



# Drug Pricing Investigation

*Amgen—Enbrel and Sensipar*

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,



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Carolyn B. Maloney  
Chairwoman

## EXECUTIVE SUMMARY

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

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

- **Uninhibited Price Increases:** Since acquiring the rights to Enbrel in 2002, Amgen has raised its price 27 times, including by nearly 30% within one 12-month period. A 50 mg dose of Enbrel is now priced at \$5,556 per month, or \$72,240 annually—a 457% increase from the date Amgen acquired the drug. Amgen also has raised the price of Sensipar more than 20 times since launching the drug in 2004. These price increases have inflated the cost of a typical yearly course of Sensipar from \$2,956 in 2004 to \$9,814 today.
- **Corporate Profits Driven by Price Increases:** From 2009 to 2019, Amgen reported more than \$57 billion in net U.S. revenue from Enbrel and Sensipar. Amgen's net U.S. revenue for Enbrel increased from \$1.25 billion in 2003 to more than \$5 billion in 2019. Amgen's net U.S. revenue for Sensipar also rose from \$36 million in 2004 to a peak of \$1.4 billion in 2018. Amgen's price increases for Enbrel and Sensipar fueled its profitability. The company's net income has grown nearly every year since it began selling Enbrel, including \$7.8 billion in net income in 2019.
- **Pricing Decisions Driven by Revenue Targets:** Internal communications show that pricing decisions by Amgen executives—including Executive Vice President Anthony Hooper—were driven primarily by the need to meet increasingly aggressive revenue targets. For example, Amgen increased the price of Sensipar by 8% in January 2017 after concluding that forgoing the price increase would cost the company \$58 million in net revenue. In 2017, Mr. Hooper pressed his team to consider larger price increases for the next year due to concerns about “how strong the erosion” was in Enbrel's net revenue forecast. Amgen increased the price of Enbrel by 9.7% on January 1, 2018, which allowed the company to meet its goal of collecting \$4.8 billion in Enbrel net U.S. revenue.
- **Executive Compensation System Incentivizes Price Increases:** Amgen's price increases for Enbrel and Sensipar led to higher bonuses for its executives. In 2017 and 2018, Amgen's top executives collected \$90 million in compensation. When executives raised prices on Enbrel and other drugs to meet net revenue projections, this in turn ensured that they would also receive their bonuses. For instance, Mr. Hooper's decision to take a higher-than-planned price increase for Enbrel in January 2018 enabled Amgen

to barely hit its \$4.8 billion revenue target for that year. Mr. Hooper, in turn, received incentive compensation of nearly \$1.8 million for the year, supplementing his base salary of \$1 million and stock and option awards worth almost \$4 million. In 2018, Amgen CEO Robert Bradway received incentive compensation of nearly \$4 million, supplementing his base salary of \$1.5 million and stock and option awards worth almost \$12.4 million.

- **Lack of Medicare Negotiation Costing Taxpayers Billions of Dollars:** U.S. law prohibits Medicare from negotiating directly with drug companies to lower prices. According to Amgen’s internal data, Medicare spent more than \$3.35 billion on Enbrel and Sensipar between 2013 and 2015 even after rebates from Amgen. If Medicare had been receiving the same discounts as the Department of Veterans Affairs or Department of Defense—which are permitted to negotiate directly for lower prices—taxpayers would have saved more than \$3.6 billion between 2013 and 2018.
- **Higher U.S. Prices:** Enbrel and Sensipar are much more expensive in the United States than in other countries that negotiate directly to lower drug prices. In 2017, Enbrel’s U.S. price was thousands of dollars more per month than in Germany, Canada, the United Kingdom, and the Netherlands. Amgen charges nearly double for Sensipar in the United States as it does in Canada.
- **Shadow Pricing with AbbVie:** Amgen’s primary brand competitor for Enbrel is Humira, AbbVie’s blockbuster biologic treatment for rheumatoid arthritis and other conditions. Instead of pricing Enbrel under Humira’s price to gain market share—as expected in a competitive market—Amgen engaged in “shadow pricing” by consistently following AbbVie’s price increases and using AbbVie’s actions as justification to increase the price of Enbrel. This led to both companies setting higher and higher prices for Enbrel and Humira. For example, shortly after AbbVie increased the price of Humira by 9.7% in January 2018, Amgen executed an identical 9.7% price increase, more than double what it had originally planned.
- **Anticompetitive Tactics to Maximize Profits:** Amgen leveraged the U.S. patent system to limit biosimilar competition for Enbrel and prevented U.S. patients from accessing lower-priced versions of the drug available to patients in other countries. Internal strategy documents indicate that Amgen used minor changes to Enbrel’s design—including a new version of the injection device called Enbrel Mini with Autotouch—to drive sales and limit competition. For Sensipar, Amgen entered into settlement agreements to delay entry of generic equivalents. Amgen also attempted to gain additional market exclusivity for Sensipar by showing that it could be used in children, despite knowledge that the FDA was unlikely to grant approval.
- **Price Increases Not Justified by Rebates:** Internal data show that Amgen’s list price increases for Enbrel outpaced any rebates paid. From 2015 to 2018, price increases allowed the company to maintain net revenue from Enbrel at levels well above 2014, despite the volume of sales declining and total rebates paid increasing. Internal data reviewed by the Committee show that Amgen’s rebates and discounts for Sensipar

remained relatively steady from 2015 to 2018 (between 23% and 29%), while Amgen raised the price of the drug five times. As a result, Sensipar's yearly net revenue rose by 34% over this period.

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## I. PRICE INCREASES

### *Enbrel*

The Food and Drug Administration (FDA) first approved Enbrel (etanercept) in 1998 as a biologic agent to treat moderate to severe rheumatoid arthritis.<sup>1</sup> Rheumatoid arthritis is a chronic autoimmune disease that affects approximately 1.3 million Americans.<sup>2</sup> Enbrel is a long-term treatment that helps the remission of rheumatoid arthritis symptoms by targeting the parts of the immune system that cause inflammation and joint and tissue damage.<sup>3</sup> Patients self-administer injections weekly, typically one 50-mg injection per week.<sup>4</sup>

Immunex Corporation owned Enbrel until 2002, when Amgen acquired Immunex for \$17.8 billion. Since then, Amgen has obtained FDA approval to market Enbrel for the treatment of four other inflammatory diseases: juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis.<sup>5</sup>

When Immunex launched Enbrel in 1998, it set the price at \$220 per 50 mg dose (\$880 per month).<sup>6</sup> When Amgen acquired Immunex four years later, the price of Enbrel was \$249 per 50 mg dose, or \$996 per month.<sup>7</sup>

Since then, Amgen has raised the price of Enbrel 27 times, including by 27.9% within one 12-month period.<sup>8</sup> In both 2014 and 2015, Amgen raised the price of Enbrel three times in

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<sup>1</sup> Letter from Jay P. Siegel, Director, Office of Therapeutics Research and Review, Food and Drug Administration, to Sally R. Gould, Immunex Corporation (Nov. 2, 1998) (online at [www.accessdata.fda.gov/drugsatfda\\_docs/appletter/1998/etanimm110298L.htm](http://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/etanimm110298L.htm)).

<sup>2</sup> Rheumatoid Arthritis Support Network, *RA Facts: What Are the Latest Statistics on Rheumatoid Arthritis?* (online at [www.rheumatoidarthritis.org/ra/facts-and-statistics/](http://www.rheumatoidarthritis.org/ra/facts-and-statistics/)) (accessed Sept. 30, 2020).

<sup>3</sup> Mayo Clinic, *Rheumatoid Arthritis* (online at [www.mayoclinic.org/diseases-conditions/rheumatoid-arthritis/symptoms-causes/syc-20353648](http://www.mayoclinic.org/diseases-conditions/rheumatoid-arthritis/symptoms-causes/syc-20353648)) (accessed Sept. 30, 2020).

<sup>4</sup> Amgen Inc., *Enbrel Prescribing Information* (online at [www.pi.amgen.com/~media/amgen/repositorysites/pi-amgen-com/enbrel/enbrel\\_pi.pdf](http://www.pi.amgen.com/~media/amgen/repositorysites/pi-amgen-com/enbrel/enbrel_pi.pdf)) (accessed Sept. 30, 2020).

<sup>5</sup> Food and Drug Administration, *Drugs@FDA: FDA-Approved Drugs* (online at [www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process](http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process)) (accessed Sept. 30, 2020); Amgen Inc. *Enbrel Prescribing Information* (online at [www.pi.amgen.com/~media/amgen/repositorysites/pi-amgen-com/enbrel/enbrel\\_pi.pdf](http://www.pi.amgen.com/~media/amgen/repositorysites/pi-amgen-com/enbrel/enbrel_pi.pdf)) (accessed Sept. 30, 2020).

<sup>6</sup> IBM Micromedex Redbook, *Wholesale Acquisition Cost History for Enbrel*. To calculate the 2002 price of a 50 mg dose of Enbrel, Committee staff doubled the 2002 25 mg dose price, a calculation supported by internal Amgen documents. See AMGN-HCOR-RR-00026574 (Graph with the heading: “Pricing (WAC) of Enbrel from Launch to Today”).

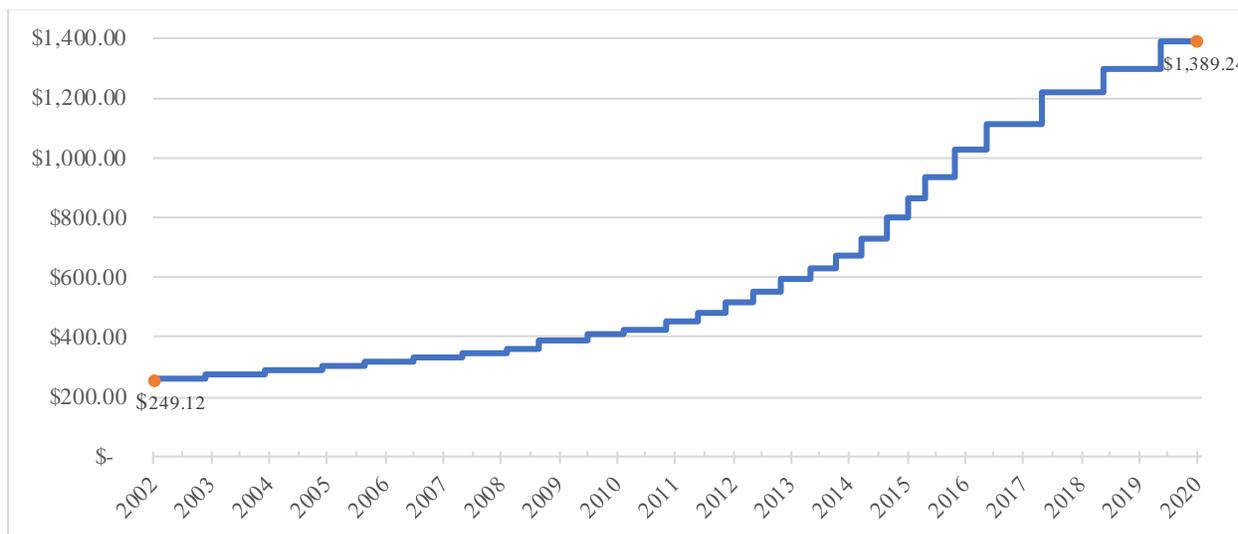
<sup>7</sup> *Id.*

<sup>8</sup> This 12-month period was from July 1, 2015, when Enbrel cost \$800.66, to July 1, 2016, when Enbrel was priced at \$1,024.44. IBM Micromedex Redbook, *Wholesale Acquisition Cost History for Enbrel*.

one year.<sup>9</sup> Enbrel is now priced at \$5,556.96 per month, or \$72,240.48 annually—a 457% increase from when it was acquired.<sup>10</sup>

Figure 1 below shows the price per 50-mg dose of Enbrel from 2002 to the present.<sup>11</sup>

Figure 1: Enbrel Price Increases



### *Sensipar*

FDA approved Amgen to market Sensipar (cinacalcet) in 2004 for the treatment of overactive parathyroid glands in dialysis patients, a common complication of chronic kidney disease.<sup>12</sup> Sensipar is also approved to treat high levels of calcium in patients with parathyroid carcinoma, a type of cancer.<sup>13</sup> Sensipar is a tablet taken orally and comes in 30, 60, or 90 mg dosages.<sup>14</sup>

<sup>9</sup> *Id.*

<sup>10</sup> *Id.*

<sup>11</sup> *Id.* This calculation reflects the Wholesale Acquisition Cost of a four-week monthly regimen of Enbrel or a 52-week yearly regimen of Enbrel.

<sup>12</sup> Letter from Robert Meyer, Director, Office of Drug Evaluation II, Food and Drug Administration, to Pamela Danagher, Manager, Regulatory Affairs, Amgen Inc. (Mar. 8, 2004) (online at [www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2004/21688ltr.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2004/21688ltr.pdf)); Noah K. Yuen, *Hyperparathyroidism of Renal Disease*, *The Permanente Journal* (Jul. 22, 2016) (online at [www.ncbi.nlm.nih.gov/pmc/articles/PMC4991918/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4991918/)).

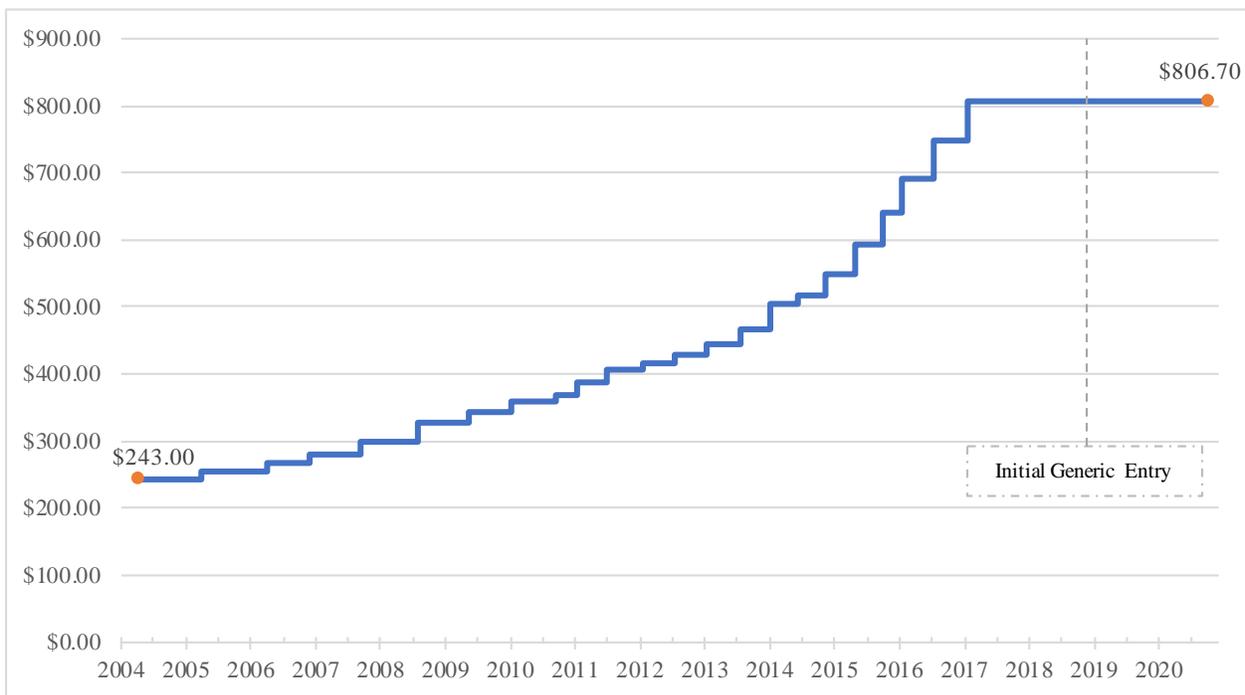
<sup>13</sup> Letter from Robert Meyer, Director, Office of Drug Evaluation II, Food and Drug Administration, to Pamela Danagher, Manager, Regulatory Affairs, Amgen Inc. (Mar. 8, 2004) (online at [www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2004/21688ltr.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2004/21688ltr.pdf)).

<sup>14</sup> Amgen Inc., *Sensipar Prescribing Information* (online at [www.pi.amgen.com/~media/amgen/repositorysites/pi-amgen-com/sensipar/sensipar\\_pi\\_hcp\\_english.pdf](http://www.pi.amgen.com/~media/amgen/repositorysites/pi-amgen-com/sensipar/sensipar_pi_hcp_english.pdf)) (accessed Sept. 30, 2020).

Since bringing Sensipar to market in 2004, Amgen has raised the price at least 20 times and sometimes multiple times per year. In 2004, a 30-tablet package of 30 mg Sensipar was priced at \$243. In 2017, the same product was priced at \$806.70. These price increases have inflated the cost of a typical yearly course of Sensipar from \$2,956 in 2004 to \$9,814.85 today.<sup>15</sup> Amgen has not increased the price of Sensipar since its primary patent on the drug expired in and generics entered the market in late 2018.<sup>16</sup>

Figure 2 below shows the price of a 30-tablet package of 30 mg Sensipar from 2004 to the present.

Figure 2: Sensipar 30 mg Price Increases (30 Tablet Package)



## II. RISING CORPORATE PROFITS

### A. Growing Revenues and Profits

#### *Enbrel*

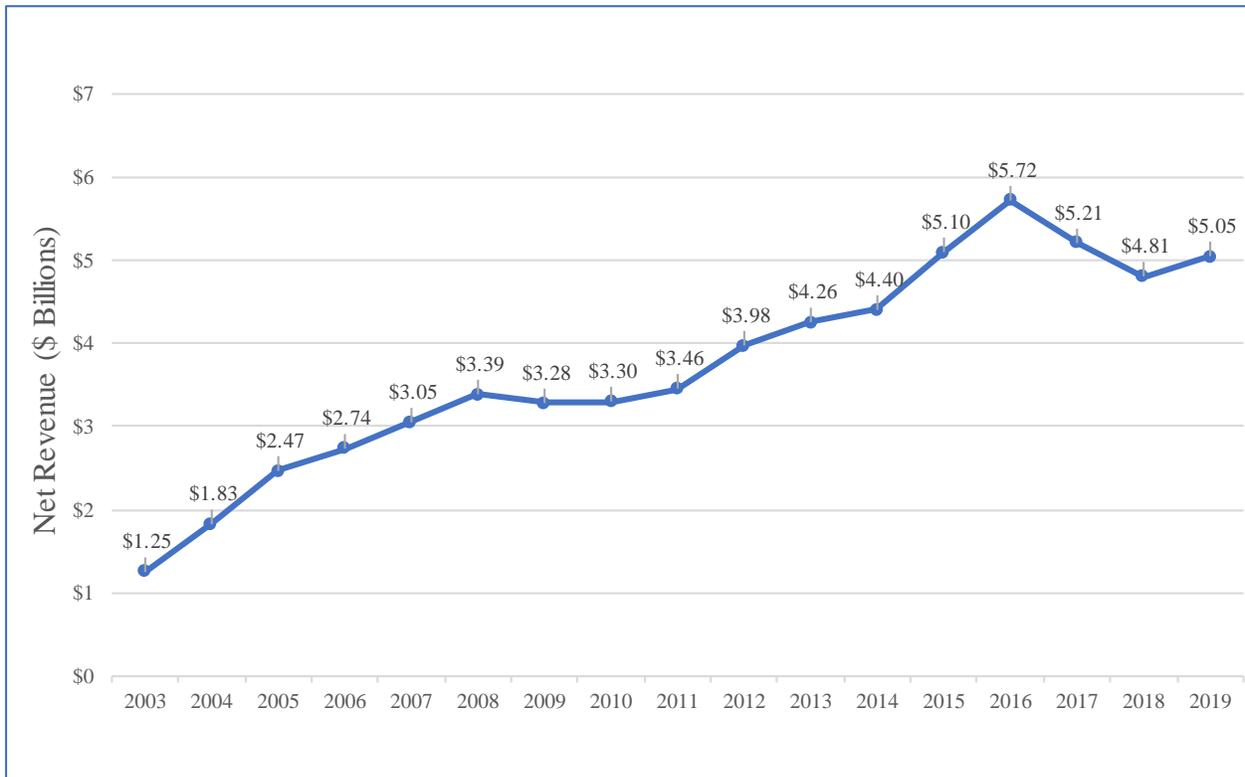
<sup>15</sup> IBM Micromedex Redbook, *Wholesale Acquisition Cost History for Sensipar*. To calculate the yearly course of Sensipar, staff multiplied the price of one 30 mg pill by 365.

<sup>16</sup> Amgen Inc., *2018 Form 10-K* (Feb. 13, 2019) (online at [www.sec.gov/Archives/edgar/data/318154/000031815418000004/0000318154-18-000004-index.htm](http://www.sec.gov/Archives/edgar/data/318154/000031815418000004/0000318154-18-000004-index.htm)); Amgen Inc., *2019 Form 10-K* (Feb. 12, 2020) (online at [www.sec.gov/ix?doc=/Archives/edgar/data/318154/000031815420000017/amgn-12312019x10kq42019.htm](http://www.sec.gov/ix?doc=/Archives/edgar/data/318154/000031815420000017/amgn-12312019x10kq42019.htm)). As explained in Section VI below, Amgen entered into an agreement with the generic manufacturer and it left the market in early 2019.

Amgen’s price increases for Enbrel have contributed to billions of dollars in net revenue for the company.<sup>17</sup> Enbrel revenue increased steadily from 2002 until 2017, when Enbrel began losing market share to Humira.<sup>18</sup> In 2019, Amgen’s net revenue for Enbrel was \$5.05 billion.<sup>19</sup>

Figure 3 below reflects Amgen’s net revenue in the U.S. for Enbrel over time.<sup>20</sup>

Figure 3: Amgen Net U.S. Revenue for Enbrel



### *Sensipar*

Amgen collected billions of dollars in net revenue from Sensipar in the years leading up to the drug’s loss of exclusivity in 2018. In 2018, Amgen reported nearly \$1.4 billion in net U.S.

<sup>17</sup> Amgen defines “net sales” as “net of accruals for estimated rebates, wholesaler chargebacks, discounts, and other deductions (collectively, sales deductions) and returns established at the time of sale.” See Letter from King & Spalding, on behalf of Amgen Inc., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Mar. 15, 2019) (Appendix A); Amgen Inc., *2019 Form 10-K* (Feb. 12, 2020) (online at [www.sec.gov/ix?doc=/Archives/edgar/data/318154/000031815420000017/amgn-12312019x10kq42019.htm](http://www.sec.gov/ix?doc=/Archives/edgar/data/318154/000031815420000017/amgn-12312019x10kq42019.htm)).

<sup>18</sup> Amgen Inc., *2017 Form 10-K* (Feb. 13, 2018) (online at [www.sec.gov/Archives/edgar/data/318154/000031815418000004/amgn-12312017x10k.htm](http://www.sec.gov/Archives/edgar/data/318154/000031815418000004/amgn-12312017x10k.htm)).

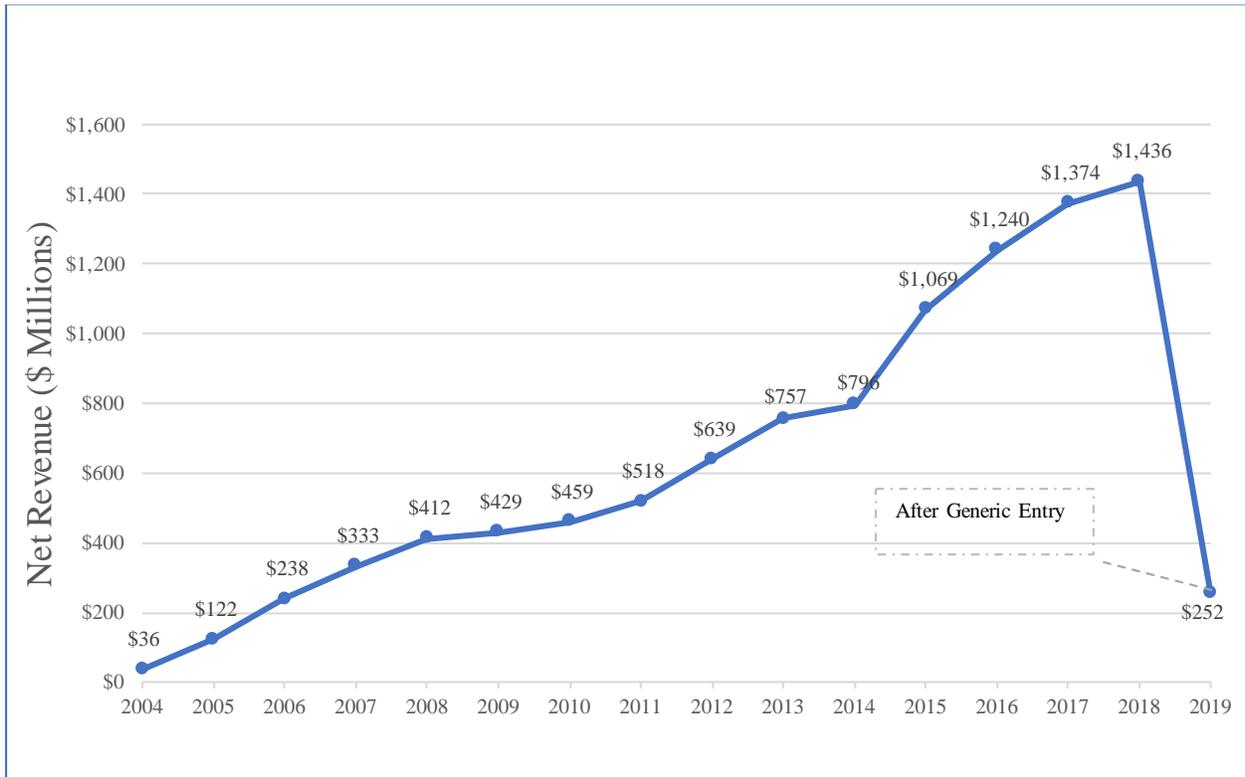
<sup>19</sup> Amgen Inc., *2019 Form 10-K* (Feb. 12, 2020) (online at [www.sec.gov/ix?doc=/Archives/edgar/data/318154/000031815420000017/amgn-12312019x10kq42019.htm](http://www.sec.gov/ix?doc=/Archives/edgar/data/318154/000031815420000017/amgn-12312019x10kq42019.htm)).

<sup>20</sup> *Id.*

revenue from Sensipar.<sup>21</sup> Amgen’s net U.S. revenue for Sensipar increased every year until generic competition entered the market.<sup>22</sup>

Figure 4 below reflects Amgen’s net revenue in the U.S. for Sensipar over time.

Figure 4: Amgen Net U.S. Revenue for Sensipar



Amgen’s price increases for Enbrel and Sensipar fueled the company’s profitability. The company’s net income has grown nearly every year since it began selling Enbrel.<sup>23</sup>

<sup>21</sup> Amgen Inc., *Form 10-K* (2004-2020) (online at [www.sec.gov/cgi-bin/browse-edgar?CIK=318154&owner=exclude](http://www.sec.gov/cgi-bin/browse-edgar?CIK=318154&owner=exclude)).

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

Figure 5 below reflects Amgen’s net worldwide income from 2009 to 2019.<sup>24</sup>

**Figure 5: Amgen Net Worldwide Income**



**B. Revenue Targets Driving Price Increases**

Documents reviewed by the Committee show that Amgen executives at the highest levels of the company, including CEO Robert Bradway and then-Executive Vice President Anthony

<sup>24</sup> Amgen’s net worldwide income dipped in 2017 because of a \$6.1 billion U.S. federal income tax liability. Amgen’s tax charge was the result of a provision in the 2017 Tax Cuts and Jobs Act (TCJA) that allowed corporations to repatriate earnings held in foreign subsidiaries at a significantly reduced tax rate. In Amgen’s case, the disclosure of a \$6.1 billion charge indicates that the company appears to have been holding between \$39 billion and \$76 billion in its foreign subsidiaries. In 2018, after the TCJA reduced the corporate income tax rate from 35% to 21%, Amgen executed a stock buyback of \$17.8 billion. Adding the \$6.1 billion back into Amgen’s net sales for 2017 would have resulted in worldwide income of more than \$8 billion, a steady climb from 2016. See Amgen Inc., 2017 Form 10-K (Feb. 13, 2018) (online at [www.sec.gov/Archives/edgar/data/318154/000031815418000004/amgn-12312017x10k.htm#sA8A2B63DD5A45730AAEAE991B8F25B56](http://www.sec.gov/Archives/edgar/data/318154/000031815418000004/amgn-12312017x10k.htm#sA8A2B63DD5A45730AAEAE991B8F25B56)); Board of Governors of the Federal Reserve System, *FEDS Notes: U.S. Corporations’ Repatriation of Offshore Profits: Evidence from 2018* (Aug. 6, 2019) (online at [www.federalreserve.gov/econres/notes/feds-notes/us-corporations-repatriation-of-offshore-profits-20190806.htm](http://www.federalreserve.gov/econres/notes/feds-notes/us-corporations-repatriation-of-offshore-profits-20190806.htm)); Tax Policy Center, *What is the TCJA Repatriation Tax and How Does it Work?* (May 2020) (online at [www.taxpolicycenter.org/briefing-book/what-tcja-repatriation-tax-and-how-does-it-work#:~:text=Before%20the%202017%20Tax%20Cuts,resents%20on%20their%20worldwide%20income.&text=Upon%20repatriation%2C%20the%20earnings%20would,credit%20for%20foreign%20taxes%20paid.](http://www.taxpolicycenter.org/briefing-book/what-tcja-repatriation-tax-and-how-does-it-work#:~:text=Before%20the%202017%20Tax%20Cuts,resents%20on%20their%20worldwide%20income.&text=Upon%20repatriation%2C%20the%20earnings%20would,credit%20for%20foreign%20taxes%20paid.)); Amgen Inc., 2018 Form 10-K (Feb. 13, 2019) (online at [www.sec.gov/Archives/edgar/data/318154/000031815419000008/amgn-12312018x10kq42018.htm#sDB332325C4E859F0B6AC70D2048D5718](http://www.sec.gov/Archives/edgar/data/318154/000031815419000008/amgn-12312018x10kq42018.htm#sDB332325C4E859F0B6AC70D2048D5718)).

Hooper, raised prices for Enbrel and Sensipar to meet or surpass increasingly aggressive sales targets and projections.

Mr. Hooper was Amgen's second highest-paid executive in 2017 and the individual responsible for approving price increases, sometimes in consultation with Mr. Bradway.<sup>25</sup> In March 2016, Mr. Hooper prepared a memorandum for Mr. Bradway reporting an increase of \$50 million in the full year sales projections due to a number of "adjustments" to the forecast. The first adjustment listed was: "Pricing Impacts in the U.S. This includes the benefit of the Dec. '15 Enbrel price increase, moving Sensipar [price increases] up to Jan./Jun. actions (vs Plan of Apr./Oct.)."<sup>26</sup>

- Pricing impacts in the US. This includes the benefit of the Dec. '15 Enbrel price increase, moving Sensipar up to Jan./Jun. actions (vs Plan of Apr./Oct.) and [Redacted - Non-Responsive] [Redacted - Non-Responsive] It also includes the improvement to the AMP Medicare rate (-\$90M).

The memo noted that net U.S. revenue for the quarter was "\$93M above Plan driven primarily by Sensipar (+\$35M), Enbrel (+\$31M), and [redacted] for the reasons described above."<sup>27</sup>

**Regional Performance Highlights QTD:**

- U.S. (Plan: Q1 +9% YoY; FY +5% YoY):
  - QTD Q1 performance is +\$93M above Plan driven primarily by Sensipar (+\$35M), Enbrel (+\$31M) and [Redacted - Non-Responsive] for the reasons described above. The March Forecast includes an increase of \$30M vs. Plan for the quarter.

Other internal pricing documents show that Amgen executives raised prices—sometimes even higher than previously planned—to meet revenue targets. For example, in June 2016, Amgen's pricing committee proposed an 8% price increase for Sensipar (the second 8% increase in 2016). The justification for the price increase was that earlier projections had assumed the 8% price increase would be taken and forgoing the price increase would result in a shortfall of \$22.5 million in 2016 and \$74.4 million in 2017.<sup>28</sup> Amgen executed the price increase on July 14, 2016.<sup>29</sup>

<sup>25</sup> Amgen Inc., *2018 Proxy Statement* (Apr. 11, 2018) (online at [www.amgen.com/~/media/amgen/full/www-amgen-com/downloads/investors/2018-proxy-statement.ashx?la=en](http://www.amgen.com/~/media/amgen/full/www-amgen-com/downloads/investors/2018-proxy-statement.ashx?la=en)).

<sup>26</sup> AMGN-HCOR-RR-00430788.

<sup>27</sup> *Id.*

<sup>28</sup> AMGN-HCOR-RR-00010804, at Slides 14-16.

<sup>29</sup> IBM Micromedex Redbook, *Wholesale Acquisition Cost History for Sensipar*.

In December 2016, the Amgen pricing committee considered how much to increase the prices of Enbrel and Sensipar in 2017. For Sensipar, the pricing committee noted that Amgen was planning an 8% price increase in January 2017 and estimated that forgoing such a price increase would cost approximately \$100 million in net revenue in 2017.<sup>30</sup> For Enbrel, prior financial projections had assumed a price increase of 6%, but the committee recommended a 7.9% price increase.<sup>31</sup> The presentation included an extensive analysis of the financial benefits of different price increase scenarios. The proposal estimated that a 7.9% price increase in December 2016 would result in 2017 net revenue of \$47.2 million, compared to net revenue of only \$5.4 million with a lower 6% increase.<sup>32</sup>

**FINANCIAL ANALYSIS OF ENBREL® PI SCENARIOS**

Oct LEDR Date of PI's Jan 6, 2017, Jan 5, 2018	Included in LE/LEDR	Comparison	Overall Est. Change in Net Revenue for 2016	Overall Est. Change in Net Revenue for 2017
Dec 22, 2016 – 6.0%	N	Compared to Oct LEDR	(\$2.1M)	\$5.4M
Dec 22, 2016 – 7.9%	N	Compared to Oct LEDR	(\$2.5M)	\$47.2M
Dec 22, 2016 – 6.0% Jul 14, 2017 PI – 7.9%	N	Compared to Oct LEDR	(\$2.1M)	\$75M
Dec 22, 2016 – 7.9% Jul 14, 2017 PI – 7.9%	N	Compared to Oct LEDR	(\$2.5M)	\$114M

Does not include WDA fee adjustment

58

Amgen Proprietary—For Internal Use Only   
Selected - Non-Responsive

AMGN CONFIDENTIAL TREATMENT REQUESTED AMGN-HCOR-PRDCT-00000054

As Amgen’s deliberations about the 2017 price increases continued, executives began warning about the financial downside of delaying the price increase. Executives informed Mr. Hooper that delaying a 6% Enbrel price increase for even one month would cost the company \$12 million in net revenue and delaying it for the year would cost \$164 million in net revenue. They also informed him that delaying Sensipar’s price increase for one month would cost Amgen \$3 million, and delaying it for 2017 would cost \$58 million in net revenue. The team recommended going forward with the Sensipar increase immediately, and Mr. Hooper agreed.<sup>33</sup>

<sup>30</sup> AMGN-HCOR-RR-00000010, at Slide 58.

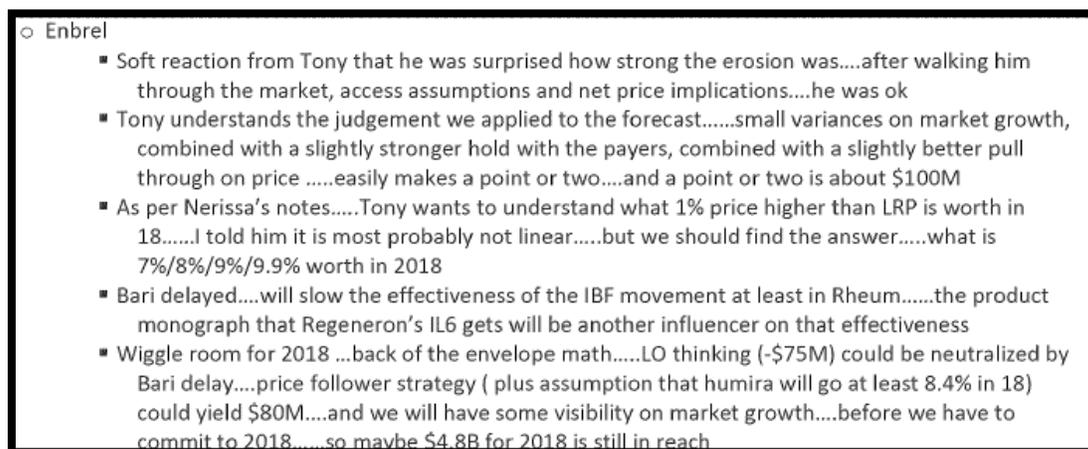
<sup>31</sup> *Id.*, at Slide 5.

<sup>32</sup> *Id.*, at Slide 55.

<sup>33</sup> AMGN-HCOR-RR-00026372.

Noting that “the sensitivity around Enbrel is higher,” the executives did not recommend immediately raising its price, but they highlighted other price increases by competitors in Enbrel’s therapeutic class.<sup>34</sup> Ten days later, Amgen decided to raise the price of Enbrel by 8.4%—even higher than previously discussed.<sup>35</sup> Amgen’s price increase came two days after AbbVie raised the price of Enbrel’s competitor drug, Humira, on January 18, 2017.<sup>36</sup> (See Section V, below, for a discussion of Amgen’s shadow pricing of AbbVie’s Humira prices).

Another 2017 email chain shows how Mr. Hooper and other executives used price increases to meet financial targets. After Mr. Hooper expressed surprise in a May 2017 meeting about “how strong the erosion was” in Enbrel’s net revenue forecast with a smaller price increase, he asked his team to calculate projected net revenue for price increases at 7%, 8%, 9%, and 9.9%. The executives brainstormed ways to increase net revenue in 2018 to meet Mr. Hooper’s expectations, including by engaging in shadow pricing with AbbVie: “price follower strategy (plus assumption that humira will go at least 8.4% in 18) could yield \$80M ... and we still have some visibility on market growth ... before we have to commit to 2018 ... so maybe \$4.8B for 2018 is still in reach.”<sup>37</sup>



o Enbrel

- Soft reaction from Tony that he was surprised how strong the erosion was....after walking him through the market, access assumptions and net price implications....he was ok
- Tony understands the judgement we applied to the forecast.....small variances on market growth, combined with a slightly stronger hold with the payers, combined with a slightly better pull through on price .....easily makes a point or two....and a point or two is about \$100M
- As per Nerissa’s notes.....Tony wants to understand what 1% price higher than LRP is worth in 18.....I told him it is most probably not linear.....but we should find the answer.....what is 7%/8%/9%/9.9% worth in 2018
- Bari delayed....will slow the effectiveness of the IBF movement at least in Rheum.....the product monograph that Regeneron’s IL6 gets will be another influencer on that effectiveness
- Wiggle room for 2018 ...back of the envelope math.....LO thinking (-\$75M) could be neutralized by Bari delay....price follower strategy ( plus assumption that humira will go at least 8.4% in 18) could yield \$80M....and we will have some visibility on market growth....before we have to commit to 2018.....so maybe \$4.8B for 2018 is still in reach

On January 1, 2018, Amgen raised the price of Enbrel by 9.7%.<sup>38</sup> Amgen met its net revenue goal of \$4.8 billion in 2018—\$1.9 billion higher than in 2009.<sup>39</sup>

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<sup>34</sup> *Id.*

<sup>35</sup> AMG-N-HCOR-RR-00039834; IBM Micromedex Redbook, *Wholesale Acquisition Cost History for Enbrel*.

<sup>36</sup> *Id.*

<sup>37</sup> AMG-N-HCOR-RR-00000904 (ellipses in original).

<sup>38</sup> IBM Micromedex Redbook, *Wholesale Acquisition Cost and Average Wholesale Price History for Enbrel*.

<sup>39</sup> See Letter from King & Spalding, on behalf of Amgen Inc., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Mar. 15, 2019) (Appendix A).

A “Global Product Strategy” presentation prepared for Enbrel in March 2018 confirmed that Amgen’s price increases for the product drove net revenue and that the company would continue such pricing strategy in the future:

Pricing has played a key role in driving net revenue in the Rheumatology and Dermatology space in recent years. Moving forward, Amgen will continue to adjust price as necessary to reflect the economic value provided while also considering competitive dynamics and patient access to care.<sup>40</sup>

### III. EXECUTIVE BONUSES

Documents and information reviewed by the Committee show that Amgen executives, including Mr. Hooper and Mr. Bradway, appear to have received higher bonuses as a direct result of their decisions to raise the prices of Enbrel and Sensipar.

Internal documents detailing Amgen’s executive compensation policy state that 60% of bonus amounts are determined by whether the company has met net revenue targets.<sup>41</sup> Given that Enbrel and Sensipar’s net U.S. revenue combined made up 28.8% of Amgen’s 2018 worldwide revenue and 26.29% of its 2017 worldwide revenue, price increases for those products appear to have been a critical factor in determining whether executives received their bonuses.<sup>42</sup>

For example, Mr. Hooper directed his team to explore taking a higher-than-planned price increase in January 2018, which would ensure that Amgen met its 2018 Enbrel revenue target of \$4.8 billion. The company proceeded to raise the price of Enbrel by 9.7%, which allowed Amgen to barely reach the revenue target (see Section II above).<sup>43</sup> Mr. Hooper, in turn, received incentive compensation of nearly \$1.8 million for the year, supplementing his salary of \$1 million and stock and option awards worth almost \$4 million.<sup>44</sup> In 2018, Mr. Bradway also received incentive compensation of nearly \$4 million, supplementing his base salary of \$1.5 million and stock and option awards worth almost \$12.4 million.<sup>45</sup>

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<sup>40</sup> AMGN-HCOR-RR-00000357, at Slide 6.

<sup>41</sup> AMGN-HCOR-RR-430634.

<sup>42</sup> Amgen Inc. *2018 Form 10-K* (Feb. 13, 2019) (online at [www.sec.gov/Archives/edgar/data/318154/000031815419000008/amgn-12312018x10kq42018.htm#sDB332325C4E859F0B6AC70D2048D5718](http://www.sec.gov/Archives/edgar/data/318154/000031815419000008/amgn-12312018x10kq42018.htm#sDB332325C4E859F0B6AC70D2048D5718)).

<sup>43</sup> IBM Micromedex Redbook, *Wholesale Acquisition Cost History for Enbrel*; Letter from King & Spalding, on behalf of Amgen Inc., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Mar. 15, 2019) (Appendix A).

<sup>44</sup> Amgen Inc., *2019 Proxy Statement* (Apr. 8, 2019) (online at [www.sec.gov/Archives/edgar/data/318154/000119312519100704/d629495ddef14a.htm#toc629495\\_41](http://www.sec.gov/Archives/edgar/data/318154/000119312519100704/d629495ddef14a.htm#toc629495_41)); AMGN-HCOR-0000001; AMGN-HCOR-RR-00000904 (2017 email chain regarding price increase for Enbrel, which was implemented on January 1, 2018).

<sup>45</sup> Amgen Inc., *2019 Proxy Statement* (Apr. 8, 2019) (online at [www.sec.gov/Archives/edgar/data/318154/000119312519100704/d629495ddef14a.htm#toc629495\\_41](http://www.sec.gov/Archives/edgar/data/318154/000119312519100704/d629495ddef14a.htm#toc629495_41)).

Amgen paid its top five highest-compensated employees over \$50 million collectively in 2018. The same year, 118 U.S. employees received more than \$1 million each in total salaries, bonuses, benefits, and stock. In 2017, Amgen paid 158 U.S. employees more than \$1 million each.<sup>46</sup>

Figure 6 below shows the compensation of top Amgen executives in 2017 and 2018.<sup>47</sup>

Figure 6: Amgen Senior Executive Compensation

Amgen Senior Executive Compensation						
2017						
	Base Salary	Incentive Compensation and Performance Bonuses	Performance Units and Restricted Stock Units	Stock Options	All Other Compensation	Total
Robert A. Bradway, CEO	\$ 1,555,962	\$ 2,683,000	\$ 8,399,812	\$ 3,599,974	\$ 661,041	\$ 16,899,789
Anthony C. Hooper, EVP, GCO	\$ 1,050,173	\$ 1,207,000	\$ 2,799,937	\$ 1,199,973	\$ 295,467	\$ 6,552,550
David W. Meline, EVP, CFO	\$ 970,769	\$ 1,116,000	\$ 2,449,878	\$ 1,049,990	\$ 271,651	\$ 5,858,288
Sean E. Harper, EVP, R&D	\$ 970,769	\$ 1,116,000	\$ 2,589,867	\$ 1,110,000	\$ 269,731	\$ 6,056,367
Jonathan P. Graham, EVP	\$ 932,577	\$ 858,000	\$ 1,749,939	\$ 749,997	\$ 231,695	\$ 4,522,208
<b>Total Executives</b>						\$ 39,889,202
2018						
	Base Salary	Incentive Compensation and Performance Bonuses	Performance Units and Restricted Stock Units	Stock Options	All Other Compensation	Total
Robert A. Bradway, CEO	\$ 1,566,000	\$ 3,898,000	\$ 8,749,818	\$ 3,749,994	\$ 591,454	\$ 18,555,266
Murdo Gordon, EVP, GCO	\$ 330,769	\$ 2,513,000	\$ 9,899,961		\$ 1,336,604	\$ 14,080,334
Anthony C. Hooper, Former EVP, GCO	\$ 1,057,050	\$ 1,754,000	\$ 2,799,925	\$ 1,199,995	\$ 254,489	\$ 7,065,459
David W. Meline, EVP, CFO	\$ 977,746	\$ 1,623,000	\$ 2,799,925	\$ 1,199,995	\$ 260,102	\$ 6,860,768
David M. Reese, EVP, R&D	\$ 697,500	\$ 1,213,000	\$ 3,029,787	\$ 269,966	\$ 129,019	\$ 5,339,272
Jonathan P. Graham, EVP	\$ 938,596	\$ 1,402,000	\$ 1,959,878	\$ 839,983	\$ 204,901	\$ 5,345,358
<b>Total Executives</b>						\$ 57,246,457

#### IV. HIGHER U.S. PRICE 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.<sup>48</sup> With the federal government unable to negotiate, U.S. patients and Medicare pay significantly more for Enbrel and Sensipar than buyers in other countries pay.

<sup>46</sup> Letter from King & Spalding, on behalf of Amgen Inc., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (July 18, 2019) (Appendix A).

<sup>47</sup> Amgen Inc., *2020 Proxy Statement* (Apr. 7, 2020) (online at [www.amgen.com/~/media/amgen/full/www-amgen-com/downloads/investors/2020\\_proxy\\_statement.ashx?la=en](http://www.amgen.com/~/media/amgen/full/www-amgen-com/downloads/investors/2020_proxy_statement.ashx?la=en)); Amgen Inc., *2018 Proxy Statement* (Apr. 11, 2018) (online at [www.amgen.com/~/media/amgen/full/www-amgen-com/downloads/investors/2018-proxy-statement.ashx?la=en](http://www.amgen.com/~/media/amgen/full/www-amgen-com/downloads/investors/2018-proxy-statement.ashx?la=en)).

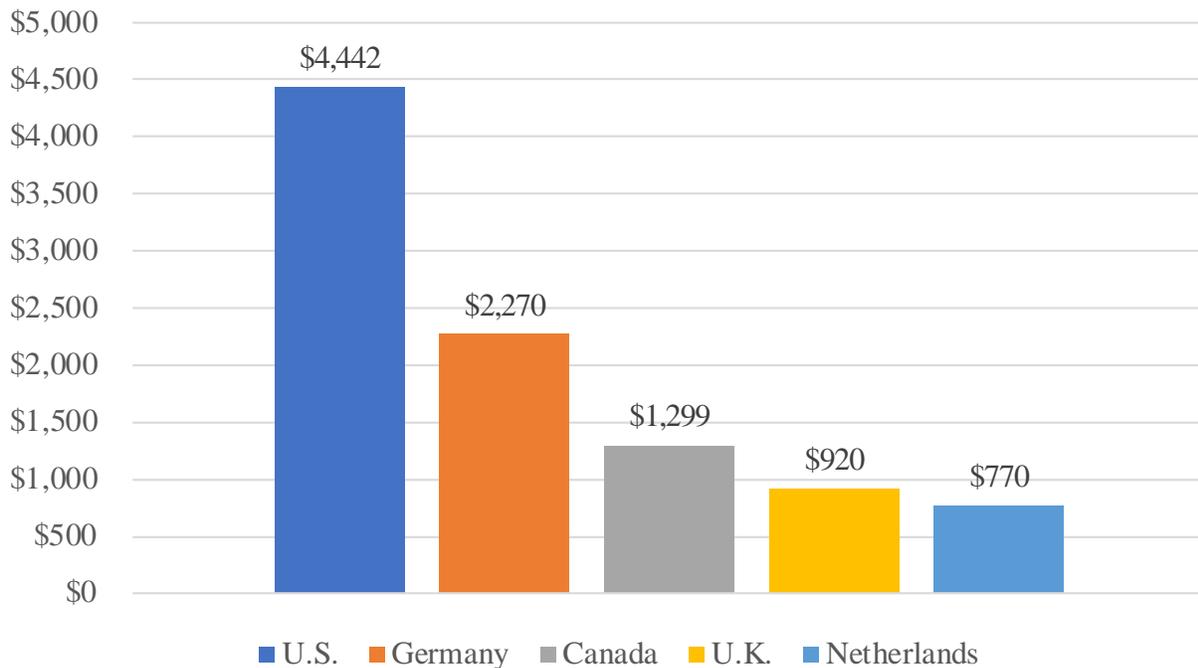
<sup>48</sup> 42 U.S.C. § 1395w-111.

### A. Targeting U.S. Market for Price Increases

Enbrel and Sensipar are priced much higher in the United States than in the rest of the world. In 2017, a monthly supply of Enbrel in the U.S. was \$4,442. This was \$3,142 more than Amgen charged for the drug in Canada, which has imposed some cost controls on pharmaceutical products.<sup>49</sup> In 2017, Pfizer, which sells Enbrel in Europe, charged \$2,270 per month in Germany, \$920 in the United Kingdom, and \$770 in the Netherlands.<sup>50</sup>

Figure 7 below shows Enbrel's U.S. price in 2017 as compared other countries.

Figure 7: Price of Monthly Supply of Enbrel in 2017



Due to this disparity, the largest share of worldwide Enbrel revenue comes from the United States. For example, in 2019, Amgen collected \$5 billion in U.S. Enbrel revenue out of \$6.7 billion in total global revenue.<sup>51</sup>

<sup>49</sup> IBM Micromedex Redbook, *Wholesale Acquisition Cost for Enbrel*; Canadian Agency for Drugs and Technology in Health, *Canadian Drug Expert Committee Recommendation: Etanercept* (July 2017) (online at [www.cadth.ca/sites/default/files/cdr/complete/SE0513\\_complete\\_Erelzi\\_Jul\\_28\\_17\\_e.pdf](http://www.cadth.ca/sites/default/files/cdr/complete/SE0513_complete_Erelzi_Jul_28_17_e.pdf)) (stating that the price of one vial of Enbrel 50mg was C\$405.99, which is \$324.79 under prevailing exchange rates).

<sup>50</sup> Statista, *Average Prices of Enbrel in Selected Countries in 2017* (Feb. 5, 2020) (online at [www.statista.com/statistics/312007/price-of-enbrel-by-country/](http://www.statista.com/statistics/312007/price-of-enbrel-by-country/)).

<sup>51</sup> Amgen Inc., *2019 Form 10-K* (Feb. 12, 2020) (online at [www.sec.gov/ix?doc=/Archives/edgar/data/318154/000031815420000017/amgn-12312019x10kq42019.htm](http://www.sec.gov/ix?doc=/Archives/edgar/data/318154/000031815420000017/amgn-12312019x10kq42019.htm)); Pfizer Inc., *2019 Financial Report* (online at <https://investors.pfizer.com/financials/annual-reports/default.aspx>) (Appendix A).

Amgen also charges nearly double the price of Sensipar in the U.S. as it does in Canada. In the U.S., a 30-tablet package of Sensipar 30 mg costs \$806.<sup>52</sup> In Canada, the same supply costs \$447.99.<sup>53</sup>

## **B. Lack of Medicare Negotiation Costing Taxpayers Billions**

Amgen's pricing practices for Enbrel and Sensipar have increased U.S. health care program expenditures, with a disproportionate impact on Medicare. According to data reviewed by the Committee, Amgen collected more than \$7 billion in Enbrel gross sales and \$4 billion in Sensipar gross sales from Medicare Part D from 2013 to 2018.<sup>54</sup>

Amgen paid a portion of these sales back in rebates and other discounts. But internal Amgen documents show that in recent years, Amgen did not provide meaningfully greater discounts to Medicare Part D plans than to commercial plans.<sup>55</sup>

In contrast, internal data show that Amgen provides discounts to the Veteran's Health Administration (VA) and the Department of Defense (DOD) for Enbrel and Sensipar that are as much as twice the discounts for Medicare plans.<sup>56</sup> If Medicare had the same discounts as VA and DOD, Medicare could have saved more than \$2.6 billion on Enbrel and \$990 million on Sensipar between 2013 and 2018. Figure 8 below highlights the differences in these discounts and the potential savings.<sup>57</sup>

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<sup>52</sup> IBM Micromedex Redbook, *Wholesale Acquisition Cost History for Sensipar*.

<sup>53</sup> Canada Pharmacy Online, *Sensipar (Cinacalcet)* (online at [www.canadapharmacyonline.com/DrugInfo.aspx?name=Sensipar6385](http://www.canadapharmacyonline.com/DrugInfo.aspx?name=Sensipar6385)) (accessed Sept. 30, 2020).

<sup>54</sup> AMGN-HCOR-RR-00012760; AMGN-HCOR-RR-00439923. These figures likely underestimate Medicare's total spending on Sensipar. On January 1, 2018, Medicare began paying for Sensipar prescribed for dialysis patients under a transitional payment system known as the Transitional Drug Add-On Payment Adjustment (TDAPA). As a result, beginning in 2018, Medicare Part B paid the TDAPA to dialysis facilities, and Medicare Part D coverage was limited to prescriptions for non-dialysis patients. Centers for Medicare and Medicaid Services, Medicare Learning Network, *Implementation of the Transitional Drug Add-On Payment Adjustment* (Aug. 9, 2017) (online at [www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10065.pdf](http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10065.pdf)). The above figures only include the Part D expenditures and do not account for the Part B expenditures.

<sup>55</sup> AMGN-HCOR-RR-00012760; AMGN-HCOR-RR-00439923.

<sup>56</sup> *Id.*

<sup>57</sup> *Id.* See also Democratic Staff, Senate Committee on Homeland Security and Governmental Affairs, *Manufactured Crisis: How Better Negotiation Could Save Billions for Medicare and America's Seniors* (Aug. 2018) (online at [www.hsgac.senate.gov/imo/media/doc/REPORT-Manufactured%20Crisis-How%20Better%20Negotiation%20Could%20Save%20Billions%20for%20Medicare%20and%20America's%20Seniors.pdf](http://www.hsgac.senate.gov/imo/media/doc/REPORT-Manufactured%20Crisis-How%20Better%20Negotiation%20Could%20Save%20Billions%20for%20Medicare%20and%20America's%20Seniors.pdf)) (estimating that Medicare Part D could save at least \$2.8 billion in one year by negotiating prices with drug manufacturers for the top 20-most prescribed drugs in Medicare).

Figure 8: Lost Medicare Part D Savings for Enbrel and Sensipar

<b>Enbrel</b>			
<b>Year</b>	<b>Gross Medicare Part D Sales</b>	<b>Lost Part D Discount % (Compared to VA/DOD/FFS)</b>	<b>Lost Part D Savings</b>
2013	\$ 893,300,000.00	35.8%	\$ 319,801,400.00
2014	\$ 1,083,800,000.00	36.9%	\$ 399,922,200.00
2015	\$ 1,092,600,000.00	35.4%	\$ 386,780,400.00
2016	\$ 1,187,900,000.00	43.0%	\$ 510,797,000.00
2017	\$ 1,406,700,000.00	39.0%	\$ 548,613,000.00
2018	\$ 1,389,200,000.00	36.5%	\$ 507,058,000.00
<b>Total</b>	<b>\$ 7,053,500,000.00</b>	<b>37.9%</b>	<b>\$ 2,672,972,000.00</b>
<b>Sensipar</b>			
<b>Year</b>	<b>Gross Medicare Part D Sales</b>	<b>Lost Part D Discount % (Compared to VA/DOD/FFS)</b>	<b>Lost Part D Savings</b>
2013	\$ 341,200,000.00	12.3%	\$ 41,967,600.00
2014	\$ 414,300,000.00	15.2%	\$ 62,973,600.00
2015	\$ 602,300,000.00	22.5%	\$ 135,517,500.00
2016	\$ 1,026,000,000.00	26.2%	\$ 268,812,000.00
2017	\$ 1,328,300,000.00	32.0%	\$ 425,056,000.00
2018	\$ 293,500,000.00	19.0%	\$ 55,765,000.00
<b>Total</b>	<b>\$ 4,005,600,000.00</b>	<b>24.7%</b>	<b>\$ 990,091,700.00</b>

**C. Harm to U.S. Patients**

Amgen’s price increases have imposed thousands of dollars in out-of-pocket costs for U.S. patients and have left many unable to afford their drugs. A recent Kaiser Family Foundation study found that the median annual out-of-pocket cost for a Medicare beneficiary on Enbrel was \$5,465 in 2019—nearly \$600 more than in 2016.<sup>58</sup> In 2019, the median income for a Medicare beneficiary was \$29,650.<sup>59</sup>

Amgen is aware of the harm its price increases impose on patients. The company has regularly received complaints from patients who are unable to afford Enbrel or Sensipar and who

<sup>58</sup> Kaiser Family Foundation, *The Out-of-Pocket Cost Burden for Specialty Drugs in Medicare Part D in 2019* (Feb. 2019) (online at <http://files.kff.org/attachment/Issue-Brief-the-Out-of-Pocket-Cost-Burden-for-Specialty-Drugs-in-Medicare-Part-D-in-2019>).

<sup>59</sup> Kaiser Family Foundation, *Medicare Beneficiaries’ Financial Security Before the Coronavirus Pandemic* (Apr. 24, 2020) (online at [www.kff.org/medicare/issue-brief/medicare-beneficiaries-financial-security-before-the-coronavirus-pandemic/](http://www.kff.org/medicare/issue-brief/medicare-beneficiaries-financial-security-before-the-coronavirus-pandemic/)).

request the company's help. Some patients reported having stopped taking Enbrel or Sensipar because of the cost.<sup>60</sup> For example:

- One patient told the Amgen call center representative: “My insurance has changed to Medicare ... the bottom line is I can no longer take Enbrel. I have severe RA [rheumatoid arthritis]. On Medicare the cost is a third of my income. Since I turned 65 in September, I just can't afford it. I've been on Enbrel for 13 years. Enbrel has saved my life. ... How horrible it is to become a senior citizen, have RA, and not be able to afford the drug that gives a quality of life.”<sup>61</sup>
- Another Medicare beneficiary told Amgen that she had been on Enbrel for 14 or 15 years, and the cost had gone up to \$5,800 during that time. The patient stated, “I will never recommend Enbrel only because of the cost.”<sup>62</sup>
- One Medicare beneficiary on Sensipar wrote: “I am a patient on dialysis and was told I need to take a prescription called Sensipar. When I went to fill this prescription, I was told it would cost me \$329.63 at this time. I am currently in the donut hole. If I fill this prescription, I cannot afford to get all my other prescriptions for the rest of this year.”<sup>63</sup>
- Another Sensipar patient wrote: “I take dialysis and our unit prescribes Sensipar for everyone. We were told Amgen has a monopoly on this drug. I called today to see about the prescription and our part is almost \$800, insurance will not cover it. The regular price was almost \$2000 a month. We need to know do you have a program that would help with the cost of this? I am being told that is the only that that works on the parathyroid. I told them I will not take the drug due to the price.”<sup>64</sup>

## V. SHADOW PRICING WITH ABBVIE

Amgen's primary competitor for Enbrel is Humira, AbbVie's blockbuster biologic treatment for rheumatoid arthritis and other conditions. Instead of pricing Enbrel under Humira's price to gain market share—as expected in a competitive market—Amgen engaged in a practice known as “shadow pricing,” consistently following AbbVie's price increases. This led to both companies setting higher and higher prices for Enbrel and Humira. Experts have warned that when companies engage in shadow pricing, patients “often bear the burden of these costs

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<sup>60</sup> AMGN-HCOR-00000017; AMGN-HCOR-00001174; Letter from King & Spalding, on behalf of Amgen Inc., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Mar. 15, 2019); Letter from King & Spalding, on behalf of Amgen Inc., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Apr. 5, 2019).

<sup>61</sup> AMGN-HCOR-0000017 to AMGN-HCOR-00000030 (ellipses in original).

<sup>62</sup> *Id.*

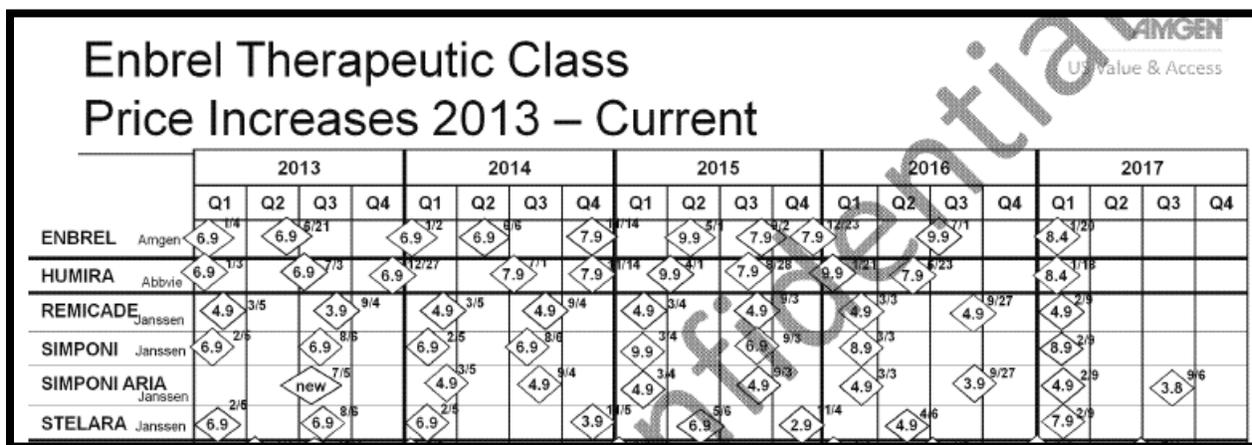
<sup>63</sup> *Id.*

<sup>64</sup> *Id.*

through increased premiums, copayments and retail prices,” and that if shadow pricing continues, “the US healthcare model is likely to become increasingly unsustainable.”<sup>65</sup>

Amgen’s internal documents indicate that when AbbVie’s price increase for Humira exceeded Amgen’s planned price increase for Enbrel, Amgen executives took higher price increases to keep pace with AbbVie. Amgen also ran its own net sales projections based on expectations of whether AbbVie’s price increases would be “conservative,” “aggressive,” or “super aggressive.”<sup>66</sup>

The chart below shows how Amgen tracked AbbVie’s price increases for Humira.<sup>67</sup>



The chart was regularly included in Amgen’s Pricing Committee presentations and emails, and it was consistently updated and distributed to reflect AbbVie’s most recent price increases.<sup>68</sup>

Amgen executives believed AbbVie’s pricing actions for Humira justified taking higher and more frequent price increases for Enbrel. For example, on May 11, 2016, the day before a meeting of Amgen’s U.S. Pricing Committee, a senior Amgen executive sent an email to Anthony Hooper requesting a price increase of “9.9 percent to match Humira’s in January which puts us behind by 2 percent.”<sup>69</sup> A presentation prepared for the May 12 meeting shows that Amgen had previously planned to take a 7.9% increase in June 2016. However, because Amgen executives believed AbbVie would again raise Humira’s price, they recommended that Amgen

<sup>65</sup> Anurag S. Rathore, Faheem Shereef, *Shadow Pricing and the Art of Profiteering from Outdated Therapies*, Nature Biotechnology (Dec. 2019) (online at <https://pubmed.ncbi.nlm.nih.gov/30809025/>).

<sup>66</sup> AMGN-HCOR-RR-00007229 (a pricing committee email from April 2016 that also noted that “the organization feels reasonably comfortable following AbbVie”).

<sup>67</sup> AMGN-HCOR-RR-00039834 (excerpt of full table).

<sup>68</sup> See, e.g., AMGN-HCOR-RR-00000010, at Slide 8; AMGN-HCOR-RR-00431334, at Slide 34; AMGN-HCOR-RR-00000176, at Slide 15; AMGN-HCOR-RR-00014573, at Slide 1.

<sup>69</sup> AMGN-HCOR-RR-00434914. The executive wrote, “The first request is 9.9 percent to match Humira’s in January which puts us behind by 2 percent. As you know this is problematic with the PBM situation.”

take a higher-than-planned price increase to match AbbVie's. The slide stated: "Approve an Enbrel® price increase of up to 9.9% prior to August 1, 2016, as soon as operationally feasible, following AbbVie's anticipated price increase." The slide made clear that AbbVie's "Price increase strategy is to follow AbbVie's price increases."<sup>70</sup>

The slide is titled "EXECUTIVE SUMMARY ENBREL® PRICE INCREASE". In the top right corner, there is a dark grey box with white text that reads "Product: ENBREL®" and "Customer or Segment: Price Increase". Below the title, there is a section labeled "Background" with a list of four bullet points: "Enbrel® last price Increase was 7.9% on Dec 23<sup>rd</sup> 2015", "Price increase strategy is to follow AbbVie's price increases", "Feb LEDR assumed a 7.9% price increase in June of 2016", and "Anticipated net sales of \$6.1B in 2016". Below this, there is a box titled "Seeking approval on:" containing one bullet point: "Approve an Enbrel® price increase up to 9.9% prior to Aug 1, 2016, as soon as operationally feasible, following AbbVie's anticipated price increase". At the bottom of the slide, there is a small number "6" and the text "Amgen Proprietary—For Internal Use Only" followed by the "AMGEN" logo.

The presentation projected that taking a 9.9% price increase by August 1, 2016, would net Amgen \$60 million in 2017.<sup>71</sup>

Mr. Hooper's team raised the issue again on June 24, 2016, after receiving confirmation of AbbVie's price increase for Humira. They recommended that Amgen take its own price increase before July 1, 2016. One analyst wrote:

My discussion with you yesterday focused on maximizing the possibility that Enbrel would be able to take a second price increase in Dec. 2016. And that the probability of a

<sup>70</sup> AMGN-HCOR-RR-000434916, at Slide 5.

<sup>71</sup> *Id.*, at Slide 6.

second PI [price increase] for Enbrel would go up if we would follow Humira as fast as possible.<sup>72</sup>

He concluded that “going as early as possible with our first PI in 2016 ... will increase our optionality about a potential December price increase.”<sup>73</sup> Mr. Hooper responded that he would “discuss at the CEO meeting this morning.”<sup>74</sup> His team continued to press him for a decision over the next few days, writing on Monday, June 27, 2016, “If we have a decision by noon today, PI could be effective on Weds., 7/29 [sic], or later.”<sup>75</sup>

Amgen took the 9.9% price increase as recommended, effective July 1, 2016.<sup>76</sup>

A few months later, in September 2016, Amgen executives discussed the feasibility of delaying the public announcement of net revenue projections to determine whether AbbVie would raise the price of Humira again, which Amgen executives believed would allow them to increase the price twice in 2017, rather than only once as previously planned. One executive wrote:

Corporate is trying to delay providing guidance on '17 in this next Earnings Call, the rationale being that we still need to wait on the outcome of certain big ticket items (e.g. will AbbVie take price and if so how big). How quick/easy is it to provide a ballpark estimate of the scenario above, assuming we follow AbbVie with two 9.9% s or 7.9% s instead of the single 6% P.I. [price increase] we assumed in Jan. '17?<sup>77</sup>

Conversations about Enbrel’s pricing continued through the end of 2016. A December 2016 pricing committee presentation included three different pricing scenarios for Enbrel based on AbbVie’s pricing of Humira. In the first scenario, Amgen would execute a 7.9% price increase for Enbrel on January 6, 2017 if AbbVie did not increase the price of Humira before January 6. If AbbVie increased the price of Humira by up to 7.9% before January 6, Amgen would increase the price of Enbrel by 7.9% on January 6. If AbbVie increased Humira’s price by more than 7.9%, the pricing committee would be consulted again and expected to increase Enbrel’s price by more than 7.9%.<sup>78</sup>

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<sup>72</sup> AMGN-HCOR-RR-00027037.

<sup>73</sup> *Id.*

<sup>74</sup> *Id.*

<sup>75</sup> *Id.*

<sup>76</sup> IBM Micromedex Redbook, *Wholesale Acquisition Cost and Average Wholesale Price History for Enbrel*.

<sup>77</sup> AMGN-HCOR-RR-00006948.

<sup>78</sup> AMGN-HCOR-RR-00438104, at Slides 9-11.

## EXECUTIVE SUMMARY

Product: Enbrel®

Customer or Segment: All

## ENBREL PRICE INCREASE PENDING LEGAL APPROVAL

### Background

- Last price increase for Enbrel® was 9.9% on July 1, 2016
- October LEDR assumed a 6.0% price increase in January 2017
- Anticipated net sales of \$5.8B in 2017

### Seeking approval to:

Execute an Enbrel price increase as follows:

- Scenario 1: Abbvie does not increase before Jan 6 → execute Enbrel price increase of 7.9% on January 6
- Scenario 2: Abbvie increases before Jan 6 by up to 7.9% → execute Enbrel price increase up to 7.9% following Abbvie on or before January 6
- Scenario 3: Abbvie increases before Jan 6 by more than 7.9% → come back to Pricing Committee for approval of higher rate

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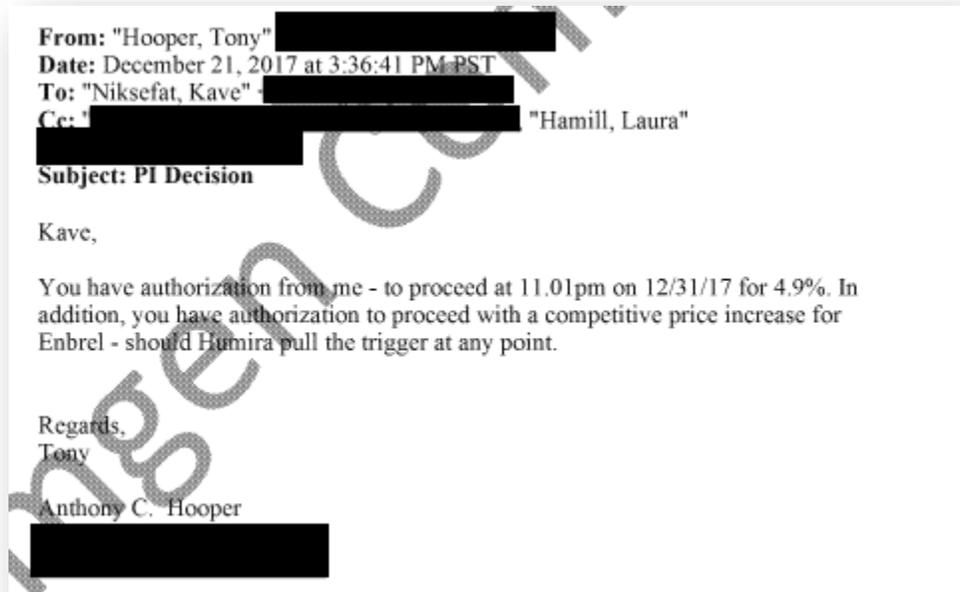
Amgen Proprietary—For Internal Use Only **AMGEN**

Amgen ultimately raised Enbrel's price by 8.4% on January 20, 2017, two days after AbbVie raised the price of Humira by 8.4% on January 18, 2017.<sup>79</sup>

Internal documents show another instance in which Amgen changed a planned price increase to match AbbVie's price for Humira. In December 2017, while approving a planned 4.9% Enbrel price increase for December 31, 2017, Mr. Hooper stated in an email, "In addition, you have authorization to proceed with a competitive price increase for Enbrel—should Humira pull the trigger at any point."<sup>80</sup>

<sup>79</sup> AMGN-HCOR-RR-00039834, at Slide 3; IBM Micromedex Redbook, *Wholesale Acquisition Cost and Average Wholesale Price History for Enbrel*.

<sup>80</sup> AMGN-HCOR-RR-00029310.



The scenario that Mr. Hooper anticipated ultimately played out. Internal emails show that after learning that AbbVie planned to raise the price of Humira by 9.7% in January 2018, Amgen executed an identical 9.7% increase for Enbrel—almost double the price increase it had planned to take on December 31, 2017.<sup>81</sup>

Another email exchange reviewed by the Committee illustrates how important Amgen executives viewed the ability to quickly match AbbVie’s prices for Humira. On January 19, 2017, a commercial contracts and pricing analyst asked a colleague about using its pharmacy relationships to gain access to a Humira price increase “on the effective day” rather the “day after.” The analyst emphasized that “Each day for which a price increase becomes effective is significant revenue for products like Enbrel.”<sup>82</sup>

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<sup>81</sup> AMGN-HCOR-RR-00030638.

<sup>82</sup> AMGN-HCOR-RR-00003911.

From: [REDACTED]  
Sent: Thursday, January 19, 2017 2:39 PM  
To: [REDACTED]  
Cc: [REDACTED]  
Subject: Question on drug purchase pricing through pharmacy

[REDACTED]

I hope all is well and you're enjoying the return to GSS. I've got an issue that I hope you can help us with a possible solution.

To refresh...I am in the US Commercial contracts & pricing area. We monitor competitor price increases which often impact our pricing strategy. For example, the Enbrel team wants to know immediately when a competitor, e.g. Humira, takes a price increase. Currently, we cannot confirm a competitor price increase until a day after the price increase because compendia price lists are typically updated at midnight at the end of the day in which the price increase became effective. We believe that a pharmacy submitting an order to a wholesaler would see the price increase on the effective day since the pharmacy must be invoiced appropriately. Wholesalers do not provide that ordering price list to Amgen. We are wondering if Amgen orders non-Amgen drugs from pharmacies and has a relationship with a pharmacy whereby we could request the pharmacy to confirm via an order form that a competitor price increase occurred.

I imagine you may want to discuss. Hopefully, you can help us with this. Each day for which a price increase becomes effective is significant revenue for products like Enbrel.

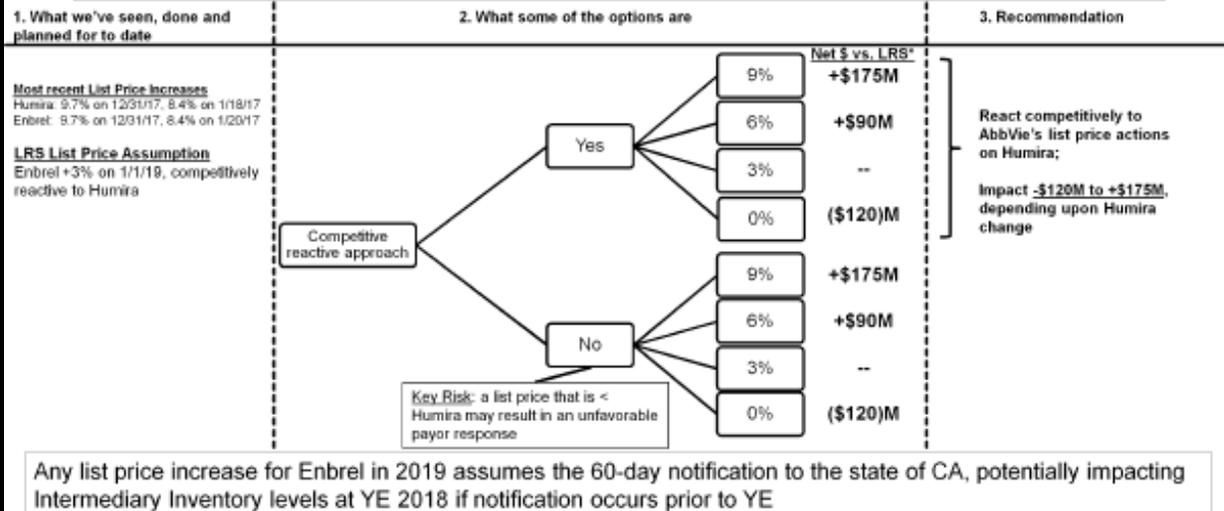
Thank you,  
[REDACTED]

Amgen's internal documents indicate that it continued shadow pricing with AbbVie through last year. A draft September 2018 strategy presentation recommended that Amgen "React competitively to AbbVie's list price actions on Humira."<sup>83</sup>

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<sup>83</sup> AMGN-HCOR-RR-00041867, at Slide 4.

## WHEN ASSESSING POTENTIAL LIST PRICE CHANGES FOR ENBREL IN 2019, NEED TO CONSIDER MAGNITUDE, AND POTENTIAL COMPETITOR AND PAYOR ACTIONS



\* Excludes potential impact of inventory changes

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When AbbVie took a 6.2% price increase for Humira January 1, 2019, Amgen took an identical price increase for Enbrel on January 17, 2019. Similarly, when AbbVie took a 7.4% price increase for Humira on January 1, 2020, Amgen took an identical price increase for Enbrel on January 17, 2020.<sup>84</sup>

## VI. ANTICOMPETITIVE TACTICS TO MAXIMIZE PROFITS

Amgen pursued numerous strategies to limit competition and extend its monopoly pricing for Enbrel and Sensipar. Amgen exploited the U.S. patent system to limit biosimilar competition for Enbrel and prevented U.S. patients from accessing lower-priced versions of the drug. In addition, Amgen entered into settlement agreements to delay entry of generic versions of Sensipar. Amgen also attempted to gain additional market exclusivity for Sensipar by showing that it could be used in children, despite serious safety risks and knowledge that the FDA was

<sup>84</sup> IBM Micromedex Redbook, *Wholesale Acquisition Cost and Average Wholesale Price History for Humira and Enbrel*.

unlikely to grant approval. As a result, Enbrel currently has no biosimilar competition.<sup>85</sup> In addition, there is only limited generic competition for Sensipar, depriving patients of significantly lower prices.<sup>86</sup>

### **A. Leveraging U.S. Patent System to Extend Enbrel's Monopoly**

Although the primary patent for Enbrel expired in 2010, Enbrel still has no biosimilar competition in the United States.<sup>87</sup> Amgen has applied for or been granted 68 patents on Enbrel.<sup>88</sup> Experts at the Initiative for Medicines, Access, and Knowledge (I-MAK) estimate that the granted patents will extend Amgen's monopoly on Enbrel until 2037.<sup>89</sup> These patents have prevented manufacturers of lower-priced biosimilars that have already been approved by the FDA from entering the U.S. market.<sup>90</sup> If the pending applications are granted, I-MAK estimates that Amgen's monopoly would be further extended to 2038.<sup>91</sup>

As its primary patent approached its expiration date, Amgen appealed two denials from the U.S. Patent and Trade Office (PTO) for additional similar patents. In 2011 and 2012, PTO granted these two patents, which had been filed in 1995.<sup>92</sup> Amgen knew that the potential payoff of appealing PTO's denials was significant: U.S. patent law gives 17 years of protection from the date of issuance *if* the patent application was filed before June 1995.<sup>93</sup> When PTO granted Amgen's additional Enbrel patents, it set their terms to last until 2028 and 2029, giving Amgen a 27-year monopoly on Enbrel.<sup>94</sup>

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<sup>85</sup> *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049 (Fed. Cir. 2020); *see also Amgen Wins Enbrel Drug Patent Appeal*, Axios (July 2, 2020) (online at [www.axios.com/amgen-enbrel-drug-patent-appeal-ebc46097-dffa-4908-a5e3-390b9ee57136.html](http://www.axios.com/amgen-enbrel-drug-patent-appeal-ebc46097-dffa-4908-a5e3-390b9ee57136.html)).

<sup>86</sup> Food and Drug Administration, *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* (online at [www.accessdata.fda.gov/scripts/cder/ob/search\\_product.cfm](http://www.accessdata.fda.gov/scripts/cder/ob/search_product.cfm)) (accessed Sept. 30, 2020). FDA estimates that the price of a prescription drug drops by nearly 40% with the entry of a single generic competitor, 54% with the entry of two generic competitors, and more than 95% with the entry of six or more competitors. Food and Drug Administration, *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices* (Dec. 2019) (online at [www.fda.gov/media/133509/download](http://www.fda.gov/media/133509/download)).

<sup>87</sup> Initiative for Medicines, Access, and Knowledge, *Overpatented, Overpriced, Special Edition Enbrel* (Nov. 30, 2018) (online at [www.i-mak.org/wp-content/uploads/2018/12/i-mak.enbrel.report-2018-11-30F.pdf](http://www.i-mak.org/wp-content/uploads/2018/12/i-mak.enbrel.report-2018-11-30F.pdf)); Initiative for Medicines, Access, and Knowledge, *Data on America's Top 12 Drugs* (online [www.i-mak.org/overpatented-data/](http://www.i-mak.org/overpatented-data/)) (accessed Sept. 30, 2020).

<sup>88</sup> *Id.*

<sup>89</sup> *Id.*

<sup>90</sup> Food and Drug Administration, *Purple Book: Database of Licensed Biological Products* (online at <https://purplebooksearch.fda.gov/>) (accessed Sept. 30, 2020) (identifying two FDA-approved biosimilars: Erelzi and Eticovo).

<sup>91</sup> *Id.*

<sup>92</sup> Patent No. 8,063,182 (filed May 19, 1995); Patent No. 8,163,522 (filed May 19, 1995).

<sup>93</sup> *Patent for Amgen Drug May Undercut Health Care Plan*, New York Times (Nov. 23, 2011) (online at [www.nytimes.com/2011/11/23/business/amgens-new-enbrel-patent-may-undercut-health-care-plan.html](http://www.nytimes.com/2011/11/23/business/amgens-new-enbrel-patent-may-undercut-health-care-plan.html)).

<sup>94</sup> Patent No. 8,063,182 (filed May 19, 1995); Patent No. 8,163,522 (filed May 19, 1995).

Soon after the 2011 patent was issued, analysts at Sanford C. Bernstein estimated that it added \$6 per share to Amgen's stock price.<sup>95</sup> With approximately 870 million outstanding shares, this single patent issuance potentially added \$5 billion to Amgen's value.<sup>96</sup>

Amgen also leveraged minor changes to Enbrel's design to extend the drug's profitably and limit the risk of competition—a strategy that the pharmaceutical industry calls “lifecycle management.” In 2017, Amgen launched a new injection formulation and device for Enbrel called “Enbrel Mini with AutoTouch.” The Enbrel Mini was no different from other forms of Enbrel other than its packaging—a single-dose, pre-filled cartridge that is designed to be used with Amgen's AutoTouch reusable autoinjector, for up to two years.<sup>97</sup>

One of Amgen's objectives in launching the Enbrel Mini was to retain patients who otherwise might switch to lower-priced medications. An internal presentation prepared for the Vice President and General Manager of Amgen's Inflammation and Nephrology Business unit highlighted that one of Amgen's top three “Keys to Enbrel Success in 2018” was to “Drive brand choice via Enbrel Mini with AutoTouch and our new formulation.”<sup>98</sup>

Internal documents indicate that the injection device and other lifecycle management activities were designed to defend Enbrel from competition.<sup>99</sup> Amgen projected that its lifecycle management tactics would net \$41 million in 2018 and add to Enbrel's market share for certain indications.<sup>100</sup>

A “Global Product Strategy” presentation in March 2018 illustrates how Amgen's patent and lifecycle management strategies work together to suppress Enbrel's competition. The presentation highlighted Enbrel's relative importance to the company's commercial success, noting: “Enbrel is a critical value driver for the Amgen portfolio, with 2017 combined US and Canadian net sales of \$5.4 billion.” The presentation then identified “protecting/enhancing intellectual property” as one of three “Critical capabilities needed to support continued success of Enbrel.” The presentation emphasized that:

“It is critical for Amgen to continue to seek new patents where possible, to further protect LCM [lifecycle management] initiatives such as the Enbrel Mini with AutoTouch and

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<sup>95</sup> *New Patent Could Be Worth \$6 A Share to Amgen*, Forbes (Nov. 28, 2011) (online at [www.forbes.com/sites/matthewherper/2011/11/28/new-patent-could-be-worth-6-a-share-to-amgen/#4be44a7a46e1](http://www.forbes.com/sites/matthewherper/2011/11/28/new-patent-could-be-worth-6-a-share-to-amgen/#4be44a7a46e1)).

<sup>96</sup> Macrotrends, *Amgen 36-Year Stock Price History* (online at [www.macrotrends.net/stocks/charts/AMGN/amgen/stock-price-history](http://www.macrotrends.net/stocks/charts/AMGN/amgen/stock-price-history)) (accessed Sept. 30, 2020).

<sup>97</sup> Amgen Inc., *ENBREL Mini® Single-Dose Prefilled Cartridge with AutoTouch Reusable Autoinjector* (online at [www.enbrel.com/support/mini-with-autotouch](http://www.enbrel.com/support/mini-with-autotouch)) (accessed Sept. 30, 2020).

<sup>98</sup> AMGN-HCOR-RR-00005265, at Slide 11.

<sup>99</sup> AMGN-HCOR-RR-00004862 (Slide titled “Lifecycle Management Launches Provide Key Near-Term Opportunities to Support 2019+ Net Sales” includes a chart of projects in the pipeline with target dates for launch).

<sup>100</sup> AMGN-HCOR-RR-00122632, at Slides 190-191 (adding the impact on rheumatology and dermatology Enbrel sales).

review the existing landscape to ensure we are appropriately protecting the value of Enbrel.<sup>101</sup>

Amgen has leveraged its patent and lifecycle management strategies to prevent competitors from introducing lower-priced biosimilar versions of Enbrel. Although FDA approved biosimilar versions of Enbrel in 2016 and 2019, Amgen sued both manufacturers for infringement of the 2011 and 2012 patents described above.<sup>102</sup>

In July 2020, a federal court of appeals ruled in Amgen's favor in the first case.<sup>103</sup> Then, in December 2019, Amgen entered into an agreement with the manufacturer of the second Enbrel biosimilar. The two companies agreed to stay the patent infringement lawsuit, and the biosimilar manufacturer agreed not to market its biosimilar unless: (1) a federal court ruled Amgen's patents invalid, and (2) 180 days passed after the manufacturer gave Amgen notice of its intent to enter the market.<sup>104</sup> U.S. patent law will allow Amgen's monopoly to continue until at least 2029.<sup>105</sup>

Amgen has used the U.S. patent system to gain more protection for the drug than in other parts of the world, which already have lower-priced Enbrel biosimilars on the market.<sup>106</sup> In Europe, where Enbrel is marketed by Pfizer Inc., biosimilars have been competing with Enbrel

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<sup>101</sup> AMGN-HCOR-RR-00000357, at Page 11.

<sup>102</sup> Food and Drug Administration, *Purple Book: Database of Licensed Biological Products* (online at <https://purplebooksearch.fda.gov/>) (accessed Sept. 30, 2020); Amgen Inc., *2019 Form 10-K* (Feb. 12, 2020) (online at [www.sec.gov/ix?doc=/Archives/edgar/data/318154/000031815420000017/amgn-12312019x10kq42019.htm](http://www.sec.gov/ix?doc=/Archives/edgar/data/318154/000031815420000017/amgn-12312019x10kq42019.htm)); *FDA Approves Biosimilar to Enbrel*, Healio (Aug. 30, 2016) (online at [www.healio.com/news/rheumatology/20160830/fda-approves-biosimilar-to-enbrel](http://www.healio.com/news/rheumatology/20160830/fda-approves-biosimilar-to-enbrel)); *FDA Approves Eticovo, Second Enbrel Biosimilar*, Healio (Apr. 26, 2019) (online at [www.healio.com/news/rheumatology/20190426/fda-approves-eticovo-second-enbrel-biosimilar](http://www.healio.com/news/rheumatology/20190426/fda-approves-eticovo-second-enbrel-biosimilar)).

<sup>103</sup> *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049 (Fed. Cir. 2020); see also *Amgen Wins Enbrel Drug Patent Appeal*, Axios (July 2, 2020) (online at [www.axios.com/amgen-enbrel-drug-patent-appeal-ebc46097-dffa-4908-a5e3-390b9ee57136.html](http://www.axios.com/amgen-enbrel-drug-patent-appeal-ebc46097-dffa-4908-a5e3-390b9ee57136.html)).

<sup>104</sup> Settlement Agreement, *Immunex v. Samsung Bioepis*, No. 19-11755 (D. N.J. Dec. 23, 2019).

<sup>105</sup> *Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049 (Fed. Cir. 2020); see also *Amgen Wins Enbrel Drug Patent Appeal*, Axios (July 2, 2020) (online at [www.axios.com/amgen-enbrel-drug-patent-appeal-ebc46097-dffa-4908-a5e3-390b9ee57136.html](http://www.axios.com/amgen-enbrel-drug-patent-appeal-ebc46097-dffa-4908-a5e3-390b9ee57136.html)).

<sup>106</sup> Mochida Pharmaceutical Co., Ltd., *Press Release: The NHI Drug Price Listing and Launch of Etanercept Biosimilar in Japan* (May 30, 2018) (online at [mochida.co.jp/english/news/docs/2018/180530etanerceptBS.pdf](http://mochida.co.jp/english/news/docs/2018/180530etanerceptBS.pdf)); Biogen Inc., *Press Release: Benepali, the First Etanercept Biosimilar Referencing Enbrel, Approved in the European Union* (Jan. 16, 2016) (online at [www.businesswire.com/news/home/20160116005011/en/BENEPALI%C2%AE-Etanercept-Biosimilar-Referencing-Enbrel%C2%AE-Approved-European](http://www.businesswire.com/news/home/20160116005011/en/BENEPALI%C2%AE-Etanercept-Biosimilar-Referencing-Enbrel%C2%AE-Approved-European)); *Biogen Launches Enbrel Biosimilar Benepali in the UK*, PharmaTimes (Feb. 16, 2016) (online at [www.pharmatimes.com/news/biogen\\_launches\\_enbrel\\_biosimilar\\_benepali\\_in\\_the\\_uk\\_1020383](http://www.pharmatimes.com/news/biogen_launches_enbrel_biosimilar_benepali_in_the_uk_1020383)).

since 2016.<sup>107</sup> By 2018, the price of Enbrel dropped in Europe by nearly 50%, and biosimilars held 40% of the market share.<sup>108</sup>

## **B. Attempting to Gain Pediatric Exclusivity for Sensipar Despite Risks**

In 2016, Amgen attempted to extend its market exclusivity for Sensipar by applying for a six-month pediatric exclusivity extension, which is granted by FDA when a drug is newly approved for pediatric use.<sup>109</sup> This exclusivity extends beyond the pediatric indication to all of the product's formulations and indications, effectively preventing generic entry for an additional six months.<sup>110</sup> In 2013, FDA suspended clinical studies of Sensipar in children after a 14-year-old child died during one study.<sup>111</sup> Amgen later applied for a pediatric extension despite knowledge that FDA was unlikely to grant approval.

Amgen's internal communications show executives focused on the income potential of the six-month extension despite its risks. In an April 2016 email prior to Amgen's application for pediatric exclusivity, an executive informed Amgen CEO Robert Bradway that even though FDA was unlikely to grant approval, Amgen was continuing to pursue the pediatric exclusivity for financial reasons.<sup>112</sup>

Bob,

Following the Quarterly Business Review, Tony asked that I clarify for you the current status of the Pediatric Exclusivity extension for Sensipar in the US, and the Product Team's expectations of securing. The current base case LRP assumes patent expiry in March of 2018 without extension, as it is not anticipated that the formal FDA requirements will be met. However the team is proceeding with filing efforts (File: November 2016), with notification of grant of exclusivity in May 2017.

<sup>107</sup> See, e.g., *Pfizer Cuts Price of Enbrel to Match Rival 'Biosimilar' Drug*, Irish Times (Oct. 25, 2016) (online at [www.irishtimes.com/business/health-pharma/pfizer-cuts-price-of-enbrel-to-match-rival-biosimilar-drug-1.2841789](http://www.irishtimes.com/business/health-pharma/pfizer-cuts-price-of-enbrel-to-match-rival-biosimilar-drug-1.2841789)); European Medicines Agency, *Enbrel* (online at [www.ema.europa.eu/en/medicines/human/EPAR/enbrel#authorisation-details-section](http://www.ema.europa.eu/en/medicines/human/EPAR/enbrel#authorisation-details-section)) (accessed Sept. 30, 2020); European Medicines Agency, *Summary of Opinion* (Nov. 19, 2015) (online at [www.pbwt.com/content/uploads/2016/09/WC500196736.pdf](http://www.pbwt.com/content/uploads/2016/09/WC500196736.pdf)).

<sup>108</sup> Initiative for Medicines, Access, and Knowledge, *Overpatented, Overpriced, Special Edition: Enbrel* (Nov. 30, 2018) (online at [www.i-mak.org/wp-content/uploads/2018/12/i-mak.enbrel.report-2018-11-30F.pdf](http://www.i-mak.org/wp-content/uploads/2018/12/i-mak.enbrel.report-2018-11-30F.pdf)).

<sup>109</sup> See 21 U.S.C. § 355a.

<sup>110</sup> *Id.*

<sup>111</sup> Food and Drug Administration, *FDA Drug Safety Communication* (Feb. 26, 2013) (online at [www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-pediatric-clinical-studies-sensipar-cinacalcet-hydrochloride-suspended](http://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-pediatric-clinical-studies-sensipar-cinacalcet-hydrochloride-suspended)).

<sup>112</sup> AMGN-HCOR-RR-00040017.

According to the executive, “despite low probability of regulatory success, the potential upside to the LRP [long range plan] is meaningful and all available options are being leveraged by the team.”<sup>113</sup>

- Despite low probability of regulatory success, the potential upside to the LRP is meaningful and all available options are being leveraged by the team.
- Notification of grant of exclusivity is anticipated 6 months following submission (May 2017).

In June 2016, Amgen executives estimated that “a six month extension of LOE for Sensipar is worth \$.25B for the 18-19 period in the U.S.”<sup>114</sup>

On Jun 29, 2016, at 5:12 AM, [REDACTED] wrote:

[REDACTED]

During one of our Parsabiv readiness meetings, the question was asked what is a potential 6 month extension on the LOE for Sensipar worth. The team ran the numbers .....and a six month extension of LOE for Sensipar is worth \$.25B for the 18-19 period in the US

Both [REDACTED] and I wanted to share this number with you.....we realize you know how important maximizing our shot of obtaining this objective is.....now it also has a dollar sign attached to it.

[REDACTED]

The company filed a pediatric exclusivity application in November 2016.<sup>115</sup> FDA denied Amgen’s request for a pediatric indication in March 2017, and Amgen sued FDA to reverse its determination. After filing suit, executives estimated that gaining the additional six-month pediatric exclusivity extension was valued at “\$100Ms in the near term.”<sup>116</sup>

In February 2018, the district court ruled against Amgen.<sup>117</sup> The court noted that FDA had required a study with at least 15 participants between the ages of 28 days to less than six

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<sup>113</sup> *Id.*

<sup>114</sup> AMGN-HCOR-RR-00040614.

<sup>115</sup> Genetic Engineering and Biotechnology News, *Amgen Sues to Reverse FDA Denial of Pediatric Exclusivity for Sensipar* (May 31, 2017) (online at [www.genengnews.com/news/amgen-sues-to-reverse-fda-denial-of-pediatric-exclusivity-for-sensipar/](http://www.genengnews.com/news/amgen-sues-to-reverse-fda-denial-of-pediatric-exclusivity-for-sensipar/)).

<sup>116</sup> AMGN-HCOR-RR-00119439.

<sup>117</sup> *Amgen Inc. v. Azar et al.*, 290 F. Supp. 3d 65 (D.D.C. 2018).

years old, but Amgen’s study included only four participants, and that “Amgen’s data did not yield ‘clinically meaningful’ information on cinacalcet’s [Sensipar] safety in that age group—a key objective of [FDA’s] written request.”<sup>118</sup> Amgen appealed the decision, but agreed to dismiss the appeal in October 2018.<sup>119</sup>

Documents reviewed by the Committee highlight that Amgen’s leveraging of pediatric exclusivity extensions was a company-wide tactic and not unique to Sensipar. Amgen’s biosimilar team circulated a document titled “Competing Intensely and Winning in Today’s Biotech Markets,” which listed strategy recommendations to combat competition. The document emphasized that all researchers should “consider potential for—and timing of—seeking additional indications to treat orphan diseases and pediatric populations” because status as an orphan disease or pediatric treatment “may result in additional orphan and pediatric regulatory exclusivity and supplemental patent protection.”<sup>120</sup>

### C. Patent Settlements to Delay Entry of Sensipar Generics

Nearly a dozen generic manufacturers have received FDA approval to sell a lower-priced generic version of Sensipar.<sup>121</sup> However, when Amgen’s primary patent on Sensipar expired in March 2018, most of these manufacturers did not enter the market. Instead, they faced lawsuits from Amgen asserting infringement of another Sensipar patent that expires in 2026.<sup>122</sup> Amgen secured settlements from many of these manufacturers to delay launching a generic in the U.S. market.<sup>123</sup>

In anticipation of Sensipar’s primary patent expiration in March 2018, Amgen aggressively raised prices to generate as much additional revenue as possible before the patent expired. In the five years before Sensipar’s patent expired, Amgen raised its price nine times for a cumulative 73% price increase.<sup>124</sup> Internal documents show that Amgen realized \$202 million in extra sales of Sensipar as the result of delaying generic entry by just ten weeks in 2018.<sup>125</sup>

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<sup>118</sup> *Id.*

<sup>119</sup> Per Curium Order, *Amgen Inc. v. Azar et al.*, Docket No. 18-5046 (D.C. Cir. Oct. 2, 2018).

<sup>120</sup> AMGN-HCOR-RR-00159468, at Page 3.

<sup>121</sup> Food and Drug Administration, *Drug Database Information on Cinacalcet* (online at [www.accessdata.fda.gov/scripts/cder/daf/](http://www.accessdata.fda.gov/scripts/cder/daf/)) (accessed Sept. 8, 2020).

<sup>122</sup> Amgen Inc., *2018 Form 10-K* (Feb. 13, 2019) (online at [www.sec.gov/Archives/edgar/data/318154/000031815418000004/0000318154-18-000004-index.htm](http://www.sec.gov/Archives/edgar/data/318154/000031815418000004/0000318154-18-000004-index.htm)); Amgen Inc., *2019 Form 10-K* (Feb. 12, 2020) (online at [www.sec.gov/ix?doc=/Archives/edgar/data/318154/000031815420000017/amgn-12312019x10kq42019.htm](http://www.sec.gov/ix?doc=/Archives/edgar/data/318154/000031815420000017/amgn-12312019x10kq42019.htm)).

<sup>123</sup> *Id.*

<sup>124</sup> IBM Micromedex Redbook, *Wholesale Acquisition Cost and Average Wholesale Price History for Sensipar*. This reflects Amgen’s list price increases for Sensipar 30 mg from March 2013 to March 2018.

<sup>125</sup> AMGN-HCOR-RR-00126493, at Slide 10.



## **B. Research and Manufacturing**

The pharmaceutical industry frequently cites the cost of manufacturing and investments in research and development (R&D) as drivers of high and rising prices. Amgen's own talking points cite these justifications. Amgen executives drafted the following response when asked by a reporter about the company's pricing practices:

At Amgen we price our products to deliver the economic value that is delivered to patients, providers and payers, the unmet medical need, the size of the patient population, the investment and risk undertaken and the need to fund continued scientific innovation.<sup>130</sup>

However, Amgen's internal data indicate that its price increases for Enbrel and Sensipar are not correlated with manufacturing costs or R&D expenditures.

### ***Enbrel***

Amgen did not develop Enbrel. When Amgen acquired Immunex, the company that developed Enbrel, Amgen already projected that Enbrel's annual revenue would grow to \$3 billion by 2005, just three years after acquisition.<sup>131</sup> Since acquisition, Amgen's R&D costs related to Enbrel have been a small fraction of its net revenue from the drug. From 2003 to 2018, Amgen's \$2 billion in total Enbrel R&D expenditures made up only 3.5% of the company's \$58.23 billion in net U.S. revenue from Enbrel over the same period.<sup>132</sup>

Amgen's Enbrel R&D expenditures as a percentage of net revenue have declined over time, making up only 2.2% of net revenue from 2015 to 2018.<sup>133</sup> In addition, Amgen's cost of manufacturing for Enbrel declined from 2009 to 2018, while its price rose.<sup>134</sup>

Figure 9 below shows Amgen's Enbrel R&D and manufacturing costs as a percentage of net revenue from 2009 to 2018.<sup>135</sup>

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<sup>130</sup> AMGN-HCOR-RR-00061731.

<sup>131</sup> *Amgen to Buy Immunex*, CNN Money (Dec. 17, 2001) (online at [https://money.cnn.com/2001/12/17/deals/amgen\\_immunex/index.htm](https://money.cnn.com/2001/12/17/deals/amgen_immunex/index.htm)).

<sup>132</sup> Letter from King & Spalding, on behalf of Amgen Inc., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Mar. 15, 2019).

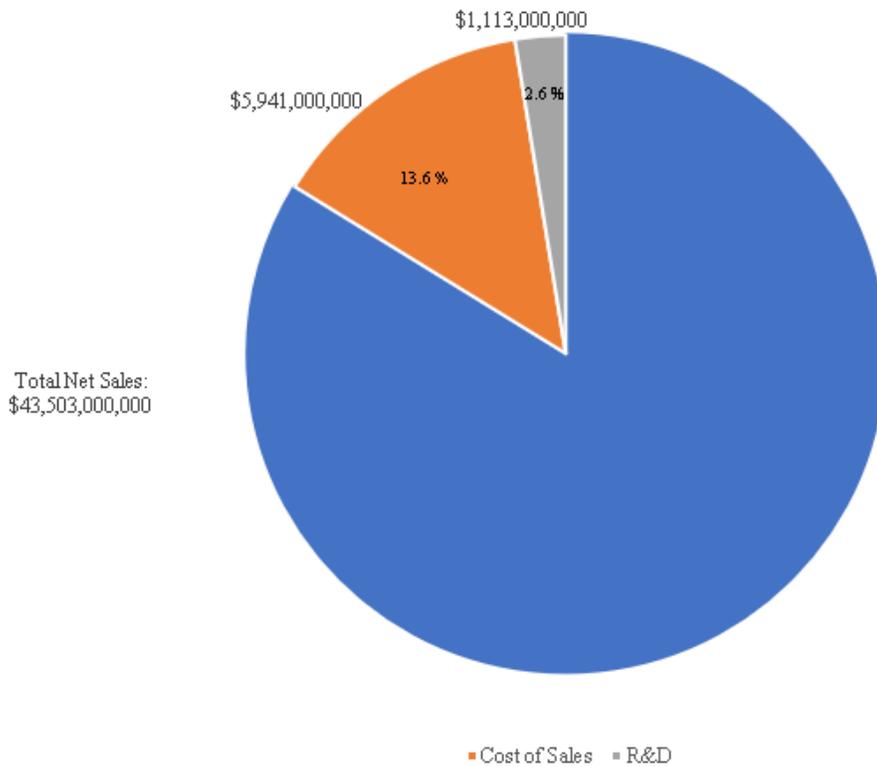
<sup>133</sup> Letter from King & Spalding, on behalf of Amgen Inc., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Mar. 15, 2019).

<sup>134</sup> AMGN-HCOR-RR-00439895; Letter from King & Spalding, on behalf of Amgen Inc., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Mar. 15, 2019).

<sup>135</sup> *Id.*

Figure 9

**Enbrel Net U.S. Revenue vs Cost of Sales and R&D from 2009-2018**



***Sensipar***

Amgen's R&D expenditures for Sensipar do not justify its price. Amgen reported to the Committee that from 2002 to 2018, it spent \$1.4 billion on Sensipar R&D, 14.6% of its \$9.8 billion in net revenue over the same period.<sup>136</sup> Amgen's R&D expenditures declined significantly over time. From 2015 to 2018, Amgen spent \$167 million on R&D related to

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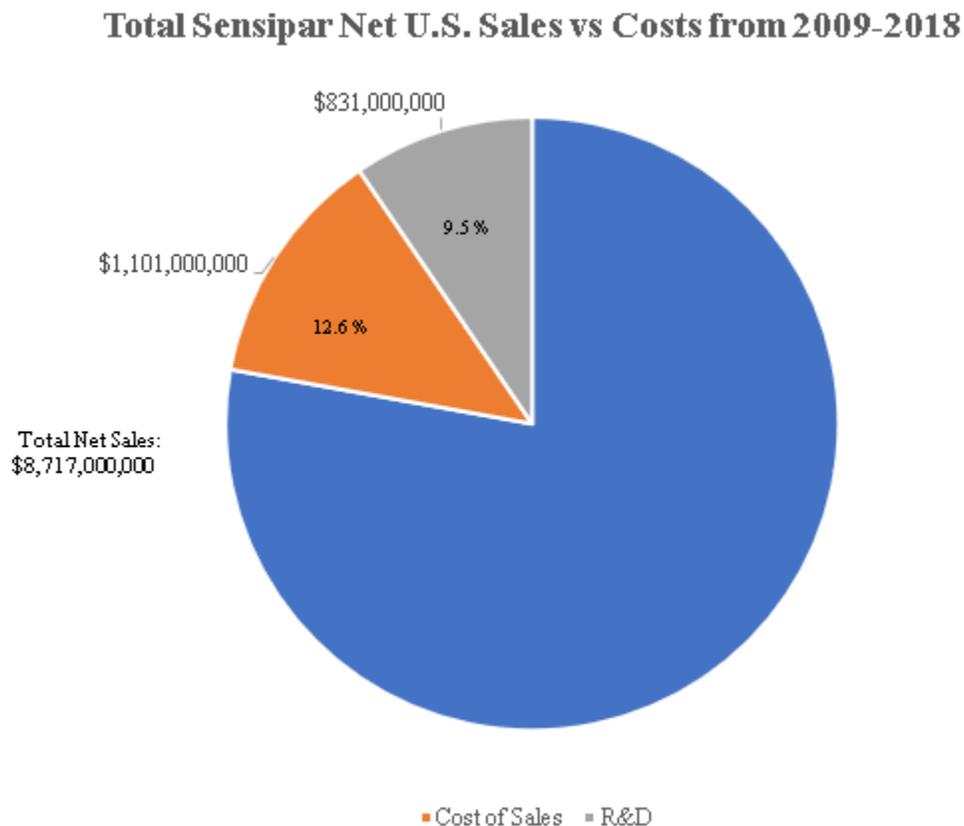
<sup>136</sup> Letter from King & Spalding, on behalf of Amgen Inc., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Mar. 15, 2019).

Sensipar, 3.3% of its net U.S. revenue from the drug over the same time period.<sup>137</sup> Amgen’s manufacturing costs for Sensipar were a fraction of its net revenue in each of these years.<sup>138</sup>

For example, Amgen spent \$198 million to manufacture Sensipar in 2016—its highest manufacturing costs for any year between 2009 and 2018.<sup>139</sup> Amgen’s net revenue from Sensipar that year were six times higher, \$1.24 billion.<sup>140</sup>

Figure 10 below shows Amgen’s Sensipar R&D and manufacturing costs as a percentage of net revenue from 2009 to 2018.<sup>141</sup>

Figure 10



Amgen has taken the position that its price increases are driven by the “need to fund continued scientific innovation.”<sup>142</sup> Over the past three years, Amgen has spent \$28.6 billion on buybacks of its own stock. This is more than double its company-wide R&D expenditures of \$11.4 billion over the same three-year period.<sup>143</sup>

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<sup>137</sup> *Id.*

<sup>138</sup> AMGN-HCOR-RR-00439895.

## VIII. CONCLUSION

Amgen's price increases and business practices for Enbrel and Sensipar 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.<sup>144</sup>

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.

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<sup>139</sup> *Id.*

<sup>140</sup> Amgen Inc., *2016 Form 10-K* (online at [www.sec.gov/Archives/edgar/data/318154/000031815416000031/amgn-12312015x10k.htm](http://www.sec.gov/Archives/edgar/data/318154/000031815416000031/amgn-12312015x10k.htm)).

<sup>141</sup> AMGN-HCOR-RR-00439895; Letter from King & Spalding, on behalf of Amgen Inc., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Mar. 15, 2019).

<sup>142</sup> See AMGN-HCOR-RR-00061731; Committee on Energy and Commerce, Subcommittee on Health, Testimony of Kave Niksefat, Vice President, U.S. Value and Access, Amgen Inc., *Hearing on Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain* (May 9, 2019) (online at [https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/KNiksefat\\_Testimony\\_FINAL\\_050919%20%28002%29.pdf](https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/KNiksefat_Testimony_FINAL_050919%20%28002%29.pdf)).

<sup>143</sup> Amgen Inc., *2018 Form 10-K* (Feb. 13, 2019) (online at [www.sec.gov/Archives/edgar/data/318154/000031815419000008/amgn-12312018x10kq42018.htm#sDB332325C4E859F0B6AC70D2048D5718](http://www.sec.gov/Archives/edgar/data/318154/000031815419000008/amgn-12312018x10kq42018.htm#sDB332325C4E859F0B6AC70D2048D5718)).

<sup>144</sup> See State of California, Office of Statewide Health Planning and Development, *Prescription Drug Wholesale Acquisition Cost (WAC) Increases* (August 17, 2020) (online at [oshpd.ca.gov/visualizations/prescription-drug-wholesale-acquisition-cost-increases/](http://oshpd.ca.gov/visualizations/prescription-drug-wholesale-acquisition-cost-increases/)).