



# Drug Pricing Investigation

Celgene and Bristol Myers Squibb—*Revlimid*

Staff Report  
Committee on Oversight and Reform  
U.S. House of Representatives  
September 2020  
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# Congress of the United States

## House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

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September 30, 2020

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

Dear Colleague:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Sincerely,



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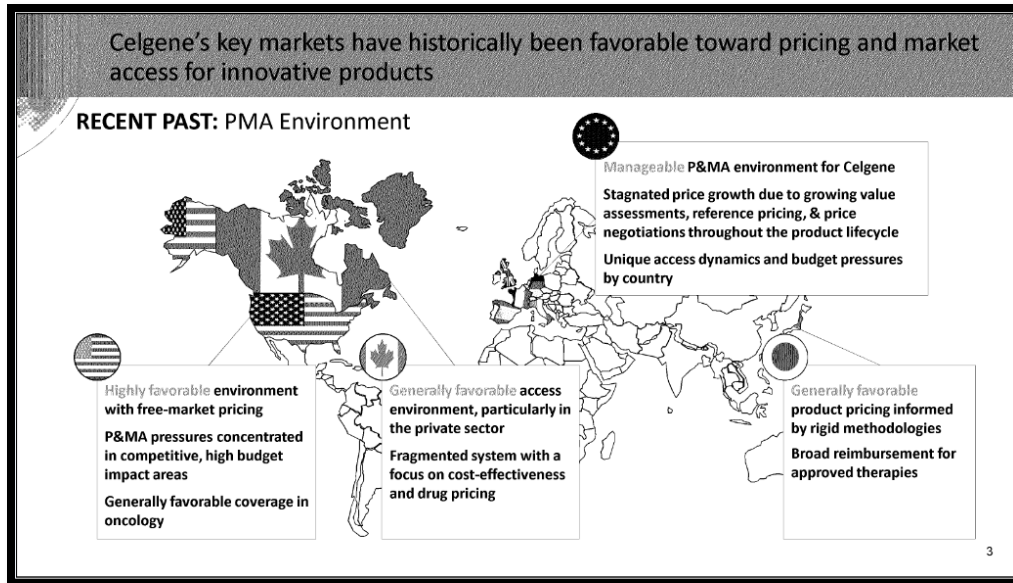
Carolyn B. Maloney  
Chairwoman

## EXECUTIVE SUMMARY

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

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

- **Uninhibited Price Increases:** Since launching Revlimid in 2005, Celgene raised the price of the drug 22 times, from \$215 per pill to \$719 per pill. After Bristol Myers Squibb obtained the rights to Revlimid last November, it raised the price of Revlimid again, to \$763 per pill. Due to these price increases, a monthly course of Revlimid is priced at \$16,023 today—more than triple the 2005 price.
- **Corporate Profits Driven by Price Increases:** Due to Revlimid price increases, from 2009 to 2018, Celgene reported over \$51 billion in net worldwide revenue from Revlimid, with the U.S. market accounting for \$32 billion of that total. Celgene's net U.S. revenue for Revlimid increased from \$1 billion in 2009 to nearly \$6.5 billion in 2018. This rise in Revlimid revenue fueled Celgene's annual profits, which increased from \$780 million in 2009 to \$4 billion in 2018.
- **Pricing Decisions Driven by Revenue and Earnings Goals:** Internal communications show that pricing decisions made by Celgene executives—including former CEO Mark Alles—were driven almost exclusively by the need to meet company revenue targets and shareholder earnings goals. In one instance, Mr. Alles orchestrated an emergency price increase for Revlimid in 2014 to ensure that Celgene met its quarterly revenue targets. To justify the price increase, Mr. Alles wrote, “I have to consider every legitimate opportunity available to us to improve our Q1 performance.”
- **Executive Compensation System Incentivizes Price Increases:** Celgene's price increases for Revlimid led directly to higher bonuses for its executives. In 2016 and 2017, Celgene's top executives earned millions in additional bonuses because of their price increases for Revlimid.
- **Targeting the U.S. for Higher Prices and Lack of Medicare Negotiation:** In internal documents, Celgene highlighted that the U.S. government is prohibited from negotiating directly to lower prices for Medicare beneficiaries. With the federal government unable to negotiate, Celgene targeted the U.S. market for price increases while maintaining or cutting prices for the rest of the world. One presentation described the U.S. as a “highly favorable environment with free-market pricing.”



- Costs to Taxpayers:** The federal government's inability to negotiate for a lower price of Revlimid has placed a significant burden on the U.S. health care system and cost taxpayers billions of dollars. From 2010 to 2018, Celgene collected \$17.5 billion from Medicare Part D. In 2018 alone, Medicare Part D plans and beneficiaries spent more than \$4 billion on Revlimid—the second-highest expenditure of any drug that year.
- Anticompetitive Tactics to Maximize Profits:** Internal presentations show that Celgene suppressed competition by abusing a government-mandated safety program. Celgene emphasized that it could use the program for the “prevention of generic encroachment.” Celgene also excluded competition by leveraging the U.S. patent system, which Celgene described internally as being far more protective of its monopoly pricing than patent systems in the rest of the world. Celgene's anticompetitive tactics are estimated to cost the U.S. health care system more than \$45 billion through 2025.
- Price Increases Not Justified by R&D Expenses:** Celgene relied heavily on taxpayer-funded academic research to develop Revlimid, and its internal pricing decisions appear to have been unrelated to past or future investment in research and development. Internal documents suggest that Celgene may have leveraged the high price of Revlimid to inhibit other companies' cancer research. In discussions about another company, one executive wrote, “Making them spend a lot more on their trials puts financial constraints on their ability to simultaneously fund lots of trials.” Another executive agreed, writing, “Anything we can do to hamper their development would help.”
- Price Increases Not Justified by Rebates:** Celgene's internal data undermine the pharmaceutical industry's claims that price increases are the result of increased rebates, discounts, and other fees provided to pharmacy benefit managers. Celgene paid no negotiated discounts to Medicare Part D plans, and the largest discount it paid in the commercial market was only 5%. Celgene's average net price per unit of Revlimid—the price of the drug after removing such rebates, discounts, and fees—increased each year the drug has been on the market.

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## I. PRICE INCREASES

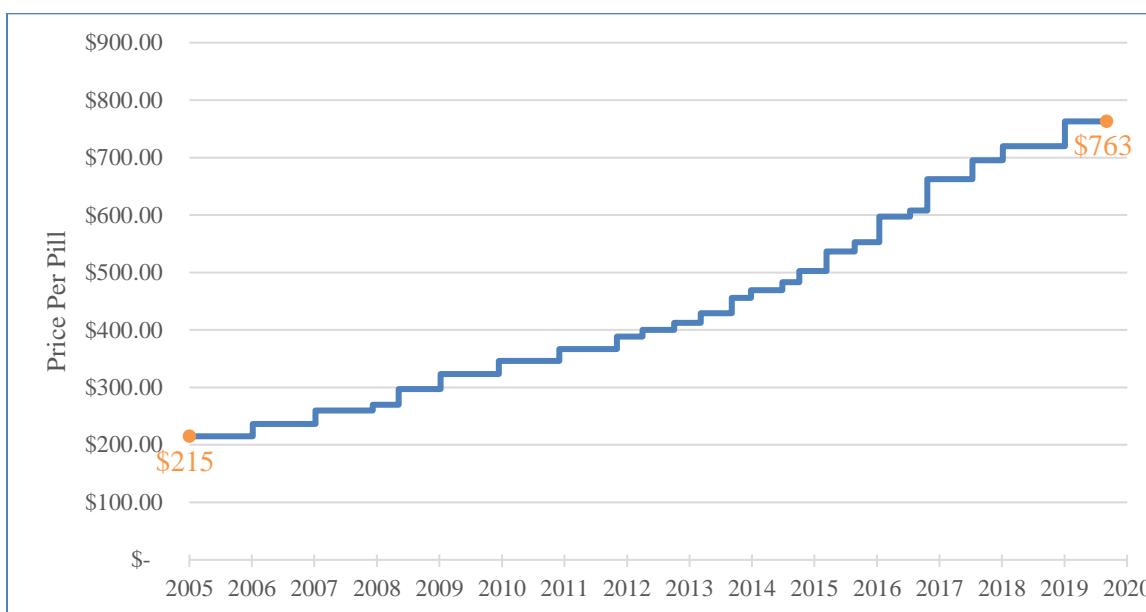
Revlimid is primarily used to treat multiple myeloma, a form of blood cancer diagnosed in approximately 30,000 Americans each year.<sup>1</sup>

After launching Revlimid in 2005, Celgene raised the price of the drug 22 times—as many as three times in a single year. Through those price increases, Celgene more than tripled the price of Revlimid—from \$215 per pill at launch to \$719 per pill in 2019. After acquiring Celgene, Bristol Myers Squibb (BMS) further increased the price of Revlimid to \$763 per pill.<sup>2</sup>

In 2005, a monthly supply of Revlimid was priced at \$4,515. Today, the same monthly supply is priced at \$16,023.

Figure 1 below shows the increase in the price per pill of Revlimid from 2005 to the present.<sup>3</sup>

Figure 1: Revlimid Price Increases



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<sup>1</sup> See Food and Drug Administration, *Approved Label for Revlimid* (Oct. 2019) (online at [www.accessdata.fda.gov/drugsatfda\\_docs/label/2019/021880s060lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021880s060lbl.pdf)). Additional background on the development of Revlimid is provided in Section VI below.

<sup>2</sup> IBM Micromedex Redbook, *Wholesale Acquisition Cost and Average Wholesale Price History for Revlimid*.

<sup>3</sup> *Id.* Revlimid is a pill taken orally that comes in six different dosages, ranging from 2.5 milligrams to 20 milligrams. The price of Revlimid does not vary based on dosage. Although the number of pills taken per month varies from patient to patient, common treatment regimens require patients to take either 21 or 28 pills per month. This calculation reflects the Wholesale Acquisition Cost of a 21-day monthly regimen of Revlimid, assuming a 5 mg pill. Using Average Wholesale Price, the monthly cost of a 21-day regimen of Revlimid has increased from \$5,906 in 2005 to \$19,227.84 today.



In addition to its recent price increase, BMS is likely to continue increasing the price of Revlimid in the future. The companies' public statements and filings with the Securities and Exchange Commission (SEC) make clear that Revlimid, which had nearly \$10 billion in annual revenue, was a key asset in the transaction.<sup>4</sup>

The companies' joint SEC filings for the merger acknowledge that Revlimid revenue was so critical that any expiration of its patent protection sooner than anticipated "would be harmful to the combined company and could have a material adverse effect on its business, financial condition or results of operations."<sup>5</sup>

BMS has a history of significantly raising the prices on other drugs. For example, BMS has steadily increased the price of Sprycel, a drug used to treat a rare form of leukemia that generated \$2 billion in revenue for BMS last year.<sup>6</sup>

## II. RISING CORPORATE PROFITS

### A. Growing Revenue and Profits

Celgene extracted billions of dollars in revenue from Revlimid as it continued to raise the price of the drug year after year. From 2009 to 2018, Celgene reported more than \$51 billion in net worldwide revenue—defined as sales minus rebates and other discounts—from Revlimid, with the U.S. market accounting for \$32 billion of that total.<sup>7</sup> Over the same period, Celgene's

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<sup>4</sup> Bristol-Myers Squibb Company and Celgene Corporation, *2019 Joint Proxy Statement* (Feb. 22, 2019) (online at [www.sec.gov/Archives/edgar/data/816284/000114036119003696/s002620x7\\_defm14a.htm](http://www.sec.gov/Archives/edgar/data/816284/000114036119003696/s002620x7_defm14a.htm)).

<sup>5</sup> *Id.*

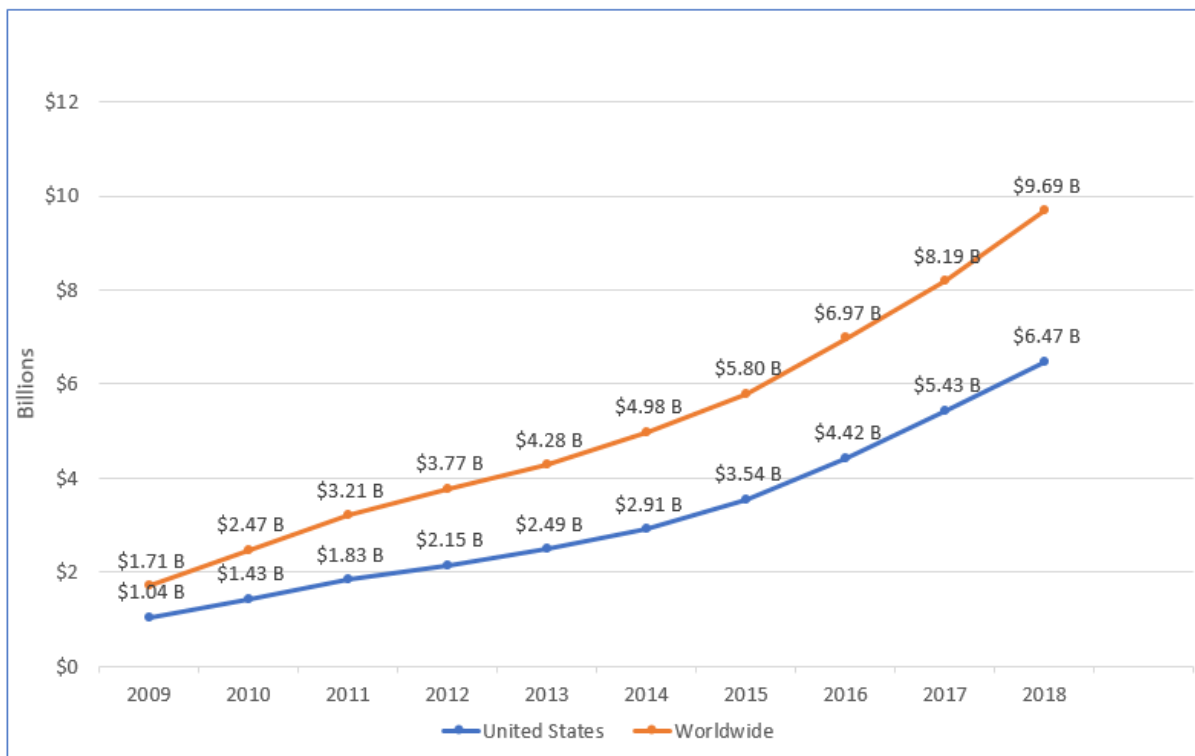
<sup>6</sup> Bristol-Myers Squibb Company, *2018 Form 10-K* (Feb. 25, 2019) (online at [www.sec.gov/Archives/edgar/data/14272/000001427219000047/0000014272-19-000047-index.htm](http://www.sec.gov/Archives/edgar/data/14272/000001427219000047/0000014272-19-000047-index.htm)). Since launching Sprycel in 2006, BMS has raised its price by 356%—from \$58.90 per pill to \$268.32 per pill—including a 6% price increase at the beginning of 2020. IBM Micromedex Redbook, *Wholesale Acquisition Cost and Average Wholesale Price History for Sprycel* (for a 50 mg pill of Sprycel).

<sup>7</sup> Letter from Covington & Burling LLP, on behalf of Celgene Corporation, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Feb. 4, 2019); Letter from Covington & Burling LLP, on behalf of Celgene Corporation, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (May 24, 2019); Celgene Corporation, *2018 Form 10-K* (Feb. 26, 2019) (online at [www.sec.gov/Archives/edgar/data/816284/000081628419000014/a2018123110-k.htm](http://www.sec.gov/Archives/edgar/data/816284/000081628419000014/a2018123110-k.htm)); Celgene Corporation, *2016 Form 10-K* (Feb. 10, 2017) (online at [www.sec.gov/Archives/edgar/data/816284/000081628417000003/a2016123110k.htm](http://www.sec.gov/Archives/edgar/data/816284/000081628417000003/a2016123110k.htm)); Celgene Corporation, *2014 Form 10-K* (Feb. 20, 2015) (online at [www.sec.gov/Archives/edgar/data/816284/000162828015000889/a2014123110k.htm](http://www.sec.gov/Archives/edgar/data/816284/000162828015000889/a2014123110k.htm)); Celgene Corporation, *2012 Form 10-K* (Feb. 15, 2013) (online at [www.sec.gov/Archives/edgar/data/816284/000104746913001186/a2212863z10-k.htm](http://www.sec.gov/Archives/edgar/data/816284/000104746913001186/a2212863z10-k.htm)).

net U.S. revenue for Revlimid also increased each year.<sup>8</sup> Celgene reported more than \$6 billion in net U.S. revenue in 2018 alone.<sup>9</sup>

Figure 2 below reflects Celgene’s net revenue worldwide and in the U.S. for Revlimid over time.

Figure 2: Net Revenue for Revlimid



Revlimid price increases fueled Celgene’s profitability. The company’s net income—defined as the company’s worldwide revenue minus all expenses, including taxes—grew nearly every year after launching the drug.

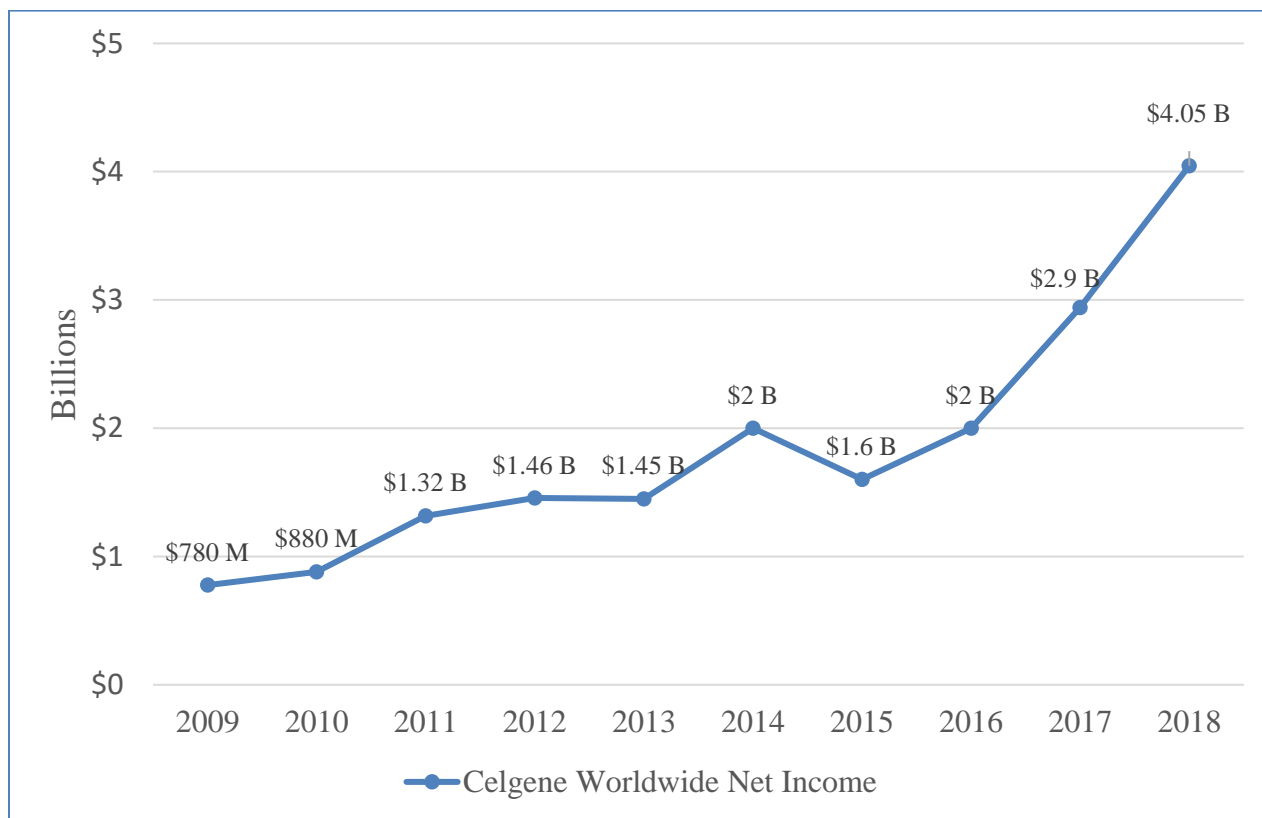
Figure 3 below shows Celgene’s net worldwide income from 2009 to 2018.<sup>10</sup>

<sup>8</sup> *Id.*

<sup>9</sup> Letter from Covington & Burling LLP, on behalf of Celgene Corporation, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Feb. 4, 2019); Letter from Covington & Burling LLP, on behalf of Celgene Corporation, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (May 24, 2019).

<sup>10</sup> Celgene Corporation, *2018 Form 10-K* (Feb. 26, 2019) (online at [www.sec.gov/Archives/edgar/data/816284/000081628419000014/a2018123110-k.htm](http://www.sec.gov/Archives/edgar/data/816284/000081628419000014/a2018123110-k.htm)); Celgene Corporation, *2016 Form 10-K* (Feb. 10, 2017) (online at [www.sec.gov/Archives/edgar/data/816284/000081628417000003/a2016123110k.htm](http://www.sec.gov/Archives/edgar/data/816284/000081628417000003/a2016123110k.htm)); Celgene Corporation, *2014 Form 10-K* (Feb. 20, 2015) (online at [www.sec.gov/Archives/edgar/data/816284/000162828015000889/a2014123110k.htm](http://www.sec.gov/Archives/edgar/data/816284/000162828015000889/a2014123110k.htm)); Celgene Corporation, *2012 Form 10-K* (Feb. 15, 2013) (online at [www.sec.gov/Archives/edgar/data/816284/000104746913001186/a2212863z10-k.htm](http://www.sec.gov/Archives/edgar/data/816284/000104746913001186/a2212863z10-k.htm)).

Figure 3: Net Worldwide Income



Celgene continued raising the price of Revlimid despite reporting record profits. In January 2019, the company raised the price of Revlimid despite doubling its net income over the previous two years.<sup>11</sup>

### **B. Revenue Targets and Earnings Goals Driving Price Increases**

Celgene's former Senior Vice President of Sales and Marketing was asked during a 2015 deposition whether it was Celgene's practice to increase the price of Revlimid on a "regular basis."<sup>12</sup> He responded that Celgene's executives could raise the price of Revlimid "any time they wanted."<sup>13</sup> Celgene's internal documents and communications confirm this statement and reveal a culture in which senior executives raised the price of Revlimid at will, often with the sole purpose of hitting revenue targets and earnings goals.

On March 5, 2014, then-Executive Vice President Mark Alles, who later became Celgene's CEO, wrote to a subordinate concerning Revlimid's lower than expected revenue in

<sup>11</sup> IBM Micromedex Redbook, *Wholesale Acquisition Cost and Average Wholesale Price History for Revlimid*.

<sup>12</sup> Deposition of Francis V. Brown, *Mylan Pharmaceuticals Inc. v. Celgene Corporation*, No. 14-CV-02094 (D. N.J.) (Dec. 2, 2015) (transcript attached as Exhibit P90 to Mylan's Response to Defendant Celgene's Statement of Material Facts).

<sup>13</sup> *Id.*

the first quarter of 2014. Mr. Alles wrote that disappointing sales of Revlimid were “forcing me to reconsider the 2014 pricing plan for REVLIMID in the US” and asked to discuss a price increase of 4% for Revlimid “no later than the end of next week,” as well as a second price increase of 3% “on September 1st rather than October 1st.” Mr. Alles concluded, “I have to consider every legitimate opportunity available to us to improve our Q1 performance.”<sup>14</sup>

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**From:** Mark Alles  
**Sent:** Saturday, March 1, 2014 10:51 AM  
**To:** [REDACTED]  
**Subject:** Q1 REVLIMID

Hi [REDACTED]

As you may have read from my overall Q1 update to the team, our latest Q1'14 global LE for REVLIMID is ~\$1,125M vs. Q4'13 actual RECLAIMED at \$1,136M (-1% Q/Q growth).

I was glad to see that your latest Q1 LE for REVLIMID was increased by \$5M to \$645M, but the current consolidated Q1 REVLIMID and total sales LE is forcing me to reconsider the 2014 pricing plan for REVLIMID in the US. I'd like to ask for you and I to discuss on Monday the pros and cons of taking a 4% price increase for REVLIMID not later than the end of next week and a second price increase of 3% on September 1<sup>st</sup> rather than October 1<sup>st</sup>.

We know that Q2 will be an excellent quarter for our US and global performance, but Q1 looks extremely challenged. I have to consider every legitimate opportunity available to us to improve our Q1 performance. Of course an early March and an early September price increase adds to the full-year not just to Q1.

Thanks [REDACTED] Hope you have a great weekend.


Mark

Four days later, Mr. Alles presented the price increase to Celgene's Corporate Market Access Committee (CMAC), the body responsible for approving Revlimid price increases. The presentation touted a projected increase in net sales of \$24.8 million as a direct result of the proposed price increase.<sup>15</sup>

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<sup>14</sup> CELG\_HCOR\_000049208. Committee staff redacted the name of a more junior executive.

<sup>15</sup> CELG\_HCOR\_000047564, at Slide 5.



2014 US MM Pricing Strategy - Revlimid

- ❖ Implemented semi-annual pricing actions approved by CMAC in 1Q2013
- ❖ Implementing a March 7 price increase of 4.0% instead of the planned 3.0% on April 1 will yield incremental net sales of \$24.8M in 2014

	1Q2014	2Q2014	3Q2014	4Q2014	2014
Incremental Net Sales	\$ 4,236,732	\$ 6,660,194	\$ 6,805,825	\$ 7,085,203	\$ 24,787,954

CMAC, March 5, 2014 Confidential – Do Not Copy – Do Not Circulate


In advance of the CMAC meeting, Mr. Alles emailed his team to ensure that the price increase would go into effect as quickly as possible to have the maximum impact on sales. He wrote, “Assuming CMAC approves the REV[LIMID] price plan today, can we take the increase tonight so that it impacts sales beginning tomorrow?”<sup>16</sup> Celgene implemented Mr. Alles’s recommended 4% price increase that evening.<sup>17</sup>

In March 2016, Celgene executives considered doubling a planned price increase and implementing it earlier than planned—from a 3% increase in April to a 6.8% increase in March—and adding an additional 3% increase in September, one month earlier than planned. An internal strategy document estimated that these price increases alone would yield \$217 million in “incremental net sales” in 2016 and 2017.<sup>18</sup>

<sup>16</sup> CELG\_HCOR\_000049244.

<sup>17</sup> IBM Micromedex Redbook, *Wholesale Acquisition Cost and Average Wholesale Price History for Revlimid*.

<sup>18</sup> CELG\_HCOR\_000042262, at Slide 13.




## Financial Impact

- ❖ A 6.80% price increase on 03/10/16 and 3.00% 09/01/16 yields \$137.4M in incremental net sales in 2016 and \$79.8M in incremental net sales first half 2017 versus Budget
- ❖ 2016 Budget assumes 3% price increase on 4/1/16 and 10/1/16

Total Incremental Net Sales (in \$M)

	2016	1H2017	Total Net Incremental Sales
Revlimid – All Strengths	\$137.4	\$79.8	\$217.2

❖ Based on demand assumption in Budget. March LE demand will change these numbers accordingly.



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Later that month, Celgene implemented the 6.8% price increase as the executives had recommended.<sup>19</sup> Internal emails show that Celgene accelerated the timing of the additional 3% price increase to August 19, 2016, because a technology upgrade would have delayed the planned September price increase for two additional weeks.<sup>20</sup>

Another document explicitly tied Celgene’s pricing strategy to meeting growing revenue targets. An April 25, 2017, presentation describing the company’s long-range projections asked whether the U.S. multiple myeloma business—which is driven primarily by Revlimid sales—could “grow” from \$4.8 billion in 2016 to \$8 billion in 2020. The slide suggested that one strategy to achieve the desired “+60% growth,” was to “realize favorable net price,” meaning to increase the price of Revlimid at a rate faster than any rebates or discounts paid to the supply chain.<sup>21</sup>

<sup>19</sup> IBM Micromedex Redbook, *Wholesale Acquisition Cost and Average Wholesale Price History for Revlimid*.

<sup>20</sup> CELG\_HCOR\_000041349, at Slides 1 and 2.

<sup>21</sup> CELG\_HCOR\_000023827, at Slide 13.



## U.S. Multiple Myeloma LRP Highlights

- Can the U.S. Multiple Myeloma franchise grow from **\$4.8B** in '16 to **\$8B** by '20?
  - In order to achieve **+60%** growth from '16 to '20:
    - Grow and protect Market Share for Rev and Pom in ndMM and rrMM segments
    - Increase Duration of Therapy in ndMM and rrMM segments
    - Ability to realize favorable net price

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Strictly confidential- for internal use only

Consistent with the recommendations in the presentation, Celgene increased the price of Revlimid by 30% between January 2017 and January 2019, including 19.7% in 2017 alone.<sup>22</sup> Leveraging these price increases, Celgene nearly met its \$8 billion revenue goal a full two years ahead of its 2020 target. In 2018, Celgene reported \$7.8 billion in net U.S. revenue for its multiple myeloma products, including \$6.46 billion for Revlimid.<sup>23</sup>

### III. EXECUTIVE BONUSES INCENTIVIZE PRICE INCREASES

Celgene paid its top executives millions of dollars in salaries and bonuses as they repeatedly increased the price of Revlimid—and as revenue and profits soared. Between 2006 and 2017, Celgene paid its top executives over \$400 million in compensation.<sup>24</sup>

Performance bonuses were a significant portion of Celgene's senior executive compensation. For example, in 2016, then-Chairman of the Board, Bob Hugin, received a bonus of more than \$6 million. This bonus supplemented Mr. Hugin's base salary of \$1.5 million and stock and option awards worth nearly \$8.5 million. The same year, then-Chief Executive Officer

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<sup>22</sup> IBM Micromedex Redbook, *Wholesale Acquisition Cost and Average Wholesale Price History for Revlimid*.

<sup>23</sup> Celgene Corporation, *2018 Form 10-K* (Feb. 26, 2019) (online at [www.sec.gov/Archives/edgar/data/816284/000081628419000014/a2018123110-k.htm](http://www.sec.gov/Archives/edgar/data/816284/000081628419000014/a2018123110-k.htm)); Letter from Covington & Burling LLP, on behalf of Celgene Corporation, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Feb. 4, 2019).

<sup>24</sup> Committee Staff calculated this figure using the Summary Compensation tables from Celgene's annual SEC filings between 2006 and 2017. See Celgene Corporation, *Proxy Statements (2006-2017)* (online at [www.sec.gov/cgi-bin/browse-edgar?CIK=816284](http://www.sec.gov/cgi-bin/browse-edgar?CIK=816284)).

(CEO) Mark Alles received a bonus worth \$3.6 million in addition to a base salary of \$1 million and stock and option awards worth \$7.4 million.<sup>25</sup>

Figure 4 below shows compensation awarded to senior Celgene executives in 2016 and 2017.<sup>26</sup>

Figure 4: Executive Compensation

<b>Celgene Senior Executive Compensation</b>					
	<b>2016</b>				
	<b>Base Salary</b>	<b>Stock &amp; Option Awards</b>	<b>Performance Bonuses</b>	<b>All Other Compensation</b>	<b>Total</b>
<b>Robert Hugin, Chairman</b>	\$ 1,500,000	\$ 8,484,785	\$ 6,294,053	\$ 247,399	\$ 16,526,237
<b>Mark Alles, CEO</b>	\$ 1,062,583	\$ 7,421,846	\$ 3,689,654	\$ 18,334	\$ 12,192,417
<b>Peter Kellogg, EVP, CFO</b>	\$ 845,667	\$ 4,554,018	\$ 2,707,912	\$ 29,677	\$ 8,137,274
<b>Jacquelyn Fouse, Strategic Advisor</b>	\$ 941,633	\$ 4,745,875	\$ 3,222,523	\$ 109,784	\$ 9,019,815
<b>Scott Smith, President, COO</b>	\$ 691,667	\$ 4,455,762	\$ 1,296,827	\$ 19,541	\$ 6,463,797
<b>Rupert Vessey, President, R&amp;ED</b>	\$ 673,141	\$ 3,159,174	\$ 1,063,826	\$ 23,850	\$ 4,919,991
<b>Total Executives</b>					\$ 57,259,531
	<b>2017</b>				
	<b>Base Salary</b>	<b>Stock &amp; Option Awards</b>	<b>Performance Bonuses</b>	<b>All Other Compensation</b>	<b>Total</b>
<b>Robert Hugin, Chairman</b>	\$ 1,500,000	\$ 8,034,415	\$ 2,175,000	\$ 245,322	\$ 11,954,737
<b>Mark Alles, CEO</b>	\$ 1,266,667	\$ 9,687,923	\$ 2,144,623	\$ 16,772	\$ 13,115,985
<b>Peter Kellogg, EVP, CFO</b>	\$ 871,250	\$ 4,735,720	\$ 800,352	\$ 28,196	\$ 6,435,518
<b>Scott Smith, President, COO</b>	\$ 833,000	\$ 4,966,932	\$ 845,495	\$ 16,772	\$ 6,662,199
<b>Rupert Vessey, President, R&amp;ED</b>	\$ 691,917	\$ 4,092,179	\$ 957,442	\$ 25,359	\$ 5,766,897
<b>Total Executives</b>					\$ 43,935,336

Documents and information obtained by the Committee suggest that Celgene's senior executives received larger bonuses for raising the price of Revlimid and other drugs.

Celgene awarded bonuses to its senior executives through two incentive plans, the Management Incentive Plan (MIP) and the Long-Term Incentive Plan (LTIP). The Committee obtained internal documents showing that more than half of the bonus formula allotted through each of these plans was based on achieving yearly revenue and earnings targets.<sup>27</sup> Celgene increased these targets by billions of dollars each year.<sup>28</sup> Because U.S. sales of Revlimid accounted for the largest share of Celgene's revenue and earnings, any increase in the U.S. price

<sup>25</sup> Celgene Corporation, *2018 Proxy Statement* (Apr. 30, 2018) (online at <https://d18rn0p25nwr6d.cloudfront.net/CIK-0000816284/555bd837-c802-436a-bccb-226e240ad28a.pdf>).

<sup>26</sup> *Id.*; Celgene Corporation, *2017 Proxy Statement* (Apr. 27, 2017) (online at [www.sec.gov/Archives/edgar/data/0000816284/000157104917004031/t1701249-proxy.htm](http://www.sec.gov/Archives/edgar/data/0000816284/000157104917004031/t1701249-proxy.htm)). Ms. Fouse was not a named executive officer for the year 2017 and retired from the company on June 30, 2017.

<sup>27</sup> See Celgene Corporation, *2016 Management Incentive Plan and Long-Term Incentive Plan*, CELG\_HCOR\_000045803, at slides 6 and 21; Celgene Corporation, *2017 Management Incentive Plan and Long-Term Incentive Plan*, CELG\_HCOR\_000045876, at Slides 18 and 29.

<sup>28</sup> *Id.*



of Revlimid was an important factor in determining whether company executives met their bonus targets that year.<sup>29</sup>

Analysis of internal company data shows that, in several different years, Celgene’s executives would not have met their bonus targets if not for their decision to increase the U.S. price for Revlimid. The 2017 MIP set a bonus revenue target of \$13-13.4 billion and the 2017 LTIP set a bonus revenue target of \$12.8 billion.<sup>30</sup> Celgene barely achieved these targets, reporting \$13 billion in net revenue in 2017, \$5.4 billion of which came from U.S. sales of Revlimid.<sup>31</sup> Without three price increases on Revlimid that year, the Committee estimates that Celgene’s revenue would have been nearly \$600 million lower and executives likely would not have achieved the revenue targets needed to receive their full bonuses.<sup>32</sup>

Figure 5 below shows the Committee’s estimates of Celgene’s additional net revenue attributable to its price increases in 2016 and 2017.

**Figure 5: Net Revenue Attributable to Price Increases**

	Price	Days at Price	Average Price for Year	Effective Price Increase for Year	Additional Net Revenue Attributable to Price Increase for Year
<b>2016</b>	\$ 502.69	68			<b>\$296,747,311.87</b>
	\$ 536.87	163			
	\$ 552.98	135			
			\$ 536.46	6.72%	
<b>2017</b>	\$ 552.98	9			<b>\$581,311,831.98</b>
	\$ 597.22	181			
	\$ 607.67	101			
	\$ 662.36	74			
			\$ 612.23	10.71%	

Based on Celgene’s internal compensation committee minutes and other documents, Celgene’s U.S. price increases on Revlimid in 2016 and 2017 appear to have accounted for more than \$2 million in additional bonuses for Celgene’s senior executives in those years.

<sup>29</sup> Celgene Corporation, 2018 Form 10-K (Feb. 26, 2019) (online at [www.sec.gov/Archives/edgar/data/816284/000081628419000014/a2018123110-k.htm](http://www.sec.gov/Archives/edgar/data/816284/000081628419000014/a2018123110-k.htm)) (reporting that U.S. revenue for Revlimid were 42% of Celgene’s total revenue in 2018, 41% in 2017, and 39% in 2016).

<sup>30</sup> CELG\_HCOR\_000045876, at Slides 18 and 29.

<sup>31</sup> Celgene Corporation, 2018 Form 10-K (Feb. 26, 2019) (online at [www.sec.gov/Archives/edgar/data/816284/000081628419000014/a2018123110-k.htm](http://www.sec.gov/Archives/edgar/data/816284/000081628419000014/a2018123110-k.htm)) (reporting 2017 net revenue and 2017 net U.S. Revlimid revenue figures).

<sup>32</sup> IBM Micromedex Redbook, *Wholesale Acquisition Cost and Average Wholesale Price History for Revlimid*. See Footnote 33, *infra*, for methodology in arriving at this estimate.

Figure 6 below provides the estimated amount of bonus compensation senior Celgene executives received in 2016 and 2017 attributable to price increases on Revlimid during those years.<sup>33</sup>

Figure 6: Compensation Attributable to U.S. Price Increases

Compensation Attributable to Revlimid U.S. Price Increases						
	2016			2017		
	MIP	LTIP	Total	MIP	LTIP	Total
<b>Robert Hugin, Executive Chairman</b>	\$ 187,500.03	\$ 202,180.75	\$ 389,680.79	\$ 337,500.00	\$ 287,097.24	\$ 624,597.24
<b>Mark Alles, CEO</b>	\$ 12,619.08	\$ 102,451.96	\$ 115,071.04	\$ 332,786.33	\$ 60,548.73	\$ 393,335.05
<b>Peter Kellogg, EVP, CFO</b>	\$ 62,731.54	\$ 104,132.66	\$ 166,864.20	\$ 124,192.55	\$ 60,548.73	\$ 184,741.28
<b>Jacquelyn Fouse, Strategic Advisor</b>	\$ 83,202.73	\$ 115,748.66	\$ 198,951.39	-	-	-
<b>Scott Smith, President, COO</b>	\$ 54,766.15	\$ 24,817.12	\$ 79,583.27	\$ 131,197.50	\$ 60,548.73	\$ 191,746.23
<b>Rupert Vessey, President, R&amp;ED</b>	\$ 46,864.09	\$ 18,605.78	\$ 65,469.87	\$ 97,622.84		\$ 97,622.84
<b>Total Executives</b>			\$ 1,015,620.55			\$1,492,042.64

BMS's acquisition of Celgene was also profitable for Celgene's senior executives. Weeks before BMS entered into its merger agreement with Celgene, Celgene instituted a new executive compensation plan that provided lucrative severance payments should the senior executives leave or be dismissed as a result of any transaction.<sup>34</sup> Under the new plan, then-CEO Mark Alles became eligible for three times his annual salary and cash incentives, plus other benefits, if he was terminated within two years of the acquisition or resigned for good reason.<sup>35</sup> Celgene's other top managers, David Elkins, Rupert Vessey, and Peter Kellogg, also became eligible for 2.5 times their annual salaries and cash incentives, plus other benefits, under the same conditions. Under the new Executive Severance Plan, Mr. Alles was awarded at least \$28 million when he left the company.<sup>36</sup>

<sup>33</sup> To arrive at these estimates, Committee staff used the following methodology: First, for 2016 and 2017, staff calculated a weighted average for the U.S. price of Revlimid that accounted for the timing of Celgene's multiple price increases within a calendar year (the "Weighted Average Price"). Next, staff compared the Weighted Average Price to the U.S. price of Revlimid at the end of the prior year, arriving at an effective price increase percentage for each year (the "Effective Price Increase Percentage"). Using the Effective Price Increase Percentage and Celgene's reported U.S. Revlimid revenue data, staff estimated Celgene's total global revenue if it had not increased the U.S. price of Revlimid in 2016 and 2017 (the "Revised Revenue Figure"). Finally, staff used the compensation committee documentation and formulas produced by Celgene to calculate the executives' bonus using the Revised Revenue Figures. The decline in compensation is estimated in the figure.

In using this methodology, the Committee assumed that U.S. demand for Revlimid was not affected by changes to the U.S. price of Revlimid, an assumption supported by deposition testimony from Celgene's former Senior Vice President of Sales and Marketing, Francis Brown. Deposition of Francis V. Brown, *Mylan Pharmaceuticals Inc. v. Celgene Corporation*, No. 14-CV-02094 (D. N.J.) (Dec. 2, 2015) (testifying that demand for Revlimid did not increase or decrease as a result of a price change) (transcript attached as Exhibit P90 to Mylan's Response to Defendant Celgene's Statement of Material Facts).

Committee staff note that these figures are likely a conservative estimate of the extent to which U.S. price increases augmented executive bonuses. The price increases also likely increased Celgene's earnings per share and other metrics included in the MIP and LTIP formulas, further increasing executive bonuses.

<sup>34</sup> *Big Companies Pay CEOs for Good Performance—and Bad*, Wall Street Journal (May 17, 2019) (online at [www.wsj.com/articles/big-companies-pay-ceos-for-good-performanceand-bad-11558085402](http://www.wsj.com/articles/big-companies-pay-ceos-for-good-performanceand-bad-11558085402)).

<sup>35</sup> Celgene Corporation, *2018 Form 8-K* (Jan. 2, 2019) (online at <http://d18rn0p25nwr6d.cloudfront.net/CIK-0000816284/8db6c359-675e-4239-aa76-57a43e1657ce.pdf#page192>).

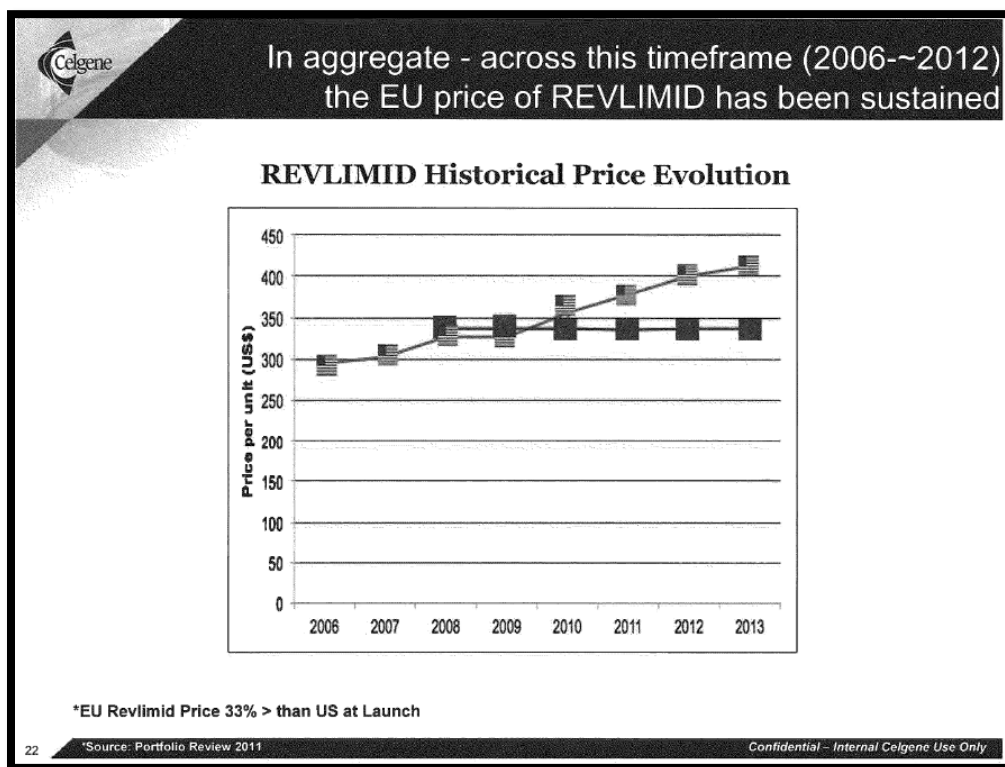
<sup>36</sup> *Id.*

#### IV. HIGHER U.S. PRICES AND LACK OF MEDICARE NEGOTIATION

Under current law, the federal government is prohibited from negotiating directly with pharmaceutical companies to lower prices for Medicare beneficiaries.<sup>37</sup> With the federal government unable to negotiate, Celgene targeted the U.S. market for price increases while maintaining or even cutting prices in the rest of the world.

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

A board presentation prepared in June 2013 illustrated how Celgene increased the price of Revlimid in the United States from 2008 to 2012 while holding the price of Revlimid steady in the European Union—even though, as the presentation notes, the launch price of Revlimid in the E.U. was 33% higher than it was in the U.S.<sup>38</sup>

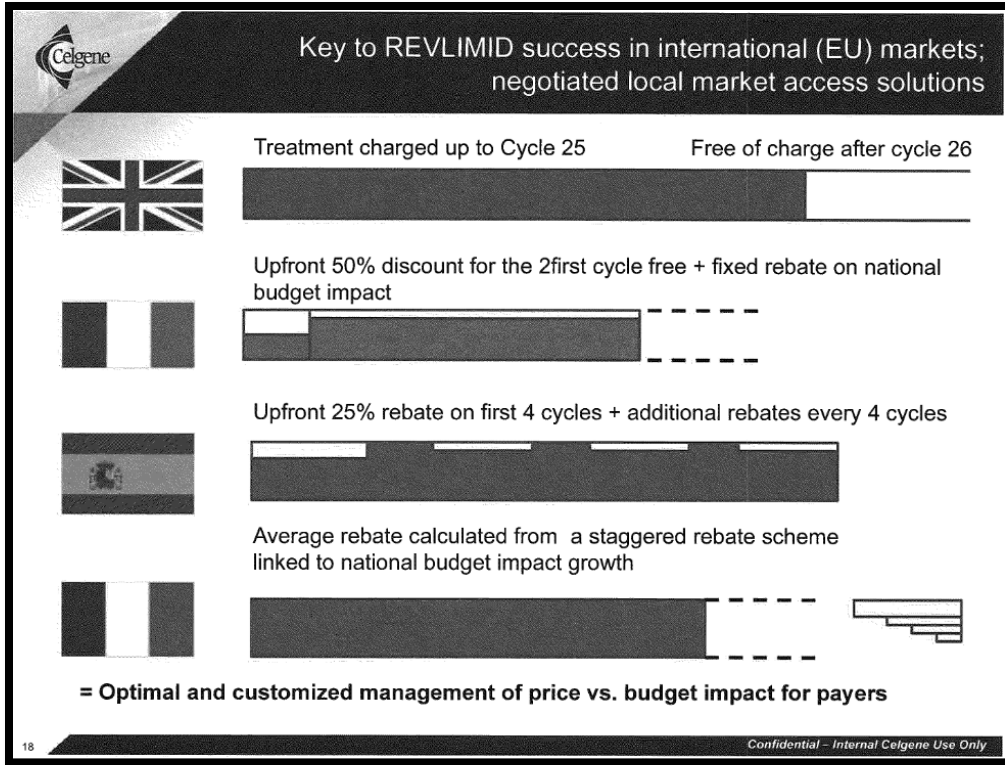


The same presentation highlighted a variety of other discounts and other pricing concessions, called “local market access solutions,” that Celgene entered with the United Kingdom and other European countries that kept the price of Revlimid lower in those countries.<sup>39</sup>

<sup>37</sup> 42 U.S.C. § 1395w-111.

<sup>38</sup> CELG\_HCOR\_000042295, at Slide 22.

<sup>39</sup> CELG\_HCOR\_000042295, at Slide 18.



The presentation forecasted that Celgene would be able to maintain a high price for Revlimid in the United States through 2025—a full 20 years after bringing the drug to market—even while drastically lowering the price for Revlimid in the European Union. The presentation noted that Celgene would continue to implement “modest price increases” that were “independent of volume,” through 2018, and projected that the price of Revlimid in the United States would eventually stabilize at approximately \$470 per pill beginning in 2019. However, Revlimid is still priced at more than \$763 per pill today.<sup>40</sup>

<sup>40</sup> CELG\_HCOR\_000042295, at Slide 23; IBM Micromedex Redbook, *Wholesale Acquisition Cost and Average Wholesale Price History for Revlimid*.



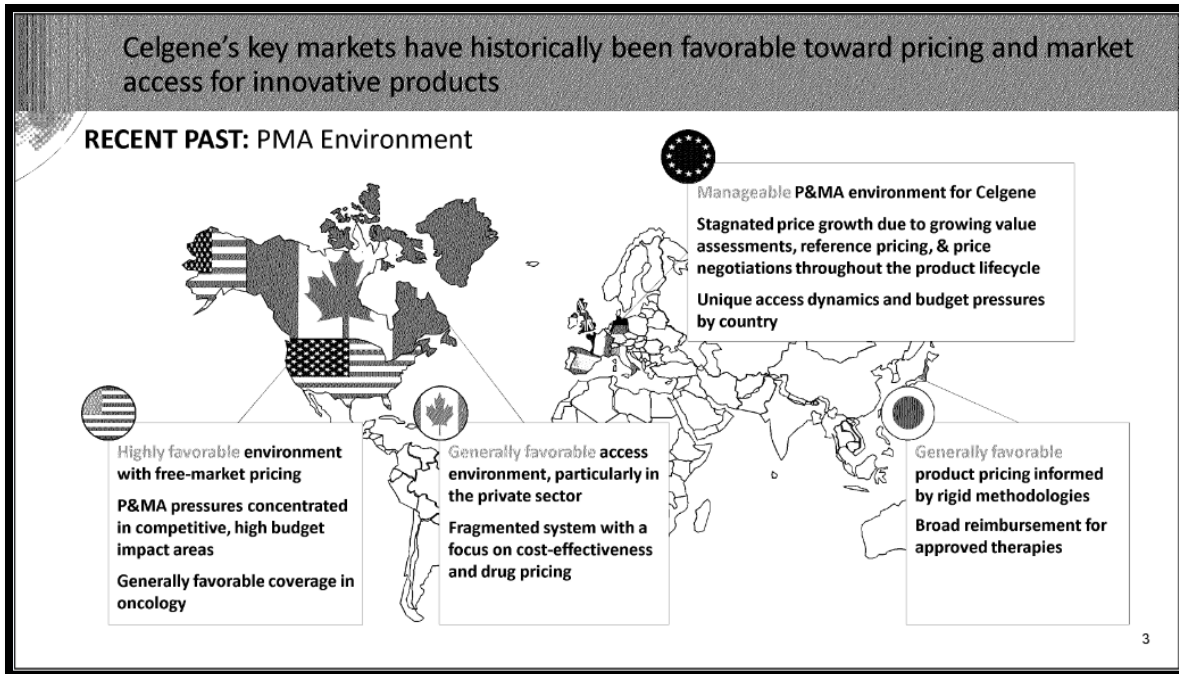
## Current long-range REVLIMID price evolution forecast



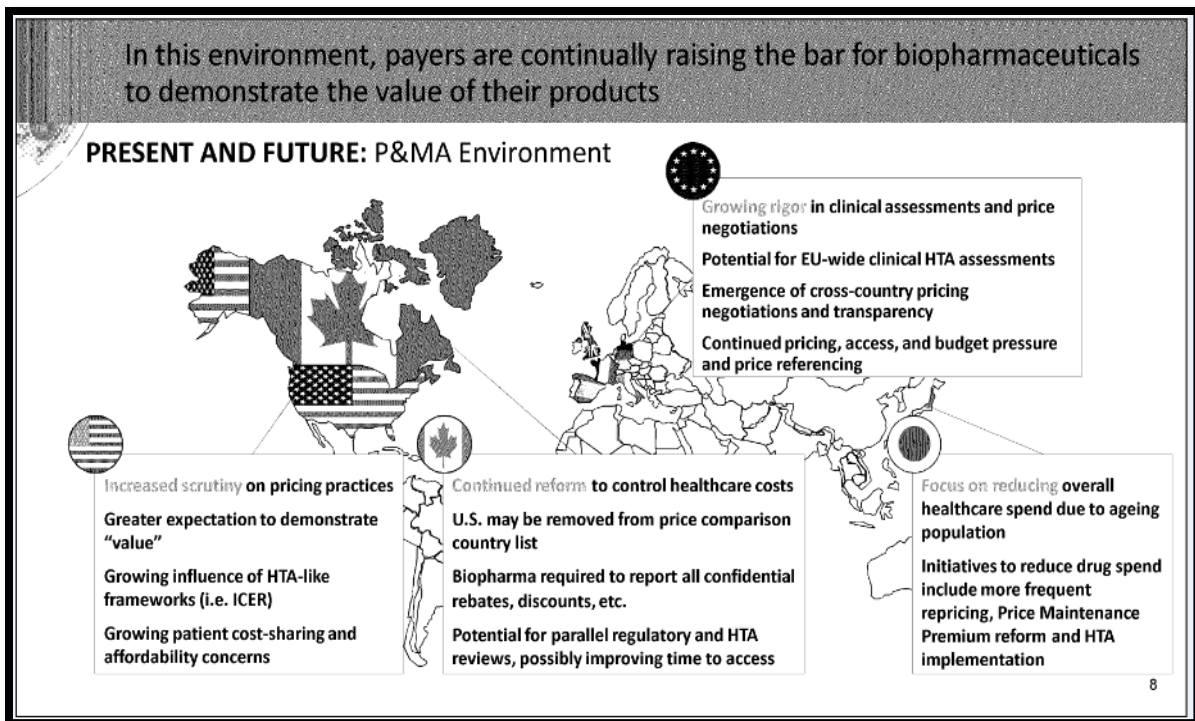
US modest price increases each year through 2018 independent of volume  
EU price decline driven by volume growth from multiple label expansions

Internal documents show that Celgene continued to view the U.S. market in particular as an opportunity to maximize profits on Revlimid. An October 2018 presentation prepared for CMAC described the United States as a “[h]ighly favorable environment with free-market pricing,” as compared to the rest of the world.<sup>41</sup>

<sup>41</sup> CELG\_HCOR\_000027347, at Slide 3.

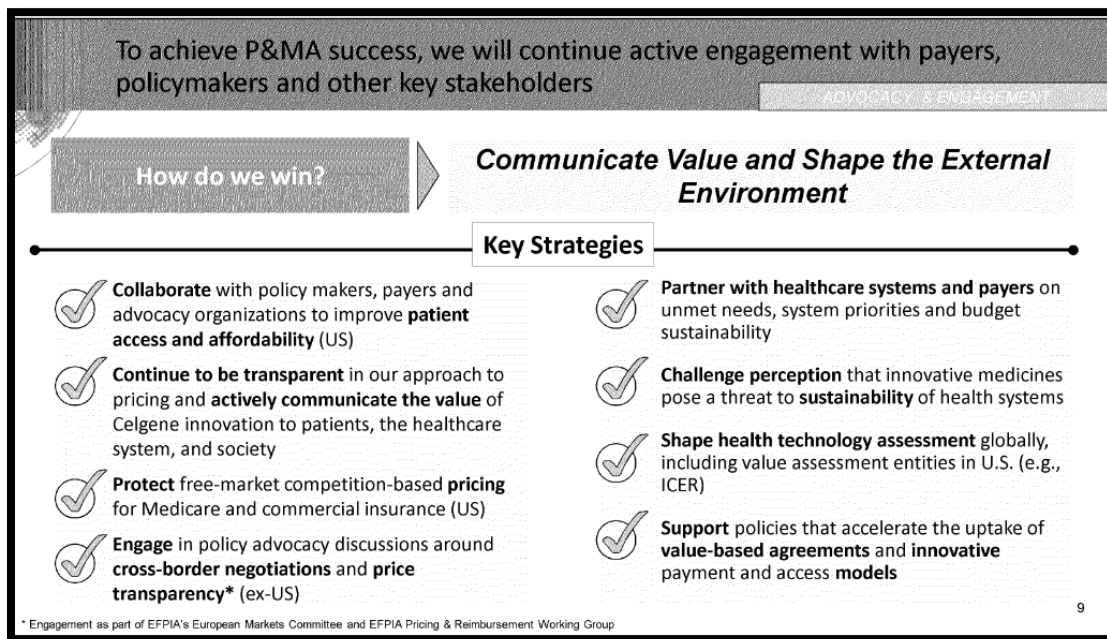


However, the presentation reflected a concern that future U.S. market dynamics may be less favorable to high prices given “increased scrutiny on pricing practices” and “greater expectation to demonstrate ‘value’” of pharmaceutical products.<sup>42</sup>



<sup>42</sup> CELG\_HCOR\_000027347, at Slide 8.

The presentation concluded that one key strategy for Celgene to “win” was to “[p]rotect free-market competition-based pricing for Medicare and commercial insurance” in the United States.<sup>43</sup>



## B. Costs to Taxpayers and Patients

Celgene’s price increases for Revlimid placed a significant burden on Medicare. From 2010 to 2018, Celgene collected \$17.5 billion from Medicare Part D. In 2018 alone, Medicare Part D plans and beneficiaries spent more than \$4 billion on Revlimid—the second-highest expenditure of any drug. The average spending per beneficiary exceeded \$100,000. According to the Centers for Medicare and Medicaid Services (CMS), Medicare Part D spending per dose of Revlimid increased by 11.5% per year between 2014 and 2018.<sup>44</sup>

Celgene’s price increases on Revlimid have imposed thousands of dollars in out-of-pocket costs on U.S. patients and have left many unable to afford Revlimid. A recent Kaiser Family Foundation study found that the median annual out-of-pocket cost for a Medicare patient

<sup>43</sup> CELG\_HCOR\_000027347, at Slide 9. Medicare Part D rules also forbid individual plans from excluding cancer drugs from their formularies, which limits the negotiating power of individual plans. *See* 42 U.S.C. § 1395w-104; 42 C.F.R. § 423.120.

<sup>44</sup> 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](http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD)). Although the Medicare Part D Spending Dashboard does not reflect manufacturer rebates and price concessions, Celgene informed the Committee that it “does not provide contracted price reductions for Medicaid, VA programs, or Medicare Part D.” Letter from Covington & Burling LLP, on behalf of Celgene Corporation, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Feb. 22, 2019).

on Revlimid was \$14,461 in 2019—nearly \$3,000 more than in 2016 and the second highest among *all* specialty drugs.<sup>45</sup>

Internal documents show that senior executives were aware that Celgene’s price increases were placing increasing financial burdens on patients. Celgene regularly received complaints from patients about the high cost of Revlimid and requests for assistance in affording its drug. For example:

- One Medicare Part D patient faced a \$5,000 co-pay due to the high price of Revlimid. The patient told Celgene’s patient support specialist that the company should be “ashamed” of its prices and that she had attempted to join a research study to gain access to her medication. When Celgene’s patient support specialist asked what the patient would do if she could not afford her medication, the patient said she would likely discontinue the medication.<sup>46</sup>
- Another patient emailed Celgene to express frustration with the price of the drug. The patient wrote that Revlimid has “been on the market for a few years now & you would think you must have received enough to pay for your research expense.”<sup>47</sup>
- Another patient who had been receiving support from Celgene’s co-pay assistance program but was no longer eligible once enrolled in Medicare, wrote: “I am not sure how your program determines that since I now pay more for monthly insurance, I am not eligible for co-pay assistance. I am disappointed that for medication that costs in excess of \$15,000 a month I no longer receive any assistance for my co-pays.”<sup>48</sup>

## V. ANTICOMPETITIVE TACTICS TO MAXIMIZE PROFITS

Celgene uses a series of anticompetitive tactics to suppress generic competition and maintain its high price for Revlimid. The Food and Drug Administration (FDA) estimates that the price of a prescription drug drops by nearly 40% when a single generic competitor enters the market, 54% when two generic competitors enter the market, and more than 95% when six or

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<sup>45</sup> Kaiser Family Foundation, *The Out-of-Pocket Cost Burden for Specialty Drugs in Medicare Part D in 2019* (Feb. 2019) (online at <http://files.kff.org/attachment/Issue-Brief-the-Out-of-Pocket-Cost-Burden-for-Specialty-Drugs-in-Medicare-Part-D-in-2019>). In 2019, Medicare defined a “specialty drug” as one that costs more than \$670 per month. See Centers for Medicare and Medicaid Services, *Announcement for Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter* (Apr. 2, 2018) (online at [www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf](http://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf)).

<sup>46</sup> CELG\_HCOR\_000006166.

<sup>47</sup> CELG\_HCOR\_000006145.

<sup>48</sup> CELG\_HCOR\_000006210.



more competitors enter the market.<sup>49</sup> Although Revlimid came to market in 2005, it currently has no generic competition.

#### **A. Abusing Government Safety Program to Delay Competition**

FDA requires drug manufacturers of certain high-risk drugs to implement a Risk Evaluation and Mitigation Strategy (REMS) “to help ensure the benefits of the medication outweigh its risks.”<sup>50</sup> Federal law prohibits manufacturers from using their REMS program to “block or delay approval” of generic manufacturers’ applications to FDA.<sup>51</sup>

In 2010, FDA required Celgene to implement a REMS safety program for Revlimid due to its risk of causing birth defects.<sup>52</sup> When FDA approved Celgene’s proposed program, the agency warned Celgene that it is illegal for the company to use its REMS program to “block or delay approval” of generic versions of the drug.<sup>53</sup>

Despite this warning, Celgene used its REMS program—which severely limits the distribution of Revlimid—to prevent generic manufacturers from purchasing the samples of Revlimid needed to obtain FDA approval of their own generic versions of the drug. An internal Celgene presentation examining whether to implement a REMS program for Thalomid, as Celgene had for Revlimid, stated that one benefit of such a program was the “prevention of generic encroachment.”<sup>54</sup>

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<sup>49</sup> Food and Drug Administration, *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices* (Dec. 2019) (online at [www.fda.gov/media/133509/download](http://www.fda.gov/media/133509/download)).


<sup>50</sup> Food and Drug Administration, *Risk Evaluation and Mitigation Strategies* (Aug. 8, 2019) (online at [www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems](http://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems)).

<sup>51</sup> 21 U.S.C. § 355-1(f)(8).

<sup>52</sup> Letter from Robert Justice, Director, Office of Drug Oncology Products, Food and Drug Administration, to Michael B. Faletto, Director of Regulatory Affairs, Celgene Corporation (Aug. 3, 2010) (online at [www.accessdata.fda.gov/drugsatfda\\_docs/applletter/2010/021880s013ltr.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/applletter/2010/021880s013ltr.pdf)).

<sup>53</sup> *Id.*

<sup>54</sup> Exhibit 68(b) to Mylan’s Response to Defendant Celgene’s Statement of Material Facts, *Mylan Pharmaceuticals Inc. v. Celgene Corporation*, No. 14-CV-02094 (D. N.J.) (Mar. 20, 2018) (discussing the benefits of modeling Thalomid’s Risk Evaluation and Mitigation Strategy program after Revlimid’s Risk Evaluation and Mitigation Strategy program).



## Key Discussion Points

- **Risk/Compliance**
  - **Risk of SAE is very great; but likelihood of SAE is very small. The human and financial cost of fetal exposure can be very high.**
  - **Compliance: significant deviation rate with retail distribution.**
- **Prevention of generic encroachment**
  - **Key assumption is that generic would be held to same standards as Thalomid, including all points in a RiskMAP.**
  - **It would be a hurdle for generic companies if specialty pharmacy is included in RiskMAP and PI and there is a requirement for counseling by specialty pharmacy**
  - **It is more difficult for generic companies to access Thalomid to conduct bioequivalence testing through specialty pharmacy**

According to FDA, Celgene used its REMS program to prevent or delay 14 generic manufacturers from purchasing sufficient samples of Revlimid to obtain FDA approval.<sup>55</sup> When Mylan Pharmaceuticals sought to purchase samples of Revlimid from Celgene in 2013, Celgene cited its REMS program and safety concerns as a reason to delay selling Mylan the samples.<sup>56</sup>

In 2014, FDA sent Celgene a letter certifying Mylan’s safety protocols and stating that it “expects Celgene to provide Mylan with sufficient quantity of REVLIMID to conduct necessary testing.”<sup>57</sup> Celgene continued to refuse, ultimately forcing Mylan to sue Celgene for access to

<sup>55</sup> Food and Drug Administration, *Reference Listed Drug (RLD) Access Inquiries* (Feb. 7, 2019) (online at <https://web.archive.org/web/20190914092445/www.fda.gov/drugs/abbreviated-new-drug-application-anda/reference-listed-drug-rlid-access-inquiries>). After passage of the CREATES Act, the Food and Drug Administration’s website removed its list of products for which generic manufacturers had trouble accessing samples. See Food and Drug Administration, *Access to Product Samples: The CREATES Act* (Mar. 13, 2020) (online at [www.fda.gov/drugs/guidance-compliance-regulatory-information/access-product-samples-creates-act](http://www.fda.gov/drugs/guidance-compliance-regulatory-information/access-product-samples-creates-act)).

<sup>56</sup> See Letter from Carmen Shepard, Senior Vice President, Mylan Pharmaceuticals, to Robert J. Hugin, Chairman and Chief Executive Officer, Celgene Corporation (May 1, 2013) (Exhibit 88 to Celgene’s Statement of Material Facts, *Mylan Pharmaceuticals Inc. v. Celgene Corporation*, No. 14-CV-02094 (D. N.J.) (Mar. 20, 2018)); Letter from Maria E. Pasquale, Senior Vice President and Deputy General Counsel, Celgene Corporation, to Carmen Shepard, Senior Vice President, Mylan Pharmaceuticals (May 14, 2013) (stating that Celgene would sell to Mylan only if it agreed to provide nine categories of information about its safety program) (Exhibit 90 to Celgene’s Statement of Material Facts, *Mylan Pharmaceuticals Inc. v. Celgene Corporation*, No. 14-CV-02094 (D. N.J.) (Mar. 20, 2018)).

<sup>57</sup> Letter from Kathleen Uhl, Acting Director, Office of Generic Drugs, Food and Drug Administration, and Carol Bennett, Acting Director, Office of Compliance, Food and Drug Administration, to Maricel Fong, Senior Director of Regulatory Affairs, Celgene Corporation (May 19, 2014) (Exhibit 93 to Celgene’s Statement of Material Facts, *Mylan Pharmaceuticals Inc. v. Celgene Corporation*, No. 14-CV-02094 (D. N.J.) (Mar. 20, 2018)).

the samples.<sup>58</sup> Mylan’s economic expert in the case estimated that Celgene’s denial of samples had the potential to cost consumers as much as \$637 million due to the absence of lower competitive prices for Revlimid.<sup>59</sup> The parties settled the case in July 2019, with Celgene paying Mylan \$62 million.<sup>60</sup>

Celgene has also stifled generic competition by filing for ten separate patents on its Revlimid REMS program and enforcing those patents against potential generic competitors.<sup>61</sup> One patent claimed the supposed invention of “delivering to a patient in need of the drug, while avoiding the occurrence of an adverse side effect known or suspected of being caused by the drug.”<sup>62</sup> Another patent claimed the purported invention of “delivering a drug to a patient in need of the drug, while restricting access to the drug for patients for whom the drug may be contraindicated.”<sup>63</sup>

In recent years, the Supreme Court has rejected “business method patents” like Celgene’s patents covering implementation of its REMS program for Revlimid.<sup>64</sup> Two of Celgene’s REMS patents recently were invalidated by the Court of Appeals for the Federal Circuit.<sup>65</sup> Nevertheless, Celgene’s Revlimid REMS patents—even if they were later invalidated—were successful in creating additional barriers for potential generic entrants.<sup>66</sup>

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<sup>58</sup> See *Mylan Pharmaceuticals Inc. v. Celgene Corporation*, No. 14-CV-02094 (D. N.J.).

<sup>59</sup> See Expert Report of Philip B. Nelson (June 8, 2016) (Exhibit P33 to Mylan’s Response to Celgene’s Statement of Material Facts, *Mylan Pharmaceuticals Inc. v. Celgene Corporation*, No. 14-CV-02094 (D. N.J.) (Mar. 20, 2018)).

<sup>60</sup> *Celgene to Pay Mylan \$62 Million to Resolve Cancer Drug Antitrust Case*, Reuters (July 30, 2019) (online at [www.reuters.com/article/health-mylan/celgene-to-pay-mylan-62-million-to-resolve-cancer-drug-antitrust-case-idUSL2N24V1IQ](http://www.reuters.com/article/health-mylan/celgene-to-pay-mylan-62-million-to-resolve-cancer-drug-antitrust-case-idUSL2N24V1IQ)).

<sup>61</sup> See CELG\_HCOR\_000000003, at Slide 2 (listing 10 patents “Directed to Methods of Using or Distributing the Compound Pursuant to a Restricted Distribution Program”).

<sup>62</sup> U.S. Patent No. 6,315,720 (filed Oct. 23, 2000); see also Robin Feldman and Evan Frondorf, *Drug Wars: How Big Pharma Raises Prices and Keeps Generics Off the Market* (2017) (documenting Celgene’s REMS patent abuses).

<sup>63</sup> U.S. Patent No. 6,561,977 (filed Sept. 27, 2001); see also Robin Feldman and Evan Frondorf, *Drug Wars: How Big Pharma Raises Prices and Keeps Generics Off the Market* (2017) (documenting Celgene’s REMS patent abuses).

<sup>64</sup> Robin Feldman and Evan Frondorf, *Drug Wars: How Big Pharma Raises Prices and Keeps Generics Off the Market* (2017) (describing the Supreme Court’s line of cases ending with *Alice Corp. Pty. Ltd. v. CLS Bank Int’l*, 573 U.S. 208 (2014)).

<sup>65</sup> See *Celgene Corp. v. Peter*, 931 F.3d 1342 (Fed. Cir. 2019).

<sup>66</sup> Celgene’s abuse of its REMS patents for Revlimid’s precursor drug, thalidomide, is illustrative of how such patents suppress competition. In 2007, the generic manufacturer Barr Laboratories attempted to market a generic version of thalidomide. Celgene sued Barr for infringing on its REMS patents. See *Celgene Corp. v. Barr Laboratories*, 07-CV-00286 (D. N.J.) (Jan. 18, 2007). To prevent Barr from developing its own REMS program that did not infringe Celgene’s patents, Celgene petitioned FDA to deny any generic thalidomide applicant on the basis that two separate REMS programs would be too confusing for patients. Celgene Corporation, *Petition to the FDA* (Sept. 20, 2007) (online at [www.regulations.gov/#!documentDetail;D=FDA-2007-P-0113-0002](http://www.regulations.gov/#!documentDetail;D=FDA-2007-P-0113-0002)); see also Ameet Sarpatwari, Jerry Avorn, and Aaron Kesselheim, *Using a Drug-Safety Tool to Prevent Competition*, *New England Journal of Medicine* (Apr. 17, 2014) (online at [www.nejm.org/doi/full/10.1056/NEJMp1400488](http://www.nejm.org/doi/full/10.1056/NEJMp1400488)) (describing Celgene’s REMS patent abuses). By the time FDA rejected Celgene’s petition in 2014, Barr

Documents obtained by the Committee show that internally, Celgene viewed its REMS program as an anticompetitive business strategy rather than a patient safety program. For example, a 2016 presentation identifying corporate goals stated that one way to “shape the operating environment to support [Celgene’s] business goals” was to “prevent legislative erosion of [its] REMS program.”<sup>67</sup>

In the three years after the 2016 presentation, Celgene—along with the pharmaceutical industry trade association PhRMA—lobbied vigorously against legislative reform that would curb the company’s ability to use REMS programs to suppress competition.<sup>68</sup>

In December 2019, Congress acted to address drug companies’ anti-competitive use of REMS. The Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act, which was enacted through appropriations legislation, establishes a private cause of action to allow a generic company to sue a brand name manufacturer to gain access to samples necessary for testing.<sup>69</sup> The CREATES Act also authorizes FDA to permit a generic company to implement its own REMS program. Prior to this legislative change, brand-name manufacturers like Celgene used the FDA’s preference for shared REMS programs between brand-name and generic competitors to block generic manufacturers from obtaining FDA approval.<sup>70</sup>

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Laboratories had already withdrawn its FDA application. *See* Letter from Janet Woodcock, Director, Center for Drug Evaluation and Research, Food and Drug Administration, to Gary L. Vernon, Sidley Austin LLP (Sept. 30, 2014) (online at [www.regulations.gov/document?D=FDA-2007-P-0113-0028](http://www.regulations.gov/document?D=FDA-2007-P-0113-0028)); *see also* Robin Feldman and Evan Frondorf, *Drug Wars: How Big Pharma Raises Prices and Keeps Generics Off the Market* (2017) (documenting Celgene’s REMS patent abuses and citing Celgene’s press release announcing Barr’s withdrawal). To date, there is no generic version of thalidomide on the U.S. market. Food and Drug Administration, *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* (showing no generic approvals for thalidomide).

<sup>67</sup> CELG\_HCOR\_000042225, at Slide 22.

<sup>68</sup> Congress first introduced the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act in 2016. S.3056, 114th Cong. (2016). Celgene and the Pharmaceutical Research & Manufacturers of America (PhRMA) lobbied against this bill each year until it was eventually incorporated into and passed through appropriations legislation in 2019. Center for Responsive Politics, *Bills Lobbied By Celgene Corp., 2016* (online at [www.opensecrets.org/federal-lobbying/clients/bills?cycle=2016&id=D000032432](http://www.opensecrets.org/federal-lobbying/clients/bills?cycle=2016&id=D000032432)); Center for Responsive Politics, *Bills Lobbied By Pharmaceutical Research & Manufacturers of America, 2016* (online at [www.opensecrets.org/federal-lobbying/clients/bills?cycle=2016&id=D000000504](http://www.opensecrets.org/federal-lobbying/clients/bills?cycle=2016&id=D000000504)); Center for Responsive Politics, *Bills Lobbied by Celgene Corp., 2017* (online at [www.opensecrets.org/federal-lobbying/clients/bills?cycle=2017&id=D000032432](http://www.opensecrets.org/federal-lobbying/clients/bills?cycle=2017&id=D000032432)); Center for Responsive Politics, *Bills Lobbied by Celgene Corp., 2018* (online at [www.opensecrets.org/federal-lobbying/clients/bills?cycle=2018&id=D000032432](http://www.opensecrets.org/federal-lobbying/clients/bills?cycle=2018&id=D000032432)); Center for Responsive Politics, *Bills Lobbied by Bristol-Myers Squibb, 2019* (online at [www.opensecrets.org/federal-lobbying/clients/bills?cycle=2019&id=D000000149](http://www.opensecrets.org/federal-lobbying/clients/bills?cycle=2019&id=D000000149)).

<sup>69</sup> Further Consolidated Appropriations Act, 2020, Pub. L. No. 116-94, § 610 (2019); Congressman David Cicilline, *Press Release: Cicilline Bill to Lower Prescription Drug Costs to Become Law Today* (Dec. 20, 2019) (online at <https://cicilline.house.gov/press-release/cicilline-bill-lower-prescription-drug-costs-become-law-today>).

<sup>70</sup> The legislation allows the generic manufacturer to choose a single, shared REMS program or a separate Risk Evaluation and Mitigation Strategy program that uses different methods or operational means, unless the Food and Drug Administration determines that “no different, comparable aspect of the elements to assure safe use can be used.” The measure does not, however, obviate the need for generic manufacturers to commence costly litigation, nor does it eliminate the possibility of manufacturers abusing Risk Evaluation and Mitigation Strategy patents to exclude competition. Further Consolidated Appropriations Act, 2020, Pub. L. No. 116-94 (2019).

The CREATES Act was enacted more than six years after Mylan first sought to purchase samples of Revlimid from Celgene.<sup>71</sup> In the intervening period, Celgene was able to use its REMS program to exclude generic competition while raising the price of Revlimid by 80%.<sup>72</sup>

## **B. Leveraging U.S. Patent System to Exclude Competition**

Celgene filed for its first patent covering the active ingredient in Revlimid in 1996. This patent expired in October 2019.<sup>73</sup> Typically, generic companies would have entered the market at that time, lowering prices for consumers. But Celgene leveraged the U.S. patent system to obtain or apply for at least 52 additional patents on Revlimid.<sup>74</sup>

Experts at the Initiative for Medicine, Access, and Knowledge estimate that these secondary patents will extend Celgene's monopoly by at least five years and will directly increase U.S. health care costs by \$45 billion.<sup>75</sup>

Generic manufacturers, patient groups, and experts have questioned the appropriateness of Celgene's secondary patents. For example, Celgene obtained or applied for 11 patents covering different chemical structures of Revlimid's active ingredient. If enforceable, these patents would exclude competition until 2027.<sup>76</sup> Critics have argued that some of Celgene's patents cover alternative forms of the same drug and should not meet the "novel" and "non-obvious" requirements for a U.S. patent.<sup>77</sup> Although the U.S. Patent and Trademark Office has

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<sup>71</sup> See Letter from Carmen Shepard, Senior Vice President, Mylan Pharmaceuticals, to Robert J. Hugin, Chairman and Chief Executive Officer, Celgene Corporation (May 1, 2013) (Exhibit 88 to Celgene's Statement of Material Facts, *Mylan Pharmaceuticals Inc. v. Celgene Corporation*, No. 14-CV-02094 (D. N.J.) (Mar. 20, 2018)).

<sup>72</sup> IBM Micromedex Redbook, *Wholesale Acquisition Cost and Average Wholesale Price History for Revlimid*.

<sup>73</sup> U.S. Patent No. 5,635,517 (filed July 24, 1996).

<sup>74</sup> Letter from Covington & Burling LLP, on behalf of Celgene Corporation, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Feb. 4, 2019); CELG\_HCOR\_000000003 (listing Celgene's patents related to Revlimid).

<sup>75</sup> Initiative for Medicine, Access, and Knowledge, *America's Overspend: How the Pharmaceutical Patent Problem is Fueling High Drug Prices* (Oct. 2017) (online at [www.i-mak.org/wp-content/uploads/2017/11/Excess-Costs-Briefing-Paper-FINAL\\_-2017-10-24.pdf](http://www.i-mak.org/wp-content/uploads/2017/11/Excess-Costs-Briefing-Paper-FINAL_-2017-10-24.pdf)).

<sup>76</sup> Letter from Covington & Burling LLP, on behalf of Celgene Corporation, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Feb. 4, 2019); CELG\_HCOR\_000000003, at Slides 1 and 2 (listing Celgene's patents related to Revlimid); Food and Drug Administration, *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* (online at [www.accessdata.fda.gov/scripts/cder/ob/index.cfm](http://www.accessdata.fda.gov/scripts/cder/ob/index.cfm)) (showing patent and exclusivity information for Revlimid).

<sup>77</sup> See, e.g., Initiative for Medicine, Access, and Knowledge, *America's Overspend: How the Pharmaceutical Patent Problem is Fueling High Drug Prices* (Oct. 2017) (online at [www.i-mak.org/wp-content/uploads/2017/11/Excess-Costs-Briefing-Paper-FINAL\\_-2017-10-24.pdf](http://www.i-mak.org/wp-content/uploads/2017/11/Excess-Costs-Briefing-Paper-FINAL_-2017-10-24.pdf)); M-CAM International, *Celgene Patent Review—Revlimid* (May 13, 2015) (online at [www.hvst.com/posts/celgene-revlimid-r-validity-review-w57TlqaW/attachment/mcam-celgene-revlimid-validity-review-pdf-705537](http://www.hvst.com/posts/celgene-revlimid-r-validity-review-w57TlqaW/attachment/mcam-celgene-revlimid-validity-review-pdf-705537)).

granted such patents, the European Patent Office invalidated Celgene's patent on these alternative forms of Revlimid in 2015.<sup>78</sup>

Celgene has also obtained or applied for 19 different patents covering the use of Revlimid to treat cancer.<sup>79</sup> These patents have the potential to exclude competition until 2028.<sup>80</sup> The U.S. Patent Trial and Appeal Board has upheld Celgene's so-called "use patents."<sup>81</sup> By contrast, the European Patent Office invalidated Celgene's patent on the use of Revlimid to treat multiple myeloma in 2013.<sup>82</sup>

Internal strategy documents obtained by the Committee show that Celgene views the U.S. patent system as far more protective of its pricing monopoly than patent systems in the rest of the world. One 2014 presentation estimated that Celgene had an 80% chance of maintaining its monopoly in the U.S. until April 2025 and a 50% chance of maintaining its monopoly in the U.S. until April 2027. In comparison, the presentation estimated that Celgene's monopoly would expire in the European Union on or before March 2023—two years prior to the *earliest* estimated U.S. expiration.<sup>83</sup>

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<sup>78</sup> See U.S. Patent No. 7465800 (filed Sept. 3, 2004); U.S. Patent No. 7855217 (filed Dec. 15, 2008); U.S. European Patent Register, *Opposition Proceedings for European Patent No. 1667682* (June 24, 2015) (online at <https://register.epo.org/application?number=EP04783095>); Celgene Corporation, *2018 Form 10-K* (Feb. 26, 2019) (online [www.sec.gov/Archives/edgar/data/816284/000081628419000014/a2018123110-k.htm](http://www.sec.gov/Archives/edgar/data/816284/000081628419000014/a2018123110-k.htm)).

<sup>79</sup> Letter from Covington & Burling LLP, on behalf of Celgene Corporation, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Feb. 4, 2019); CELG\_HCOR\_000000003, at Slide 1 and 2 (listing Celgene's patents related to Revlimid).

<sup>80</sup> Food and Drug Administration, *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* (online at [www.accessdata.fda.gov/scripts/cder/ob/index.cfm](http://www.accessdata.fda.gov/scripts/cder/ob/index.cfm)) (showing patent and exclusivity information for Revlimid).

<sup>81</sup> See *Apotex Inc. v. Celgene Corporation*, IPR2018-00685 (PTAB Sept. 27, 2018); *Dr. Reddy's Laboratories, Inc. v. Celgene Corporation*, IPR2018-01504 (PTAB Feb. 11, 2019); *Dr. Reddy's Laboratories, Inc. v. Celgene Corporation*, IPR2018-01507 (PTAB Feb. 11, 2019); *Dr. Reddy's Laboratories, Inc. v. Celgene Corporation*, IPR2018-01509 (PTAB Feb. 11, 2019); *Dr. Reddy's Laboratories, Inc. v. Celgene Corporation*, IPR2018-01504 (PTAB Feb. 11, 2019); *Alvogen Pine Brook LLC v. Celgene Corporation*, IPR2018-01714 (PTAB Mar. 14, 2019).

<sup>82</sup> European Patent Register, *Opposition Proceedings for European Patent No. 1505973* (Feb. 25, 2013) (online at <https://register.epo.org/application?number=EP03728969&tab=main&lng=en>).

<sup>83</sup> CELG\_HCOR\_000047526, at Slide 8 (redaction in original).



## IP/Exclusivity Assumptions

Compound	% Prob.	US	% Prob.	EU	% Prob.	JP	% Prob.	CN	% Prob.	AU
Lenalidomide		Sept. 2024		June 2022		2020		2017		2022
	80%	April 2025	80%	March 2023	80%	2021	80%	2018	50%	2023
	65%	April 2026			70%	2022	70%	2019		
	50%	April 2027			60%	2023	65%	2020		
					50%	2024	60%	2021		
							55%	2022		
							50%	2023		

\*Up to 5 year PTE (Patent Term Extension)

\*\* Pending inclusion of Pom/dex combination in label

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## VI. RESEARCH EXPENDITURES DO NOT JUSTIFY PRICE OF REVLIMID

Celgene has cited its research and development (R&D) expenditures as justification for the high price of Revlimid.<sup>84</sup> However, the Committee's investigation reveals that Celgene relied heavily on taxpayer-funded academic research to develop Revlimid as a treatment for multiple myeloma. Internal documents reviewed by the Committee indicate that Celgene's pricing decisions with respect to Revlimid were divorced from the company's calculus regarding future R&D investments or the recoupment of past R&D expenditures.

### A. Revlimid Developed Using Federal Research Dollars and Academic Research

While Celgene has collected more than \$53 billion in net worldwide revenue from Revlimid since 2005, the company contributed very little to the science first establishing that drugs like Revlimid could be an effective treatment for multiple myeloma.<sup>85</sup> Rather, Celgene

<sup>84</sup> See Letter from Covington & Burling LLP, on behalf of Celgene Corporation, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Feb. 4, 2019).

<sup>85</sup> Celgene Corporation, *2018 Form 10-K* (Feb. 26, 2019) (online at [www.sec.gov/Archives/edgar/data/816284/000081628419000014/a2018123110-k.htm](http://www.sec.gov/Archives/edgar/data/816284/000081628419000014/a2018123110-k.htm)); Celgene Corporation, *2016 Form 10-K* (Feb. 10, 2017) (online at [www.sec.gov/Archives/edgar/data/816284/000081628417000003/a2016123110k.htm](http://www.sec.gov/Archives/edgar/data/816284/000081628417000003/a2016123110k.htm)); Celgene Corporation, *2014 Form 10-K* (Feb. 20, 2015) (online at

benefited from the acquisition of a decades-old product, academic and non-profit research, and at least eight federally funded studies. Although Celgene claims that it invested “\$800 million in research and development” for Revlimid, the company did not invest substantially in Revlimid until other research made it clear that Revlimid was likely to become a blockbuster drug.<sup>86</sup>

Celgene’s reliance on preexisting and federally funded research began with its acquisition of the rights to sell Revlimid’s precursor drug, thalidomide, from Rockefeller University in 1992.<sup>87</sup> Thalidomide was not a new drug at the time. Thalidomide was first used in the 1950s as treatment for morning sickness in pregnant women, but it was removed from commercial markets after being found to cause severe birth defects.<sup>88</sup> Researchers continued to study how the drug worked, and doctors around the world began to use the drug to treat leprosy and other rare diseases.<sup>89</sup>

In the early 1990s, researchers at Rockefeller University—funded in part by the U.S. Public Health Service—patented research suggesting that thalidomide could be effective in treating HIV/AIDS and other diseases. This research showed that thalidomide could improve the quality of life for patients with HIV/AIDS and certain types of cancer.<sup>90</sup>

When Celgene first licensed the patent on thalidomide from Rockefeller University in 1992, it sought FDA approval to market the drug—under the brand name Thalomid—only for the treatment of a form of leprosy.<sup>91</sup> In reviewing Celgene’s application, FDA noted that Celgene was seeking approval for “an indication for which the drug had been used for over 30

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[www.sec.gov/Archives/edgar/data/816284/000162828015000889/a2014123110k.htm](http://www.sec.gov/Archives/edgar/data/816284/000162828015000889/a2014123110k.htm)); Celgene Corporation, 2012 *Form 10-K* (Feb. 15, 2013) (online at [www.sec.gov/Archives/edgar/data/816284/000104746913001186/a2212863z10-k.htm](http://www.sec.gov/Archives/edgar/data/816284/000104746913001186/a2212863z10-k.htm)); Celgene Corporation, 2008 *Form 10-K* (Feb. 17, 2009) (online at [www.sec.gov/Archives/edgar/data/816284/000136231009002329/c80967e10vk.htm](http://www.sec.gov/Archives/edgar/data/816284/000136231009002329/c80967e10vk.htm)); Celgene Corporation, 2007 *Form 10-K* (Feb. 20, 2008) (online at [www.sec.gov/Archives/edgar/data/816284/000095012308001878/y49949e10vk.htm](http://www.sec.gov/Archives/edgar/data/816284/000095012308001878/y49949e10vk.htm)).

<sup>86</sup> Letter from Covington & Burling LLP, on behalf of Celgene Corporation, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Feb. 4, 2019).

<sup>87</sup> See Celgene Corporation, 1995 *Form 10-K* (Apr. 1, 1996) (online at [www.sec.gov/Archives/edgar/data/816284/0000950117-96-000268.txt](http://www.sec.gov/Archives/edgar/data/816284/0000950117-96-000268.txt)) (noting the 1992 licensing agreement).

<sup>88</sup> Waqas Rehman, Lisa M. Arfons, and Hillard M. Lazarus, *The Rise and Fall and Subsequent Triumph of Thalidomide: Lessons Learned in Drug Development*, Therapeutic Advances in Hematology (Oct. 2011) (online at [www.ncbi.nlm.nih.gov/pmc/articles/PMC3573415/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3573415/)). Thalidomide technically was never approved in the U.S. due to the heroic work of the Food and Drug Administration scientist Frances Kelsey, but nevertheless was widely distributed by its manufacturer prior to approval.

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

<sup>90</sup> Elizabeth P. Sampaio et al., *Thalidomide Selectively Inhibits Tumor Necrosis Factor  $\alpha$  Production by Stimulated Human Monocytes*, Journal of Experimental Medicine (Mar. 1991) (online at [www.ncbi.nlm.nih.gov/pmc/articles/PMC2118820/pdf/je1733699.pdf](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2118820/pdf/je1733699.pdf)) (“These studies were supported in part by U.S. Public Health Service grant AI-22616.”); U.S. Patent No. 5,385,901 (filed Oct. 2, 1992).

<sup>91</sup> See Letter from Murray M. Lumpkin, Deputy Center Director, Center for Drug Evaluation and Research, Food and Drug Administration, to Dr. Steve Thomas, Celgene Corporation (July 16, 1998) (online at [www.accessdata.fda.gov/drugsatfda\\_docs/appletter/1998/20785ltr.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/20785ltr.pdf)).



years.”<sup>92</sup> The company and FDA expected that it could be prescribed off label to patients with HIV and AIDS based on the ongoing studies by Rockefeller University researchers and others.<sup>93</sup> FDA granted Celgene’s application in 1998.<sup>94</sup>

Celgene collected only limited revenue in the first few years of selling Thalomid.<sup>95</sup> To reverse its fortunes, Celgene relied upon the ingenuity of researchers at Boston Children’s Hospital (BCH). In 1993, BCH researchers discovered that both thalidomide and its chemical analog, EM-12, could inhibit tumor growth by stunting the development of new blood vessels.<sup>96</sup> EM-12, which Celgene would later name Revlimid, has an almost identical molecular structure to thalidomide.<sup>97</sup> The BCH researchers registered patents on the discovery that thalidomide and other similar chemical compounds could prevent the growth of tumors.<sup>98</sup>

In 1996, the same BCH researchers—at the request of the wife of a dying multiple myeloma patient—convinced Dr. Bart Barlogie of the University of Arkansas Medical Center to try using thalidomide to treat three patients with multiple myeloma.<sup>99</sup> Two of the patients improved dramatically, inspiring Dr. Barlogie to launch a larger study with 84 multiple myeloma patients.<sup>100</sup> The larger study proved that thalidomide was effective in treating multiple

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<sup>92</sup> Food and Drug Administration, *Dermatologic and Ophthalmic Drugs Advisory Committee Tr. at 14* (Sept. 4, 1997) (attached to Celgene’s Statement of Material Facts in *Mylan Pharmaceuticals Inc. v. Celgene Corporation*, No. 14-CV-02094 (D. N.J.) (Mar. 20, 2018)). Both Celgene and the Food and Drug Administration expected that Thalomid also would be prescribed off-label to patients with HIV/AIDS and other conditions. *See id.*

<sup>93</sup> *Id.*

<sup>94</sup> *See* Letter from Murray M. Lumpkin, Deputy Center Director, Center for Drug Evaluation and Research, Food and Drug Administration, to Dr. Steve Thomas, Celgene Corporation (July 16, 1998) (online at [www.accessdata.fda.gov/drugsatfda\\_docs/appletter/1998/20785ltr.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/20785ltr.pdf)).

<sup>95</sup> *See* CELG\_HCOR\_000000001 (listing Celgene’s revenue from 1992-2018).

<sup>96</sup> Robert J. D’Amato, et al., *Thalidomide is an Inhibitor of Angiogenesis*, Proceedings of the National Academies of Sciences (April 1994) (online at [www.ncbi.nlm.nih.gov/pmc/articles/PMC43727/pdf/pnas01131-0614.pdf](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC43727/pdf/pnas01131-0614.pdf)); *see also* Boston Children’s Hospital, *From Thalidomide to Pomalyst: Better Living Through Chemistry* (Apr. 2, 2013) (online at <https://vector.childrenshospital.org/2013/04/from-thalidomide-to-pomalyst-better-living-through-chemistry/>).

<sup>97</sup> *How a Drugmaker Gamed the System to Keep Generic Competition Away*, National Public Radio (Mar. 17, 2018) (online at [www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away](http://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away)).

<sup>98</sup> *See, e.g.*, U.S. Patent No. 5,629,327 (filed Dec. 15, 1993); U.S. Patent No. 5,593,990 (filed Jan. 13, 1995); *see also* Boston Children’s Hospital’s Statement of Undisputed Material Facts, *Children’s Medical Center Corp. v. Celgene Corporation*, No. 13-cv-11573 (D. Mass) (Aug. 4, 2015).

<sup>99</sup> Boston Children’s Hospital, *From Thalidomide to Pomalyst: Better Living Through Chemistry* (Apr. 2, 2013) (online at <https://vector.childrenshospital.org/2013/04/from-thalidomide-to-pomalyst-better-living-through-chemistry/>); *Lawyer Says Drugmaker Celgene Stole Her Idea*, *Forbes* (Aug. 25, 2009) (online at [www.forbes.com/2009/08/25/celgene-jacobson-thalomid-business-healthcare-cancer.html#d8cb3842c86a](http://www.forbes.com/2009/08/25/celgene-jacobson-thalomid-business-healthcare-cancer.html#d8cb3842c86a)).

<sup>100</sup> Seema Singhal, Bart Barlogie, et al., *Antitumor Activity of Thalidomide in Refractory Multiple Myeloma*, *New England Journal of Medicine* (Nov. 18, 1999) (online at [www.nejm.org/doi/full/10.1056/NEJM199911183412102](http://www.nejm.org/doi/full/10.1056/NEJM199911183412102)); Boston Children’s Hospital, *From Thalidomide to Pomalyst: Better Living Through Chemistry* (Apr. 2, 2013) (online at [vector.childrenshospital.org/2013/04/from-thalidomide-to-pomalyst-better-living-through-chemistry/](https://vector.childrenshospital.org/2013/04/from-thalidomide-to-pomalyst-better-living-through-chemistry/)).

myeloma.<sup>101</sup> This study was supported by a \$2.3 million grant from the National Institutes of Health (NIH). Celgene provided free drug samples for the study and contributed to data collection and analysis.<sup>102</sup>

Celgene's revenue for sales of thalidomide increased after Dr. Barlogie published the results of his federally funded study in December 1999.<sup>103</sup> It was only after learning of the initial success of this study that Celgene decided to invest in larger trials that would be needed to receive FDA approval to sell thalidomide as a treatment for multiple myeloma.<sup>104</sup>

As Celgene began to collect millions of dollars from selling thalidomide, other academic researchers—funded by taxpayer dollars—were already exploring whether drugs with a similar chemical structure to thalidomide, including the compound that would later become known as Revlimid, might be more effective than thalidomide in treating multiple myeloma. These chemicals had existed for many years, but the recent research into thalidomide prompted renewed interest into its analogs. Once again, Celgene capitalized on this academic and federally funded research to eventually launch Revlimid.

First, in 2000 and 2001, researchers at the Dana Farber Cancer Institute published two studies showing that certain variations of thalidomide—including the compound that Celgene would later name Revlimid—appeared to be more effective than thalidomide in treating multiple

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<sup>101</sup> *Id.*

<sup>102</sup> *Id.*; National Institutes of Health, *Project Information for Project 2P01CA055819-05A1* (online at [projectreporter.nih.gov/project\\_info\\_details.cfm?aid=2893415&icde=48912205](http://projectreporter.nih.gov/project_info_details.cfm?aid=2893415&icde=48912205)).

<sup>103</sup> The rapid revenue growth likely was due to doctors prescribing Thalomid off-label to treat multiple myeloma while larger studies and the Food and Drug Administration review were ongoing. *See* CELG\_HCOR\_000000001 (listing Celgene's research expenditures and revenue from 1992-2018); Letter from Renata Albrecht, Division Director, Division of Special Pathogen and Transplant Products, Food and Drug Administration, and Robert L. Justice, Acting Division Director, Division of Drug Oncology Products, Food and Drug Administration, to Megan Parsi, Director of Regulatory Affairs, Celgene Corporation (May 25, 2006) (online at [www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2006/021430s000,%20020785s031LTR.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2006/021430s000,%20020785s031LTR.pdf)).

<sup>104</sup> CELG\_HCOR\_000000001 (listing Celgene's research expenditures and revenue from 1992 to 2018); National Institutes of Health, *Clinical Trials Sponsored by Celgene Corporation from 1996 to 2000* (online at [www.clinicaltrials.gov](http://www.clinicaltrials.gov)) (showing that Celgene-sponsored multiple myeloma trials began after Dr. Barlogie's first trial was collecting data from all 84 of its enrolled patients and 8 months after Dr. Barlogie's first trial began treating its patients); Seema Singhal, Bart Barlogie, et al., *Antitumor Activity of Thalidomide in Refractory Multiple Myeloma*, *New England Journal of Medicine* (Nov. 18, 1999) (online at [www.nejm.org/doi/full/10.1056/NEJM199911183412102](http://www.nejm.org/doi/full/10.1056/NEJM199911183412102)) (stating that enrollment occurred from Dec. 1997 to June 1998).

myeloma.<sup>105</sup> The two studies were supported by more than \$3 million in grants from NIH.<sup>106</sup> The same Dana Farber researchers then conducted a small-scale study showing that the compound that would be named Revlimid was superior to thalidomide in treating relapsed multiple myeloma patients.<sup>107</sup> That study was also funded by more than \$1 million in grants from NIH.<sup>108</sup> It was only after these three federally funded studies demonstrated positive results for Revlimid that Celgene invested in additional trials to obtain FDA approval to sell Revlimid to patients with multiple myeloma.

On June 29, 2006, Celgene received FDA approval to market Revlimid for use “in combination with dexamethasone for the treatment of multiple myeloma patients who have received at least one prior therapy.”<sup>109</sup> This approval was only for multiple myeloma patients who had received another treatment that had failed, and it did not allow Celgene to market Revlimid as the initial therapy for newly diagnosed multiple myeloma patients—a large percentage of patients with the disease.<sup>110</sup>

To gain approval for newly diagnosed multiple myeloma patients, Celgene again relied on federally funded research. In 2005, Dr. S. Vincent Rajkumar and his fellow researchers at the

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<sup>105</sup> Teru Hideshima, Kenneth C. Anderson, et al., *Thalidomide and Its Analogs Overcome Drug Resistance of Human Multiple Myeloma Cells to Conventional Therapy*, *Blood* (Nov. 1, 2000) (online at <https://ashpublications.org/blood/article/96/9/2943/181233/Thalidomide-and-its-analogs-overcome-drug>) (“Supported by National Institutes of Health grant PO1 78378.”); Faith E. Davies, Kenneth C. Anderson, et al., *Thalidomide and Immunomodulatory Derivatives Augment Natural Killer Cell Cytotoxicity in Multiple Myeloma*, *Blood* (July 1, 2001) (online at <https://ashpublications.org/blood/article/98/1/210/88908/Thalidomide-and-immunomodulatory-derivatives>) (supported by “National Institutes of Health grant PO-1 78378.”). The two articles use the label IMiD3 to refer to lenalidomide, which Celgene later named Revlimid. See Yu-Tzu Tai, Kenneth C. Anderson, et al., *Immunomodulatory Drug Lenalidomide (CC-5013, IMiD3) Augments Anti-CD40 SGN-40-Induced Cytotoxicity in Human Multiple Myeloma: Clinical Implications*, *Cancer Research* (Dec. 2005) (online at <https://cancerres.aacrjournals.org/content/65/24/11712.long>).

<sup>106</sup> *Id.*; National Institutes of Health, *Project Information for Project 5P01CA078378-02* (online at [projectreporter.nih.gov/project\\_info\\_details.cfm?aid=2896554&icde=48914442](https://projectreporter.nih.gov/project_info_details.cfm?aid=2896554&icde=48914442)); National Institutes of Health, *Project Information for Project 5P01CA078378-03* (online at [https://projectreporter.nih.gov/project\\_info\\_details.cfm?aid=6174254&icde=48914442](https://projectreporter.nih.gov/project_info_details.cfm?aid=6174254&icde=48914442)).

<sup>107</sup> Paul Richardson, Kenneth C. Anderson, et al., *Immunomodulatory Drug CC-5013 Overcomes Drug Resistance and Is Well Tolerated in Patients with Relapsed Multiple Myeloma*, *Blood* (Nov. 1, 2002) (online at <https://ashpublications.org/blood/article-lookup/doi/10.1182/blood-2002-03-0996>) (“Supported by National Institutes of Health grants RO-1 50947 and PO-78378.”).

<sup>108</sup> *Id.*; National Institutes of Health, *Project Information for Project 5P01CA078378-05* (online at [https://projectreporter.nih.gov/project\\_info\\_details.cfm?aid=6513266&icde=48914442](https://projectreporter.nih.gov/project_info_details.cfm?aid=6513266&icde=48914442)); National Institutes of Health, *Project Information for Project 5R01CA050947-11* (online at [https://projectreporter.nih.gov/project\\_info\\_details.cfm?aid=6512662&icde=48914667](https://projectreporter.nih.gov/project_info_details.cfm?aid=6512662&icde=48914667)).

<sup>109</sup> See Letter from Robert Justice, M.D., Division Director, Division of Drug Oncology Products, Food and Drug Administration, to Gretchen Toolan, Director of Regulatory Affairs, Celgene Corporation (June 29, 2006) (online at [www.accessdata.fda.gov/drugsatfda\\_docs/applletter/2006/021880s001LTR.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/applletter/2006/021880s001LTR.pdf)). The previous December, Celgene received approval to market Revlimid to treat a subset of patients with a rare blood disorder known as myelodysplastic syndrome. See Letter from Richard Pazdur, Director, Office of Oncology Drug Products, Food and Drug Administration, to Gretchen Toolan, Director of Regulatory Affairs, Celgene Corporation (Dec. 27, 2005). But the commercial market for this approval was very limited.

<sup>110</sup> *Id.*; American Cancer Society, *Key Statistics About Multiple Myeloma* (Jan. 8, 2020) (online at [www.cancer.org/cancer/multiple-myeloma/about/key-statistics.html](http://www.cancer.org/cancer/multiple-myeloma/about/key-statistics.html)).

Mayo Clinic published a study showing that Revlimid, combined with another drug, dexamethasone, was effective in treating newly diagnosed multiple myeloma patients.<sup>111</sup> This study was supported by nearly \$300,000 in funding from NIH, with Celgene providing additional support.<sup>112</sup>

Building on the Mayo Clinic study, Dr. Rajkumar and researchers in the Eastern Cooperative Oncology Group (ECOG) conducted a larger study showing that Revlimid combined with a low-dose of dexamethasone was more effective than Revlimid combined with a high-dose of dexamethasone in treating newly diagnosed multiple myeloma patients.<sup>113</sup> The study was funded primarily by NIH, including more than \$70 million in general support funding to ECOG over the course of the study.<sup>114</sup>

Once again, it was only after two federally funded studies had demonstrated positive results that Celgene invested in the trials that would be required to obtain FDA approval to sell Revlimid to newly diagnosed multiple myeloma patients.

An internal “Strategic Rationale” memorandum from April 2009 shows that Celgene relied on the ECOG study as reason to invest in a larger study.<sup>115</sup> The memorandum emphasized the “Financial Opportunity” of the investment, describing the newly diagnosed patient population as “the largest commercial opportunity for the multiple myeloma franchise.” The memorandum estimated a net present value of “nearly \$1.5 billion” and an “internal rate of return on investment of 114%.” The memorandum concluded: “No other current or planned Celgene program approaches the financial value represented by realizing the assumptions in our current newly diagnosed multiple myeloma global sales forecast.”<sup>116</sup>

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<sup>111</sup> S. Vincent Rajkumar et al., *Combination Therapy with Lenalidomide Plus Dexamethasone (Rev/Dex) for Newly Diagnosed Myeloma*, *Blood* (Dec. 15, 2005) (online at <https://ashpublications.org/blood/article/106/13/4050/133250/Combination-therapy-with-lenalidomide-plus>) (“Supported in part by grants CA93842 and CA10080 from the National Cancer Institute, National Institutes of Health, and the Department of Health and Human Services and Celgene Corporation”).

<sup>112</sup> *Id.*; National Institutes of Health, *Project Information for Project 5R01CA093842-03* (online at [https://projectreporter.nih.gov/project\\_info\\_details.cfm?aid=6739049&icde=48917597](https://projectreporter.nih.gov/project_info_details.cfm?aid=6739049&icde=48917597)).

<sup>113</sup> S.V. Rajkumar et al., *Lenalidomide Plus High-Dose Dexamethasone versus Lenalidomide Plus Low-Dose Dexamethasone As Initial Therapy for Newly Diagnosed Multiple Myeloma: An Open-Label Randomized Controlled Trial*, *Lancet Oncology* (Jan. 2010) (online at [www.ncbi.nlm.nih.gov/pmc/articles/PMC3042271/pdf/nihms241183.pdf](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3042271/pdf/nihms241183.pdf)) (“This study was funded and sponsored by the US National Cancer Institute (NCI)” and “supported by Public Health Service Grants CA23318, CA66636, CA21115, CA13650, and CA93842 from the National Cancer Institute.”).

<sup>114</sup> National Institutes of Health, *Project Information for Projects 5U10CA021115, 5U10CA023318, 5U10CA066636 for Fiscal Years 2004 to 2008* (online at [https://projectreporter.nih.gov/Reporter\\_Viewsh.cfm?sl=15E1C00A468DC7DF7598B8961CAA4A01A2FFCEB861BF](https://projectreporter.nih.gov/Reporter_Viewsh.cfm?sl=15E1C00A468DC7DF7598B8961CAA4A01A2FFCEB861BF))

<sup>115</sup> CELG\_HCOR\_000051077, at Pages 1-7.

<sup>116</sup> *Id.*

### Financial Opportunity

The newly diagnosed patient population is equally split between those patients that are considered eligible for stem cell transplantation and those that are considered ineligible for transplantation. However, the newly diagnosed non-stem cell eligible patient population represents the largest commercial opportunity for the multiple myeloma franchise as the anticipated duration of therapy is longer within this segment (ASCT eligible – 8 months vs. NSCT – 15 months).

As a result, the projected total global net revenue exceeds \$8.6 billion over the patent life of REVLIMID (expiry in 2026). The anticipated worldwide peak sales for this patient segment are reached in 2021 and are approximately \$915 million. Finally, the REVLIMID Global Project Team estimates that the NPV for aggressive pursuit of this patient segment is nearly \$1.5 billion, which represents an internal rate of return on investment of 114%.

No other current or planned Celgene program approaches the financial value represented by realizing the assumptions in our current newly diagnosed multiple myeloma global sales forecast.

In 2015, Celgene received FDA approval to market Revlimid for the treatment of newly diagnosed patients.<sup>117</sup> The next year, then-CEO Mark Alles sent the “Strategic Rationale” memorandum to a colleague and boasted that the analysis had “grossly underestimated the cumulative and annual sales potential for Revlimid.”<sup>118</sup>

In 2017, Celgene received FDA approval to market Revlimid as maintenance therapy for yet another segment of multiple myeloma patients: those who had already received stem cell transplants.<sup>119</sup> Celgene once again relied on federally funded research to obtain this approval. Nearly five years earlier, the publicly funded Alliance for Clinical Trials in Oncology had published the results of a 460-patient study showing that Revlimid maintenance therapy extended the survival of multiple myeloma patients who had received stem cell transplants.<sup>120</sup> The study was funded primarily by NIH, including more than \$80 million in general support funding to Alliance over the course of the study.<sup>121</sup> Celgene provided drug samples, but otherwise “had no involvement in the study design or conduct of the study.”<sup>122</sup>

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<sup>117</sup> Letter from Ann T. Farrell, Director, Division of Hematology Products, Food and Drug Administration, to Maricel Fong, Senior Manager of Regulatory Affairs, Celgene Corporation (Feb. 17, 2015) (online at [www.accessdata.fda.gov/drugsatfda\\_docs/applletter/2015/021880Orig1s0411tr.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/applletter/2015/021880Orig1s0411tr.pdf)).

<sup>118</sup> CELG\_HCOR\_000051076.

<sup>119</sup> Letter from Ann T. Farrell, Director, Division of Hematology Products, Food and Drug Administration, to Michael B. Faletto, Executive Director of Regulatory Affairs, Celgene Corporation (Feb. 22, 2017) (online at [www.accessdata.fda.gov/drugsatfda\\_docs/applletter/2017/021880Orig1s0491tr.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/021880Orig1s0491tr.pdf)).

<sup>120</sup> Philip L. McCarthy, Charles Linker, et al., *Lenalidomide After Stem-Cell Transplantation for Multiple Myeloma*, *New England Journal of Medicine* (May 10, 2012) (online at [www.ncbi.nlm.nih.gov/pmc/articles/PMC3744390/pdf/nihms381526.pdf](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3744390/pdf/nihms381526.pdf)) (“The NCI sponsored the study. Celgene provided the lenalidomide and placebo to the NCI, which in turn provided the study drugs to the investigators. Celgene had no involvement in the study design or conduct of the study or in the analysis or reporting of the data.”)

<sup>121</sup> National Institutes of Health, *Project Information for Projects 5U10CA0319466 for Fiscal Years 2005 to 2012* (online at [https://projectreporter.nih.gov/Reporter\\_Viewsh.cfm?sl=15E1C00A4685C3D37598B8961CAA4A01A2FFCEB861BF](https://projectreporter.nih.gov/Reporter_Viewsh.cfm?sl=15E1C00A4685C3D37598B8961CAA4A01A2FFCEB861BF)). Technically, the National Institutes of Health grants were to the research consortium Cancer and Leukemia Group B, which merged with two other consortiums in 2011 to form Alliance for Clinical Trials in Oncology.

<sup>122</sup> *Id.*

## **B. Price Increases Unrelated to Research Expenditures**

Documents reviewed by the Committee show that Celgene's internal pricing decisions were divorced from its calculus regarding future R&D or recouping of past R&D expenditures.

In response to the Committee's document requests, Celgene produced dozens of CMAC presentations memorializing its rationale for various Revlimid price increases from May 2009 to December 2018.<sup>123</sup> The vast majority of these presentations do not mention past or future R&D expenditures.<sup>124</sup> Instead, they focus primarily on how price increases will impact the company's revenue and other financial targets, whether Celgene's price increases are in line with price increases by competitors, and the regulatory environment.<sup>125</sup>

Documents obtained by the Committee show that when Celgene executives did engage in discussions about research related to Revlimid, they focused primarily on demonstrating Revlimid's "value"—as shown by research into the drug's effectiveness—to justify raising its price. However, the Committee's investigation reveals that Celgene did not fund most of the research used by executives to justify the price increases.

For example, in a November 2016 CMAC presentation, Celgene executives outlined a plan to increase Revlimid's price by a total of 40% through six different price increases between 2017 and 2019. Under each individual price increase, the executives cited various clinical trials involving Revlimid to justify the price increase.<sup>126</sup>

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<sup>123</sup> See, e.g., CELG\_HCOR\_000000104 to CELG\_HCOR\_000000341; CELG\_HCOR\_000042264, at Slides 9-13.

<sup>124</sup> *Id.*

<sup>125</sup> See, e.g., CELG\_HCOR\_000000329, at Slide 3 (May 2009 presentation analyzing "incremental net revenue" of various price increases); CELG\_HCOR\_000042262, at Slide 13 (Mar. 2016 presentation noting that price increase "yields a \$137.4M in incremental net sales in 2016"); CELG\_HCOR\_000000179, at Slide 10 (Sept. 2013 presentation analyzing price increases of competitors); CELG\_HCOR\_000000152, at Slide 4 and 5 (Mar. 2014 presentation showing "incremental net sales" of price increases and analyzing price increases of competitors); CELG\_HCOR\_000000316, at Slides 4-6 (Aug. 2014 presentation showing incremental net sales of price increases and analyzing price increases of competitors); CELG\_HCOR\_000000279, at Slide 4 (Aug. 2016 presentation stating that price increase "is not an outlier with other oral oncology products."); CELG\_HCOR\_000000139, at Slides 7-10 (Nov. 2016 presentation showing price increase's impact on net sales, analyzing price increases of competitors, and weighing "legislative considerations"); CELG\_HCOR\_000000213, at Slide 3 (Oct. 2017 presentation showing financial analysis of accelerating 9% price increase).

<sup>126</sup> CELG\_HCOR\_000000135, at Slide 5. The box titled "1Q2017 Rev SCT-M" is not a clinical trial and instead references the 2017 FDA approval for maintenance therapy for multiple myeloma patients who received stem cell transplantation. See also Letter from Ann T. Farrell, Director, Division of Hematology Products, Food and Drug Administration, to Michael B. Faletto, Executive Director of Regulatory Affairs, Celgene Corporation (Feb. 22, 2017) (online at [www.accessdata.fda.gov/drugsatfda\\_docs/applletter/2017/021880Orig1s049ltr.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/applletter/2017/021880Orig1s049ltr.pdf)).

## Revlimid Proposed Pricing Based On 3 Year Window of Innovation

	2017					2018					2019				
	1Q	2Q	3Q	4Q	Total	1Q	2Q	3Q	4Q	Total	1Q	2Q	3Q	4Q	Total
Planned	3.00%	0.00%	3.00%	0.00%	6.09%	3.00%	0.00%	3.00%	0.00%	6.09%	3.00%	0.00%	3.00%	0.00%	6.09%
Recommended	8.00%	0.00%	1.75%	0.00%	9.89%	0.00%	3.00%	0.00%	6.80%	10.00%	0.00%	4.00%	0.00%	5.50%	9.72%
Incremental Net Sales	\$ 52	\$ 56	\$ 43	\$ 43	\$ 194	\$ 7	\$ 51	\$ 8	\$ 116	\$ 182	\$ 65	\$ 139	\$ 91	\$ 195	\$ 490

1Q2017  
POLLUX  
Dara + Rd  
vs Rd L2

1Q2017  
Rev SCT-  
M

2Q2018  
SWOG0777  
RVd vs Rd  
TNE

4Q2018  
ELOQUENT-1  
RVd vs Rd TNE

4Q2018  
RELEVANCE  
RD + ritux. Vs  
ritux + chemo

4Q2018  
AUGMENT  
RD + ritux. Vs  
ritux + placebo

2Q2019  
TOURMAL  
INE-2  
Ixa + Rd  
TNE

4Q2019  
ROBUST  
RD + R-  
CHOP21



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More than half of the clinical trials used to justify the price increases were funded by an entity other than Celgene:<sup>127</sup>

- The POLLUX trial was sponsored and funded by Janssen Pharmaceuticals (Janssen);<sup>128</sup>
- The SWOG0777 trial was sponsored and primarily funded by the NIH;<sup>129</sup>
- The ELOQUENT-1 trial was sponsored and funded by BMS, when it was entirely independent of Celgene;<sup>130</sup> and

<sup>127</sup> CELG\_HCOR\_000000135, at Slide 5. The box titled “1Q2017 Rev SCT-M” is not a clinical trial and instead refers to the FDA’s approval of Revlimid for maintenance therapy after stem cell transplantation.

<sup>128</sup> National Institutes of Health, *Information for Clinical Trials Identifier NCT02076009* (online at <https://clinicaltrials.gov/ct2/show/NCT02076009>).

<sup>129</sup> National Institutes of Health, *Information for Clinical Trials Identifier NCT00644228* (online at <https://clinicaltrials.gov/ct2/show/NCT00644228>).

<sup>130</sup> National Institutes of Health, *Information for Clinical Trials Identifier NCT01335399* (online at <https://clinicaltrials.gov/ct2/show/NCT01335399>).

- The TOURMALINE-2 trial was sponsored and funded by Millennium Pharmaceuticals, a subsidiary of Takeda Pharmaceutical Company.<sup>131</sup>

Internal emails obtained by the Committee suggest that while Celgene used other drug companies' research to justify its price increases, Celgene leveraged the high price of Revlimid to limit the same companies' ability to conduct research into competing cancer therapies.

For example, in one email exchange, senior executives discussed Janssen's request for discounted Revlimid for its cancer trials. One executive recommended against providing Janssen a discount because "[t]hey are the biggest threat to our Revlimid and Pomalyst business" and "[m]aking them spend a lot more on their trials puts financial constraints on their ability to simultaneously fund lots of trials." The executive estimated that without a discount, Janssen would be forced to pay \$190 million to \$200 million annually for the drug. Another executive responded, "Anything we can do to hamper their development would help." Celgene's then-President of Hematology and Oncology, Nadim Ahmed, commented in response that the decision of whether to provide discounted product "should be based on benefit to Celgene and strategic fit. Development capacity or lack thereof for Janssen is their issue to deal with."<sup>132</sup>

## VII. OTHER COSTS DO NOT JUSTIFY PRICE INCREASES

### A. Rebates

The pharmaceutical industry often attributes price increases to the need to account for rebates, discounts, and other fees provided to pharmacy benefit managers (PBMs) and other third parties within the distribution chain. PhRMA, the pharmaceutical industry's trade association, has claimed that "[n]early half of brand medicine spending goes to the supply chain and others."<sup>133</sup>

Celgene's internal data suggest that its price increases for Revlimid cannot be attributed to growing rebates or discounts provided to PBMs, health insurance plans, employers, or other payors. Rebate and discount data produced by Celgene show that, from 2012 to 2017, the largest negotiated discount that Celgene provided for Revlimid in the commercial market was 5%.<sup>134</sup> With respect to government health care programs, Celgene reported to the Committee that it "does not provide contracted price reductions for Medicaid, VA programs, or Medicare Part D."<sup>135</sup>

Internal data show that Celgene's average net price per unit of Revlimid—the price of the drug after subtracting rebates and discounts—continued to increase each year the drug was on

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<sup>131</sup> National Institutes of Health, *Information for Clinical Trials Identifier NCT01850524* (online at <https://clinicaltrials.gov/ct2/show/NCT01850524>).

<sup>132</sup> CELG\_HCOR\_000042767.

<sup>133</sup> Pharmaceutical Research and Manufacturers of America, *Let's Talk About Cost* (online at [www.letstalkaboutcost.org/](http://www.letstalkaboutcost.org/)) (accessed Sept. 28, 2020).

<sup>134</sup> Letter from Covington & Burling LLP, on behalf of Celgene Corporation, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Feb. 22, 2019).

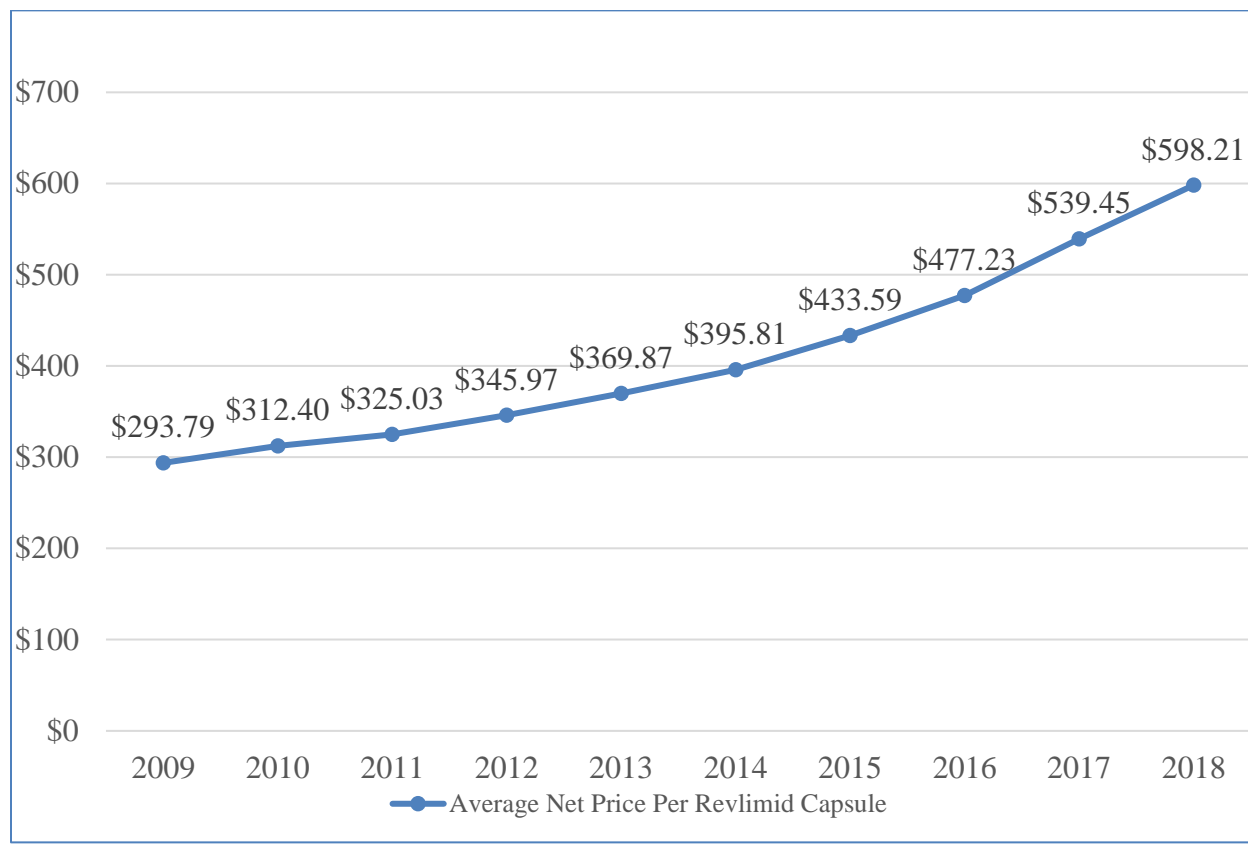
<sup>135</sup> *Id.*



the market, meaning any rebates or discounts from the list price of the drug were outpaced by the company's price increase.<sup>136</sup>

Figure 7 below shows this increase in average net price per unit of Revlimid from 2009 to 2018.

Figure 7: Average Net Price Per Unit of Revlimid



## **B. Manufacturing and Sales**

Pharmaceutical companies also frequently cite rising costs of manufacturing, sales, or other commercial expenses to justify their pricing practices. But internal data produced by Celgene do not support this justification for the price of Revlimid.

Although Celgene reported to the Committee that it “does not track cost of goods sold on a product-specific basis,” Revlimid revenue dwarfed Celgene’s reported manufacturing costs for *all* of its products.<sup>137</sup>

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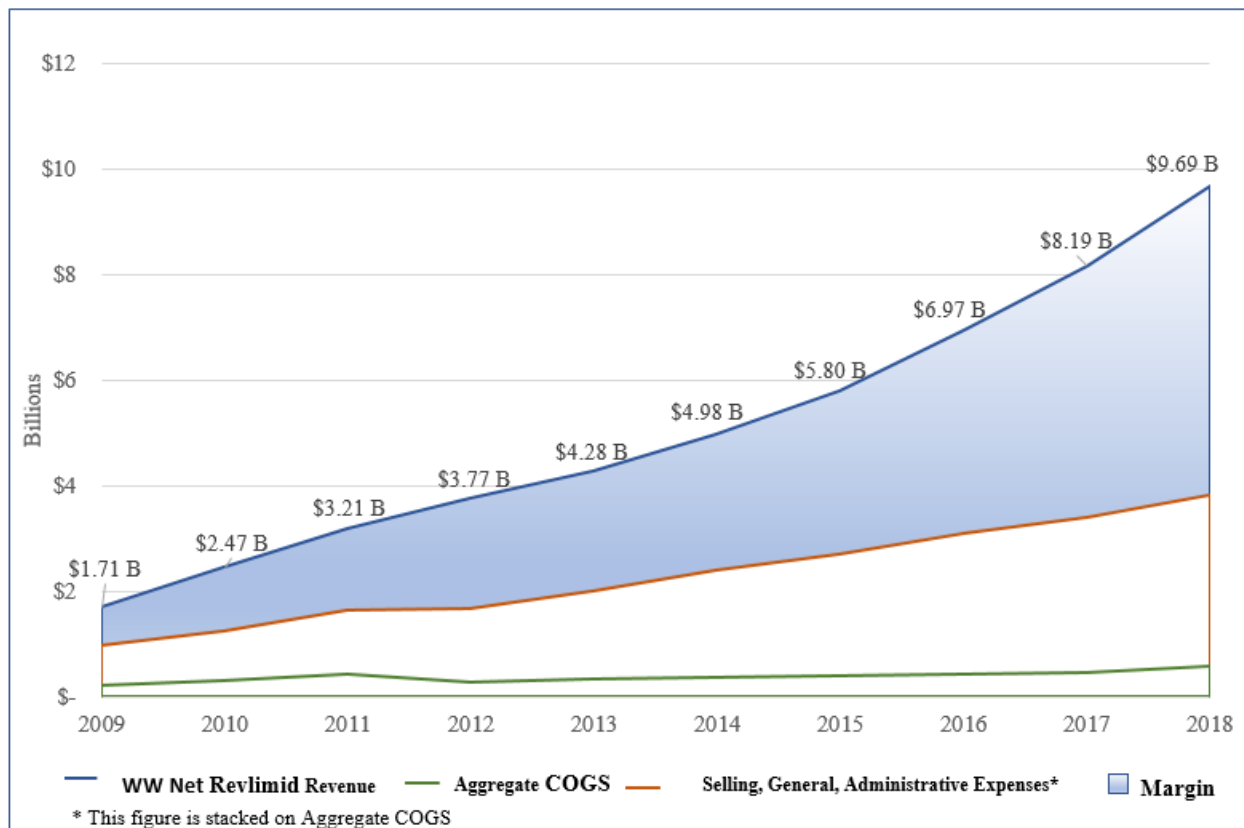
<sup>136</sup> *Id.*; Letter from Covington & Burling LLP, on behalf of Celgene Corporation, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (May 24, 2019).

<sup>137</sup> Letter from Covington & Burling LLP, on behalf of Celgene Corporation, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (May 24, 2019).

In addition, even when taking into account selling, general, and administrative expenses (SG&A) for *all* of the company’s products, sales revenue from Revlimid far exceeded costs and expenses in every year for which data were provided. While some of the company’s SG&A expenses increased over time, manufacturing costs remained relatively stable. Nevertheless, the company managed to substantially grow the profit margins that it derived from Revlimid.

Figure 8 below shows the year-over-year gross profit margins for Revlimid.<sup>138</sup>

**Figure 8: Revlimid Sales Revenue Compared to Costs**



### C. Patient Assistance Programs

In responding to criticism of its pricing of Revlimid, Celgene has frequently highlighted the generosity of its programs that help patients defray the costs of its price increases.<sup>139</sup>

<sup>138</sup>*Id.*; Celgene Corporation, 2018 Form 10-K (Feb. 26, 2019) (online at [www.sec.gov/Archives/edgar/data/816284/000081628419000014/a2018123110-k.htm](http://www.sec.gov/Archives/edgar/data/816284/000081628419000014/a2018123110-k.htm)); Celgene Corporation, 2016 Form 10-K (Feb. 10, 2017) (online at [www.sec.gov/Archives/edgar/data/816284/000081628417000003/a2016123110k.htm](http://www.sec.gov/Archives/edgar/data/816284/000081628417000003/a2016123110k.htm)); Celgene Corporation, 2014 Form 10-K (Feb. 20, 2015) (online at [www.sec.gov/Archives/edgar/data/816284/000162828015000889/a2014123110k.htm](http://www.sec.gov/Archives/edgar/data/816284/000162828015000889/a2014123110k.htm)); Celgene Corporation, 2012 Form 10-K (Feb. 15, 2013) (online at [www.sec.gov/Archives/edgar/data/816284/000104746913001186/a2212863z10-k.htm](http://www.sec.gov/Archives/edgar/data/816284/000104746913001186/a2212863z10-k.htm)).

<sup>139</sup> See, e.g., Celgene Corporation, *Celgene Patient Support* (online at [patient.revlimid.com/mcl-patient/getting-revlimid/how-can-celgene-patient-support-help-me/](http://patient.revlimid.com/mcl-patient/getting-revlimid/how-can-celgene-patient-support-help-me/)) (accessed Mar. 8, 2020).

However, these programs do not provide reliable support for patients, do not address the burden that Celgene's pricing practices place on the larger health care system, and had a negligible effect on Celgene's bottom line. When Celgene launched its commercial co-pay assistance program in 2011, it estimated that the program would cost at most 0.3–0.4% of Celgene's gross revenue for Revlimid.<sup>140</sup> In fact, according to information obtained by the Committee, Celgene's commercial co-pay program cost the company only 0.16% of its net U.S. revenue for Revlimid from 2011 to 2018.<sup>141</sup>

Celgene reported to the Committee that, between 2007 and 2017, it contributed approximately \$505 million to “independent charitable patient support foundations dedicated to assisting patients with out-of-pocket prescription costs.”<sup>142</sup> These donations account for less than one percent of Celgene's \$67 billion in net worldwide revenue from that same period.<sup>143</sup> In addition, Celgene has acknowledged that these contributions were tax-deductible, meaning that Celgene's actual cost for the \$505 million donation was much less.<sup>144</sup>

Internal Celgene communications suggest that Celgene executives analyzed how high they could raise Revlimid's price before the drug would become unaffordable to patients, necessitating additional assistance that would diminish the financial value of the price increase. In April 2018, one executive wrote the following when discussing Celgene's price increases:<sup>145</sup>

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<sup>140</sup> CELG\_HCOR\_000020856, at Slide 2.

<sup>141</sup> Letter from Covington & Burling LLP, on behalf of Celgene Corporation, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Feb. 4, 2019); Letter from Covington & Burling LLP, on behalf of Celgene Corporation, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (May 24, 2019).

<sup>142</sup> Letter from Covington & Burling LLP, on behalf of Celgene Corporation, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Feb. 4, 2019).

<sup>143</sup> *Id.*; Celgene Corporation, *2018 Form 10-K* (Feb. 26, 2019) (online at [www.sec.gov/Archives/edgar/data/816284/000081628419000014/a2018123110-k.htm](http://www.sec.gov/Archives/edgar/data/816284/000081628419000014/a2018123110-k.htm)); Celgene Corporation, *2016 Form 10-K* (Feb. 10, 2017) (online at [www.sec.gov/Archives/edgar/data/816284/000081628417000003/a2016123110k.htm](http://www.sec.gov/Archives/edgar/data/816284/000081628417000003/a2016123110k.htm)); Celgene Corporation, *2014 10-K* (Feb. 20, 2015) (online at [www.sec.gov/Archives/edgar/data/816284/000162828015000889/a2014123110k.htm](http://www.sec.gov/Archives/edgar/data/816284/000162828015000889/a2014123110k.htm)); Celgene Corporation, *2012 Form 10-K* (Feb. 15, 2013) (online at [www.sec.gov/Archives/edgar/data/816284/000104746913001186/a2212863z10-k.htm](http://www.sec.gov/Archives/edgar/data/816284/000104746913001186/a2212863z10-k.htm)).

<sup>144</sup> Letter from Covington & Burling LLP, on behalf of Celgene Corporation, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Feb. 4, 2019).

<sup>145</sup> CELG\_HCOR\_000026237.

**From:** [REDACTED]  
**Sent:** Friday, April 27, 2018 3:30 AM  
**To:** Richard Bagger; [REDACTED]  
**Cc:** [REDACTED] Nadim Ahmed  
**Subject:** Re: Corporate Market Access Committee Meeting - Friday, April 27, 2018 at 8:30am EDT

H Rich,

Won't be able to dial in, but I got a question regarding the US price increase.

Has the US team ran an analysis in how far the price increase for Rev/Pom drives an increase of free goods which would offset the benefit of the price increase? The sooner in the year patients cannot afford Revlimid & we provide free goods, the bigger the negative impact. There should be a point where the benefit of a price increase hits a break-even point with the loss due to an increase in free goods. Would be good to see where that break-even point is.

Thanks a lot!

This email suggests that Celgene executives fully expected their price increases to make Revlimid unaffordable for patients.

In response to public criticism about the price of its drugs, Celgene announced a pricing policy in July 2018 that would limit price increases to “no more than once a year and at a level no greater than the Centers for Medicare and Medicaid Services projected increase in National Health Expenditures for the year.”<sup>146</sup> At the time Celgene implemented its pricing policy, it had raised the price of Revlimid by approximately 20% over the previous 18 months and 220% since the drug came to market in 2005.<sup>147</sup> The pricing policy included an exception that permitted Celgene to ignore pricing limits in “exceptional circumstances.”<sup>148</sup>

After acquiring Celgene in November 2019, BMS appears to have abandoned Celgene’s pricing policy. As noted above, BMS increased the price of Revlimid by 6% at the beginning of 2020, compared to a projected increase in 2020 National Health Expenditures of 5.4%.<sup>149</sup>

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<sup>146</sup> Celgene Corporation, *Enabling Innovation and Creating Value: Our Approach to Pharmaceutical Pricing* (June 25, 2018) (online at [https://web.archive.org/web/20180927122428/www.celgene.com/enabling-innovation-and-creating-value/?mod=article\\_inline](https://web.archive.org/web/20180927122428/www.celgene.com/enabling-innovation-and-creating-value/?mod=article_inline)) (the webpage was removed after BMS acquired Celgene). National Health Expenditures increase by approximately 3-6% from year to year. Centers for Medicare and Medicaid Services, *National Health Expenditures and Selected Economic Indicators, Levels and Annual Percent Change: Calendar Years 2011-2027* (online at [www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected](http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected)).

<sup>147</sup> IBM Micromedex Redbook, *Wholesale Acquisition Cost and Average Wholesale Price History for Revlimid*.

<sup>148</sup> Celgene Corporation, *Enabling Innovation and Creating Value: Our Approach to Pharmaceutical Pricing* (June 25, 2018) (online at [https://web.archive.org/web/20180927122428/www.celgene.com/enabling-innovation-and-creating-value/?mod=article\\_inline](https://web.archive.org/web/20180927122428/www.celgene.com/enabling-innovation-and-creating-value/?mod=article_inline)) (the webpage was removed after BMS acquired Celgene).

<sup>149</sup> IBM Micromedex Redbook, *Wholesale Acquisition Cost and Average Wholesale Price History for Revlimid*; Centers of Medicare and Medicaid Services, *National Health Expenditures and Selected Economic Indicators, Levels and Annual Percent Change: Calendar Years 2011-2027* (online at [www.cms.gov/Research-](http://www.cms.gov/Research-)

## VIII. CONCLUSION

BMS and Celgene's price increases and business practices for Revlimid are not unique. During President Trump's first term, drug companies have continued to aggressively raise prices. A recent report found that drug companies have raised list price of over 600 single-source brand name drugs by a median 21.4% between January 2018 and June 2020.<sup>150</sup>

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

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Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected).

<sup>150</sup> See State of California, Office of Statewide Health Planning and Development, *Prescription Drug Wholesale Acquisition Cost (WAC) Increases* (Aug. 17, 2020) (online at [oshpd.ca.gov/visualizations/prescription-drug-wholesale-acquisition-cost-increases/](https://oshpd.ca.gov/visualizations/prescription-drug-wholesale-acquisition-cost-increases/)).