



Drug Pricing Investigation

Teva—Copaxone

Staff Report
Committee on Oversight and Reform
U.S. House of Representatives
September 2020
oversight.house.gov

Congress of the United States
House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

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September 30, 2020

Members of the Committee on Oversight and Reform
U.S. House of Representatives
Washington, D.C. 20515

Dear Colleague:

Last year, the Committee on Oversight and Reform launched one of the most comprehensive and in-depth investigations of drug price increases that Congress has ever conducted. Initiated by then-Chairman Elijah E. Cummings as our first investigation of the 116th Congress, the Committee sent letters on January 14, 2019, to some of the largest and most profitable drug companies in the world. These letters sought a broad range of documents and information regarding price increases, executive compensation, and strategies the companies use to limit competition and maximize profits.

Based on dramatic price increases over many years, Chairman Cummings made this sweeping investigation a top priority. He explained:

For the past decade, I have been trying to investigate the actions of drug companies for all sorts of drugs—old and new, generic and brand-name. We have seen time after time that drug companies make money hand over fist by raising the prices of their drugs—often without justification, and sometimes overnight—while patients are left holding the bill.

After Chairman Cummings passed away in October 2019, we continued to aggressively pursue this investigation, repeatedly pressing the companies for documents and information in response to the Committee's requests.

As a result, the Committee has now reviewed more than a million pages of documents. Many of these documents are internal corporate strategy documents and communications among top executives that provide significant new insights into how and why drug companies keep increasing their prices so dramatically. The Committee has given each company an opportunity to explain the context and significance of these documents as we determined which to release to the American public.

This week, in conjunction with our hearings with drug company CEOs, I will begin releasing a number of staff reports describing these documents and explaining in detail the following key findings based on our review:

- At the broadest level, the Committee’s investigation shows that although drug companies make products we all need for our health and well-being, their skyrocketing price increases are simply unsustainable going forward.
- The Committee’s investigation also reveals new details about the specific tactics drug companies are using to raise prices, maximize profits, and suppress competition among other companies.
- Finally, the Committee’s investigation demonstrates that drug companies are taking full advantage of the federal law that currently prohibits Medicare from negotiating directly with drug companies to lower prices. The drug companies are bringing in tens of billions of dollars in revenues, making astronomical profits, and rewarding their executives with lavish compensation packages—all without any apparent limit on what they can charge.

One of the key legislative reforms being considered by Congress is to finally allow Medicare to negotiate directly with drug companies to lower prices. On March 8, 2017, Chairman Cummings went to the White House with Committee Member Peter Welch to meet with President Trump, to present their draft legislation to implement this change, and to seek his support for their legislation.

They were hopeful because President Trump, as a candidate and as President-elect, had promised that Americans could save hundreds of billions of dollars if Medicare were allowed to negotiate directly with drug companies. “We don’t do it,” the President said. “Why? Because of the drug companies.” He said the U.S. must “create new bidding procedures for the drug industry.” He added: “Pharma has a lot of lobbies and a lot of lobbyists and a lot of power, and there’s very little bidding on drugs.” He pledged to create a “fair and competitive bidding process” that would result in prices “coming way, way, way down.” He also warned that the pharmaceutical industry is “getting away with murder.”

According to a statement from Chairman Cummings after the White House meeting, President Trump “seemed enthusiastic about the idea” and pledged to work together. However, despite numerous good faith efforts by Chairman Cummings to follow-up, President Trump never responded again. Instead, he abandoned his commitment to work jointly on this issue.

On December 12, 2019, the House of Representatives passed H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act, landmark legislation that includes the key provision to allow Medicare to negotiate directly with drug companies to lower prices. Unfortunately, this legislation has languished as President Trump openly opposed it and Senate Republicans refused to schedule a vote. The White House issued a statement opposing the legislation, declaring, “If H.R. 3 were presented to the President in its current form, he would veto the bill.”

Instead of supporting H.R. 3, taking on the pharmaceutical industry, and giving Medicare the authority to negotiate directly, President Trump appointed former pharmaceutical industry executives to key health care positions, including Secretary of Health and Human Services Alex Azar and former Director of White House Domestic Policy Council Joe Grogan. Mr. Grogan,

who met with drug company executives on multiple occasions, led the Administration's opposition to H.R. 3, even penning an op-ed opposing the legislation a week before it was passed by the House of Representatives.

Now, as the November election draws near, President Trump is scrambling to create the impression that he is addressing a problem he has failed to take on for the past four years. But his actions—such as claiming he will send seniors a "\$200 drug discount card" for medications that cost tens of thousands of dollars per month, or approving a "demonstration project" after failing to reach a voluntary deal with the pharmaceutical industry—are deficient and inconsequential, according to experts.

The bottom-line is that, as a result of the President's decision to go back on his campaign promise, drug prices have continued to skyrocket over the past four years. A recent report found that drug companies have raised the list prices of more than 600 single-source brand name drugs by a median 21.4% between January 2018 and June 2020.

My hope is that these hearings and staff reports will shed additional light on this problem and spur the President and the Senate to finally act on H.R. 3. While the current trajectory of drug prices rewards corporate executives handsomely, it is not sustainable for the American taxpayers or American families.

Sincerely,



Carolyn B. Maloney
Chairwoman

EXECUTIVE SUMMARY

This staff report describes the actions of Teva Pharmaceuticals in repeatedly raising the price of Copaxone, a drug used to treat multiple sclerosis. Copaxone is Teva's leading brand name medicine, accounting for nearly a fifth of the company's North America net revenue from 2017 to 2019.

The Committee has reviewed more than 300,000 pages of internal documents, communications and data related to Copaxone. This staff report focuses on Teva's pricing practices, business strategies to maximize sales, and tactics it uses to minimize generic competition.

- **Uninhibited Price Increases:** Since launching Copaxone in 1997, Teva raised the price of the drug 27 times. Due to these price increases, a yearly course of Copaxone is priced at nearly \$70,000 today as compared to less than \$10,000 in 1997.
- **Price Increases Driving Growing Corporate Revenue:** Teva's price increases enabled the company to collect more than \$34 billion in Copaxone net U.S. revenue since launching the drug in 1997. Teva's net U.S. revenue for Copaxone increased from \$411 million in 2002 to over \$3.3 billion in 2016.
- **Millions in Executive Compensation and Bonuses:** As Teva raised the price of Copaxone, it paid its top executives millions of dollars per year. From 2012 to 2017—Teva's peak years for U.S. Copaxone revenue—the company paid its top executives more than \$190 million. Lower level employees were aware of the direct link between their compensation and Copaxone's price and revenue. In response to a February 2017 advisory notice that generic competition to Copaxone had been delayed, one executive told his colleagues that the delay "[m]ight be good for cash flow and debt pay down and some of your bonuses."
- **Targeting the U.S. for Higher Prices and Lack of Medicare Negotiation:** With the federal government prohibited from negotiating directly with drug companies to lower prices, Teva targeted the U.S. market for price increases while maintaining or cutting prices for the rest of the world. Internal Teva documents warned that the legislative reform that posed the greatest threat to Teva's future revenue was "Medicare Reform: Removal of government non-interference." In 2015, the net price of Copaxone 40 mg/ml was \$126 per day in the U.S., as compared to \$33 in Germany, \$26 in Spain, \$25 in the United Kingdom, and \$18 in Russia. Teva emphasized that one of its key strengths was its ability to "increase prices successfully," which was "influenced heavily by US [Teva's U.S. Business] being allowed to hike prices."

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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- **Lobbying Campaign Opposing Reform:** In response to the threat of reform, Teva's senior executives engaged in an intense lobbying campaign, including meeting with senior Trump Administration officials on three occasions in 2017. Two meetings included Joe Grogan, former pharmaceutical executive and then-Associate Director of Health Programs at the Office of Management and Budget. Mr. Grogan later became Director of the Domestic Policy Council in the White House, where he mobilized the Administration against Medicare negotiation.
- **Costs to Medicare:** Medicare spent hundreds of millions of dollars more on Copaxone each year because of its inability to negotiate directly to lower prices. Teva's internal data shows that from 2010 to 2013, taxpayers and patients would have spent \$1.4 billion less on Copaxone if Medicare had received the same price as the Department of Defense and Department of Veterans Affairs, which are permitted to negotiate directly.
- **Harm to Patients:** Teva's price increases on Copaxone have resulted in thousands of dollars in out-of-pocket costs for U.S. patients and have left many unable to afford the drug. A recent study found that the median annual out-of-pocket cost for a Medicare patient on Copaxone was \$6,672 in 2019. Even Teva's own employees could not afford Copaxone at its price. In one July 2018 exchange, a Teva employee explained that she could no longer afford Copaxone because she would have to pay \$1,673.33 out of pocket as compared to \$12 for Mylan's generic product. Ultimately, Teva gave the employee free product, a solution unavailable to most Copaxone patients
- **Donation to Third-Party Foundations as "Investment" to Drive Medicare Sales:** Internal presentations, emails, and payment authorization documents reveal that between 2008 and 2017, Teva paid hundreds of millions of dollars to third-party foundations to subsidize co-pay and other cost-sharing obligations incurred by Medicare Part D patients.

Teva referred to these donations as an “investment” for future returns, with an expectation that the donations would drive Copaxone sales. For example, Teva’s 2008 Copaxone Work Plan estimated that the company would spend approximately \$97 million on “Medicare Financial Assistance” between 2008 and 2011 and that this expenditure would result in the sale of an additional 155,113 units of Copaxone worth nearly \$300 million.

- **Donations to Third-Party Foundations Continuing Through 2018:** The Department of Justice recently filed a civil suit against Teva alleging that its donations from 2006 to 2015 violated the federal Anti-Kickback Statute. The Committee’s investigation suggests that Teva continued this conduct through at least 2018—three years beyond the scope of DOJ’s complaint. Teva’s donations from 2016 to 2018 appear to have continued to be made with the expectation that they would be delivered to Copaxone patients to drive Teva’s Medicare sales.
- **Profit-Driven Co-Pay Assistance Program:** Teva’s internal strategy documents frequently emphasized the rate of return of its co-pay assistance program for commercial patients. A 2011 presentation touted that Teva’s co-pay program had an average return on investment of 451%.

COPAXONE Expense Drivers		
Expense Driver	Budget	ROI (>0 is considered positive)
Patient Assistance	\$81M direct	<ul style="list-style-type: none"> Returns for commercial patients average 451% with a range of 205% to 761% Medicare D grants are not included in the assessment
Sales Force	\$41M people related	<ul style="list-style-type: none"> 178% short term ROI 95% carryover at 6 months
Patient Services	\$14M direct \$17M people related	<ul style="list-style-type: none"> 29M invested in 2011 generated \$363M with a ROI of 1152% PAP is not included in this ROI
Opportunity and Educational Funds	\$17M direct	<ul style="list-style-type: none"> Not tracked, but assumed similar to Peer to Peer
Peer to Peer	\$10M direct	<ul style="list-style-type: none"> AHM is the surrogate metric Average ROI for AHM programs is 701%
Scientific Communications	\$7M	<ul style="list-style-type: none"> Not Tracked

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According to internal figures, Teva collected \$257.5 million in net revenue from \$54.6 million in expenditures on commercial co-pay programs in 2014 and \$148.2 million in net revenue from \$68.4 million in expenditures on the programs in 2015.

- **New Dosage as “Generic Defense Strategy”**: In 2014, Teva introduced a 40 mg/ml formulation of Copaxone in part to extend its monopoly pricing for Copaxone by shifting patients to that formulation—which still enjoyed market exclusivity—before the 20 mg/ml formulation began facing lower-priced generic competition. To push patients to the 40 mg/ml formulation of Copaxone, Teva increased the price of the 20 mg/ml formulation. To press patients to make the move, Teva explored a plan to “Discontinue 20mg Financial Programs (Patient Services),” its financial assistance program for patients. Teva’s strategy was successful in maintaining its profits and limiting competition. Experts estimate that the strategy cost the U.S. health care system between \$4.3 and \$6.5 billion in excess spending.
- **Exclusionary Tactics to Limit Generic Competition**: After Mylan introduced a lower-priced generic version of Copaxone 40 mg/ml in October 2017, Teva implemented several new exclusionary tactics to limit generic competition and maintain profits. First, Teva contracted with specialty pharmacies and pharmacy benefit managers to limit generic substitution. Second, Teva lobbied doctors to write prescriptions for Copaxone that prohibited generic substitution. Third, Teva used its patient programs to convince patients to remain on the more expensive brand name version of the drug. Teva summarized these strategies in the following slide to its Board of Directors:

Key Activities to Defend Against Generic Erosion

- Brand over Generic (House Brand) Contracting Strategy**
 - Contracting with major payors, PBMs and pharmacies
 - Contracts range from Brand over Generic terms (all 40mg Rx will be switched to Brand), to loyalty allowing access to COPAXONE 40mg alongside generic
- Sales force DAW messaging and activities**
 - Sales force proactively messages to HCP customers the need for “Dispense as Written” on all new Rx and refills
 - Working with office accounts to ensure they have the capabilities and resources need to communicate DAW through verbal, written and electronic means
- Outbound efforts to 40mg patients through Shared Solutions**
 - Call center outbound effort to contact all current 40mg patients with active marketing authorization
 - Emails to all patients with DAW messaging
 - Ability to produce current 40mg patient lists for HCP offices to proactively DAW scripts
- Legal pathways also being explored**

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- **Price Increases Not Justified by Rebates:** Teva’s internal data undermine the pharmaceutical industry’s claims that price increases are the result of increased rebates, discounts, and other fees provide to pharmacy benefit managers. The average net price per unit of Copaxone—the amount of money the company makes on the drug after all rebates and discounts—increased for both the 20 mg/ml and 40 mg/ml doses of Copaxone from 2009 to 2017. The annual rise in average net price ended only after Mylan introduced generic versions of both doses.
- **Price Increases Not Justified by R&D:** Contrary to its public talking points, Teva invested only a small portion of its Copaxone revenue in further research and development to help Copaxone patients. Teva identified a total of \$689 million in research and development expenditures related to Copaxone since 1987—only 2% of its \$34.2 billion in net U.S. revenue of Copaxone from 2002 to 2019.

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I. PRICE INCREASES

Copaxone (glatiramer acetate) is an injectable drug approved to treat relapsing forms of multiple sclerosis (MS). MS is a disease of the central nervous system that afflicts nearly one million adults in the United States.¹

Teva first launched Copaxone in March 1997 as a 20 mg/ml injection administered once per day.² In 2014, Teva launched a 40 mg/ml injection administered three times per week and at least 48 hours apart.³

Since launching Copaxone 20 mg/ml, Teva has raised the price of the drug 27 times. As a result of Teva's price increase, the price of Copaxone 20 mg/ml today is almost ten times the price of the drug in 1997. Today, a monthly course of Copaxone 20 mg/ml is priced at \$7,114, as compared to \$769.15 in 1997. A monthly course of Copaxone 40 mg/ml is priced at \$5,832 today.⁴

(See Section VI for Teva's business rationale for launching the 40 mg/ml dose of Copaxone and pricing Copaxone 40 mg/ml lower than Copaxone 20 mg/ml as a tactic to limit generic competition.)

MS patients take Copaxone month after month, year after year. The price of an annual course of Copaxone 20 mg/ml has jumped from \$9,230 in 1997 to \$85,368 today.⁵ The cost of an annual course of Copaxone 40 mg/ml is \$69,984.⁶

Figure 1 below shows the increase in the price of a monthly course of Copaxone injections from 1997 to the present.

¹ Teva Pharmaceuticals Industries, Ltd., *Annual Report (Form 10-K) for Fiscal Year 2019* (Feb. 21, 2020) (online at www.sec.gov/ix?doc=/Archives/edgar/data/818686/000119312520044221/d852939d10k.htm); National Multiple Sclerosis Society, *Landmark Study Estimates Nearly 1 Million in the U.S. Have Multiple Sclerosis* (Feb. 15, 2019) (online at www.nationalmssociety.org/About-the-Society/News/Landmark-Study-Estimates-Nearly%2%A01-Million-in-the-U).

² Letter from Robert Temple, Director, Office of Drug Evaluation, Food and Drug Administration, to Debora Jaskot, Teva Pharmaceuticals USA (Dec. 20, 1996) (online at www.accessdata.fda.gov/drugsatfda_docs/nda/pre96/020622Orig1s000rev.pdf).

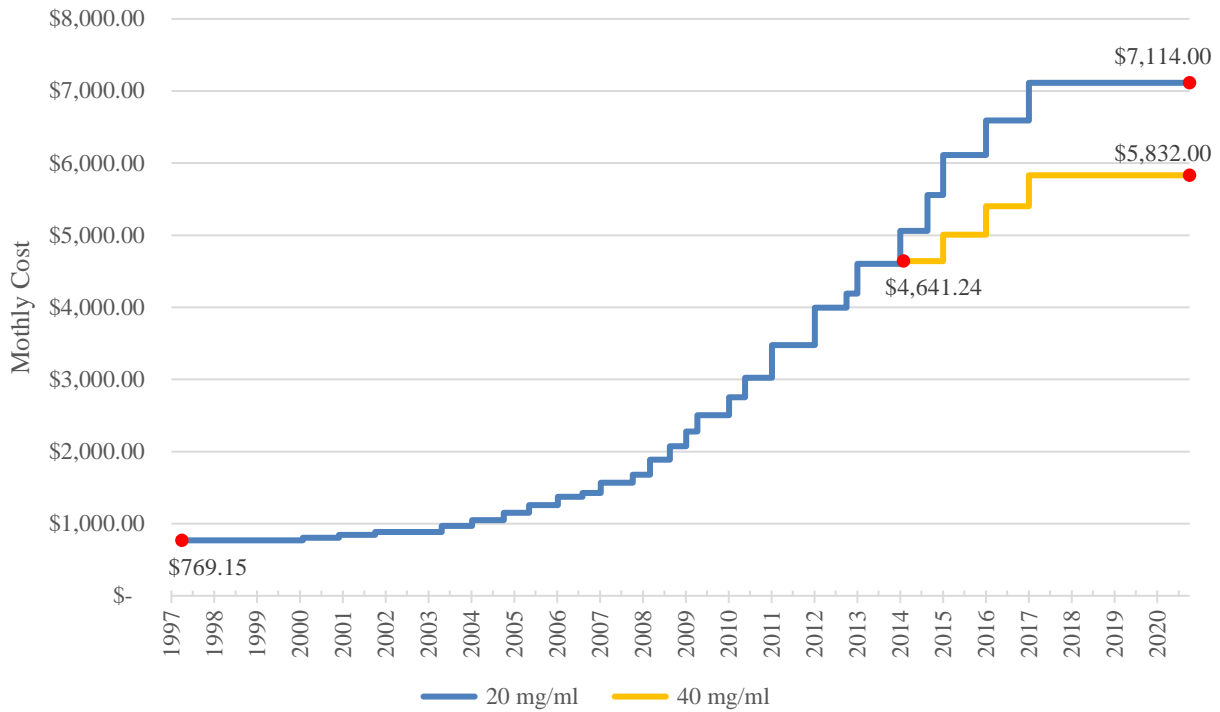
³ Letter from Billy Dunn, Acting Director, Division of Neurology Products, Food and Drug Administration, to Dennis Ahern, Teva Pharmaceuticals USA (Jan. 28, 2014) (online at www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/020622Orig1s089ltr.pdf).

⁴ IBM Micromedex Redbook, *Wholesale Acquisition Cost and Average Wholesale Price History for Copaxone*.

⁵ This calculation is based on the Whole Sale Acquisition cost of 12 monthly packages of Copaxone 20 mg/ml, each of which includes 30 syringes.

⁶ This calculation is based on the Whole Sale Acquisition cost of 12 monthly packages of Copaxone 40 mg/ml, each of which includes 12 syringes.

Figure 1: Copaxone Price Increases 1997-2020



II. GROWING CORPORATE REVENUE

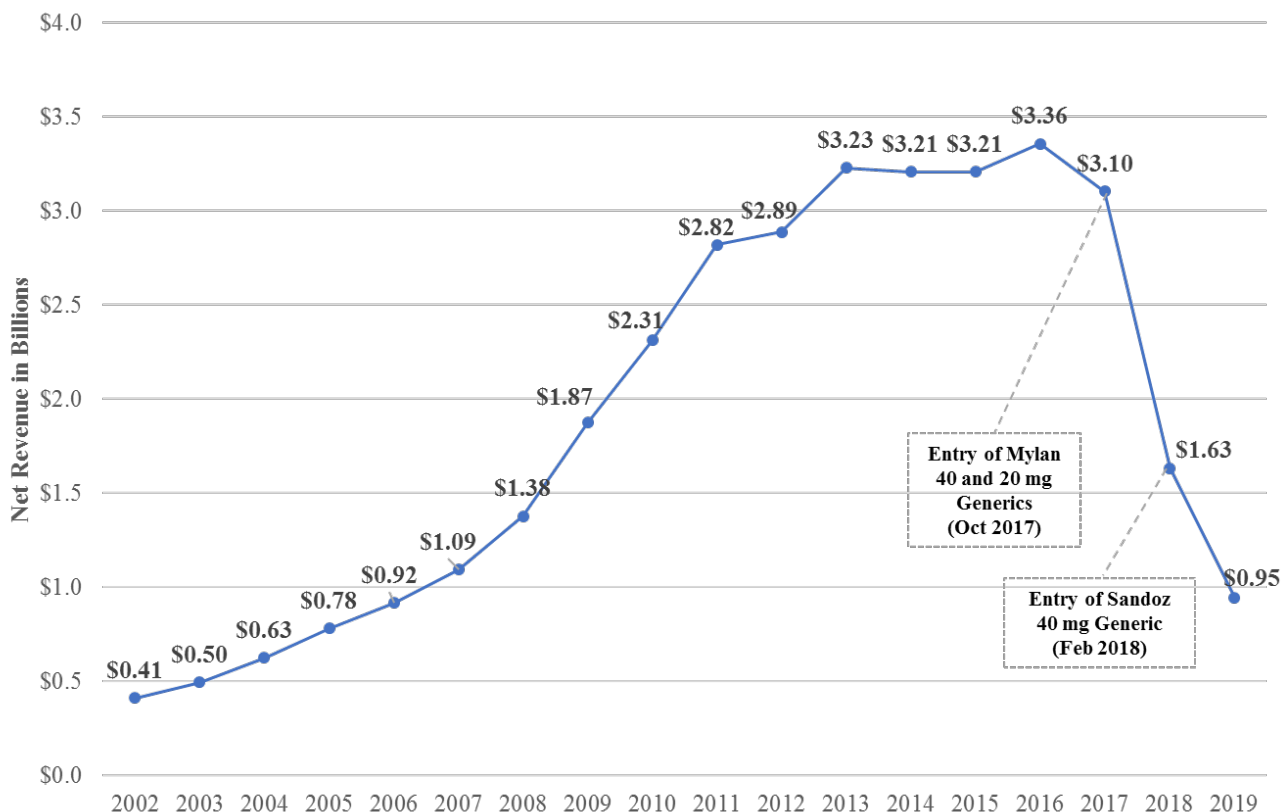
Teva’s price increases have fueled significant growth in net U.S. revenue for Copaxone. In 2002, Teva reported net U.S. revenue of \$411 million. Net U.S. revenue grew consistently for the next 11 years, peaking at \$3.2 billion in 2013. From 2014 to 2017, Copaxone net U.S. revenue leveled at between \$3.1 billion and 3.3 billion per year—nearly an eight-fold increase over 2002. Teva’s net U.S. revenue began to decrease only when the first 40 mg/ml generic and the second 20 mg/ml generic came to market in October 2017.⁷

Figure 2 below reflects Teva’s net U.S. revenue over time.⁸

⁷ Letter from Kirkland and Ellis LLP, on behalf of Teva Pharmaceuticals Industries, Ltd., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Aug. 25, 2020); Letter from Kirkland and Ellis LLP, on behalf of Teva Pharmaceuticals Industries, Ltd., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (July 18, 2019); Teva Pharmaceuticals Industries, Ltd., *Annual Reports (Forms 10-K or 20-F)* (2002-2019) (online at <https://ir.tevapharm.com/financials/sec-filings/default.aspx>).

⁸ *Id.*

Figure 2: Net U.S. Revenue for Copaxone



III. EXECUTIVE BONUSES

From 2012 to 2017, Teva’s net U.S. revenue for Copaxone averaged more than \$3 billion per year, driven in part by its executives’ decision to raise the list price of Copaxone from \$3,475 to \$5,832 per month.⁹ Teva’s top executives were in turn paid more than \$190 million in total compensation over that same period.¹⁰

Teva’s compensation policy makes clear that a significant portion of its executive compensation is based on “overall company performance measures,” including net revenue and

⁹ Teva Pharmaceuticals Industries, Ltd., *Annual Reports (Forms 10-K or 20-F)* (2002-2019) (online at <https://ir.tevapharm.com/financials/sec-filings/default.aspx>); IBM Micromedex Redbook, *Wholesale Acquisition Cost and Average Wholesale Price History for Copaxone*. The 2012 price is for a daily 20 mg/ml dose on January 1, 2012, while the 2017 price is for a 40 mg/ml dose taken three times per week (which is less expensive than the 20 mg/ml dose) on Jan. 1, 2017. The 40 mg/ml dose was not introduced until 2014. From 2012 to 2017, the average net price of Copaxone increased from \$3,113 to \$3,886 per month. Letter from Kirkland and Ellis LLP, on behalf of Teva Pharmaceuticals Industries, Ltd., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Aug. 25, 2020); Letter from Kirkland and Ellis LLP, on behalf of Teva Pharmaceuticals Industries, Ltd., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (July 18, 2019).

¹⁰ Teva Pharmaceuticals Industries, Ltd., *Annual Reports (Forms 10-K or 20-F)* (2002-2019) (online at <https://ir.tevapharm.com/financials/sec-filings/default.aspx>). The 2012 to 2016 figures are based on Teva’s reporting of aggregate executive compensation for executive officers. The 2017 figure is based on Teva’s reporting of compensation for ten named executive officers.

earnings.¹¹ From 2012 to 2017, Copaxone’s net U.S. revenue made up 15% of Teva’s net worldwide revenue for all products. Teva’s price increases for Copaxone had a direct impact on executive bonuses.¹²

Figure 3 below provides compensation data for Teva’s highest compensated executives in 2015 and 2016—two of the years with the highest net revenue from Copaxone.¹³

Figure 3

Teva Senior Executive Compensation					
	2015				
	Base Salary	Cash Bonuses	Stock & Option Awards	All Other Compensation	Total
Erez Vigodman, President and CEO	\$ 1,363,692	\$ 2,253,581	\$ 1,327,657.00	\$ 722,627	\$ 5,667,557
Michael Hayden, President of Global R&D and Chief Scientific Officer	\$ 1,050,000	\$ 1,608,239	\$ 2,295,677.00	\$ 1,449,857	\$ 6,403,773
Eyal Desheh, Chief Financial Officer	\$ 733,863	\$ 1,110,824	\$ 1,701,057.00	\$ 786,020	\$ 4,331,764
Sigurdur Olafsson, President, Global Generic Medicines Group	\$ 954,955	\$ 1,499,375	\$ 958,432	\$ 537,507	\$ 3,950,269
Carlo de Notaristefani, EVP, Global Operations	\$ 877,231	\$ 1,189,398	\$ 1,559,349	\$ 204,297	\$ 3,830,275
Total					\$ 24,183,638
	2016				
	Base Salary	Cash Bonuses	Stock & Option Awards	All Other Compensation	Total
Erez Vigodman, Former President and CEO	\$ 1,528,437	\$ -	\$ 2,952,979	\$ 824,040	\$ 5,305,456
Michael Hayden, President of Global R&D	\$ 1,071,000	\$ 970,202	\$ 2,155,849	\$ 1,401,419.00	\$ 5,598,470
Richard Egosi, Former Group Executive Vice President	\$ 743,487	\$ 458,949	\$ 3,837,397	\$ 304,285	\$ 5,344,118
Sigurdur Olafsson, Former President, Global Generic Medicines Group	\$ 1,060,084	\$ 885,822	\$ 2,623,004	\$ 131,109.00	\$ 4,700,019
Carlo de Notaristefani, EVP, Global Operations	\$ 835,832	\$ 872,532	\$ 2,013,316	\$ 228,467	\$ 3,950,147
Total					\$ 24,898,210

Internal documents produced by Teva suggest that employees at all levels of the company were incentivized to exceed financial targets. For example, a 2016 strategy presentation

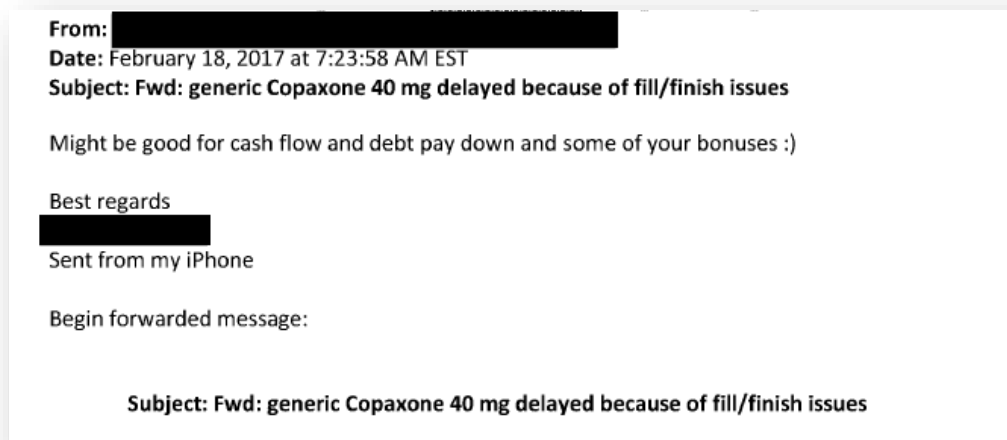
¹¹ *Id.*; see also Letter from Kirkland and Ellis LLP, on behalf of Teva Pharmaceuticals Industries, Ltd., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Aug. 28, 2020)

¹² *Id.*; Letter from Kirkland and Ellis LLP, on behalf of Teva Pharmaceuticals Industries, Ltd., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Aug. 25, 2020); Letter from Kirkland and Ellis LLP, on behalf of Teva Pharmaceuticals Industries, Ltd., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (July 18, 2019).

¹³ Teva Pharmaceuticals Industries, Ltd., *Annual Reports (Forms 10-K or 20-F) (2015-2017)* (online at <https://ir.tevapharm.com/financials/sec-filings/default.aspx>).

recommended that the company build “more attractive career paths for pricers, train them and reward them based on profit.”¹⁴

Email exchanges between employees show that they were aware of the direct link between compensation and Copaxone sales. In response to a February 2017 advisory notice that generic competition to Copaxone had been delayed, one executive told his colleagues that the delay “[m]ight be good for cash flow and debt pay down and some of your bonuses.”¹⁵



IV. HIGH U.S. PRICES AND LACK OF MEDICARE NEGOTIATION

Under current law, the federal government is prohibited from negotiating directly with pharmaceutical companies to lower prices for Medicare beneficiaries.¹⁶ With the federal government unable to negotiate, Teva targeted the U.S. market for price increases while maintaining or cutting prices in the rest of the world.

A. Targeting U.S. Market for Price Increases

Teva’s 2007-2009 strategic plan warned that the company was facing “downward prices [sic] pressure in Europe.”¹⁷ Over the same two year period, Teva raised the U.S. price of Copaxone by 60%.¹⁸ By 2013, Teva was charging more than three times as much for Copaxone

¹⁴ TEVA_HCO_IC_005040409, at Page 42.

¹⁵ TEVA_HCO_IC_005008955 (Feb. 2017 email regarding delay of generic Copaxone 40 mg because of fill/finish issues).

¹⁶ 42 U.S.C. § 1395w-111.

¹⁷ TEVA_HCO_IC_005182598, at Slide 19.

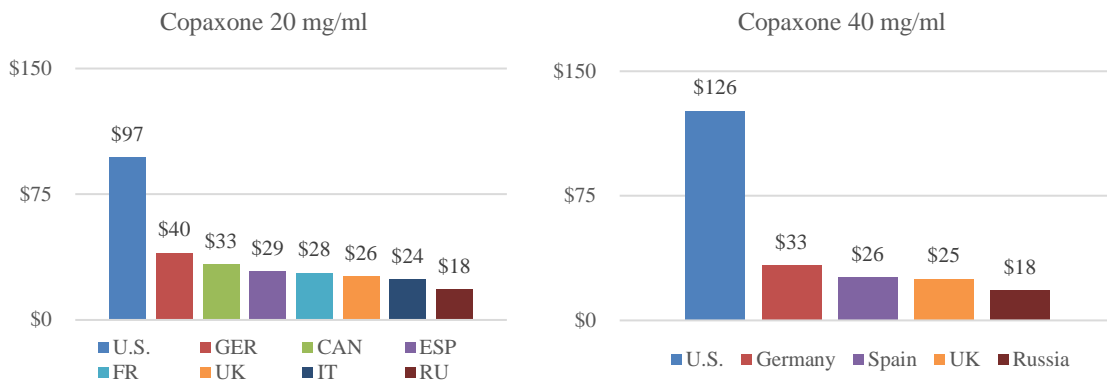
¹⁸ *Id.*; IBM Micromedex Redbook, *Wholesale Acquisition Cost and Average Wholesale Price History for Copaxone*.

in the United States than in England, New Zealand, the Netherlands, and Spain, according to an independent study by the International Federation of Health Plans.¹⁹

An internal Teva presentation from 2016 compared the price of Copaxone in the United States to the rest of the world. According to the presentation, the 2015 net price of Copaxone 20 mg/ml was \$97 per day of therapy in the United States as compared to \$18 per day in Russia, \$24 per day in Italy, \$26 per day in the United Kingdom, \$28 per day in France, \$29 per day in Spain, \$33 per day in Canada, and \$40 per day in Germany. The net price difference between the U.S. and the rest of the world for Copaxone 40 mg/ml was even more drastic: \$126 per day of therapy in the U.S., as compared to \$18 per day in Russia, \$25 per day in the United Kingdom, \$26 per day in Spain, and \$33 in Germany.²⁰

Figure 4 below summarizes the prices listed in the presentation.

Figure 4: 2015 Net Price Per Day of Therapy²¹



In another 2016 presentation, Teva emphasized that one of its key strengths was its ability to “increase prices successfully,” which was “influenced heavily by US [Teva’s U.S. Business] being allowed to hike prices.”²²

¹⁹ International Federation of Health Plans, *2013 Comparative Price Report: Variation in Medical and Hospital Prices by Country* (2013) (online at <https://s3.amazonaws.com/assets.fiercemarkets.net/public/005-LifeSciences/ifhpreport.pdf>).

²⁰ TEVA_HCO_IC_005025464, at Slide 27.

²¹ *Id.*

²² 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
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- 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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A draft 2017 presentation comparing Copaxone pricing trends in the United States to Europe emphasized that in the United States, “Premium prices are available—current list prices average \$80k per patient per year,” while in Europe, “Current list price (average \$13k per patient per year) [is] much lower than US price.” The presentation also emphasized that in the United States, “Payers do not generally dictate prescribing despite higher cost.”²³

DRAFT

Pricing Trends

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

	US dynamic	EU dynamic
Current pricing dynamic	<ul style="list-style-type: none"> ▪ 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 ~23% 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 	<ul style="list-style-type: none"> ▪ 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 than EMA labelling
Future pricing dynamic	<ul style="list-style-type: none"> ▪ Generitization of oral (small molecule) DMTs could potentially drive pricing erosion of ~85% within two years¹ ▪ Biosimilars expected to drive pricing erosion of only ~35% within two years¹ <ul style="list-style-type: none"> ▪ 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 	<ul style="list-style-type: none"> ▪ (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: Exidra Policy Change presentation, Feb 2017; Decision Resources Disease Landscape & Forecast, November 2016 BY2015
1. Decision Resources Market Forecast Assumptions, November 2016 BY2015

teva

²³ TEVA_HCO_IC_005199492, at Slide 12.

By contrast, Teva has been forced to *decrease* 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 2019.²⁴ 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).”²⁵

B. Cost to Medicare and Patients

Taxpayers and patients spent hundreds of millions of dollars more on Copaxone each year because of the prohibition on Medicare’s ability to negotiate directly for lower prices.

Teva’s internal data show that government payers that are permitted to negotiate directly with manufacturers—such as the Department of Defense (DOD) and the Department of Veterans Affairs (VA)—obtained much larger discounts on Copaxone, even when there was no lower-priced generic on the market.²⁶ In 2013, the average net price that VA and DOD paid for a monthly course of Copaxone 20 mg/ml was \$2019.88, while Medicare Part D plans paid on average \$4,206.33. If Medicare had secured the same net price as the VA and DOD, Medicare would have saved more than \$1.4 billion on Copaxone from 2010 to 2013.²⁷ Figure 5 below highlights the differences in these discounts and the lost savings.

Figure 5: Lost Medicare Part D Savings for Copaxone 20 mg/ml²⁸

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	\$ 539,431,248.38	7.1%	\$ 501,131,629.75	48.6%	\$ 277,267,661.67	\$ 223,863,968.08
2011	\$ 707,725,488.16	10.5%	\$ 633,414,311.90	54.5%	\$ 322,015,097.11	\$ 311,399,214.79
2012	\$ 911,468,903.08	10.9%	\$ 812,118,792.64	47.4%	\$ 479,432,643.02	\$ 332,686,149.62
2013	\$ 1,120,491,044.47	8.6%	\$ 1,024,128,814.65	56.1%	\$ 491,895,568.52	\$ 532,233,246.12
Total	\$ 3,279,116,684.09	9.40%	\$ 2,970,793,548.94	52.10%	\$ 1,570,610,970.32	\$ 1,400,182,578.62

²⁴ TEVA_HCO_IC_005093861, at Slide 2.

²⁵ TEVA_HCO_IC_005008283.

²⁶ Although the Veterans Health Care Act of 1992 set a ceiling price that may be charged to the Department of Veterans Affairs (VA), the Department of Defense, the Public Health Service, and the Coast Guard for prescription drugs, the VA uses a national formulary to secure even steeper discounts on behalf of beneficiaries. See Health Affairs, *Health Policy Brief: Veterans Health Administration* (Aug. 10, 2017) (online at www.healthaffairs.org/doi/10.1377/hpb20171008.000174/full/healthpolicybrief_174.pdf).

²⁷ See Letter from Kirkland and Ellis LLP, on behalf of Teva Pharmaceuticals Industries, Ltd., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Sept. 25, 2020) (stating average discount percentages for 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 & Data* (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD).

²⁸ *Id.*

Medicare Part D also paid thousands of dollars more for Copaxone 40 mg/ml than the VA or DOD. Figure 6 below shows the difference between Medicare Part D’s net price for Copaxone 40 mg/ml and VA and DOD’s net price for Copaxone 40 mg/ml.

Figure 6: Medicare Part D’s Higher Price for Copaxone 40 mg/ml²⁹

Monthly Pack of Copaxone 40 mg/ml	
Year	Medicare Part D's Additional Cost (Compared to VA/DOD)
2014	\$ 1,903.14
2015	\$ 2,015.10
2016	\$ 2,420.91
2017	\$ 2,473.47
2018	\$ 1,453.95
2019	\$ 1,334.74

Teva’s price increases on Copaxone have imposed thousands of dollars in out-of-pocket costs on U.S. patients and have left many unable to afford the drug. A recent Kaiser Family Foundation study found that the median annual out-of-pocket cost for a Medicare patient on Copaxone was \$6,672 in 2019.³⁰

Internal documents indicate that Teva executives understood that their price increases contributed to higher out-of-pocket costs. For example, in 2016, one Teva employee reported to General Manager of Teva Neuroscience John Hassler, “you can definitely see a trend in the increase in OOP [out of pocket] costs that the payers are shifting to patients and some of this may be our price increases as well.”³¹

²⁹ *Id.*

³⁰ Kaiser Family Foundation, *The Out-of-Pocket Cost Burden for Specialty Drugs in Medicare Part D in 2019* (Feb. 2019) (online at <http://files.kff.org/attachment/Issue-Brief-the-Out-of-Pocket-Cost-Burden-for-Specialty-Drugs-in-Medicare-Part-D-in-2019>).

³¹ TEVA_HCO_IC_005001166 (Aug. 2016 email exchange analyzing Teva’s expenditures on patient assistance programs).

From: [REDACTED]
Sent: Thursday, August 18, 2016 4:56 PM
To: John Hassler
Subject: RE: Financial Assistance

Hi John,

Please see the attached summary of the activity that we have been seeing on Copaxone over the past few years. There definitely have been increases in out of pocket costs to patients. As you look at the first graph, please take note that the 'patient cost' reflects the amount that Teva incurs on behalf of the patient and in 2014 to 2015 is when we introduced the \$0 program. Some of the increased costs during this time period relates to the additional \$35 that we were picking up for transition or new 40mg patients, not all of this is attributable to plan designs. However, you can definitely see a trend in the increase in OOP costs that the payers are shifting to patients and some of this may be our price increases as well. Please let me know if you have any questions.

Even Teva's own employees could not afford Copaxone at its price. In one July 2018 exchange, a Teva employee explained that she could no longer afford Copaxone because she would have to pay \$1,673.33 out of pocket as compared to \$12 for Mylan's generic. Ultimately, Teva gave the employee free product, a solution unavailable to most Copaxone patients.³²

Some Teva employees urged the company to slow its price increases or reduce the price of Copaxone. According to a December 2017 spreadsheet summarizing employee responses to solicitation for social impact ideas, one employee proposed capping price increases and reducing the price of Copaxone, and another suggested that Teva should commit to not increasing list prices above a certain percentage each year.³³

C. Lobbying Campaign to Prevent Negotiation and Other Reforms

Teva's internal documents reveal a deep concern that Congress would pass drug pricing legislation to allow direct negotiations that could harm the company's bottom line. In response, Teva launched a "Drug Price Task Force" and an associated lobbying campaign to identify the risks of various potential reforms and develop a strategy to defeat them.³⁴

In May 2017, the Drug Price Task Force emphasized that the reform presenting the greatest threat to Teva's future revenue was "Medicare Reform: Removal of government non-interference," which refers to repealing the prohibition on Medicare negotiating directly with drug companies to lower prices.³⁵

In response to the threat of reform, Teva engaged in an intense lobbying campaign. From 2017 to 2020, Teva reported spending \$11.6 million to lobby the House of Representatives and

³² TEVA_HCO_IC_005127328.

³³ TEVA_HCO_IC_005062856.

³⁴ TEVA_HCO_IC_005121399.

³⁵ *Id.*

the Senate.³⁶ Senior Teva executives also met with senior Trump Administration officials on three occasions in 2017.³⁷ Two of these meetings included Joe Grogan, former pharmaceutical executive and then Associate Director of Health Programs at the Office of Management and Budget.³⁸

Mr. Grogan later became the Director of the Domestic Policy Council at the White House, where he argued against Medicare negotiation—the same reform that Teva’s Drug Price Task Force had identified as the company’s greatest threat.³⁹

Teva also relied on the trade association, Pharmaceutical Research and Manufacturers of America (PhRMA), to lobby against reforms that would lower the price of drugs like Copaxone. For example, in May 2017, Teva executives discussed sharing talking points with PhRMA to address criticisms of Copaxone’s price. The talking points emphasized that “Teva makes financial contributions/donations to patient assistance funds annually to help patients with out of pocket costs.”⁴⁰ As explained in Section V below, Teva’s contributions and donations were in its own self-interest and drove millions of dollars in additional sales.

Teva’s talking points for PhRMA attempted to justify Copaxone’s price by stressing that “Copaxone is a complex molecule which requires precise manufacturing capabilities” and noting that manufacturers “offer different levels of discounts and rebates to make the medications more affordable.”⁴¹ As explained in Section VIII below, Teva’s own internal data undermine its claims that manufacturing costs or rebates drove its price increases for Copaxone.

In an email to Teva’s Senior Director of Public Policy in April 2017, a Teva executive identified “two issues I would like to see Pharma start lobbying for:” imposing a statute of limitation on when states could seek Medicaid rebates; and second, by reducing or exempting Medicaid rebates on beneficiaries who are dually eligible for Medicaid and Medicare.⁴²

³⁶ United States Congress Lobbying Disclosure Database, *Query Results for Teva Pharmaceuticals USA, Inc.* (online at www.senate.gov/legislative/Public_Disclosure/LDA_reports.htm) (accessed Sept. 28, 2020).

³⁷ Letter from Kirkland and Ellis LLP, on behalf of Teva Pharmaceuticals Industries, Ltd., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Mar. 19, 2019).

³⁸ *Id.*

³⁹ *Grogan and Philipson: We Can Lower Drug Prices and Spur Medical Innovation. Pelosi’s H.R. 3 is Not the Answer*, Fox Business (Dec. 6, 2019) (online at www.foxbusiness.com/money/lower-drug-prices-medical-innovation-pelosi-hr3-grogan-philipson).

⁴⁰ TEVA_HCO_IC_005022375.

⁴¹ *Id.*

⁴² TEVA_HCO_IC_005007009.

From: Katie Hiett
Sent: Thursday, April 06, 2017 4:21 PM
To: [REDACTED]
Subject: Question

I am looking for some direction on who can help me with some policy changes I would like to see Pharma start pushing for when it comes to the Medicaid program and Medicaid Expansion.

There are two issues I would like to see Pharma start lobbying for.

- There is no statute of limitation on the states on when they can submit Medicaid. They can go back forever and we have no way of knowing about these liabilities. We continue to get hit with surprises and if Medicaid continues to expand this will only get worse. This is millions of dollars for Teva and I know all other pharma gets hit with the same amounts. It has been referenced on some earnings calls when they miss earnings.
- Medicaid currently collects 100% of the rebate even if they only pay a penny against the claim. We are seeing more and more of this with the aging population. They have dual coverage so we get hit with the rebate from the payer claim and then we get hit with the full rebate from Medicaid even though Medicaid was the secondary payer. Currently Teva has several products that have 100% rebate in Medicaid due to best price and a long history of price increases or just being on the market for a long time. Copaxone 20, [REDACTED] are all at 100% WAC rebate in Medicaid meaning we don't ever cover our COGS or other GTN discounts.

I think we need to start advancing some of these changes given the massive increase in this program since ACA and our voice needs to be heard. Don't know where to start.

In April 2017, Teva pressed the American Academy of Neurology (AAN) not to criticize the price of Copaxone during an upcoming AAN webinar on drug pricing and other policy priorities. Prior to the webinar, a Teva executive spoke with AAN's corporate relations department and "expressed our [Teva's] displeasure that Copaxone was the only MS drug mentioned in their policy paper on drug pricing." After watching the webinar, the executive reported to his colleagues that "Copaxone was not mentioned during today's webinar."⁴³

V. PROFIT-DRIVEN PATIENT SUPPORT PROGRAMS

In recent years, Teva has responded to criticism about the price of Copaxone by citing its patient assistance programs.⁴⁴ These programs consist primarily of three separate initiatives:

- "Copaxone Co-Pay Solutions," which covers the co-pays of Copaxone patients with commercial insurance;⁴⁵

⁴³ TEVA_HCO_IC_005039313.

⁴⁴ See, e.g., TEVA_HCO_IC_005000887 (Oct. 2016 talking points instructing Teva executives to pivot to Teva's "Copaxone Co-Pay Solutions" and other Shared Solutions services if asked "How can you justify the price escalation of Copaxone over the last decade?"); Letter from Debra Barrett, Senior Vice President of Global Government Affairs and Public Policy, Teva Pharmaceuticals, to Ranking Member Elijah E. Cummings, Committee on Oversight and Government Reform (Oct. 6, 2017) (emphasizing patient programs in response to previous Congressional inquiry).

⁴⁵ See Teva Neuroscience Inc., *Teva's Shared Solutions for Copaxone* (online at www.copaxone.com/shared-solutions) (accessed Sept. 28, 2020).

- Cash donations to third-party foundations that pay the out-of-pocket costs of Medicare beneficiaries;⁴⁶ and
- Patient services, including injection training.⁴⁷

In contrast to Teva’s public claims that its programs justify its price increases, the Committee’s investigation revealed that Teva profited greatly from increased sales due to these same programs.

A. Commercial Co-Pay Program

Teva’s internal strategy documents frequently emphasize the rate of return of its commercial co-pay program. For example, Teva’s 2008 Copaxone Work Plan estimated that the company would spend approximately \$70 million on “Private Insurance Financial Assistance” between 2008 and 2011 and that this expenditure would result in the sale of 198,930 units of Copaxone that otherwise would have been lost.⁴⁸ Assuming a list price of \$1,886 per unit (the price of Copaxone on the date of the presentation), these sales were worth \$373,484,580—a 433% return on investment.⁴⁹

The 2008 Work Plan’s estimate proved conservative. Its Workplan for 2012 to 2014 reported that Teva’s co-pay program had an average return on investment of 451% for commercial patients.⁵⁰

⁴⁶ See TEVA_HCO_IC_005095143 (Jan. 17, 2017, email and attachments documenting \$38 million in total “2017 Copaxone donations” to HealthWell Foundation’s MS Medicare Access Fund, PAN Foundation’s “MS Fund,” and The Assistance Fund’s “MS Copay Assistance Program”); see also Exhibit 1 to Complaint, *United States v. Teva Pharmaceuticals USA, Inc.*, No. 20-11548 (D. Mass. Aug. 18, 2020) (online at www.justice.gov/usao-ma/press-release/file/1305491/download) (showing \$328,632,000 in payments to two foundations between 2006 and 2015).

⁴⁷ See Teva Neuroscience Inc., *Teva’s Shared Solutions for Copaxone* (online at www.copaxone.com/shared-solutions) (accessed Sept. 28, 2020).

⁴⁸ TEVA_HCO_IC_005141925, at Slide 37. To arrive at this calculation, Committee staff totaled the “Cost” and “Units Not Lost” figures for “Private Insurance Financial Assistance” from 2008 to 2011.

⁴⁹ *Id.*; IBM Micromedex Redbook, *Wholesale Acquisition Cost and Average Wholesale Price History for Copaxone*. Committee staff used list price here because Teva did not provide the Committee with Copaxone’s net price per unit for 2008. But the \$1,886 list price used in this analysis is significantly lower than the drug’s net price in 2009-2011, making the analysis conservative.

⁵⁰ TEVA_HCO_IC_005142081, at Slide 27. The presentation was careful to note that “Medicare D grants are not included in the assessment.”

COPAXONE Expense Drivers		
Expense Driver	Budget	ROI (>0 is considered positive)
Patient Assistance	\$81M direct	<ul style="list-style-type: none"> Returns for commercial patients average 451% with a range of 205% to 761% Medicare D grants are not included in the assessment
Sales Force	\$41M people related	<ul style="list-style-type: none"> 178% short term ROI 95% carryover at 6 months
Patient Services	\$14M direct \$17M people related	<ul style="list-style-type: none"> 29M invested in 2011 generated \$363M with a ROI of 1152% PAP is not included in this ROI
Opportunity and Educational Funds	\$17M direct	<ul style="list-style-type: none"> Not tracked, but assumed similar to Peer to Peer
Peer to Peer	\$10M direct	<ul style="list-style-type: none"> AHM is the surrogate metric Average ROI for AHM programs is 701%
Scientific Communications	\$7M	<ul style="list-style-type: none"> Not Tracked

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In the years that followed, Teva continued to profit from its investments in commercial co-pay programs. Internal strategy documents indicate that Teva collected \$257.5 million in net revenue from its \$54.6 million in expenditures on the commercial co-pay programs in 2014.⁵¹ Teva collected \$148.2 million in net revenue from its \$68.4 million in expenditures on the programs in 2015.⁵²

A 2017 strategy presentation explained that the commercial co-pay programs benefited Teva’s sales by ensuring that patients stayed on Copaxone over time. Teva estimated that a patient on the program was 15% more likely to stay on the drug for 12 months than a patient that was not on the program.

B. Donations to Third-Party Foundations

⁵¹ TEVA_HCO_IC_005083616, at Slide 11. To arrive at this calculation, Committee staff totaled the expenditures and net sales figures for “Commercial Co-Pay (PAP)” and “Coupon (CCS)” (which stands for Commercial Co-Pay Solutions), which were Teva’s two commercial co-pay programs at the time.

⁵² TEVA_HCO_IC_005083616, at Slide 16. To arrive at this calculation, Committee staff totaled the expenditures and net sales figures for “Commercial Co-Pay (PAP)” and “Coupon (CCS)” (which stands for Commercial Co-Pay Solutions), which were Teva’s two commercial co-pay programs at the time.

The federal Anti-Kickback Statute prohibits pharmaceutical manufacturers from subsidizing the co-pay and other cost-sharing obligations incurred by Medicare Part D patients.⁵³ Manufacturers are permitted to make donations to “independent, *bona fide* charitable assistance programs” when appropriate safeguards exist.⁵⁴ According to the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS): “Simply put, the independent charity PAP [patient assistance program] must not function as a conduit for payments by the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries drug choices.”⁵⁵

The documents reviewed by the Committee indicate that Teva’s donations to third-party foundations were made as an “investment” for future returns, with the expectation that such donations would drive Copaxone sales.⁵⁶ For example, Teva’s 2008 Copaxone Work Plan estimated that the company would spend approximately \$97 million on “Medicare Financial Assistance” between 2008 and 2011 and that this expenditure would result in the sale of an additional 155,113 units of Copaxone that were “incremental” or “not lost.”⁵⁷ Assuming a list price of \$1,886 per unit (the price of Copaxone on the date of the presentation), these Part D sales were worth \$292,543,118—a 200% return on investment.⁵⁸

Teva’s 2008 Copaxone Work Plan estimated that Teva would lose \$11.4 million in sales if it reduced its “investment” in “Medicare Part D Grants” by \$4.3 million. Similarly, the Work Plan estimated that Copaxone net sales would decline by \$16 million in 2009, \$33 million in 2010, and \$45 million in 2011 if Teva were to “eliminate Medicare PAP Investment.”⁵⁹

⁵³ See 42 U.S.C. § 1320a-7b(b); Department of Health and Human Services, Office of Inspector General, *Special Advisory Bulletin: Patient Assistance Programs for Medicare Part D Enrollees*, 70 Fed. Reg. 70623 (Nov. 22, 2005) (online at www.govinfo.gov/content/pkg/FR-2005-11-22/pdf/05-23038.pdf); Department of Health and Human Services, Office of Inspector General, *Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs*, 79 Fed. Reg. 31120 (May 30, 2014) (online at <https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/independent-charity-bulletin.pdf>).

⁵⁴ Department of Health and Human Services, Office of Inspector General, *Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees*, 70 Fed. Reg. 70623 (Nov. 22, 2005) (online at www.govinfo.gov/content/pkg/FR-2005-11-22/pdf/05-23038.pdf).

⁵⁵ *Id.*

⁵⁶ TEVA_HCO_IC_005141925, at Slide 50.

⁵⁷ TEVA_HCO_IC_005141925, at Slide 37. To arrive at this calculation, Committee staff totaled the “Incremental Units,” “Units Not Lost,” and “Cost” figures for “Medicare Financial Assistance” from 2008 to 2011.

⁵⁸ *Id.*; IBM Micromedex Redbook, *Wholesale Acquisition Cost and Average Wholesale Price History for Copaxone*. Committee staff used list price here because Teva did not provide the Committee with Copaxone’s net price per unit for 2008. But the \$1886 list price used in this analysis is significantly lower than the drug’s net price in 2009-2011, making the analysis conservative.

⁵⁹ TEVA_HCO_IC_005141925, at Slide 46, 50. At Teva’s request, Committee staff agreed to redact non-relevant information.



Downside to Plan V1

Probable Net Sales	1,742	1,957	2,150
Downside Events:	2009	2010	2011
No Pricing Action	(144)	(324)	(517)
Discount Rx - No Impact on Compliance	(53)	(74)	(75)
Eliminate Medicare PAP investment	(16)	(33)	(45)
[REDACTED]			
Private PAP Programs does not increase Patients	(14)	(26)	(35)
Probable Contribution	894	1,390	1,671
Downside Events:	2009	2010	2011
No Pricing Action	(94)	(272)	(468)
Discount Rx - No Impact on Compliance	(34)	(63)	(68)
Eliminate Medicare PAP investment	(11)	(28)	(41)
[REDACTED]			
Private PAP Programs does not increase Patients	(9)	(22)	(31)

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A September 23, 2015, email reveals that Teva's most senior executives were required to approve large donations to the third-party foundations, such as the investments described above. The email explains that after Teva received "a request for Copaxone donations from The Assistance Fund" and determined the timing of the donation, it would need "written documentation from the appropriate approval authority."⁶⁰ The email lists the "Approval Authority Levels" as:

Approval Authority Levels

\$0.5M Sr. Director

\$1M VP

\$5M SVP (Larry Downey in the past)

\$15M TEC members (Rob Koremans)

\$25M CFO (Eyal Desheh)

>\$25M CEO (Erez Vigodman)

Given the size of Teva's donations to third-party foundations, this policy would have required them to have been approved by the company's Executive Committee, Chief Financial Officer (CFO), or Chief Executive Officer (CEO).⁶¹

⁶⁰ TEVA_HCO_IC_005095970.

⁶¹ *Id.* Teva originally attempted to redact this portion of the email in its productions to the Committee. Teva reversed course after the Department of Justice released a version of this email that was unredacted. *See* Letter

On August 18, 2020, the Department of Justice (DOJ) filed a civil lawsuit against Teva regarding its payments to third-party foundations. DOJ's complaint alleged:

During the period from late 2006 through at least 2015, Teva knowingly and willfully violated the anti-kickback statute, 42 U.S.C. § 1320a-7b(b), by paying over \$300 million to two third-party foundations, Chronic Disease Fund ("CDF") and The Assistance Fund ("TAF"), to cover the Medicare co-pay obligations of Copaxone patients. This conduct generated hundreds of millions of dollars in false claims to Medicare and a corresponding amount of revenue for Teva.⁶²

DOJ's complaint also alleged:

Teva paid CDF and TAF tens of millions of dollars each year because it knew that the foundations would use Teva's money to cover Copaxone co-pays, thus increasing Copaxone sales and enriching Teva in amounts that far exceeded its payments to the foundations.⁶³

According to data attached to DOJ's complaint, Teva paid a total of \$328,632,000 to CDF and TAF between December 2006 and December 2015.⁶⁴

Documents reviewed by the Committee indicate that Teva continued its payments to TAF and other third-party foundations through at least 2018—three years beyond the scope of DOJ's complaint. These documents suggest that Teva's donations continued to be based on the expectation that they ultimately would be delivered to Copaxone patients.

In January 2016, executives sought approval for a \$10 million "Copaxone Donation wire transfer" to TAF. In seeking the approval, the executives emphasized that "this is a common payment we make each year."⁶⁵

from Kirkland and Ellis LLP, on behalf of Teva Pharmaceuticals Industries, Ltd., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Sept. 10, 2020).

⁶² Complaint, *U.S. v. Teva Pharmaceuticals USA, Inc.*, No. 1:20-cv-11548 (D. Mass.) (Aug. 18, 2020) (www.justice.gov/usao-ma/press-release/file/1305806/download).

⁶³ *Id.*

⁶⁴ Exhibit 1 to Complaint, *U.S. v. Teva Pharmaceuticals USA, Inc.*, No. 1:20-cv-11548 (D. Mass.) (Aug. 18, 2020) (online at www.justice.gov/usao-ma/press-release/file/1305491/download) (showing \$328,632,000 in payments to two foundations between 2006 and 2015).

⁶⁵ TEVA_HCO_IC_05293411.


From: David Loughery
Sent: Thursday, January 28, 2016 11:26 AM
To: Larry Downey; Michael McClellan
Cc: [REDACTED]
Subject: Copaxone Donation wire transfer -\$10M January 2016-.xlsx
Attachments: Copaxone Donation wire transfer -\$10M January 2016-.xlsx

Larry/Mike,

Attached is a request to pay another \$10M for Copaxone donations. Mike Sheehy has approved. As this is a common payment we make each year, I'm not clear on what further approvals we need beyond the 2 of you. This amount is included in the 2016 AOP.

DL

In October 2016, executives circulated a business plan that included a \$40 million “Medicare donation” as part of its Copaxone “marketing” strategy.⁶⁶



Marketing: Supporting Activities and Spend

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KBQ: What supporting activities are needed to successfully execute key tactics?

\$ million

SI	CSF	Key Tactics	Supporting Activities	Owner	Start Month	End Month	Budget
1	a.	HCP Personal HCP Promotion	<i>Field Sales and Materials</i>	<i>US Sales</i>	Jan	Dec	2
			<i>Speaker Programs</i>	<i>US Marketing / US Sales</i>	Jan	Dec	7
			<i>Conventions</i>	<i>US Marketing</i>	Jan	Dec	1
1	a	HCP Non Personal Promotion	<i>COPAXONEHCP.com</i>	<i>US Marketing</i>	Jan	Dec	4
			<i>MSKnowledgeSeries.com (unbranded)</i>				
			<i>Email and other Digital Media</i>				
2	a	Medicare Donation	-	<i>US Marketing</i>	Jan	Dec	40
1	a	Advocacy	<i>Charitable Donations and Sponsorships</i>	<i>US Marketing</i>	Jan	Dec	2

Continued on next slide

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In January 2017, an executive sought approval for “3 payments totaling \$38M related to 2017 Copaxone Donations.”⁶⁷ Attached to the email were three spreadsheets:

⁶⁶ TEVA_HCO_IC_005036573, at Slide 28

⁶⁷ TEVA_HCO_IC_005095143.

- A Payment Request Form to deliver \$10 million to HealthWell Foundation, Inc. for its “MS Medicare Access Fund;”⁶⁸
- A Payment Request Form to deliver \$13 million to the Patient Access Network (PAN) Foundation for its “MS Fund;”⁶⁹ and
- A Payment Request Form with the filename “Copaxone Donation wire transfer,” which requested payment of \$15 million to TAF for its “MS Copay Assistance Program.”⁷⁰

Later in 2017, Teva Neuroscience requested an additional \$5 million payment for the PAN Foundation. In discussing whether to approve the request for funds, David Loughery, Teva’s Vice President of Finance for North America Specialty Medicines (NASM), told NASM President Larry Downey:

Considering how hard we’ve cut other areas, I would suggest we ask them [Teva Neuroscience] to find other areas to cover this. I don’t doubt this makes sense but maybe we need to reduce other areas that are less impactful.⁷¹

Teva Neuroscience agreed to make future cuts to its fourth quarter 2017 budget to fund the payment to PAN Foundation.⁷² This decision indicates that Teva’s Vice President for Finance viewed the payment to PAN Foundation as an “impactful” business investment, and more impactful than other business expenses that it had.

As Teva began planning for 2018, early drafts of one of its strategic documents noted that eliminating its “Medicare Donation” to third-party foundations would cost Teva up to \$261 million in Copaxone sales.⁷³

⁶⁸ TEVA_HCO_IC_005095144.

⁶⁹ TEVA_HCO_IC_005095146

⁷⁰ TEVA_HCO_IC_005095148.

⁷¹ TEVA_HCO_IC_005011650, at Slide 1.

⁷² TEVA_HCO_IC_005012554; TEVA_HCO_IC_005000898. It appears that the payment was delayed until May 2017. See TEVA_HCO_IC_005095844.

⁷³ TEVA_HCO_IC_005001347, at Slide 1. Committee staff accommodated Teva’s request that its Sales Force expenditure be redacted.

COPAXONE Highlights - Changes on August 3 from June Submission and Subsequent August 21st Changes

Summary of Changes	Total 2018 expense reduction of \$71M (31%), \$159M vs. original submission of \$229M
Key Areas of Change	<ul style="list-style-type: none"> Sales Force reduced by \$ [REDACTED] <ul style="list-style-type: none"> - Assumes Sales Force COPAXONE weighting reduced from 60% to 50% Marketing Direct Tactical reduced by \$2M Medicare Donation reduced by \$22M - <i>Donation reduced a further \$21M to \$0M</i> Commercial Operations reduced by \$3M Patient Solutions reduced by \$11M <ul style="list-style-type: none"> - Anticipate 75% reduction in call center capacity <i>Market Access reduced by \$3M</i> <i>Marketing other reduced \$1M</i>
Risk to Topline (Net Sales) By Areas of Change	<ul style="list-style-type: none"> Sales Force: [REDACTED] Marketing Direct Tactical: \$5 - \$14M Medicare Donation: \$0 - \$128M - <i>revised impact \$0M-\$261M</i> Patient Solutions: \$50 - \$80M
Overall Risk to Topline	<ul style="list-style-type: none"> \$75M - <i>\$413M (revised total impact)</i>

On August 30, 2017, Mr. Loughery told General Manager of Teva Neuroscience John Hassler to remove the analysis from the presentation because he was “not comfortable including the sales impact of the reduced donations.”⁷⁴

From: David Loughery
Sent: Wednesday, August 30, 2017 3:49 PM
To: John Hassler
Subject: FW: LRP Expense Reduction

John,

Larry forwarded this to me and I then asked Mark to prepare something similar for Respiratory that I could then consolidate and allow Larry to provide to Rob. I am not comfortable including the sales impact of the reduced donations. Since the table is attached as a picture, could you have someone send this to me with the 0-\$128M range line excluded. I will however, add a comment that we believe that reducing the level of donations could mean that a significant number of patients will not be able to remain on Copaxone due to financial constraints.

Thanks,

DL

⁷⁴ TEVA_HCO_IC_005001345.

Documents and information reviewed by the Committee indicate that Teva continued making donations to third-party foundations in 2018. Teva reported to the Committee that it provided \$23,286,429 in “charitable cash contributions in connection with Copaxone” in 2018.⁷⁵

At the beginning of 2018, Teva’s Executive Vice President for North America Brendan O’Grady received a presentation on the company plan for the year. One slide emphasized:

27% of patients on Copaxone 40mg are Medicare Part D. Patients who are unable to meet the donut hole deductible in Q1 may not fill Rx and go off therapy, which would result in a negative impact to the brand of \$210-280M.⁷⁶

COPAXONE Executive Summary

COPAXONE: Upside and Downside

- Compared to current AOP (1st Gx Oct 2017, 2nd Gx April 2018); less than anticipated erosion of COPAXONE 40mg post generic introduction has led to a Q4 2017 upside and an anticipated Q1 2018 upside of approximately \$174M.
- Current COPAXONE brand AOP net sales: \$1.054B
- Potential revised AOP net sales with Q1 adjustment: \$1.228B
- Additionally, competitive intelligence suggests a delay in introduction of 2nd generic to the market, which may lead to further upside in 2018.
- Potential revised AOP net sales with Q1 adjustment and 2nd Gx in Dec: \$1.562B
- Forecast Risk: 27% of patients on COPAXONE 40mg are Medicare Part D. Patients who are unable to meet the donut hole deductible in Q1 may not fill Rx and go off therapy, which would result in a negative impact to the brand of \$210-280M.
- Holding the execution of high priority tactics during ongoing budget reviews may place additional risk in the topline forecast.
- Current AOP investment: \$65.6M (minus labor e.g. sales force and ShS).
- [REDACTED] direct marketing investment planned for 2018 ([REDACTED] tactical marketing, [REDACTED] shared services direct marketing) + [REDACTED] indirect marketing costs (driven by MR, MCM and HSM)
- Need to confirm we are covering expenses beyond labor that are included with indirect expense [REDACTED]

teva

In the speaker’s notes to that slide, Teva executives identified “Donations” as one of the “High priority projects for execution.”⁷⁷

⁷⁵ Letter from Kirkland and Ellis LLP, on behalf of Teva Pharmaceutical Industries, Ltd., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (May 24, 2019).

⁷⁶ TEVA_HCO_IC_005028530, at Slide 5.

⁷⁷ *Id.*

High priority projects for execution:
 Q1 patient programs
 Donations
 Cover my meds

A few weeks after receiving that presentation, Mr. O’Grady told a colleague that an insurer’s decision to move Copaxone to the non-preferred tier of its formulary for both commercial and Medicare patients “means little because we buy the patients [sic] copay down to zero anyway.”⁷⁸

C. Patient Services

Through its Shared Solutions program, Teva offers injection training and other educational resources to Copaxone patients. Internal documents show that Teva also relied on these services to drive additional Copaxone sales.

For example, Teva’s 2012-2014 workplan reported that its \$29 million “investment” in patient services in 2011 had “generated” \$363 million in sales. The workplan emphasized that this expenditure reflected a significant return on investment: “ROI of 1152%.”⁷⁹

COPAXONE Expense Drivers		
Expense Driver	Budget	ROI (>0 is considered positive)
Patient Assistance	\$81M direct	<ul style="list-style-type: none"> Returns for commercial patients average 451% with a range of 205% to 761% Medicare D grants are not included in the assessment
Sales Force	\$41M people related	<ul style="list-style-type: none"> 178% short term ROI 95% carryover at 6 months
Patient Services	\$14M direct \$17M people related	<ul style="list-style-type: none"> 29M invested in 2011 generated \$363M with a ROI of 1152% PAP is not included in this ROI
Opportunity and Educational Funds	\$17M direct	<ul style="list-style-type: none"> Not tracked, but assumed similar to Peer to Peer
Peer to Peer	\$10M direct	<ul style="list-style-type: none"> AHM is the surrogate metric Average ROI for AHM programs is 701%
Scientific Communications	\$7M	<ul style="list-style-type: none"> Not Tracked

We make quality healthcare accessible around the world 27

⁷⁸ TEVA_HCO_IC_005002063.

⁷⁹ TEVA_HCO_IC_005142081, at Slide 27.

Similarly, Teva executives estimated in 2017 that conducting an additional 1,200 injection trainings would cost the company \$250,000, but “net \$2.5M [million] in incremental sales.”⁸⁰

Teva also uses its patient services to promote Copaxone over lower-priced generics. An October 2017 presentation to Teva’s Board of Directors identified Teva’s Shared Solutions services as “key activities to defend Copaxone Against Generic erosion.”⁸¹

Key Activities to Defend Against Generic Erosion

Brand over Generic (House Brand) Contracting Strategy

- Contracting with major payors, PBMs and pharmacies
- Contracts range from Brand over Generic terms (all 40mg Rx will be switched to Brand), to loyalty allowing access to COPAXONE 40mg alongside generic

Sales force DAW messaging and activities

- Sales force proactively messages to HCP customers the need for “Dispense as Written” on all new Rx and refills
- Working with office accounts to ensure they have the capabilities and resources need to communicate DAW through verbal, written and electronic means

Outbound efforts to 40mg patients through Shared Solutions

- Call center outbound effort to contact all current 40mg patients with active marketing authorization
- Emails to all patients with DAW messaging
- Ability to produce current 40mg patient lists for HCP offices to proactively DAW scripts

Legal pathways also being explored

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In 2017, Teva launched a Dispense As Written (DAW) campaign to convince doctors to place a special notation on their prescriptions of Copaxone to prevent pharmacists from substituting the brand name with a lower-priced generic equivalent.⁸² (See Section VII below for more information on Teva’s DAW strategy.) According to the presentation, Teva employees used the Shared Solutions services to “contact all current 40mg patients with active marketing authorization” and send “Emails to all patients with DAW messaging.”⁸³ An August 2018

⁸⁰ TEVA_HCO_IC_005104023 (June 2017 email exchange regarding investments in Copaxone marketing/support).

⁸¹ TEVA_HCO_IC_005021634, at Slide 4.

⁸² See, e.g., William H. Shrank, et al., *The Consequences of Requesting “Dispense as Written,”* American Journal of Medicine (Apr. 2011) (online at https://scholar.harvard.edu/files/nkc/files/2011_dispense_as_written_am_j_med.pdf).

⁸³ TEVA_HCO_IC_005021634, at Slide 4.

presentation emphasized the need to “reinforce DAW on every call” and use “Marketing driven patient programs and telecons to supplement patient education/support.”⁸⁴

VI. NEW DOSE AS “GENERIC DEFENSE STRATEGY”

In 2002, Teva’s senior executives began holding meetings on Copaxone “Life Cycle Management,” an industry term for the use of incremental research to extend a profitable drug’s market monopoly.⁸⁵ The executives later emphasized to Teva’s Board of Directors that one objective of life cycle management was to “Minimize the risk of generic competition.”⁸⁶

Over the past decade, Teva’s research and development decisions have focused on maximizing profits by shielding Copaxone from generic competition for as long as possible. Teva’s primary strategy to extend the life cycle of Copaxone was to introduce a new formulation of Copaxone—a 40 mg/ml dose injected three times per week. Teva publicly framed the new dose as more convenient than the 20 mg/ml formulation, which is injected every day.⁸⁷ Internal company documents, however, reveal that Teva developed Copaxone 40 mg/ml in part to extend its monopoly pricing for Copaxone by shifting patients to the new dose—which still enjoyed market exclusivity—before the existing 20 mg/ml dose began facing generic competition.

Teva introduced Copaxone 40 mg/ml in 2014.⁸⁸ Through this strategy, Teva was able to shift many patients to the new dose before another pharmaceutical company, Sandoz, released Glatopa, a lower-priced generic version of Copaxone 20 mg/ml, in 2015. Independent experts estimate that Teva’s 40 mg/ml strategy cost the U.S. health care system between \$4.3 billion and \$6.5 billion in additional health care expenditures.⁸⁹

A. Launching Copaxone 40 mg to Extend Monopoly and Minimize Competition

Until 2008, Teva’s strategy to minimize generic competition for Copaxone centered on introducing a daily dose of Copaxone 40 mg/ml, which it believed would be more effective than generic versions of Copaxone 20 mg/ml.⁹⁰ In support of a daily version of Copaxone 40 mg/ml,

⁸⁴ TEVA_HCO_IC_005126952, at Slide 10.

⁸⁵ See TEVA_HCO_IC_005158339, at Pages 18-21 (summary of 2002 meeting in Boca Raton, Florida); TEVA_HCO_IC_05220331 (summary of 2002 meeting in Berlin, Germany).

⁸⁶ TEVA_HCO_IC_005132388, at Slide 2.

⁸⁷ Teva Pharmaceuticals, Ltd., *Press Release: Teva Announces U.S. FDA Approval of Three-Times-a-Week Copaxone (Glatiramer Acetate Injection) 40 mg/mL* (Jan. 28, 2014) (online at www.businesswire.com/news/home/20140128006747/en/Teva-Announces-U.S.-FDA-Approval-Three-Times-a-Week-COPAXONE%20AE).

⁸⁸ Letter from Billy Dunn, Acting Director, Division of Neurology Products, Food and Drug Administration, to Dennis Ahern, Senior Director for Regulatory Affairs, Teva Pharmaceuticals USA (Jan. 28, 2014) (online at www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/020622Orig1s0891tr.pdf).

⁸⁹ Benjamin N. Rome, et al., *US Spending Associated with Transition from Daily to 3-Times-Weekly Glatiramer Acetate*, *Journal of the American Medical Association Internal Medicine* (July 20, 2020) (online at <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2768653>).

⁹⁰ See National Institutes of Health, *Information for Clinical Trial Identifier NCT00202982* (online at <https://clinicaltrials.gov/ct2/show/record/NCT00202982>) (2003 Teva-sponsored Phase II study examining efficacy

Teva sponsored the FORTE Trial, a Phase III clinical trial examining its efficacy, safety, and tolerability as compared to daily Copaxone 20 mg/ml.⁹¹ In July 2008, Teva announced that the trial had found no difference in efficacy between the two doses of Copaxone.⁹²

Unable to market Copaxone 40 mg/ml as a *more* effective dose of Copaxone, Teva shifted its strategy to selling Copaxone 40 mg/ml as an equally effective—but less frequent—dose. Notably, Teva had previously rejected this strategy as less profitable. In January 2007, one executive wrote:

The reason I've been given why less frequent dosing of a higher dose of glatiramer should not even be considered is pricing: for the 40 mg once daily, one can not [sic] double the price, let alone when 40 mg would be used less frequent dosing ie [sic] once a week. Moreover, it has also been argued that some patients may use 20 mg less frequently in case 40 mg will show an efficacy when used in less frequent dosing than once daily and this will cut sales of 20mg. A counterargument in that case could be that 20 mg should no longer be available in the market. I of course do not suggest that such arguments be exposed to external people.⁹³

Another executive had previously noted that Teva had “no data to support similar / better efficacy of GA [Copaxone] 40mg in every other day administration.” The executive also emphasized that “every other day over once daily does not represent a significant improvement in convenience” and that “GA 40 mg every other day will result in price reduction by half, being much lower than GA 20mg!!”⁹⁴

After the FORTE Trial failed, Teva began reexamining whether it could combat generic competition through the launch of Copaxone 40 mg/ml injected three times per week. Within weeks of announcing the FORTE Trial's results, Teva's executives presented new Copaxone “Life Cycle Initiatives” to the company's Board of Directors, including “40 mg every other day.”⁹⁵

of Copaxone 40 mg/ml); TEVA_HCO_IC_05210570 (Aug. 2007 presentation to Board of Directors on daily Copaxone 40 mg/ml); TEVA_HCO_IC_05253089 (Jan. 2008 strategy document on pricing for daily Copaxone 40 mg/ml if Phase III clinical trial was successful).

⁹¹ See National Institutes of Health, *Information on Clinical Trial Identifier NCT00337779* (online at <https://clinicaltrials.gov/ct2/show/NCT00337779>).

⁹² Teva Pharmaceuticals, Ltd., *Press Release: Teva Provides Update on FORTE Trial* (July 7, 2008) (online at <https://ir.tevapharm.com/news-and-events/press-releases/press-release-details/2008/Teva-Provides-Update-on-FORTE-Trial/default.aspx>).

⁹³ TEVA_HCO_IC_005152181.

⁹⁴ TEVA_HCO_IC_005152124.

⁹⁵ TEVA_HCO_IC_005235121, at Slide 6.



GA Life Cycle Initiatives
Lower frequency of injections

No formal dose ranging or frequency humans studies (PK/PD) have been performed to link with clinical outcomes

- **40 mg every other day**
 - ❖ Based upon "sameness" of 40mg to 20mg in the FORTE trial
 - ❖ **Issue:** existing data from every other day with Copaxone may prompt patients using generic COPAXONE every other day

- **Higher doses in less frequent dose regimen (i.e once weekly)**
 - ❖ How do we justify the use of higher doses after Forte?
 - ❖ Solubility of a higher dose, increased injection site reactions
 - ❖ Once weekly injections of 15 and 30 mg TV-5010 in MS patients provided equivocal MRI results, anti TV5010 antibodies profile looks different from that induced by daily GA

- **Issue for consideration : costs of yearly treatment of the lower frequency regimen compared with COPAXONE daily**


6
Global Innovative Products 

In August 2008, the executives also began asking whether Teva could “patent the frequency” of injections, thereby limiting the ability of generic competitors to introduce a similar generic version of the drug.⁹⁶

From: [REDACTED]
Sent: Tuesday, August 26, 2008 8:26 PM
To: [REDACTED]
Cc: [REDACTED]
Subject: Re: brief update from GIR meeting on GA LCM

Thanks for the update. A few points:

1. The limiting step with GA is the density of the solution. I assume that [REDACTED] has the information for the 60mg back from the days we have worked on the 80mg.
2. Please consider the ISR we saw in the rats with the 80mg (so we may not want to go to high).
3. In addition, we have currently a 5 fold safety ration based on monkeys only and excluding the ISRs - we should consider whether this should guide us when choosing the next dose.
4. What is the TPP - efficacy as 20mg?
5. Can we patent the frequency?
6. This is also a long term plan, assuming Phase II and Phase III bringing us to 2016 - still relevant?

[REDACTED]

By December 2008, Teva’s business executives had decided to pursue research supporting a Copaxone dose of three times per week. Many of Teva’s scientists opposed this decision. One scientist wrote that Teva’s Innovative Research and Development (IR&D)

⁹⁶ TEVA_HCO_IC_005132452.

management was “strongly against” Teva’s study into the less-frequent dosing of Copaxone “since it has no scientific rationale/value”:⁹⁷

Dear both,

Please find below the presentation prepared for the discussion in the GA LCM meeting one month ago (the relevant study design can be found in slides 7-9- Option 2- Superiority study GA 32 mg thrice a week vs, placebo, and the appropriate FTE slide can be found in [slide 14](#)).

I would like to make it clear that the IR&D management, led by [REDACTED] are **strongly against the study** since it has no scientific rationale/ value. The IR&D decision was conveyed to the GA LCM team; however, the GA LCM members, though agree with IR&D decision, think that such a study has its business value.

I know from [REDACTED] that a GIR meeting is planned for 08-09 Jan 09, so I assume that a final decision will be taken then by [REDACTED]

Please contact me if you need any further clarifications.

All the best

[REDACTED]

In June 2009, Teva’s executives prepared a presentation on “Copaxone LCM—Mid Term Initiatives” for then-CEO Shlomo Yanai. The presentation stressed the need to “Develop a low frequency formulation of GA” to ensure “the competitiveness of Copaxone in the future and address the market [sic] unmet need for less frequent injections.”⁹⁸

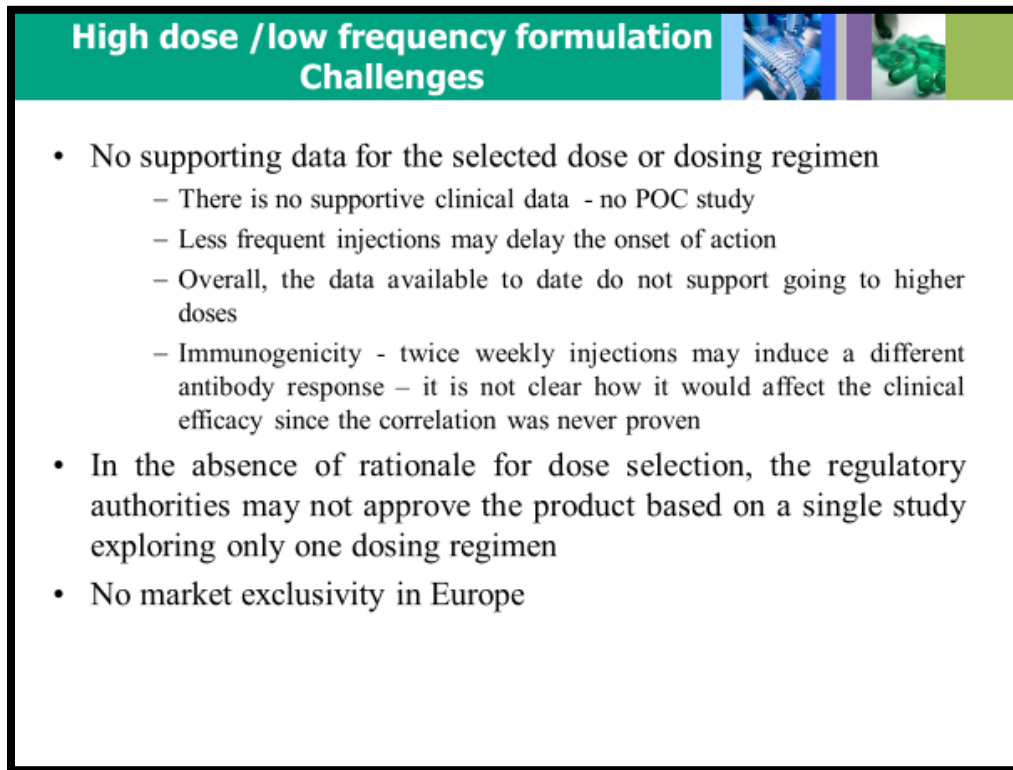
Development of High dose/ low frequency formulation of GA

- **Situation**
 - There is a need to develop a low frequency formulation of GA to:
 - Ensure the competitiveness of Copaxone in the future and to address the market unmet need for less frequent injections
 - Prepare a mid-term solution as an insurance policy in case [REDACTED] fail and our next launch is not before 2016 / 17
- **Complications**
 - No supporting clinical data for the selected dose or dosing regimen
 - Regulatory authorities may request a dose range finding study and comparison of the new formulation to daily GA and placebo
 - The new formulation must be approved no later than 2014
- **Possible Resolution**
 - To conduct a 2 -arm PC study, using the 40mg/ml configuration e.g. 32-40 mg GA 2-3 times a week
 - Do not consult with regulatory authorities before study initiation – they will most probably not accept this design
- **Risks**
 - The cost of the study is \$52 M
 - Regulatory authorities may not approve the new formulation based on a single study results
 - Recruitment to a PC study will be slow and the TTM may be later than 2014

⁹⁷ TEVA_HCO_IC_005233185.

⁹⁸ TEVA_HCO_IC_005159378, at Slide 2.

The presentation acknowledged that, at that time, there was “No supporting clinical data for the selected dose or dosing regimen.” The presentation also suggested that the strategy would be more profitable in the United States than in Europe because Teva would get “No market exclusivity in Europe.”⁹⁹



High dose /low frequency formulation Challenges

- No supporting data for the selected dose or dosing regimen
 - There is no supportive clinical data - no POC study
 - Less frequent injections may delay the onset of action
 - Overall, the data available to date do not support going to higher doses
 - Immunogenicity - twice weekly injections may induce a different antibody response – it is not clear how it would affect the clinical efficacy since the correlation was never proven
- In the absence of rationale for dose selection, the regulatory authorities may not approve the product based on a single study exploring only one dosing regimen
- No market exclusivity in Europe

Internal discussions in November 2009 undermine Teva’s claims that it launched the 40 mg/ml three times per week to benefit patients and not to protect the Copaxone franchise. That month, Teva decided against doing research on the efficacy of administering Copaxone 40 mg/ml *once* per week—which presumably would have been even more convenient for patients. Teva’s then-CEO Shlomo Yanai feared that such research would lead patients to take two injections of a cheaper generic version of Copaxone 20 mg/ml once per week rather than Teva’s Copaxone 40 mg/ml.¹⁰⁰

In 2010, Teva sponsored the GALA Trial, a Phase III trial examining the efficacy of Copaxone 40 mg/ml administered three times per week.¹⁰¹ As it awaited the results of the trial, Teva continued assessing the business strengths of the new dose. Teva’s marketing team circulated a draft analysis noting that the new formulation of Copaxone would provide a “Patent

⁹⁹ *Id.* at Slide 5; *see also* TEVA_HCO_IC_005151509 (similar presentation for Teva’s Chief Executive Officer).

¹⁰⁰ TEVA_HCO_IC_005151470 (“As you stated Shlomo does not support this for fear of a follow on GA [i.e. generic Copaxone] being used 20 mg two shots, once a week (BIW).”).

¹⁰¹ *See* National Institutes of Health, *Information on Clinical Trial Identifier NCT01067521* (online at <https://clinicaltrials.gov/ct2/show/study/NCT01067521>).

protection extension” in addition to “better convenience, compliance, adherence, resulting in theoretical better QoL [quality of life].” The team emphasized that the new dose would be a “Barrier to Generic entrance.” Given Teva’s status as the largest generic manufacturer in the world, a more senior executive suggested that the team replace the words “Barrier to Generic entrance” with “extension of Life Cycle” noting, “we don’t want to be seen as ‘creating’ barriers to generics as this is Teva’s core business.”¹⁰²

GA 40mg– Opportunities & Threats

Opportunities	Threats
<ul style="list-style-type: none"> ● Barrier to Generic entrance – Suggest the opportunity is extension of Life Cycle and new IP vs. your proposed statement – we don’t want to be seen as “creating” barriers to generics as this is Teva’s core business ● Capture IFN patients that switch because of Tolerability (no flu-like syndrome, same convenience) ● Capture GA 20mg aiming at less injection / more convenience ● Reinforce the “franchise in MS” of Teva. 	<ul style="list-style-type: none"> ● Crowded & competitive market, physicians not ready to accept additional “minor” innovation/benefit <ul style="list-style-type: none"> ○ Peg-avonex ○ Orals (Gilenya, ██████████, TeriF, BG12) ○ ██████████ ● GA 20mg <ul style="list-style-type: none"> ○ CIS Indication ○ Owns positioning territory ● Challenging Teva MS franchise Strategy [20mg, 40mg, ██████████, 0.5 ml at the horizon] ● We are putting patients in play for a switch who might have been otherwise satisfied ● GA market share is declining overtime due to fragmentation of the market ● Generic or biosimilar GA

The analysis also acknowledged that the new dose provided “No major advantage on GA 20 mg.”¹⁰³

After the GALA Trial demonstrated that Copaxone 40 mg/ml three times per week was safe and effective, Teva sought approval from the Food and Drug Administration (FDA) to

¹⁰² TEVA_HCO_IC_05239258, at Slide 4.

¹⁰³ *Id.* at Slide 3.

market the new dose. FDA granted Teva's application on January 28, 2014.¹⁰⁴ Teva launched the drug the next day.¹⁰⁵

B. Price Increases, Contracting, and Marketing to Pressure Patients to Switch

Teva launched Copaxone 40 mg/ml nearly 18 months before Sandoz launched Glatopa, a lower-priced generic competitor to Copaxone 20 mg/ml.¹⁰⁶ During the intervening period, Teva implemented a comprehensive "generic defense strategy" to switch patients to Copaxone 40 mg/ml and avoid generic competition.¹⁰⁷

To incentivize patients and payers to make the switch, Teva set a launch price for Copaxone 40 mg/ml that was slightly less expensive per week of treatment than Copaxone 20 mg/ml. Teva's internal documents indicate that this decision was a tactic to minimize future generic competition rather than to reduce costs for patients. In its memorandum approving the decision, Teva's pricing committee emphasized: "We want rapid transition of COPAXONE 20mg to 40mg prior to expected generics in mid-2014."¹⁰⁸

To further encourage patients to switch from Copaxone 20 mg/ml to Copaxone 40 mg/ml, Teva also increased the price of Copaxone 20 mg/ml by 9.8% on August 22, 2014.¹⁰⁹ This price increase was part of Teva's 2014 strategic plan, which emphasized that one method to "Divert to 40" was to "raise 20mg price."¹¹⁰ Some Teva executives advocated for the price increase to happen earlier. One wrote:

Just for clarity ... an important part of our generic defense strategy is creating price separation between 20mg and 40mg. We can do that via increased discounts on 40mg or raising the price on 20mg. I prefer the latter. Delaying a pricing action to mid-August or later, impedes our ability to gain access for 40mg with resistant payers, [sic] makes a generic more appealing to payers, and could dampen further conversion strategies.¹¹¹

In addition to increasing the price of Copaxone 20 mg/ml, Teva explored a plan to "Discontinue 20mg Financial Programs (Patient Services)"—its financial assistance program for

¹⁰⁴ Letter from Billy Dunn, Acting Director, Division of Neurology Products, Food and Drug Administration, to Dennis Ahern, Teva Pharmaceuticals USA (Jan. 28, 2014) (online at www.accessdata.fda.gov/drugsatfda_docs/applletter/2014/020622Orig1s089ltr.pdf).

¹⁰⁵ IBM Micromedex Redbook, *Wholesale Acquisition Cost and Average Wholesale Price History for Copaxone*.

¹⁰⁶ *Id.*; Sandoz, *Press Release: Sandoz Announces U.S. Launch of Glatopa, the First Generic Competitor to Copaxone 20 mg* (June 19, 2015) (online at www.us.sandoz.com/news/media-releases/sandoz-announces-us-launch-glatopatm-first-generic-competitor-copaxoner-20mg).

¹⁰⁷ TEVA_HCO_IC_005147355.

¹⁰⁸ TEVA_HCO_IC_005135778, at Page 5.

¹⁰⁹ IBM Micromedex Redbook, *Wholesale Acquisition Cost and Average Wholesale Price History for Copaxone*.

¹¹⁰ TEVA_HCO_IC_005134707, at Page 13.

¹¹¹ TEVA_HCO_IC_005147355 (ellipses in original).

patients—which would make it more expensive for patients to remain on the lower dose of the medication.¹¹²

Marketing: Deliverables				
Deliverables	Status	Responsible Party	Start Date	Completion Date
Pre-Gx Launch				
Gx Strategy	Complete	Jeff	8/14	8/14
Tactical Plan	In Development	Jeff / Marcy	8/14	10/14
Field Communications / TPs	Complete	Scott / Karen	2/14	4/14
Discontinue 20mg Financial Programs (Patient Services)	In Process	Karen / DeAnne	8/14	12/14
Post-Gx Launch				
Tactical Plan	In Development	Jeff / Marcy	8/14	10/14
Field Communications / TPs	In Development	Marcy / Karen	9/14	12/14

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COPAXONE
(glatiramer acetate injection)

Documents show that Teva exerted pressure on pharmacy benefit managers (PBMs) by tying contractual rebates on Copaxone 20 mg/ml—the discounts provided to PBMs that are primarily passed on to insurance plans to reduce premiums—to adding Copaxone 40 mg/ml to their formularies.¹¹³ For example, Teva’s internal emails suggest that on PBM forfeited its 2015 rebates on Copaxone 20 mg/ml because it declined to add Copaxone 40 mg/ml to its formulary.¹¹⁴ This pressure campaign was successful. The PBM added 40 mg/ml to its formulary the next year.¹¹⁵

¹¹² TEVA_HCO_IC_005141157, at Slide 41.

¹¹³ TEVA_HCO_IC_005006452; Department of Health and Human Services, Office of Inspector General, *Rebates for Brand Name Drugs in Part D Substantially Reduced the Growth in Spending from 2011 to 2015* (Sept. 2019) (online at <https://oig.hhs.gov/oei/reports/oei-03-19-00010.pdf>).

¹¹⁴ TEVA_HCO_IC_005006452.

¹¹⁵ *Id.*

Teva incentivized other PBMs to lobby doctors on behalf of Copaxone 40 mg/ml. For example, after generic Glatopa entered the market, Teva contracted with Humana to implement a “Copaxone conversion initiative.” Teva internally described the arrangement as follows:

Humana is committed to converting current Copaxone 20mg patients over to Copaxone 40mg with their physician members. Specifically, Humana is contacting the prescribers via fax and phone to make them aware of which patients are still on Copaxone 20mg and encourage them to switch these patients to Copaxone 40mg. Should a prescriber choose not to switch, the patient would simply remain on Copaxone 20mg.¹¹⁶

Teva also incentivized its sales force to convert patients to Copaxone 40 mg/ml by making their bonuses entirely dependent on 40 mg/ml sales.¹¹⁷

Finally, Teva executed a marketing campaign to encourage patients and physicians to switch to 40 mg/ml Copaxone. Teva’s 2014 strategic plan included telling patients that switching to Copaxone 40 mg/ml would give them the “Freedom to ... Be Bold. Be True. Be You. It’s your future.”¹¹⁸

The company targeted doctors through its sales force. Teva’s “Brand Plan” for 2017 identified the following “Behavioral Objectives” for physicians:

- “Encourage physicians to initiate and upgrade any remaining patients to TIW [three times weekly] Copaxone 40mg”;
- “Encourage physicians to switch patients to TIW Copaxone 40mg if payers force to generic GA for daily dose”;
- “Prescribe Copaxone DAW [Dispense as Written] for new and existing patients”;
and
- “Encourage their patients to accept only branded Copaxone.”¹¹⁹

¹¹⁶ TEVA_HCO_IC_005006534; *see also* TEVA_HCO_IC_005141157, at Slide 43.

¹¹⁷ *Id.*; TEVA_HCO_IC_005001181, at Page 1 (“The sales force is only paid on 40mg sales.”); *see also* TEVA_HCO_IC_005028494 (Jan. 2018 presentation suggesting that Teva continued to structure its sales representatives’ bonuses to drive “transition from Copaxone 20 mg to 40mg while protecting total Copaxone share”).

¹¹⁸ TEVA_HCO_IC_005134707, at Page 15 (ellipses in original).

¹¹⁹ TEVA_HCO_IC_005102935, at Page 10.

C. Strategy Successfully Maintained High Prices

The introduction of Copaxone 40 mg/ml successfully increased Teva's market share and profits despite the launch of Glatopa, Sandoz's lower-priced generic version of Copaxone, in June 2015.

In December 2015, then-CEO Erez Vigodman boasted that Teva had successfully converted 76.9% of Copaxone patients to 40 mg/ml and had limited "Glatopa 20mg Market Share" to 19.3%.¹²⁰ In June 2016—nearly one year after Glatopa entered the market—General Manager of Teva Neuroscience John Hassler circulated a presentation which boasted in the speaker's notes: "The strategy of switching patients to 40mg version of the medicine is

¹²⁰ TEVA_HCO_IC_005188452, at Slide 15.

continuing to be successful and reduce [sic] the impact of generic competition.”¹²¹ An outside consultant to Teva agreed with the assessment, writing:

Prior to Glatopa’s launch, Teva released and promoted a long-acting Copaxone 40MG, effectively pushing existing and new patients to the branded 40MG and minimizing generic substitution.¹²²

Teva is interested in understanding payer control in MS, anticipating a potential entry of generic Copaxone 40mg

Market and Project Background

- Teva's Copaxone franchise is a mature MS brand and long time market leader
- Copaxone currently has two formulations – 20MG and 40MG, and the 20MG formulation's branded generic Glatopa was launched in 2015 by Sandoz
- Prior to Glatopa's launch, Teva released and promoted a long-acting Copaxone 40MG, effectively pushing existing and new patients to the branded 40MG and minimizing generic substitution
- As part of Copaxone's life-cycle management and preparing for its LoE, Teva is interested in contracting strategy optimization

Project Objectives

- The primary objective for the project is to assist Teva in understanding payer control across therapeutic areas – namely Multiple Sclerosis (MS), Rheumatoid Arthritis (RA), and Type II Diabetes (GLP-1s)
- Our segmentation analysis examines a payer's willingness to control vs. its ability to control utilization, using analog markets to assess risk of increased controls

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By shifting patients to Copaxone 40 mg/ml, Teva reduced its rebate obligations to health insurance plans. Teva’s internal data show that in every year since 2014, the average negotiated payer discount to commercial and Medicare Part D plans for Copaxone 40 mg/ml was lower than Copaxone 20 mg/ml—with the difference in the commercial channel exceeding 10% in some years.¹²³

Teva also avoided paying millions in rebates to Medicaid by shifting of patients to Copaxone 40 mg/ml. According to data Teva produced to the Committee, between 2014 and

¹²¹ TEVA_HCO_IC_005018280, at Slide 1.

¹²² TEVA_HCO_IC_005045517, at Slide 2.

¹²³ Letter from Kirkland and Ellis LLP, on behalf of Teva Pharmaceuticals Industries, Ltd., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Sept. 25, 2020).

2018, Teva paid Medicaid rebates for Copaxone 20 mg/ml equal to nearly 100% of its list price, due to the inflationary rebates that manufacturers are required to pay when they raise prices.¹²⁴ Over the same period, Teva paid Medicaid rebates for Copaxone 40 mg/ml equal to between 23% and 68% of its list price because it was a new product that had not yet increased in price.¹²⁵ Shifting a patient from Copaxone 20 mg/ml to 40 mg/ml allowed Teva to collect from Medicaid between \$1,852 and \$3,569 in additional net revenue, per patient per month.¹²⁶

Teva's internal documents support this conclusion. A September 2015 presentation calculated, "For each unit of Cop 20 converted to Cop 40, Teva saves \$3180 in rebate."¹²⁷ Similarly, in November 2016, a Teva executive estimated that Teva pays a 100% rebate to Medicaid for Copaxone 20 mg/ml but nets "\$2500 on 40mg after rebates."¹²⁸

By shifting patients from Copaxone 20 mg/ml to 40 mg/ml, Teva maintained more than \$3 billion in annual net revenue from 2015 to 2017, despite competition from Sandoz's 20 mg/ml Glatopa.¹²⁹ Researchers at Harvard University estimate that Teva's strategy of shifting patients from Copaxone 20 mg/ml to Copaxone 40 mg/ml prior to generic entry created a 2.5 year delay in generic completion and cost the U.S. health care system between \$4.3 and \$6.5 billion in excess expenditures.¹³⁰

VII. EXCLUSIONARY TACTICS TO LIMIT GENERIC COMPETITION

Documents reviewed by the Committee indicate that Teva implemented several new exclusionary tactics aimed at limiting generic competition and maintaining profits. A presentation to Teva's Board of Directors identified three "Key Activities to Defend Against Generic Erosion."¹³¹ First, Teva contracted with specialty pharmacies and PBMs to limit generic substitution. Second, Teva lobbied doctors to write prescriptions for Copaxone that prohibited generic substitution. Third, Teva used its patient programs to convince patients to remain on the more expensive brand name version of the drug (see Section V above for more information regarding patient programs).¹³²

¹²⁴ TEVA_HCO_IC_005012834

¹²⁵ *Id.*

¹²⁶ *Id.*

¹²⁷ TEVA_HCO_IC_005053396.

¹²⁸ TEVA_HCO_IC_005117117.

¹²⁹ Letter from Kirkland and Ellis LLP, on behalf of Teva Pharmaceuticals Industries, Ltd., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (July 18, 2019).

¹³⁰ Benjamin N. Rome, et al., *US Spending Associated with Transition from Daily to 3-Times-Weekly Glatiramer Acetate*, *Journal of the American Medical Association Internal Medicine* (July 20, 2020) (online at <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2768653>).

¹³¹ TEVA_HCO_IC_005021634, at Slide 4.

¹³² *Id.*

Key Activities to Defend Against Generic Erosion

Brand over Generic (House Brand) Contracting Strategy

- Contracting with major payors, PBMs and pharmacies
- Contracts range from Brand over Generic terms (all 40mg Rx will be switched to Brand), to loyalty allowing access to COPAXONE 40mg alongside generic

Sales force DAW messaging and activities

- Sales force proactively messages to HCP customers the need for “Dispense as Written” on all new Rx and refills
- Working with office accounts to ensure they have the capabilities and resources need to communicate DAW through verbal, written and electronic means

Outbound efforts to 40mg patients through Shared Solutions

- Call center outbound effort to contact all current 40mg patients with active marketing authorization
- Emails to all patients with DAW messaging
- Ability to produce current 40mg patient lists for HCP offices to proactively DAW scripts

Legal pathways also being explored

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4

Through these tactics, Teva successfully defended Copaxone 40 mg/ml’s market share. Nearly two years after Mylan began selling a generic version of Copaxone 40 mg/ml in October 2017, and after Sandoz followed suit by introducing Glatopa in February 2018, Teva reported that it maintained 63% of the market despite Copaxone having a higher list price than its generic alternatives.¹³³

A. “House Brand” Contracting Strategy

Teva responded to generic entry by implementing a “House Brand Strategy” to contract with—and pay rebates to—PBMs and specialty pharmacies to make Copaxone 40 mg/ml the only version of the drug covered or dispensed.¹³⁴ A January 2017 document titled “At-Risk Gx [Generic] Readiness” explained that the strategy would prevent a patient’s insurance plan from covering a generic alternative to Copaxone and prevent a specialty pharmacy from dispensing the generic:

- “2 of the House Brand target accounts will be executed at the formulary level. Blocking the generic via formulary restriction”; and

¹³³ Teva Pharmaceuticals Industries, Ltd., *Third Quarter 2019 Results* (Nov. 7, 2019) (online at https://s24.q4cdn.com/720828402/files/doc_presentations/Teva_Q3-2019_Earnings-Presentation_FINAL.pdf).

¹³⁴ It is Committee staff’s understanding that such contracts required the pharmacy to ensure that patients and health plans are left in the same position as if the prescription had been filled with the generic. *See, e.g.*, TEVA_HCO_IC_005119478 (February 2018 contract with a specialty pharmacy).


- “2 of the House Brand target accounts will be executed at the specialty pharmacy level. Pharmacy will fill brand regardless if prescribed as generic.”¹³⁵

Market Access Update

- House Brand Accounts:
 - Contracting Strategy for Brand over Generic. Discussions have taken place with these designated accounts.
 - 2 of the House Brand target accounts will be executed at the formulary level. Blocking the generic via formulary restriction.
 - 2 of the House Brand target accounts will be executed at the specialty pharmacy level. Pharmacy will fill brand regardless if prescribed as generic.

- Loyalty Accounts:
 - Contracting for continued formulary access, without any step edits through Gx. These plans may decide to add Gx to their formulary. Assume modest increases in rebate for this strategy (1-5 points)
 - HCP loyalty and DAW strategy will help retain many of these branded units.
 - Assumed retention of 50% of 40mg units

11 3-TIMES-A-WEEK 40 mg/mL



When Mylan received FDA approval on October 3, 2017, to bring its generic version of Copaxone to market, Teva immediately began executing the House Brand Strategy. On October 26, 2017, General Manager of Teva Neuroscience John Hassler notified Teva CNS CEO Larry Downey: “Two weeks post generic approval, the team has had early success in achieving key Brand Over Generic goals,” and “45% of units have been targeted via House Brand Agreements.”¹³⁶

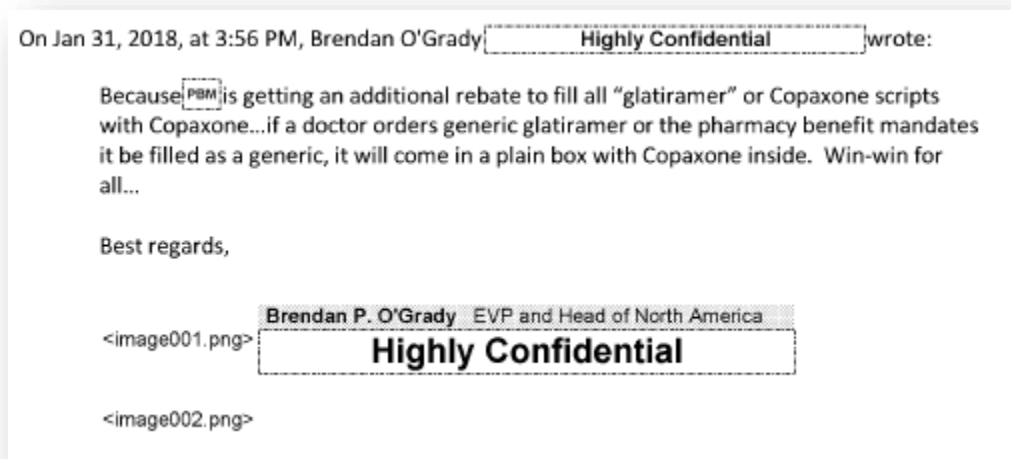
In a series of emails in January 2018, Teva’s Executive Vice President for North America, Brendan O’Grady, explained how Teva’s House Brand agreement with a specialty pharmacy was successfully preventing generic competition. An employee asked Mr. O’Grady whether Teva’s position would be harmed by a health insurer decision to place Copaxone 40 mg/ml on more restrictive tiers on commercial and Medicare Part D formularies, in favor of generic alternatives. Mr. O’Grady responded that the insurer’s decision had “almost zero impact on actual prescriptions.” At the time, the insurer’s patients accessed Copaxone through a

¹³⁵ TEVA_HCO_IC_005035591, at Slide 11.

¹³⁶ TEVA_HCO_IC_005001334.

specialty pharmacy, which is wholly owned by a pharmacy benefit manager. According to Mr. O’Grady:

Because [PBM] is getting an additional rebate to fill all ‘glatiramer’ or Copaxone scripts with Copaxone ... if a doctor orders generic glatiramer or the pharmacy benefit mandates it be filled as a generic, it will come in a plain box with Copaxone inside. Win-win for all¹³⁷



Earlier in the email, a Teva executive had warned subordinates that the contract with [specialty pharmacy] should “not be formally shared with the sales team” because of the “confidential nature of the [specialty pharmacy] House Brand strategy.”¹³⁸

¹³⁷ TEVA_HCO_IC_005002063 (ellipses in original). Committee staff accommodated Teva’s request for redactions of the specific PBM, specialty pharmacy, or payor in the email.

¹³⁸ *Id.*

In follow-up to our discussion on this topic from last Friday's call, [REDACTED] the COPAXONE brand team, [REDACTED] and I agreed that the house brand strategy with [REDACTED] Specialty Pharmacy that impacts this formulary change should not be formally shared with the sales team. We did agree, however, to communicate this detail with [REDACTED] and the ASDs personally - which I completed yesterday. I also confirmed with the COPAXONE IC team that representatives WILL get credit for scripts getting filled with the brand at [REDACTED] Specialty Pharmacy through [REDACTED] Insurer

When supporting the TN sales force on this coverage change, please align to the confidential nature of the [REDACTED] Specialty Pharmacy House Brand strategy and encourage representatives to use DAW as their reactive response in the field.

Don't hesitate to reach out to [REDACTED] or me if you would like to discuss further.

Best regards,

By April 2018, Teva had entered into House Brand Agreements with a number of PBMs for Medicare and commercial patients. Some of these agreements blocked generics from formularies while others replaced generics at the specialty pharmacy.¹³⁹

B. “Dispense as Written” Campaign

Pharmacists are permitted to substitute brand-name drugs with lower-cost generic versions if patients consent.¹⁴⁰ However, doctors can prohibit substitutions by writing “Dispense as Written” (DAW) on prescriptions.¹⁴¹ In response to the introduction of generics, Teva lobbied doctors to write DAW on prescriptions of Copaxone to prevent generic substitution. Teva’s DAW campaign limited generic market share, despite their lower prices.

Teva’s strategy documents identified the DAW campaign as a key tactic to limiting generic competition. In the months leading up to Mylan’s 40 mg/ml generic entering the market, Teva began encouraging physicians to: “Prescribe Copaxone DAW for new and existing patients.”¹⁴² Teva also leveraged its patient support program, “Shared Solutions,” to push the DAW campaign on patients. According to an internal analysis in August 2017, DAW was written on 87% of Copaxone 40 mg/ml prescriptions requested through Teva’s “Shared Solutions Copaxone Prescription Service Request Form.”¹⁴³

¹³⁹ TEVA_HCO_IC_005007799, at Slides 2-3.

¹⁴⁰ Yan Song and Douglas Barthold, *The Effects of State-Level Pharmacist Regulations on Generic Substitution of Prescription Drugs*, Health Economics (Nov. 2018) (online at [ncbi.nlm.nih.gov/pmc/articles/PMC6172151/pdf/nihms975944.pdf](https://pubmed.ncbi.nlm.nih.gov/pmc/articles/PMC6172151/pdf/nihms975944.pdf)) (summarizing state generic substitution laws).

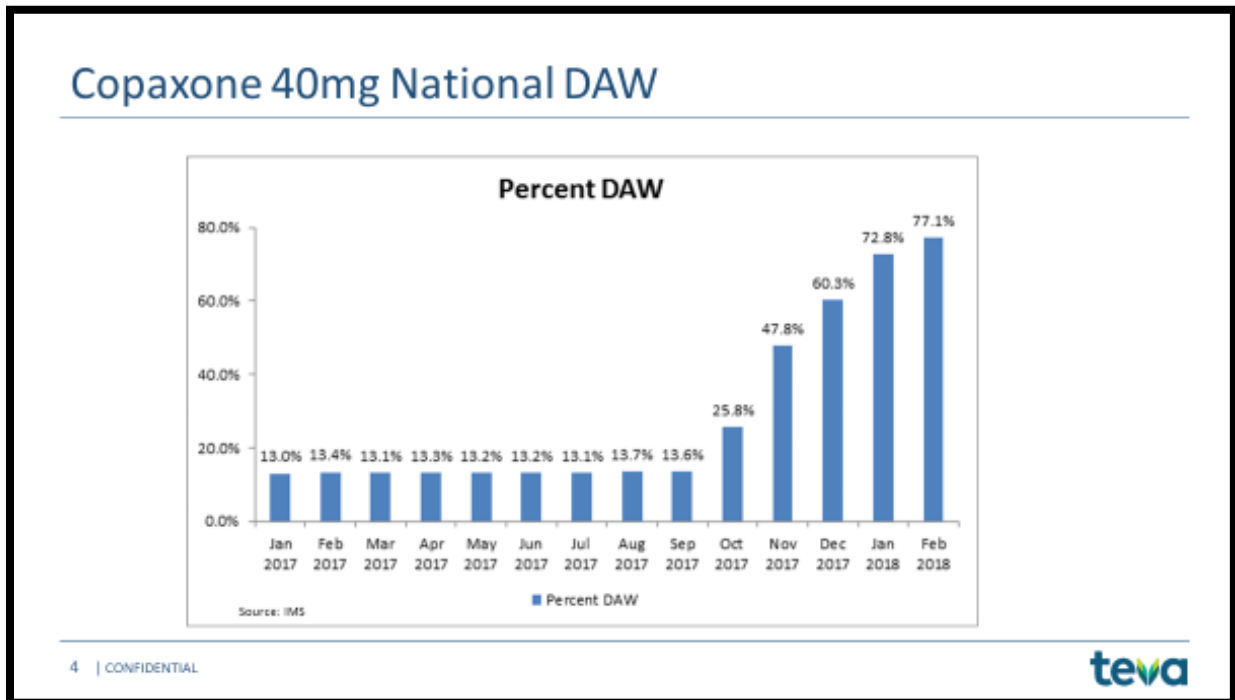
¹⁴¹ William H. Shrank, et al., *The Consequences of Requesting “Dispense as Written,”* American Journal of Medicine (Apr. 2011) (online at https://scholar.harvard.edu/files/nkc/files/2011_dispense_as_written_am_j_med.pdf).

¹⁴² TEVA_HCO_IC_005102935, at Page 10.

¹⁴³ TEVA_HCO_IC_005002781.

When Mylan’s generic entered the market in October 2017, Teva intensified its DAW campaign. In a presentation to Teva’s Board of Directors, executives emphasized that they would engage in “Outbound efforts to 40mg patients through Shared Solutions,” including sending “Emails to all patients with DAW messaging.” The executives also touted their “Ability to produce current 40mg patient lists for HCP [Health Care Professional] offices” to “proactively” write DAW on prescriptions.¹⁴⁴

Teva’s DAW campaign changed doctors’ prescribing patterns. By February 2018, 77% of Copaxone prescriptions were written with the “DAW” notation.¹⁴⁵



In August 2018, Executive Vice President for North America Brendan O’Grady congratulated his team on the success of the DAW strategy:

Keep up pressure on Copaxone and maximize office calls up to the launch of [Another Teva Product]. The DAW campaign combined with the legacy and house brand access strategy has paid great dividends. I want to exceed \$1.5b for the year on Copaxone. We did \$900m in H1 so we only need to do \$500m+ in H2 to accomplish this goal.¹⁴⁶

¹⁴⁴ TEVA_HCO_IC_005021634.

¹⁴⁵ TEVA_HCO_IC_005007799, at Slide 4.

¹⁴⁶ TEVA_HCO_IC_005127231.

Teva achieved Mr. O’Grady’s goal. In 2018, the company collected \$1.6 billion in net revenue for Copaxone despite competition from generics.¹⁴⁷

VIII. COSTS DO NOT JUSTIFY PRICE OF COPAXONE

A. Rebates and Manufacturing

The pharmaceutical industry often attributes price increases to rebates, discounts, and other fees provided to PBMs and other third parties within the distribution chain.¹⁴⁸ Teva’s internal data, however, suggest that its decades of price increases for Copaxone cannot be attributed to growing rebates or discounts provided to PBMs, pharmacies, health insurance plans, employers, or other payers.

The average net price per unit of Copaxone—the amount of money the company makes on the drug after all rebates—increased for both the 20 mg/ml and 40 mg/ml doses of Copaxone from 2009 to 2017. This rise ended only after Mylan introduced its 20 mg/ml and 40 mg/ml generics.¹⁴⁹

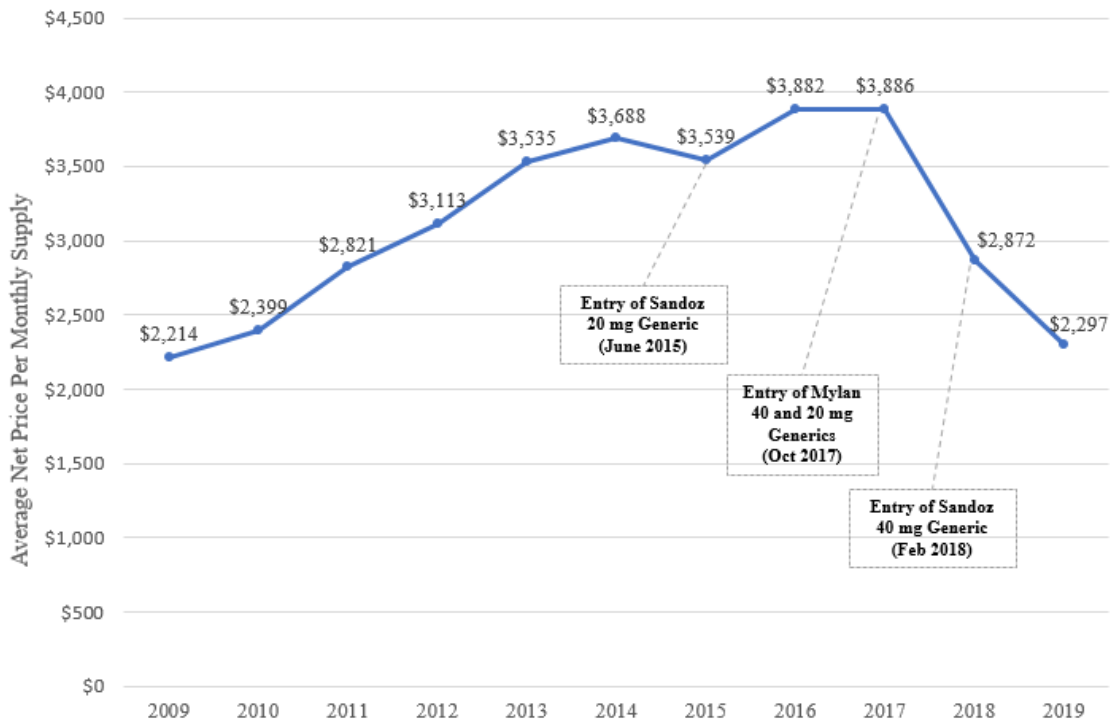
¹⁴⁷ Letter from Kirkland and Ellis LLP, on behalf of Teva Pharmaceuticals Industries, Ltd., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (July 18, 2019).

¹⁴⁸ See Pharmaceutical Research and Manufacturers of America, *Let’s Talk About Cost* (online at www.letstalkaboutcost.org/).

¹⁴⁹ Letter from Kirkland and Ellis LLP, on behalf of Teva Pharmaceuticals Industries, Ltd., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Aug. 25, 2020); Letter from Kirkland and Ellis LLP, on behalf of Teva Pharmaceuticals Industries, Ltd., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (July 18, 2019).

Figure 7 below shows the average net price per unit for Copaxone between 2009 and 2019.

Figure 7: Net Price Per Unit Increased Until Generic Entry¹⁵⁰



Teva cannot attribute its price increases for Copaxone to the cost of manufacturing the drug. According to internal data, Teva’s cost of goods sold for Copaxone is miniscule—between 0.5% and 3% of the net price of the drug.¹⁵¹ From 2013 to 2018, Teva’s costs to manufacture Copaxone declined significantly while Teva increased the list price of Copaxone 20 mg/ml by \$2,053 per month and the list price of Copaxone 40 mg/ml increased by \$1,190 per month.¹⁵²

B. Research and Development

Teva has attempted to defend its Copaxone price increases by claiming that they are needed to fund future research and development (R&D). For example, in October 2016, Teva

¹⁵⁰ Letter from Kirkland and Ellis LLP, on behalf of Teva Pharmaceuticals Industries, Ltd., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Aug. 25, 2020).

¹⁵¹ Letter from Kirkland and Ellis LLP, on behalf of Teva Pharmaceuticals Industries, Ltd., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (July. 18, 2019); Letter from Kirkland and Ellis LLP, on behalf of Teva Pharmaceuticals Industries, Ltd., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Aug. 9, 2019).

¹⁵² IBM Micromedex Redbook, *Wholesale Acquisition Cost and Average Wholesale Price History for Copaxone*. Letter from Kirkland and Ellis LLP, on behalf of Teva Pharmaceuticals Industries, Ltd., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Aug. 9, 2019).

developed talking points directing executives to emphasize that the price of Copaxone “reflects the clinical utility of the drug, while maintaining [Teva’s] commitment to ongoing clinical research.” The talking points instructed executives to argue that Teva’s prices increases are justified because the company continues “to invest in researching new developments that directly translate to increased options for Copaxone patients.”¹⁵³

Contrary to Teva’s talking points, the company was unable to identify any R&D expenditures related to Copaxone after 2015.¹⁵⁴ In fact, internal data show that Teva invested only a small portion of its Copaxone revenue in further R&D to help Copaxone patients.

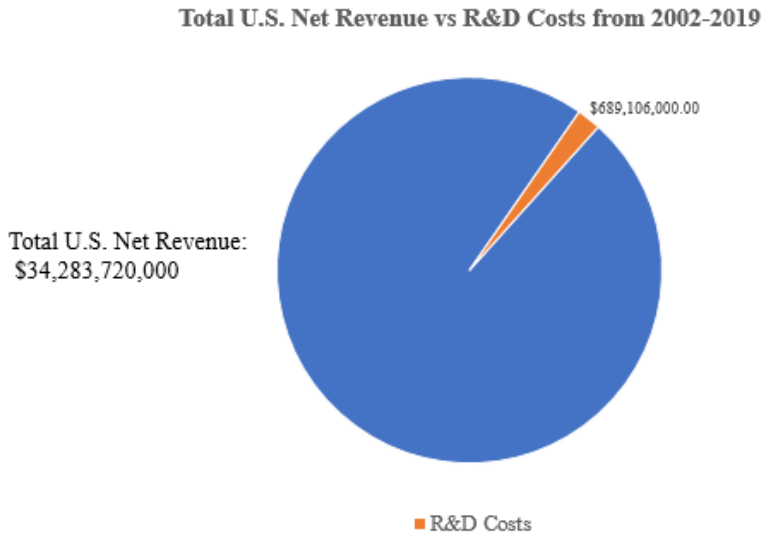
Figure 8 below reflects Teva’s total R&D expenditures for Copaxone compared to its net U.S. revenue for the drug. Teva identified a total of \$689 million R&D expenditures related to Copaxone since 1987—only 2% of its \$34.2 billion in net U.S. revenue of Copaxone from 2002 to 2019.¹⁵⁵

¹⁵³ Bates No. TEVA_HCO_IC_005000887, at Page 5.

¹⁵⁴ Letter from Kirkland and Ellis LLP, on behalf of Teva Pharmaceuticals Industries, Ltd., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Aug. 9, 2019); Letter from Kirkland and Ellis LLP, on behalf of Teva Pharmaceuticals Industries, Ltd., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Aug. 25, 2020) (“Teva is writing to confirm that it had no additional Copaxone research and development expenditures other than those identified in our prior letter.”).

¹⁵⁵ Letter from Kirkland and Ellis LLP, on behalf of Teva Pharmaceuticals Industries, Ltd., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Aug. 9, 2019); Letter from Kirkland and Ellis LLP, on behalf of Teva Pharmaceuticals Industries, Ltd., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (July 18, 2019); Teva Pharmaceuticals Industries, Ltd., *Annual Reports (Forms 10-K or 20-F) 2002-2019* (online at <https://ir.tevapharm.com/financials/sec-filings/default.aspx>).

Figure 8



A 2016 internal presentation to the Science and Technology Committee of Teva’s Board of Directors confirmed that Teva spent the least on R&D among all major pharmaceutical companies.¹⁵⁶

Benchmarking our budget and multiples

	R&D Budget (Est. 2015 \$M)	R&D Budget (2015 % of Rev)	EPS (Est. 2015)	Multiples (Est. 2015) ↓
UCB	1,116	26.6%	1.9	48.4
Novo Nordisk	2,214	13.5%	2	28.4
Celgene	2,394	25.9%	4.1	28.3
Eli Lilly	4,821	24.0%	3.3	24.6
Roche	8,380 (2014)	21.5%	15	19.1
Biogen	2,093	19.4%	16	18.5
GSK	4,802	12.8%	1.2	18.3
Bayer	2,283 (2014)	15.6%	7.9	17.4
Novartis	7,331 (2014)	22.4%	5.3	16.9
J&J	6,213 (2014)	19.2%	6.3	16.3
Pfizer	7,510	15.8%	2.1	16
Sanofi	5,864 (2014)	14.3%	6.3	15.4
Merck	6,744	16.7%	3.6	15.2
Abbvie	3,630	15.8%	4.3	15
Teva (specialty)	897	10.0%	5.4	11.2
AstraZeneca	5,211	22.5%	4.1	7.8

Source: EvaluatePharma (where indicated, 2014 data was used due to lack of separate forecast for pharma segment)

¹⁵⁶ TEVA_HCO_IC_005178747, at Slide 3.

IX. CONCLUSION

Teva's price increases and business practices for Copaxone are not unique. During President Trump's first term, drug companies have continued to aggressively raise prices. A recent report found that drug companies have raised list price of over 600 single-source brand name drugs by a median 21.4% between January 2018 and June 2020.¹⁵⁷

The Committee's investigation makes clear that without significant structural reforms like Medicare negotiation, the pharmaceutical industry will continue to raise prices on critical and lifesaving medications, and many Americans will remain unable to afford their prescriptions.

¹⁵⁷ See State of California, Office of Statewide Health Planning and Development, *Prescription Drug Wholesale Acquisition Cost (WAC) Increases* (Aug. 17, 2020) (online at oshpd.ca.gov/visualizations/prescription-drug-wholesale-acquisition-cost-increases/).