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
Drug Pricing Investigation

Amgen—Enbrel and Sensipar

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

This staff report describes the actions of Amgen, Inc. in repeatedly raising the price of two drugs: Enbrel and Sensipar. Since 2002, Amgen has been the sole U.S. manufacturer of Enbrel, a drug used to treat rheumatoid arthritis and other painful inflammatory diseases. Enbrel is one of the world’s most profitable drugs. From 2004 until 2018, Amgen was also the sole U.S. manufacturer of Sensipar, a drug approved to help decrease high levels of calcium in the body due to kidney failure and parathyroid cancer.

This staff report is based on the Committee’s review of more than 400,000 pages of internal communications and data related to Enbrel and Sensipar from 2009 to the present. This staff report focuses on Amgen’s pricing practices, business strategies to maximize sales, and tactics it uses to minimize generic competition.

- **Uninhibited Price Increases**: Since acquiring the rights to Enbrel in 2002, Amgen has raised its price 27 times, including by nearly 30% within one 12-month period. A 50 mg dose of Enbrel is now priced at $5,556 per month, or $72,240 annually—a 457% increase from the date Amgen acquired the drug. Amgen also has raised the price of Sensipar more than 20 times since launching the drug in 2004. These price increases have inflated the cost of a typical yearly course of Sensipar from $2,956 in 2004 to $9,814 today.

- **Corporate Profits Driven by Price Increases**: From 2009 to 2019, Amgen reported more than $57 billion in net U.S. revenue from Enbrel and Sensipar. Amgen’s net U.S. revenue for Enbrel increased from $1.25 billion in 2003 to more than $5 billion in 2019. Amgen’s net U.S. revenue for Sensipar also rose from $36 million in 2004 to a peak of $1.4 billion in 2018. Amgen’s price increases for Enbrel and Sensipar fueled its profitability. The company’s net income has grown nearly every year since it began selling Enbrel, including $7.8 billion in net income in 2019.

- **Pricing Decisions Driven by Revenue Targets**: Internal communications show that pricing decisions by Amgen executives—including Executive Vice President Anthony Hooper—were driven primarily by the need to meet increasingly aggressive revenue targets. For example, Amgen increased the price of Sensipar by 8% in January 2017 after concluding that forgoing the price increase would cost the company $58 million in net revenue. In 2017, Mr. Hooper pressed his team to consider larger price increases for the next year due to concerns about “how strong the erosion” was in Enbrel’s net revenue forecast. Amgen increased the price of Enbrel by 9.7% on January 1, 2018, which allowed the company to meet its goal of collecting $4.8 billion in Enbrel net U.S. revenue.

- **Executive Compensation System Incentivizes Price Increases**: Amgen’s price increases for Enbrel and Sensipar led to higher bonuses for its executives. In 2017 and 2018, Amgen’s top executives collected $90 million in compensation. When executives raised prices on Enbrel and other drugs to meet net revenue projections, this in turn ensured that they would also receive their bonuses. For instance, Mr. Hooper’s decision to take a higher-than-planned price increase for Enbrel in January 2018 enabled Amgen
to barely hit its $4.8 billion revenue target for that year. Mr. Hooper, in turn, received incentive compensation of nearly $1.8 million for the year, supplementing his base salary of $1 million and stock and option awards worth almost $4 million. In 2018, Amgen CEO Robert Bradway received incentive compensation of nearly $4 million, supplementing his base salary of $1.5 million and stock and option awards worth almost $12.4 million.

- **Lack of Medicare Negotiation Costing Taxpayers Billions of Dollars:** U.S. law prohibits Medicare from negotiating directly with drug companies to lower prices. According to Amgen’s internal data, Medicare spent more than $3.35 billion on Enbrel and Sensipar between 2013 and 2015 even after rebates from Amgen. If Medicare had been receiving the same discounts as the Department of Veterans Affairs or Department of Defense—which are permitted to negotiate directly for lower prices—taxpayers would have saved more than $3.6 billion between 2013 and 2018.

- **Higher U.S. Prices:** Enbrel and Sensipar are much more expensive in the United States than in other countries that negotiate directly to lower drug prices. In 2017, Enbrel’s U.S. price was thousands of dollars more per month than in Germany, Canada, the United Kingdom, and the Netherlands. Amgen charges nearly double for Sensipar in the United States as it does in Canada.

- **Shadow Pricing with AbbVie:** Amgen’s primary brand competitor for Enbrel is Humira, AbbVie’s blockbuster biologic treatment for rheumatoid arthritis and other conditions. Instead of pricing Enbrel under Humira’s price to gain market share—as expected in a competitive market—Amgen engaged in “shadow pricing” by consistently following AbbVie’s price increases and using AbbVie’s actions as justification to increase the price of Enbrel. This led to both companies setting higher and higher prices for Enbrel and Humira. For example, shortly after AbbVie increased the price of Humira by 9.7% in January 2018, Amgen executed an identical 9.7% price increase, more than double what it had originally planned.

- **Anticompetitive Tactics to Maximize Profits:** Amgen leveraged the U.S. patent system to limit biosimilar competition for Enbrel and prevented U.S. patients from accessing lower-priced versions of the drug available to patients in other countries. Internal strategy documents indicate that Amgen used minor changes to Enbrel’s design—including a new version of the injection device called Enbrel Mini with Autotouch—to drive sales and limit competition. For Sensipar, Amgen entered into settlement agreements to delay entry of generic equivalents. Amgen also attempted to gain additional market exclusivity for Sensipar by showing that it could be used in children, despite knowledge that the FDA was unlikely to grant approval.

- **Price Increases Not Justified by Rebates:** Internal data show that Amgen’s list price increases for Enbrel outpaced any rebates paid. From 2015 to 2018, price increases allowed the company to maintain net revenue from Enbrel at levels well above 2014, despite the volume of sales declining and total rebates paid increasing. Internal data reviewed by the Committee show that Amgen’s rebates and discounts for Sensipar
remained relatively steady from 2015 to 2018 (between 23% and 29%), while Amgen raised the price of the drug five times. As a result, Sensipar’s yearly net revenue rose by 34% over this period.
Drug Pricing Investigation
Celgene and Bristol Myers Squibb—Revlimid

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

This staff report describes the actions of Celgene Corporation and Bristol Myers Squibb Company in repeatedly raising the price of Revlimid, a critical drug to treat multiple myeloma and other forms of cancer. From 2005 to 2019, Celgene was the sole U.S. manufacturer of Revlimid. In November 2019, Bristol Myers Squibb acquired Celgene and, along with it, the rights to Revlimid.

The Committee has reviewed more than 50,000 pages of internal communications and data from 2009 to the present regarding Revlimid. This staff report focuses primarily on Celgene’s pricing practices before it was acquired, and it provides additional information on Bristol Myers Squibb’s price increases since November 2019.

• **Uninhibited Price Increases:** Since launching Revlimid in 2005, Celgene raised the price of the drug 22 times, from $215 per pill to $719 per pill. After Bristol Myers Squibb obtained the rights to Revlimid last November, it raised the price of Revlimid again, to $763 per pill. Due to these price increases, a monthly course of Revlimid is priced at $16,023 today—more than triple the 2005 price.

• **Corporate Profits Driven by Price Increases:** Due to Revlimid price increases, from 2009 to 2018, Celgene reported over $51 billion in net worldwide revenue from Revlimid, with the U.S. market accounting for $32 billion of that total. Celgene’s net U.S. revenue for Revlimid increased from $1 billion in 2009 to nearly $6.5 billion in 2018. This rise in Revlimid revenue fueled Celgene’s annual profits, which increased from $780 million in 2009 to $4 billion in 2018.

• **Pricing Decisions Driven by Revenue and Earnings Goals:** Internal communications show that pricing decisions made by Celgene executives—including former CEO Mark Alles—were driven almost exclusively by the need to meet company revenue targets and shareholder earnings goals. In one instance, Mr. Alles orchestrated an emergency price increase for Revlimid in 2014 to ensure that Celgene met its quarterly revenue targets. To justify the price increase, Mr. Alles wrote, “I have to consider every legitimate opportunity available to us to improve our Q1 performance.”

• **Executive Compensation System Incentivizes Price Increases:** Celgene’s price increases for Revlimid led directly to higher bonuses for its executives. In 2016 and 2017, Celgene’s top executives earned millions in additional bonuses because of their price increases for Revlimid.

• **Targeting the U.S. for Higher Prices and Lack of Medicare Negotiation:** In internal documents, Celgene highlighted that the U.S. government is prohibited from negotiating directly to lower prices for Medicare beneficiaries. With the federal government unable to negotiate, Celgene targeted the U.S. market for price increases while maintaining or cutting prices for the rest of the world. One presentation described the U.S. as a “highly favorable environment with free-market pricing.”
• **Costs to Taxpayers:** The federal government’s inability to negotiate for a lower price of Revlimid has placed a significant burden on the U.S. health care system and cost taxpayers billions of dollars. From 2010 to 2018, Celgene collected $17.5 billion from Medicare Part D. In 2018 alone, Medicare Part D plans and beneficiaries spent more than $4 billion on Revlimid—the second-highest expenditure of any drug that year.

• **Anticompetitive Tactics to Maximize Profits:** Internal presentations show that Celgene suppressed competition by abusing a government-mandated safety program. Celgene emphasized that it could use the program for the “prevention of generic encroachment.” Celgene also excluded competition by leveraging the U.S. patent system, which Celgene described internally as being far more protective of its monopoly pricing than patent systems in the rest of the world. Celgene’s anticompetitive tactics are estimated to cost the U.S. health care system more than $45 billion through 2025.

• **Price Increases Not Justified by R&D Expenses:** Celgene relied heavily on taxpayer-funded academic research to develop Revlimid, and its internal pricing decisions appear to have been unrelated to past or future investment in research and development. Internal documents suggest that Celgene may have leveraged the high price of Revlimid to inhibit other companies’ cancer research. In discussions about another company, one executive wrote, “Making them spend a lot more on their trials puts financial constraints on their ability to simultaneously fund lots of trials.” Another executive agreed, writing, “Anything we can do to hamper their development would help.”

• **Price Increases Not Justified by Rebates:** Celgene’s internal data undermine the pharmaceutical industry’s claims that price increases are the result of increased rebates, discounts, and other fees provided to pharmacy benefit managers. Celgene paid no negotiated discounts to Medicare Part D plans, and the largest discount it paid in the commercial market was only 5%. Celgene’s average net price per unit of Revlimid—the price of the drug after removing such rebates, discounts, and fees—increased each year the drug has been on the market.
Drug Pricing Investigation
Mallinckrodt—*H.P. Acthar Gel*

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

This staff report describes the actions of Mallinckrodt Pharmaceuticals in acquiring and pricing H.P. Acthar Gel, a drug used to treat a rare infant seizure disorder and other autoimmune and inflammatory disorders. Acthar was approved in 1952 and sold for decades at less than $40 a vial. Today, however, a typical vial of Acthar is priced at $39,864—approximately 140,000% more expensive than when it was approved 68 years ago. Acthar is one of the 20 most expensive medications in the United States. In 2014, Mallinckrodt acquired Questcor Pharmaceuticals, which owned the rights to Acthar.

The Committee has reviewed more than 140,000 pages of internal communications and data from 2014 to 2018 regarding Acthar. This staff report focuses primarily on Mallinckrodt’s acquisition of Questcor and pricing practices for Acthar after acquisition, but it also provides relevant information about Questcor’s pricing and business strategies for Acthar prior to the sale.

- **Uninhibited Price Increases:** Acthar has increased in price by almost 100,000% since Questcor acquired the rights to the drug in 2001. Questcor raised Acthar’s price from $40 a vial to more than $31,000 a vial. Mallinckrodt acquired Questcor in large part because of Acthar’s already high price and has since raised the price of the drug by more than $8,200 per vial—an additional 26% increase. Mallinckrodt executives have attempted to minimize public criticism of Acthar’s price. For example, in June 2018, Mallinckrodt CEO Mark Trudeau directed company leaders to explore the possibility of selling smaller vials of Acthar at a lower price to make the drug seem less expensive. Mr. Trudeau “was razor focused on being able to say” that “‘Acthar cost [sic] 25k not 38k [per vial].’”

- **Corporate Profits Driven by Acthar:** Mallinckrodt generated nearly $6 billion in net sales of Acthar from 2014 through 2019. Sales of Acthar have accounted for nearly one-third of Mallinckrodt’s total net sales from 2017 through 2019.

- **Use of Price Increases to Meet Revenue Goals:** After Mallinckrodt acquired Questcor, the company continued to raise Acthar prices as high as possible to meet financial targets. One executive offered the following assessment of Mallinckrodt’s pricing strategy: “Bottom line is any price increase obviously has positive results. Really comes down to what we are comfortable with externally. Personally I would go high. We will receive the same press regardless within these ranges.” In 2017, Mallinckrodt raised Acthar’s price to compensate for lower-than-expected sales volumes. One Executive Vice President wrote, “The vast majority of the projected growth for Acthar in 2017 will come from price appreciation as opposed to volume growth.” A commercial strategic plan prepared for the Board in 2018 initially referred to Acthar as a “cash cow.” After one executive asked, “do we really want to say ‘cash cow’ to the board?” the company’s Chief Commercial Officer responded, “Instead of ‘cash cow,’ I will replace it with profit maximizer.”

- **Executive Compensation System Incentivizes Price Increases:** Mallinckrodt executives’ annual incentive compensation is linked to each executive’s individual contribution to certain financial measures, including the company’s earnings per share.
and net sales revenue. More than 90% of CEO Mark Trudeau’s direct pay is linked to these performance goals. Mr. Trudeau’s overall compensation has more than doubled since Mallinckrodt acquired Questcor in 2014. Over that same period, Mallinckrodt increased the price of Acthar by more than $8,000 per vial.

**Acquisition Driven by High Price and Profit Margin:** Before acquiring Acthar, Mallinckrodt executives emphasized that Questcor had “adopted aggressive pricing strategy based on Orphan designation”—the Food and Drug Administration’s (FDA) approval for drugs that treat rare diseases with small patient populations. As a result, Acthar was a “premium-priced product” with a “robust cash flow profile” that would enable the company to “Achieve aspirational goals with a single transaction.” Soon after acquisition, Mallinckrodt executives highlighted that Acthar had contributed $123 million towards net sales in just the six weeks since it was acquired. CEO Mark Trudeau explained to investors that Mallinckrodt’s primary goal was to deliver “top-level shareholder returns” by focusing on “highly profitable” specialty drugs and noted that the margins from specialty pharmaceuticals are typically higher than average. In that same briefing, the President of Mallinckrodt’s Autoimmune and Rare Diseases division noted that Acthar “is a product which is approaching $1 billion in revenue; it is growing [sic] double digit rates.”

**Lack of Medicare Negotiation Costing Taxpayers Billions of Dollars:** Because Medicare is prohibited from negotiating directly for lower drug prices, it pays more for Acthar than any other government or commercial payer. In 2018, Medicare Part D plans spent more than $700 million on Acthar—up more than $220 million since 2015 and more than 14 times higher than in 2011. From 2015 to 2018, Medicare spent more than $2.5 billion on Acthar. Internal data show that Mallinckrodt’s discounts to Medicare Part D averaged less than 1% from 2015 through 2018, as compared to approximately 6% for the commercial market and 26.6% for Tricare. If Medicare Part D had received the same discounts as Tricare, taxpayers would have saved $656 million between 2015 and 2018. Mallinckrodt has increasingly relied on Medicare to drive sales revenues for Acthar. An internal draft strategic plan from 2017 noted that Medicare accounted for 50% of Acthar sales for the year to date. Long-term planning documents reveal that Mallinckrodt expects Medicare to contribute even more to Acthar sales in the future—as much as 70-75% by 2025.

**High Price Costing Local Governments:** Acthar’s price has harmed local governments. For example, the cities of Rockford, Illinois, and Marietta, Georgia, each spent approximately $500,000 for a handful of patients to be treated with Acthar. A city official from Marietta, Georgia wrote to Mallinckrodt in 2017: “We can’t sustain this. We have gone over budget and have had to raise the premiums on all of our employees and pre-age 65 retirees because of this one drug. This is maddening.”

**Tactics to Maximize Profits:** When Mallinckrodt acquired Questcor, it expected little to no competition for Acthar—in part because Questcor had also acquired the rights to market Synacthen, Acthar’s closest competitor drug. In researching whether to acquire Questcor, Mallinckrodt’s market assessment concluded that Acthar “will face limited/no competition in future.” In 2017, Mallinckrodt entered into a $100 million settlement with
the Federal Trade Commission (FTC) over Questcor’s acquisition of the rights to Synacthen, which FTC described as intended to “maintain its monopoly pricing” and “forestall future competition.”

- **Marketing to Physicians to Leverage Acthar’s High Price:** In pre-acquisition analysis, Mallinckrodt executives projected that Acthar revenue would grow exponentially if the company maintained the drug’s high price while expanding sales volume in current and new on-label indications. Before acquisition, one consultant emphasized to the company that Acthar’s growth potential for non-orphan indications was “directly linked to, and driven by, size and aggressiveness of specialty sales force.” Company talking points prepared immediately after the acquisition in 2014 emphasized, “We believe that the sales potential for Acthar hasn’t even scratched the surface.” Mallinckrodt drove sales through aggressive marketing to physicians. In September 2019, Mallinckrodt paid $15.4 million to settle Department of Justice (DOJ) claims that Questcor had paid illegal kickbacks to doctors from 2009 through 2013 to induce prescriptions for the treatment of complications from multiple sclerosis.

- **Price Increases Not Justified by R&D:** To justify the price of Acthar, Mallinckrodt claims that it has invested more than $500 million into the drug. Yet, information provided to the Committee shows that Mallinckrodt spent $363 million on research and development (R&D) between 2014 and 2018, while the rest of its investment went to “modernization efforts” focused on improving manufacturing and production. This expenditure is less than 7.3% of the net revenue it received from Acthar during the same period. Mallinckrodt’s R&D expenditures for Acthar are intended to drive prescription volume and support payer reimbursement rather than provide the most clinically useful data. Internally, Mallinckrodt described its R&D (and modernization) as a way to “legitimize the brand” and respond to patient and physician skepticism. Although Mallinckrodt frequently highlights six company-sponsored controlled trials relating to the drug’s efficacy, according to a researcher of pharmacoepidemiology: “These studies will likely not provide the clinically relevant information necessary to support Acthar’s effectiveness over lower-cost treatments.”

- **Price Increases Not Justified by Other Expenses:** Internal data reveal that Acthar’s average net price—the price of the drug after subtracting rebates, distributor fees, and pharmacy price concessions—has continued to increase each year, meaning any rebates or discounts from the list price of the drug were outpaced by the company’s price increases. Manufacturing costs have also remained relatively stable since Mallinckrodt acquired Acthar and are minimal compared to net revenue.

On September 25, 2020, Mallinckrodt announced that it is readying a bankruptcy filing within weeks and talking to creditors about a restructuring plan covering more than $5 billion in debt due to a $1.6 billion global settlement of claims regarding the abusive promotion of highly addictive opioids and a $640 million court ruling that the company failed to pay statutorily-required Medicaid rebates. Yet, directly ahead of Mallinckrodt’s possible bankruptcy filing, the company’s announced on September 1, 2020, that it paid more than $5 million in cash bonuses to its top five executives—in addition to their base compensation. The same executives collected $30.6 million in total compensation in 2019.
Drug Pricing Investigation
Novartis—Gleevec

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

This staff report describes the actions of Novartis International AG in repeatedly raising the price of Gleevec, a drug best known for treating chronic myeloid leukemia, a rare form of cancer of the blood and bone marrow, as well as other cancers and rare diseases. From 2001 to early 2016, Novartis was the sole manufacturer of Gleevec.

This staff report is based on the Committee’s review of more than 100,000 pages of internal documents and data from 2009 to the present, as well as publicly available information. This staff report focuses on Novartis’ pricing strategies, business strategies to maximize sales, and tactics used to minimize generic competition.

- **Uninhibited Price Increases:** Since launching a 400 mg tablet of Gleevec in 2003, Novartis has raised the price of the drug 22 times. A yearly course of Gleevec is priced at more than $123,000 today compared to just under $25,000 in 2003, an increase of more than 395%. Novartis raised the price of Gleevec steadily—and at a steeper rate—as it approached its loss of primary patent exclusivity in early 2016. Between 2010 and 2015, Novartis raised the price of Gleevec 12 times. In 2013 alone, the price increased by 20%.

- **Corporate Profits Driven by Price Increases:** Due to Gleevec price increases, from 2009 to 2019, Novartis collected nearly $14.8 billion in U.S. net revenue for the drug, with U.S. net revenue for Gleevec increasing from $1 billion in 2009 to more than $2.5 billion in 2015.

- **Price Increases Driven by Revenue and Earnings Goals:** Internal communications show that, in order to maximize revenue, Novartis adopted an “Aggressive” pricing strategy that would provide the “greatest upside while keeping single increases below 10% threshold,” a target that appears to have been intended to minimize public pushback. Executives weighed raising prices to meet revenue goals against potential negative public attention triggered by pricing decisions. Internal documents suggest that Novartis executives considered shifting the company’s public message on price increases from justifications based on cost and research and development, to justifications based on the company’s investment in assistance programs that help patients defray the cost of drugs. In discussing a July 2013 price increase, the former Novartis U.S. Country President wrote: “I don’t like the plan on key messages. They are the old, stale, nonimpactful blah blah blah. Suggest the patient access approach with our increasing commitment to copay foundation at $25M, dollar value of PAP [patient assistance programs] etc.”

- **Executive Compensation System Incentivizes Price Increases:** As Novartis raised the price of Gleevec, the company paid its top executives millions of dollars per year. In 2014 and 2015, two years with the highest net revenue from Gleevec, more than 100 Novartis employees were paid more than $1 million. Since Novartis’ compensation plan linked annual incentive compensation to revenue goals, which were driven by sales of Gleevec, Novartis executives were incentivized to consistently raise the price of Gleevec.
• **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, Novartis priced Gleevec in the United States higher than in the rest of the world. In 2015, the price of one month of Gleevec in the United States was more than $10,000, while the average price in other countries was approximately $2,500 per month. Medicare spent hundreds of millions of dollars more on Gleevec each year because of its inability to negotiate directly for lower prices. At its peak in 2015, Medicare spending on Gleevec totaled more than $1.2 billion. From 2011 to 2018, Medicare spent more than $5.6 billion on the drug. If Medicare had received the same discounts on Gleevec that the VA received from 2011 to 2015, taxpayers would have saved more than $2 billion.

• **Tactics to Delay Generic Competition:** Novartis used several anticompetitive tactics to delay generic competition and maintain its profits. First, Novartis undertook regulatory steps to extend its primary base compound patent on Gleevec for 26 months, from May 2013 to July 2015. Novartis also engaged in a practice known as “pay for delay,” where the company struck a deal with the first generic entrant to delay entry of the generic by six months. Although the generic company had initially announced that it would price its generic 30% below the price of Gleevec, the generic company ultimately entered the market at a price just 6.4% lower than Gleevec’s price. Novartis executives hailed this high generic price in an email: “That’s good news.” Experts estimate that these strategies—a six-month delay for generic entry and then a six-month duopoly—resulted in $700 million in excess costs to payers in the one-year period from 2015 to 2016.

• **Strategies to Minimize Competition After Loss of Exclusivity:** As Gleevec approached the end of its patent exclusivity period, Novartis contracted with health plans and pharmacy benefit managers to ensure that Gleevec would be the only version of the drug covered or dispensed, rather than the generic—a strategy referred to as a National Drug Code, or NDC, block. Novartis also lobbied doctors to write prescriptions for Gleevec that prohibited generic substitution and used its patient programs and other customer outreach to convince patients to remain on the brand name version of the drug. In addition, Novartis developed new packaging for the 400 mg tablets and sought to shift patients to this new 30-day blister packaging in January 2015, before the drug began facing lower-priced generic competition. An internal email noted that these strategies exceeded the company’s financial expectations: in 2016, Gleevec sales came in “over $400MM over a stretch budget target of $770MM, retaining nearly 50% o[f] prior year’s nets [sic] sales with a Feb. 1 generic entrant.”

• **Price Increases Not Justified by Rebates:** Novartis’ internal data undermines the pharmaceutical industry’s claims that price increases are the result of increased rebates, discounts, and other fees provided to pharmacy benefit managers. The average net price per unit of Gleevec—the amount of money the company makes on the drug after all rebates—increased year after year for the 400 mg tablet from 2001 to 2015. This rise ended only after a generic version entered the market in 2016.

• **Price Increases Not Justified by R&D:** Novartis reported to the Committee that it had no specific data on R&D expenditures related to Gleevec prior to FDA approval because
“the Company no longer has access to the records reflecting the very significant Gleevec development spend by the Company prior to FDA approval.” Novartis explained that, between 2001 and 2019, its Gleevec developmental costs exceeded $700 million—representing a tiny fraction of Gleevec’s net U.S. revenue during the same time period. For each year from 2009 through 2016, Novartis made more than it spent on Gleevec R&D combined during a 19-year period. Public documents also indicate that Gleevec’s preclinical R&D costs were almost entirely funded by grants from the National Cancer Institute and nonprofit organizations.

- **Profit-Driven Patient Assistance Program:** Patient assistance programs allowed Novartis to reduce patient price sensitivity, and Novartis used its co-payment programs to drive demand, particularly after loss of exclusivity. In a 2013 document, while acknowledging that research had found an association between higher co-pays and reduced adherence or patient abandonment of a drug, Novartis highlighted: “Because oncologic drugs are a necessity for patients, there is less sensitivity to price increases.” While Novartis externally marketed its co-pay programs as ensuring that “every patient who needs Gleevec has access to it,” internal documents indicate that enhanced patient assistance programs were a crucial piece of Novartis’ strategy to mitigate its loss of exclusivity for Gleevec, encouraging patients to stay on the branded drug even after generic entry. Novartis’ internal strategy documents estimated the potential rate of return of its co-pay assistance program at six months prior to the loss of exclusivity was $8.90 for every dollar invested.
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.”
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%.

<table>
<thead>
<tr>
<th>Expense Driver</th>
<th>Budget</th>
<th>ROI (&gt;0 is considered positive)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Assistance</td>
<td>$81M direct</td>
<td>• Returns for commercial patients average 451% with a range of 206% to 761%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Medicare D grants are not included in the assessment</td>
</tr>
<tr>
<td>Sales Force</td>
<td>$41M people related</td>
<td>• 17% short term ROI</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 95% carryover at 6 months</td>
</tr>
<tr>
<td>Patient Services</td>
<td>$14M direct, $17M people related</td>
<td>• $29M invested in 2011 generated $353M with a ROI of 116%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• PAP is not included in this ROI</td>
</tr>
<tr>
<td>Opportunity and</td>
<td>$17M direct</td>
<td>• Not tracked, but assumed similar to Peer to Peer</td>
</tr>
<tr>
<td>Educational Funds</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peer to Peer</td>
<td>$10M direct</td>
<td>• AHM is the surrogate metric</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Average ROI for AHM programs is 70%</td>
</tr>
<tr>
<td>Scientific Communications</td>
<td>$7M</td>
<td>• Not Tracked</td>
</tr>
</tbody>
</table>
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**
---
• **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.