473,383,591
2017	$ 2,517,073,735	34.0%	$ 1,662,023,787	42.4%	$ 1,449,834,471	$ 212,189,316
2018	$ 2,950,257,661	35.9%	$ 1,890,230,083	49.6%	$ 1,485,749,758	$ 404,480,325
Total	**$ 13,205,828,244**	**29.4%**	**$ 9,091,592,865**	**49.1%**	**$ 6,707,984,191**	**$ 2,383,608,673**

v. Novartis—Gleevec

Novartis did not offer any negotiated rebates for its blockbuster cancer drug, Gleevec, to Medicare Part D plans between 2009 and 2014, despite the fact that the company provided discounts of more than 50% to other government programs. Novartis only began offering Medicare plans Gleevec rebates greater than 1% in 2016, the same year the drug began facing generic competition.[29] Novartis collected more than $5.6 billion from gross Medicare sales of Gleevec between 2011 and 2018.[30] If Medicare Part D plans had secured the same discounts that Novartis offered to the VA between 2011 and 2015, taxpayers could have saved more than $2.1 billion.[31] Figure 7 below shows Medicare's lost savings over this period.

[29] NOVARTIS.HCOR20190114.0001060.

[30] Centers for Medicare and Medicaid Services, *Medicare Part D Spending Dashboard and Historical Data* (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Historical_Data) (accessed Sept. 21, 2021).

[31] NOVARTIS.HCOR20190114.0001060 (providing average discount percentages offered to Medicare Part D and the VA for each year). To arrive at this calculation, Committee staff also relied on gross sales data published by the Centers for Medicare and Medicaid Services. *See* Centers for Medicare and Medicaid Services, *Medicare Part D Spending Dashboard and Historical Data* (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Historical_Data) (accessed Sept. 21, 2021).

Figure 7: Lost Medicare Part D Savings for Gleevec

Gleevec						
Year	Gross Medicare Part D Sales	Average Part D Discount %	Net Part D Expenditures	Average VA Discount %	Net Part D Expenditures if VA Discount	Lost Part D Savings
2011	$ 483,395,344	0.0%	$ 483,395,344	52.0%	$ 232,029,765	$ 251,365,579
2012	$ 601,652,853	0.0%	$ 601,652,853	51.0%	$ 294,809,898	$ 306,842,955
2013	$ 779,575,542	0.0%	$ 779,575,542	54.0%	$ 358,604,749	$ 420,970,793
2014	$ 995,836,212	0.0%	$ 995,836,212	52.0%	$ 478,001,382	$ 517,834,830
2015	$ 1,232,939,891	1.0%	$ 1,220,610,492	56.0%	$ 542,493,552	$ 678,116,940
Total	**$ 4,093,399,841**	**0.2%**	**$ 4,081,070,442**	**53.0%**	**$ 1,905,939,346**	**$ 2,175,131,097**

vi. Mallinckrodt—H.P. Acthar Gel

Internal documents show that Mallinckrodt provided Medicare with almost no discounts for its drug H.P. Acthar Gel, which is priced at $39,864 per vial and used to treat infantile spasms and other autoimmune and inflammatory diseases. Between 2015 and 2018, the rebates paid to Medicare averaged less than 1%. By contrast, DOD's TRICARE program secured an average rebate of 26.6% over the same time period.[32]

Mallinckrodt's internal documents indicated that the average net price per Acthar vial for Medicare Part D plans in 2018 was $4,300 more than for commercial plans, $10,000 more than for DOD's TRICARE program, and over $17,000 more than for Medicaid.[33]

In 2018, Medicare spent more than $700 million on Acthar—up by more than $220 million from 2015. From 2015 to 2018, Medicare spent a total of more than $2.5 billion on Acthar, after rebates and discounts.[34] If Medicare plans had secured the same discounts as DOD, taxpayers would have saved over $656 million from 2015 to 2018.[35] Figure 8 shows Medicare lost savings over this period.

[32] MNK_InCamera-000000142895, at Page 1.

[33] *Id.*

[34] Centers for Medicare and Medicaid Services, *Medicare Part D Drug Spending Dashboard and Historical Data, Historical Data* (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Historical_Data) (accessed Sept. 21, 2021).

[35] MNK_InCamera-000000142895, at Page 1 (providing average discount percentages offered to Medicare Part D and TRICARE for each year). To arrive at this calculation, Committee staff also relied on gross sales data published by the Centers for Medicare and Medicaid Services. *See* Centers for Medicare and Medicaid Services, *Medicare Part D Drug Spending Dashboard and Historical Data* (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Historical_Data) (accessed Sept. 21, 2021).

Figure 8: Lost Medicare Part D Savings for Acthar[36]

Acthar						
Year	Gross Medicare Part D Sales	Average Part D Discount %	Net Part D Expenditures	Average TRICARE Discount %	Net Part D Expenditures if TRICARE Discount	Lost Part D Savings
2015	$ 503,999,371	0.4%	$ 502,235,374	25.7%	$ 374,471,533	$ 127,763,841
2016	$ 636,174,840	0.5%	$ 632,993,966	29.4%	$ 449,203,054	$ 183,790,911
2017	$ 680,958,459	0.6%	$ 677,213,188	23.0%	$ 524,201,822	$ 153,011,366
2018	$ 724,638,119	1.9%	$ 711,087,386	28.3%	$ 519,348,140	$ 191,739,246
Total	**$ 2,545,770,789**	**0.9%**	**$ 2,523,529,913**	**26.7%**	**$ 1,867,224,549**	**$ 656,305,364**

vii. Teva—Copaxone

Between 2010 and 2013, Teva collected over $2.9 billion in net Medicare Part D sales for Copaxone, after rebates and discounts.[37] If Medicare Part D plans had secured the same discounts as the VA and DOD, taxpayers could have saved more than $1.4 billion on Copaxone 20 mg/ml from 2010 to 2013.[38] Figure 9 shows Medicare's lost savings over this period.

Figure 9: Lost Medicare Part D Savings for Copaxone 20 mg/ml

Copaxone 20 mg/mL						
Year	Gross Medicare Part D Sales	Average Part D Discount %	Net Part D Expenditures	Average VA/DOD Discount %	Net Part D Expenditures if VA/DOD Discount	Lost Part D Savings
2010	$ 539,431,248	7.1%	$ 501,131,630	48.6%	$ 277,267,662	$ 223,863,968
2011	$ 707,725,488	10.5%	$ 633,414,312	54.5%	$ 322,015,097	$ 311,399,215
2012	$ 911,468,903	10.9%	$ 812,118,793	47.4%	$ 479,432,643	$ 332,686,150
2013	$ 1,120,491,044	8.6%	$ 1,024,128,815	56.1%	$ 491,895,569	$ 532,233,246
Total	**$ 3,279,116,684**	**9.4%**	**$ 2,970,793,549**	**52.1%**	**$ 1,570,610,970**	**$ 1,400,182,579**

viii. AbbVie—Humira and Imbruvica

Between 2010 and 2018, AbbVie collected more than $13.4 billion in gross Medicare revenue for its blockbuster drug Humira, which is used to treat rheumatoid arthritis and other painful inflammatory diseases, although AbbVie paid a portion of this revenue back through

[36] TRICARE is the health care system for the Department of Defense.

[37] Centers for Medicare and Medicaid Services, *Medicare Part D Drug Spending Dashboard and Historical Data* (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Historical_Data) (accessed Sept. 21, 2021).

[38] *See* Letter from Kirkland & Ellis LLP, on behalf of Teva Pharmaceuticals Industries, Ltd., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Sept. 25, 2020) (providing average discount percentages offered to Medicare Part D and "VA/DOD"). To arrive at this calculation, Committee staff also relied on gross sales data published by the Centers for Medicare and Medicaid Services. *See* Centers for Medicare and Medicaid Services, *Medicare Part D Drug Spending Dashboard and Historical Data* (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Historical_Data) (accessed Sept. 21, 2021).

rebates and other discounts.[39] Over this same period, taxpayers could have saved more than $7.4 billion on Humira if Part D plans had secured the same discounts as DOD, and more than $7 billion if Part D plans had secured the same discounts as the VA.[40] Figures 10 and 11 show Medicare lost savings over this period.

Figure 10: Lost Medicare Part D Savings for Humira as Compared to DOD

Humira			
Year	Gross Medicare Part D Sales	Lost Part D Discount % (Compared to DOD)	Lost Part D Savings
2010	$ 405,044,145	51.0%	$ 206,572,514
2011	$ 513,090,759	49.0%	$ 251,414,472
2012	$ 674,609,130	55.0%	$ 371,035,022
2013	$ 955,331,811	54.0%	$ 515,879,178
2014	$ 1,239,853,884	54.0%	$ 669,521,097
2015	$ 1,662,281,578	56.0%	$ 930,877,684
2016	$ 2,198,072,891	56.0%	$ 1,230,920,819
2017	$ 2,638,613,641	58.0%	$ 1,530,395,912
2018	$ 3,168,910,239	56.0%	$ 1,774,589,734
Total	**$ 13,455,808,078**	**55.6%**	**$ 7,481,206,431**

Figure 11: Lost Medicare Part D Savings for Humira as Compared to the VA

Humira			
Year	Gross Medicare Part D Sales	Lost Part D Discount % (Compared to VA)	Lost Part D Savings
2010	$ 405,044,145	44.0%	$ 178,219,424
2011	$ 513,090,759	43.0%	$ 220,629,026
2012	$ 674,609,130	50.0%	$ 337,304,565
2013	$ 955,331,811	50.0%	$ 477,665,905
2014	$ 1,239,853,884	51.0%	$ 632,325,481
2015	$ 1,662,281,578	52.0%	$ 864,386,420
2016	$ 2,198,072,891	53.0%	$ 1,164,978,632
2017	$ 2,638,613,641	55.0%	$ 1,451,237,503
2018	$ 3,168,910,239	53.0%	$ 1,679,522,427
Total	**$ 13,455,808,078**	**52.1%**	**$ 7,006,269,384**

From 2014 to 2018, AbbVie and its partner Janssen Biotech, Inc., a Johnson & Johnson subsidiary, generated more than $5 billion in gross Medicare sales from Imbruvica, a drug

[39] Centers for Medicare and Medicaid Services, *Medicare Part D Drug Spending Dashboard and Historical Data* (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Historical_Data) (accessed Sept. 21, 2021).

[40] Letter from Gibson, Dunn & Crutcher LLP, on behalf of AbbVie Inc., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Sept. 11, 2020) (providing average discount percentages offered to Medicare Part D, the VA, and DOD for each year). To arrive at this calculation, Committee staff also relied on gross sales data published by the Centers for Medicare and Medicaid Services. *See* Centers for Medicare and Medicaid Services, *Medicare Part D Drug Spending Dashboard and Historical Data* (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Historical_Data) (accessed Sept. 21, 2021).

approved to treat mantle cell lymphoma and certain other forms of cancer.[41] According to AbbVie's internal data, if Medicare had received the same discounts as DOD and the VA, taxpayers could have saved more than $1.6 billion on Imbruvica during that period.[42] Figure 12 shows Medicare lost savings over this period.

Figure 12: Lost Medicare Part D Savings for Imbruvica

Imbruvica			
Year	Gross Medicare Part D Sales	Lost Part D Discount (Compared to VA/DOD)	Lost Part D Savings
2014	$ 266,744,335	18.0%	$ 48,013,980
2015	$ 590,946,242	39.0%	$ 177,283,873
2016	$ 978,350,728	36.0%	$ 352,206,262
2017	$ 1,368,727,295	38.0%	$ 520,116,372
2018	$ 1,867,207,013	32.0%	$ 597,506,244
Total	**$ 5,071,975,613**	**33.4%**	**$ 1,695,126,731**

ix. Amgen—Enbrel and Sensipar

Between 2013 and 2018, Amgen collected more than $7 billion in gross Medicare sales for Enbrel, a drug used to treat rheumatoid arthritis and other painful inflammatory diseases, and more than $4 billion in gross Medicare sales for Sensipar, a drug approved to help decrease high levels of calcium in the body due to kidney failure and parathyroid cancer.[43] The Committee's analysis found that Medicare could have saved more than $2.6 billion on Enbrel and $990

[41] Centers for Medicare and Medicaid Services, *Medicare Part D Drug Spending Dashboard and Historical Data* (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Historical_Data) (accessed Sept. 21, 2021). Under a 2011 collaboration and license agreement, AbbVie's subsidiary, Pharmacyclics, sells Imbruvica in the United States in partnership with Janssen Biotech, Inc., and the companies share equally in the profits from Imbruvica. *See* Collaboration and License Agreement, ABV-HOR-3128.

[42] Letter from Gibson, Dunn and Crutcher LLP, on behalf of AbbVie Inc., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Jan. 22, 2021) (providing average discount percentages offered to Medicare Part D, and a combined DOD/VA discount rate for each year). To arrive at this calculation, Committee staff also relied on gross sales data published by the Centers for Medicare and Medicaid Services. *See* Centers for Medicare and Medicaid Services, *Medicare Part D Drug Spending Dashboard and Historical Data* (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Historical_Data) (accessed Sept. 21, 2021).

[43] AMGN-HCOR-RR-00012760; AMGN-HCOR-RR-00439923. These figures likely underestimate Medicare's total spending on Sensipar. On January 1, 2018, Medicare began paying for Sensipar prescribed for dialysis patients under a transitional payment system known as the Transitional Drug Add-On Payment Adjustment (TDAPA). Beginning in 2018, Medicare Part B paid the TDAPA to dialysis facilities, and Medicare Part D coverage was limited to prescriptions for non-dialysis patients. Medicare Learning Network, Centers for Medicare and Medicaid Services, *Implementation of the Transitional Drug Add-On Payment Adjustment* (Aug. 9, 2017) (online at www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10065.pdf). The above figures only include the Part D expenditures and do not account for the Part B expenditures.

million on Sensipar during this period if Part D plans had received the same discounts as the VA and DOD.[44] Figure 13 shows Medicare lost savings over this period.

Figure 13: Lost Medicare Part D Savings for Enbrel and Sensipar

Enbrel			
Year	Gross Medicare Part D Sales	Lost Part D Discount % (Compared to VA/DOD/FFS)	Lost Part D Savings
2013	$ 893,300,000	35.8%	$ 319,801,400
2014	$ 1,083,800,000	36.9%	$ 399,922,200
2015	$ 1,092,600,000	35.4%	$ 386,780,400
2016	$ 1,187,900,000	43.0%	$ 510,797,000
2017	$ 1,406,700,000	39.0%	$ 548,613,000
2018	$ 1,389,200,000	36.5%	$ 507,058,000
Total	**$ 7,053,500,000**	**37.9%**	**$ 2,672,972,000**
Sensipar			
Year	Gross Medicare Part D Sales	Lost Part D Discount % (Compared to VA/DOD/FFS)	Lost Part D Savings
2013	$ 341,200,000	12.3%	$ 41,967,600
2014	$ 414,300,000	15.2%	$ 62,973,600
2015	$ 602,300,000	22.5%	$ 135,517,500
2016	$ 1,026,000,000	26.2%	$ 268,812,000
2017	$ 1,328,300,000	32.0%	$ 425,056,000
2018	$ 293,500,000	19.0%	$ 55,765,000
Total	**$ 4,005,600,000**	**24.7%**	**$ 990,091,700**

B. Companies Exploit Medicare's Inability to Negotiate to Drive Revenues

The Committee's investigation found that drug manufacturers rely on Medicare to drive revenues, particularly when faced with pricing pressures from other payers. For several of the drugs investigated, Medicare sales made up a significant and growing portion of the drug's sales revenue year after year.

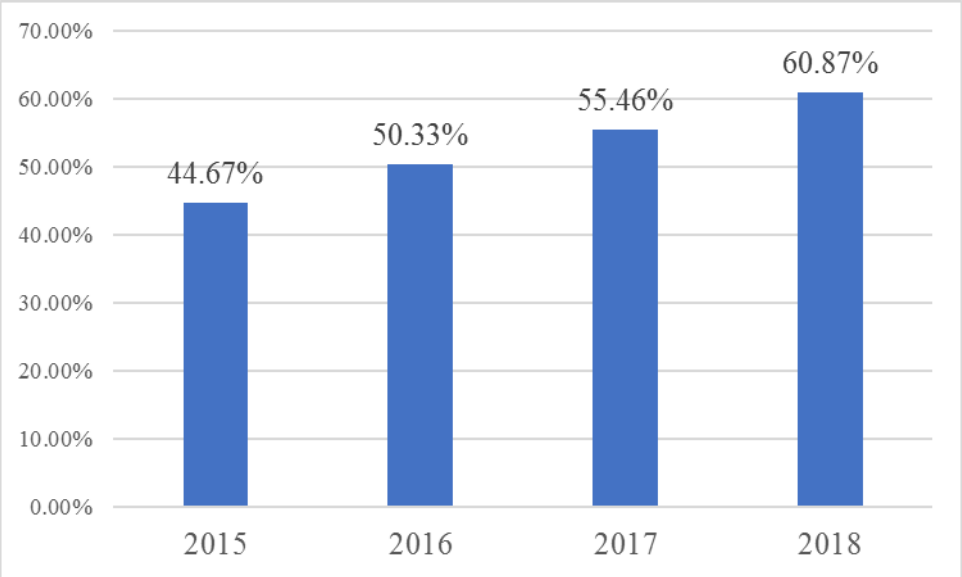
For example, since 2015, Mallinckrodt has relied on Medicare for an increasing share of net sales revenues for Acthar. Although Medicare accounted for approximately 25% of Acthar's overall business around the time Mallinckrodt acquired the drug in 2014, by 2018 Medicare accounted for 55% of Acthar vials sold and constituted more than 60% of Mallinckrodt's net sales from Acthar.[45] That year, Mallinckrodt collected more than $700 million from sales to

[44] AMGN-HCOR-RR-00012760; AMGN-HCOR-RR-00439923 (providing average discount percentages offered to Medicare Part D and "VA/DoD/FFS" for each year, as well as gross Medicare Part D sales for each year); *see also* Democratic Staff, Senate Committee on Homeland Security and Governmental Affairs, *Manufactured Crisis: How Better Negotiation Could Save Billions for Medicare and America's Seniors* (Aug. 2018) (online at www.hsgac.senate.gov/imo/media/doc/REPORT-Manufactured%20Crisis-How%20Better%20Negotiation%20Could%20Save%20Billions%20for%20Medicare%20and%20America's%20Seniors.pdf) (estimating that Medicare Part D could save at least $2.8 billion in one year by negotiating prices with drug manufacturers for the top 20 most prescribed drugs in Medicare).

[45] MNK_InCamera-000000135183, at Page 5; MNK_InCamera-000000142895, at Page 2.

Medicare—more than 14 times the company's Medicare sales in 2011.[46] Long-term planning documents reviewed by the Committee show that Mallinckrodt is counting on Medicare to represent an even higher portion of its sales in the future. An internal presentation estimated that competition and other pressures would reduce sales revenues from commercial payers and could result in Medicare accounting for as much as 70% to 75% of Acthar's sales by 2025.[47] Figure 14 below shows the growing contribution of Medicare Part D sales to Mallinckrodt's overall net sales for Acthar.[48]

Figure 14: Medicare Part D Contributions to Mallinckrodt's Total Acthar Net Sales



An internal 2018 draft business planning document obtained by the Committee identified one reason that Medicare spending on Acthar has continued to increase. The document noted that "Acthar currently has higher than average approval rates in Medicare Part D business, with approvals in the 85% range," which compared to average commercial rates of approximately 45% among the same plan sponsors.[49] The document acknowledged that these approvals were not based on greater clinical acceptance among physicians prescribing to Medicare beneficiaries, but rather on limitations on Medicare's ability to manage drug utilization:

> However, these approvals are not based on plan sponsor clinical acceptance of Acthar, but rather limitations in the effectiveness of utilization management techniques, such are

[46] Centers for Medicare and Medicaid Services, *Medicare Part D Drug Spending Dashboard and Historical Data* (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Historical_Data) (accessed Sept. 21, 2021). Medicare Part D Spending Dashboard does not reflect manufacturer rebates and price concessions, which were almost zero.

[47] MNK_INCamera-000000045618, at Slide 10; *see also* MNK_INCamera-000000067071, at Slide 3.

[48] MNK_InCamera-000000142895, at Page 2.

[49] MNK_InCamera-000000063852, at Slide 3.

[*sic*] cost differentials. In addition a regulated and uniformed appeals process that ultimately results in the approval of any product with and [*sic*] FDA approval.[50]

The narrative concluded, "If plan sponsors were granted the ability to manage Part D exactly as they manage commercial books of business this would have a significant impact on Acthar."[51] In 2017, Medicare beneficiaries' average annual out-of-pocket cost for Acthar was $12,030—higher than for any other drug that year.[52]

Internal documents and data obtained by the Committee show that Medicare has been a major source of revenue for several other companies in the Committee's investigation:

- **Novo Nordisk:** New internal data obtained by the Committee show that Medicare accounted for 41% of Novo Nordisk's insulin sales in 2014.[53] An internal Medicare Part D slide deck from October 2013 emphasized that "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.[54]

[50] *Id.*

[51] *Id.*, at Slides 3–4

[52] Kaiser Family Foundation, *How Many Medicare Part D Enrollees Had High Out-of-Pocket Drug Costs in 2017?* (July 21, 2019) (online at www.kff.org/medicare/issue-brief/how-many-medicare-part-d-enrollees-had-high-out-of-pocket-drug-costs-in-2017/) (noting that Part D enrollees without low-income subsidies who had high out-of-pocket drug costs in 2017, on average, spent $12,030 for H.P. Acthar).

[53] NNI-ERR_0083344, at Page 35.

[54] NNI-ERR_0045711, at Page 2.

- **Pfizer:** According to documents obtained by the Committee, Medicare comprised 35% of gross Lyrica sales in 2017. A 2018 internal presentation on Lyrica's "2019 Operating Plan" revealed that Medicare was projected to account for 42% of Pfizer's gross Lyrica sales in 2019.[55] Lyrica's average annual out-of-pocket cost for Medicare beneficiaries increased by 39% over a five-year period, from $264 in 2011 to $367 in 2015.[56]

- **Novartis:** Between 2011 and 2018, Medicare spent more than $5.6 billion on Novartis's cancer drug Gleevec. At its peak in 2015, gross Medicare spending on Gleevec totaled more than $1.2 billion.[57] 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."[58] According to the Centers for Medicare and Medicaid Services, the average annual out-of-pocket cost for a Medicare beneficiary on Gleevec increased by almost 24% in a five-year period, from $3,566 in 2011 to $4,418 in 2015.[59]

C. Targeting the U.S. Market

Internal company documents and communications obtained by the Committee highlight that features of the U.S. health care market—including Medicare's inability to negotiate—led drug companies to target the United States for price increases while maintaining or lowering prices in the rest of the world.

Insulin prices in the United States are the highest in the world.[60] According to one report, the United States accounts for 50% of global insulin revenue even though it comprises only 15% of the insulin market.[61] Novo Nordisk's 2018 Annual Report noted that around half of the company's global sales are generated in the United States and, therefore, that "the dynamics in

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[55] SRR_PFIZHCOR_00004032.00001, at Slide 29.

[56] Centers for Medicare and Medicaid Services, *Medicare Part D Drug Spending Dashboard and Historical Data* (online at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Historical_Data) (accessed Sept. 21, 2021).

[57] Centers for Medicare and Medicaid Services, *Medicare Part D Spending Dashboard and Historical Data* (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Historical_Data) (accessed Sept. 21, 2021).

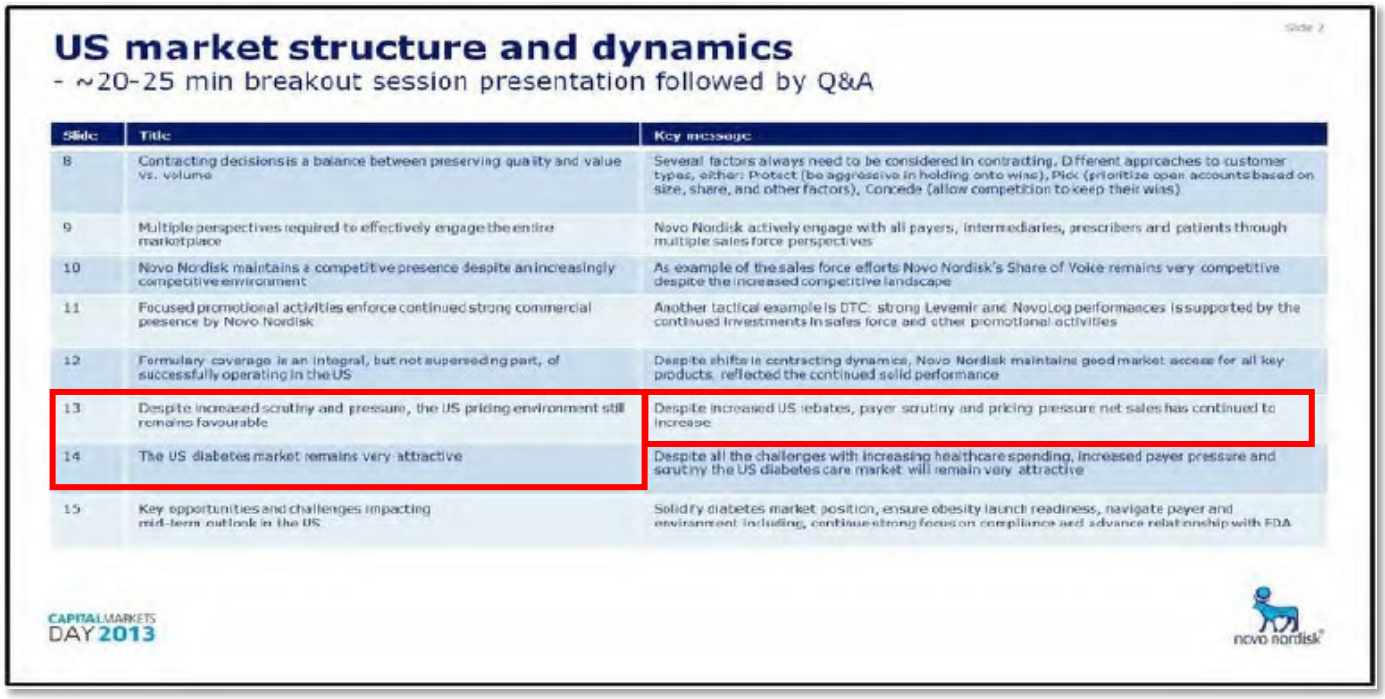
[58] CTRL-0124740, at Page 2.

[59] Centers for Medicare and Medicaid Services, *Medicare Part D Spending Dashboard and Historical Data* (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Historical_Data) (accessed Sept. 21, 2021).

[60] *See* S. Vincent Rajkumar, *The High Cost of Insulin in the United States: An Urgent Call to Action,* Mayo Clinic Proceedings (online at www.mayoclinicproceedings.org/article/S0025-6196(19)31008-0/fulltext) ("The most commonly used forms of analog insulin cost 10 times more in the United States than in any other developed country.").

[61] *See, e.g.*, Ryan Knox, *Insulin Insulated: Barriers to Competition and Affordability in the United States Insulin Market*, Journal of Law and Biosciences (Oct. 9, 2020) (online at https://doi.org/10.1093/jlb/lsaa061).

this market are closely monitored."[62] A 2013 investor presentation noted: "Despite increased scrutiny and pressure, the US pricing environment still remains favourable." One of the presentation's key messages was, "Despite increased US rebates, payer scrutiny and pricing pressure, net sales has continued to increase."[63] The presentation also emphasized, "The US diabetes market remains very attractive," and described the positive pricing environment as a key opportunity impacting the U.S. outlook.[64]



US market structure and dynamics

- ~20-25 min breakout session presentation followed by Q&A

Slide	Title	Key message
8	Contracting decisions is a balance between preserving quality and value vs. volume	Several factors always need to be considered in contracting. Different approaches to customer types, either: Protect (be aggressive in holding onto wins), Pick (prioritize open accounts based on size, share, and other factors), Concede (allow competition to keep their wins)
9	Multiple perspectives required to effectively engage the entire marketplace	Novo Nordisk actively engage with all payers, intermediaries, prescribers and patients through multiple sales force perspectives
10	Novo Nordisk maintains a competitive presence despite an increasingly competitive environment	As example of the sales force efforts Novo Nordisk's Share of Voice remains very competitive despite the increased competitive landscape
11	Focused promotional activities enforce continued strong commercial presence by Novo Nordisk	Another tactical example is DTC: strong Levemir and NovoLog performances is supported by the continued investments in sales force and other promotional activities
12	Formulary coverage is an integral, but not superseding part, of successfully operating in the US	Despite shifts in contracting dynamics, Novo Nordisk maintains good market access for all key products, reflected the continued solid performance
13	Despite increased scrutiny and pressure, the US pricing environment still remains favourable	Despite increased US rebates, payer scrutiny and pricing pressure net sales has continued to increase
14	The US diabetes market remains very attractive	Despite all the challenges with increasing healthcare spending, increased payer pressure and scrutiny the US diabetes care market will remain very attractive
15	Key opportunities and challenges impacting mid-term outlook in the US	Solidify diabetes market position, ensure obesity launch readiness, navigate payer and environment including, continue strong focus on compliance and advance relationship with FDA

CAPITAL MARKETS DAY 2013

novo nordisk

Pfizer similarly focused on the United States to generate revenues for its blockbuster drug Lyrica. Between 2010 and 2018, the U.S. share of worldwide Lyrica net revenues increased from less than 50% to approximately 72%.[65] In a November 2016 email, Pfizer executives acknowledged that the U.S. market was the "main driver" of Lyrica sales growth for the most recent quarter and noted that U.S. Lyrica sales were expected to grow by 13% in 2017 and 8% in 2018, driven by planned price increases and expected volume growth.[66] A draft internal presentation from 2016 explicitly linked Pfizer's profitability across the globe to its ability to

[62] Novo Nordisk, *Annual Report 2018* (Feb. 1, 2019) (online at www.novonordisk.com/content/dam/nncorp/global/en/investors/irmaterial/annual_report/2019/NN-AR18_UK_Online.pdf).

[63] NNI-ERR_0011316, at Slide 2.

[64] *Id*. (highlighting added by Committee).

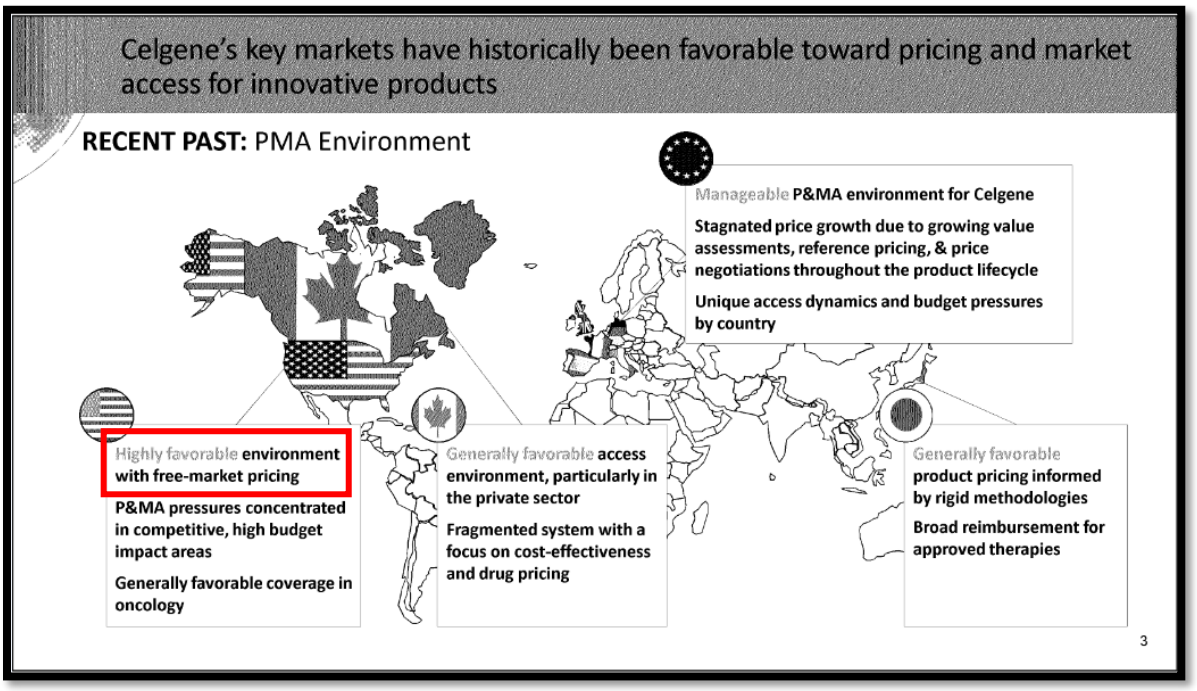
[65] Letter from King & Spalding, on behalf of Pfizer Inc., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Mar. 4, 2019), at Page 3; Pfizer Inc., *Financial Reports* (2010 and 2018) (online at https://investors.pfizer.com/financials/annual-reports/default.aspx).

[66] SRR_PFIZHCOR_000027011, at Page 1.

raise prices in the United States, noting that in addition to a "focus across geographies on Neuropathic Pain," growth was driven by "price increases in the U.S."[67] According to a 2019 study, Pfizer's price increases in 2017 and 2018 alone cost U.S. patients and insurers an estimated $688 million in additional expenditures.[68]

These new findings build on evidence previously obtained by the Committee about the pricing practices of other companies, including Celgene and Teva.

A 2018 Celgene multinational market analysis characterized the United States as a "[h]ighly favorable environment with free-market pricing."[69]



The presentation included one of the key strategies for Celgene to "win": "Protect free-market competition-based pricing for Medicare and commercial insurance" in the United States.[70] However, the presentation reflected a concern that future U.S. market dynamics may be

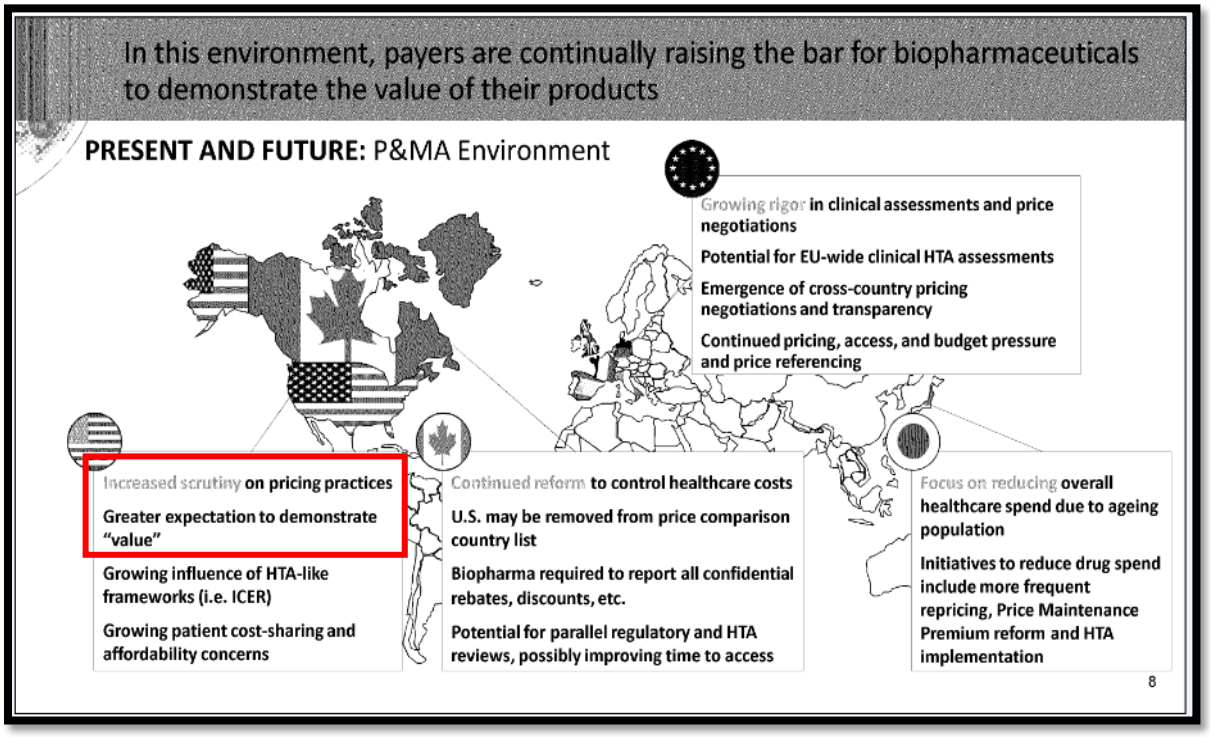
[67] SRR_PFIZHCOR_00020368.00001, at Slide 5 (this presentation was a draft and subject to further internal company review).

[68] Institute for Clinical and Economic Review, *ICER Identifies Costliest US Drug-Price Hikes That Are Not Supported by New Clinical Evidence*, at Page 7 (Oct. 8, 2019) (updated Nov. 6, 2019) (online at https://icer.org/news-insights/press-releases/icer-identifies-costliest-us-drug-price-hikes-that-are-not-supported-by-new-clinical-evidence/).

[69] CELG_HCOR_000027347, at Slide 3 (highlighting added by Committee).

[70] *Id.*, at Slide 9. Medicare Part D rules also forbid individual plans from excluding cancer drugs from their formularies, which limits the negotiating power of individual plans. *See* 42 U.S.C. § 1395w-104; 42 C.F.R. § 423.120.

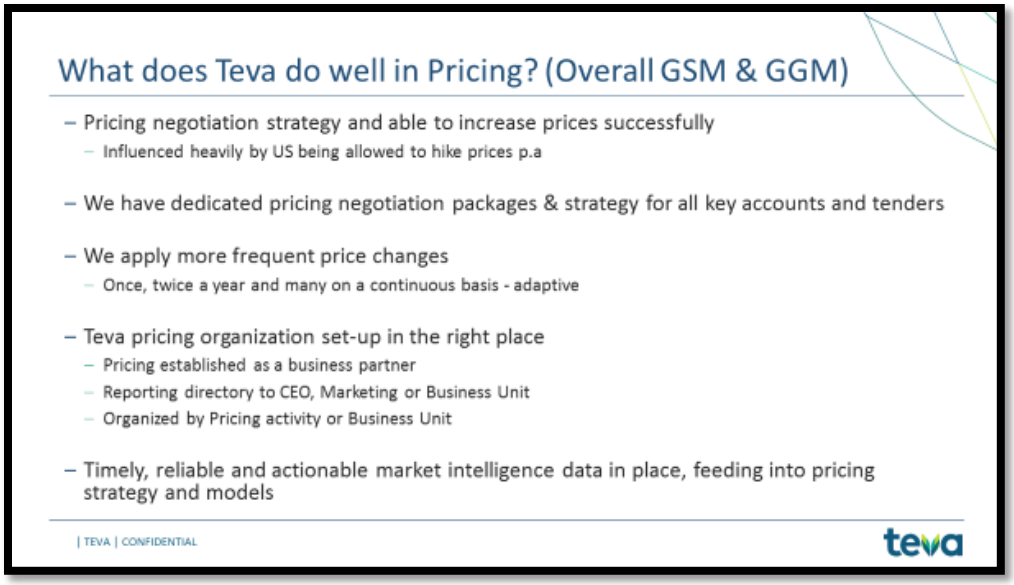
less favorable to high prices given "[i]ncreased scrutiny on pricing practices" and "[g]reater expectation to demonstrate 'value'" of pharmaceutical products.[71]



Teva similarly emphasized the ability to raise prices in the United States as a critical component to its pricing strategy. In answer to the question "What does Teva do well in Pricing?" the presentation noted, "Pricing negotiation strategy and able to increase prices successfully / Influenced heavily by US [Teva's U.S. Business] being allowed to hike prices."[72]

[71] *Id.*, at Slide 8 (highlighting added by Committee).

[72] TEVA_HCO_IC_005040409, at Slide 32.



What does Teva do well in Pricing? (Overall GSM & GGM)

- Pricing negotiation strategy and able to increase prices successfully
  - Influenced heavily by US being allowed to hike prices p.a
- We have dedicated pricing negotiation packages & strategy for all key accounts and tenders
- We apply more frequent price changes
  - Once, twice a year and many on a continuous basis - adaptive
- Teva pricing organization set-up in the right place
  - Pricing established as a business partner
  - Reporting directory to CEO, Marketing or Business Unit
  - Organized by Pricing activity or Business Unit
- Timely, reliable and actionable market intelligence data in place, feeding into pricing strategy and models

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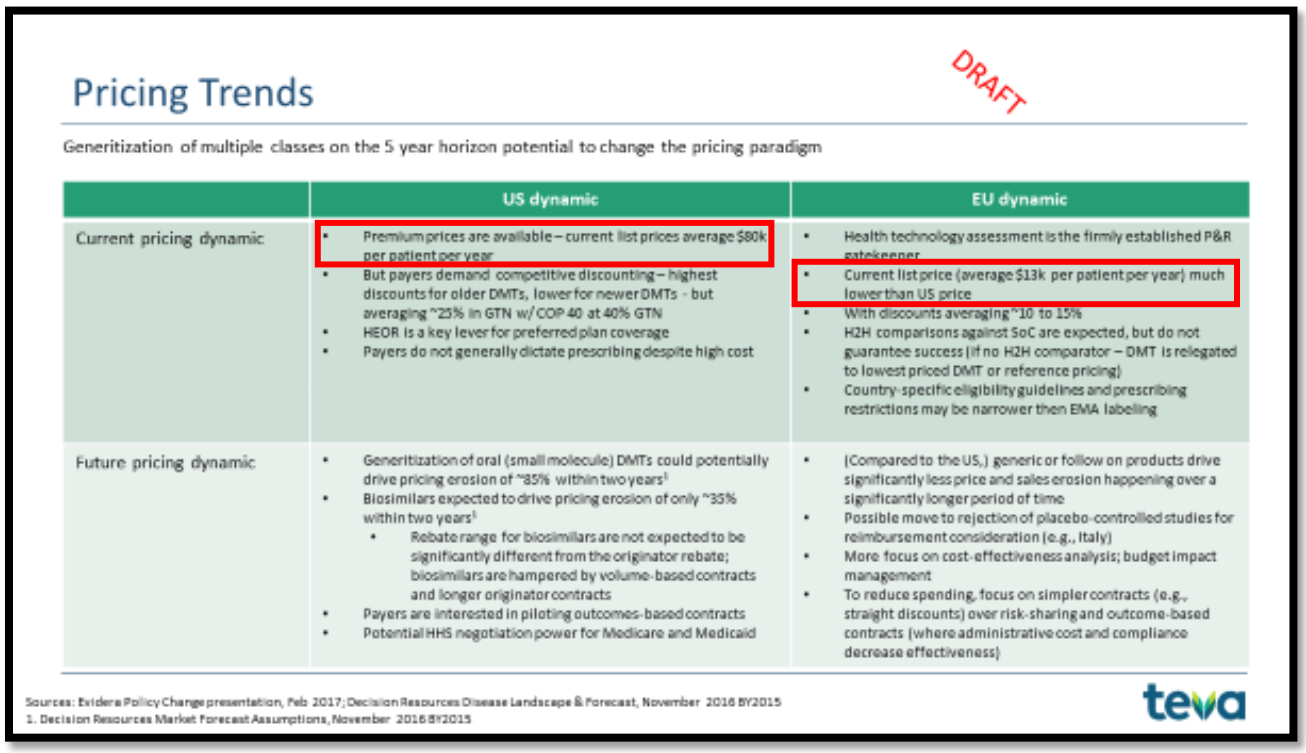
teva

A draft 2017 presentation comparing Copaxone pricing trends in the United States to those in Europe emphasized that, in the United States, "[p]remium prices are available—current list prices average $80k per patient per year," while in Europe, "[c]urrent list price (average $13k per patient per year) [is] much lower than US price." The presentation also emphasized that, in the United States, "[p]ayers do not generally dictate prescribing despite higher cost."[73]



Pricing Trends

DRAFT

Generitization of multiple classes on the 5 year horizon potential to change the pricing paradigm

	US dynamic	EU dynamic
Current pricing dynamic	• Premium prices are available – current list prices average $80k per patient per year • But payers demand competitive discounting – highest discounts for older DMTs, lower for newer DMTs - but averaging ~25% in GTN w/ COP 40 at 40% GTN • HEOR is a key lever for preferred plan coverage • Payers do not generally dictate prescribing despite high cost	• Health technology assessment is the firmly established P&R gatekeeper • Current list price (average $13k per patient per year) much lower than US price • With discounts averaging ~10 to 15% • H2H comparisons against SoC are expected, but do not guarantee success (if no H2H comparator – DMT is relegated to lowest priced DMT or reference pricing) • Country-specific eligibility guidelines and prescribing restrictions may be narrower then EMA labeling
Future pricing dynamic	• Generitization of oral (small molecule) DMTs could potentially drive pricing erosion of ~35% within two years[1] • Biosimilars expected to drive pricing erosion of only ~35% within two years[1] • Rebate range for biosimilars are not expected to be significantly different from the originator rebate; biosimilars are hampered by volume-based contracts and longer originator contracts • Payers are interested in piloting outcomes-based contracts • Potential HHS negotiation power for Medicare and Medicaid	• (Compared to the US,) generic or follow on products drive significantly less price and sales erosion happening over a significantly longer period of time • Possible move to rejection of placebo-controlled studies for reimbursement consideration (e.g., Italy) • More focus on cost-effectiveness analysis; budget impact management • To reduce spending, focus on simpler contracts (e.g., straight discounts) over risk-sharing and outcome-based contracts (where administrative cost and compliance decrease effectiveness)

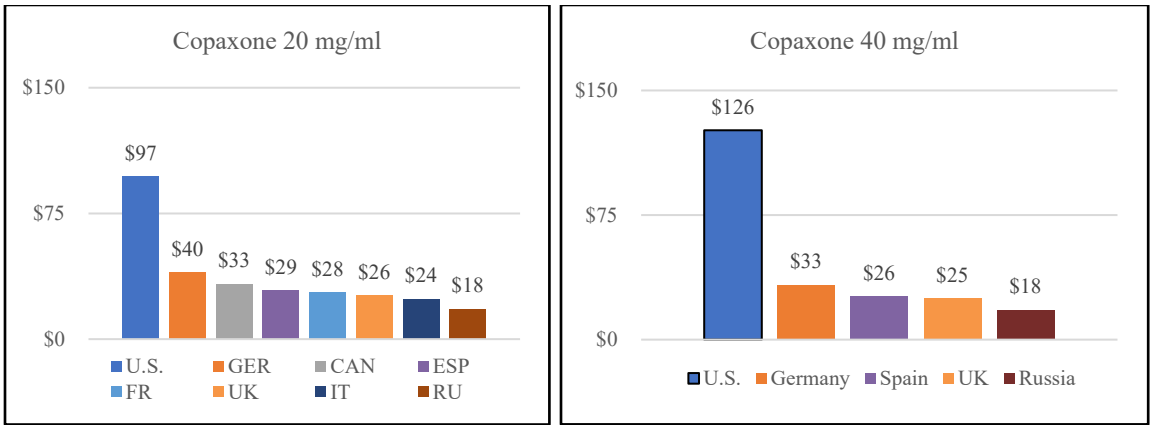
Sources: Evidera Policy Change presentation, Feb 2017; Decision Resources Disease Landscape & Forecast, November 2016 BY2015
1. Decision Resources Market Forecast Assumptions, November 2016 BY2015

teva

[73] TEVA_HCO_IC_005199492, at Slide 12 (highlighting added by Committee).

In contrast, Teva has *decreased* the list price of Copaxone 40 mg/ml in other countries. For example, an October 2017 internal presentation noted that Australia was expected to impose "a mandatory price decrease of 15%" in 2018 because Copaxone was an "old product" and that France was expected to impose a mandatory price decrease of 11% when a generic version of the drug entered the market in 2019.[74] In May 2018, Teva executives expressed concerns that an expected "25–30% transparent price reduction on Copaxone 20 and Copaxone 40 in Canada" might "harm the situation of Copaxone in US in any way (e.g. from public perception of view, due to the large difference in price levels)."[75] An internal Teva presentation from 2016 compared the price of Copaxone in the United States to its prices in the rest of the world.[76] Figure 15 below summarizes the prices identified in the presentation.

Figure 15: 2015 Copaxone 20mg/ml and 40mg/ml Price Per Day of Therapy



In testimony before the Committee, Teva Chief Executive Officer Kåre Schultz acknowledged that foreign governments that negotiate on behalf of their citizens are able to secure lower prices while still accounting for reasonable corporate profits. Under questioning from Representative Alexandria Ocasio-Cortez, Mr. Schultz said:

> Mr. Schultz: [I]n many European countries, you're only negotiating with one party. And typically, there's a big volume on the table, and, of course, your negotiating position will change. That's also why the consolidation of PBMs has led to higher discounts.
>
> Ms. Ocasio-Cortez: Thank you. And Mr. Schultz, sir, I have one last question. Even with charging those lower prices, does Teva turn a profit in Europe?

[74] TEVA_HCO_IC_005093861, at Slide 2.

[75] TEVA_HCO_IC_005008283.

[76] TEVA_HCO_IC_005025464, at Slide 27.

Mr. Schultz: Yes. Teva has, overall for the total business, a profit in Europe, yes.[77]

A 2017 presentation from Teva's Drug Price Task Force referred to "Medicare Reform: Removal of government non-interference" as a "Main Risk Event" with the largest potential impact on future revenues.[78]

II. CONCLUSION

The Committee's investigation revealed new information about how the pharmaceutical industry has exploited the prohibition on the Department of Health and Human Services from negotiating directly with drug companies to lower drug prices in the Medicare Part D program. Non-public pricing data obtained by the Committee demonstrates that the Medicare program is losing out on billions of dollars in savings because Part D plans are failing to secure the same discounts obtained by other federal health care programs—in several cases for drugs that have been on the market without generic or biosimilar competition for far longer than their intended market monopolies.

This report also reveals how drug companies are targeting patients in the United States for price increases while other countries have taken steps to reduce prices for their own citizens. Allowing Medicare to directly negotiate drug pricing would help put an end to the industry's abusive pricing practices and move our country towards a more sustainable drug pricing system. The Committee's previous analysis of drug company financial data indicates that even if the pharmaceutical industry collected less revenue due to pricing reforms, drug companies could maintain or even exceed their current research and development expenditures if they reduced spending on buybacks and dividends.[79] Taken together, these findings demonstrate the need for legislative action to empower Medicare to negotiate directly with pharmaceutical companies for lower drug prices, which would save billions in taxpayer dollars and help ensure that patients have access to innovative, lifesaving medications.

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[77] Committee on Oversight and Reform, *Hearing on Unsustainable Drug Prices: Testimony from the CEOs (Part I)*, 116th Cong. (Sept. 30, 2020) (online at http://docs.house.gov/meetings/GO/GO00/20200930/111055/HHRG-116-GO00-Transcript-20200930.pdf).

[78] TEVA_HCO_IC_005121399, at Slides 4–5.

[79] Majority Staff, Committee on Oversight and Reform, *Drug Pricing Investigation: Industry Spending on Buybacks, Dividends, and Executive Compensation* (July 2021) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/COR%20Staff%20Report%20-%20Pharmaceutical%20Industry%20Buybacks%20Dividends%20Compared%20to%20Research.pdf).