

Drug Pricing Investigation

AbbVie—*Humira and Imbruvica*

Staff Report

Committee on Oversight and Reform

U.S. House of Representatives

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oversight.house.gov

EXECUTIVE SUMMARY

This staff report describes the actions of AbbVie Inc. in repeatedly raising the prices of two of its blockbuster drugs: Humira (adalimumab) and Imbruvica (ibrutinib). These price hikes contributed to billions of dollars in corporate profits and enriched company executives while harming American patients and taxpayers. AbbVie pursued a variety of tactics to increase drug sales while raising prices for Americans, including exploiting the patent system to extend its market monopoly, abusing orphan drug protections to further block competition, and engaging in anticompetitive pricing practices.

Humira, a drug used to treat rheumatoid arthritis and other autoimmune diseases, is the highest grossing drug in the world. In 2020 alone, AbbVie collected $16 billion in U.S. net revenue for Humira. Today, AbbVie charges approximately $77,000 for a year's supply of Humira—470% more than when the drug was launched in 2003.

AbbVie and its partner Janssen Biotech, Inc., a Johnson & Johnson subsidiary, are the sole U.S. manufacturers of Imbruvica, a drug approved to treat mantle cell lymphoma and certain other forms of cancer. Under the companies' collaboration agreement, AbbVie is responsible for marketing Imbruvica in the United States, including pricing decisions. Today, AbbVie and Janssen charge over $181,529 for a year's supply of Imbruvica—82% more than when the drug was launched in 2013. Experts estimate that by 2026, Imbruvica will be the fourth highest grossing drug in the United States, in part because of price increases.

The findings in this report are based on the Committee's review of more than 170,000 pages of internal documents, communications, and data related to Humira and Imbruvica from 2009 to the present. The Committee requested these materials more than two years ago, but AbbVie obstructed the Committee's investigation. In September 2020, Chairwoman Carolyn B. Maloney notified Committee Members of her intent to issue a subpoena to AbbVie due to the company's refusal to cooperate with the Committee's investigation. After this notice, AbbVie finally began to produce long overdue materials in response to the Committee's requests.

The Committee's investigation uncovered the following key findings:

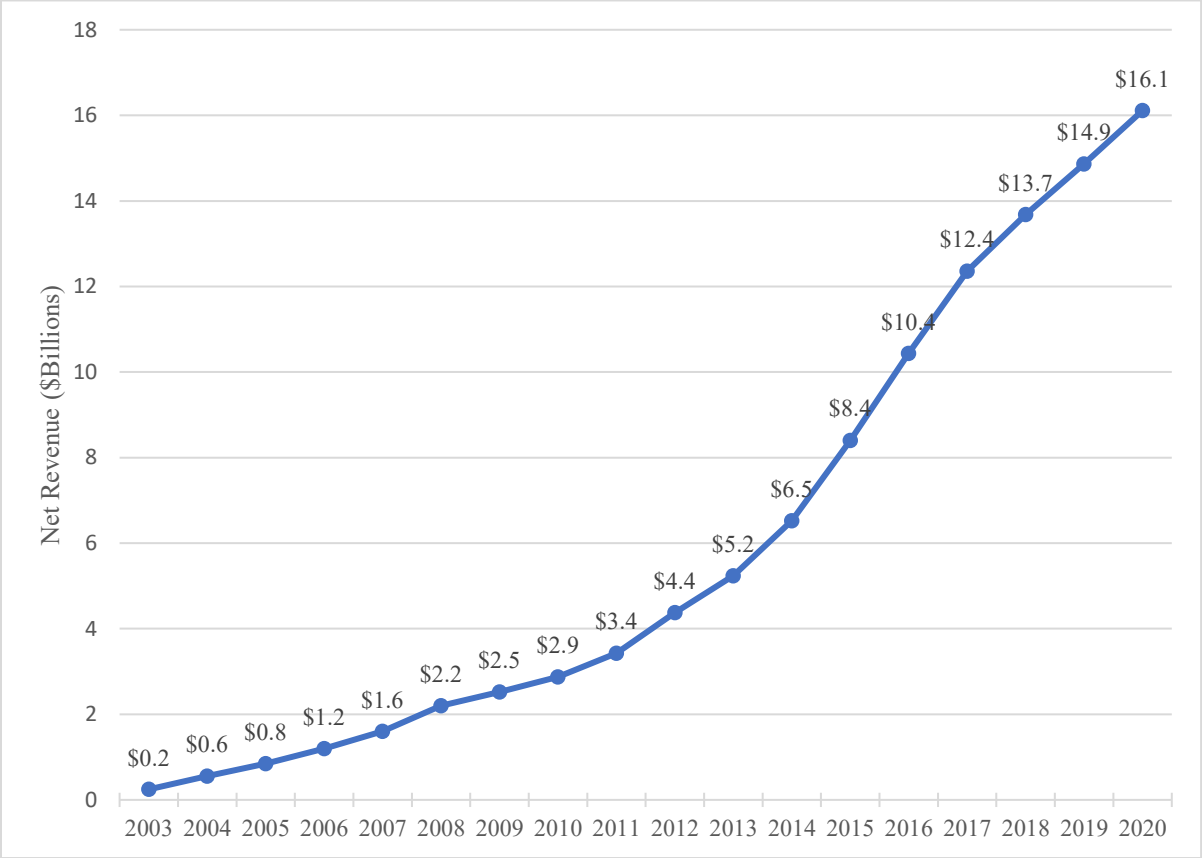
- **Uninhibited Price Increases:** Since launching Humira in 2003, AbbVie (and its predecessor company Abbott Laboratories) have raised the drug's price 27 times, including by nearly 30% in one 10-month period. A 40-milligram syringe of Humira is now priced at $2,984, or $77,586 annually—a 470% increase from the drug's launch. AbbVie has also raised the price of Imbruvica by 82% since launching the drug in 2013. Today, Imbruvica is priced at $181,529 per year for a patient taking three pills per day, compared to $99,776 per year at launch.

- **Price Increases Not Justified by Rebates:** Internal data show that AbbVie's list price increases for Humira and Imbruvica far outpaced any discounts and rebates paid to pharmacy benefit managers and other members of the supply chain. Humira's net price—which subtracts discounts and rebates—increased by 110% between 2009 and 2018, from $16,663 per year to $35,041 per year. For a patient taking 3 tablets daily, the

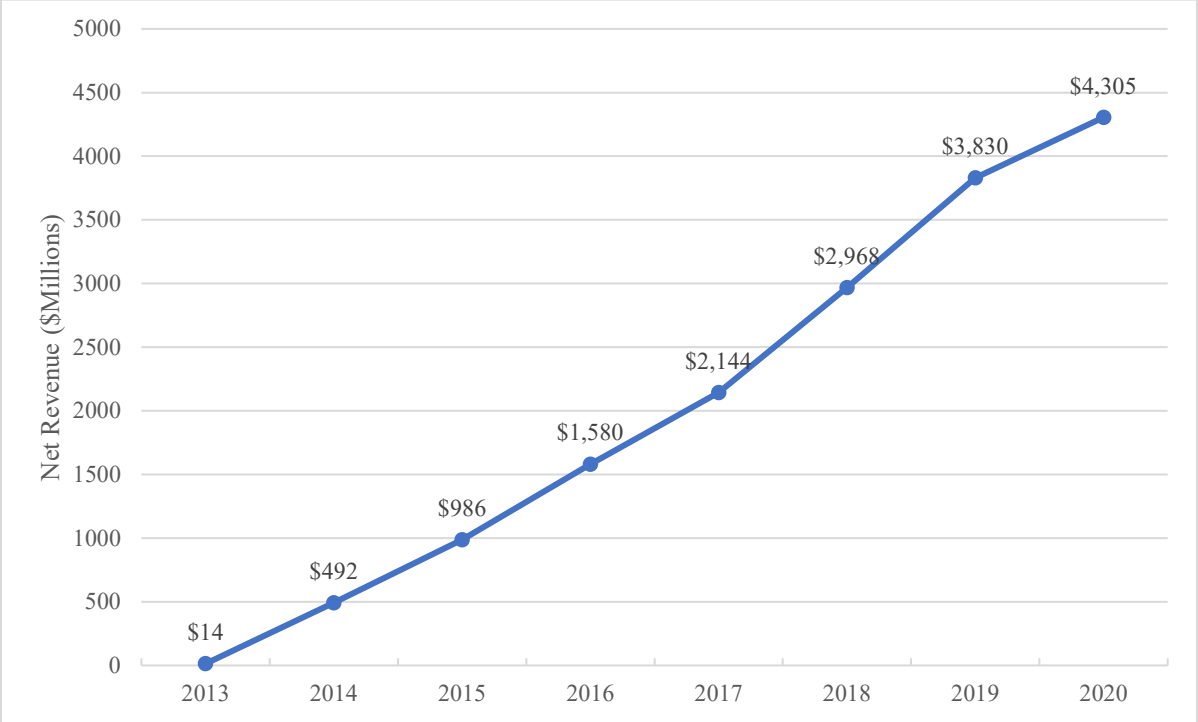
annual net price of Imbruvica increased from $72,587 in 2013 to $115,533 in 2017 (the last year for which AbbVie provided the Committee data).

- **Record Corporate Revenue Driven by Price Increases:** Since 2003, AbbVie has collected over $107 billion in U.S. net revenue from Humira. AbbVie's yearly U.S. net revenue from Humira more than tripled from $5.3 billion in 2013—the year it separated from Abbott—to $16.1 billion in 2020. Due in large part to AbbVie's price increases, Humira is the highest grossing drug in the United States. U.S. net revenue for Imbruvica has increased from $492 million in 2014 to $4.3 billion in 2020. AbbVie's U.S. net revenue for both drugs has increased every year since the drugs entered the market, as shown in the two graphs below.

AbbVie U.S. Net Revenue for Humira



AbbVie and Janssen U.S. Net Revenue for Imbruvica

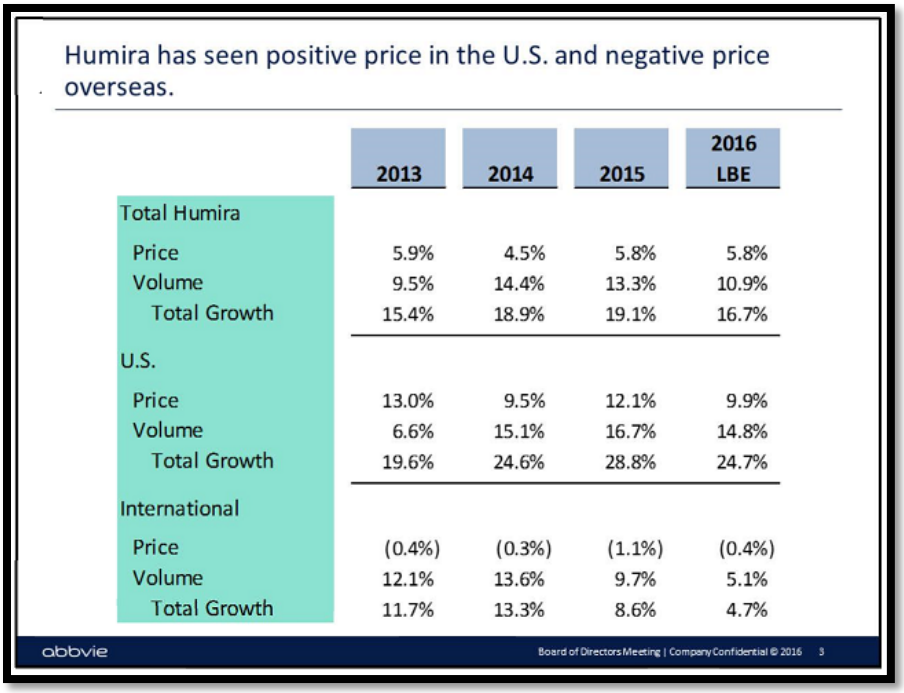


- **Hundreds of Millions in Executive Compensation and Bonuses:** Since separating from Abbott in 2013, AbbVie has paid its highest-ranking executives over $480 million in compensation. AbbVie's CEO Richard Gonzalez alone was paid nearly $170 million over that period. AbbVie's internal documents show that from 2015 to 2018, senior executive bonuses were tied directly to Humira net revenue, allowing them to profit from AbbVie's price increases. The first year this net revenue incentive was added to the calculation coincided with the highest period of price increases in Humira's history—over 30% in a 10-month period.

- **Lack of Medicare Negotiation Costing Taxpayers Billions:** U.S. law prohibits Medicare from negotiating directly with drug companies to lower prices. According to AbbVie's internal data, the company collected nearly $10 billion in Humira net revenue from Medicare Part D between 2010 and 2018. If Medicare had received the same discounts during that period as the Department of Defense—which is permitted to negotiate directly for lower prices—taxpayers would have saved $7.4 billion. Similarly, if Medicare had received the same discounts during that period as the Department of Veterans Affairs, taxpayers would have saved $7 billion. AbbVie also collected $4.7 billion in Imbruvica net revenue from Medicare Part D between 2014 and 2018. If Medicare had received the same discounts as the Department of Defense and Department of Veterans Affairs, taxpayers would have saved $1.6 billion.

- **Targeting the U.S. for Higher Prices:** Humira and Imbruvica are much more expensive in the United States than in other countries that negotiate directly with drug companies to

lower prices. In 2015, a single syringe of Humira cost $1,000 more in the United States than in countries such as Canada, Japan, Korea, and the United Kingdom. Over time, AbbVie raised the price of Humira in the United States while being forced to reduce the price internationally.



Humira has seen positive price in the U.S. and negative price overseas.

	2013	2014	2015	2016 LBE
Total Humira				
Price	5.9%	4.5%	5.8%	5.8%
Volume	9.5%	14.4%	13.3%	10.9%
Total Growth	15.4%	18.9%	19.1%	16.7%
U.S.				
Price	13.0%	9.5%	12.1%	9.9%
Volume	6.6%	15.1%	16.7%	14.8%
Total Growth	19.6%	24.6%	28.8%	24.7%
International				
Price	(0.4%)	(0.3%)	(1.1%)	(0.4%)
Volume	12.1%	13.6%	9.7%	5.1%
Total Growth	11.7%	13.3%	8.6%	4.7%

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Similarly, in 2018, AbbVie charged nearly double for Imbruvica in the United States as compared to Australia and countries in Europe, such as the United Kingdom and France. AbbVie's internal records include hundreds of pages of complaints from U.S. patients and caretakers who described the tremendous burden Humira's constantly increasing price placed on them and their loved ones. One retiree with Crohn's disease who could not afford the drug called AbbVie's pricing "unconscionable." The daughter of another patient who relied on Humira wrote to AbbVie that its efforts to block more affordable alternatives from coming to market were "cold, and heartless."

- **Exploitation of the U.S. Patent System to Extend Humira and Imbruvica Monopolies:** Internal company documents show that AbbVie views the U.S. patent system as far more protective of its pricing monopoly than patent systems in the rest of the world. AbbVie has obtained or applied for over 250 patents on Humira to block competition from lower-priced biosimilars. The last of these patents is set to expire in 2037. Approximately 90% of AbbVie's patent applications were filed after Humira was already approved and brought to market, suggesting that they were intended to block competition and protect revenue rather than necessary to incentivize the company's development of the drug. AbbVie's CEO has publicly acknowledged the company's strategy of overwhelming competitors by filing hundreds of patents on Humira, regardless of whether they are valid under U.S. law. The company has also obtained or

filed for over 150 patents on Imbruvica to delay generic competition, with the last of these patents set to expire in 2036.

- **Patent Settlements Delayed U.S. Entry of Humira Competition, Costing U.S. Health Care System $19 Billion:** AbbVie delayed competition from lower-priced biosimilar versions of Humira until January 2023 by entering into settlement agreements with potential competitors that challenged Humira's patents. New documents show that these settlements allowed AbbVie to delay competition far beyond what its own internal assessments of the strength of its patent portfolio predicted. In 2014, AbbVie's executives estimated that three to five biosimilar competitors would enter the market by the first quarter of 2017. AbbVie ultimately entered into settlement agreements with four of these competitors, delaying their entry into the market until 2023.

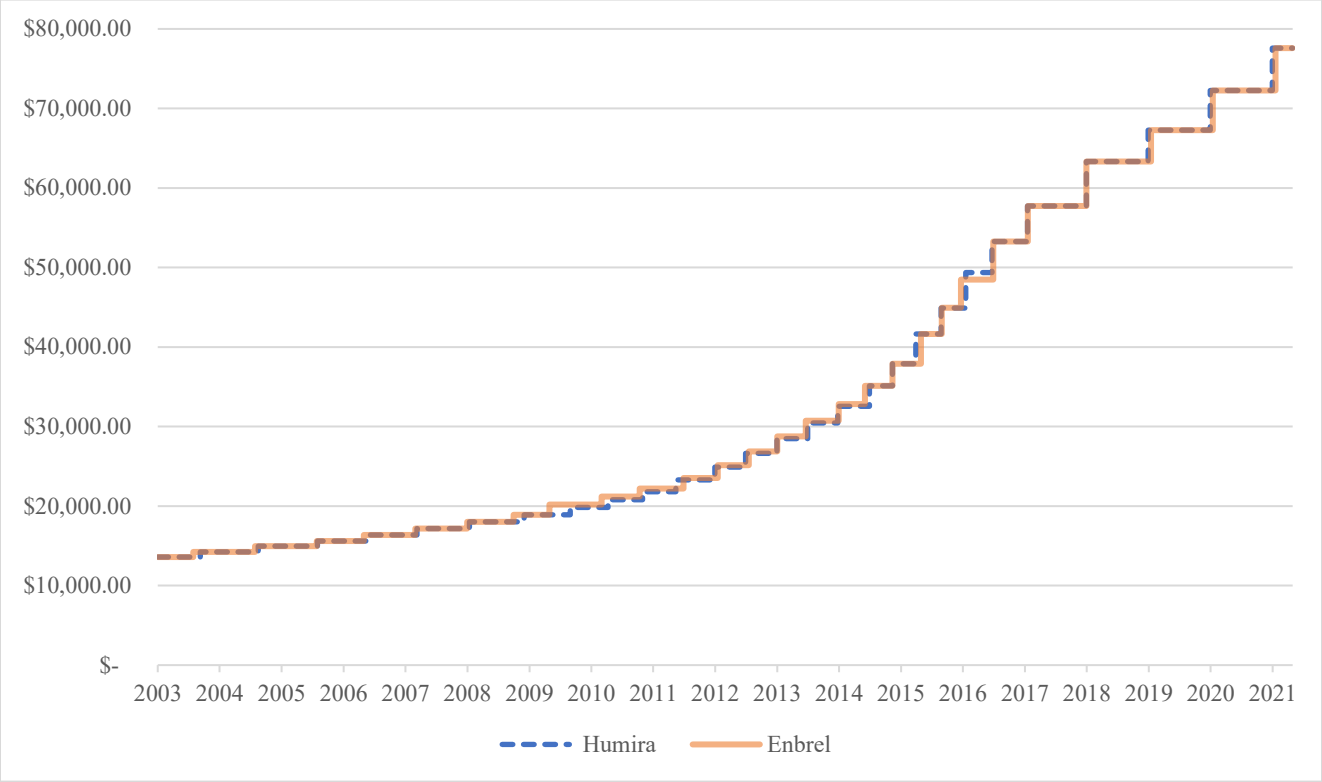
  Internal analyses obtained by the Committee raise new questions about whether the 2023 entry dates agreed to between AbbVie and its competitors were truly negotiated compromises reflecting the odds of the parties' success in patent litigation or whether AbbVie—in violation of U.S. antitrust law—transferred items of value to its competitors in exchange for them staying off the market.

  According to an internal analysis obtained by the Committee, earlier biosimilar entry would have forced a reduction in the price of Humira that would have saved the U.S. health care system at least $19 billion from 2016 to 2023.

- **Abuse of the Orphan Drug Act:** AbbVie protected its Humira monopoly by abusing the Orphan Drug Act (ODA), a law that incentivizes the development of drugs that treat rare diseases and conditions. Contrary to the stated purpose of the ODA, AbbVie sought orphan drug protections for Humira even though it was a blockbuster drug with billions of dollars in sales each year. Today, AbbVie holds eight orphan designations and approvals for Humira. AbbVie also secured longer market exclusivity periods under the ODA by seeking separate, staggered market approvals and exclusivity periods for different age groups of patients affected by the same rare disease.

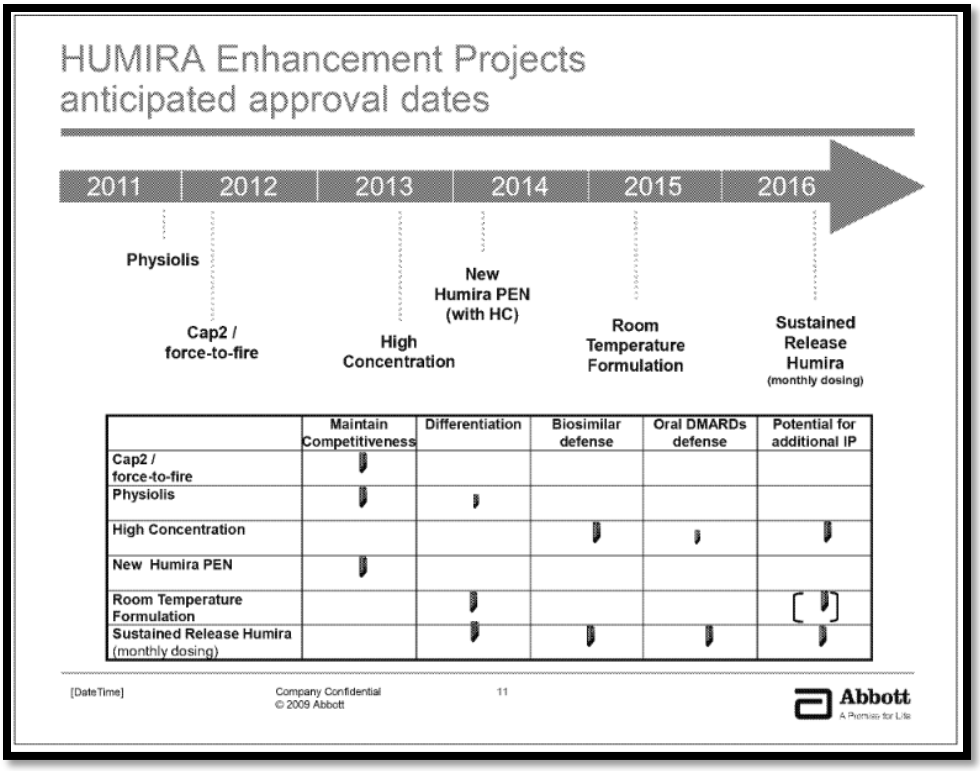
- **Shadow Pricing with Amgen:** AbbVie's largest competitor for Humira is Enbrel, Amgen's blockbuster biologic treatment for rheumatoid arthritis and other conditions. Instead of pricing Humira and Enbrel below one another to gain market share—as expected in a competitive market—AbbVie and Amgen engaged in a practice known as "shadow pricing," consistently following the other company's price increases. As a result, both companies repeatedly raised the price of Humira and Enbrel by nearly identical amounts. The graph below shows AbbVie's and Amgen's pricing for Humira and Enbrel from 2003 to 2021.

Humira and Enbrel: Price of an Annual Course of Treatment



- **Profit-Driven Research Expenditures:** In response to the Committee's request, AbbVie identified a total of $5.19 billion in "Humira Research & Development" expenditures between 2009 and 2018—approximately 4.2% of the company's Humira worldwide net revenue over that period.

  AbbVie's internal documents and data show that a large portion of AbbVie's research expenditures on Humira were dedicated to extending its market monopoly by limiting biosimilar competition through "enhancements" to Humira. One internal presentation emphasized that one objective of the "enhancement" strategy was to "raise barriers to competitor ability to replicate." The presentation also identified the "Humira High Concentration" and "Sustained Release" formulations as furthering AbbVie's goal of "Biosimilar defense."



Although AbbVie has argued that its clinical trial expenditures are made with "low odds of success," the Committee's investigation found that AbbVie internally assessed that its expenditures on Humira clinical trials were relatively low-risk and predicted they would result in substantial returns even after adjusting for the possibility of failure. For example, while the projected cost of clinical studies to evaluate Humira as a treatment for mild to moderate Crohn's disease was estimated at $34.63 million, the company projected the risk-adjusted value of the project to be $923 million.

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I. PRICE INCREASES

Humira

The Food and Drug Administration (FDA) first approved Humira (adalimumab) in December 2002 as an injectable biologic agent to treat moderate to severe rheumatoid arthritis.[1] FDA later approved the use of Humira for the treatment of other inflammatory diseases, including: psoriatic arthritis, ankylosing spondylitis, Crohn's disease, plaque psoriasis, juvenile idiopathic arthritis, ulcerative colitis, pediatric Crohn's disease, hidradenitis suppurativa, and uveitis.[2] Patients self-administer injections, with the most common dose requiring one 40-milligram injection every other week.[3]

When AbbVie's precursor, Abbott Laboratories, launched Humira in 2003, it set the price at $522 per 40-milligram syringe.[4] Abbott Laboratories raised the price of Humira 13 times to $1,024 per syringe by 2013.[5] In January 2013, Abbott Laboratories spun off AbbVie as a separate company.[6]

After the spinoff, AbbVie raised the price of Humira another 14 times, including by 30% within one 10-month period.[7] Humira is now priced at $2,984 per syringe, or $77,586 annually—a 470% increase from when the drug entered market.[8] Figure 1 below shows the price for a Humira syringe from 2003 to the present.[9]

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[1] Letter from Director Jay P. Siegel, Center for Biologics Evaluation and Research, Food and Drug Administration, to Jeanne Fox, Senior Director, PPD Regulatory Affairs, Abbott Laboratories (Dec. 31, 2002) (online at www.accessdata.fda.gov/drugsatfda_docs/appletter/2002/adalabb123102L.htm).

[2] *See* Food and Drug Administration, *Approved Label for Humira* (Mar. 2020) (online at www.accessdata.fda.gov/drugsatfda_docs/label/2020/125057s415lbl.pdf).

[3] AbbVie Inc., *Humira (adalimumab): Moderate to Severe Rheumatoid Arthritis* (online at www.humira.com/rheumatoid-arthritis/after-starting-treatment) (accessed on May 18, 2021).

[4] IBM Micromedex Redbook, *Wholesale Acquisition Cost for Humira.*

[5] *Id.*

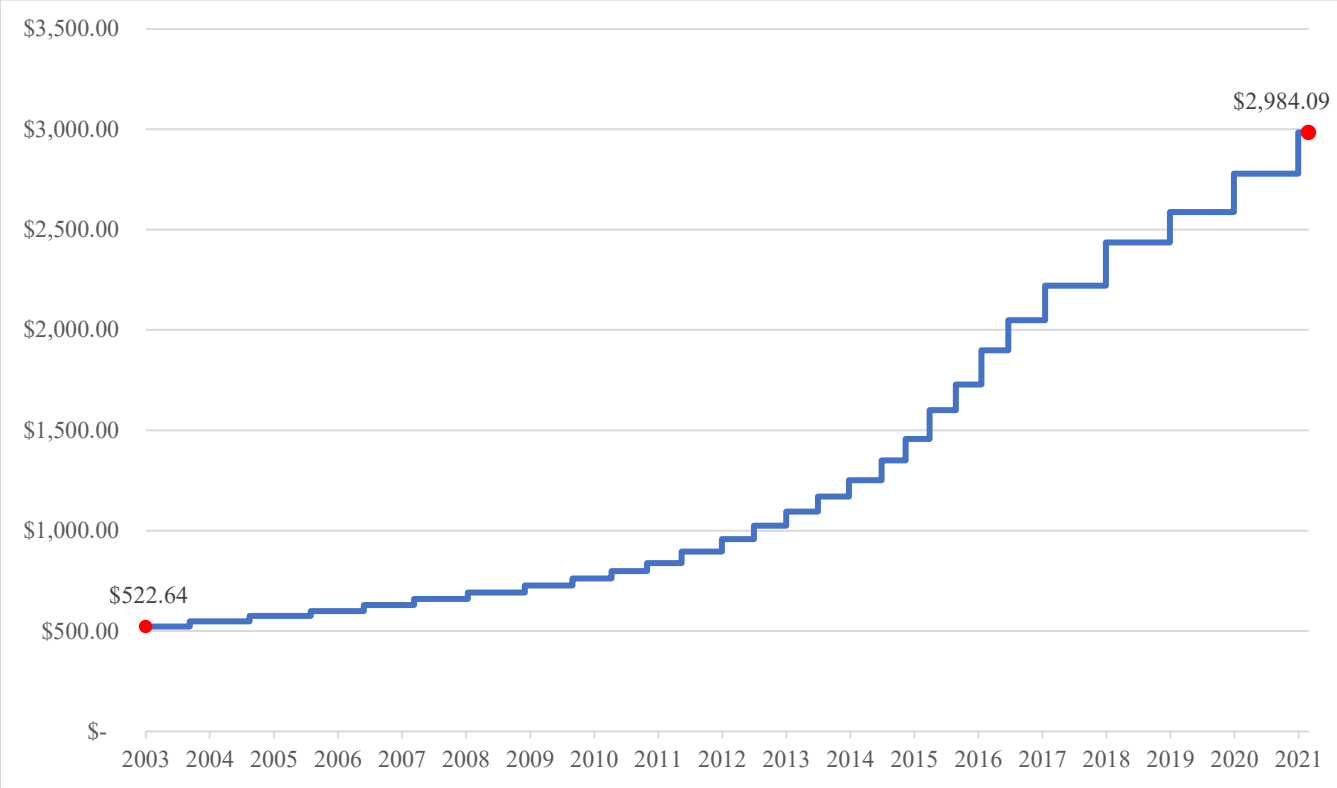
[6] This memorandum uses "AbbVie" to describe the company both before and after the spinoff except where the distinction between Abbott and AbbVie is relevant.

[7] *Id.* This 10-month period was from March 31, 2015, when the price of one Humira injection was $1,456, and January 21, 2016, when Humira was priced at $1,898.

[8] IBM Micromedex Redbook, *Wholesale Acquisition Cost for Humira.* The annual calculation is for a patient that injects Humira every other week.

[9] IBM Micromedex Redbook, *Wholesale Acquisition Cost for Humira.*

Figure 1: Price of Humira 40-Milligram Syringe



These price increases cannot be fully explained by rising discounts and rebates paid to pharmacy benefit managers and other members of the pharmaceutical supply chain. As explained in Section IX below, AbbVie's price increases far outpaced any rebates and discounts. The net price of Humira—the drug's price after accounting for all discounts and rebates—increased by 110% from 2009 to 2018.[10]

Imbruvica

FDA first approved Imbruvica (ibrutinib) in November 2013 to treat mantle cell lymphoma. FDA later approved Imbruvica for the treatment of five other cancers or conditions. The FDA-approved label directs patients to take three to four tablets of 140-milligram Imbruvica daily, depending on the patient's condition.[11]

Under a 2011 collaboration and license agreement, AbbVie's subsidiary, Pharmacyclics, sells Imbruvica in the United States in partnership with Janssen Biotech, Inc. (Janssen), a

[10] Letter from Gibson, Dunn and Crutcher LLP, on behalf of AbbVie Inc., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Sept. 11, 2020). Although the Committee's investigation only obtained data through 2018, it is likely that this trend continued into 2021.

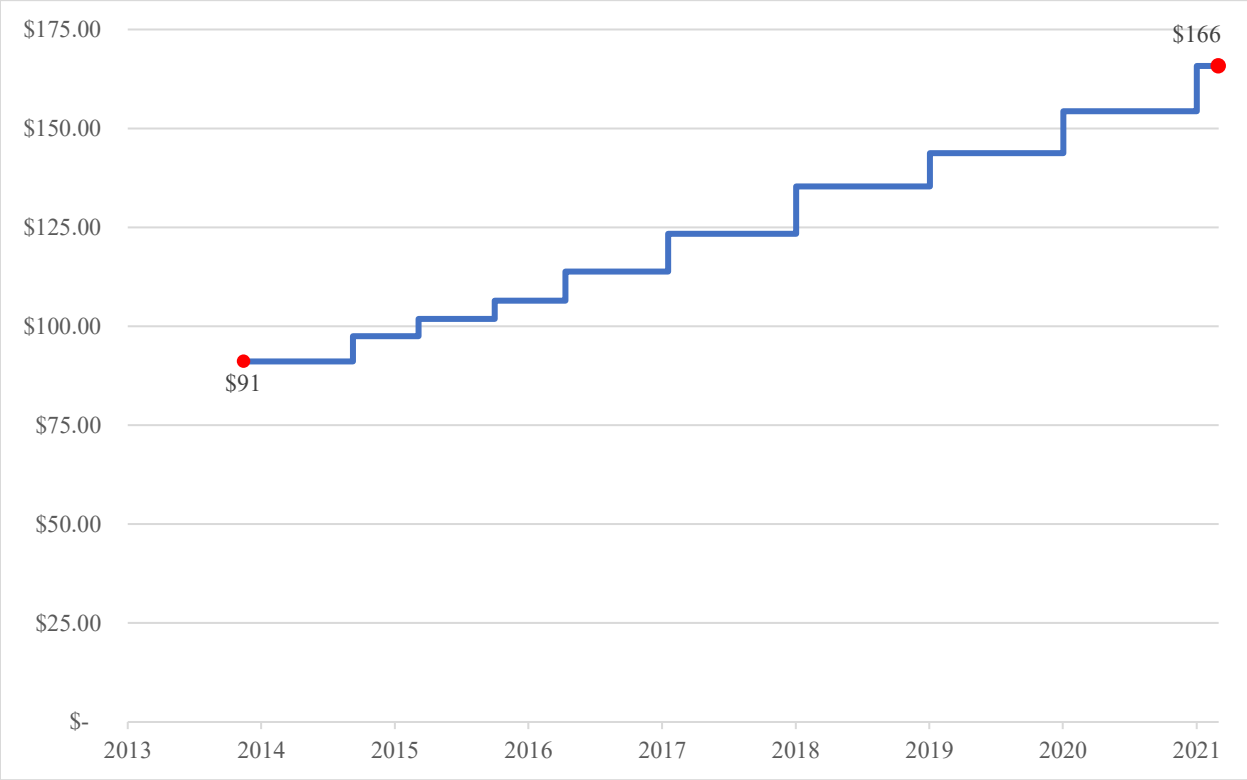
[11] Food and Drug Administration, *Imbruvica® (ibrutinib) capsules, for oral use; Imbruvica® (ibrutinib) tablets, for oral use* (Feb. 2018) (online at www.accessdata.fda.gov/drugsatfda_docs/label/2018/210563s000lbl.pdf).

subsidiary of Johnson & Johnson.[12] The companies share equally in the profits from Imbruvica.[13] Although the companies also share decision-making authority, AbbVie is the lead party for commercialization efforts in the United States, including pricing.[14]

When introduced in 2013, the price of Imbruvica was $91.11 per 140-milligram tablet—a yearly price of $99,766 for patients taking three tablets daily and $133,022 for patients taking four tablets daily. The companies have since raised the price of the drug nine times. Today, the price of an annual course of treatment is $181,529 for a patient taking three tablets daily, and the price of an annual course of treatment is $242,039 for a patient taking four tablets daily.[15]

Figure 2 shows the price of Imbruvica tablet from 2013 to the present.

Figure 2: Price of Imbruvica 140-Milligram Tablet



The price increases for Imbruvica cannot be fully explained by rising discounts and rebates paid to pharmacy benefit managers and other members of the pharmaceutical supply chain. As explained in Section IX below, the annual net price of Imbruvica—which accounts for

[12] The original agreement was between Pharmacyclics and Janssen Biotech, Inc. In 2015, AbbVie acquired Pharmacyclics for $21 billion. *AbbVie to Buy Pharmacyclics in $21 Billion Deal*, Wall Street Journal (Mar. 5, 2015) (online at www.wsj.com/articles/abbvie-to-buy-pharmacyclics-in-21-billion-deal-1425528086).

[13] *See* Collaboration and License Agreement, ABV-HOR-3128.

[14] *See id.* at 3188 (Collaboration and License Agreement § 5.1.3).

[15] IBM Micromedex Redbook, *Wholesale Acquisition Cost for Imbruvica.*

rebates and other discounts—increased from $72,587 in 2013 to $115,533 in 2017 for a patient taking three tablets daily.[16]

II. RISING CORPORATE PROFITS

A. Growing Revenues

Humira

AbbVie's price increases for Humira have enabled the company to increase its revenue by tens of billions of dollars. Since 2003, AbbVie has collected over $170 billion in worldwide net revenue from Humira, including $107 billion from the U.S. health care system.[17]

These price increases have made Humira the highest-grossing drug in the United States. In 2020 alone, AbbVie collected nearly $16 billion in U.S. net revenue for Humira—nearly $10 billion more than 2014.[18] For comparison, the total net revenue for the second-best selling drug in the United States in 2019—the cancer medication Keytruda—was $6.3 billion.[19]

Figure 3 below reflects AbbVie's U.S. net revenue for Humira since its introduction.[20]

[16] Letter from Gibson, Dunn and Crutcher LLP, on behalf of AbbVie Inc., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Jan. 22, 2021). AbbVie stated that it was unable to provide the 2018 figure due to complexities associated with the company's introduction of a single tablet formulation that year.

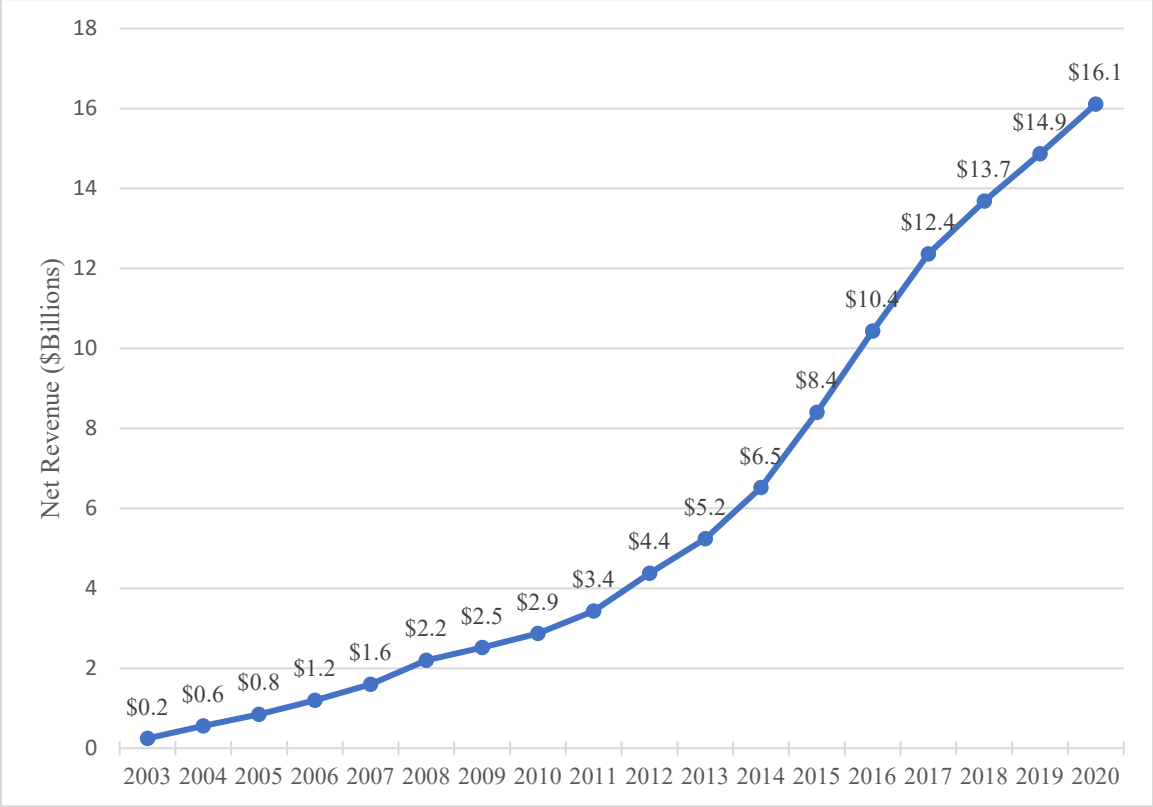
[17] Letter from Gibson, Dunn and Crutcher LLP, on behalf of AbbVie Inc., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Feb. 4, 2019); Letter from Gibson, Dunn and Crutcher LLP, on behalf of AbbVie Inc., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Jan. 14, 2021); Abbott Laboratories, *Form 10-K* (2003-2013) (online at www.abbottinvestor.com/financials/sec-filings); AbbVie Inc., *Annual Reports* (2013-2020) (online at https://investors.abbvie.com/sec-filings).

[18] AbbVie Inc., *2020 Form 10-K Annual Report* (Feb. 19, 2021) (online at https://investors.abbvie.com/sec-filings/sec-filing/10-k/0001551152-21-000008).

[19] *The Top-Selling Drugs in the U.S. in 2019*, Axios (Aug. 12, 2020) (online at www.axios.com/top-selling-drugs-america-2019-f32a8818-a37c-4581-a805-bcf73942c1de.html); Merck & Co., Inc., *2019 Form 10-K Annual Report* (Feb. 26, 2020) (online at www.sec.gov/Archives/edgar/data/0000310158/000031015820000005/mrk1231201910k.htm).

[20] Letter from Gibson, Dunn and Crutcher LLP, on behalf of AbbVie Inc., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Feb. 4, 2019); Letter from Gibson, Dunn and Crutcher LLP, on behalf of AbbVie Inc., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Jan. 14, 2021); Abbott Laboratories, *Form 10-K* (2003-2013) (online at www.abbottinvestor.com/financials/sec-filings). AbbVie Inc., *Annual Reports* (2013-2020) (online at https://investors.abbvie.com/sec-filings).

Figure 3: AbbVie U.S. Net Revenue for Humira



Imbruvica

AbbVie's price increases for Imbruvica have also led to billions in revenue for the company. AbbVie and its partner, Janssen, have collected over $16 billion in U.S. net revenue from Imbruvica, including nearly $15 billion since AbbVie acquired Pharmacyclics in 2015. In 2020 alone, AbbVie and Janssen collected more than $4.3 billion in U.S. net revenue for Imbruvica, nearly nine times the amount collected in 2014.[21]

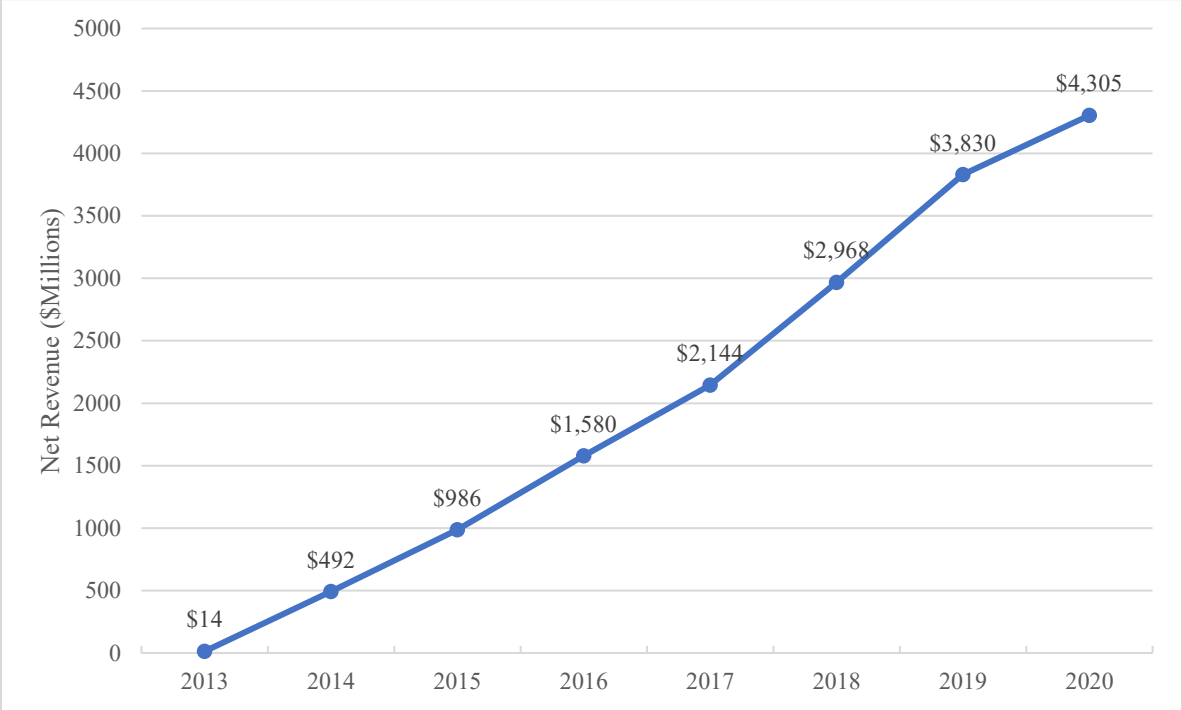
Experts estimate that by 2026, Imbruvica will be the fourth highest selling drug in the United States.[22]

[21] AbbVie Inc., *2020 Form 10-K Annual Report* (Feb. 19, 2021) (online at https://investors.abbvie.com/static-files/b1ca3ffe-226e-499d-992e-344f42d470d1); Letter from Gibson, Dunn and Crutcher LLP, on behalf of AbbVie Inc., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Mar. 21, 2019).

[22] Evaluate, *EvaluatePharma World Preview 2020, Outlook to 2026* (July 2020) (online at www.evaluate.com/thought-leadership/pharma/evaluatepharma-world-preview-2020-outlook-2026).

Figure 4 below reflects U.S. net revenue for Imbruvica over time.[23]

Figure 4: AbbVie and Janssen U.S. Net Revenue for Imbruvica



Together, AbbVie's U.S. net revenue for Humira and Imbruvica totaled over $80 billion between 2015 and 2020. This amounted to 49.7% of the company's global revenue, even though the company sells over a dozen drugs worldwide.[24]

B. Revenue Targets Driving Price Increases

Since Humira came to market in 2003, AbbVie and its predecessor company, Abbott, have raised the price 27 times.[25] Internal documents suggest that AbbVie executives made pricing decisions—including accelerating previously planned price increases—to reach revenue targets.

For example, in March 2011, company executives began considering whether to accelerate a 6.9% price increase from September 2011 to August 2011. They circulated an

[23] AbbVie Inc., *2020 Form 10-K Annual Report* (Feb. 19, 2021) (online at https://investors.abbvie.com/static-files/b1ca3ffe-226e-499d-992e-344f42d470d1); Letter from Gibson, Dunn and Crutcher LLP, on behalf of AbbVie Inc., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Mar. 21, 2019).

[24] AbbVie Inc., *Annual Reports* (2013-2020) (online at https://investors.abbvie.com/sec-filings).

[25] IBM Micromedex Redbook, *Wholesale Acquisition Cost for Humira.*

analysis that estimated the change would yield $22.6 million in additional net revenue.[26] The company ultimately moved the price increase even earlier to May 2011, raising the price of Humira from $838 to $896 per syringe.[27]

Similarly, in March 2013, executives began expressing concerns about Humira revenue falling behind the company's revenue targets, despite the company having already increased the price by 6.9% in January 2013.[28] A few months later, executives recommended that AbbVie increase the price of Humira by 6.9% in July 2013, explaining that such an increase would result in "$153MM incremental 2013 Net Sales and $132MM Margin."[29] AbbVie executed that price increase on July 3, 2013, raising the price of Humira from $1,095 to $1,170 per syringe. On December 27, 2013, AbbVie again raised the price of Humira by 6.9%—the third time that year. As a result of these price increases, AbbVie collected more than $5.2 billion in Humira U.S. net revenue in 2013, which alone accounted for more than 27% of the company's worldwide net revenue that year.[30]

In July 2014, AbbVie increased the price of Humira by 7.9%.[31] Later that year, AbbVie executives estimated that the net revenue for its immunology business group would fall $50.3 million short of its target. In response, the company moved forward a planned second 7.9% price increase for Humira from late-December to mid-November 2014. According to the executives, accelerating the price increase would collect $31.6 million in additional net revenue. AbbVie executed that price increase on November 14, 2014.[32]

AbbVie executives again increased prices and accelerated planned price increases in 2016 to meet and exceed revenue targets. In January 2016, executives circulated an analysis finding that moving a planned 9.9% price increase from March to February and a planned 7.9% price increase from September to August would generate an additional $55 million in Humira net revenue.[33] The executives ultimately moved both price increases even earlier, to January 21, 2016, and June 23, 2016.[34]

AbbVie executives warned colleagues internally that even a short delay in taking planned price increases would cost the company millions of dollars. For example, one executive circulated an analysis on October 8, 2018, estimating that delaying a planned Humira price increase by 14 days—from January 1, 2019 to January 14, 2019—would cause the company to

[26] ABV-HOR-00032430.

[27] IBM Micromedex Redbook, *Wholesale Acquisition Cost for Humira.*

[28] ABV-HOR-00032882; IBM Micromedex Redbook, *Wholesale Acquisition Cost for Humira.*

[29] ABV-HOR-00036813.

[30] AbbVie Inc., *2013 Form 10-K Annual Report* (Feb. 21, 2014) (online at https://investors.abbvie.com/node/8386/html).

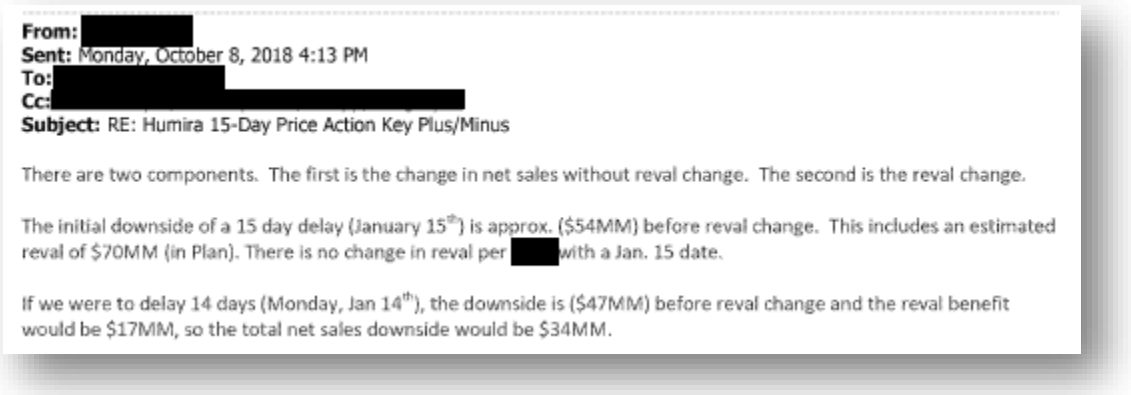
[31] IBM Micromedex Redbook, *Wholesale Acquisition Cost for Humira.*

[32] ABV-HOR-00040491; IBM Micromedex Redbook, *Wholesale Acquisition Cost for Humira.*

[33] ABV-HOR-00036196; ABV-HOR-0003619697.

[34] IBM Micromedex Redbook, *Wholesale Acquisition Cost for Humira.*

forgo upwards of $30 million in revenue.[35] In light of this analysis, AbbVie kept its plans to raise Humira's price on January 1, 2019.[36]



From: [redacted]
Sent: Monday, October 8, 2018 4:13 PM
To: [redacted]
Cc: [redacted]
Subject: RE: Humira 15-Day Price Action Key Plus/Minus

There are two components. The first is the change in net sales without reval change. The second is the reval change.

The initial downside of a 15 day delay (January 15th) is approx. ($54MM) before reval change. This includes an estimated reval of $70MM (in Plan). There is no change in reval per [redacted] with a Jan. 15 date.

If we were to delay 14 days (Monday, Jan 14th), the downside is ($47MM) before reval change and the reval benefit would be $17MM, so the total net sales downside would be $34MM.

III. EXECUTIVE BONUSES INCENTIVIZING PRICE INCREASES

Since spinning off from Abbott in 2013, AbbVie has collected over $100 billion dollars in U.S. net revenue from Humira and Imbruvica, driven in large part by AbbVie executives' decision to repeatedly raise the prices of Humira and Imbruvica.[37] AbbVie's highest-ranking executives were paid over $480 million in compensation during this period, much of which was directly linked to revenue increases.[38] AbbVie's Chief Executive Officer Richard Gonzalez alone was paid nearly $170 million from 2013 to 2020.[39]

Figure 5 below shows AbbVie's compensation package awarded to its highest-ranking executives in 2020.[40]

[35] ABV-HOR-00032081.

[36] IBM Micromedex Redbook, *Wholesale Acquisition Cost for Humira.*

[37] AbbVie Inc., *Annual Reports* (2013–2020) (online at https://investors.abbvie.com/sec-filings); IBM Micromedex Redbook, *Wholesale Acquisition Cost for Humira and Imbruvica.*

[38] Committee Staff calculated this figure using the Summary Compensation tables from AbbVie's annual SEC filings between 2013 and 2021. *See* AbbVie Inc., *Proxy Statements* (2013–2020) (online at www.sec.gov/cgi-bin/browse-edgar?CIK=1551152).

[39] *Id.*

[40] *Id.*

Figure 5

AbbVie Senior Executive Compensation					
	2020				
	Base Salary	Stock & Option Awards	Performance Bonuses	All Other Compensation	Total
Richard A. Gonzalez, Chairman and CEO	$ 1,688,462	$ 14,426,658	$ 4,908,750	$ 2,983,721.00	**$ 24,007,591**
Robert A. Michael, CFO	$ 1,064,385	$ 6,697,992	$ 2,110,000	$ 3,621,252.00	**$ 13,493,629**
Laura J. Schumacher, CLO	$ 1,211,808	$ 7,213,232	$ 2,550,000	$ 6,151,236.00	**$ 17,126,276**
Carlos Alban, CCO	$ 1,211,808	$ 7,213,232	$ 2,475,000	$ 5,953,886.00	**$ 16,853,926**
Michael E. Severino, Vice Chairman	$ 1,369,923	$ 7,213,232	$ 2,700,000	$ 2,127,903.00	**$ 13,411,058**
Total					**$ 84,892,480**

Documents and information obtained by the Committee indicate that AbbVie's senior executives received larger bonuses by raising the price of Humira, Imbruvica, and other drugs.

Between 2015 and 2018, senior executive bonuses were tied directly to Humira net revenue—providing a clear incentive to raise U.S. prices. As part of AbbVie's "short-term incentives," executives were compensated based on whether the company achieved predetermined targets for "Humira Sales."[41]

In 2014—the year before this incentive was introduced—Humira's U.S. net revenue was $6.52 billion.[42] The year the incentive was introduced, in 2015, AbbVie executives implemented a 9.9% price increase in April—the largest-ever price increase for the drug—and a 7.9% price increase in August. Overall, the first year of the incentive coincided with AbbVie's largest price increase in Humira's history—over 30% in a 10-month period.[43] As a result, Humira's U.S. net revenue increased to $8.4 billion, the largest one-year increase to date.[44]

In 2018—the final year of the incentive—Mr. Gonzalez was paid $21.2 million in compensation. AbbVie's internal documents reveal that a key factor in determining his bonus amount was a determination that the company had "mostly achieved" its Humira net revenue goal of $20.1 billion by collecting $19.7 billion in worldwide sales.[45] U.S. sales of Humira comprise nearly 70% of the drug's total worldwide sales. Mr. Gonzalez would likely not have

[41] *See* AbbVie Inc., *Proxy Statements* (2013–2020) (online at www.sec.gov/cgi-bin/browse-edgar?CIK=1551152).

[42] AbbVie Inc., *2014 Form 10-K Annual Report* (Feb. 20, 2015) (online at https://investors.abbvie.com/static-files/9553e87d-3b88-4b34-be3d-e1ff94c89bfa).

[43] IBM Micromedex Redbook, *Wholesale Acquisition Cost for Humira.*

[44] *Id.*

[45] ABV-HOR-00172913. Due to an adjustment for currency exchange rates, the company's executive compensation analysis reports worldwide Humira net revenue as $19.7 billion as compared to $19.9 billion in the company's SEC filings. *See* AbbVie Inc., *2019 Form 10-K Annual Report* (Feb. 21, 2020) (online at https://investors.abbvie.com/sec-filings/sec-filing/10-k/0001551152-20-000007).

met this goal without AbbVie's 9.7% U.S. price increase in January 2018.[46]

Even in years when AbbVie's executive bonus calculations were not expressly tied to sales of Humira or Imbruvica, U.S. price increases for these drugs were critical to executives' bonus calculations. In 2019, the bonus calculation focused heavily on AbbVie meeting its net revenue and pre-tax income targets.[47] As much as 80% of the bonus calculations for the executives was tied to pre-tax income and net revenue targets.[48] The executives barely met their worldwide net revenue target of $33.3 billion. Without raising the price of Humira and Imbruvica by 6.2% in 2019, the Committee estimates that AbbVie would have missed this goal.[49] Because AbbVie met its income and revenue targets in these years, however, AbbVie's senior-most executives were paid $70 million in compensation in 2019.[50]

IV. CHARGING MORE TO U.S. PATIENTS AND TAXPAYERS

Under current law, the federal government is prohibited from negotiating directly with pharmaceutical companies to lower prices for Medicare beneficiaries.[51] With the federal government unable to negotiate, U.S. patients and Medicare pay significantly more for Humira and Imbruvica than purchasers in other countries.

A. Targeting U.S. Market for Price Increases

AbbVie has steadily increased the list price of Humira in the United States, even as other countries have paid significantly lower prices for the drug.

The Committee obtained an internal AbbVie presentation revealing the company's overseas pricing of Humira in 2015. According to the presentation, the 2015 list price of a single 40-milligram syringe of Humira was $1,727 per syringe in the United States, compared to $965

[46] Based on the U.S. net price information AbbVie provided to the Committee, the company's U.S. net revenue would have fallen approximately $544 million in 2018 without the price increase, assuming a steady demand for the drug. With this decrease, the company would have fallen $600 million short of its worldwide net revenue target. *See* Letter from Gibson, Dunn and Crutcher LLP, on behalf of AbbVie Inc., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Sept. 11, 2020); AbbVie Inc., *2019 Form 10-K Annual Report* (Feb. 21, 2020) (online at https://investors.abbvie.com/sec-filings/sec-filing/10-k/0001551152-20-000007).

[47] *See* AbbVie Inc., 2019 *Proxy Statements* (Mar. 22, 2019) (online at https://investors.abbvie.com/static-files/a7335bdf-48b2-44a2-b0bd-21ec26843d05).

[48] *Id.*

[49] Committee staff estimate that without these price increases and assuming a corresponding change in net price of the products, AbbVie worldwide net revenue would have fallen to $32.1 billion. *See* AbbVie Inc., *2019 Form 10-K Annual Report* (Feb. 21, 2020) (online at https://investors.abbvie.com/sec-filings/sec-filing/10-k/0001551152-20-000007).

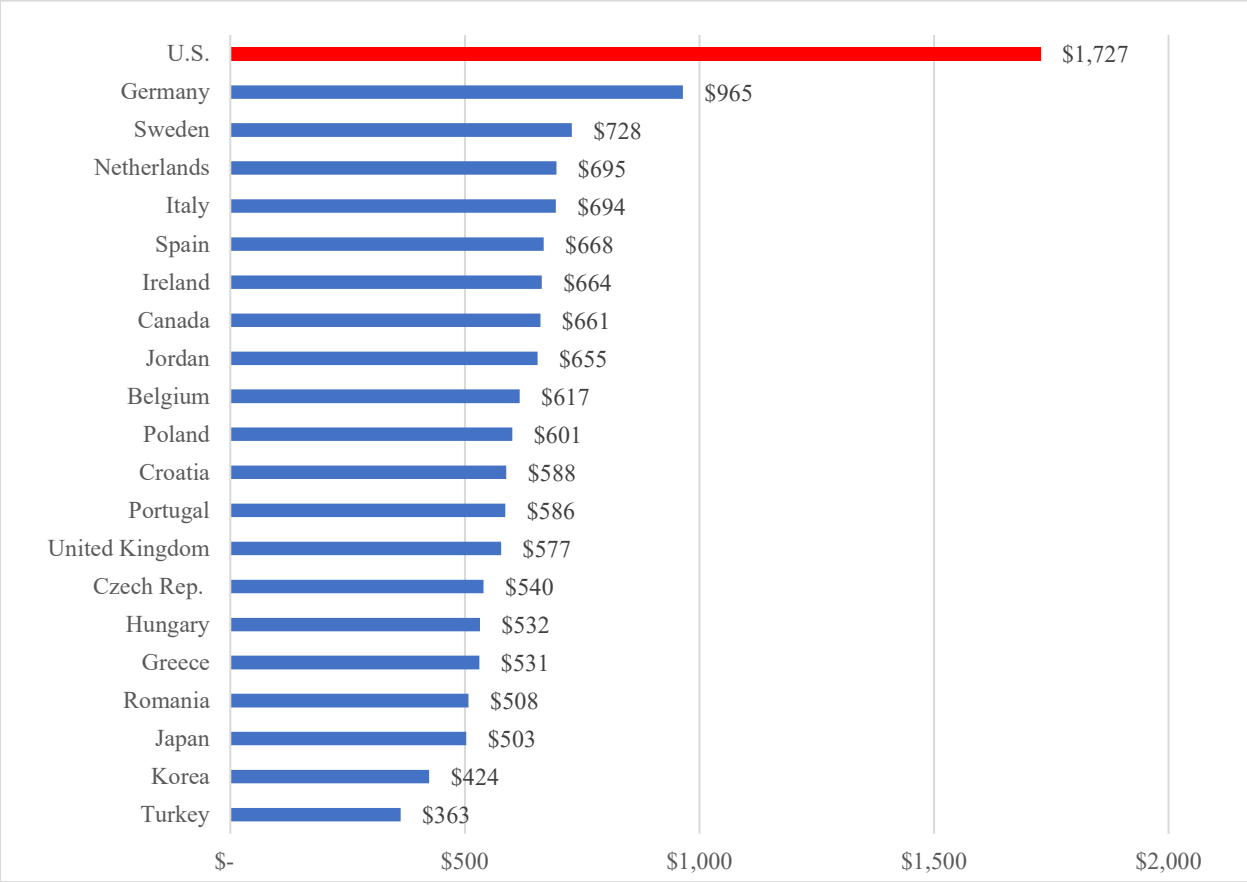
[50] *See* AbbVie Inc., 2020 *Proxy Statements* (Mar. 23, 2020) (online at https://investors.abbvie.com/sec-filings/sec-filing/def-14a/0001047469-20-001710).

[51] 42 U.S.C. § 1395w-111.

per syringe in Germany, $661 in Canada, $577 in the United Kingdom, $503 in Japan, and $424 in South Korea.[52]

Figure 6 below shows the prices listed in the presentation.[53]

Figure 6: 2015 List Prices of a 40-milligram Humira Syringe

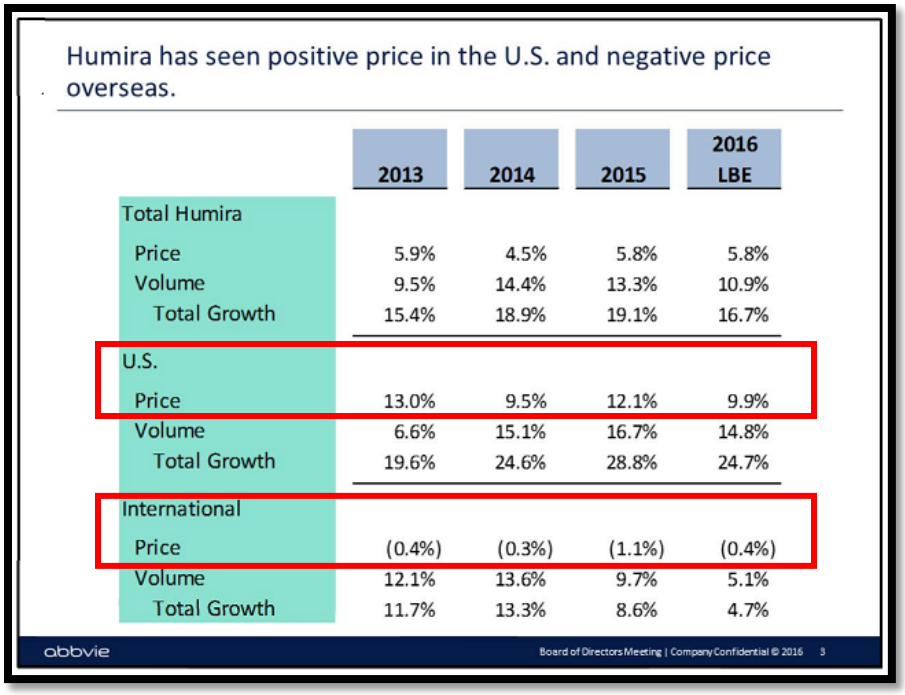


Even as the price of Humira skyrocketed in the United States, AbbVie *lowered* the drug's price in other countries. A 2016 internal presentation obtained by the Committee analyzed the percentage change in price for the U.S. and international markets, characterizing these disparities as "positive price in the U.S. and negative price overseas." The presentation highlighted that Humira's price in the U.S. rose by 13% in 2013, 9.5% in 2014, and 12.1% in 2015, with a 9.9% increase planned for 2016. During the same period, the price of Humira fell internationally—by 0.4% in 2013, 0.3% in 2014, and 1.1% in 2015, with a 0.4% decrease expected in 2016.[54]

[52] ABV-HOR-00033181.

[53] ABV-HOR-00033181, slides 8-9.

[54] ABV-HOR-00033663.



Humira has seen positive price in the U.S. and negative price overseas.

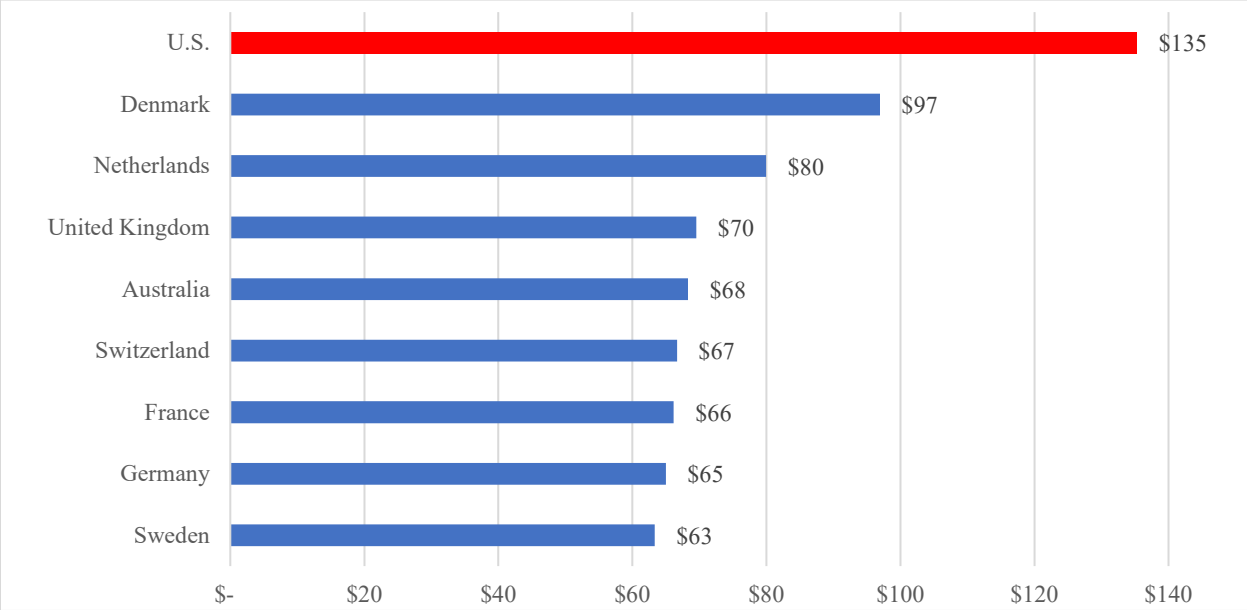
	2013	2014	2015	2016 LBE
Total Humira				
Price	5.9%	4.5%	5.8%	5.8%
Volume	9.5%	14.4%	13.3%	10.9%
Total Growth	15.4%	18.9%	19.1%	16.7%
U.S.				
Price	13.0%	9.5%	12.1%	9.9%
Volume	6.6%	15.1%	16.7%	14.8%
Total Growth	19.6%	24.6%	28.8%	24.7%
International				
Price	(0.4%)	(0.3%)	(1.1%)	(0.4%)
Volume	12.1%	13.6%	9.7%	5.1%
Total Growth	11.7%	13.3%	8.6%	4.7%

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AbbVie also raised the price of Imbruvica in the United States while charging significantly lower prices abroad. In 2018, the price of Imbruvica in the United States was double the price in other countries. Figure 7 shows the 2018 price of a 140-milligram tablet of Imbruvica around the world, based on an analysis by the House Committee on Ways and Means.[55]

[55] Committee on Ways and Means, *A Painful Pill to Swallow: U.S. vs. International Drug Prices* (Sept. 2019) (online at https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf).

Figure 7: 2018 List Prices of a 140-milligram Imbruvica Tablet



B. Lack of Medicare Negotiation Costing Taxpayers Billions

AbbVie's pricing practices for Humira and Imbruvica have increased U.S. health care program expenditures, especially for Medicare.

AbbVie collected more than $13.4 billion in Humira gross revenue from Medicare from 2010 to 2018.[56] Although AbbVie paid a portion of this revenue back in rebates and other discounts, the discounts to Medicare were significantly smaller than its discounts to other government programs permitted to negotiate directly for lower prices. AbbVie's Humira net revenue from Medicare—a figure that subtracts discounts and rebates—was $9.9 billion from 2010 to 2018. [57]

If Medicare had received the same discounts as the Department of Defense, it would have saved more than $7.4 billion on Humira from 2010 to 2018. Similarly, if Medicare had received the same discounts as the Department of Veterans Affairs, it would have saved $7 billion on Humira from 2010 to 2018. Figures 8 and 9 below highlight the difference in these discounts and the potential savings.[58]

[56] Centers for Medicare and Medicaid Services, *Medicare Part D Drug Spending Dashboard & Data* (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD).

[57] Letter from Gibson, Dunn and Crutcher LLP, on behalf of AbbVie Inc., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Sept. 11, 2020).

[58] *Id.*

Figure 8: Lost Medicare Part D Savings for Humira as Compared to DOD

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

Figure 9: Lost Medicare Part D Savings for Humira as Compared to VA

Humira				
Year	Gross Medicare Part D Sales		Lost Part D Discount % (Compared to VA)	Lost Part D Savings
2010	$	405,044,145.14	44.0%	$ 178,219,423.86
2011	$	513,090,759.27	43.0%	$ 220,629,026.49
2012	$	674,609,130.28	50.0%	$ 337,304,565.14
2013	$	955,331,810.70	50.0%	$ 477,665,905.35
2014	$	1,239,853,884.21	51.0%	$ 632,325,480.95
2015	$	1,662,281,577.72	52.0%	$ 864,386,420.41
2016	$	2,198,072,890.76	53.0%	$ 1,164,978,632.10
2017	$	2,638,613,640.93	55.0%	$ 1,451,237,502.51
2018	$	3,168,910,239.26	53.0%	$ 1,679,522,426.81
Total/Average	**$**	**13,455,808,078.27**	**52.1%**	**$ 7,006,269,383.62**

AbbVie also collected more than $5 billion in Imbruvica gross revenue from Medicare from 2014 to 2018.[59] Although AbbVie paid a portion of this revenue back in rebates and other discounts, its discounts to Medicare were again significantly smaller than its discounts to other government programs permitted to negotiate directly for lower prices. AbbVie's Imbruvica net revenue from Medicare was $4.74 billion from 2014 to 2018. [60]

[59] Centers for Medicare and Medicaid Services, *Medicare Part D Drug Spending Dashboard & Data* (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD).

[60] Letter from Gibson, Dunn and Crutcher LLP, on behalf of AbbVie Inc., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Jan. 22, 2021).

According to AbbVie's internal estimates, if Medicare had received the same discounts as the Departments of Defense and Veterans Affairs, taxpayers would have saved more than $1.6 billion on Imbruvica from 2014 to 2018. Figure 10 below highlights the difference in these discounts and the potential savings.[61]

Figure 10: Lost Medicare Part D Savings for Imbruvica

Imbruvica			
Year	Gross Medicare Part D Sales	Lost Part D Discount % (Compared to DOD/VA)	Lost Part D Savings
2014	$266,744,335.26	18.0%	$ 48,013,980
2015	$590,946,241.88	30.0%	$ 177,283,873
2016	$978,350,728.24	36.0%	$ 352,206,262
2017	$1,368,727,294.80	38.0%	$ 520,116,372
2018	$1,867,207,012.50	32.0%	$ 597,506,244
Total	**$5,071,975,612.68**	**33.4%**	**$ 1,695,126,731**

C. Harm to U.S. Patients and Local Governments

AbbVie's price increases have placed significant strain on U.S. patients and their families.

A patient's out-of-pocket costs are often directly tied to the list price of a drug. As AbbVie has increased the price of an annual course of Humira by thousands of dollars each year, patients' out-of-pocket costs have also grown. A 2019 Kaiser Family Foundation study found that the median annual out-of-pocket cost for Medicare patients on Humira was $5,471 in 2019, which is $606 more than in 2016.[62] The 2019 median out-pocket-cost for Medicare patients on Humira was nearly a fifth of the median per capita income of Medicare beneficiaries.[63]

On July 26, 2019, the Committee held a hearing titled "The Patient Perspective: The Devastating Impacts of Skyrocketing Drug Prices on American Families." During this hearing, the Committee heard from Ashley Krege—a 35-year-old woman from Houston, Texas who takes Humira to treat her psoriasis. In her written testimony, Ms. Krege described her experience trying to afford Humira:

[61] *Id.* Unlike the separate DOD and VA discount rates for Humira, AbbVie provided a blended DOD/VA discount rate for Imbruvica.

[62] 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).

[63] *Id.*; Kaiser Family Foundation, *Medicare Beneficiaries' Financial Security Before the Coronavirus Pandemic* (April 24, 2020) (online at www.kff.org/medicare/issue-brief/medicare-beneficiaries-financial-security-before-the-coronavirus-pandemic) (finding that the median per capita income among Medicare beneficiaries was $29,650 in 2019).

> To say this was a financial hardship would be an understatement. The drug costs more than my car payment. More than my business insurance. More than my food bill each month. But I made the decision to suck it up and pay because the drug worked.
>
> But after months of successful pain and symptom management on Humira, I was informed that the drug maker, AbbVie, raised the price. My new monthly payment was going to be almost $1,100 a month.
>
> I simply could not afford it any longer. I had to make the difficult decision to wean myself off the drug that had provided me months of relief. It was already too expensive for me at $750 per month. I couldn't afford the 40% price hike.[64]

AbbVie produced to the Committee more than two hundred pages of Humira patient complaints detailing experiences similar to Ms. Krege's.[65] In these documents, patients and caretakers describe the burden Humira's high—and constantly increasing—price has placed on them and their loved ones. These complaints also reveal the shortcomings of AbbVie's attempts to defray the high cost of Humira through its patient assistance programs. For many patients—including Medicare beneficiaries who are not eligible to participate—the high price of Humira proved prohibitive.

- A retired teacher and Medicare beneficiary with Crohn's disease wrote that despite having a supplemental health insurance plan, her out-of-pocket costs for Humira were more than $2,600 for a month's supply, preventing her from receiving treatment. She told AbbVie that it was "unconscionable that [she] or any human being would be expected to pay such an exorbitant cost" and asked the company to explain how AbbVie "can and does charge such an outlandish sum of money."[66]

- A caretaker for a Crohn's disease patient credited Humira with restoring her father's way of life but described the company's efforts to block more affordable Humira alternatives from coming to market as "cold, and heartless."[67]

AbbVie's pricing practices for Humira also strain local governments. For example, Rockford, Illinois Mayor Tom McNamara reported to the Committee that between August 2013 and July 2020, his city spent more than $2.5 million on Humira alone. According to data Mayor McNamara provided to the Committee, more than 5% of the city's employee health plan expenditures were for Humira.[68]

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[64] Committee on Oversight and Reform, Testimony of Ashley Krege, *Hearing on the Patient Perspective: The Devastating Impacts of Skyrocketing Drug Prices on American Families*, 116th Cong. (July 26, 2019) (online at https://docs.house.gov/meetings/GO/GO00/20190726/109861/HHRG-116-GO00-Wstate-KregeA-20190726.pdf).

[65] ABV-HOR-RR-4605.

[66] ABV-HOR-RR-4605, p. 141.

[67] ABV-HOR-RR-4605, p. 28.

[68] Email from Mayor Tom McNamara, Rockford, Illinois, to Staff, Committee on Oversight and Reform (Sept. 1, 2020).

The Committee also obtained internal assessments from AbbVie showing that the company was aware that its price increases for Imbruvica contributed to higher out-of-pocket costs for patients—particularly Medicare beneficiaries. For these patients, out-of-pocket costs are directly tied to the list price of the drug.[69] An October 2018 company presentation produced to the Committee notes that the rate of Imbruvica abandonment among patients covered under traditional Medicare is 15%. The presentation also notes that traditional Medicare patients are "exposed to the highest costs" and states that "Medicare patient cost distribution has shifted slightly upward year over year, likely due to a combination of price increases and benefit design changes."[70]

The Committee has received testimony from Lynn Scarfuto, a patient who has struggled to afford Imbruvica. Ms. Scarfuto, a retired nurse from Herkimer, New York who lives with leukemia and lung cancer, pays $13,000 per month in out-of-pocket costs for her Imbruvica. Ms. Scarfuto told the Committee:

> I spent the last years of my nursing career working to ensure my cancer patients had the best treatment possible. Now, I am terrified I won't be able to obtain those same resources for myself. Instead of enjoying my retirement and focusing on my health, I carry around the overwhelming burden of Imbruvica's price.[71]

D. Patient Support Programs Generate Profits for AbbVie

In response to criticism about the price of Humira, AbbVie frequently touts its support programs to lower patients' out-of-pocket costs.[72] AbbVie maintains an in-house copay assistance program for commercially insured patients and also makes donations to third party foundations that provide financial assistance to Medicare beneficiaries struggling to afford copays for Humira and Imbruvica.[73] The Committee's investigation found that these programs have generated profits for AbbVie through increased sales.

Between 2009 and 2018, AbbVie transferred more than $39 million to a non-profit called the Patient Access Network (PAN) Foundation.[74] Internal communications between AbbVie and

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[69] 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) (identifying the role of list price in co-insurance rates).

[70] ABV-HOR-RR-0006005, Slides 8, 12.

[71] Video Statement of Lynn Scarfuto, Committee on Oversight and Reform Hearing on "Unsustainable Drug Prices (Part III): Testimony from AbbVie CEO Richard Gonzalez" (May 18, 2021).

[72] AbbVie, *Making Medicines Accessible* (online at www.abbvie.com/responsibility/patient-health-and-well-being/making-medicines-accessible.html) (accessed May 13, 2021).

[73] AbbVie, *myAbbVieAssist Overview* (online at www.abbvie.com/patients/patient-assistance.html) (accessed May 13, 2021); Letter from Gibson, Dunn and Crutcher LLP, on behalf of AbbVie Inc., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Sept. 18, 2020).

[74] Letter from Gibson, Dunn and Crutcher LLP, on behalf of AbbVie Inc., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Sept. 18, 2020).

the PAN Foundation reveal AbbVie's financial incentives for funding these programs in order to attract and retain Humira patients who otherwise might not use the drug. On November 28, 2017, Dan Klein, the President and CEO of the PAN Foundation, emailed AbbVie's Director of Patient Access Programs to request a donation from the company. Mr. Klein explained that if patients' out-of-pocket costs were reduced through financial assistance, they would be more likely to continue taking their "treatment"—an indirect reference to Humira:

> Based upon data from CMS and the National Health and Nutrition Examination Survey, we know that as many as one million people with ankylosing spondylitis, plaque psoriasis, psoriatic arthritis and rheumatoid arthritis are eligible for assistance from PAN. We also know these patients would be much more likely to start and stay on treatment if they were not stymied by high out-of-pocket costs.[75]

Mr. Klein's appeal to AbbVie underscores the perverse incentives of a system that relies on financial assistance programs to help patients afford their medications. These programs allow the companies to generate higher revenues by maintaining demand while raising prices. Although the program might shield some patients from increases in out-of-pocket costs, the overall cost to the health care system has increased due to price increases. This cost is in turn passed on to all patients in the form of higher insurance premiums.

Internal documents show how AbbVie sought to frame its patient assistance programs as charity, despite the financial incentive for these payments. In an April 6, 2016, email, the Senior Director of Global Philanthropy at the AbbVie Foundation wrote to AbbVie's Director of Patient Assistance Programs:

> I would like to craft a few topline narrative points for consideration that pull a story together and will work on that tomorrow (i.e. in 2015, we made ~ $1B of a $14B product available at no cost, aggregated numbers around what we contributed charitably in the disease space over the last 3 years, etc…).[76]

Even as AbbVie made these donations, the company continued to raise the price of Humira. Over the same three-year period described in the April 6, 2016, email, AbbVie raised the price of Humira eight times—including three times in 2013, twice in 2014, twice in 2015, and once in 2016—which together resulted in an 85% increase in price. Shortly after that email, AbbVie raised the price again.[77] Over the same period, the company's U.S. net revenue for Humira increased from $5.2 billion in 2013 to $10.4 billion in 2016.[78]

AbbVie and Janssen's internal discussions regarding Imbruvica also reveal the financial motivations behind their donations to copay foundations. One 2016 presentation on the "optimal

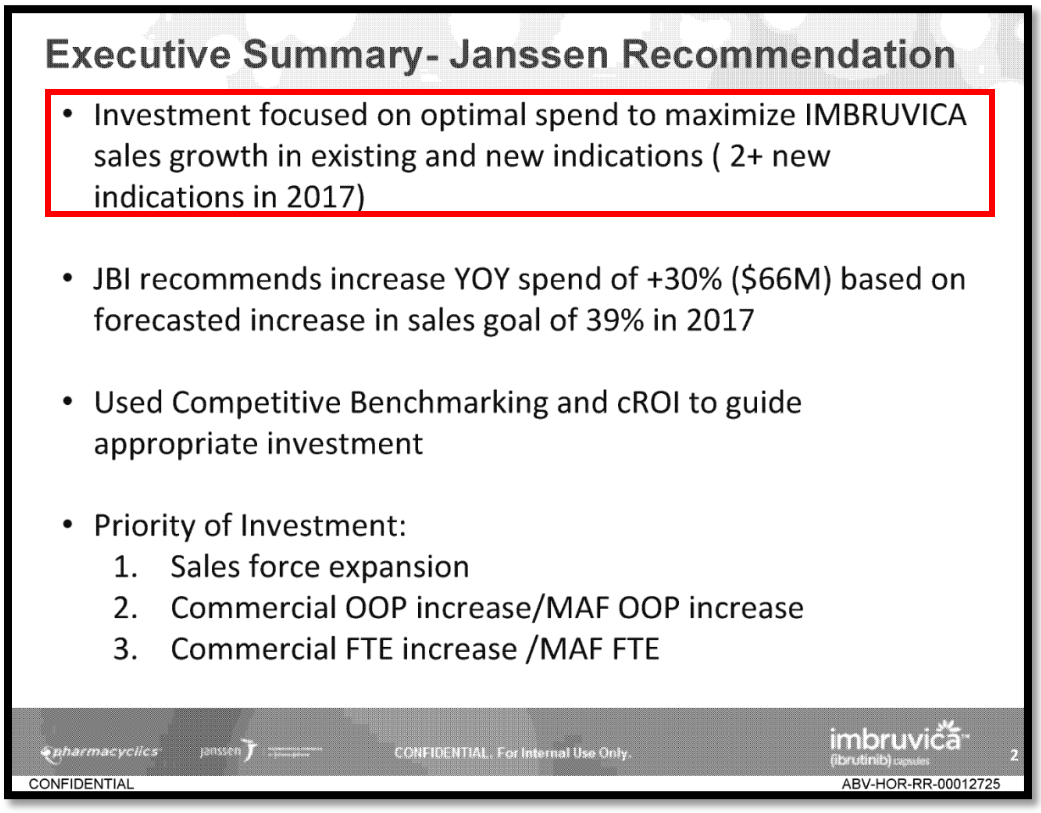
[75] ABV-HOR-00039036.

[76] ABV-HOR-00039140.

[77] IBM Micromedex Redbook, *Wholesale Acquisition Cost for Humira.*

[78] AbbVie Inc., *Annual Reports* (2013-2016) (online at https://investors.abbvie.com/sec-filings).

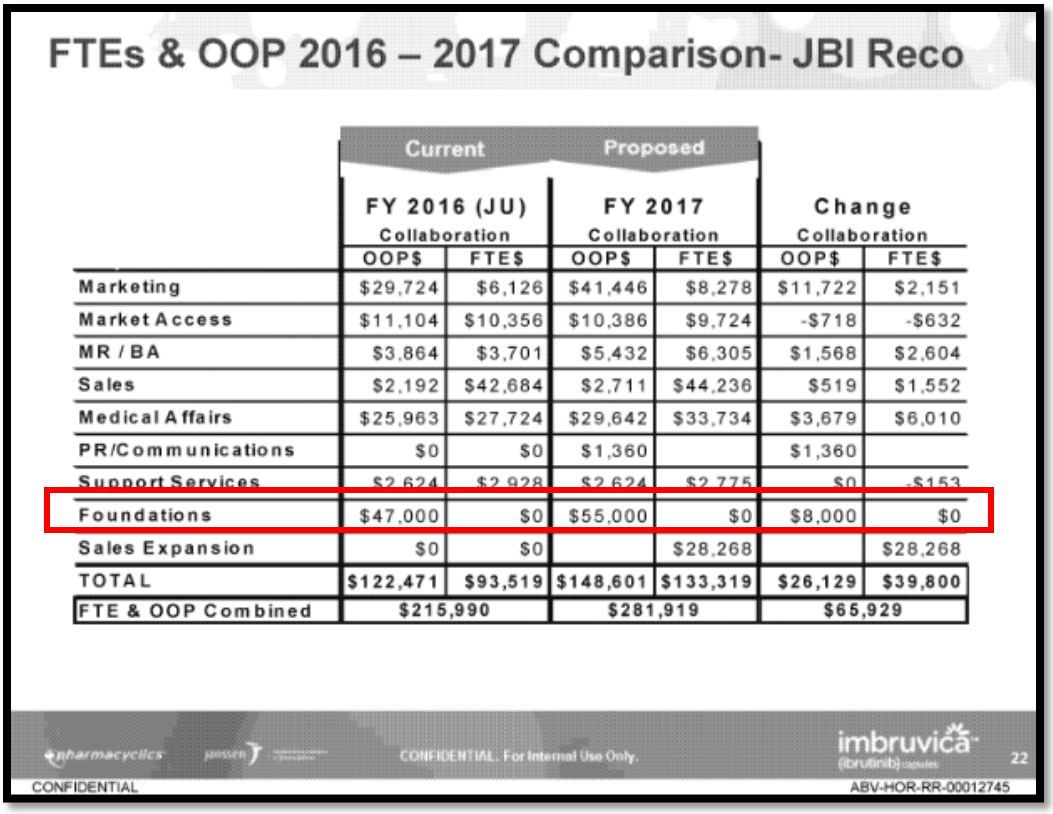
spend to maximize IMBRUVICA sales growth in existing and new indications in 2017" identified payments to patient assistance foundations as one way to increase sales.[79]



The presentation recommended increasing payments to foundations from $47 million to $55 million—the single largest individual expenditure in the companies' Imbruvica promotional budget.[80]

[79] ABV-HOR-RR-00012724.

[80] *Id.*



FTEs & OOP 2016 – 2017 Comparison- JBI Reco

	Current		Proposed			
	FY 2016 (JU) Collaboration		FY 2017 Collaboration		Change Collaboration	
	OOP$	FTE$	OOP$	FTE$	OOP$	FTE$
Marketing	$29,724	$6,126	$41,446	$8,278	$11,722	$2,151
Market Access	$11,104	$10,356	$10,386	$9,724	-$718	-$632
MR / BA	$3,864	$3,701	$5,432	$6,305	$1,568	$2,604
Sales	$2,192	$42,684	$2,711	$44,236	$519	$1,552
Medical Affairs	$25,963	$27,724	$29,642	$33,734	$3,679	$6,010
PR/Communications	$0	$0	$1,360		$1,360	
Support Services	$2,624	$2,928	$2,624	$2,775	$0	-$153
Foundations	$47,000	$0	$55,000	$0	$8,000	$0
Sales Expansion	$0	$0		$28,268		$28,268
TOTAL	$122,471	$93,519	$148,601	$133,319	$26,129	$39,800
FTE & OOP Combined	$215,990		$281,919		$65,929	

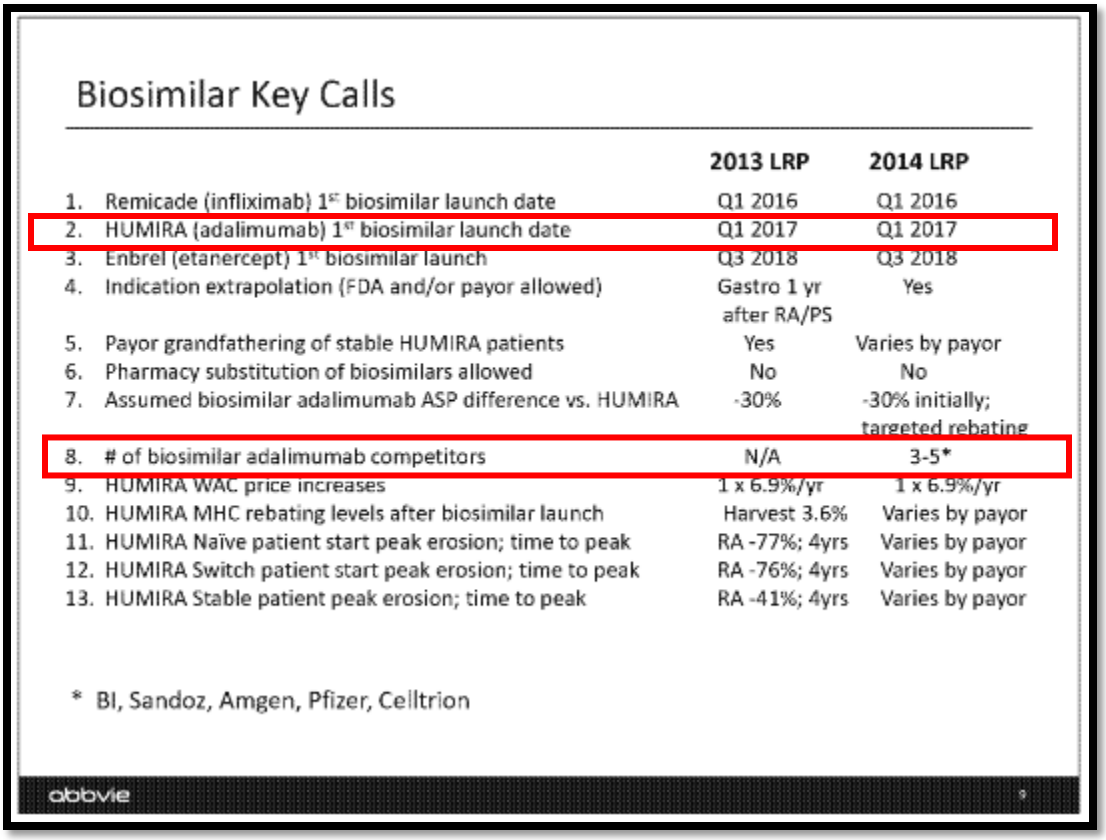
V. ANTICOMPETITIVE CONDUCT TO DELAY HUMIRA BIOSIMILARS

The Biologics Price Competition and Innovation Act of 2009 created an abbreviated pathway for biosimilars (the term for versions of the same biologic drug produced by different manufacturers) to enter the U.S. market and compete with brand-name biologic drugs, such as Humira.[81] The Committee's investigation found that AbbVie engaged in a series of anticompetitive strategies to block lower-priced biosimilar versions of Humira from entering the U.S. market. These strategies include exploiting the U.S. patent system to obtain over a hundred patents on Humira, entering into settlement agreements with potential competitors, and abusing the Orphan Drug Act, a law intended to incentivize the development of drugs to treat rare diseases.

AbbVie's conduct has suppressed biosimilar competition far beyond AbbVie's own internal projections. In February 2014, AbbVie executives circulated a presentation on "US Humira Biosimilar Erosion" that projected that three to five biosimilar competitors would enter the market by the first quarter of 2017.[82]

[81] 42 U.S.C. § 262.

[82] ABV-HOR00032198, Slide 9; *see also* ABV-HOR-00033937 (Feb. 2013 presentation estimating U.S. biosimilar entry in Q1 2017 based on "IP strategy.").



Biosimilar Key Calls

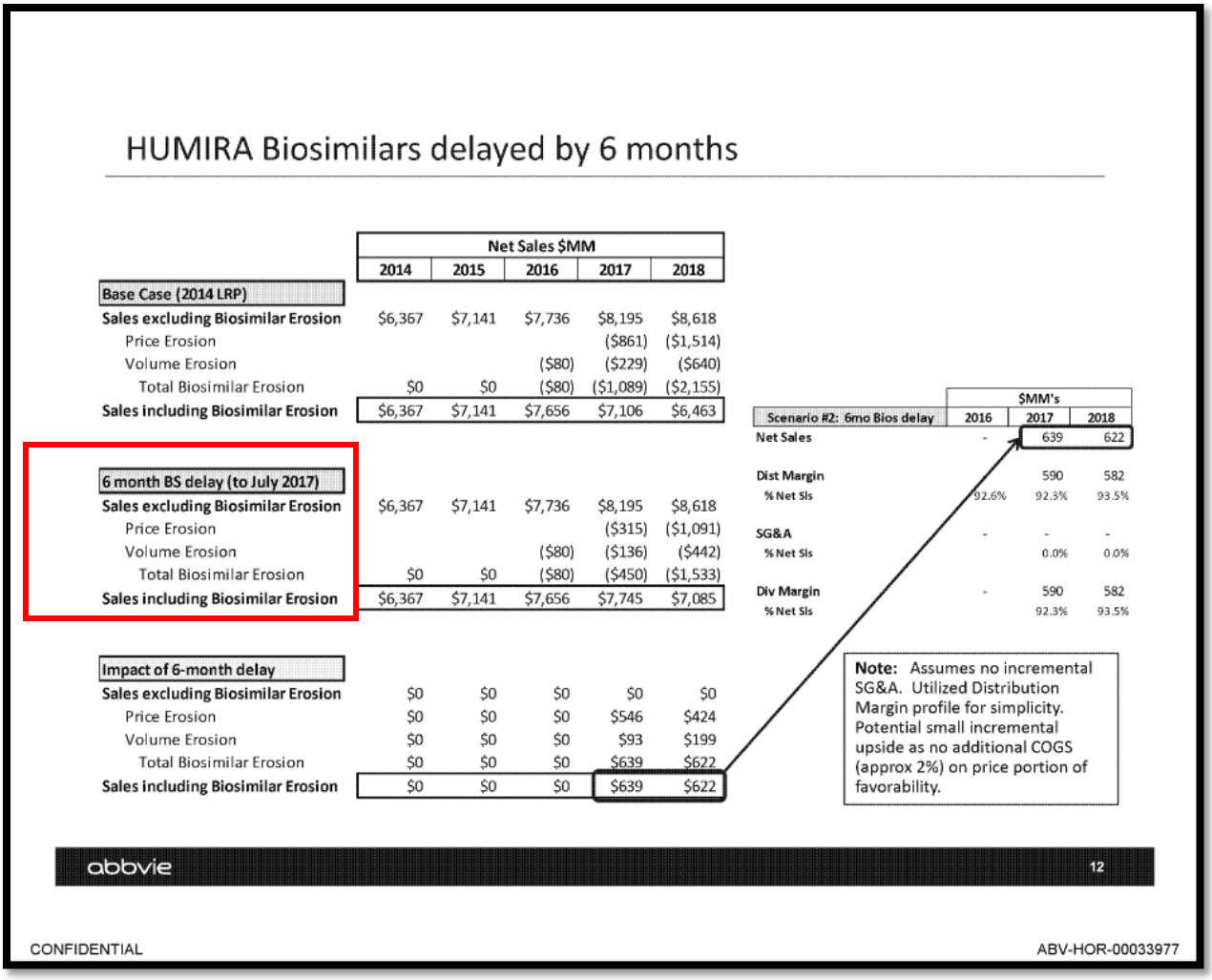
		2013 LRP	2014 LRP
1.	Remicade (infliximab) 1st biosimilar launch date	Q1 2016	Q1 2016
2.	HUMIRA (adalimumab) 1st biosimilar launch date	Q1 2017	Q1 2017
3.	Enbrel (etanercept) 1st biosimilar launch	Q3 2018	Q3 2018
4.	Indication extrapolation (FDA and/or payor allowed)	Gastro 1 yr after RA/PS	Yes
5.	Payor grandfathering of stable HUMIRA patients	Yes	Varies by payor
6.	Pharmacy substitution of biosimilars allowed	No	No
7.	Assumed biosimilar adalimumab ASP difference vs. HUMIRA	-30%	-30% initially; targeted rebating
8.	# of biosimilar adalimumab competitors	N/A	3-5*
9.	HUMIRA WAC price increases	1 x 6.9%/yr	1 x 6.9%/yr
10.	HUMIRA MHC rebating levels after biosimilar launch	Harvest 3.6%	Varies by payor
11.	HUMIRA Naïve patient start peak erosion; time to peak	RA -77%; 4yrs	Varies by payor
12.	HUMIRA Switch patient start peak erosion; time to peak	RA -76%; 4yrs	Varies by payor
13.	HUMIRA Stable patient peak erosion; time to peak	RA -41%; 4yrs	Varies by payor

* BI, Sandoz, Amgen, Pfizer, Celltrion

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In August 2014, AbbVie executives sent CEO Richard Gonzalez another financial analysis projecting that Humira would face biosimilar competition in the United States no later than July 2017 and predicted this would cause "Price Erosion" and "Volume Erosion" for Humira sales.[83]

[83] ABV-HOR-00033966, Slide 12.



However, the company engaged in a series of anticompetitive strategies (described in detail below) to successfully delay biosimilar entry until 2023—nearly six years beyond the date when AbbVie had previously projected biosimilars would enter the market.

By delaying biosimilar entry, AbbVie extracted billions of dollars from the U.S. health care system. AbbVie estimated internally that had lower-priced biosimilars entered the market in the first quarter of 2017, AbbVie's U.S. net revenue would have decreased by $1.5 billion in 2017. According to this internal analysis, biosimilar competition would have forced a reduction in the price of Humira that would have saved the U.S. health care system at least $19 billion from 2016 to 2023.[84]

[84] *See* ABV-HOR-00032198, Slide 15. The $19 billion figure is the total "price variance" estimate of biosimilar erosion. The U.S. health care system would have likely saved additional costs from a subset of patients purchasing lower-priced biosimilars rather than Humira.

2014 LRP Biosimilar Erosion	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Total HUMIRA Var	$0	$0	$0	($77)	($1,562)	($2,808)	($3,695)	($4,535)	($4,966)	($5,365)	($5,744)
% Var	0%	0%	0%	-1%	-20%	-34%	-42%	-50%	-52%	-55%	-57%
Price Var	$0	$0	$0	($8)	($1,259)	($1,968)	($2,399)	($3,044)	($3,289)	($3,537)	($3,797)
Vol Var	$0	$0	$0	($69)	($303)	($840)	($1,296)	($1,490)	($1,676)	($1,828)	($1,947)

A. Exploiting U.S. Patent System to Extend Humira's Monopoly

The U.S. patent system seeks to incentivize innovation by granting an individual or entity that invents a new, useful, and non-obvious process, machine, product, or substance a time-limited right to exclude others from using that invention (i.e. a patent). To receive a patent, the inventor must publicly disclose the details of the invention, thereby allowing other entities to use and replicate it when the patent term expires (typically 20 years after the date on which the patent application was filed).[85]

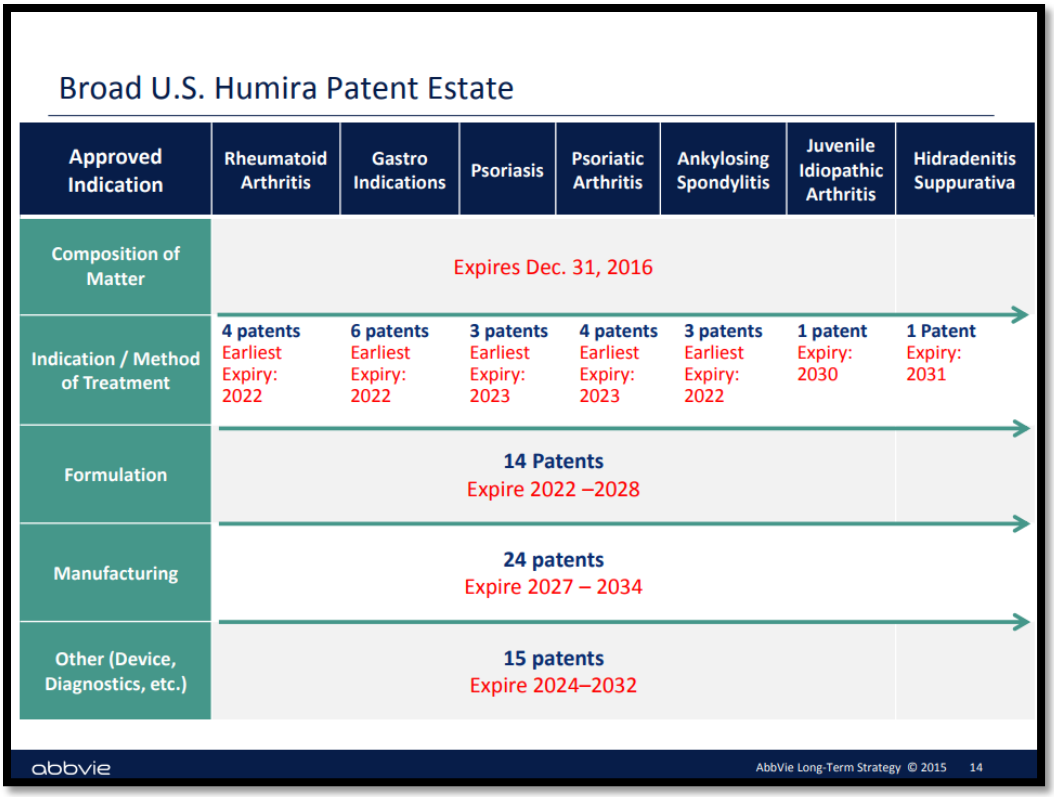
AbbVie's patent on Humira's active ingredient expired on December 31, 2016. At that time, competitors should have been free to enter the market. However, the company exploited the patent system to obtain or apply for over 200 *additional* patents on Humira to block biosimilar competition.[86]

In a presentation to investors on October 30, 2015, AbbVie CEO Richard Gonzalez used the following slide to tout AbbVie's "Broad U.S. Humira Patent Estate."[87]

[85] 35 U.S.C. §§101-103; 112.

[86] *See* U.S. Patent No. 6,090,382 (filed Feb. 9, 1996).

[87] AbbVie, *Long-Term Strategy* (Oct. 30, 2015) (online at https://investors.abbvie.com/static-files/af79eef2-5901-4b62-9354-982d2d95404e).



The slide identifies AbbVie's patents on a range of purported inventions related to Humira, including the use of Humira to treat certain conditions, Humira's formulation, Humira's manufacturing process, and devices used to inject Humira.[88] In the five years since that presentation, AbbVie's patent portfolio has continued to grow. Today, the company owns or has filed for at least 257 Humira-related patents, the last of which is set to expire in 2037—21 years after Humira's original patent expired.[89]

To receive a patent under U.S. law, a claimed invention must be "novel" and "non-obvious."[90] Experts question whether AbbVie's Humira patents meet these requirements.[91] For example, AbbVie's patent covering the use of Humira to treat conditions such as rheumatoid arthritis and ankylosing spondylitis expired in 2016.[92] But AbbVie obtained additional patents

[88] *Id.*

[89] Initiative for Medicine, Access, and Knowledge, *Overpatented, Overpriced: America's Best Selling Drugs of 2019* (online at www.i-mak.org/2019-bestselling/) (accessed May 13, 2020).

[90] 35 U.S.C. §§101-103.

[91] *See, e.g.*, Initiative for Medicine, Access, and Knowledge, *Overpatented, Overpriced: Special Humira Edition* (online at www.i-mak.org/wp-content/uploads/2020/10/i-mak.humira.report.3.final-REVISED-2020-10-06.pdf).

[92] *See* U.S. Patent No. 6,509,015 (filed Mar. 3, 2000). Technically, the patent was originally filed by BASF AG, which later sold its pharmaceutical business to AbbVie's predecessor, Abbott Laboratories. Abbott Laboratories, *Form 8-K* (Mar. 2, 2001) (online at

covering the treatment of those two conditions with a 40-milligram injection of Humira.[93] By simply specifying the dose of Humira—something that was already known to the public and emphasized in AbbVie's marketing materials—AbbVie extended its patent protection by 6 to 11 years.[94] In 2017, the U.S. Patent Trial and Appeal Board (PTAB) invalidated three additional Humira patents that covered dosing for the treatment of rheumatoid arthritis because the dosing was "obvious" and therefore unpatentable.[95]

A recent antitrust lawsuit against AbbVie raises further questions about the validity of a large subset of the company's formulation and manufacturing patents—many of which do not expire until 2035. The lawsuit asserts that AbbVie delayed filing for these patents long after it had used the same formulation and manufacturing processes to put Humira on the market in 2003. The lawsuit argues that the purported "inventions" described in the patents were not "novel" under U.S. patent law because they were already known to the public.[96]

AbbVie's patent strategy is particularly abusive because it seeks to overwhelm potential competitors with the sheer number of patents on Humira regardless of whether individual patents were properly granted under U.S. law. If one patent is invalidated, AbbVie has another patent waiting. Thus, if a competitor wants to enter the market, it must slice its way through the entire patent thicket—a process that is both expensive and slow. For example, shortly before PTAB invalidated AbbVie's rheumatoid arthritis dosing patents, Mr. Gonzalez assured investors that the challenge would have little impact on AbbVie's monopoly:

> [I]f you look at our level of confidence in what we've described to the market about our ability to protect HUMIRA, it remains the same, and that confidence was built around a large portfolio of IP [intellectual property]. It was never contingent upon any one set of IP or any single set of patents or individual patents. We have a large portfolio of formulation patents that have come under challenge and have been successful and successfully navigated through those challenges. We have now the beginning of these

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www.sec.gov/Archives/edgar/data/1800/000091205701007683/a2040697z8-k.htm) (acquiring BASF AG's pharmaceutical business); *see also* Initiative for Medicine, Access, and Knowledge, *Overpatented, Overpriced: Special Humira Edition* (online at www.i-mak.org/wp-content/uploads/2020/10/i-mak.humira.report.3.final-REVISED-2020-10-06.pdf).

[93] *See* U.S. Patent No. 8,926,975 (filed June 17, 2014) (anticipated expiration in 2027); U.S. Patent No. 9,546,212 (filed June 6, 2016) (anticipated expiration in 2022).

[94] *Id. See* Food and Drug Administration, *Approved Label for Humira* (July 2006) (online at www.accessdata.fda.gov/drugsatfda_docs/label/2006/125057s062lbl.pdf) (listing the dosing regimen covered in AbbVie's subsequent patents).

[95] *See Coherus Biosciences Inc. v. AbbVie*, IPR2016-00172 (PTAB May 16, 2017); *Coherus Biosciences Inc. v. AbbVie*, IPR2016-00189 (PTAB June 9, 2017); *Boehringer Ingelheim v. AbbVie*, IPR2016-00408 (PTAB July 6, 2017). The Federal Circuit upheld the decision without opinion in January 2020. *See AbbVie v. U.S. & Iancu*, No. 17-2304 (Fed. Cir.) (Jan. 7, 2020).

[96] See *In re Humira (Adalimumab) Antitrust Litig*., No. 19-cv-01873 (N.D. Il.) (Aug. 9, 2019) (Amended Complaint at ¶¶ 122-133). The case is on appeal after the district court dismissed the plaintiffs' claims as unactionable under U.S. antitrust law. The district court's opinion did not challenge plaintiffs' arguments questioning the validity of AbbVie's Humira formulation and manufacturing patents. *See In re Humira (Adalimumab) Antitrust Litig.*, 465 F. Supp. 3d 811 (N.D. Il.) (June 8, 2020).

> dosing patents. We have a large portfolio of dosing patents. We have dosing patents beyond '135 [one of the invalidated patents] in RA [rheumatoid arthritis], so beyond the ones being challenged. And so, I'd say our level of confidence in the outcome, the overall outcome that we anticipate, it remains the same, it remains high.[97]

The timing of AbbVie's patent applications for Humira makes clear that most of these patents were not necessary to incentivize the company's development of the drug. Approximately 90% of AbbVie's applications were filed after Humira was already approved and brought to market. Nearly half of Humira's patent applications are from 2014 onwards—more than a decade after Humira was brought to market.[98]

Internal company documents obtained by the Committee show that AbbVie views the U.S. patent system as far more permissive than patent systems in the rest of the world. For example, an internal white paper noted that Europe's patent system precluded many of the same patents it obtained in the United States, including a subset of its formulation patents and at least one of its patents related to the use of Humira for the treatment of psoriasis.[99]

In October 2018, AbbVie began facing competition in Europe from five different biosimilars, which together reduced the price of Humira by as much as 80%.[100] Due to this biosimilar competition, AbbVie's non-U.S. sales for Humira dropped by 31% in 2019, while its U.S. sales increased by 8.6%.[101]

B. Patent Settlements to Delay U.S. Entry of Humira Biosimilars

AbbVie has also suppressed biosimilar competition by entering into settlement agreements with competitors that have challenged Humira's patents.

AbbVie's settlements have delayed entry by all six competitors with biosimilar versions of Humira that have received approval from FDA, as well as three additional competitors that have applications pending with FDA.[102] In 2017, AbbVie secured an agreement with Amgen to delay Amgen's U.S. launch of a Humira biosimilar until January 31, 2023. Over the next two years, AbbVie entered into agreements with eight other companies to delay the U.S. launch of

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[97] AbbVie, Q1 2017 Earnings Call Transcript (Apr. 27, 2017) (online at https://seekingalpha.com/symbol/ABBV/earnings/transcripts).

[98] Initiative for Medicine, Access, and Knowledge, Humira's Patent Wall (Oct. 22, 2020) (online at www.i-mak.org/wp-content/uploads/2020/12/Humira-deck-2020-10-22.pdf); Initiative for Medicine, Access, and Knowledge, *Overpatented, Overpriced: Special Humira Edition* (Oct. 6, 2020) (online at www.i-mak.org/wp-content/uploads/2020/10/i-mak.humira.report.3.final-REVISED-2020-10-06.pdf).

[99] ABV-HOR-RR-00001181.

[100] AbbVie, Q3 2018 Earnings Call Transcript (Nov. 2, 2018) (online at https://seekingalpha.com/symbol/ABBV/earnings/transcripts).

[101] AbbVie Inc., *2019 Form 10-K Annual Report* (Feb. 21, 2020) (online at https://investors.abbvie.com/sec-filings/sec-filing/10-k/0001551152-20-000007).

[102] Food and Drug Administration, *Database of Licensed Biological Products* (accessed May 13, 2020) (online at https://purplebooksearch.fda.gov/).

Humira biosimilars. Under those agreements, the biosimilar manufacturers will also pay royalties to AbbVie for a period after entering the market. Figure 11 below summarizes AbbVie's agreements delaying entry of biosimilar competition.[103]

Figure 11

AbbVie - Humira Patent Settlements				
Biosimilar Competitor	**Settlement Date**	**European License Date**	**U.S. FDA Approval**	**Originally Agreed U.S. Launch***
Amgen, Inc.	9/28/2017	10/16/2018	9/23/2016	1/31/2023
Samsung Bioepis	4/5/2018	10/16/2018	7/23/2019	6/30/2023
Mylan	7/17/2018	-	7/6/2020	7/31/2023
Novartis/Sandoz	10/11/2018	10/16/2018	10/30/2018	9/30/2023
Fresenius Kabi	10/18/2018	10/17/2018	-	9/30/2023
Momenta	11/6/2018	11/6/2018	-	11/20/2023
Pfizer	11/28/2018	11/30/2018	11/15/2019	11/20/2023
Coherus	1/25/2019	1/25/2019	-	12/15/2023
Boehringer Ingelheim	5/13/2019	-	8/25/2017	7/1/2023
*The Committee's review of these agreements shows that the Boeghringer Ingelheim settlement led to Samsung Bioepis, Mylan, Novartis/Sandoz, Fresenius Kabi, Momenta, Pfizer, and Coherus all moving their entry date to 7/1/2023 under most-favored nation clauses in their agreements.				

[103] *See* FTC_MMA_1416-2944. In response the Committee's request, the Federal Trade Commission provided the Committee with the agreements related to Humira and Imbruvica. Letter from Secretary April J. Tabor, Federal Trade Commission, to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Dec. 9, 2020); Letter from Secretary April J. Tabor, Federal Trade Commission, to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Feb. 26, 2021). The key terms of the agreements are also publicly available. *See e.g.*, Amgen, *Press Release: Amgen and AbbVie Agree to Settlement Allowing Commercialization of Amgevita* (Sept. 28, 2017) (online at www.amgen.com/newsroom/press-releases/2017/09/amgen-and-abbvie-agree-to-settlement-allowing-commercialization-of-amgevita).

Of the five biosimilar competitors AbbVie originally expected would enter the market in the first quarter of 2017, AbbVie has entered into patent settlement agreements with four of them.[104]

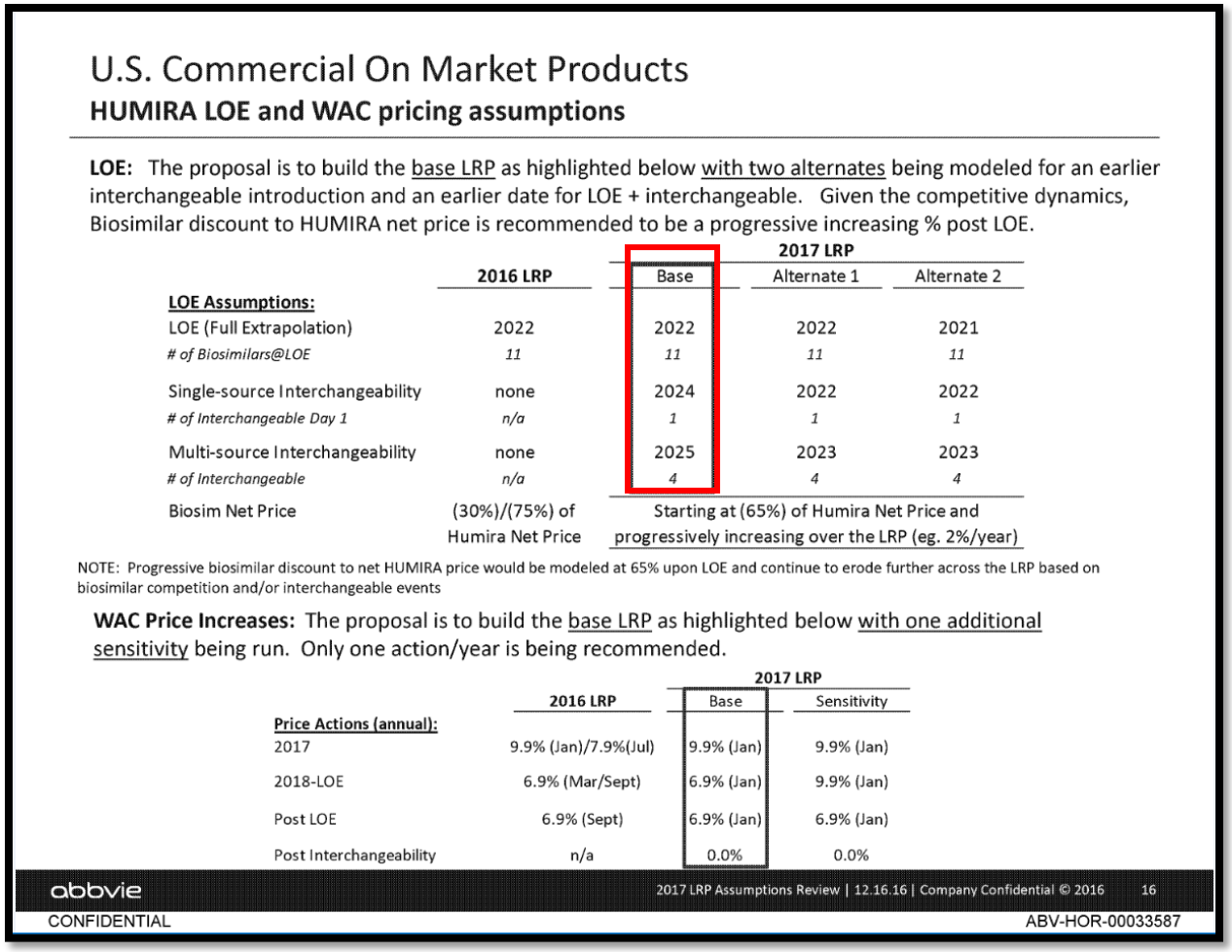
AbbVie has defended these settlement agreements by claiming they allow biosimilars to enter the market "early," as compared to 2037, when the last of AbbVie's patents on Humira would expire if not invalidated. [105] But AbbVie's "early" entry argument is inconsistent with AbbVie's internal assessments of the strength of its patent portfolio, which originally projected biosimilar entry between January and July 2017. Amgen's planned January 31, 2023, U.S. entry date for a Humira biosimilar is *six years later* than AbbVie's original projections, and other competitors are slated to enter the market even later than Amgen.

In December 2017—three months after its settlement agreement with Amgen—AbbVie executives predicted that its patent portfolio would only prevent biosimilar entry until 2022, at which point Humira would face 11 biosimilar competitors.[106]

[104] ABV-HOR00032198, Slide 9.

[105] *See e.g.*, *In re Humira (Adalimumab) Antitrust Litig*., No. 19-cv-01873 (N.D. Il.) (Oct. 11, 2019) (AbbVie's Memorandum in Support of Defendants' Motion to Dismiss). This argument assumes that all of the patents are valid and that biosimilar entry would have infringed those patents—an assumption that is not the case. A report from the Federal Trade Commission estimates that when generic companies challenge secondary patents, the patent holder loses 75% of the time. *See* Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration* (July 2002) (online at www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf).

[106] ABV-HOR-00033572, Slide 16.



U.S. Commercial On Market Products

HUMIRA LOE and WAC pricing assumptions

LOE: The proposal is to build the base LRP as highlighted below with two alternates being modeled for an earlier interchangeable introduction and an earlier date for LOE + interchangeable. Given the competitive dynamics, Biosimilar discount to HUMIRA net price is recommended to be a progressive increasing % post LOE.

	2016 LRP	2017 LRP Base	2017 LRP Alternate 1	2017 LRP Alternate 2
LOE Assumptions:				
LOE (Full Extrapolation)	2022	2022	2022	2021
# of Biosimilars@LOE	*11*	*11*	*11*	*11*
Single-source Interchangeability	none	2024	2022	2022
# of Interchangeable Day 1	*n/a*	*1*	*1*	*1*
Multi-source Interchangeability	none	2025	2023	2023
# of Interchangeable	*n/a*	*4*	*4*	*4*
Biosim Net Price	(30%)/(75%) of Humira Net Price	Starting at (65%) of Humira Net Price and progressively increasing over the LRP (eg. 2%/year)		

NOTE: Progressive biosimilar discount to net HUMIRA price would be modeled at 65% upon LOE and continue to erode further across the LRP based on biosimilar competition and/or interchangeable events

WAC Price Increases: The proposal is to build the base LRP as highlighted below with one additional sensitivity being run. Only one action/year is being recommended.

	2016 LRP	2017 LRP Base	2017 LRP Sensitivity
Price Actions (annual):			
2017	9.9% (Jan)/7.9%(Jul)	9.9% (Jan)	9.9% (Jan)
2018-LOE	6.9% (Mar/Sept)	6.9% (Jan)	9.9% (Jan)
Post LOE	6.9% (Sept)	6.9% (Jan)	6.9% (Jan)
Post Interchangeability	n/a	0.0%	0.0%

abbvie 2017 LRP Assumptions Review | 12.16.16 | Company Confidential © 2016 16

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The company's internal projections raise serious questions about whether the 2023 biosimilar entry dates agreed to between AbbVie and its competitors were truly negotiated compromises reflecting the odds of the parties' success in patent litigation or whether AbbVie—in violation of U.S. antitrust law—transferred items of value to its competitors in exchange for them staying off the market longer than they likely would if the patents were litigated.[107]

There are at least two different items of value that AbbVie may have provided to competitors in exchange for staying off the market. First, with respect to Amgen, AbbVie allowed Amgen to enter the market five months before any other biosimilar competitor. In light of AbbVie's $14.8 billion in U.S. net revenue for Humira in 2019, this early entry is worth at

[107] AbbVie may argue that its competitors' agreement to pay royalties forecloses the possibility of payment from AbbVie to its competitors. However, the fact that these settlements allowed AbbVie to delay competition so many years beyond its internal assessments raises questions of whether there was anything of larger value flowing in the other direction.

least $493 million to Amgen.[108] Second, although the agreements kept biosimilar competition out of the U.S. market, they allowed at least six competitors to enter the European market in 2018—over four years before U.S. entry.[109] This effectively divided the market, with the biosimilar companies gaining market share in Europe while AbbVie retained its monopoly pricing in the much larger United States market. As noted above, biosimilar competition in Europe has forced AbbVie to lower the price of Humira in Europe by as much as 80%.[110]

C. Abusing Orphan Drug Act to Defend Humira Monopoly

AbbVie has also protected its Humira monopoly by abusing the Orphan Drug Act (ODA), a law intended to incentivize the development of drugs that treat rare diseases and conditions.

Congress passed the ODA to promote the development of drugs for which the target population might be too small to give companies a reasonable expectation of recovering development costs.[111] The ODA grants two primary forms of incentives. First, during the development process, pharmaceutical companies can obtain an "orphan designation" for a drug that shows promise in the treatment of a rare disease or condition (*i.e.* one that affects fewer than 200,000 people in the United States or one for which "there is no reasonable expectation" of recovering research and development costs). This designation allows the company to gain certain development incentives, including a tax credit for qualifying clinical trial costs. Second, if FDA approves the drug for an indication within the scope of its orphan designation, the manufacturer receives a seven-year exclusivity period, starting at the date of FDA approval, during which FDA may not approve another version of the same drug for the same indication.[112]

Contrary to the stated purpose of the ODA, AbbVie sought protections for Humira under the Act despite already collecting billions of dollars in Humira sales each year.[113] Today,

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[108] To arrive at this estimate, Committee staff assumed biosimilar market capture of 20% at a price reduction of 20% and Amgen avoiding competition from one other biosimilar competitor. AbbVie Inc., *2019 Form 10-K Annual Report* (Feb. 21, 2020) (online at https://investors.abbvie.com/sec-filings/sec-filing/10-k/0001551152-20-000007).

[109] *See* Figure 11, *supra*.

[110] *See* AbbVie, Q3 2018 Earnings Call Transcript (Nov. 2, 2018) (online at https://seekingalpha.com/symbol/ABBV/earnings/transcripts).

[111] *See* 21 U.S.C. § 360aa note ("[B]ecause so few individuals are affected by any one rare disease or condition, a pharmaceutical company which develops an orphan drug may reasonably expect the drug to generate relatively small sales in comparison to the cost of developing the drug and consequently to incur a financial loss.")

[112] *See* 21 U.S.C. § 360aa *et seq*.

[113] Letter from Gibson, Dunn and Crutcher LLP, on behalf of AbbVie Inc., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Feb. 4, 2019); Letter from Gibson, Dunn and Crutcher LLP, on behalf of AbbVie Inc., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Jan. 14, 2021); Abbott Laboratories, Form 10-K (2003-2013) (online at www.abbottinvestor.com/financials/sec-filings); AbbVie Inc., Annual Reports (2013-2020) (online at https://investors.abbvie.com/sec-filings).

AbbVie holds eight orphan designations and approvals for Humira, which are summarized in Figure 12 below.[114]

Figure 12

Humira - Orphan Designations and Approvals				
Designation Date	**Orphan Designation**	**Approved Labeled Indication**	**Marketing Approval Date**	**Orphan Exclusivity End Date**
3/21/2005	Juvenile Rheumatoid Arthritis	Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients **4 years of age and older**	2/21/2008	2/21/2015
3/21/2005	Juvenile Rheumatoid Arthritis	Reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients **2 years of age and older**	9/30/2014	9/30/2021
10/19/2006	Pediatric Crohn's Disease	Reducing signs and symptoms and inducing and maintaining clinical remission in patients **6 years of age and older** with moderately to severely active Crohn's disease who have had an inadequate response to corticosteroids or immunomodulators such as azathioprine, 6-mercaptopurine, or methotrexate	9/23/2014	9/23/2021
5/13/2014	Non-infectious Intermediate, Posterior, or Panuveitis, or Chronic Non-Infectious Anterior Uveitis	Indicated for the treatment of non-infectious intermediate, posterior and panuveitis in **adult** patients	6/30/2016	6/30/2023
5/13/2014	Non-infectious Intermediate, Posterior, or Panuveitis, or Chronic Non-Infectious Anterior Uveitis	Treatment of non-infectious intermediate, posterior, and panuveitis in adults and **pediatric patients 2 years of age and older**	9/28/2018	9/28/2025
5/13/2015	Treatment of moderate to severe hidradenitis suppurativa	Treatment of moderate to severe hidradenitis suppurativa	9/9/2015	9/9/2022
5/13/2015	Treatment of moderate to severe hidradenitis suppurativa	Treatment of moderate to severe hidradenitis suppurativa in patients **12 years of age and older**	10/16/2018	10/16/2025
5/11/2011	Treatment of pediatric patients with ulcerative colitis	Treatment of moderately to severly active ulcerative colitis in pediatric patients 5 years of age and older.	2/24/2021	2/24/2028

The ODA's incentives play an important role in some companies' decisions to pursue research into treatment for rare diseases, but internal AbbVie documents suggest that the company did not need ODA incentives to pursue research into Humira's potential application to these conditions.

For example, AbbVie had already planned to conduct research into treating the skin condition hidradenitis suppurativa (HS) even without incentives under the ODA. In an April 2008 memorandum summarizing the company's development strategy, executives stated that studying the effectiveness of Humira in treating this condition would support four strategic objectives, including the need to "competitively position [Humira] against new market entrants" and "generate patient demand for biologics in dermatology."[115] The memorandum did not

[114] Food and Drug Administration, *Database of Orphan Drug Designations and Approvals* (accessed May 13, 2021) (online at www.accessdata.fda.gov/scripts/opdlisting/oopd/).

[115] ABV-HOR-00042146.

mention incentives under the ODA. Another internal AbbVie analysis in October 2008 confirmed that the company viewed HS as a profitable market, without ODA incentives:

> Lastly, with a successful outcome, this study may ultimately lead to a development path for a new label indication in the treatment of moderate to severe HS. Based on our current understanding of the prevalence of HS and the number of severe patients that are potentially suitable for systemic treatment with biologic therapy **we would also expect an HS indication to contribute to overall sales in dermatology (potentially up to additional 30% of current psoriasis sales).** Broadening the Humira profile with further indications such as HS also has the benefit of providing a level of protection for the Humira brand from future biosimilar competition expected as early as 2014 with the anticipated introduction of etanercept biosimilars.[116]

The October 2008 analysis also noted that health care databases likely underestimated the number of treatable HS patients in the United States and that the "true scope of an eligible patient population would be expected to be significantly larger with the introduction of a proven effective therapy."[117]

For HS and another condition, juvenile rheumatoid arthritis (JRA), AbbVie secured longer periods of exclusivity by seeking separate, staggered market approvals for subsets of patients affected by the same rare disease for which AbbVie was granted an orphan drug designation—a practice referred to as "salami slicing."[118] By using this tactic, AbbVie gained greater protection under the ODA than Congress intended. AbbVie's use of this tactic is described further below.

Hidradenitis Suppurativa

On May 13, 2015, FDA granted Humira an orphan designation for the treatment of moderate to severe HS. AbbVie leveraged this designation into two separate orphan exclusivity periods by splitting the patient population into two groups: the general population and patients 12 years of age and older. AbbVie's HS orphan exclusivity for the general population runs from September 9, 2015, to September 9, 2022, while the exclusivity for patients 12 years of age and older lasts from October 16, 2018, to October 16, 2025.[119] Combined, AbbVie enjoys a ten-year

[116] ABV-HOR-00042168 (emphasis added).

[117] *Id.*

[118] *See, e.g.*, Robin Feldman, *Regulatory Property: The New IP*, Columbia Journal of Law and Arts (2016) (online at https://repository.uchastings.edu/cgi/viewcontent.cgi?article=2544&context=faculty_scholarship); *Drugs for Rare Diseases Have Become Uncommonly Rich Monopolies*, NPR (Jan. 17, 2017) (online at www.npr.org/sections/health-shots/2017/01/17/509506836/drugs-for-rare-diseases-have-become-uncommonly-rich-monopolies).

[119] Food and Drug Administration, Database of Orphan Drug Designations and Approvals (accessed May 13, 2021) (online at www.accessdata.fda.gov/scripts/opdlisting/oopd/).

period of HS orphan exclusivity—three years longer than the seven years intended under the ODA.

Juvenile Rheumatoid Arthritis

On March 21, 2005, FDA granted Humira an orphan designation for the treatment of JRA.[120] To leverage this designation into 13 years of orphan exclusivity—rather than the statutory 7 years—AbbVie split its research and marketing applications into two groups: children four years of age and older and children between the ages of two and four.

In January 2005, AbbVie completed a clinical trial demonstrating Humira's efficacy in treating children ages 4 to 17 years old with JRA.[121] On February 21, 2008, based on the results of this trial, AbbVie received marketing approval and a seven-year orphan exclusivity for Humira's use in treating JRA in children four years of age and older.

Given the success of the first clinical trial into JRA, one might have expected AbbVie to immediately launch a second trial examining whether Humira could also help children under the age of four with JRA. But AbbVie waited until March 2009 to start this trial, which was not completed until March 2013.[122] On September 30, 2014, AbbVie received the marketing approval for Humira to treat JRA patients two years of age and older—granting AbbVie a new orphan exclusivity that does not expire until September 30, 2021, over 13 years after its first orphan exclusivity for JRA began.[123]

AbbVie's delay in conducting trials for JRA patients under the age of four may also have harmed that group of children by hindering their access to the drug for at least five years (2008 to 2013). Without trials showing efficacy for that age group, insurance companies may have been less willing to pay for the drug.

VI. SHADOW PRICING WITH AMGEN

One significant competitor to Humira is Enbrel, Amgen's blockbuster biologic treatment for rheumatoid arthritis and other conditions. Instead of pricing Humira and Enbrel below one another to gain market share—as expected in a competitive market—AbbVie and Amgen engaged in a practice known as "shadow pricing," consistently following the other company's price increases. As a result, both companies repeatedly set higher, near-identical prices for

[120] Food and Drug Administration, *Database of Orphan Drug Designations and Approvals* (accessed May 13, 2021) (online at www.accessdata.fda.gov/scripts/opdlisting/oopd/).

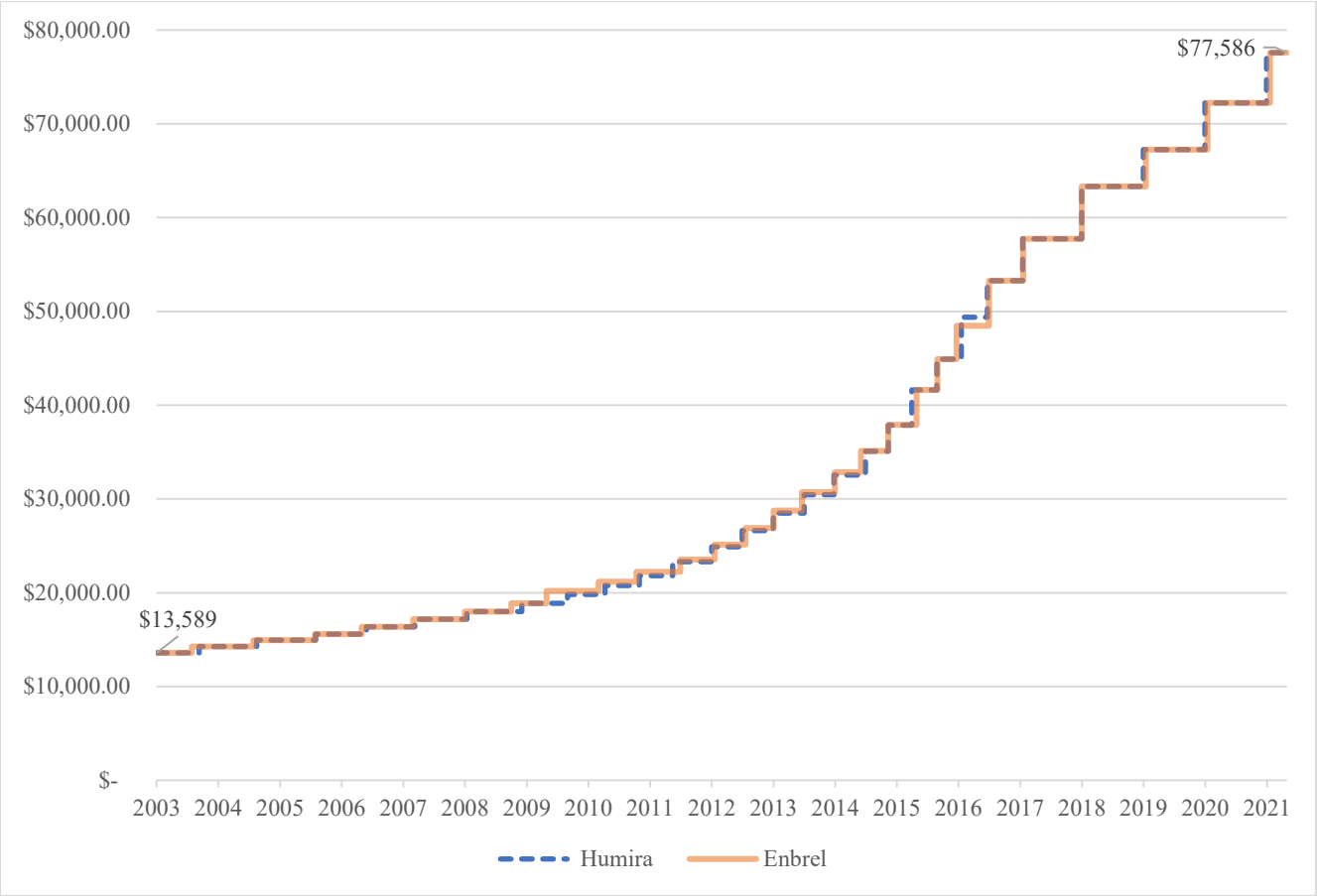
[121] National Institutes of Health, *Information for Clinical Trials Identifier NCT00048542* (online at https://clinicaltrials.gov/ct2/show/NCT00048542).

[122] National Institutes of Health, *Information for Clinical Trials Identifier NCT00775437* (online at https://clinicaltrials.gov/ct2/show/NCT00775437).

[123] Food and Drug Administration, Database of Orphan Drug Designations and Approvals (accessed May 13, 2021) (online at www.accessdata.fda.gov/scripts/opdlisting/oopd/).

Humira and Enbrel. The graph below shows AbbVie's and Amgen's pricing for a year's course of Humira and Enbrel from 2003 to 2021.[124]

Figure 13: Humira and Enbrel: Price of an Annual Course of Treatment



Internal AbbVie documents obtained by the Committee reveal that the company viewed Amgen's price increases as providing cover for its own price increases. For example, one company executive reported to current CEO and then-Executive Vice President Richard Gonzalez that it was a "Great week-end" after learning that Amgen had increased the price of Enbrel on January 20, 2012, to $25,150 annually.[125] The email thread noted that earlier that month, AbbVie had increased the price of Humira to $24,913 annually.[126] In July, AbbVie would top Amgen again by raising the price of Humira to $26,632. Less than 3 weeks later, Amgen followed suit with another price increase.[127]

[124] IBM Micromedex Redbook, *Wholesale Acquisition Cost for Humira and Enbrel*.

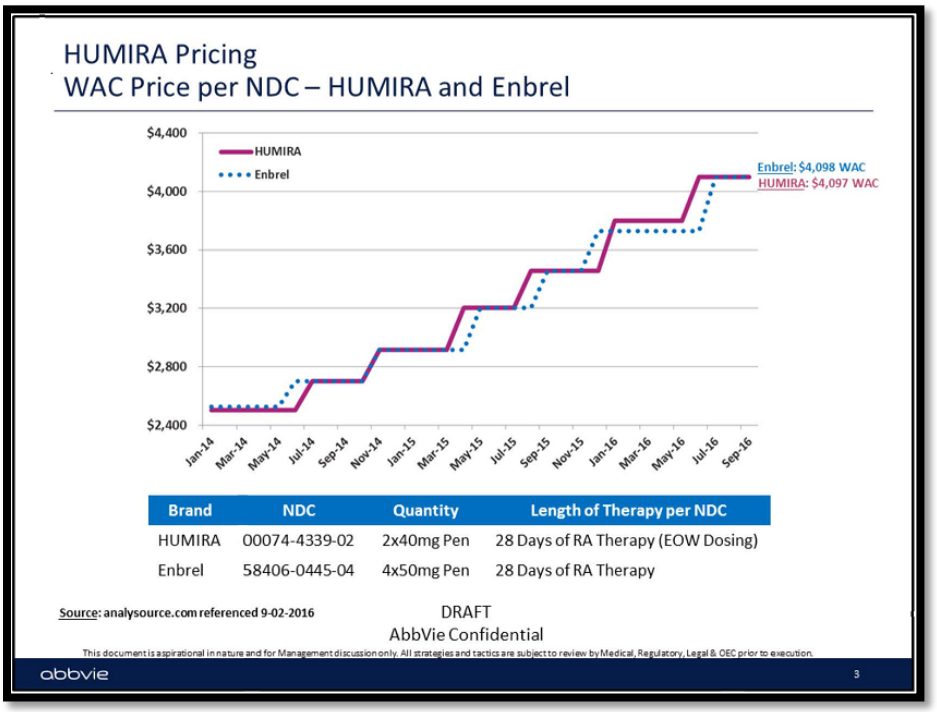
[125] ABV-HOR-00136539.

[126] *Id.*

[127] IBM Micromedex Redbook, *Wholesale Acquisition Cost for Humira and Enbrel*.

To ensure that its price increases were in lockstep with Amgen, AbbVie circulated internal documents comparing its price increases to those of Amgen and other competitors. A slide deck dated May 15, 2013, shows that on three different occasions—January 2012, July 2012, and January 2013—AbbVie and Amgen moved in lockstep to increase the price of Humira and Enbrel respectively. The slide deck also shows that in the 12-month period preceding May 2013, Humira and Enbrel both experienced cumulative price increases of 14.3%, and in the 24-month period preceding May 2013, Humira's price increased cumulatively by 30.6%, while Enbrel's price increased cumulatively 29.4%.[128]

In these internal "pricing analysis" presentations, AbbVie also frequently included a graph showing the price of Humira as compared to Enbrel. For example, its September 2016 presentation included the below graph of shadow pricing between the two companies.[129]



Experts warn that when companies like AbbVie and Amgen engage in shadow pricing, patients "often bear the burden of these costs through increased premiums, copayments and retail prices," and that if shadow pricing continues, "the US healthcare model is likely to become increasingly unsustainable."[130]

[128] ABV-HOR-24886.

[129] ABV-HOR-48274, Slide 3; *see also* ABV-HOR-36178 (Jan. 2016 presentation).

[130] 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/).

VII. LEVERAGING U.S. PATENT SYSTEM TO DELAY IMBRUVICA GENERICS

AbbVie has also exploited the U.S. patent system to extend its market monopoly for Imbruvica. Pharmacyclics—which was later acquired by AbbVie—filed for its first patents on the active ingredient in Imbruvica in 2006. Although these patents are expected to expire in 2026, AbbVie has obtained or filed for over 150 additional patents to delay generic competition until 2036. The Initiative for Medicine, Access, and Knowledge (I-MAK) estimates that during this additional exclusivity period, the U.S. health care system will spend $41 billion dollars on Imbruvica absent generic competition.[131]

AbbVie extended its exclusivity period for Imbruvica by using what I-MAK calls a "drip feed" patent strategy. Under this strategy, AbbVie filed multiple additional patents covering aspects of Imbruvica that had already been disclosed in earlier patents but with more specificity. Because the U.S. patent system grants a 20-year patent term to all approved patents no matter what the patent covers, the successive patents effectively reset the clock for the same "invention."[132]

According to I-MAK, one example of this "drip feed" strategy was AbbVie's collection of patents related to the use of Imbruvica to treat chronic lymphocytic leukemia (CLL) and Waldenstrom macroglobulinemia (WM).[133] AbbVie first disclosed that Imbruvica could be formulated to treat these conditions in a 2006 patent application that broadly covered Imbruvica's active ingredient.[134] After obtaining that patent, which expires in 2026, AbbVie later filed for patents in 2013 and 2014 that specifically cover the *dosing* of Imbruvica to treat CLL and WM.[135] Those patents expire in 2031—providing five additional years of protection. AbbVie then went one step further in 2016 by filing for a patent covering *a solid tablet formulation* of Imbruvica for use to treat CLL and WM.[136] That patent expires in 2036—providing another five years of protection. Through this strategy, AbbVie has effectively received 30 years of patent protection on the use of Imbruvica to treat CLL and WM.[137]

As with Humira, the timing of AbbVie's patents on Imbruvica also undermines arguments that the additional patents were necessary to incentivize the company's development

[131] Initiative for Medicine, Access, and Knowledge, *Imbruvica's Patent Wall* (July 2020) (online at www.i-mak.org/wp-content/uploads/2020/08/I-MAK-Imbruvica-Patent-Wall-2020-07-42F.pdf).

[132] *Id.*

[133] *Id.*

[134] U.S. Patent No. 7,514,444 (filed Dec. 3, 2006).

[135] U.S. Patent No. 9,801,881 (filed Nov. 26, 2013); U.S. Patent No. 9,125,889 (filed July 31, 2014).

[136] U.S. Patent No. 9,655,857 (filed Mar. 3, 2016).

[137] Initiative for Medicine, Access, and Knowledge, *Imbruvica's Patent Wall* (July 2020) (online at www.i-mak.org/wp-content/uploads/2020/08/I-MAK-Imbruvica-Patent-Wall-2020-07-42F.pdf).

of the drug. Approximately 55% of the patent applications on Imbruvica have been filed after it first received FDA approval.[138]

Nearly a dozen generic manufacturers have sought approval from FDA to sell lower-priced generic versions of Imbruvica. In response, AbbVie filed patent infringement cases under the Hatch-Waxman Act against each generic manufacturer. To avoid judicial scrutiny of its Imbruvica patents, however, AbbVie then entered into confidential settlement agreements with almost all the potential generic entrants. Figure 14 summarizes these agreements, which will collectively delay generic entry until March 2032—six years after AbbVie's original patents on Imbruvica expire.[139]

Figure 14

AbbVie - Imbruvica Patent Settlements		
Generic Competitor	**Settlement Date**	**Originally Agreed Upon U.S Launch Date***
Teva	2/5/2019	12/3/2033
Hetero	2/5/2019	12/3/2033
Shilpa	3/5/2019	12/3/2033
Fresenius Kabi	2/7/2020	7/28/2033
Sun Pharma	5/19/2020	7/28/2033
Zydus	10/12/2020	3/30/2032
* The Committee's review of these agreements reveals that AbbVie's settlements with Fresenius Kabi and Zydus likely led to other biosimilar competitors relying on most favored nation clauses in their agreements to elect to move their U.S. launch date to March 30, 2032. In addition, the entry date may move earlier if the FDA fails to grant AbbVie pediatric exclusivity.		

VIII. PROFIT-DRIVEN RESEARCH EXPENDITURES

AbbVie has attempted to justify the high price of Humira and Imbruvica with claims that it invested billions of dollars in research and development expenses related to the drugs.[140] AbbVie's internal documents, however, show that a large portion of AbbVie's research expenditures focused on limiting biosimilar competition through "enhancements" to Humira.

A. Humira Research Focused on "Biosimilar Defense"

The Committee's investigation found that AbbVie's research expenditures focused principally on defending Humira's market share from lower-priced biosimilars and other competitor drugs rather than innovation.

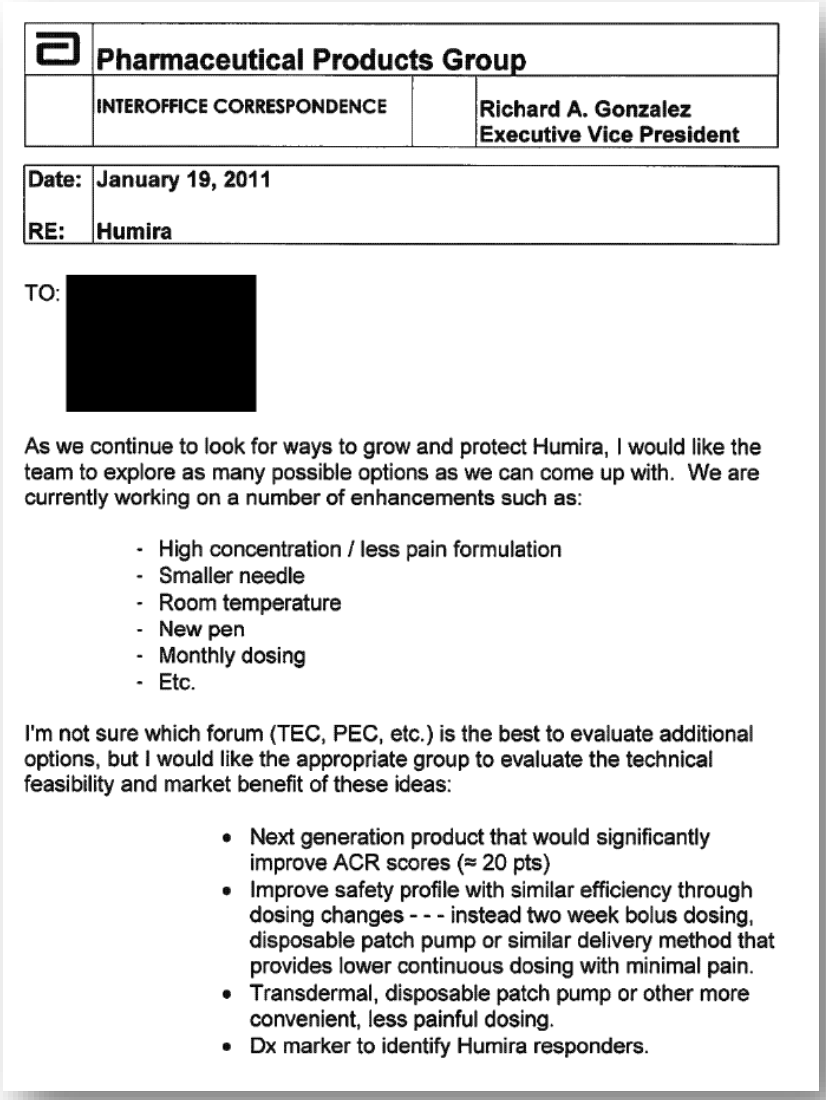
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[138] *Id.*

[139] FTC_MMA_1416-1815.

[140] *See, e.g.*, Letter from Gibson, Dunn and Crutcher LLP, on behalf of AbbVie Inc., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Aug. 31, 2020) (emphasizing research expenditures); ABV-HOR-RR-00000739 (filing to Vermont Attorney General emphasizing research expenditures).

In a January 19, 2011, memorandum to company executives, then-Abbott Executive Vice President and current AbbVie CEO Richard Gonzalez directly linked research into Humira "enhancements"—such as a higher concentration formulation, a smaller needle, a new dispensing pen, and a monthly dosing regimen—with the company's long-term strategy "to grow and protect Humira." He went on to direct his team to "evaluate additional options" based on their "technical feasibility and market benefit." [141]



Pharmaceutical Products Group

	INTEROFFICE CORRESPONDENCE		Richard A. Gonzalez Executive Vice President

Date:	January 19, 2011
RE:	Humira

TO: [redacted]

As we continue to look for ways to grow and protect Humira, I would like the team to explore as many possible options as we can come up with. We are currently working on a number of enhancements such as:

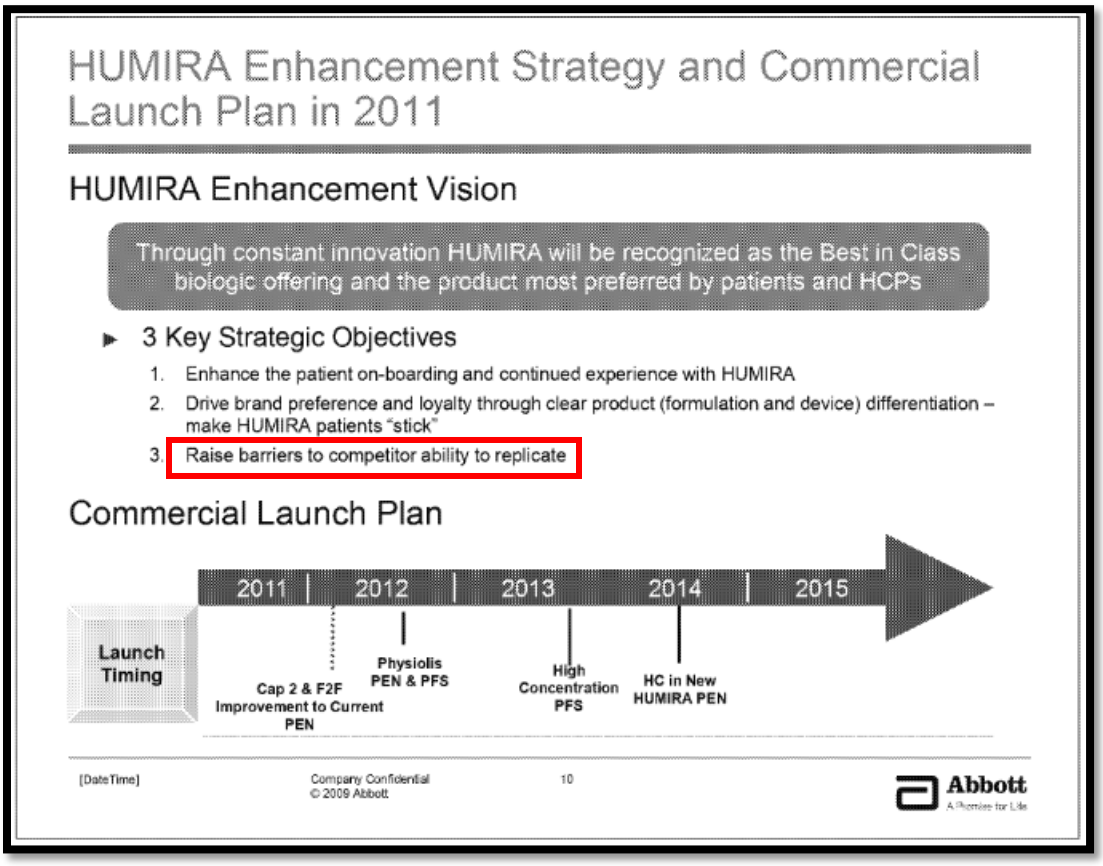
- High concentration / less pain formulation
- Smaller needle
- Room temperature
- New pen
- Monthly dosing
- Etc.

I'm not sure which forum (TEC, PEC, etc.) is the best to evaluate additional options, but I would like the appropriate group to evaluate the technical feasibility and market benefit of these ideas:

- Next generation product that would significantly improve ACR scores (≈ 20 pts)
- Improve safety profile with similar efficiency through dosing changes - - - instead two week bolus dosing, disposable patch pump or similar delivery method that provides lower continuous dosing with minimal pain.
- Transdermal, disposable patch pump or other more convenient, less painful dosing.
- Dx marker to identify Humira responders.

[141] ABV-HOR-31271.

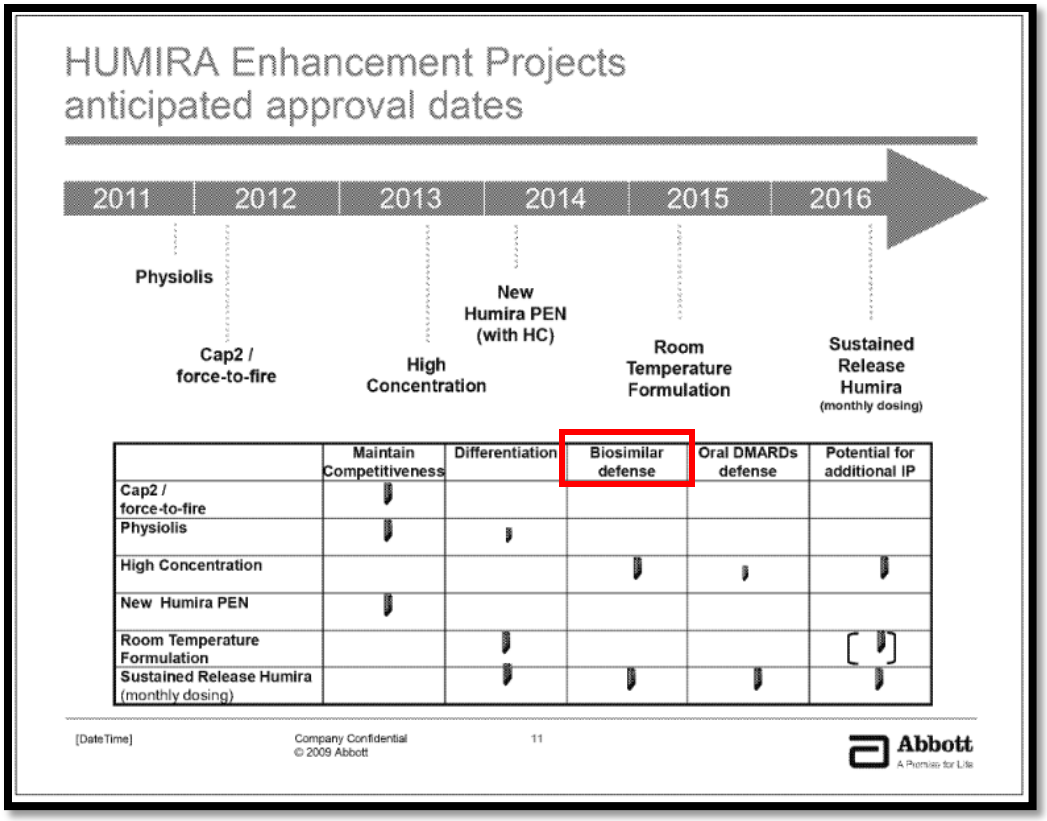
In June 2011, company executives circulated a presentation further emphasizing that one objective of the "enhancement" strategy was to "raise barriers to competitor ability to replicate."[142]



The presentation also explicitly identified "Humira High Concentration" and "Sustained Release" formulations as furthering AbbVie's goal of "Biosimilar defense."[143]

[142] ABV-HOR-34291.

[143] *Id.*



In 2012, AbbVie executives sent Mr. Gonzalez a global strategy document warning that Humira would lose its market share to biosimilars if there were "no enhancements to HUMIRA that result in protective differentiation versus competitors."[144]

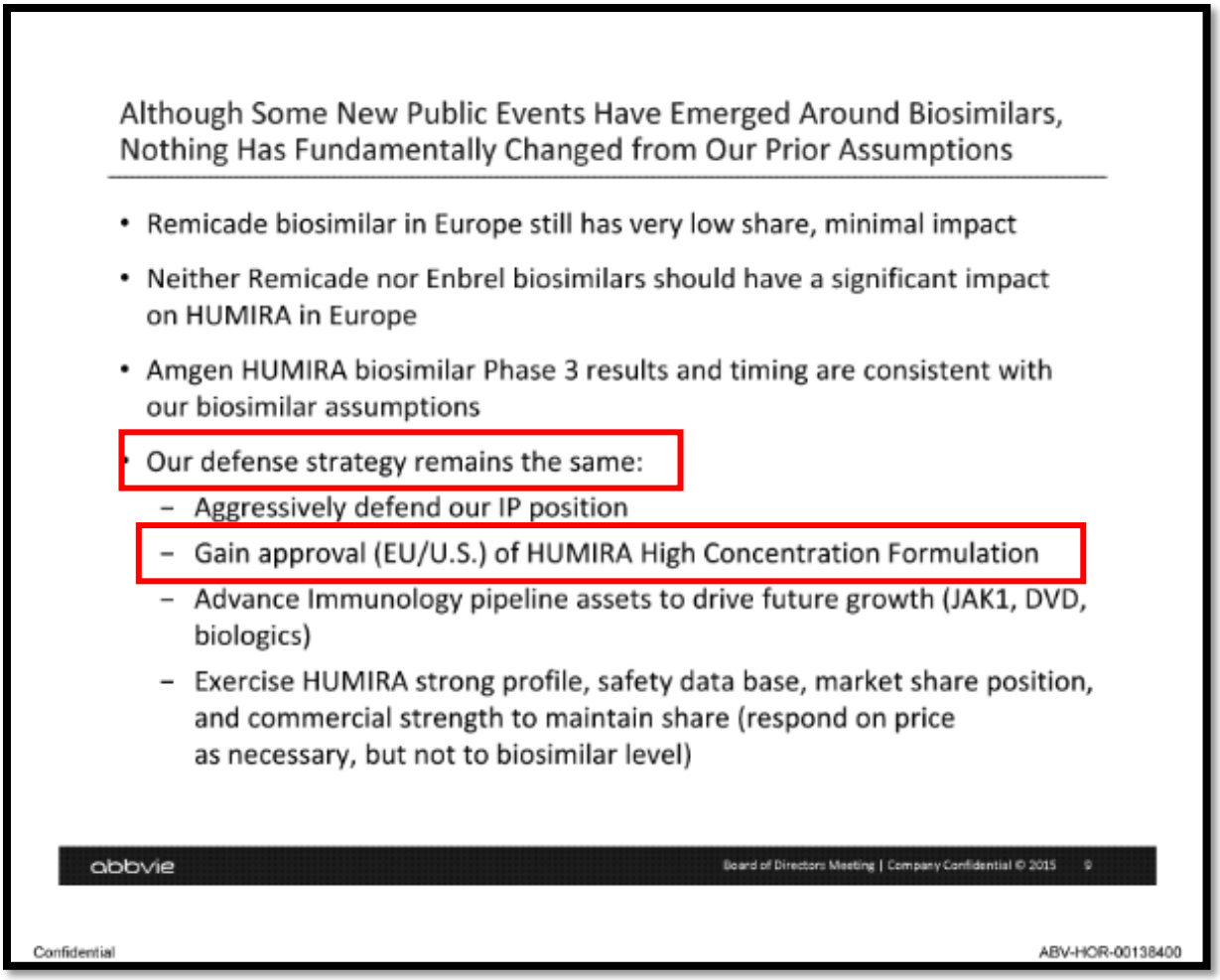
AbbVie's focus on "enhancements" proved successful. In November 2015, AbbVie received FDA approval for a high concentration formulation of Humira.[145] To defend its market share from lower-priced biosimilars that may enter the market, AbbVie shifted patients to the high concentration formulation—an anti-competitive strategy commonly referred to as a "product hop."

Although AbbVie publicly marketed the new formulation to patients as a means of reducing injection site pain, internal discussions characterized the new formulation as a biosimilar defense strategy. In 2015, AbbVie's executives emphasized to AbbVie's board of directors that a key part of its biosimilar "defense strategy" was to "Gain approval (EU/U.S.) of Humira High Concentration Formulation."[146]

[144] ABV-HOR-00034241.

[145] Letter from Director Badrul A. Chowdhury, Center for Drug Evaluation and Research, to Richard J. Perner, Manager, Regulatory Affairs, AbbVie Inc. (Nov. 12, 2015) (online at www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/125057Orig1s394ltr.pdf).

[146] ABV-HOR-00138392.

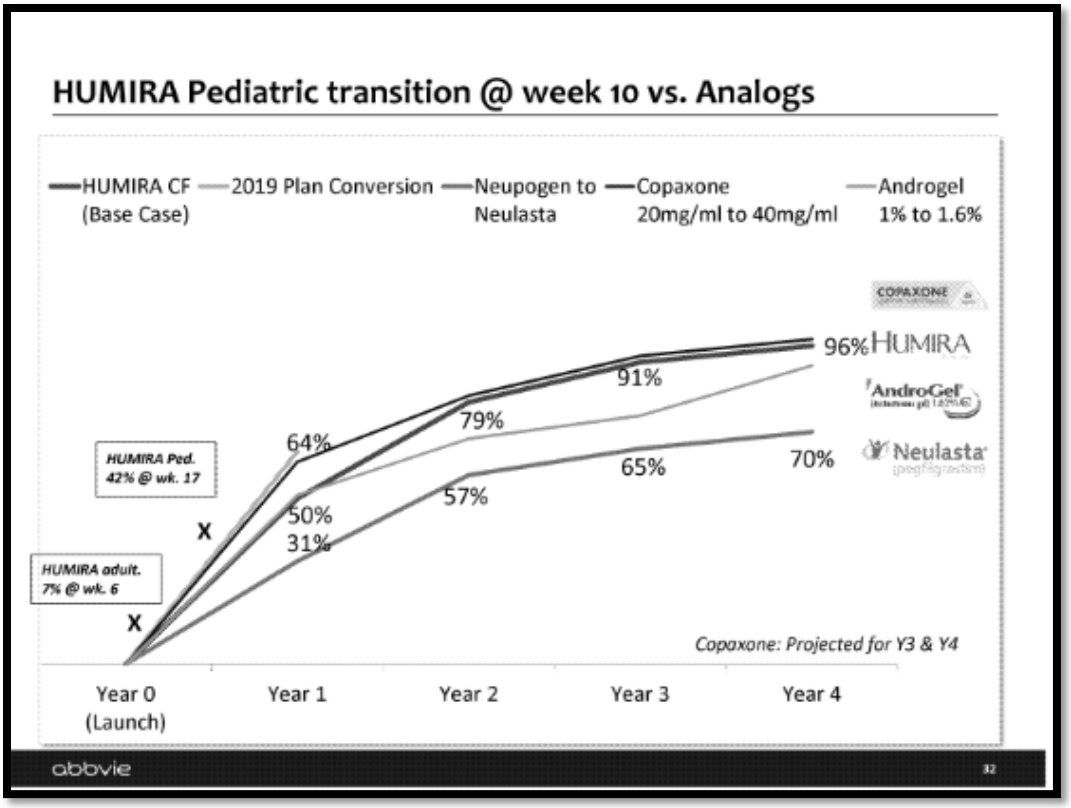


If AbbVie had truly developed the concentration formulation to reduce pain for patients, it would have launched the drug immediately. Instead, AbbVie held the formulation off the market until July 2018, possibly waiting until biosimilar manufacturers had invested significant resources in developing biosimilar versions of the original formulation of Humira.[147]

After launching the high concentration formulation in 2018, executives compared the rate at which patients were transitioning to the new formulation to the rate of such transition for other notorious product hops, including Teva's Copaxone and AbbVie's AndroGel.[148]

[147] Center for Biosimilars, *Adalimumab Biosimilars Face Product Obsolescence Before Launch* (Jan. 6, 2021) (online at www.centerforbiosimilars.com/view/adalimumab-biosimilars-face-product-obsolescence-before-launch).

[148] ABV-HOR-00092105. Although the title of the slide references "Humira Pediatric," it includes progress for both adult and pediatric populations.



Wall Street analysts applauded AbbVie for this strategy, with one external analyst report emphasizing:

> We expect ABBV [AbbVie] to replicate its ex-US strategy by switch [sic] a meaningful portion of its US Humira users to its new formulation prior to biosimilar entry in early 2023E. The switch to a less painful/low [sic] concentration Humira formulation should blunt the impact of biosimilar competition.[149]

Today, market experts are concerned that AbbVie's success in shifting patients to the high concentration formulation of Humira will prevent lower-priced biosimilars from gaining market share. Currently, FDA has only approved biosimilar versions of the low concentration formulation of Humira, creating an additional barrier to biosimilar competition.[150]

Overall, approximately 90% of Humira's patent applications were filed after Humira was first approved and brought to market, and more than 50% were filed after 2013—reflecting that

[149] ABV-HOR-RR-00001539.

[150] Center for Biosimilars, *Adalimumab Biosimilars Face Product Obsolescence Before Launch* (Jan. 6, 2021) (online at www.centerforbiosimilars.com/view/adalimumab-biosimilars-face-product-obsolescence-before-launch).

Humira "enhancements" were intended to protect the drug from biosimilar competition more than a decade after it was brought to market. [151]

B. Research Expenditures Were a Small Fraction of Revenue

AbbVie's total research and development expenditures for Humira represented only a small fraction of its net revenue from this drug. In response to the Committee's request, AbbVie identified a total of $5.19 billion in "Humira Research & Development" between 2009 and 2018—approximately 7.4% of its Humira U.S. net revenue and 4.2% of its Humira worldwide net revenue over that period. Even this research and development spending may be overstated, as AbbVie initially identified only $2.17 billion in Humira-specific research and development costs in response to the Committee's requests—and identified an additional $3.03 billion in spending more than eight months later, just prior to the publication of this report. [152]

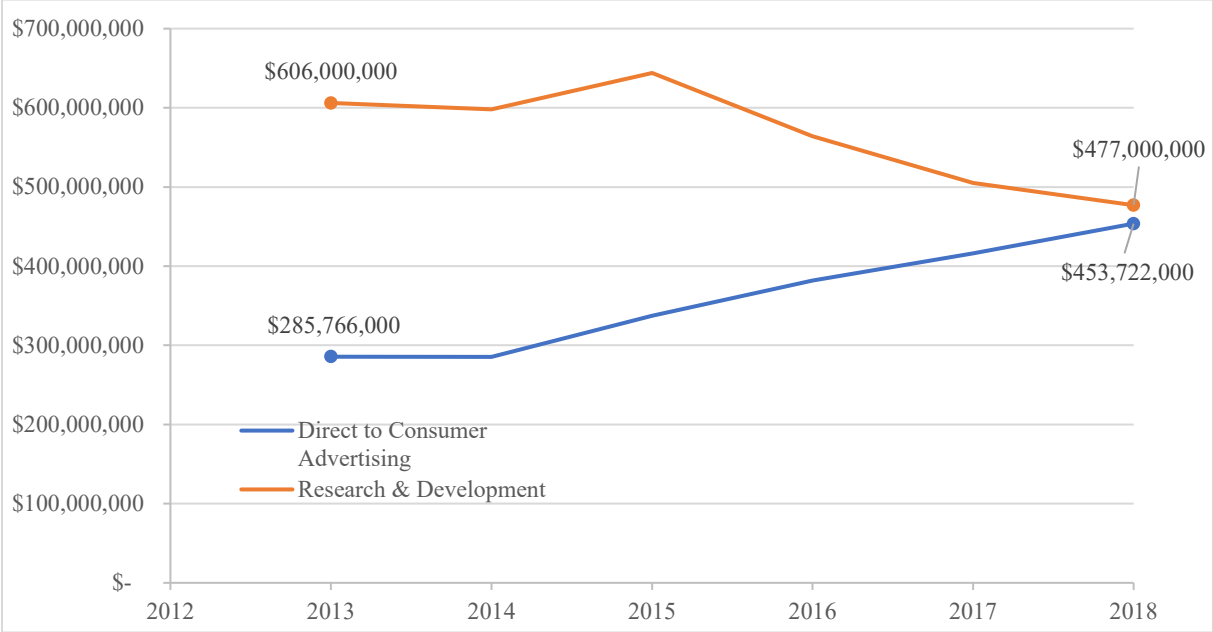
Since spinning off from Abbott in 2013, AbbVie's Humira research and development decreased over time, while its expenditures on direct-to-consumer advertising grew significantly. Figure 15 below shows AbbVie's expenditures on direct-to-consumer advertising compared to Humira-specific research and development. [153]

[151] Initiative for Medicine, Access, and Knowledge, Humira's Patent Wall (Oct. 22, 2020) (online at www.i-mak.org/wp-content/uploads/2020/12/Humira-deck-2020-10-22.pdf); Initiative for Medicine, Access, and Knowledge, *Overpatented, Overpriced: Special Humira Edition* (Oct. 6, 2020) (online at www.i-mak.org/wp-content/uploads/2020/10/i-mak.humira.report.3.final-REVISED-2020-10-06.pdf).

[152] In September 2020, AbbVie represented to the Committee that it identified $2.166 billion in "Humira Research & Development." At that time, AbbVie noted that these figures do not include other Humira research and development costs that it failed to track at the product-specific level. Five days prior to the release of this report, AbbVie apparently identified an additional $3.026 billion in Humira-specific research. Committee staff have serious questions about AbbVie's methodology in allocating research and development expenditures to Humira, and the Committee will continue to scrutinize the veracity of these figures. *See* Letter from Gibson, Dunn and Crutcher LLP, on behalf of AbbVie Inc., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Sept. 11, 2020); Letter from Gibson, Dunn and Crutcher LLP, on behalf of AbbVie Inc., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (May 13, 2021).

[153] Letter from Gibson, Dunn and Crutcher LLP, on behalf of AbbVie Inc., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Feb. 4, 2019); Letter from Gibson, Dunn and Crutcher LLP, on behalf of AbbVie Inc., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (May. 13, 2021).

Figure 15: Humira Direct-to-Consumer Advertising Compared to R&D



AbbVie has also argued that its clinical trial expenditures are made with "low odds of success," and that this risk must be considered when evaluating the price of Humira.[154] However, the Committee's investigation found that AbbVie internally estimated that its expenditures were relatively low-risk and highly valuable, as they were predicted to result in substantial returns *even after adjusting for the risk that the clinical trial would fail*. For example, a July 16, 2010, slide deck on Humira's global development plan and life cycle management strategy detailed AbbVie's expected return on investment for clinical studies evaluating Humira as a treatment for gastroenterological conditions. The projected cost of clinical studies to evaluate Humira as a treatment for mild to moderate Crohn's disease was estimated to be $34.63 million with a 60% probability of success, and the company projected a *risk-adjusted* net present value of the project to be $923 million.[155] Another clinical study to evaluate the optimal use of Humira for treating Crohn's disease was projected to cost approximately $13.8 million with a 90% probability of success, and the project had a risk-adjusted net present value of $750 million.[156]

[154] Letter from Gibson, Dunn and Crutcher LLP, on behalf of AbbVie Inc., to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Feb. 4, 2019).

[155] ABV-HOR-30706. The risk-adjusted net present value of a drug undergoing a clinical trial is a measure of the current value of the trial when factoring in the possibility that the trial could fail and cause the drug to lose its value.

[156] *Id.*

For Imbruvica, AbbVie estimates that the total research and development expenditures from 2013 to 2018 totaled $2.45 billion—approximately 30% of total U.S. net revenue for Imbruvica over the period.[157]

IX. PRICE INCREASES NOT JUSTIFIED BY COSTS

A. Rebates

AbbVie and other pharmaceutical companies often blame price increases on rising discounts and rebates paid to pharmacy benefit managers and other members of the supply chain. The companies claim these rebates cause pharmaceutical companies to capture only a fraction of their price increases.[158]

However, AbbVie's internal data reveals that these discounts do not fully account for AbbVie's price increases for Humira and Imbruvica.

Based on data obtained by the Committee, the net price of Humira, which is the drug's price after accounting for all discounts and rebates, has consistently increased since 2009, meaning that increases in Humira's list price outpaced rebate increases. Humira's net price increased by 110% between 2009 and 2018.[159] Figure 16 below displays the net price of Humira between 2009 and 2018.[160]

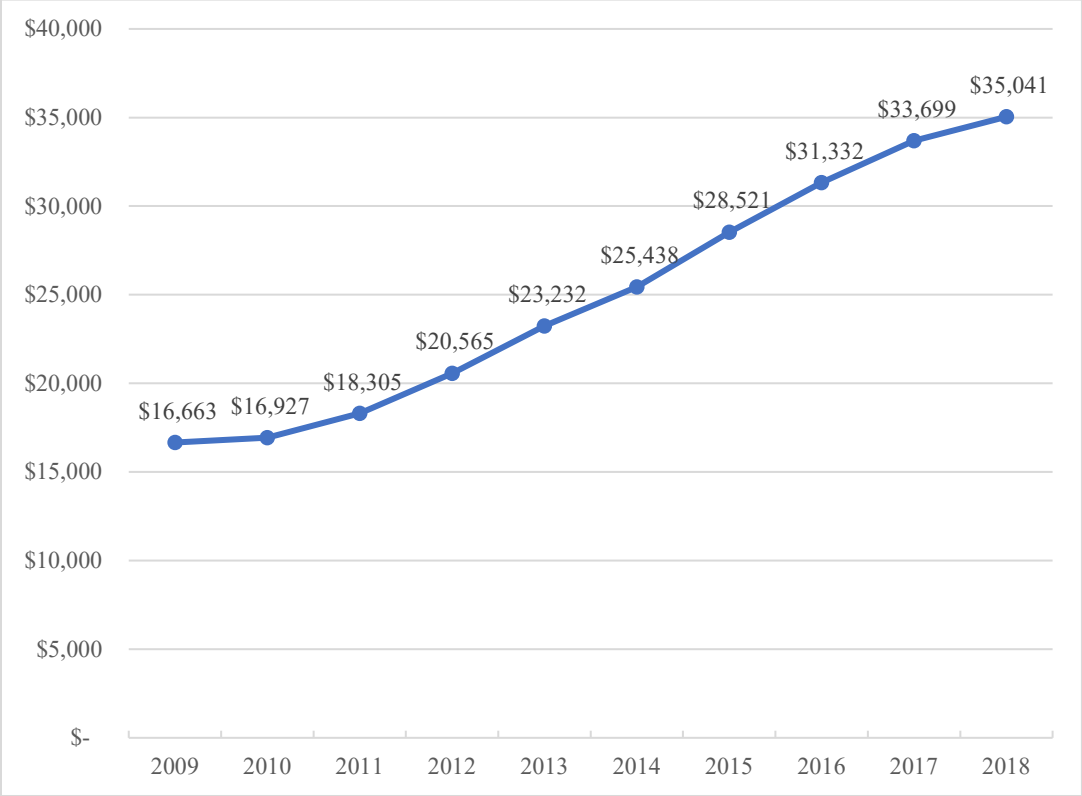
[157] Letter from Gibson, Dunn and Crutcher LLP, on behalf of AbbVie Inc., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Jan. 18, 2021).

[158] ABV-HOR-00032366.

[159] Letter from Gibson, Dunn and Crutcher LLP, on behalf of AbbVie Inc., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Sept. 11, 2020).

[160] *Id.*

Figure 16: Humira Annual Net Price (Bi-Weekly Dose)



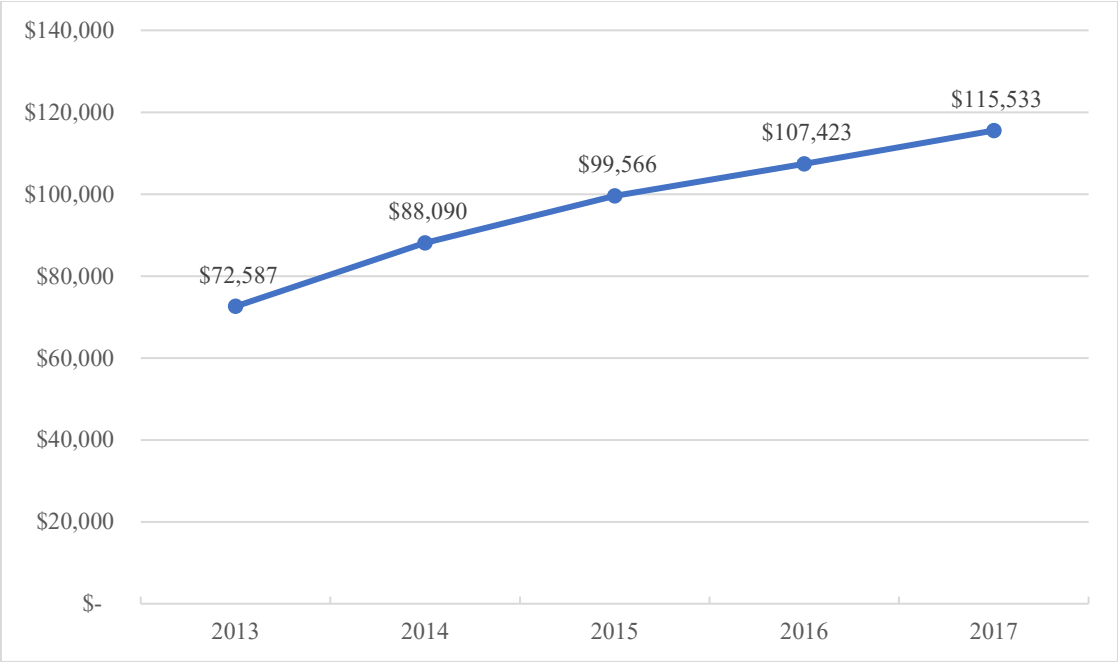
If the Medicaid sales channel—which receives statutorily-mandated rebates—is removed from the analysis, the net price of Humira has increased substantially more. Within the Medicare channel, the net price of Humira increased from $17,184 in 2009 to $43,159 in 2018—an increase of 151%. Similarly, within the commercial channel, the net price of Humira increased from $17,833 in 2009 to $42,418 in 2018—an increase of 137%.[161]

AbbVie's rebates for Imbruvica are smaller than the rebates for Humira. AbbVie reported to the Committee that the estimated rebates and discounts for Imbruvica in the Medicare and Commercial channels from 2013 to 2018 ranged from 4% to 11%. Figure 17 below shows

[161] *Id.*

the annual net price of Imbruvica between 2013 and 2017, during which the net price increased by 59%.[162]

Figure 17: Imbruvica Annual Net Price (420 mg per day dosing)



As with Humira, the impact of rebates for Imbruvica in the Medicare and Commercial channels was even smaller. In the Medicare channel, the estimated annual net cost of Imbruvica increased from $74,449 in 2013 to $125,622 in 2017—an increase of 68%. In the commercial channel, the estimated annual net cost of Imbruvica increased from $78,740 to $128,022—an increase of 62%.

B. Manufacturing

Manufacturing costs for Humira represent a fraction of AbbVie's revenues from selling Humira. From 2009 to 2018, AbbVie collected $121 billion in net worldwide revenue from Humira.[163] The total cost of producing and selling Humira between 2009 and 2018 was $13.9 billion, or 11% of AbbVie's revenues from Humira in the same period.[164]

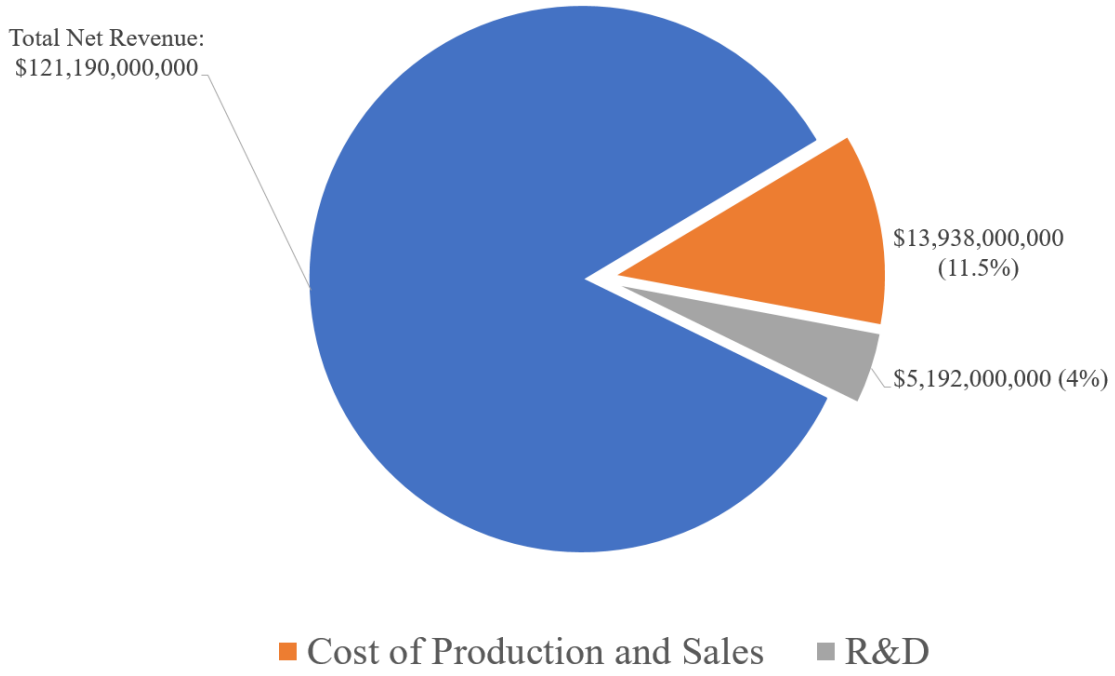
[162] Letter from Gibson, Dunn and Crutcher LLP, on behalf of AbbVie Inc., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Jan. 22, 2021). AbbVie was unable to provide the 2018 figure due to complexities associated with its introduction of a single tablet formulation that year.

[163] AbbVie Inc., *2019 Form 10-K Annual Report* (Feb. 21, 2020) (online at https://investors.abbvie.com/sec-filings/sec-filing/10-k/0001551152-20-000007); AbbVie Inc., *2016 Form 10-K Annual Report* (Feb. 17, 2017) (online at https://investors.abbvie.com/node/10016/html); AbbVie Inc., *2015 Form 10-K Annual Report* (Feb. 19, 2016) (online at https://investors.abbvie.com/node/9521/html).

[164] Letter from Gibson, Dunn and Crutcher LLP, on behalf of AbbVie Inc., to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Sept. 11, 2020). Committee staff were unable to provide a similar

Figure 18 below displays the annual cost of research and development and cost of producing and selling Humira from 2009 to 2018.[165]

Figure 18: Humira Net Worldwide Revenue vs Cost of Sales and R&D 2009-2018



analysis for Imbruvica because of complexities related to cost-sharing and worldwide revenue due to AbbVie's collaboration with Janssen.

[165] *Id.*