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Drug Pricing Investigation: Novartis--Gleevec

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Drug Pricing Investigation

Novartis—*Gleevec*

Staff Report
Committee on Oversight and Reform
U.S. House of Representatives
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Congress of the United States
House of Representatives

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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 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 Executive Vice President, Head of U.S. Oncology 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.

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I. PRICE INCREASES

Gleevec (imatinib) is an oral medicine used to treat leukemia and other rare forms of cancer and blood disorders. The Food and Drug Administration (FDA) has approved Gleevec for use in adults and children for approximately ten indications, but a significant portion of sales are for treating chronic myeloid leukemia and gastrointestinal stromal tumors.¹ Gleevec is sold in both 400 mg and 100 mg tablets and is taken daily.² Most adult patients with chronic myeloid leukemia take 400 mg of Gleevec indefinitely or the disease will rapidly recur.³

At the time of its approval in 2001, Gleevec was the first targeted treatment for chronic myeloid leukemia. Prior to its introduction, the only treatment options for patients with chronic myeloid leukemia were generalized chemotherapy or bone marrow transplants.⁴ Today, a chronic myeloid leukemia patient in remission after taking Gleevec for two years has the same life expectancy as someone without cancer.⁵

There are now multiple approved treatments for chronic myeloid leukemia, including Novartis' second-generation drug, Tasigna, but Gleevec is still the only FDA-approved imatinib mesylate option for gastrointestinal stromal tumors, and its patent for the indication is set to expire in December 2021.⁶

¹ See Food and Drug Administration, *Approved Label for Gleevec (2001)* (online at www.accessdata.fda.gov/drugsatfda_docs/label/2008/021588s024lbl.pdf). See also Novartis, *Gleevec* (online at www.hcp.novartis.com/products/gleevec/gleevehcp/) (accessed Sept. 30, 2020).

² When Gleevec first launched in 2001, it was offered in 50 mg and 100 mg capsules. The capsules were discontinued in 2003 when Novartis introduced the 100 mg and 400 mg tablets. The 100 mg tablet was intended for remission maintenance and today is presumably used for patients who cannot tolerate the side effects of higher doses. See, e.g., Grezegorz Helbig et al., *A Single Weekly Dose of Imatinib is Sufficient to Induce and Maintain Remission of Chronic Eosinophilic Leukemia in FIP1L1-PDGFR α -expressing Patients*, *British Journal of Hematology* (Mar. 18, 2008) (online at <https://onlinelibrary.wiley.com/doi/full/10.1111/j.1365-2141.2008.07033.x>).

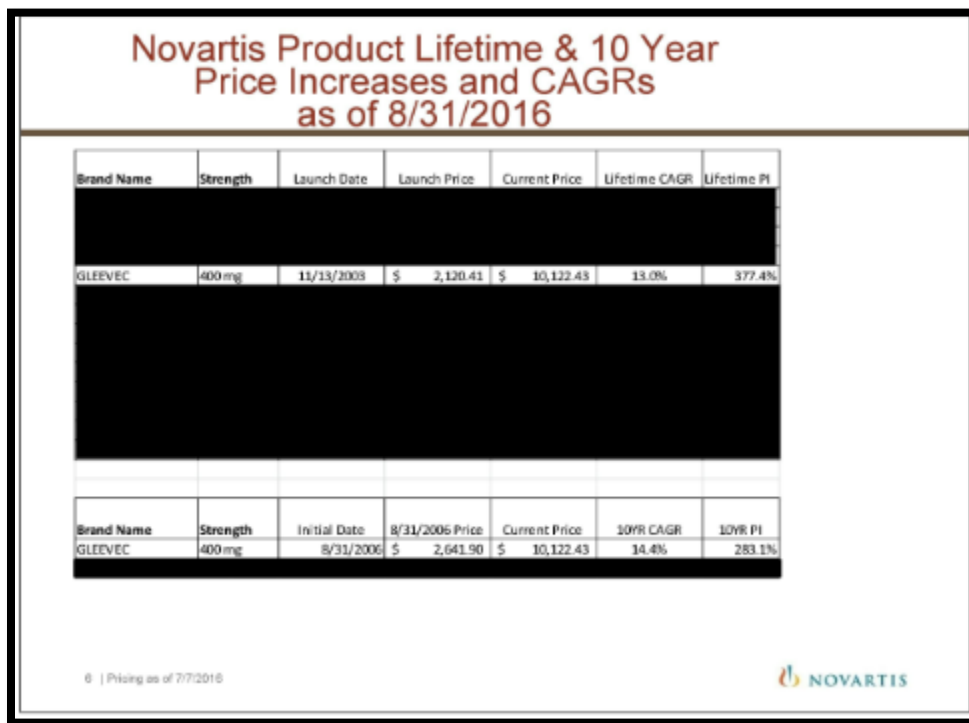
³ D. Russo et al., *Managing Chronic Myeloid Leukemia in the Elderly with Intermittent Imatinib Treatment*, *Blood Cancer Journal* (Sept. 18, 2015) (online at www.ncbi.nlm.nih.gov/pmc/articles/PMC4648524/). The recommended dose of Gleevec depends on the type of disease, the condition of the patient, and patient age. See Food and Drug Administration, *Approved Label for Gleevec (2001)* (online at www.accessdata.fda.gov/drugsatfda_docs/label/2008/021588s024lbl.pdf).

⁴ *Cancer Pill Gleevec Keeps Patients Alive and Well for a Decade*, NBC News (Mar. 9, 2017) (online at www.nbcnews.com/health/cancer/cancer-pill-gleevec-keeps-patients-alive-well-decade-n730951).

⁵ National Institutes of Health, National Cancer Institute, *How Imatinib Transformed Leukemia Treatment and Cancer Research* (Apr. 11, 2018) (online at www.cancer.gov/research/progress/discovery/gleevec).

⁶ CTRL-0025801, at Slide 7. See also Novartis, *2018 Form 20-F* (Jan. 30, 2019) (online at www.sec.gov/Archives/edgar/data/1114448/000104746918000380/a2234185z20-f.htm); Letter from Hogan Lovells, on behalf of Novartis Pharmaceuticals Corporation, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Feb. 4, 2019).

Since launching the 400 mg tablet in 2003, Novartis has raised the price of the drug 22 times.⁷ In 2003, the 400 mg tablet was priced at \$68.16, or \$24,878, for a year of treatment.⁸ Today, a 400 mg Gleevec tablet costs \$337.41, and a typical year of treatment is priced at more than \$123,000.⁹ In one document obtained by the Committee, Novartis executives noted internally that the 400 mg tablet had a compound annual growth rate of 13% as of August 31, 2016.¹⁰



As Gleevec neared the end of its primary patent exclusivity period, Novartis increased its price more rapidly. For example, in 2013 alone, Novartis increased the price of Gleevec by 20%. From January 2014 to July 2015, Novartis increased the price of Gleevec by 32%.¹¹

Figure 1 below shows the price of 100 mg and 400 mg Gleevec per tablet since 2003.

⁷ IBM Micromedex Redbook, *Wholesale Acquisition Cost and Average Wholesale Price History for Gleevec*.

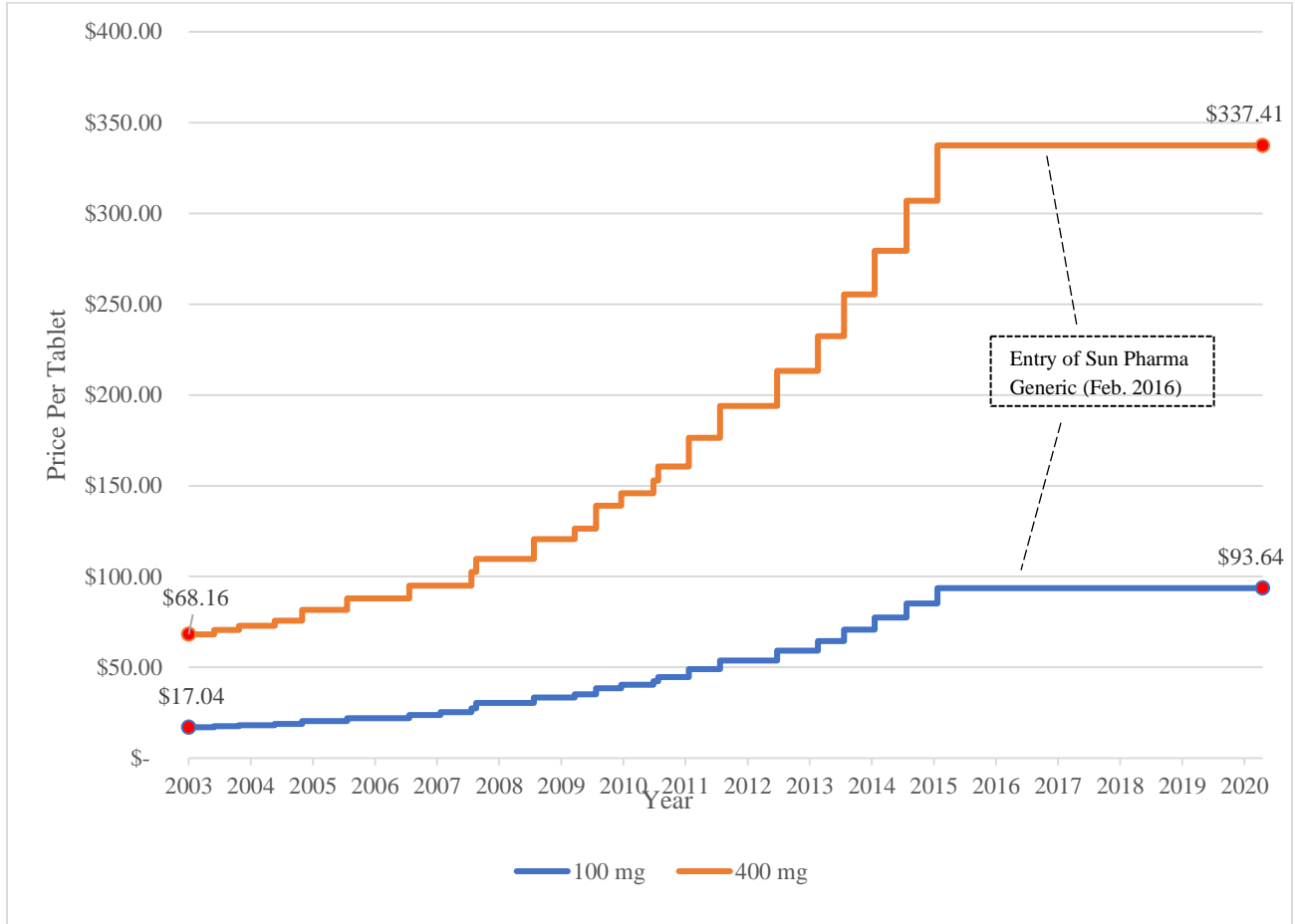
⁸ *Id.*

⁹ *See Id.*; Food and Drug Administration, *Gleevec Label* (online at www.accessdata.fda.gov/drugsatfda_docs/label/2016/021588s047lbl.pdf).

¹⁰ CTRL-0003501, at Page 6.

¹¹ *See IBM Micromedex Redbook, Wholesale Acquisition Cost and Average Wholesale Price History for Gleevec.*

Figure 1: Gleevec Price Increases



II. RISING CORPORATE PROFITS

A. Growing Revenues and Profits

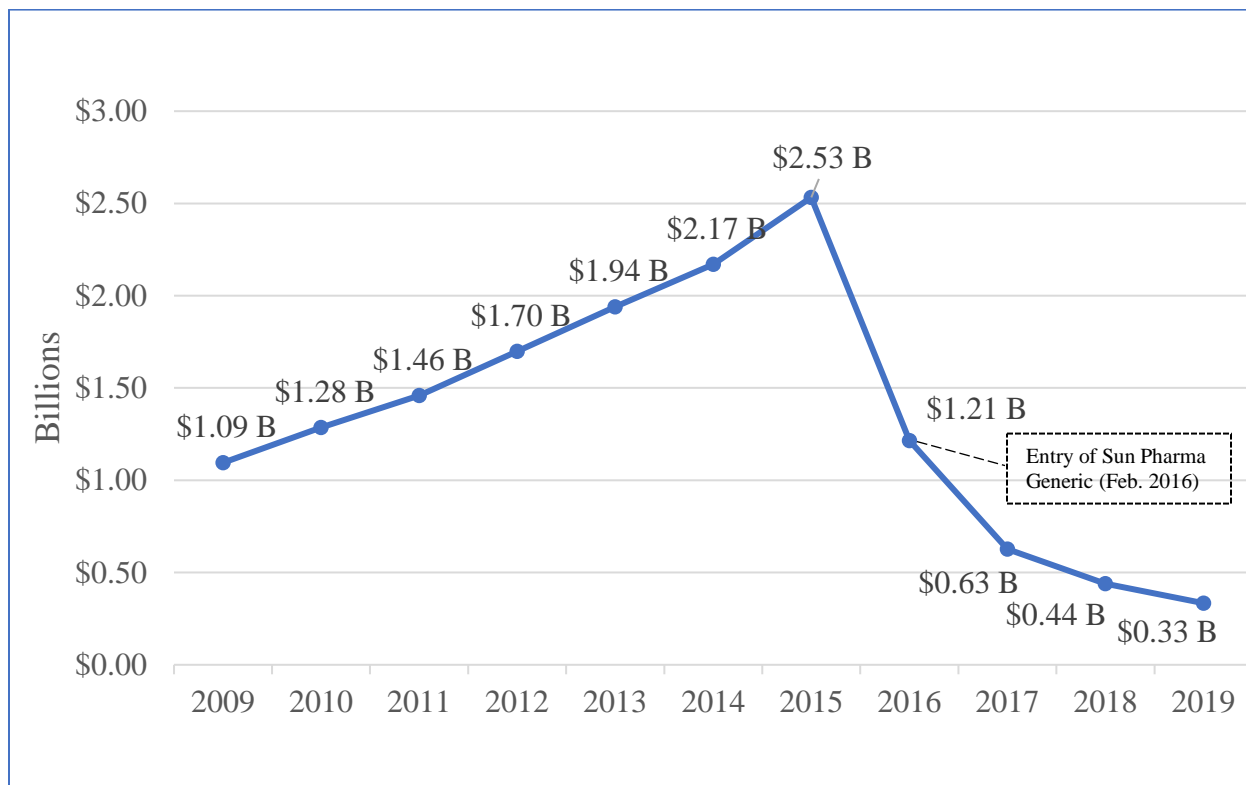
Novartis used its pricing strategy to reap massive profits from Gleevec, contributing significantly to the company’s worldwide revenue. From 2009 to 2019, Novartis reported more than \$39.7 billion in net worldwide revenue from Gleevec, with the U.S. market accounting for nearly \$14.8 billion of that total.¹² Novartis’ net U.S. revenues for Gleevec increased each year

¹² Novartis Incorporated, 2020 Form 20-F (Jan. 29, 2020) (online at www.sec.gov/Archives/edgar/data/1114448/000137036820000003/a20012920f.htm); Novartis Incorporated, 2017 Form 20-F (Jan. 25, 2017) (online at www.sec.gov/Archives/edgar/data/1114448/000104746917000338/a2230622z20-f.htm); Novartis Incorporated, 2014 Form 20-F (Jan. 29, 2014) (online at www.sec.gov/Archives/edgar/data/1114448/000104746914000415/a2217883z20-f.htm#dc19401_3.a_selected_financial_data); NOVARTIS.HCOR20190114.00001017 (net sales is defined as “Total Gross Sales minus contract discounts, rebates, returns, prompt payment discounts, copay card support, and any prior period adjustments related to these items.”).

until the drug lost exclusivity protections in 2016. Novartis reported more than \$2.5 billion in net U.S. revenue from Gleevec in 2015 alone.

Figure 2 below shows Gleevec’s net U.S. revenue over time.¹³

Figure 2: Novartis Net U.S. Revenue



In 2016 and 2017, the two years after Gleevec lost patent exclusivity for the chronic myeloid leukemia indication and began facing generic competition, U.S. net revenue from Gleevec decreased significantly, although the company still earned almost \$2 billion in those years from sales of the drug in the United States, and more than \$5 billion worldwide.¹⁴

B. Price Increases to Meet Revenue Goals

The Committee’s investigation reveals that Novartis’ price increases were based on meeting revenue goals, particularly as the drug approached the loss of its patent exclusivity. In order to maximize revenue, Novartis’ strategy was to increase the price of Gleevec more frequently—and at a steeper rate—as the drug got closer to losing exclusivity. The company

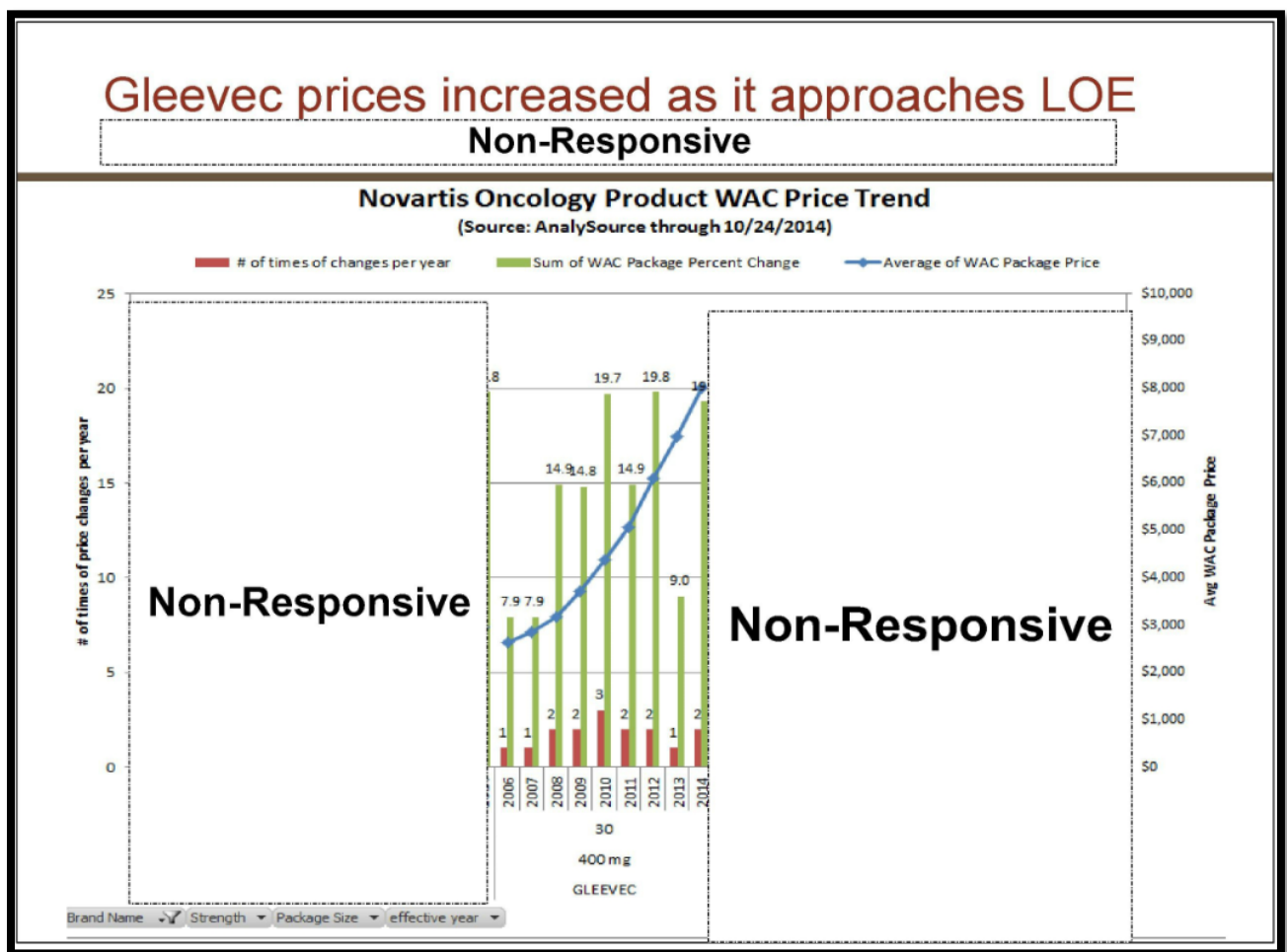
¹³ NOVARTIS.HCOR20190114.00001017.

¹⁴ NOVARTIS.HCOR20190114.00001017; Novartis Incorporated, *2017 Form 20-F* (Jan. 24, 2018) (online at www.sec.gov/Archives/edgar/data/1114448/000104746918000380/a2234185z20-f.htm); Novartis Incorporated, *2016 Form 20-F* (Jan. 25, 2017) (online at www.sec.gov/Archives/edgar/data/1114448/000104746917000338/a2230622z20-f.htm).

anticipated negative public attention from its price increases and strategized ways to minimize negative publicity while still raising prices.

In 2012, three years before Gleevec was expected to lose patent protection, Novartis executives explained the company’s pricing strategy for the drug in the lead up to the loss of exclusivity: “Maximize value of brand prior to LOE [loss of exclusivity].” Executives subsequently recommended a 9.9% price increase, which took effect later in 2012.¹⁵

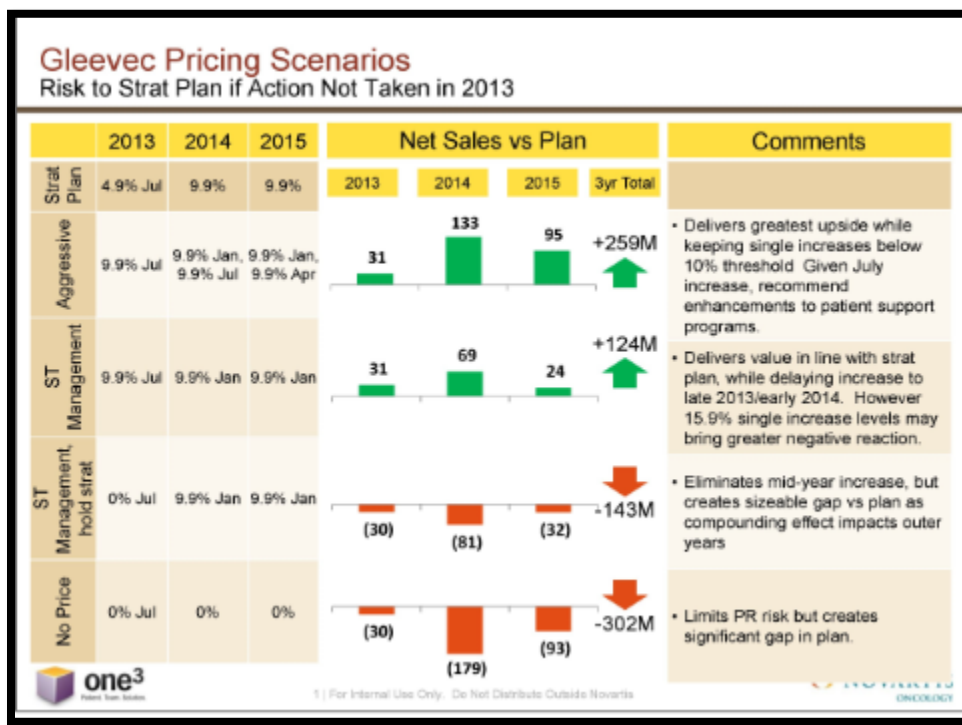
Another internal pricing presentation from October 2014 included a slide titled, “Gleevec prices increased as it approaches LOE [loss of exclusivity],” which highlighted both the number of price increases each year between 2005 and 2014 and the sum of the wholesale acquisition cost (WAC) package percent change each year.¹⁶



¹⁵ CTRL-0096280, at Slide 4. Throughout this report, the term “loss of exclusivity” refers to the time when this primary patent expires.

¹⁶ CTRL-0118195, at Slide 3.

One internal document prepared in 2013, titled “Gleevec Pricing Scenarios, Risk to Strat[egic] Plan if Action Not Taken in 2013,” analyzed a range of Gleevec pricing options for 2013, 2014, and 2015, comparing the impacts of a range of pricing actions on the company’s net sales goals for Gleevec. The analysis estimated that an “Aggressive” pricing model (which contemplated five separate increases of 9.9% from July 2013-2015) would lead to \$259 million of incremental net sales over three years while taking no price increase would result in net sales \$302 million lower than planned. The document concluded, “Aggressive” pricing strategy would provide the “greatest upside while keeping single increases below 10% threshold,” a target that appears to have been intended to minimize public pushback. The “No Price” strategy was described as follows: “Limits PR risk but creates significant gap in plan.”¹⁷



Novartis went with the pricing strategy that would maximize net sales—increasing Gleevec’s price five times between 2013 to 2015 with an average increase of just under 9.9% each time.¹⁸

In an email transmitting a May 29, 2013, “Pricing Board Discussion,” a senior executive wrote that, at the mid-year point, pricing strategies for Gleevec focused on the “need to

¹⁷ CTRL-0007100.

¹⁸ IBM Micromedex Redbook, *Wholesale Acquisition Cost and Average Wholesale Price History for Gleevec*.

maximize value while balancing corporate reputation.”¹⁹ The Pricing Board Discussion slides recommended a 9.9% mid-year price increase.²⁰

Another internal pricing slide deck from October 2014 listed the factors executives considered when making pricing decisions for Gleevec: “1. If the drug is covered under medical benefit; 2. Product price relative to its competitors in the same class; 3. Product actual sales vs. budget; and 4. PR impact.”²¹ The presentation also tracked the price increases for competitor drugs, noting that “annual price increases are generally under 10%.”²² It recommended a price increase of between 6% and 9.9%.²³ In January of the next year, Novartis raised Gleevec’s price by 9.9%.²⁴

C. Justifications Inconsistent with Internal Messaging

Publicly, Novartis has taken the position that pricing decisions for Gleevec are based on the drug’s value to the health care system, cost, and investments in research and development (R&D). For example, talking points from April 2013 addressing questions about Gleevec’s pricing stated: “At Novartis, we price our medications in consideration of the value they bring to patients and society, the growing costs of operating at the highest standards, and significant investments in research and development.”²⁵

But internal documents reviewed by the Committee show that Novartis executives weighed raising prices to meet revenue goals against potential negative public attention triggered by pricing decisions. A 2012 pricing action presentation comparing Gleevec to other drugs on the market asked, “What level of Gleevec price increase is acceptable? Are we prepared for media scrutiny? What messaging/value story will be communicated?” The slide deck went on to note that, with a price increase of 9.9%, the company would “Need to be prepared to respond to external customer/media.”²⁶

¹⁹ CTRL-0017831.

²⁰ CTRL-0017832, at Slide 5.

²¹ CTRL-0118195, at Slide 2.

²² CTRL-0118195, at Slide 4.

²³ CTRL-0118195, at Slide 6.

²⁴ IBM Micromedex Redbook, *Wholesale Acquisition Cost and Average Wholesale Price History for Gleevec*.

²⁵ CTRL-0096027, at Page 1.

²⁶ CTRL-0096280, at Slide 4.

Tsg/Glv Pricing Strategy Discussion

Current Pricing Strategy


- Decrease the pricing gap between Gleevec and Tasigna
 - Recommendation was to only take price increase on Gleevec
- 2013 Budget: 4.9% July Gleevec, none for Tasigna

Discussion Points

1. Does the current pricing strategy apply given the recent market insights?
 - Decreasing Tasigna's premium vs Gleevec was important given our payer strategy
 - Market insight from the recent Gleevec LOE workshop indicated that payers are going to prefer generic Gleevec anyway and that pricing/contracting will not impact decision
2. What level of Gleevec price increase is acceptable?
 - Are we prepared for media scrutiny
 - What messaging/value story will be communicated
3. When should we take a price increase on Tasigna?

Recommendation

- Gleevec: Maximize value of brand prior to LOE-9.9% in July
 - Need to be prepared to respond to external customer/media
- Tasigna: Take smaller (2-3%), more frequent price increases . Could start as early as July.
 - Minimizes pricing gap vs Sprycel if BMS decides not to follow suit and customer/public reaction

 -4-

Executives were particularly concerned about negative public relations after a coalition of chronic myeloid leukemia experts wrote a May 2013 article in *Blood* (the academic journal of the American Society of Hematology) that described the prices of Gleevec and other cancer drugs as “unsustainable” and noted that the price increases for Gleevec, in particular, may have “set the pace for the rising cost of cancer drugs.”²⁷

In response to the *Blood* article, Novartis executives developed a reactive messaging campaign.²⁸ A May 14, 2013, internal presentation, titled “Global Payer Messages in Response to Blood Editorial,” encouraged executives to adopt the following narratives: “Adjusting prices ensures that we continuously reflect the value of the treatment,” and “in pricing our products we take into consideration the scientific innovation they represent, overall medical costs, cost effectiveness and total cost to the healthcare system.”²⁹ The talking points asserted, “There is no

²⁷ Experts in Chronic Myeloid Leukemia, *The Price of Drugs for Chronic Myeloid Leukemia (CML) is a Reflection of the Unsustainable Prices of Cancer Drugs: From the Perspective of a Large Group of CML Experts*, *Blood* (May 30, 2013) (online at <https://ashpublications.org/blood/article/121/22/4439/31343/The-price-of-drugs-for-chronic-myeloid-leukemia>).

²⁸ CTRL-0006511, at Pages 1-3.

²⁹ CTRL-0109843, Slides 4 and 9. A May 2014 document prepared to provide “topline messaging” on Gleevec pricing repeated many of the same messages: “We price our medicine in consideration of the value they bring to patients and society. Other important contributing factors include the significant investment in research, the scientific innovation the product represents, the growing cost of operating at the highest standards, the level of unmet medical need and the clinical value that the drug delivers to patients.” CTRL-0006511, Page 2.

set schedule for adjusting the prices of our medicines.”³⁰ In contrast, documents reviewed by the Committee indicate that Novartis developed a strategy of raising the price of Gleevec by at least 9.9% each year until its loss of exclusivity.³¹

Two weeks later, Novartis’ Vice President and North America Oncology Finance Head sent an email seeking the financial impacts of a number of different pricing scenarios. He wrote:

As you know, we have in our budget a planned price increase actions for Gleevec and [other Novartis product] in July 2013. Given the current situation known by you all, we need to prepare pricing scenarios for discussion with Herve on June 13, 2013. The scenarios should consider not only the economic impact short- and long-term but also the PR impact. We need to prepare pro’s and con’s (financially as well as PR) for the following potential scenarios.³²

Internal documents indicate that Novartis executives also considered shifting the company’s public message on price increases from justifications based on cost and R&D to the company’s investment in assistance programs that help patients defray the cost of drugs. In June 2013, executives developed a stakeholder assessment of upcoming proposed price actions.³³ Under “Public Relations,” the assessment noted: “Heightened risk of media coverage for any mid-year price action on Gleevec and Tasigna following *Blood* article. The assessment also emphasized:

If taking price in CML [chronic myeloid leukemia] this July, should enhance Patient Support Programs to reduce potential patient burden and further develop communication plan to address PR concerns.³⁴

The PR assessment concluded: “Preference is for larger increases (<10%) at lesser intervals rather than several smaller repeated increases throughout year.”³⁵

³⁰ CTRL-0109843, Slide 4.

³¹ *Id.*; IBM Micromedex Redbook, *Wholesale Acquisition Cost and Average Wholesale Price History for Gleevec*.

³² CTRL 0147756, at Page 1.


³³ CTRL-0029114, at Slide 1.

³⁴ *Id.*


³⁵ *Id.*

Stakeholder Assessment of Proposed Price Actions

Public Relations	<ul style="list-style-type: none"> • Heightened risk of media coverage for any mid-year price action on Gleevec and Tasigna following <i>Blood</i> article; less risk for Afinitor. Risk in CML may be less by year end. • <i>If taking price in CML this July, should enhance Patient Support Programs to reduce potential patient burden and further develop communication plan to address PR concerns.</i> • <i>Preference is for larger increases (<10%) at lesser intervals rather than several smaller repeated increases throughout year.</i>
Payers	<ul style="list-style-type: none"> • Low risk that product reimbursement will be negatively impacted in any of the scenarios considered based on relative product value and historical trends of manufacturer mid-year price actions in CML, RCC and Breast Cancer
Patients	<ul style="list-style-type: none"> • Low risk of increased patient out of pocket costs from price increases (XX / % of pts) and largely mitigated by co-pay assistance programs, foundation support or Novartis' Patient Assistance Program. Enhancements to program to address patient gaps recommended.
Providers	<ul style="list-style-type: none"> • Low risk of reduced prescribing; physician concern over price tends to be focused on patient out of pocket cost rather than product list price, most of whom are unaware of price. Should develop key communication messages for field force to address if issue is raised by customer.



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In a further discussion of the planned July 2013 price increase, the Executive Vice President, Head of U.S. Oncology 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."³⁶

From: [REDACTED] CCF: Confidential Commercial & Financial Information

Date: July 12, 2013, 8:16:13 AM CDT

To: [REDACTED]

Cc: [REDACTED] CCF: Confidential Commercial & Financial Information

Subject: Re: For your approval: Gleevec pricing action at end of July

Thanks [REDACTED]

I agree with end of July.

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 etc

[REDACTED]

³⁶ CTRL-0007430.

Novartis took the planned price increase of 9% on August 2, 2013.³⁷

III. EXECUTIVE BONUSES INCENTIVIZE PRICE INCREASES

In 2014 and 2015, the two years that Novartis collected the highest net U.S. revenue from Gleevec, more than 100 Novartis employees earned more than \$1 million each.³⁸ In those years, members of the company's Executive Committee earned a total of more than \$120 million Swiss Francs.³⁹

From 2011 to 2015—the five years prior to loss of exclusivity—members of Novartis' Executive Committee earned a total of more \$429 million.⁴⁰ Novartis' CEO alone earned a total of \$72 million over that period.⁴¹ Figure 3 below represents total executive compensation from 2011 to 2015, the five years prior to loss of exclusivity.

³⁷ IBM Micromedex Redbook, *Wholesale Acquisition Cost and Average Wholesale Price History for Gleevec*.

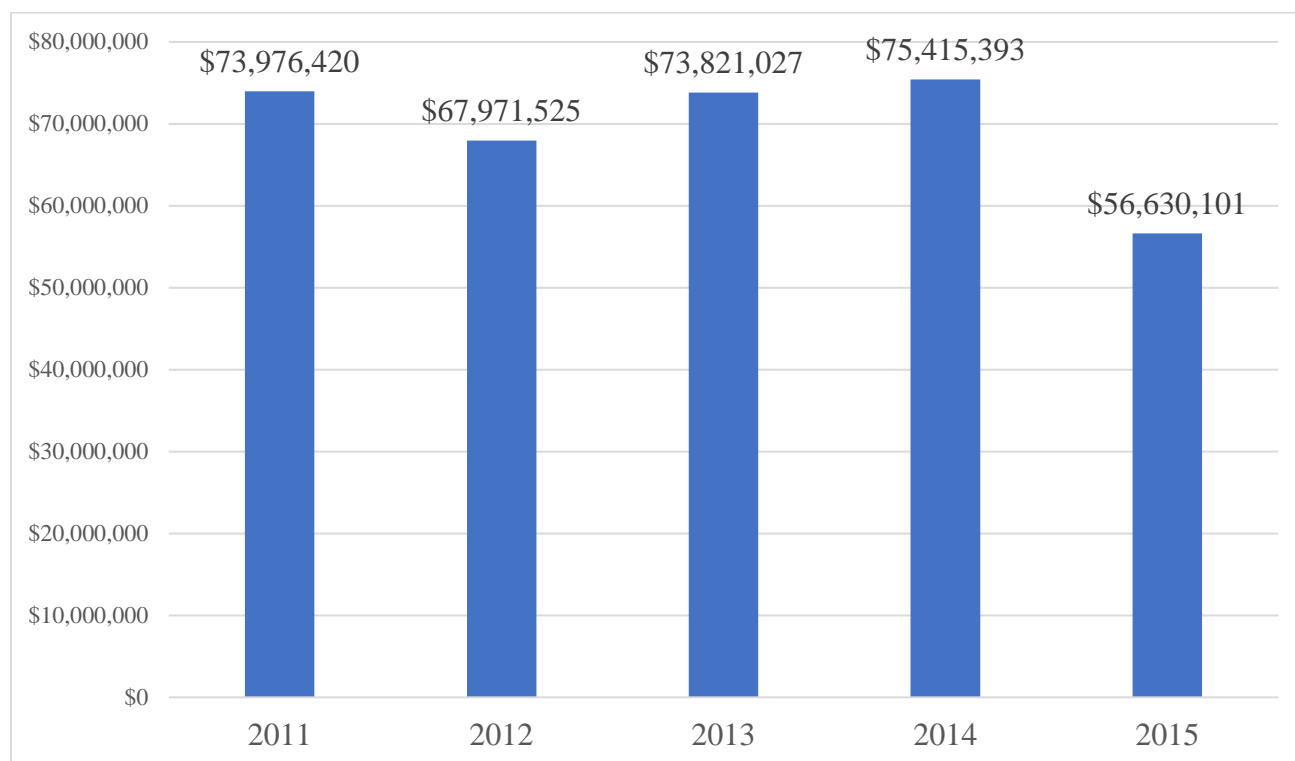
³⁸ Letter from Hogan Lovells, on behalf of Novartis Pharmaceuticals Corporation, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (July 18, 2019).

³⁹ Novartis Incorporated, *2015 Form 20-F* (online at www.sec.gov/Archives/edgar/data/1114448/000104746915000433/a2222787z20-f.htm#6.B); Novartis Incorporated, *2016 Form 20-F* (online at www.sec.gov/Archives/edgar/data/1114448/000104746916009872/a2227040z20-f.htm#aa1).

⁴⁰ Novartis Incorporated., *Annual Reports (Form 20-F) (2011-2015)* (online at www.novartis.com/investors/novartis-annual-reporting-suite/annual-report-and-20-f-archive#ui-id-1=4). The figures are based on Novartis' reporting of aggregate executive compensation for executive officers. Committee staff converted the compensation from Swiss Francs to U.S. dollars using the exchange rate on the date of this report.

⁴¹ *Id.*

Figure 3: Novartis Executive Committee Compensation for 2011-2015⁴²



Novartis reported to the Committee that it does not have any compensation policies related to pricing.⁴³ However, company documents show that Novartis' top executives were incentivized to raise prices for Gleevec. All three forms of variable compensation earned by the CEO and Executive Committee members—annual incentive, long-term performance, and long-term relative performance—are directly related to company revenue, which was driven by Gleevec's price increases.⁴⁴

IV. HIGHER 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.⁴⁵ Unable to negotiate, Medicare paid more for Gleevec than any other government or commercial payer before generic competition entered the market.

⁴² *Id.*

⁴³ *Id.*

⁴⁴ Novartis Incorporated, 2015 Form 20-F (online at www.sec.gov/Archives/edgar/data/1114448/000104746915000433/a2222787z20-f.htm#6.B); Novartis Incorporated, 2016 Form 20-F (online at www.sec.gov/Archives/edgar/data/1114448/000104746916009872/a2227040z20-f.htm#aa1).

⁴⁵ 42 U.S.C. § 1395w-111.

A. Targeting U.S. Market for Price Increases

Novartis priced Gleevec significantly higher in the U.S. than in other countries. In 2015, the price of one month of Gleevec in the United States was more than \$10,000, while the average price of Gleevec in other countries was approximately \$2,500 per month.⁴⁶ One study that compared the prices of cancer drugs around the world from November 2015 to January 2016 found that the price of Gleevec in the U.S. was nearly three times the price of the next highest country.⁴⁷ An internal analysis conducted by Novartis in October 2016 comparing Novartis' pricing for Gleevec around the world noted that Gleevec's price in Canada and Germany was 38% of the U.S. price in 2013 and 39% of the U.S. price in 2016.⁴⁸

Novartis executives expressed concern that U.S. legislative reforms would negatively impact their future revenue. In the days leading up to the 2016 election, the Novartis Board of Directors held a strategy session to discuss drug pricing policy reforms and the impact on Novartis revenue.⁴⁹ Following the Board meeting, analysts prepared a presentation analyzing the impact of three possible policy scenarios: the first scenario anticipated administrative actions and state level initiatives, the second scenario considered U.S. prices referenced to international pricing over time, and the third anticipated an "extreme" scenario in which prices were suddenly reset to German net price levels.⁵⁰ This presentation noted that "Novartis 2020 revenue risk ranges" from over \$1 billion for the first scenario to over \$9 billion with the third scenario.⁵¹ Under scenario two, titled "Major federal level healthcare reform," the presentation estimated that if Novartis were required to report to CMS the prices it charges outside the U.S. for specialty products and bring the U.S. in line with international pricing, Novartis would lose \$2 billion to \$3 billion dollars in revenue in 2020.⁵²

⁴⁶ See IBM Micromedex Redbook, *Wholesale Acquisition Cost and Average Wholesale Price History for Gleevec*; Class Action Complaint, *United Food and Commercial Workers v. Novartis*, 1:15 cv 12732 (D. Mass.) (6/22/2015) (online at www.wexlerwallace.com/wp-content/uploads/2016/08/Gleevec-Antitrust-Litigation-Class-Action-Complaint.pdf).

⁴⁷ Daniel Goldstein et al., *A Global Comparison of the Cost of Patented Cancer Drugs in Relation to Global Differences in Wealth*, *Oncotarget* (May 9, 2017) (online at www.ncbi.nlm.nih.gov/pmc/articles/PMC5641070/).

⁴⁸ CTRL-0130193, Slide 16.

⁴⁹ *Id.*, at Slide 2.

⁵⁰ *Id.*, at Slide 3.

⁵¹ *Id.*

⁵² *Id.*, at Slide 8. As an accommodation, the Committee redacted bottom left corner of the slide, which revealed the methodology of the calculations in the slides.

Scenario 2: Major federal level healthcare reform

Worst case “possible” scenario with very low probability

Potential actions	2020 NVS revenue impact (\$ Billions)
<ul style="list-style-type: none"> • International net price referencing for specialty products. CMS requires companies to self-report US and ex-US net prices for all specialty products; mandates a glide path towards ex-US net prices over a 5-10 year period. <ul style="list-style-type: none"> ➢ Assume implementation begins 2018 	\$2.0 – 3.0 B ¹
<ul style="list-style-type: none"> • Personal importation approved for non-specialty, oral drugs (up to 90 day supply) from select countries beginning in 2019. Assume that ex-US CPOs increase sales from importation, so US business impact is ~2x Novartis Group impact. <ul style="list-style-type: none"> ➢ Assume implementation begins 2019 	\$0.5 - \$0.7 B ²
<ul style="list-style-type: none"> • All actions from Scenario 1 	\$1.5 - \$2.0 B

\$4.0 - \$5.7 B

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B. Costs to Taxpayers and Patients

Novartis’ price increases for Gleevec have imposed significant out-of-pocket costs on U.S. patients. While Novartis has claimed that the majority of chronic myeloid leukemia patients pay less than \$100 out-of-pocket per month for Gleevec, one research study found that the average monthly copayment for a Gleevec patient increased from \$55 per month in 2002 to \$145 in 2010.⁵³ Even using Novartis’ estimates, an average copayment of \$100 a month leaves patients with \$1,200 in yearly out-of-pocket expenses for the drug.

According to the Centers for Medicare and Medicaid Services, in 2011, the average annual out of pocket cost for a Medicare beneficiary on Gleevec was \$3,566.84, or \$297.23 per month—more than three times the average co-payment amount cited by Novartis. By 2015, the

⁵³ See CTRL-0124633, and Stacie B. Dusetzina et al., *Cost Sharing and Adherence to Tyrosine Kinase Inhibitors for Patients with Chronic Myeloid Leukemia*, Journal of Clinical Oncology (Feb. 1, 2014) (online at <https://ascopubs.org/doi/full/10.1200/JCO.2013.52.9123?sid=377543aa-e54e-4834-a1c3-4d3df9ddc833>).

most recent year for which Medicare data is available, the average annual out-of-pocket cost of Gleevec for a Medicare beneficiary had increased to \$4,418.81.⁵⁴

Documents reviewed by the Committee indicate that Novartis, through its Customer Interactions Center, received numerous complaints from patients about Gleevec's high price and requests for assistance in paying for the drug:

- One patient complained that even with private employer-sponsored insurance *and* Novartis' co-payment assistance card, a 30-day supply of Gleevec 400 mg still cost \$1,700.
- One individual trying to help her 91-year-old mother complained that her mother's "old drug plan was discontinued and she chose a plan under which she was told her Gleevec costs would rise from \$400 per year to \$6,000 per year. But now she's actually on the plan, her costs are \$1,600 PER MONTH, which she cannot afford!"
- Yet another complained: "My wife has been using Gleevec for thirteen years, she has GIST. ... Now our medical coverage is stating that we must now pay the \$4,200/mnth and it does not contribute to our deductible. If we are forced to pay the \$4,200/mth [sic] we will have to sell our home because we will not be able to pay the mortgage and the cost of the medication. My wife is precious to me and our three beautiful daughters. Please help."⁵⁵

Novartis' price increases for Gleevec have also placed a significant burden on the Medicare program, and Medicare has been a major source of revenue for the drug. A 2016 presentation prepared by an outside consultant stated, "Medicare is critical to brand success, CMS spent ~\$1 billion on Gleevec in 2014."⁵⁶

At its peak in 2015, Medicare spending on Gleevec totaled more than \$1.2 billion. Generic competition for Gleevec significantly reduced Medicare spending on the drug. But in 2018, three years after Gleevec lost market exclusivity, Part D plans still spent more than \$250 million on Gleevec. Between 2011 and 2018, Medicare spent more than \$5.6 billion on the drug.⁵⁷

⁵⁴ Centers for Medicare and Medicaid Services, *Medicare Part D Spending Dashboard & Data, Historical Data* (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Historical_Data) (accessed Sept. 30, 2020).

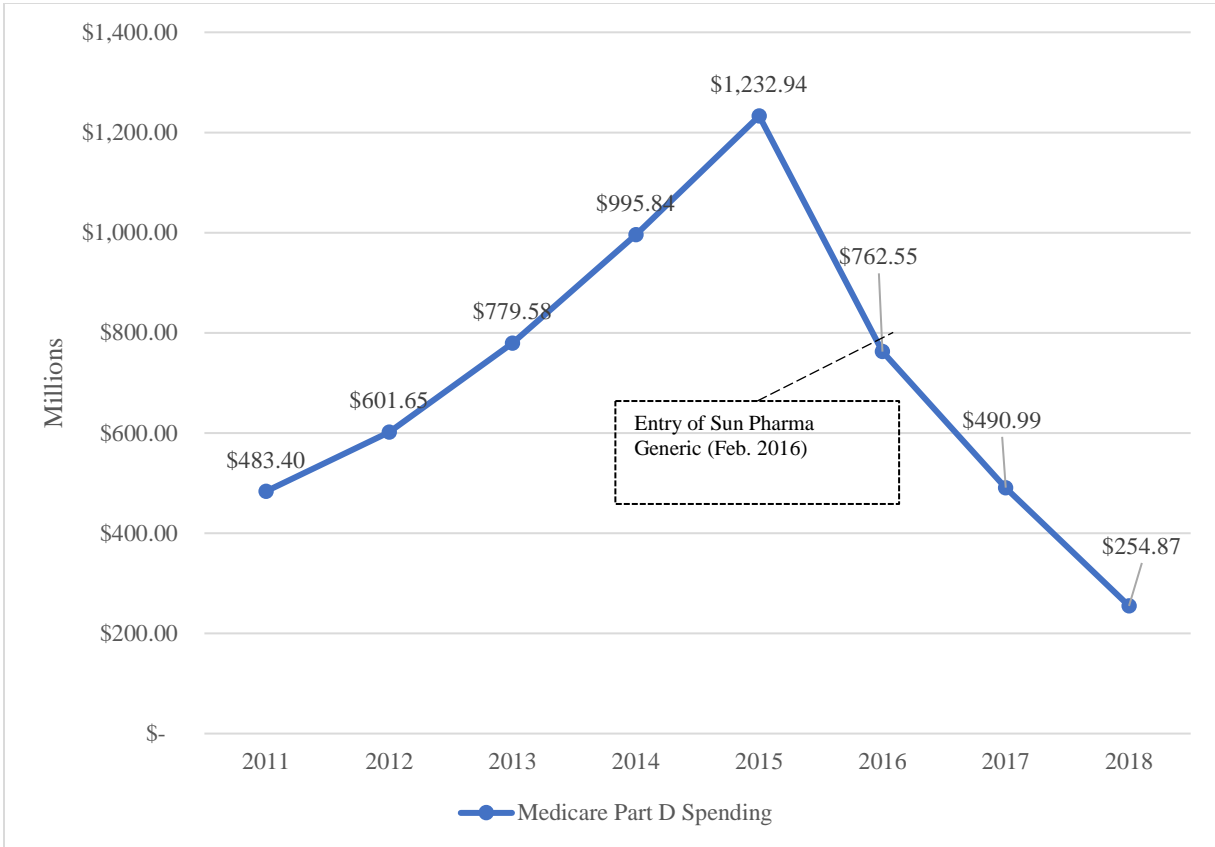
⁵⁵ NOVARTIS.HCOR20190114.00001059.

⁵⁶ CTRL-0124740, at Page 2.

⁵⁷ Centers for Medicare and Medicaid Services, *Medicare Part D Spending Dashboard & Data, Historical Data* (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Historical_Data) (accessed Aug. 13, 2020).

Figure 4 below illustrates the growth in Medicare Part D spending on Gleevec since 2011.

Figure 4: Medicare Part D Spending on Gleevec



Documents reviewed by the Committee indicate that Medicare pays significantly more for Gleevec than any other payer. From 2009 through 2014, Novartis did not offer any negotiated rebates to Medicare Part D plans, and Novartis’ rebate on Gleevec was only 1% in 2015.⁵⁸

Only in 2016, when Novartis began facing generic competition, did the company begin offering higher rebates to Medicare. In contrast, rebates offered to the Veterans Administration (VA), which can negotiate drug prices, averaged 53% in the five years prior to generic entry and Medicaid rebates averaged 80% for those years. If Medicare had received the discounts on Gleevec that the VA received in the five years prior to generic entry, taxpayers would have saved more than \$2.1 billion from 2011 to 2015.⁵⁹

Figure 5 below highlights the differences in these discounts and the potential savings.

⁵⁸ NOVARTIS.HCOR20190114.0001060.

⁵⁹ *Id.*

Figure 5: Lost Medicare Part D Savings on Gleevec

Gleevec						
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
2011	\$483,395,344.12	0.0%	\$ 483,395,344.12	52.0%	\$ 232,029,765.18	\$ 251,365,578.94
2012	\$601,652,852.54	0.0%	\$ 601,652,852.54	51.0%	\$ 294,809,897.74	\$ 306,842,954.80
2013	\$779,575,541.87	0.0%	\$ 779,575,541.87	54.0%	\$ 358,604,749.26	\$ 420,970,792.61
2014	\$995,836,211.55	0.0%	\$ 995,836,211.55	52.0%	\$ 478,001,381.54	\$ 517,834,830.01
2015	\$1,232,939,891.30	1.0%	\$ 1,220,610,492.39	56.0%	\$ 542,493,552.17	\$ 678,116,940.22
Total	\$ 4,093,399,841.38	0.20%	\$ 4,081,070,442.47	53.00%	\$ 1,905,939,345.90	\$ 2,175,131,096.57

V. ANTICOMPETITIVE TACTICS TO MAXIMIZE PROFITS

Gleevec’s history of market dominance and continued high prices resulted, in part, from Novartis’ aggressive tactics to delay the entry of a generic competitor, which resulted in significant costs to purchasers and the health care system.

Gleevec was first approved to treat chronic myeloid leukemia in 2001, with the gastrointestinal stromal tumor indication approval shortly thereafter.⁶⁰ The primary patent on the base compound ingredients in Gleevec was initially set to expire in the United States in May 2013.⁶¹ Typically, generic companies would have entered the market at that time, lowering prices for consumers. However, Novartis leveraged the U.S. patent system to extend its monopoly on Gleevec for nearly three additional years, during which Novartis collected approximately \$6.6 billion in net U.S. revenue from Gleevec.⁶²

To extend Gleevec’s exclusivity period, Novartis filed for patent term restoration on the primary patent.⁶³ This granted additional exclusivity for the length of time the drug was under FDA review, plus one half of the clinical trial testing period. For Gleevec, this resulted in an

⁶⁰ Letter from Richard Pazdur, Director, Division of Oncology Drug Products, Food and Drug Administration, to Robert Miranda, Associate Director of Drug Regulatory Affairs, Novartis Pharmaceuticals Corporation (Apr. 18, 2003) (online at www.accessdata.fda.gov/drugsatfda_docs/appletter/2003/215881tr.pdf); Letter from Robert Temple, Director, Office of Drug Evaluation I, Food and Drug Administration, to Robert Miranda, Associate Director of Drug Regulatory Affairs, Novartis Pharmaceuticals (May 10, 2001) (online at www.accessdata.fda.gov/drugsatfda_docs/appletter/2001/213351tr.pdf). See also *New Drug Fights Second Kind of Cancer*, New York Times (May 14, 2001) (online at www.nytimes.com/2001/05/14/us/new-drug-fights-second-kind-of-cancer.html).

⁶¹ United States Patent and Trademark Office, *Certificate for Extending Patent Term Under 35 U.S.C. § 156* (online at www.uspto.gov/sites/default/files/web/offices/pac/dapp/opla/term/certs/5521184.pdf).

⁶² This figure is estimated based on the fact that generic entry was delayed from May 2013 to Feb. 2016, and net U.S. revenue from Gleevec aggregated across 2013, 2014, and 2015 was \$6.63 billion. Letter from Hogan Lovells, on behalf of Novartis Pharmaceuticals Corporation, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Feb. 4, 2019).

⁶³ United States Patent and Trademark Office, *Patent Terms Extended Under 35 U.S.C. § 156* (online at www.uspto.gov/patent/laws-and-regulations/patent-term-extension/patent-terms-extended-under-35-usc-156).

additional 586 days of exclusivity.⁶⁴ Novartis also filed for and received 180 days of exclusivity in exchange for conducting pediatric trials of the drug.⁶⁵ These strategies extended the exclusivity period for Gleevec's base patent until July 2015.⁶⁶

Subsequently, Novartis filed a number of secondary patents to extend Gleevec's exclusivity period. According to experts at the Initiative for Medicines, Access, and Knowledge, Novartis has filed a total of 73 patents related to Gleevec.⁶⁷ Out of 29 granted patents, 28 are secondary patents, covering alternative forms of the same drug such as the formulation of the drug and methods of treatment.⁶⁸

Novartis also engaged in aggressive patent litigation to delay generic entry, a practice known as "pay for delay." Sun Pharmaceuticals was the first manufacturer to file an application to create a generic version of Gleevec, and followed a common practice of asserting that it was not infringing on the patents held by Novartis because it deemed them invalid.⁶⁹ Instead of litigating the legitimacy of its patents, Novartis entered into a settlement agreement with Sun under which Sun agreed to not market a generic version of Gleevec in the United States until February 1, 2016, and Novartis was able to extend its exclusivity on Gleevec for six months.⁷⁰

In total, Novartis sued at least five companies in order to prevent generic competition for Gleevec, leading to a class action lawsuit alleging that Novartis was engaging in sham

⁶⁴ Christopher Chen and Aaron Kesselheim, *Journey of Generic Imatinib: A Case Study in Oncology Drug Pricing*, *Journal of Oncology Practice* (June 1, 2017) (online at <https://ascopubs.org/doi/full/10.1200/JOP.2016.019737>).

⁶⁵ *Id.*

⁶⁶ *Id.*

⁶⁷ The 73 patents are broken down as follows: 23 non-expired, granted patents; 5 now-expired, granted patents; 1 pending application; and 44 abandoned applications. Initiative for Medicines, Access, And Knowledge, *America's Overspend: How the Pharmaceutical Patent Problem is Fueling High Drug Prices* (Oct. 2017) (online at http://www.i-mak.org/wp-content/uploads/2017/11/Excess-Costs-Briefing-Paper-FINAL_-2017-10-24.pdf).

⁶⁸ Initiative for Medicines, Access, and Knowledge, *America's Overspend: How the Pharmaceutical Patent Problem is Fueling High Drug Prices* (Oct. 2017) (online at www.i-mak.org/wp-content/uploads/2017/11/Excess-Costs-Briefing-Paper-FINAL_-2017-10-24.pdf). The 73 patents are broken down as follows: 23 non-expired, granted patents; 5 now-expired, granted patents; 1 pending application; and 44 abandoned applications.

⁶⁹ *Id.*

⁷⁰ See *Id.*; Novartis, *Press Release: Novartis Settles Patent Litigation on Gleevec (imatinib mesylate) with SunPharma Subsidiary* (May 14, 2014) (online at www.novartis.cz/cs/node/10571). According to one article, the settlement included a combination of reverse payment and perhaps the promise of Novartis not to introduce an authorized generic. Hagop Kantarjian, M.D., *The Arrival of Generic Imatinib Into the U.S. Market: An Educational Event*, *ASCO Post* (May 25, 2016) (online at <https://ascopost.com/issues/may-25-2016/the-arrival-of-generic-imatinib-into-the-us-market-an-educational-event/>),

litigation.⁷¹ Despite the controversy surrounding the Sun Pharmaceutical settlement, delays in generic entry were enormously profitable for Novartis and costly for U.S. payers. The company reported \$1.3 billion in U.S. net revenue in the six months from August 2015 through January 2016, after which time generic competition finally came to market.⁷²

Because Sun Pharmaceuticals was the first generic manufacturer to file for approval, it was entitled to 180 days of generic exclusivity, which meant that no other generic could enter the market—and thus Novartis would face limited competition—until February 2016. Although Sun Pharmaceuticals initially announced that it would price its generic 30% below the price of Gleevec, the company ultimately entered the market at a price just 6.4% less than Gleevec’s price for the 400 mg tablet.⁷³ Novartis executives hailed this high generic price in a January 2016 email: “That’s good news.”⁷⁴

High prices for both generic and branded Gleevec persisted throughout this market period. Experts estimate that these strategies resulted in \$700 million in excess costs to payers in the one-year period from 2015 to 2016.⁷⁵

VI. STRATEGIES TO MINIMIZE COMPETITION AFTER LOSS OF EXCLUSIVITY

It is common practice for drug companies to strategically plan for and manage a product’s loss of exclusivity to extend the drug’s revenue stream—this is known as lifecycle management of the drug. Documents indicate that Novartis executives aimed to establish Gleevec as the “new benchmark in lifecycle management”⁷⁶ by maintaining as much market share as possible once Gleevec’s primary patent expired in 2015 and the company expected generic competition.

As early as three years before Gleevec lost patent protection, Novartis created a comprehensive life cycle management strategy that aimed to target all Gleevec stakeholders—

⁷¹ Class Action Complaint, *United Food and Commercial Workers v. Novartis*, 1:15 cv 12732 (D. Mass.) (6/22/2015) (online at www.wexlerwallace.com/wp-content/uploads/2016/08/Gleevec-Antitrust-Litigation-Class-Action-Complaint.pdf).

⁷² Initiative for Medicines, Access, and Knowledge, *America’s Overspend: How the Pharmaceutical Patent Problem is Fueling High Drug Prices* (Oct. 2017) (online at www.i-mak.org/wp-content/uploads/2017/11/Excess-Costs-Briefing-Paper-FINAL_-2017-10-24.pdf).

⁷³ See, e.g., Hagop Kantarjian, M.D., *The Arrival of Generic Imatinib Into the U.S. Market: An Educational Event*, ASCO Post (May 25, 2016) (online at <https://ascopost.com/issues/may-25-2016/the-arrival-of-generic-imatinib-into-the-us-market-an-educational-event/>), and CTRL-0016482.

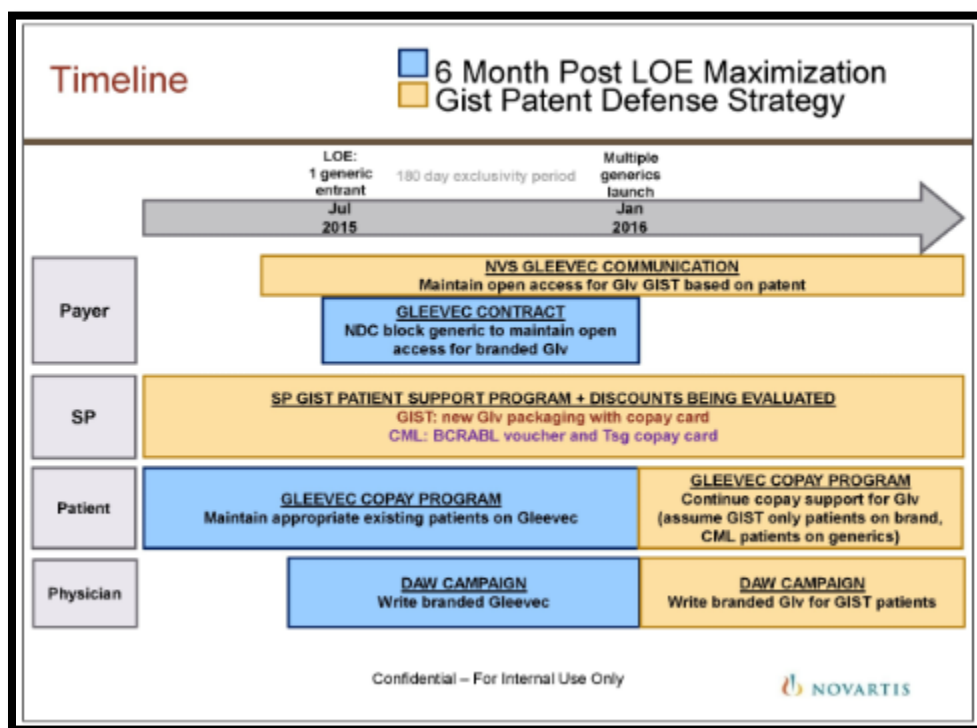
⁷⁴ CTRL-0016482.

⁷⁵ Initiative for Medicines, Access, and Knowledge, *America’s Overspend: How the Pharmaceutical Patent Problem is Fueling High Drug Prices* (Oct. 2017) (online at www.i-mak.org/wp-content/uploads/2017/11/Excess-Costs-Briefing-Paper-FINAL_-2017-10-24.pdf).

⁷⁶ CTRL-0039882, at Slide 4.

physicians, patients, pharmacies, and payers. One presentation described the strategy as causing: physicians to prescribe Gleevec over generics; patients to prefer or accept Gleevec over generics; pharmacies to dispense Gleevec over generics; and payers to provide access and reimbursement for Gleevec.⁷⁷

Key parts of this strategy included exclusive contracting to block generic competitors from being covered by insurance, a “Dispense-As-Written” campaign aimed at health care providers and patients, a co-pay card for patients and a copay promotion campaign, and evaluating the development of Novartis’ own authorized generic.⁷⁸ The loss of exclusivity strategy was also designed to strengthen and protect Novartis’ existing patent for the gastrointestinal stromal tumors indication, which was set to expire in December 2021.⁷⁹



Documents reviewed by the Committee indicate that Novartis viewed the life cycle management strategy as critically important to preserving sales revenue for Gleevec in the face of generic competition and to helping the company meet its overall revenue goals.⁸⁰ In a “US Gleevec LOE [loss of exclusivity]” presentation prepared in July 2015, a slide titled

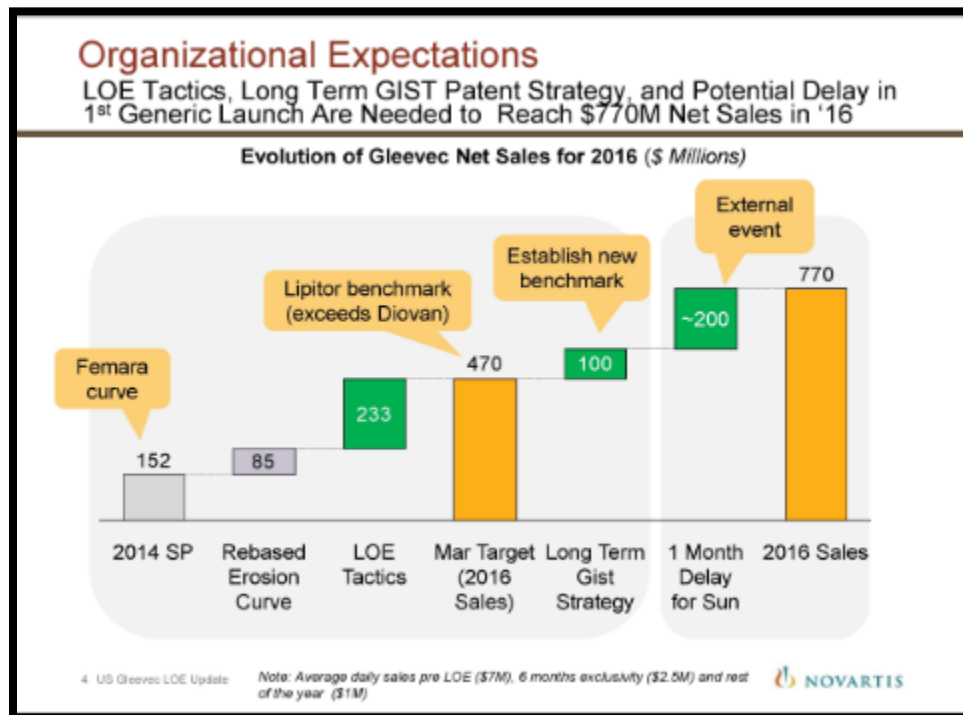
⁷⁷ CTRL-0027659, Slide 10.

⁷⁸ CTRL-0025801, at Slide 12.

⁷⁹ CTRL-0027659, at Slide 9. Core tactics to maintain the gastrointestinal stromal tumor patent are listed as: method of use defense, specialty pharmacy channel, and obtaining separate International Classification of Disease Codes for the GIST indication. *Id.*, at Slide 13.

⁸⁰ CTRL-0025043, at Slide 2.

“Organizational Expectations” read: “LOE Tactics, Long-Term GIST Patent Strategy, and Potential Delay in 1st Generic Launch Are Needed to Reach \$770M Net Sales in ‘16.”⁸¹



Another slide noted, “Current goal of \$770M net sales of Gleevec in 2016; Gleevec LOE initiatives and contracting need to generate \$520M net sales.”⁸²

A November 2015 U.S. Gleevec Loss of Exclusivity Update presentation noted that Gleevec was on track to achieve its strategic imperative and stated that the vision was to “Establish Gleevec LOE as the new benchmark in Lifecycle Management.”⁸³ Documents indicate that, beginning in 2016, Novartis executives generated weekly US Gleevec LOE Performance Trackers.⁸⁴

⁸¹ CTRL-0084047, at Slide 4.

⁸² *Id.*, at Slide 5.

⁸³ CTRL-0039882, at Slide 4.

⁸⁴ See, e.g., CTRL-0149114 (Feb. 15, 2016 Weekly US Gleevec Tracker); CTRL-0149236 (US Gleevec LOE Overview, May 13, 2016); CTRL-0023074 (Mar. 21, 2016 Weekly US Gleevec LOE Tracker).

After nearly two years of generic competition and several generic entrants, studies found that the price for one month of generic Gleevec treatment dropped by only 10%.⁸⁵ By maintaining prices, Novartis collected hundreds of millions of dollars in additional revenue. In 2016, the company collected more than \$1.2 billion in net revenue for Gleevec despite competition from generics, and Novartis noted that Gleevec retained approximately 54% of the market share of the imatinib molecule.⁸⁶

In 2017, Novartis' internal analyses concluded, "Gleevec in the US has continued to outperform benchmarks for LOE erosion. Through competitive contracting and DAW [Dispense As Written] campaign, branded Gleevec maintained ~54% market share of the imatinib [Gleevec] molecule in the US."⁸⁷

The Gleevec loss of exclusivity strategy was so successful that the team members received the Global CEO award in May 2017.⁸⁸ An internal email about this award noted that 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."⁸⁹ One team member was told, "Thank you for saving the company this year."⁹⁰

⁸⁵ Ashley L. Cole and Stacie B. Dusetzina, *Generic Price Competition For Specialty Drugs: Too Little, Too Late?*, Health Affairs (May 2018) (online at www.healthaffairs.org/doi/abs/10.1377/hlthaff.2017.1684?journalCode=hlthaff).

⁸⁶ NOVARTIS.HCOR20190114.00001017; CTRL-0105488, at Slide 9; CTRL-0095377, at Page 4.

⁸⁷ CTRL-0048869, at Page 3.

⁸⁸ CTRL-0004074, at Pages 1-2.

⁸⁹ *Id.*

⁹⁰ *Id.* In this email, "Joe" likely refers to Novartis' former CEO Joe Jimenez.

From: [REDACTED]
Sent: Thursday, February 1, 2018 12:39 PM
To: [REDACTED]
Subject: Gleevec LOE team Recognition background

[REDACTED]
Below is the information around the Gleevec LOE team performance and subsequent recognition. Appreciate your willingness to try and address with [REDACTED] on behalf of the team.

The Gleevec LOE team started working 2 years prior to LOE and for some of us up until now. There were weekly senior management meetings after normal working hours for over a year and extensive global reporting and communication that took place in addition to developing and executing our strategy. Extensive time (almost 2 years) spent with Sandoz to counter their interest to launch AGx. In a video conference with Joe, to explain why the gleevec LOE went so well in late 2016, Joe said "I now understand why launching an AGx would have been a disaster"

For 2016 the brand came in over \$400MM over a stretch budget target of \$770MM, retaining nearly 50% of prior year's net sales with a Feb 1 generic entrant. In December of 2016 [REDACTED] was told by [REDACTED] "thank you for saving the company this year". The team was eventually recognized with a Global CEO award in May of 2017 which awarded 10 team members \$1,000 each, payable at end of July 2017. When [REDACTED] announced the award to the team back in May he indicated that he was not sure what the award amount was and that if it was not sufficient the US OBU would supplement. 2017 results were also above expectations with net sales of \$627 MM. Team has worked extensively with other brands both within Oncology and Pharma to share learnings in preparing for future LOEs.

Team members currently with company: **CCFI: Confidential Commercial & Financial Information**
CCFI: Confidential Commercial & Financial Information

Details from award submission:

- o Situation – US business was facing significant challenge due to expected entry of generics for Gleevec in the market. Gleevec is an important product not only for the organization (generated \$2.5B in '15 net

A. Shifting Patients to More Expensive Therapy

Novartis sought to maintain its dominance in chronic myeloid leukemia therapy by introducing a new treatment, Tasigna, for newly diagnosed patients. FDA approved Tasigna for newly diagnosed chronic myeloid leukemia patients in 2007, and Novartis began a campaign to steer patients toward Tasigna and away from Gleevec, which would soon face generic competition. Novartis began trials to show that Tasigna could be even more effective at controlling chronic myeloid leukemia than Gleevec.⁹¹

As early as 2011, Novartis began developing a contracting strategy to shift patients from Gleevec to Tasigna "in order to maximize long-term net sales." A "Tasigna & Gleevec Payer Contracting Strategy" presentation from April 2011 noted that a Tasigna patient from 2011 to 2015 would yield \$54,000 in incremental net sales over Gleevec, and, if they remained on Tasigna through 2020, would yield an incremental \$518,000.⁹²

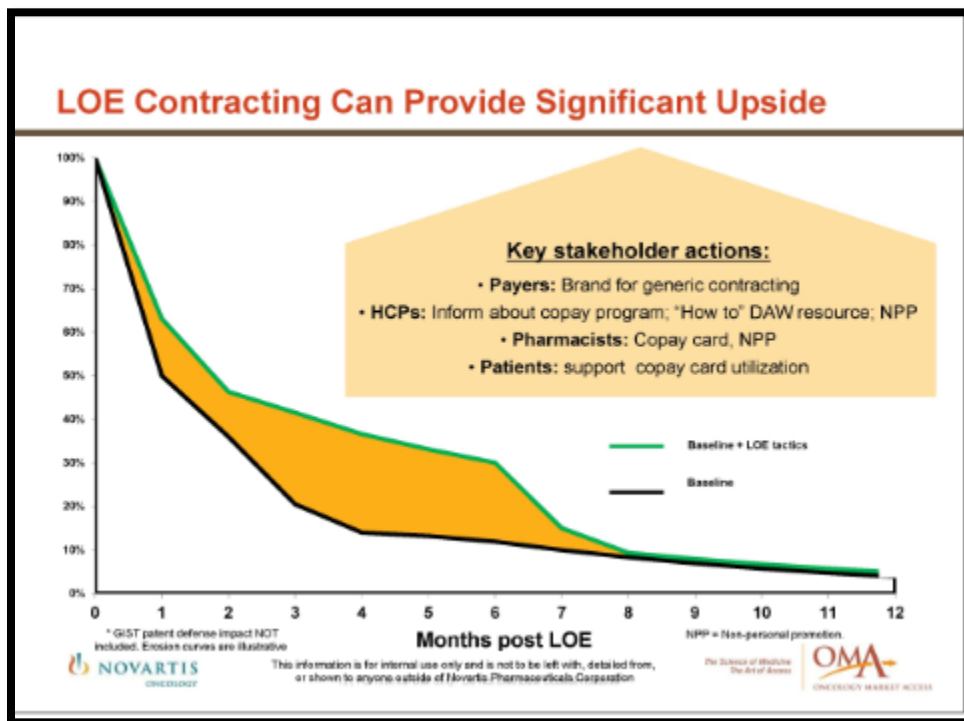
⁹¹ *Novartis Cannibalizes Gleevec to Boost New Cancer Drug*, Bloomberg (Oct. 25, 2012) (online at www.bloomberg.com/news/articles/2012-10-25/novartis-cannibalizes-gleevec-to-boost-new-cancer-drug).

⁹² CTRL-0094383, at Slide 3.

This presentation assumed Gleevec brand sales would stop at the time of loss of exclusivity, which did not occur because other strategies were effective in preserving Gleevec’s market share.⁹³ Another presentation from February 2013 titled “Tasigna/Gleevec Pricing & Contracting Strategy Recommendation” estimated: “A Patient Started on Tasigna Today is Valued at ~\$973M (sic) through Tasigna LOE of July 2023 (or incremental \$794k over Gleevec)” and noted that “Any Margin Given Today Helps to Secure the Future Value of a Tasigna Patient ~\$490k [Net Present Value].”⁹⁴

B. Contracting Strategies to Minimize Competition and Maintain Market Share

A core tactic employed by Novartis to prepare for loss of exclusivity and maintain Gleevec’s market share was to contract with health plans and pharmacies to make Gleevec the only version of the drug covered or dispensed. A March 2015 “Contract Process” presentation stated the purpose of the strategy: “Objective is to maximize Gleevec revenue and protect Tasigna first-line status.”⁹⁵ Novartis’ presentations regularly included a slide on the “significant upside” that LOE contracting can provide.⁹⁶



⁹³ *Id.*

⁹⁴ CTRL-0028152, at Slide 8.

⁹⁵ CTRL-0035215, at Slide 6.

⁹⁶ CTRL-0025801, at Slide 12.

One of the most important types of contracts Novartis pursued was brand-for-generic contracting, under which Novartis offered higher Gleevec rebates, or discounts, to a health plan in exchange for the plan agreeing to block the generic version of Gleevec from its covered drug list.⁹⁷ Specifically, Novartis offered significant Gleevec rebates to plans offering to place Gleevec in a preferred place on their formulary and block generic imatinib from their covered drug list. This meant that the insurance plan would not cover the generic drug if prescribed to a patient. This strategy was commonly referred to as a National Drug Code (NDC) Lock on Generic, or NDC block.⁹⁸

Novartis began exploring the NDC block strategy with health plans as early as February 2014. At that time, the head of Novartis' Strategic Pricing Group asked his team for a list of accounts that had implemented an NDC block on other drugs.⁹⁹ Novartis targeted health plans that were capable of blocking the generic and that had a minimum of \$2 million in annual Gleevec sales.¹⁰⁰ As of October 2015, Novartis was tracking dozens of contracts in process covering more than 33 million people.¹⁰¹

The Committee's investigation reveals Novartis pursued these contracts even when the blocks violated the plans' own policies. Some plans have a corporate policy against brand-for-generic contracts because they suppress generic competition. Other plans have generic first policies that prefer generic drugs over brands.

For example, an April 2014 presentation on Payer Contracting noted that not all plans would be willing to engage in the NDC blocking contract: "Appetite for brand-for generic contracts is likely to be limited among payers but high among SP [Specialty Pharmacy]/Mail-order pharmacies." The presentation noted, "Some plans will not engage in Brand-for-Gx [generic] deals," and it cited an example from one national payer that was offered these contracts in the past, but did not accept them because "they go against our corporate philosophy."¹⁰²

Another outline for a presentation of the "Gleevec Contracting Strategy" prepared in April 2016 highlighted the relevant market dynamics: "Only a select number of payers are willing/able to enforce NDC blocks depending upon their ability to execute operationally (e.g. system programming) and their Gx [generic] philosophy/existing contract language preventing to

⁹⁷ CTRL-0025001, at Slide 5. This presentation also described this strategy as: "Discount Gleevec to establish brand only contracts." *Id.* at Slide 11. Documents provided to the Committee offer varying estimates of the rebates Novartis expected to offer.

⁹⁸ CTRL-0031715, at Slide 2.

⁹⁹ CTRL-0032908, at Page 2.

¹⁰⁰ CTRL-0031715, at Slide 3.

¹⁰¹ CTRL-0024326. A Jan. 2016 email exchange demonstrated that, at this time, Gleevec had several national and regional plans signed up for their brand for generic deals, and one or two pharmacy deals in which "Gleevec will be there [sic] house generic" and Novartis expected to have roughly 30%+ of its business under contract." CTRL-0057918, at Page 1.

¹⁰² CTRL-0027659, at Slide 26.

delay Gx entry.”¹⁰³ In another case, an email from an account manager in August 2015 indicated that one plan requested a term sheet so they could “run the numbers and establish protocol for an NDC block and circumvent their generics first policy before they consider extending for the full year.”¹⁰⁴ Despite the fact that the plan would need to “circumvent policy,” the plan agreed to the NDC block when Novartis offered increased rebates, apparently because, “They believe to justify circumventing policy and providing an NDC block the numbers at [redacted percentage] are viable.”¹⁰⁵

Documents reviewed by the Committee indicate that Novartis executives tried to find workarounds when they discovered that NDC contracts might violate state laws. For example, when a senior regional account manager discovered that state law prohibited an NDC block, Novartis executives explored ways for the plan to “work around the NDC block issue.”¹⁰⁶ Similarly, an April 2016 email exchange with the account manager for another plan indicated that plan wanted an amendment to the NDC block sections that added the language, “To the extent permitted by applicable law.”¹⁰⁷

Documents reviewed by the Committee indicate that Novartis aimed to enter into these contracts for both commercial and Medicare patients and that its loss of exclusivity contracting strategy was particularly important for its Medicare business. In March 2016, Novartis brought in a consulting company to explore “ways to retain the most profitable access for Gleevec, e.g., keeping the generic off formulary” and “Part D-specific economic drivers that could impact Gleevec’s erosion curve.”¹⁰⁸

For Medicare Part D plans, Novartis explored ways to work around requirements that plans not disadvantage a generic. For example, in an email in March 2016, Novartis account manager and executive discussed changes requested to a contract by one Part D plan. A Novartis executive noted that Part D plans cannot implement the normal NDC block for generics, nor could they put the generic on the non-preferred tier. The executive suggested instead putting Gleevec and the generic on the same tier, but requiring prior authorization for both drugs. The executive explained that the PBM had its own in-house specialty pharmacy and would direct the pharmacy to dispense Gleevec rather than the generic. The account manager wrote, “With the Generic in the same Tier and as Gleevec (equal), it satisfies the Med D requirement. Since they have a SP [specialty pharmacy] requirement, they have set it up with their network SPs to ensure Gleevec is dispensed vs the generic.”¹⁰⁹

¹⁰³ CTRL-0058868, at Page 1.

¹⁰⁴ CTRL-0082317, at Page 2.

¹⁰⁵ CTRL-0078238, at Page 2. Committee staff accommodated Novartis’ request that this percentage not be disclosed to the public.

¹⁰⁶ CTRL-0057916, at Page 1.

¹⁰⁷ CTRL-0059827, at Page 1.

¹⁰⁸ CTRL-0124740, at Slide 2.

¹⁰⁹ CTRL-0052051, at Pages 10-11.

Some payers agreed to keep the NDC block in place beyond the generic’s 180-day exclusivity period. A November 2016 Gleevec LOE Performance Tracker reported that contracting was ahead of estimates and that Novartis had “Extended >90% of the contracts from the 6 month exclusivity period.”¹¹⁰

C. “Dispense As Written” Campaign

Pharmacists are permitted to substitute a brand-name drug with a lower-cost generic version if the patient consents.¹¹¹ Doctors, however, can expressly prohibit such substitution by writing “Dispense as Written” or “DAW” on a patient’s prescription.¹¹² Novartis’ dispense as written campaign was part of its effort to mitigate the effects of loss of exclusivity. This campaign was intended to persuade patients and health care providers to prescribe Gleevec with dispense as written to ensure Gleevec would be dispensed at the pharmacy rather than the generic.¹¹³ The campaign, budgeted at approximately \$1 million, was projected to start in the second quarter of 2015.¹¹⁴

To support this strategy, Novartis executives prepared targeted messages to patients and health care providers. For example, draft document circulated messages designed to encourage patients to ask for and providers to request dispense as written.¹¹⁵ These included: “Generic imatinib does not have the Gleevec name imprinted on the tablet”; “It’s your right to ask your pharmacist for branded Gleevec. Tell them to dispense as written”; and “The power is in your hands—demand the brand.”¹¹⁶ These messages also aimed to sway patients away from generics: “Multiple generics can lead to patient confusion”; “If you get generic, your medication may change shape, color, size from month-to-month”; and “Disease can reoccur. Is it physiological or is it loss of efficacy of the medication?”¹¹⁷ It is unclear whether or how Novartis shared these messages with patients or providers.

¹¹⁰ CTRL-0051145, at Slide 10.

¹¹¹ Yan Song and Douglas Barthold, *The Effects of State-Level Pharmacist Regulations on Generic Substitution of Prescription Drugs*, Health Economics, (July 10, 2018) (online at <https://ncbi.nlm.nih.gov/pmc/articles/PMC6172151/pdf/nihms975944.pdf>) (summarizing state generic substitution laws).

¹¹² 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).

¹¹³ CTRL-0088450, at Slide 4 (providing a complete description of the Dispense as Written Campaign: “Comprehensive education to HCP/Patients on DAW and how to remain on the brand (EHR communications, email series, SP communication, Journal ads, PR platform, patent expiration guide, EMR, etc.)”).

¹¹⁴ *Id.*

¹¹⁵ CTRL-0088408, at Page 1.

¹¹⁶ *Id.*

¹¹⁷ *Id.*

Message Audience	Access/Co-Pay	Heritage/Clinical	Patient Support	Loyalty/DAW	Gx Consideration
Patient/HCP	<ul style="list-style-type: none"> • Save big on Gleevec – Pay as little as \$10 • Gleevec gives • @LOE (once we know OOP for Gx): With brand Gleevec, you may save \$XXX/ year vs with generics. 	<ul style="list-style-type: none"> • Gleevec is the only imatinib approved for GIST • Sarcoma specialist: “Gleevec changed the way doctors treat cancer” • Gleevec changed the life of your patients. Don’t let pharmacists change what you intend for your patients • Comfort/ predictability of the imatinib studied in clinical trials • 15 years of efficacy and safety data in more than x patients, x patient years experience, x clinical trials, x indications, x trials ongoing, • The #1 prescribed brand for GIST • The brand most trusted for treating GIST • Novartis #X largest R&D company • After GIST surgery, ensure the consistency you expect by sticking with Gleevec • Branded Gleevec is produced in a single factory 	<ul style="list-style-type: none"> • We’re here for you and your loved ones to help you stay with branded Gleevec • We support your choice of branded Gleevec • Gleevec, helping patients beyond their prescriptions • Stand up 2 Cancer, Stand Up for Gleevec – we’ll support you • Discuss with HCP if your payor or pharmacy is switching • Do not risk losing patient response – resources are available for them to stay on Gleevec 	<ul style="list-style-type: none"> • Generic imatinib does not have the Gleevec name imprinted on the tablet • Stay on a drug you know and trust • It’s your right to ask your pharmacist for branded Gleevec. Tell them to dispense as written. • There is no diagnostic test in GIST to assess efficacy of Gleevec or generics • Gleevec your trusted partner through your journey • There are things worth changing in your life – is your Gleevec one of them? • Stick with what works for you • The power is in your hands – demand the brand • What is worse than telling the patients their cancer is back? • Make the milestones in life 	<ul style="list-style-type: none"> • Multiple generics can lead to patient confusion • If you get generic, your medication may change shape, color, size from month-to-month • Generic drugs have the same active ingredients but not necessarily the same fillers • Generic drugs are bioequivalent to brands but NOT to each other • Dosages vary (80-120%) with generic, unlike branded drugs • Disease can recur. Is it physiological or is it loss of efficacy of the medication?

Novartis also crafted proposed language to promote the “dispense-as-written” campaign to payers. In an April 2016 email exchange, a Novartis executive included talking points to share with Part D payers who removed Gleevec from formulary, including: “The decision to remove Gleevec from your Part D formulary may have a substantially negative impact on many of your patients. Nearly 2/3 of patients today have either patient or physician DAW requests”; and “Physicians may write DAW and patients may ask for DAW for specific reasons and a non-formulary status could delay patients from getting the branded product.”¹¹⁸

Documents reviewed by the Committee indicate that Novartis closely tracked the success of the Dispense as Written campaign, just as it tracked the success of all the loss of exclusivity strategies, and these efforts limited generic market share. Novartis kept track of how many Gleevec prescriptions were “Dispense as Written” requests from the prescriber and from the patients. For example, a March 2016 “Weekly US Gleevec LOE Tracker” noted that 57% of total Gleevec prescriptions were indicated as Dispense as Written and, of those, 41% of requests were initiated by the patient and 16% indicated by the prescriber.¹¹⁹ The presentation also noted

¹¹⁸ CTRL-0129671, at Page 1.

¹¹⁹ CTRL-0023074, at Slide 10.

that the Dispense as Written Campaign “shows uptake ahead of benchmark, 57% of total Gleevec Rxs.”¹²⁰

A January 2018 Loss of Exclusivity Performance Tracker continued to track Dispense as Written efforts and noted that, during the last few months of 2017, 20% of imatinib prescriptions were Gleevec “Dispense as Written” prescriptions, almost equally split between physician and patient requests.¹²¹ This report also noted the percentage of Gleevec prescriptions with Dispense as Written was ahead of benchmarks: “DAW at 66.3% of Total Branded Gleevec RXs, 29% Points Ahead of Benchmarks.”¹²²

D. Packaging Changes

Documents reviewed by the Committee indicate that Novartis developed new packaging in order to encourage patients to stay on Gleevec. In January 2015, Novartis introduced a “blister package” with a 30 day supply of Gleevec 400 mg tablets.¹²³ With blister packaging, each dose is separated into perforated sections, as opposed to a bottle of pills, so it is easier for a patient to remove a single dose.¹²⁴

Documents reviewed by the Committee indicate that Novartis took this step only when Gleevec was facing loss of exclusivity, and then only for its most popular dose. One document indicates that Novartis considered packaging changes not to serve the customer, but to differentiate Gleevec from the generic alternatives that would come in pill bottles: “Brand is not looking at this as offering the customer options ... they need the blister to drive the copay program and differentiate themselves from the generics that will be in bottle.”¹²⁵

Another document titled, “Customer’s First Initiative Financial Details—Incremental Revenue,” evaluated the package change as follows: “Improved packaging can have 2 effects on Gleevec sales. 1) Improved packaging can increase adherence. 2) Improved packaging can slow generic erosion (impact would occur in 2016).” The document calculated that such increased adherence over six months could have an incremental impact of \$12.5 million.¹²⁶

¹²⁰ *Id.*, at Slide 2. The benchmark Novartis used was in comparison to other drugs—Xeloda at 41% and Temodar at 22%. *Id.*, at Slide 10.

¹²¹ CTRL-0056960, at Slide 7.

¹²² *Id.* at Slide 18.

¹²³ CTRL-0025586, at Pages 1-2.

¹²⁴ See Surbhi Shah et al., *Impact of Bubble Packaging on Adherence to Long-Term Oral Medications Used to Prevent Cardiovascular Disease*, *Journal of Pharmacy Technology* (Apr. 4, 2017) (online at www.ncbi.nlm.nih.gov/pmc/articles/PMC5998413/).

¹²⁵ CTRL-0106729, at Page 1 (ellipses in original).

¹²⁶ CTRL-0061584, at Page 1.

Customer's First Initiative Financial Details - Incremental Revenue				
Initiative Name	Initiative Description	Project Owner	Project Timing	Divisions Included
US15411_Gleevec Packaging	Assessing the impact of the new Gleevec packaging with the blister packs. Key Learnings from the Diovan LOE are leveraged as we prepare for the Gleevec LOE. Key learnings shared on Diovan for the Gleevec packaging to blister pack.		Continued through 2015 to 2016	US General Medicines US Oncology
Financial Methodology and Assumptions				
Improved packaging can have 2 effects on Gleevec sales. 1) Improved packaging can increase adherence. 2) Improved packaging can slow generic erosion (impact would occur in 2016).				
Initiative Assumptions				
Non-Responsive				
Financial Calculations				
2.5 billion x 1% adherence increase x 6 months (2nd half of year) = \$12,500,000.				

Novartis also changed the 400 mg tablet itself by inscribing “Gleevec” on the tablet itself.¹²⁷

E. Method of Use Defense

Documents reviewed by the Committee indicate that as part of its loss of exclusivity strategy, Novartis considered a plan to prevent generics from including an indication for gastrointestinal stromal tumors on their label, which would prevent generic manufacturers from marketing their products as treatment for that disease.¹²⁸ Novartis aimed to do this by defending its “method of use patent” on the gastrointestinal stromal tumors indication, which is set to expire in December 2021—providing approximately six years of additional patent protection for this indication over Novartis’ now-expired base compound patent.¹²⁹

¹²⁷ CTRL-0024850, at Slide 12. This slide notes that the 100 mg tablet and packaging would remain the same.

¹²⁸ See CTRL-0011516, at Slides 6 and 12.

¹²⁹ See CTRL-0011516, at Slide 6. See generally Roger D. Blair and Anita N. Walsh, *Method of Use Patents, Appropriability and Antitrust Policy*, Review of Industrial Organization (Mar. 10, 2010) (online at <https://link.springer.com/article/10.1007/s11151-020-09753-3>).

In a presentation titled, “Gleevec 2015 Tactical Plan,” Novartis predicted that defending the method of use patent would have a higher sales impact than any other element of its loss of exclusivity strategy.¹³⁰

In this same presentation, Novartis considered how to “Appropriately Maximize GIST” and considered a plan to request that payers and pharmacies identify how they are honoring the GIST patent and also a litigation strategy to defend the patent against those payers and pharmacies who refused.¹³¹ The presentation noted that “[d]efending method of use patent may have [a] negative impact on reputation” and that preparation of a mitigation strategy was recommended to avoid negative publicity.¹³² Documents reviewed by the Committee do not indicate whether these strategies were implemented.

VII. OTHER COSTS DO NOT JUSTIFY PRICE INCREASES

A. Rebates

The pharmaceutical industry often attributes price increases to the need to account for rebates, discounts, and other fees provided to pharmacy benefit managers and other third parties within the distribution chain. The Pharmaceutical Research and Manufacturers of America, the pharmaceutical industry’s trade association, has claimed that “nearly half of brand medicine spending goes to the supply chain and others.”¹³³

Documents and information reviewed by the Committee indicate that price increases for Gleevec cannot be attributed to growing rebates or discounts provided to pharmacy benefit managers, health insurance plans, employers, or other payers. Novartis’ net price per unit of Gleevec—the price of the drug after subtracting rebates and discounts—continued to increase each year through 2015 (when the drug lost patent exclusivity), meaning any rebates or discounts from the list price of the drug were outpaced by the company’s price increase.¹³⁴ One internal report noted that the net price of Gleevec increased by double digits each year from 2011 to 2015, until the drug’s loss of exclusivity in 2016.¹³⁵

Figure 6 below shows this increase in net effective price for Gleevec from 2009 to 2018.¹³⁶

¹³⁰ CTRL-0011516, at Slide 24.

¹³¹ *Id.*, at Slide 12.

¹³² *Id.*, at Slide 6.

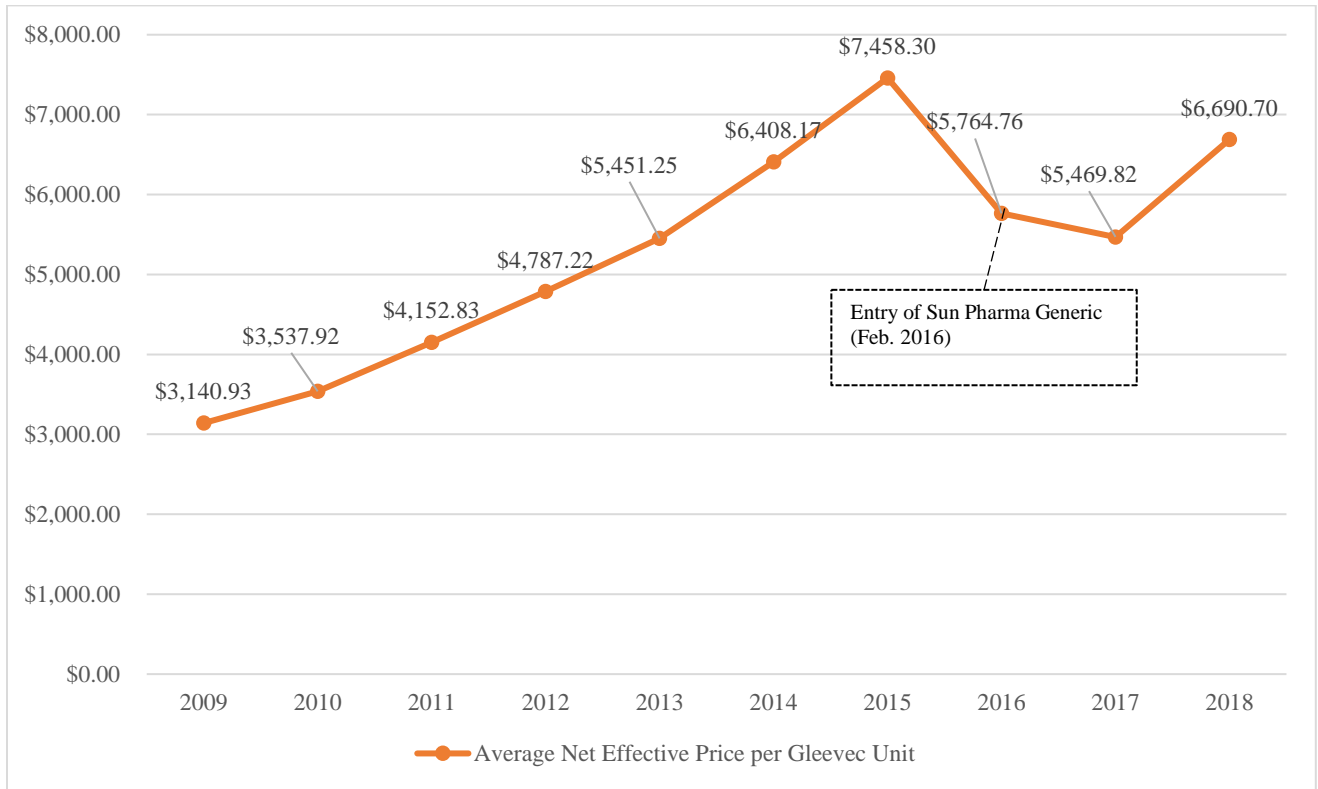
¹³³ Pharmaceutical Research and Manufacturers of America, *Let’s Talk About Cost* (online at www.letstalkaboutcost.org/) (accessed Sept. 30, 2020).

¹³⁴ NOVARTIS.HCOR20190114.00001017.

¹³⁵ CTRL-0004032, at Page 2. According to this document, when Gleevec lost exclusivity in 2016, the average discount doubled to 40%, leading to -22.6% decline in net price.

¹³⁶ NOVARTIS.HCOR20190114.00001017.

Figure 6: Average Net Effective Price Per Unit of Gleevec



The average of all discounts, rebates, returns, and co-payment amounts provided by Novartis for Gleevec sales between 2009 and 2015 was just 15% of total gross sales.¹³⁷ After Gleevec lost exclusivity in 2016 and began facing generic competition, the average percent of discount across all sales channels increased to 40.8%.¹³⁸ However, Gleevec’s average net effective price for 2016 was still double the net price in 2009.¹³⁹

B. Research and Development

Pharmaceutical companies frequently claim that high prices are justified by the high costs of research and development to discover innovative therapies. Contrary to the company’s external talking points, documents and information reviewed by the Committee indicate that Novartis’ pricing decisions were not intended to recoup R&D expenditures.

¹³⁷ *Id.* To arrive at this number, the average percentage per year was added from 2009 to 2015 and divided by the number of years.

¹³⁸ Letter from Hogan Lovells, on behalf of Novartis Pharmaceuticals Corporation, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (May 23, 2019).

¹³⁹ NOVARTIS.HCOR20190114.00001017.

In response to the Committee’s request for data regarding the company’s spending on research and development related to Gleevec, Novartis noted that “the Company no longer has access to the records reflecting the very significant Gleevec development spend by the Company prior to FDA approval.” With respect to its R&D spending after FDA approval, Novartis initially told the Committee that: “The data after that initial FDA approval to which the Company still has access is incomplete and is only a small fraction of the significant overall spend by the Company on Gleevec development.”¹⁴⁰

In a subsequent letter, Novartis stated that its best estimate is that Gleevec development costs from 2001 through 2019 exceeded \$700 million.¹⁴¹ Novartis reported that it claimed no R&D tax credits from 2009 to 2018.¹⁴² Novartis’ claimed expenditure on Gleevec R&D—\$700 million between 2001 to 2019—is a tiny fraction of Gleevec’s billions of dollars in U.S. revenue.¹⁴³ For example, Novartis made more in any given year between 2009 and 2016 than it spent on Gleevec R&D combined during a 19-year period.¹⁴⁴

Public documents reveal that Gleevec’s preclinical R&D costs were almost entirely funded by grants from the National Cancer Institute and nonprofit organizations. Fifty percent of preclinical funding came from the National Cancer Institute, while an additional 30% came from the Leukemia and Lymphoma Society and 10% came from Oregon Health & Science University.¹⁴⁵ Although Novartis invested heavily in clinical trials and development of the drug, it did so after preclinical effectiveness was well-established and commercial promise was readily apparent.¹⁴⁶ In total, academics estimate that Novartis invested between \$10 million to \$24 million in direct Gleevec development costs, and \$38 million to \$96 million after accounting for risk and opportunity costs, such as foregone costs of other candidate trials or cash investment opportunities.¹⁴⁷ In 2012, a year of relatively average net revenue from Gleevec across the period analyzed, Novartis earned \$100 million every 13 days from Gleevec.¹⁴⁸

¹⁴⁰ Letter from Hogan Lovells, on behalf of Novartis Pharmaceuticals Corporation, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Apr. 4, 2019).

¹⁴¹ Letter from Hogan Lovells, on behalf of Novartis Pharmaceuticals Corporation, to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Sept. 25, 2020).

¹⁴² Letter from Hogan Lovells, on behalf of Novartis Pharmaceuticals Corporation, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (July 18, 2019).

¹⁴³ Letter from Hogan Lovells, on behalf of Novartis Pharmaceuticals Corporation, to Chairwoman Carolyn Maloney, Committee on Oversight and Reform (Sept. 25, 2020).

¹⁴⁴ *Id.*

¹⁴⁵ *A Note on Dr. Brian Druker’s Involvement in the Research and Development of Gleevec*, Consumer Project on Technology (online at <http://cptech.org/ip/health/gleevec/druker.html>).

¹⁴⁶ B.J. Druker et al., *Effects of a Selective Inhibitor of the Abl Tyrosine Kinase on the Growth of Bcr-Abl Positive Cells*, National Library of Medicine, National Center for Biotechnology Information (May 1996) (online at <https://pubmed.ncbi.nlm.nih.gov/8616716/>).

¹⁴⁷ *R&D costs for Gleevec*, Knowledge Ecology International (Apr. 3, 2013) (online at www.keionline.org/22170).

¹⁴⁸ *Id.*

Novartis failed to acknowledge federal funding it received for a key Gleevec patent for 18 years after the original patent application—only doing so after the Committee’s investigation was launched.¹⁴⁹ The Bayh-Dole Act of 1980 requires companies to disclose the receipt of federal funding used in a patented drug.¹⁵⁰ Failure to timely make such a disclosure allows the federal government to “receive title to any subject invention.”¹⁵¹

Novartis’ early correspondence to the Committee stated that no patents for Gleevec’s active ingredients, methods of use, or indication “were originally obtained under the Patent and Trademark Law Amendments Act (the Bayh-Dole Act) or otherwise developed under federally-sponsored research.”¹⁵² However, the company later notified the Committee that one of its patents, covering the gastrointestinal stromal tumors indication, had been corrected in July of 2019 to provide notice that “federal funds were used in support of the invention.”¹⁵³ The grant associated with the correction is associated with 23 NIH projects at Oregon Health and Science University.¹⁵⁴ By failing to disclose this federal funding, Novartis furthered its public message that the company spends significant amounts on research and development.

C. Patient Assistance Programs

In responding to criticism of Gleevec pricing, Novartis has emphasized the generosity of its patient assistance programs that help defray the costs of price increases. Documents reviewed by the Committee indicate that these programs do not address the burden that Novartis’ pricing practices place on the larger health care system, and also allowed Novartis to reduce patient price sensitivity and drive demand, particularly after loss of exclusivity.

Novartis reported to the Committee that its Patient Assistance Foundation provides free medication to individuals experiencing financial hardship and who have limited or no prescription drug coverage. Novartis noted that individual patients earning up to \$75,000 a year may qualify for Foundation support, but did not specify either the number of individuals who do

¹⁴⁹ James Love, *Novartis, Dana Farber, Oregon Health & Science University Wait 18 Years to Disclose NIH Funding in Key Gleevec Patent* (Oct. 11, 2019) (online at <https://blog.petrieflom.law.harvard.edu/2019/10/11/novartis-dana-farber-oregon-health-science-university-wait-18-years-to-disclose-nih-funding-in-key-gleevec-patent/>).

¹⁵⁰ 35 U.S.C. § 202(c)(1).

¹⁵¹ 35 U.S.C. § 202(c)(1).

¹⁵² Letter from Hogan Lovells, on behalf of Novartis Pharmaceuticals Corporation, to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Feb. 4, 2019).

¹⁵³ Letter from Hogan Lovells, on behalf of Novartis Pharmaceuticals Corporation, to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Nov. 22, 2019).

¹⁵⁴ James Love, *Novartis, Dana Farber, Oregon Health & Science University Wait 18 Years to Disclose NIH Funding in Key Gleevec Patent* (Oct. 11, 2019) (online at <https://blog.petrieflom.law.harvard.edu/2019/10/11/novartis-dana-farber-oregon-health-science-university-wait-18-years-to-disclose-nih-funding-in-key-gleevec-patent/>).

ultimately receive such assistance or their average income.¹⁵⁵ Novartis did not provide how much it contributed every year to the Foundation, but reported that in 2018, the Foundation helped over 6,000 U.S. patients.¹⁵⁶ In addition, Novartis has acknowledged that its charitable contributions are tax deductible, meaning the actual cost for its donations are less.¹⁵⁷

The company also reported to the Committee that, for patients with commercial insurance, it offers “copay assistance programs so that eligible patients pay no more than \$30 for a 30-day prescription” for many of the company’s brand and biosimilar products.¹⁵⁸ Novartis reported that 590,000 patients were helped via its company-wide co-payment programs in 2018, although the company did not provide a precise figure for Gleevec patients.¹⁵⁹

Documents reviewed by the Committee indicate that Novartis did consider the impact of cost on patients and sought “enhancements to program[s] to address patient gaps.”¹⁶⁰ For example, the company conducted a literature review in 2013 that showed an association between higher co-pays and reduced adherence or patient abandonment of a drug.¹⁶¹ However, the review also concluded, “Because oncologic drugs are a necessity for patients, there is less sensitivity to price increases. However, research shows that there is an upper limit of OOP costs (\$200-\$500 per claim) at which patient adherence begins to decline”¹⁶²

¹⁵⁵ Letter from Hogan Lovells, on behalf of Novartis Pharmaceuticals Corporation, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Feb. 4, 2019).

¹⁵⁶ Letter from Hogan Lovells, on behalf of Novartis Pharmaceuticals Corporation, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (July 18, 2019). Novartis noted that it provided \$400 million in free Gleevec medicine in 2018 but it is unclear if that amount is based on list price or actual cost. The letter noted that the tax deduction taken that year was \$14.8 million and a subsequent letter told the Committee that amount “represents the value of Gleevec donated to the Novartis Patient Assistance Fund.” Letter from Hogan Lovells, on behalf of Novartis Pharmaceuticals Corporation, to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Sept. 25, 2020).

¹⁵⁷ *Id.*

¹⁵⁸ Letter from Hogan Lovells, on behalf of Novartis Pharmaceuticals Corporation, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Feb. 4, 2019).

¹⁵⁹ *Id.*


¹⁶⁰ CTRL-0029114, at Slide 1.

¹⁶¹ CTRL-0095459, at Slide 17

¹⁶² *Id.*, at Slide 19.

■ Cost & Patient Adherence
Evidence for the impact of copayments on CML patient adherence. Very few US patients will have a co-pay over \$100 per month for Tasigna or Gleevec

- **The current data regarding TKI shows that copays are low for most patients.**
 - In studies of TKI use in CML, the median copay is \$25-30, (75th percentile: \$63, 95th percentile: \$122) ^{6, 7}
- **However for the patients who have higher copays, cost is a risk factor for non-adherence.**
 - In a study of patient adherence to imatinib, 1/3 of patients were shown to be poorly adherent. Risk factors include high starting dose, a longer time lag between CML diagnosis and prescription fill, and a higher percentage of copayment.⁹
- **There is some data that suggests higher copays may have a “designer drug” effect and lead to improved adherence, however most studies refute this finding.¹⁰**
- **Because oncologic drugs are a necessity for patients, there is less sensitivity to price increases. However, research shows that there is an upper limit of OOP costs (\$200-\$500 per claim) at which patient adherence begins to decline. ^{5, 6, 8, 9}**



Documents reviewed by the Committee indicate that co-pay programs allowed Novartis to further reduce patient price sensitivity and that Novartis strategically used its co-payment programs to drive demand, particularly after the loss of exclusivity. 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 co-pay programs were a crucial piece of Novartis’ loss of exclusivity strategy for Gleevec, encouraging patients to stay on the branded drug even after generic entry.¹⁶³ A 2015 Gleevec CoPay Strategy presentation noted: “Copay is an Important Component of the Gleevec [loss of exclusivity] Strategy.”¹⁶⁴ Another set of slides described the Company’s co-pay promotion efforts as a way to “Help to keep current customers on prescription by lessening the gap between Rx [Gleevec] and Gx [Generic] costs.”¹⁶⁵

In company slides related to co-pay strategies before and after the loss of exclusivity, the company determined that enhancing the co-pay programs six months before the loss of exclusivity would result in the greatest return on investment by keeping patients on Gleevec before lower-cost generics entered the market.¹⁶⁶ This document indicated that Novartis valued

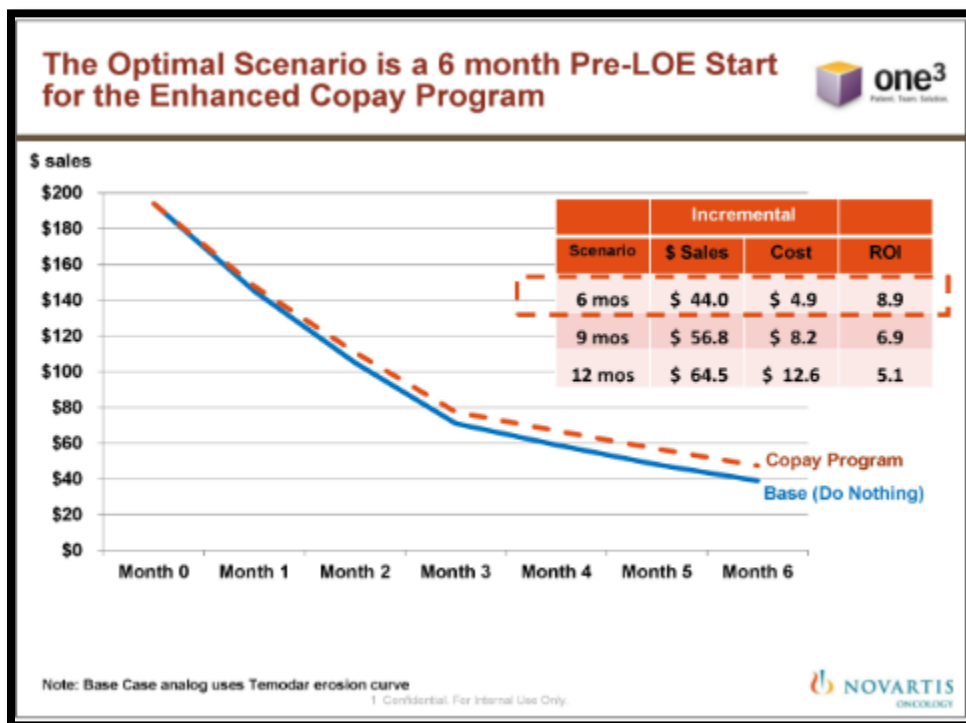
¹⁶³ Letter from Hogan Lovells, on behalf of Novartis Pharmaceuticals Corporation, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Feb. 4, 2019); CTRL-0086985, at Slide 2.

¹⁶⁴ *Id.*, at Slide 3.

¹⁶⁵ CTRL-0088450, at Slide 3.

¹⁶⁶ CTRL-0092356, at Slides 1-4.

patient assistance programs starting six months prior to the loss of exclusivity as providing a return on investment of 8.90 dollars for every one dollar spent on the program.¹⁶⁷



Another “Gleevec Copay Strategy” presentation from February 2015 detailed a host of co-pay “tactics” to reach patients through multiple channels, including online Facebook posts, PharmAlerts for pharmacists, and journal ads for physicians.¹⁶⁸

Novartis regularly tracked the return on its investment in patient initiatives in its “Weekly US. Gleevec LOE Tracker.” In March 2016, the tracker noted success with the co-payment card: “Over 5000 eligible commercial patients have activated Gleevec CoPay card.”¹⁶⁹ In February 2017, the tracker noted that, although 40% of prescriptions were written for patients whose insurance plans had greater than \$100 per month in out-of-pocket costs, 94% of those plans would have an out-of-pocket cost of less than \$100 with copay assistance and patient assistance programs.¹⁷⁰

¹⁶⁷ *Id.*

¹⁶⁸ CTRL-0086985.

¹⁶⁹ CTRL-0023074, at Slide 10.

¹⁷⁰ CTRL-0037898, at Slide 15.

VIII. CONCLUSION

Novartis' price increases and business practices for Gleevec 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 2020.¹⁷¹

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.

¹⁷¹ 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/).