



# Drug Pricing Investigation

*Mallinckrodt—H.P. Acthar Gel*

Staff Report

Committee on Oversight and Reform

U.S. House of Representatives

October 2020

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**Congress of the United States**  
**House of Representatives**

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September 30, 2020

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

Dear Colleague:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Sincerely,



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Carolyn B. Maloney  
Chairwoman

## EXECUTIVE SUMMARY

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

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

- **Uninhibited Price Increases:** Acthar has increased in price by almost 100,000% since Questcor acquired the rights to the drug in 2001. Questcor raised Acthar's price from \$40 a vial to more than \$31,000 a vial. Mallinckrodt acquired Questcor in large part because of Acthar's already high price and has since raised the price of the drug by more than \$8,200 per vial—an additional 26% increase. Mallinckrodt executives have attempted to minimize public criticism of Acthar's price. For example, in June 2018, Mallinckrodt CEO Mark Trudeau directed company leaders to explore the possibility of selling smaller vials of Acthar at a lower price to make the drug seem less expensive. Mr. Trudeau "was razor focused on being able to say" that "'Acthar cost [sic] 25k not 38k [per vial].'"
- **Corporate Profits Driven by Acthar:** Mallinckrodt generated nearly \$6 billion in net sales of Acthar from 2014 through 2019. Sales of Acthar have accounted for nearly one-third of Mallinckrodt's total net sales from 2017 through 2019.
- **Use of Price Increases to Meet Revenue Goals:** After Mallinckrodt acquired Questcor, the company continued to raise Acthar prices as high as possible to meet financial targets. One executive offered the following assessment of Mallinckrodt's pricing strategy: "Bottom line is any price increase obviously has positive results. Really comes down to what we are comfortable with externally. Personally I would go high. We will receive the same press regardless within these ranges." In 2017, Mallinckrodt raised Acthar's price to compensate for lower-than-expected sales volumes. One Executive Vice President wrote, "The vast majority of the projected growth for Acthar in 2017 will come from price appreciation as opposed to volume growth." A commercial strategic plan prepared for the Board in 2018 initially referred to Acthar as a "cash cow." After one executive asked, "do we really want to say 'cash cow' to the board?" the company's Chief Commercial Officer responded, "Instead of 'cash cow,' I will replace it with profit maximizer."
- **Executive Compensation System Incentivizes Price Increases:** Mallinckrodt executives' annual incentive compensation is linked to each executive's individual contribution to certain financial measures, including the company's earnings per share

and net sales revenue. More than 90% of CEO Mark Trudeau’s direct pay is linked to these performance goals. Mr. Trudeau’s overall compensation has more than doubled since Mallinckrodt acquired Questcor in 2014. Over that same period, Mallinckrodt increased the price of Acthar by more than \$8,000 per vial.

- **Acquisition Driven by High Price and Profit Margin:** Before acquiring Acthar, Mallinckrodt executives emphasized that Questcor had “adopted aggressive pricing strategy based on Orphan designation”—the Food and Drug Administration’s (FDA) approval for drugs that treat rare diseases with small patient populations. As a result, Acthar was a “premium-priced product” with a “robust cash flow profile” that would enable the company to “Achieve aspirational goals with a single transaction.” Soon after acquisition, Mallinckrodt executives highlighted that Acthar had contributed \$123 million towards net sales in just the six weeks since it was acquired. CEO Mark Trudeau explained to investors that Mallinckrodt’s primary goal was to deliver “top-level shareholder returns” by focusing on “highly profitable” specialty drugs and noted that the margins from specialty pharmaceuticals are typically higher than average. In that same briefing, the President of Mallinckrodt’s Autoimmune and Rare Diseases division noted that Acthar “is a product which is approaching \$1 billion in revenue; it is growing [sic] double digit rates.”
- **Lack of Medicare Negotiation Costing Taxpayers Billions of Dollars:** Because Medicare is prohibited from negotiating directly for lower drug prices, it pays more for Acthar than any other government or commercial payer. In 2018, Medicare Part D plans spent more than \$700 million on Acthar—up more than \$220 million since 2015 and more than 14 times higher than in 2011. From 2015 to 2018, Medicare spent more than \$2.5 billion on Acthar. Internal data show that Mallinckrodt’s discounts to Medicare Part D averaged less than 1% from 2015 through 2018, as compared to approximately 6% for the commercial market and 26.6% for Tricare. If Medicare Part D had received the same discounts as Tricare, taxpayers would have saved \$656 million between 2015 and 2018. Mallinckrodt has increasingly relied on Medicare to drive sales revenues for Acthar. An internal draft strategic plan from 2017 noted that Medicare accounted for 50% of Acthar sales for the year to date. Long-term planning documents reveal that Mallinckrodt expects Medicare to contribute even more to Acthar sales in the future—as much as 70-75% by 2025.
- **High Price Costing Local Governments:** Acthar’s price has harmed local governments. For example, the cities of Rockford, Illinois, and Marietta, Georgia, each spent approximately \$500,000 for a handful of patients to be treated with Acthar. A city official from Marietta, Georgia wrote to Mallinckrodt in 2017: “We can’t sustain this. We have gone over budget and have had to raise the premiums on all of our employees and pre-age 65 retirees because of this one drug. This is maddening.”
- **Tactics to Maximize Profits:** When Mallinckrodt acquired Questcor, it expected little to no competition for Acthar—in part because Questcor had also acquired the rights to market Synacthen, Acthar’s closest competitor drug. In researching whether to acquire Questcor, Mallinckrodt’s market assessment concluded that Acthar “will face limited/no competition in future.” In 2017, Mallinckrodt entered into a \$100 million settlement with

the Federal Trade Commission (FTC) over Questcor’s acquisition of the rights to Synacthen, which FTC described as intended to “maintain its monopoly pricing” and “forestall future competition.”

- **Marketing to Physicians to Leverage Acthar’s High Price:** In pre-acquisition analysis, Mallinckrodt executives projected that Acthar revenue would grow exponentially if the company maintained the drug’s high price while expanding sales volume in current and new on-label indications. Before acquisition, one consultant emphasized to the company that Acthar’s growth potential for non-orphan indications was “directly linked to, and driven by, size and aggressiveness of specialty sales force.” Company talking points prepared immediately after the acquisition in 2014 emphasized, “We believe that the sales potential for Acthar hasn’t even scratched the surface.” Mallinckrodt drove sales through aggressive marketing to physicians. In September 2019, Mallinckrodt paid \$15.4 million to settle Department of Justice (DOJ) claims that Questcor had paid illegal kickbacks to doctors from 2009 through 2013 to induce prescriptions for the treatment of complications from multiple sclerosis.
- **Price Increases Not Justified by R&D:** To justify the price of Acthar, Mallinckrodt claims that it has invested more than \$500 million into the drug. Yet, information provided to the Committee shows that Mallinckrodt spent \$363 million on research and development (R&D) between 2014 and 2018, while the rest of its investment went to “modernization efforts” focused on improving manufacturing and production. This expenditure is less than 7.3% of the net revenue it received from Acthar during the same period. Mallinckrodt’s R&D expenditures for Acthar are intended to drive prescription volume and support payer reimbursement rather than provide the most clinically useful data. Internally, Mallinckrodt described its R&D (and modernization) as a way to “legitimize the brand” and respond to patient and physician skepticism. Although Mallinckrodt frequently highlights six company-sponsored controlled trials relating to the drug’s efficacy, according to a researcher of pharmacoepidemiology: “These studies will likely not provide the clinically relevant information necessary to support Acthar’s effectiveness over lower-cost treatments.”
- **Price Increases Not Justified by Other Expenses:** Internal data reveal that Acthar’s average net price—the price of the drug after subtracting rebates, distributor fees, and pharmacy price concessions—has continued to increase each year, meaning any rebates or discounts from the list price of the drug were outpaced by the company’s price increases. Manufacturing costs have also remained relatively stable since Mallinckrodt acquired Acthar and are minimal compared to net revenue.

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

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## I. PRICE INCREASES

Acthar is an injectable drug that is sold in a 5-milliliter vial, containing 80 units per milliliter.<sup>1</sup> Acthar is not marketed outside the United States. Acthar is currently approved for the treatment of infantile spasms and acute exacerbations in multiple sclerosis and may be used for 17 other disorders and diseases.<sup>2</sup> Acthar dosing varies depending on the disease and medical condition of the patient, but a typical course of treatment is between three and five vials.<sup>3</sup>

For decades, Acthar was available for less than \$40 per vial. After Questcor acquired the rights to sell Acthar from Aventis in 2001 for a \$100,000 fee plus royalties, it raised the price over several years to \$1,650 per vial by the beginning of 2007.<sup>4</sup> In August 2007, Questcor raised the price of Acthar to more than \$23,000 per vial.<sup>5</sup>

In August 2014, Mallinckrodt acquired the rights to market Acthar by purchasing Questcor in a cash and stock transaction valued at approximately \$5.8 billion.<sup>6</sup> Since the acquisition, Mallinckrodt has raised the price of Acthar an additional five times in five years, collecting nearly \$6 billion in net sales from Acthar over that period.<sup>7</sup>

Mallinckrodt asserts that, since it acquired Acthar, it has made only “modest price adjustments,” and it has pledged that increases in the list price will be less than 10 percent per

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<sup>1</sup> See Food and Drug Administration, *Approved Label for H.P Acthar Gel* (Oct. 2010) (online at [www.accessdata.fda.gov/drugsatfda\\_docs/label/2010/022432s0001b1.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022432s0001b1.pdf)).

<sup>2</sup> *Id.* Mallinckrodt states in public materials that Acthar is “approved for 19 indications.” The FDA label is more precise—it states that it is indicated for two conditions and may be used in 17 other diseases or disorders.

<sup>3</sup> *Id.*

<sup>4</sup> Medispan Price Rx, *Wholesale Acquisition Cost and Average Wholesale Price H.P. Acthar Gel*. Securities and Exchange Commission, *Asset Purchase Agreement between Questcor Pharmaceuticals, Inc. Aventis Pharmaceuticals Product Inc.* (July 27, 2001) (online at [www.sec.gov/Archives/edgar/data/891288/000089843002003069/dex106.htm](http://www.sec.gov/Archives/edgar/data/891288/000089843002003069/dex106.htm)). According to the Asset Purchase Agreement, Questcor paid Aventis a fee and agreed to pay an annual royalty on net sales above a predetermined amount and to acquire inventory at a predetermined price. News articles indicate that the fee was \$100,000. See *Questcor Finds Profits, at \$28,000 a Vial*, New York Times (Dec. 29, 2012) (online at [www.nytimes.com/2012/12/30/business/questcor-finds-profit-for-acthar-drug-at-28000-a-vial.html](http://www.nytimes.com/2012/12/30/business/questcor-finds-profit-for-acthar-drug-at-28000-a-vial.html)).

<sup>5</sup> Medispan Price Rx, *Wholesale Acquisition Cost and Average Wholesale Price H.P. Acthar Gel*.

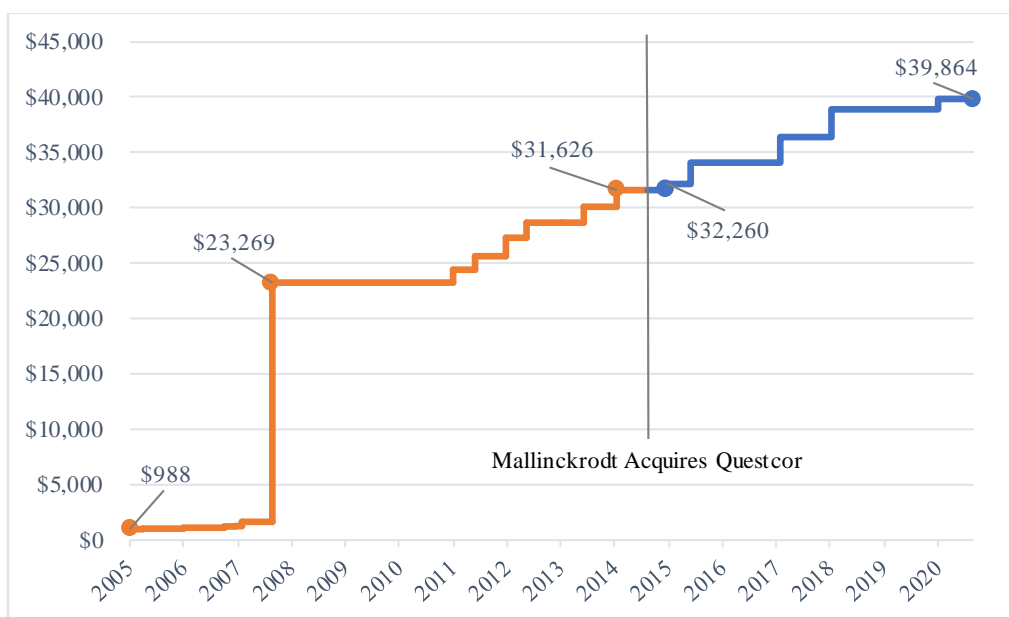
<sup>6</sup> Letter from Hogan Lovells, on behalf of Mallinckrodt Pharmaceuticals, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Feb. 4, 2019).

<sup>7</sup> See MNK-COR-00001947, Page 2; see also Mallinckrodt plc, *2019 Form 10-K* (Feb. 26, 2020) (online at [www.sec.gov/Archives/edgar/data/0001567892/000156789220000005/mnk10-k122719.htm](http://www.sec.gov/Archives/edgar/data/0001567892/000156789220000005/mnk10-k122719.htm)); Mallinckrodt plc, *2018 Form 10-K* (Feb. 26, 2019) (online at [www.sec.gov/Archives/edgar/data/0001567892/000156789219000009/mnk10-k122818.htm](http://www.sec.gov/Archives/edgar/data/0001567892/000156789219000009/mnk10-k122818.htm)); Mallinckrodt plc, *2017 Form 10-K* (Feb., 27, 2018) (online at [www.sec.gov/Archives/edgar/data/0001567892/000156789218000010/mnk10-k122917.htm](http://www.sec.gov/Archives/edgar/data/0001567892/000156789218000010/mnk10-k122917.htm)); Mallinckrodt plc, *2016 Form 10-K* (Nov. 29, 2016) (online at [www.sec.gov/Archives/edgar/data/0001567892/000156789216000098/mnk10-k93016.htm](http://www.sec.gov/Archives/edgar/data/0001567892/000156789216000098/mnk10-k93016.htm)).

year.<sup>8</sup> Despite negative publicity and criticism from payers, patients, and physicians that the price of Acthar is unsustainable, the company has steadily raised the price five times by an average of 6% each time—a cumulative increase of more than \$8,200 per vial since acquiring the drug.<sup>9</sup>

Mallinckrodt currently prices Acthar at \$39,864 per vial.<sup>10</sup> This price is nearly 1,000 times greater than its price of \$40 in 2001.<sup>11</sup> Figure 1 below shows the increase in the price per vial of Acthar from 2005 to the present.

Figure 1: Acthar Price Increases



Internal documents show that Mallinckrodt executives explored strategies to make Acthar seem less expensive—without actually lowering the price—in the face of significant “headwinds” that affected sales in 2017. These headwinds stemmed from legal challenges, increasing scrutiny from payers on reimbursement, and negative media coverage—including coverage of a 2017 FTC settlement over alleged anticompetitive practices.<sup>12</sup>

<sup>8</sup> MNK\_InCamera-000000016085, at Page 2; MNK\_InCamera-000000047617, at Page 3; Mallinckrodt Pharmaceuticals, *Pledge on Drug Pricing and Innovation* (online at [www.mallinckrodt.com/pledge](http://www.mallinckrodt.com/pledge)) (accessed on Sept. 30, 2020).

<sup>9</sup> See, e.g., MNK\_InCamera-000000030207, at Slide 10; MNK\_InCamera-000000123846, at Page 2; Medispan Price Rx, *Wholesale Acquisition Cost and Average Wholesale Price H.P. Acthar Gel*.

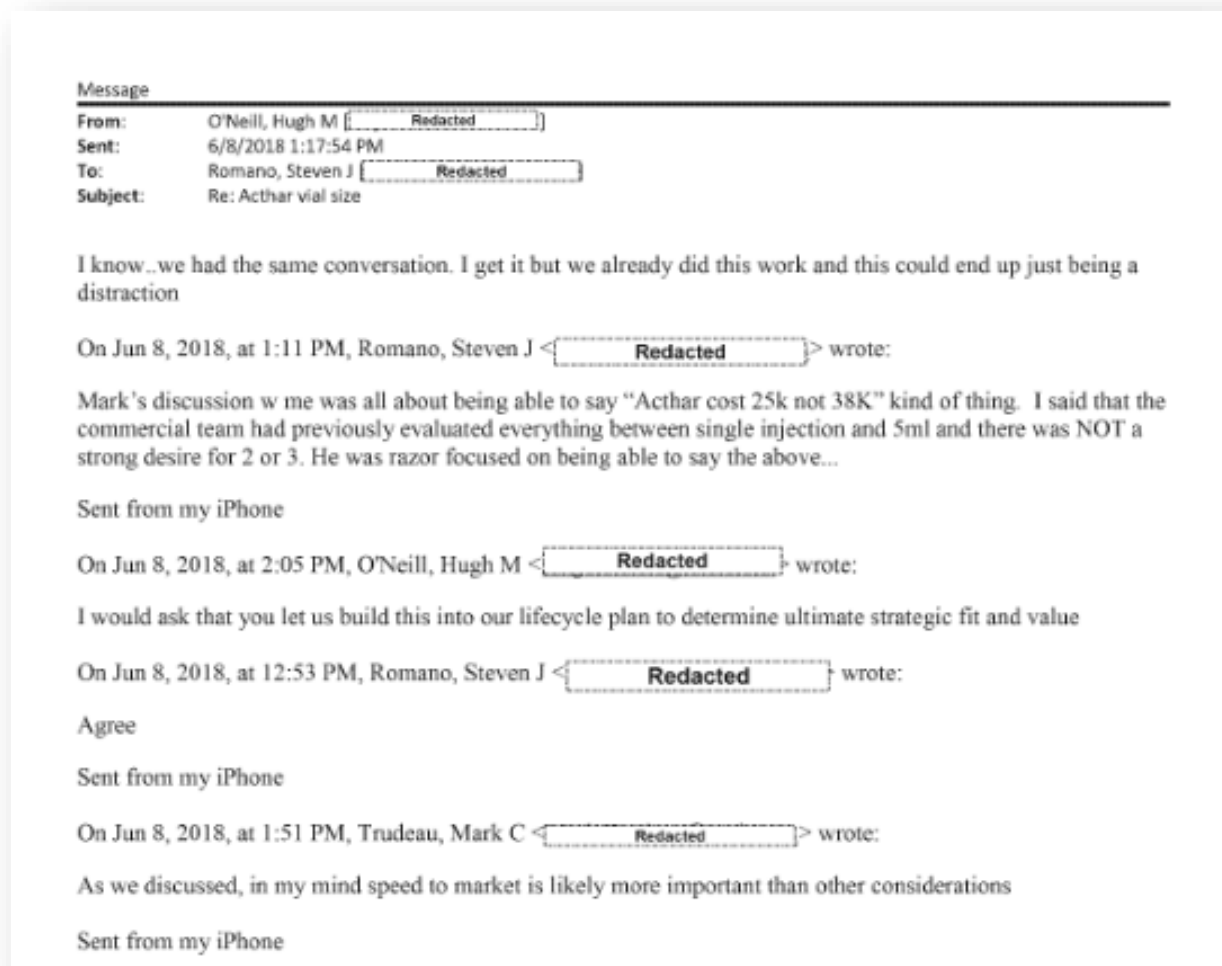
<sup>10</sup> Medispan Price Rx, *Wholesale Acquisition Cost and Average Wholesale Price H.P. Acthar Gel*.

<sup>11</sup> *Id.*; see also *Questcor Finds Profits, at \$28,000 a Vial*, New York Times (Dec. 29, 2012) (online at [www.nytimes.com/2012/12/30/business/questcor-finds-profit-for-acthar-drug-at-28000-a-vial.html](http://www.nytimes.com/2012/12/30/business/questcor-finds-profit-for-acthar-drug-at-28000-a-vial.html)).

<sup>12</sup> MNK\_InCamera-000000051322, at Slide 5.

In June 2018, Mallinckrodt CEO Mark Trudeau directed company leaders to explore the possibility of selling smaller vials of Acthar at a lower price to make the drug seem less expensive. Executive Vice President and Chief Scientific Officer Steve Romano relayed Mr. Trudeau's request and asked executives to develop a plan to market a smaller vial of Acthar. He explained that Mr. Trudeau "was razor focused on being able to say" that "Acthar cost [sic] 25k not 38k [per vial.]"<sup>13</sup>

When Mr. Romano emailed the draft timeline of the project to Mr. Trudeau, Mr. Trudeau replied, "This would seem to be interesting" and added, "in my mind, speed to market is likely more important than other considerations."<sup>14</sup> Mr. Romano replied, "We should definitely discuss the strategic value of pursuing this."<sup>15</sup>



<sup>13</sup> MNK\_InCamera-000000127369, at Page 1.

<sup>14</sup> *Id.*, at Pages 1-2.

<sup>15</sup> *Id.*, at Page 1.

The following month, Executive Vice President Hugh O’Neill proposed a confidential effort called “Project Phoenix” to explore a reduction in Acthar’s price “to change the perception of Acthar and, as importantly, MNK [Mallinckrodt].”<sup>16</sup> Mr. O’Neill emailed CEO Mark Trudeau on July 2, 2018 to describe the proposal:

In light of the compounding noise in the market (media, public, payers, policy, etc.) regarding MNK [Mallinckrodt] and Acthar, I have sponsored a small work team to look at strategic options for Acthar including but not limited to a price reduction. I realize what it would do to the net sales line but we need to quantify the broader impact of the move.<sup>17</sup>

Mr. Trudeau responded: “Always good to look at options. I like the thinking.”<sup>18</sup> Mallinckrodt did not follow through with the price reduction.

Three months later, in September 2018, Mr. Romano proposed another way to make it appear that Mallinckrodt was responding to pressure on Acthar’s price without losing any profit. He asked Mr. O’Neill and Mr. Trudeau, “Could we make a bolder move that would garner appropriate attention but allow us to manage financials—for ex[ample]: ‘we will reduce the list price for Acthar 10% annually blah blah blah.’ I assume we could do this and manage profitability through contract details.”<sup>19</sup>

Mr. O’Neill and Mr. Trudeau responded that they had discussed similar tactics. Mr. Trudeau wrote, “Hugh and I have had similar discussions and I know that he and his team are thinking about options.”<sup>20</sup>

Mallinckrodt did not reduce Acthar’s list price, despite the concerns that led executives to explore ways to obscure the price. Mallinckrodt executives held the price of Acthar steady for a year, primarily to limit negative publicity, and Mallinckrodt raised Acthar’s price by \$1,000 on December 31, 2019.<sup>21</sup>

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<sup>16</sup> MNK\_InCamera-000000135091, at Pages 1-2.

<sup>17</sup> MNK\_InCamera-000000135097, at Page 1.

<sup>18</sup> MNK\_InCamera-000000135101.

<sup>19</sup> MNK\_InCamera-000000117189.

<sup>20</sup> MNK\_InCamera-000000117189.

<sup>21</sup> MNK\_InCamera-000000000052, at Slide 10. Executives recommended a gainst raising the price because of “market scrutiny, future competitive landscape, and changing policy environment.” MNK\_InCamera-000000118343, at Slide 7; Medispan Price Rx, *Wholesale Acquisition Cost and Average Wholesale Price H.P. Acthar Gel*.

## II. CORPORATE PROFITS

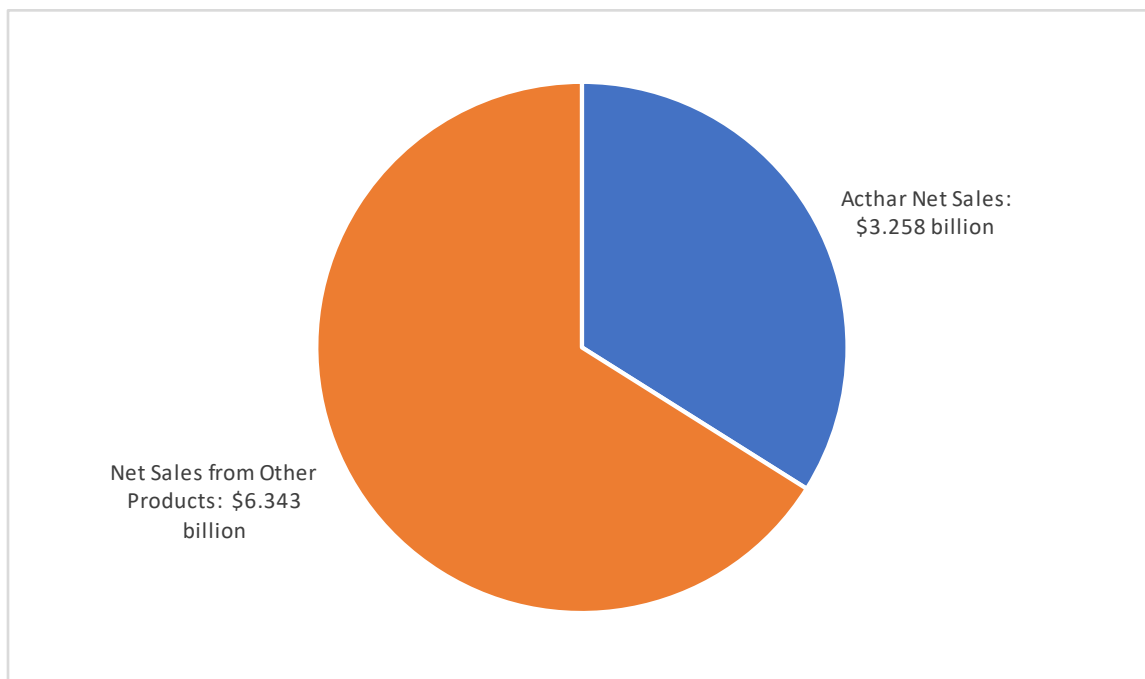
Mallinckrodt has made billions of dollars in revenue from Acthar as it has repeatedly raised its price year after year. Internal documents obtained by the Committee show that Mallinckrodt executives raised Acthar's price as high as possible to meet revenue and earnings goals and to compensate for lower-than-expected sales volumes in certain years.

### A. Acthar Sales Drive Corporate Profits

Mallinckrodt has generated, in total, nearly \$6 billion in net sales from Acthar from the time it acquired the drug from Questcor through end of the 2019 fiscal year.<sup>22</sup> Acthar has contributed to nearly one-third of Mallinckrodt's total net sales each year since 2017.

Figure 2 below reflects Mallinckrodt's net sales for Acthar as a percent of its total sales for 2017 through 2019.<sup>23</sup>

Figure 2: Net Acthar Sales v. Non-Acthar Net Sales from 2017-2019



<sup>22</sup> See MNK-COR-00001947, at Page 2; Mallinckrodt plc, *2019 Form 10-K* (Feb. 26, 2020) (online at [www.sec.gov/Archives/edgar/data/0001567892/000156789220000005/mnk10-k122719.htm](http://www.sec.gov/Archives/edgar/data/0001567892/000156789220000005/mnk10-k122719.htm)).

<sup>23</sup> MNK-COR-00001947, at Page 2; See MNK-COR-00001947, at Page 2; Mallinckrodt plc, *2019 Form 10-K* (Feb. 26, 2020) (online at [www.sec.gov/Archives/edgar/data/0001567892/000156789220000005/mnk10-k122719.htm](http://www.sec.gov/Archives/edgar/data/0001567892/000156789220000005/mnk10-k122719.htm)); Mallinckrodt plc, *2018 Form 10-K* (Feb. 26, 2019) (online at [www.sec.gov/Archives/edgar/data/0001567892/000156789219000009/mnk10-k122818.htm](http://www.sec.gov/Archives/edgar/data/0001567892/000156789219000009/mnk10-k122818.htm)); Mallinckrodt plc, *2017 Form 10-K* (Feb., 27, 2018) (online at [www.sec.gov/Archives/edgar/data/0001567892/000156789218000010/mnk10-k122917.htm](http://www.sec.gov/Archives/edgar/data/0001567892/000156789218000010/mnk10-k122917.htm)). These years reflect the time period when Mallinckrodt's calendar year and fiscal year align, which was not the case for 2015 and 2016.

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

Documents reviewed by the Committee indicate that Mallinckrodt executives raised prices as high as possible to meet financial targets while attempting to minimize negative public attention. For example, in considering how high to raise prices in 2017, Mallinckrodt executives focused on how the proposed increases would impact the bottom line. In January 2017, the company evaluated three different price increases (5%, 6.5%, or 6.9%) based solely on their impact on net sales.<sup>24</sup> The presentation recommended an increase of 6.9%, noting that the impact would be an increase of \$2,348 per vial and “\$33MM positive impact over budget.”<sup>25</sup>

**Acthar Price Increase Considerations and Recommendation**

- ▶ Recommendation
  - ▶ Implement 6.9% price change
  - ▶ Effective date: Close of Business Thursday, January 26, 2017
- ▶ Impact
  - ▶ Revised vial price \$36,382
  - ▶ Increase of \$2,348 per vial
  - ▶ \$33MM positive impact over budget\* (details on next slide)

\*Does not consider potential impact of volume decreases resulting from an increase in price

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Executives recommended this increase despite data illustrating that that the 6.9% price increase would be the largest percent increase since 2011.<sup>26</sup>

When Mallinckrodt executives discussed taking another price increase in 2018, they focused again on the bottom line. As they evaluated increases of 7%, 8%, 9%, or 9.9%, one Mallinckrodt executive offered the following assessment of the company’s pricing approach:

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<sup>24</sup> MNK\_InCamera-000000123912, at Slide 3. Mallinckrodt acknowledged that price increases have the potential to decrease volume.

<sup>25</sup> *Id.*, at Slide 2.

<sup>26</sup> *Id.*, at Slide 4.

Bottom line is any price increase obviously has positive results. Really comes down to what we are comfortable with externally. Personally I would go high. We will receive the same press regardless within these ranges.<sup>27</sup>



Another executive wrote that a price increase of more than 8% had “more risk with less to gain” and might impact sales volumes.<sup>28</sup> Ultimately, the company increased the price in January 2018 by 6.9% to a price of \$38,892 per vial.<sup>29</sup>

Mallinckrodt acknowledged that it used price increases to meet revenue goals when experiencing a decline in sales volume. In a July 2017 email, Executive Vice President Hugh O’Neill wrote, “The vast majority of the projected growth for Acthar in 2017 will come from price appreciation as opposed to volume growth.” He went on to write that the price increase reflected “the need to dig out of the hole created by the significant loss of returning patients.”<sup>30</sup>

Internal talking points for the first quarter of 2017 confirmed Mr. O’Neill’s assessment: “Q1 2017 was a strong quarter with net sales growing 9% vs. prior year (\$272M vs. \$248M prior year), largely driven by price increase.”<sup>31</sup> Another internal document confirmed the same assessment for the second quarter of 2017: “Growth driven by price increase.”<sup>32</sup>

<sup>27</sup> MNK\_InCamera-000000104743, at Page.1. Committee staff redacted the names of junior executives.

<sup>28</sup> MNK\_InCamera-000000023611, at Page 1.

<sup>29</sup> Medispan Price Rx, *Wholesale Acquisition Cost and Average Wholesale Price H.P. Acthar Gel*.

<sup>30</sup> MNK\_InCamera-000000013838.

<sup>31</sup> MNK\_InCamera-000000119302, at Page 1.

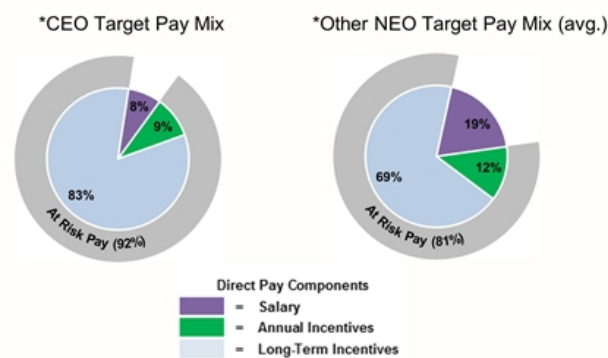
<sup>32</sup> MNK\_InCamera-000000127104, at Slide 4.

### III. EXECUTIVE BONUSES

Company documents show that Mallinckrodt’s top executives were incentivized to raise prices for Acthar. The company’s incentive program for its executive officers links compensation to three major elements: (1) base salary; (2) annual incentive compensation;<sup>33</sup> and (3) long-term incentive compensation.<sup>34</sup> In 2019, 80% of compensation for non-CEO named executive officers was “at-risk pay,” linked to the company’s performance goals and stock value. More than 90% of CEO Mark Trudeau’s direct pay was linked to these performance goals.<sup>35</sup>

Figure 3 below illustrates the major elements of Mallinckrodt’s compensation program for CEOs and executives.

Figure 3: Distribution of Value Among Three Elements of Compensation



Mallinckrodt executives’ annual incentive compensation is linked to each executive’s individual contribution to certain financial measures, including the company’s earnings per share and net sales revenue. In fiscal year 2019, Mallinckrodt assigned a 25% weight to an executive’s contribution to net sales.<sup>36</sup> Given that price increases have contributed to Acthar’s net sales revenue, executives have been incentivized to increase Acthar’s price so they can increase their own bonuses.

Mallinckrodt’s proxy statements have also explicitly linked executive compensation with Acthar’s profitability. For example, the company’s 2019 proxy statement explained that Mr.

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<sup>33</sup> Annual incentive compensation is designed to drive “specific behaviors that foster short-and long-term growth and profitability.” Mallinckrodt plc, *2019 Proxy Statement* (Apr. 2, 2020) (online at <https://mallinckrodt.gcs-web.com/static-files/6370495b-468b-4755-91a7-30d6a9acc994>).

<sup>34</sup> Half of long-term incentive compensation is based on the adjusted net revenue compound annual growth rate, and half is based on shareholder return. Mallinckrodt plc, *2019 Proxy Statement* (Apr. 2, 2020) (online at <https://mallinckrodt.gcs-web.com/static-files/6370495b-468b-4755-91a7-30d6a9acc994>).

<sup>35</sup> Mallinckrodt plc, *2019 Proxy Statement* (Apr. 2, 2020) (online at <https://mallinckrodt.gcs-web.com/static-files/6370495b-468b-4755-91a7-30d6a9acc994>).

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



Trudeau’s lack of salary increases between 2018 and 2019 can be attributed, in part, to “Overall net sales decline [of] 2%, primarily due to continued pressure on Acthar.”<sup>37</sup>

Mallinckrodt’s shareholders have pressured executives to maximize revenue. Recognizing negative scrutiny over Mallinckrodt’s ongoing opioid litigation and Acthar sales, shareholders approved a proposal in 2019 requiring the company to disclose when senior executives have had to forfeit incentive compensation upon a failure to meet key performance indications—including revenue targets.<sup>38</sup>

Mr. Trudeau’s compensation—including base salary, bonuses, stock and option awards, and non-equity incentive compensation—more than doubled after Mallinckrodt acquired Acthar in 2014. Since the acquisition, the average compensation for other named executive officers has increased by 77%. Over that same period, Mallinckrodt increased the price of Acthar by over \$8,000.

Figure 4 below shows Mr. Trudeau’s compensation since the company acquired Questcor in 2014.<sup>39</sup>

**Figure 4: CEO Mark Trudeau Compensation**



<sup>37</sup> *Id.*

<sup>38</sup> *Id.*

<sup>39</sup> See Mallinckrodt plc, *2019 Proxy Statement* (Apr. 2, 2020) (online at <https://mallinckrodt.gcs-web.com/static-files/6370495b-468b-4755-91a7-30d6a9acc994>); Mallinckrodt plc, *2018 Proxy Statement* (Apr. 3, 2019) (online at <https://mallinckrodt.gcs-web.com/static-files/f2836cbe-6079-4cdd-89b3-0dab08afcba9>); Mallinckrodt plc, *2017 Proxy Statement* (Apr. 4, 2018) (online at <https://mallinckrodt.gcs-web.com/static-files/c07f7e2b-4003-41fc-a65b-333d4fb26260>); Mallinckrodt plc, *2016 Proxy Statement* (Jan. 18, 2017) (online at <https://mallinckrodt.gcs-web.com/static-files/3d618123-566f-4b3a-aea6-782bbcd62fd5>); Mallinckrodt plc, *2015 Proxy Statement* (Jan. 22, 2016) (online at <https://mallinckrodt.gcs-web.com/static-files/1aec45d1-baf5-49cd-ae0b-1b0170cedb4b>); Mallinckrodt plc, *2014 Proxy Statement* (Dec. 19, 2014) (online at <https://mallinckrodt.gcs-web.com/static-files/a4313a2e-a8bd-4c72-b0f0-31cdd31445d9>).

#### IV. ACQUISITION DRIVEN BY HIGH PRICE AND PROFIT MARGINS

Mallinckrodt has sought to blame Questcor for price increases for Acthar. For example, talking points prepared for CEO Mark Trudeau to respond to a *60 Minutes* story on Acthar stated:

The previous owner of the product—while facing financial insolvency—raised the price on the compound *significantly* 10 years ago, as part of a survival strategy to keep it on the market. As a result, there continues to be focus—much of it unwarranted—on the compound and its history.<sup>40</sup>

In a call with investors in 2017, Mr. Trudeau stated: “The pricing actions that were taken previously, under Questcor’s ownership, happened more than a decade ago.”<sup>41</sup> In response to a question about pricing, he argued:

There does seem to be some confusion in the marketplace about what Mallinckrodt has done on pricing, what was done historically under Questcor’s ownership. Recognize under Mallinckrodt’s ownership, our pricing approach to Acthar has been very modest and it’s consistent with our corporate pledge.<sup>42</sup>

In another example, a media statement prepared to respond to questions about Acthar’s 2017 price increase claimed that Acthar is not an example of “pharmaceutical price gouging” because “the last significant price increase on Acthar was nine years ago in 2007—seven full years before Mallinckrodt acquired it.”<sup>43</sup>

Yet, the documents reviewed by the Committee show that Mallinckrodt purchased Questcor primarily because of Acthar’s high price and expected profit margins, and that Acthar quickly delivered on expectations. Mallinckrodt then proceeded to raise Acthar’s price even further.

##### A. Acthar’s Orphan Drug Status and High Price

Mallinckrodt pursued the Questcor acquisition in part because it saw a market opportunity to capitalize on Acthar’s high price increase by aggressively expanding the market for Acthar to other approved uses with larger patient populations.

FDA granted Acthar an orphan drug designation in 2003 to research its use in treating infantile spasms, a rare form of epilepsy that affects about 2,000 children in the United States

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<sup>40</sup> MNK\_InCamera-000000136209.

<sup>41</sup> MNK\_InCamera-000000124567, at Page 10.

<sup>42</sup> *Id.*

<sup>43</sup> MNK\_InCamera-000000125058, at Page 2.

every year.<sup>44</sup> Orphan drug designations are intended to spur investment and innovation in rare disease therapies that typically target fewer than 200,000 patients, and they come with tax credits for research and development (R&D), as well as extended market exclusivity if products receive FDA approval to bring them to market.<sup>45</sup>

When Questcor was near bankruptcy in 2007, the company raised the price of Acthar to a level “they believed was in line with orphan drug pricing” in order to keep the drug on the market for children afflicted with infantile spasms.<sup>46</sup> In 2010, FDA approved Acthar for the treatment of infantile spasms and granted orphan drug exclusivity—a seven-year market exclusivity for the designated use.<sup>47</sup>

Mallinckrodt’s pre-acquisition documents emphasized that Questcor had leveraged the 2010 orphan drug exclusivity for infantile spasms to raise the price of Acthar again, despite the fact that the drug was by that time marketed for a number of other indications that did not have orphan drug status because of their larger patient populations.<sup>48</sup>

One internal presentation included a slide on “Acthar Pricing” that noted: “New CEO adopted aggressive pricing strategy based on Orphan designation,” “Pricing strategy contributes to company’s growth,” and “Price increment due to orphan designation for IS [infantile spasms]; same leveraged for other indications (MS and NS).” This document also noted that, after Acthar received orphan drug exclusivity in 2010, the company increased the price by 5% three separate times within an 18-month period.<sup>49</sup>

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<sup>44</sup> Food and Drug Administration, *Orphan Drug Designations and Approval* (online at <https://www.accessdata.fda.gov/scripts/opdlisting/ood/>) (accessed on Sept. 3, 2020).

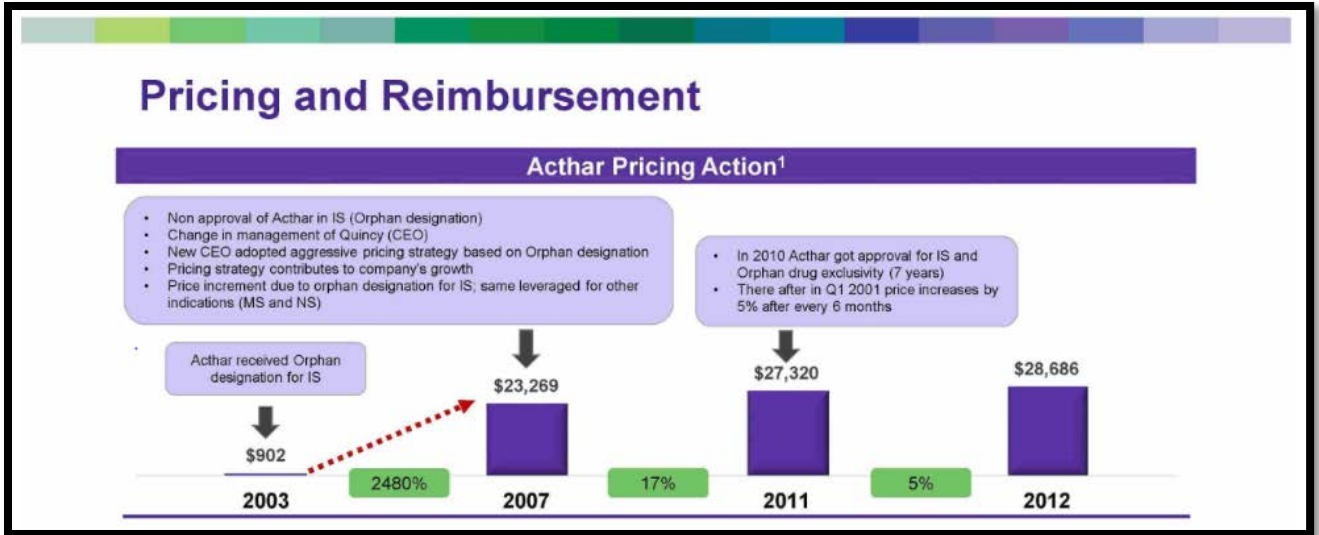
<sup>45</sup> In documents reviewed by the Committee, Mallinckrodt notes that it has used Orphan Drug Credits related to Acthar to reduce its tax burden. *See, e.g.*, MNK-COR-00001894. In 2013, FDA granted Mallinckrodt’s request for orphan status to use Acthar in patients with a myotrophic lateral sclerosis (ALS), also known as Lou Gehrig’s disease. *See* Food and Drug Administration, *Orphan Drug Designations and Approval* (online at [www.accessdata.fda.gov/scripts/opdlisting/ood/detailedIndex.cfm?cfgridkey=20133991](https://www.accessdata.fda.gov/scripts/opdlisting/ood/detailedIndex.cfm?cfgridkey=20133991)) (accessed Sept. 3, 2020). Mallinckrodt initiated a Phase 2 trial to assess the efficacy of Acthar to treat this disease, but the study was terminated in 2019 because of safety issues. *See Mallinckrodt Halts Phase 2B Trial Investigating the Use of Acthar Gel (Repository Corticotropin Injection) in Amyotrophic Lateral Sclerosis (ALS)*, PRNewswire (July 16, 2019) (online at [www.prnewswire.com/news-releases/mallinckrodt-halts-phase-2b-trial-investigating-the-use-of-acthar-gel-repository-corticotropin-injection-in-amyotrophic-lateral-sclerosis-als-300886128.html](https://www.prnewswire.com/news-releases/mallinckrodt-halts-phase-2b-trial-investigating-the-use-of-acthar-gel-repository-corticotropin-injection-in-amyotrophic-lateral-sclerosis-als-300886128.html)).

<sup>46</sup> Letter from Hogan Lovells, on behalf of Mallinckrodt Pharmaceuticals, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Feb. 4, 2019); MNK\_InCamera-00000024471, at Page 1. In August 2007, Questcor raised the price from \$1,650 per vial to \$23,289.

<sup>47</sup> Food and Drug Administration, *Orphan Drug Designations and Approval* (online at [www.accessdata.fda.gov/scripts/opdlisting/ood/](https://www.accessdata.fda.gov/scripts/opdlisting/ood/)) (last accessed Sept. 3, 2020).

<sup>48</sup> MNK\_InCamera-000000128172, at Slides 9 and 21.

<sup>49</sup> *Id.*, at Slide 9.



Although Mallinckrodt has sought to deflect blame to Questcor for Acthar’s price increases, internal documents show that Mallinckrodt executives were aware that Questcor had “adopted aggressive pricing strategy’ based on Acthar’s Orphan designation” and planned to expand marketing the drug for other indications at the same price.<sup>50</sup>

For example, one document indicated that Mallinckrodt pursued the Acthar acquisition in part because Questcor’s orphan drug designation allowed Questcor to set a “premium price” that could then be leveraged for larger patient populations.<sup>51</sup> Documents provided to the Committee demonstrate that Mallinckrodt sought to drive revenue growth by expanding Acthar’s sales volumes across its non-orphan indications, primarily through aggressive marketing to providers and patients, as discussed in Section VI below.

Before the acquisition, an outside consultant warned Mallinckrodt that it might face challenges justifying Acthar’s premium price if it expanded the drug to indications with large patient populations. The consultant noted that Questcor may have been able to justify its price increase in 2007 because the “price was necessary solely to insure [sic] supply for IS [infantile spasms], but was then followed by an unforeseeable expansion in use.” The consultant cautioned Mallinckrodt, however, that the “same narrative cannot be used with the same degree of plausibility by an acquirer of Questcor.”<sup>52</sup>

<sup>50</sup> *Id.*

<sup>51</sup> See, e.g., MNK\_InCamera-000000070570, at Page 1.

<sup>52</sup> MNK\_InCamera-000000131863, at Slide 22.

## Sociopolitical

- Public, turned to political, reaction to high prices of drugs in general, and drugs for rare, life-threatening, diseases in particular, amplified by “over night” price escalation of Acthar.
- Questcor’s defense: price was necessary solely to insure supply for IS, but was then followed by an unforeseeable expansion in use. Once successful at high price-point, fiduciary responsibility to shareholders precluded price reduction.
- The same narrative cannot be used with the same degree of plausibility by an acquirer of Questcor.

### **B. Acthar as “Cash Cow”**

Mallinckrodt acquired Questcor in August 2014 for \$5.8 billion. The company told investors that the acquisition was part of its strategic plan to increase profits and divest lower-margin, slower-growing businesses.<sup>53</sup>

Mallinckrodt executives consistently described Acthar to investors as a “durable asset with significant growth potential” that offered the fastest way for Mallinckrodt to meet its financial goals.<sup>54</sup> Company talking points prepared just after acquisition described the deal as “executing against our strategic plan, with a focus on driving revenues, increasing profit margins and growing shareholder value.”<sup>55</sup>

Internal documents reveal that, both before and after acquisition, Mallinckrodt executives viewed Acthar as a product that would enable the company to quickly achieve its revenue goals. In internal documents, Mallinckrodt executives described the potential acquisition of Questcor (codename “Quincy”) as “a unique opportunity that should be pursued urgently” because the “Deal would provide rapid revenue and earnings growth in the short- and medium-term.”<sup>56</sup> Pre-acquisition analysis prepared for the Board in March 2014 described Acthar as a “premium-priced product” with a “robust cash flow profile.”<sup>57</sup>

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<sup>53</sup> MNK-COR-00001283.

<sup>54</sup> *See, e.g.*, MNK-COR-00001314.

<sup>55</sup> MNK\_InCamera-000000135171, at Page 8.

<sup>56</sup> MNK\_InCamera-000000128109, at Slide 6.

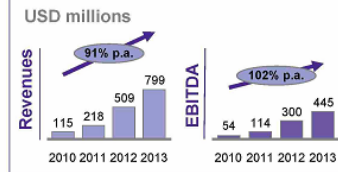
<sup>57</sup> MNK\_InCamera-000000142599, at Slides 3 and 4.

## Quincy is a rapidly growing specialty pharmaceutical company with a premium-priced product

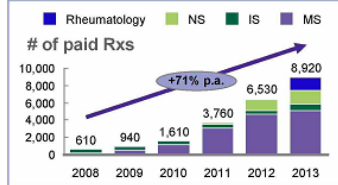
### Company overview

- Quincy is focused on serious, difficult-to-treat autoimmune and inflammatory disorders
- H.P. Acthar Gel is a repository corticotropin injection with 19 approved indications in 4 markets:
  - Acute exacerbations of **multiple sclerosis (MS)**
  - Proteinuria in idiopathic types of **Nephrotic Syndrome (NS)**
  - Infantile spasms (IS)** in children < 2 years old
  - Rheumatology** related conditions; polymyositis (PM) and dermatomyositis (DM), with potential for new on-label indications
- Manufacturing process** is a trade secret
- Employees:** ~560 as of Jan 31, 2013 (sales force of ~230)

### Historical revenues and earnings



### Prescription trends show historical growth in existing and new indications



Source: Barclays analysis; Quincy Earnings Conference, February 25, 2014



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## Quincy transaction would increase our scale and support key strategic initiatives for the combined portfolio

*A broad-based specialty pharma with a differentiated growth strategy*

### NewCo

- Scale: potential market cap exceeding \$9B with EBITDA approaching \$1B and greater capacity to grow organically and inorganically
- Strong, double-digit growth on both top and bottom lines with competitive positions through (at least) the end of the decade
- Irish domicile and global footprint
- Multiple growth platforms in inflammation/immunotherapies, specialty generics/API, hospital products, and office-based pain/controlled substances
- Combined management team and board that can craft and execute strategy

Mallinckrodt and Quincy have complementary strengths



- Specialty focus in difficult to manufacture and controlled substances
- Optimal tax structure
- Global footprint
- Integrated supply chain

### Quincy

- Protected franchise with significant growth potential
- Robust cash flow profile
- Strong record of execution



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The presentation also noted that the acquisition would enable Mallinckrodt to “Achieve aspirational goals with a single transaction.”<sup>58</sup>


<sup>58</sup> *Id.*, at Slide 16.

WHY QUINCY?

**The possible transaction with Quincy is a unique opportunity**

Quincy 

<i>Why Quincy?</i>	<i>Why now?</i>
<ul style="list-style-type: none"> <li>▪ Highly profitable company with unrivaled growth prospects among peers</li> <li>▪ Good strategic fit</li> <li>▪ Excellent size match with Mallinckrodt</li> <li>▪ Achieve aspirational goals with a single transaction</li> <li>▪ Best use of tax advantage of domicile</li> <li>▪ Social issues straightforward</li> </ul>	<ul style="list-style-type: none"> <li>▪ Willingness to strike an immediate deal</li> <li>▪ Highly active and competitive M&amp;A environment with a dwindling number of mid-sized targets</li> <li>▪ Deal would provide rapid revenue and earnings growth</li> <li>▪ Debt markets are currently very attractive</li> </ul>

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Soon after the Questcor acquisition, Mallinckrodt executives boasted about how well this strategy was working. In earnings scripts at the end of the fourth quarter of 2014, Mallinckrodt executives highlighted that Acthar had contributed \$123 million towards net sales in just the six weeks since it acquired the product in mid-August.<sup>59</sup>

In an investor briefing in October 2014, CEO Mark Trudeau emphasized that Mallinckrodt’s primary goal was to deliver “top-level shareholder returns” by focusing on “highly profitable” specialty drugs and noted that the margins from specialty pharmaceuticals are typically higher than average.<sup>60</sup> In that same briefing, Gary Phillips, then-Senior Vice President and President of Autoimmune and Rare Diseases, said Acthar “is a product which is approaching \$1 billion in revenue; it is growing [sic] double digit rates.”<sup>61</sup>

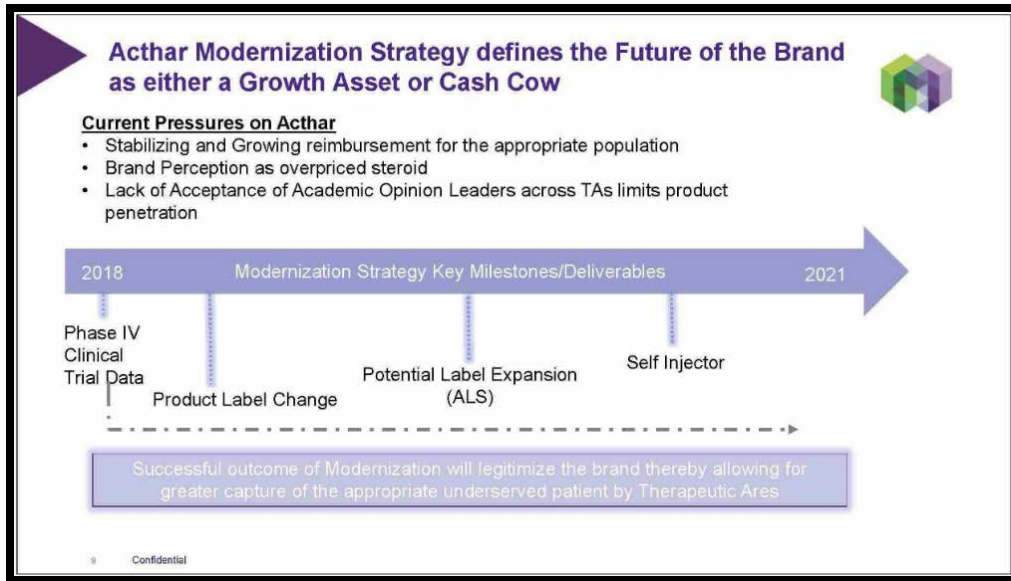
A commercial strategic plan prepared for the Board in 2018 provides the clearest insight into Mallinckrodt’s internal view of Acthar’s potential. The first slide of a draft strategic plan being prepared for the Board of Directors initially read: “Acthar Modernization Strategy Defines the Future of the Brand as either a Growth Asset or Cash Cow.”<sup>62</sup>

<sup>59</sup> MNK-COR-00001446.

<sup>60</sup> MNK\_InCamera-000000129996, at Page 4.

<sup>61</sup> *Id.*, at Page 8.

<sup>62</sup> MNK\_InCamera-00000045618, at Slide 9; *see also* MNK\_InCamera-000000045539, Slide 9.



In discussing the presentation, one executive asked, “do we really want to say ‘cash cow’ to the board?” Mr. O’Neill, who was then the company’s Chief Commercial Officer, responded, “Instead of ‘cash cow,’ I will replace it with profit maximizer.”<sup>63</sup>

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

Internal documents show that Mallinckrodt was aware of the burden Acthar’s high price places on U.S. patients. Documents also show that Mallinckrodt charges Medicare more than any other payer and that the company has relied on Medicare for a growing share of sales in recent years. Mallinckrodt expects that, by 2025, Medicare will make up as much as 70%-75% of Acthar sales.

##### A. Harm to U.S. Patients

Mallinckrodt’s price increases for Acthar have imposed thousands of dollars in out-of-pocket costs on U.S. patients and left many unable to afford the drug. The average out-of-pocket cost for a Medicare beneficiary on Acthar was \$8,007 in 2015.<sup>64</sup> This is more than double what it was in 2011, before Mallinckrodt acquired the drug.<sup>65</sup>

<sup>63</sup> MNK\_InCamera-000000116094, at Page 1. The language “cash cow” was removed in the final presentation for the Board. MNK\_InCamera-000000116096, at Slide 9.

<sup>64</sup> In 2011, the average out-of-pocket cost for a Medicare beneficiary on Acthar was \$3,555. Centers for Medicare and Medicaid Services, *Medicare Part D Drug Spending Dashboard and Data, Historical Data* (online at [www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD/Historical\\_Data](http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD/Historical_Data)); see also MNK\_InCamera-000000020263 (noting that, for non-low-income subsidized Medicare patients, the share of Acthar cost per patient is \$8,000).

<sup>65</sup> *Id.*



Mallinckrodt informed the Committee that any “changes in the product’s list or discounted price would likely have little or no impact on the out-of-pocket costs of Medicare beneficiaries.”<sup>66</sup> However, in 2017—when Mallinckrodt raised the price of Acthar by more than \$2,000—Medicare beneficiaries’ average annual out-of-pocket cost for Acthar was \$12,030—higher than any other drug that year.<sup>67</sup>

Internal documents show that Mallinckrodt regularly received complaints from patients about Acthar’s high price and requests for assistance in affording the drug. For example:

- One father contacted Mallinckrodt’s medical information line to ask for help with the cost of his son’s treatment for infantile spasms. The father reported that his son’s doctor ordered a six-week treatment of Acthar requiring six vials of the drug, but his insurance plan only covered four vials. The father wrote: “We are in a serious bind here. Your medication is extremely expensive and we are unable to afford the 80,000 dollars needed for the remaining 2 vials.”<sup>68</sup>
- Another patient called Acthar patient support to express frustration with Acthar’s increasing price. The multiple sclerosis patient, who said that she had never made a call like this before, said: “My cost in 1978 was \$35. I got my summary for the last quarter. We use CVS Silver Script. It said \$166K.” The patient further said, “I think it’s a ripoff. I think it’s illegal. I’m upset. What is going on? I have to go to the assistance fund.”<sup>69</sup>
- Another complaint came from a market assistant at Walmart who expressed frustration with the price on behalf of a patient: “The cost of this drug, even with insurance coverage makes this necessary drug completely unattainable for this patient.”<sup>70</sup>

## **B. Burden on Medicare and Taxpayers**

Acthar’s high price has placed a significant burden on the U.S. health care system and on taxpayers. Documents and information reviewed by the Committee indicate that Medicare pays significantly more for Acthar than any other payer, and that, in recent years, Mallinckrodt has relied on Medicare for a growing share of Acthar sales.

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<sup>66</sup> Letter from Hogan Lovells, on behalf of Mallinckrodt Pharmaceuticals, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Mar. 29, 2019).

<sup>67</sup> Kaiser Family Foundation, *How Many Medicare Part D Enrollees Had High Out-of-Pocket Drug Costs in 2017?* (July 21, 2019) (online at [www.kff.org/medicare/issue-brief/how-many-medicare-part-d-enrollees-had-high-out-of-pocket-drug-costs-in-2017/](http://www.kff.org/medicare/issue-brief/how-many-medicare-part-d-enrollees-had-high-out-of-pocket-drug-costs-in-2017/)).

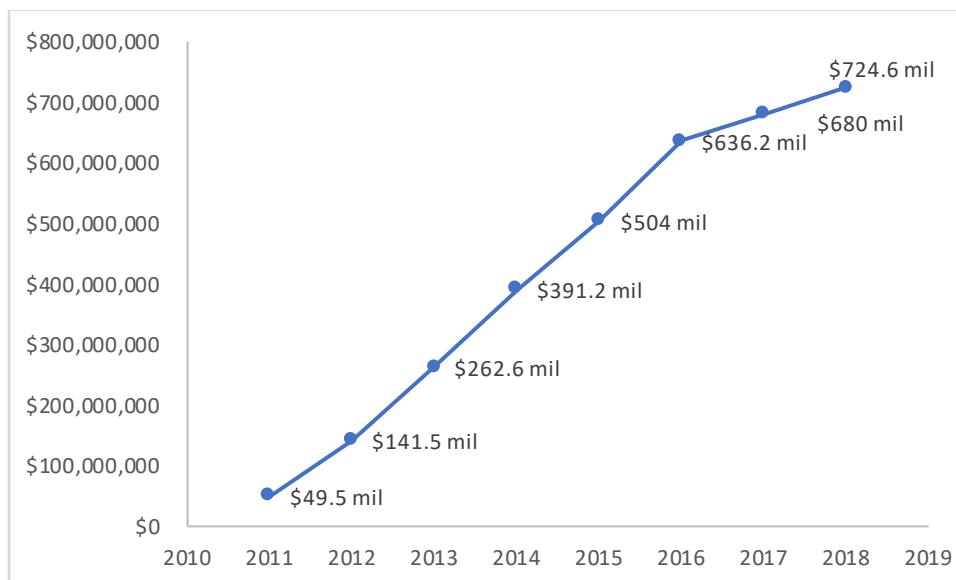
<sup>68</sup> MNK-COR-00001949, at Page 7.

<sup>69</sup> *Id.*, at Page 8. One of the assistance programs, the Acthar Independent Charitable Foundation, provides funding for government-insured patients seeking financial support.

<sup>70</sup> *Id.*, at Page 10.

In 2018, Medicare Part D plans spent more than \$700 million on Acthar—up by more than \$220 million since 2015 and more than 14 times higher than in 2011.<sup>71</sup> From 2015 to 2018, Medicare spent a total of more than \$2.5 billion on Acthar. Figure 5 below illustrates the growth in Medicare Part D spending on Acthar since 2011.

Figure 5: Medicare Part D Spending on Acthar



Although the above figure does not include rebates Mallinckrodt paid to Medicare, those rebates were miniscule and averaged less than 1% from 2015 to 2018. In contrast, Tricare rebates averaged 26.6%.

Medicare therefore paid thousands of dollars more per vial than any other payer—in 2018, Medicare’s average net price per vial was \$4,300 more than commercial payers, \$10,000 more than Tricare, and over \$17,000 more than Medicaid.<sup>72</sup> If Medicare had received the discounts on Acthar that Tricare received, taxpayers would have saved over \$656 million from 2014 to 2018. Figure 6 below highlights the differences in these discounts and the potential savings.

<sup>71</sup> Centers for Medicare and Medicaid Services, *Medicare Part D Drug Spending Dashboard and Data, Historical Data* (online at [www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Historical\\_Data](http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Historical_Data)) (accessed on Aug. 13, 2020). Medicare Part D Spending Dashboard does not reflect manufacturer rebates and price concessions, but as noted in Section VIII, these discounts were relatively limited.

<sup>72</sup> MNK\_InCamera-000000142895, at Page 1.

Figure 6: Lost Medicare Part D Savings on Acthar

Acthar						
Year	Gross Medicare Part D Sales	Average Part D Discount %	Net Part D Expenditures	Average Tricare Discount %	Net Part D Expenditures if Tricare Discount	Lost Part D Savings
2015	\$503,999,371.37	0.35%	\$ 502,235,373.57	25.7%	\$ 374,471,532.93	\$ 127,763,840.64
2016	\$636,174,839.71	0.50%	\$ 632,993,965.51	29.39%	\$ 449,203,054.32	\$ 183,790,911.19
2017	\$680,958,459.15	0.55%	\$ 677,213,187.62	23.02%	\$ 524,201,821.85	\$ 153,011,365.77
2018	\$724,638,119.00	1.87%	\$ 711,087,386.17	28.3%	\$ 519,348,139.89	\$ 191,739,246.29
<b>Total</b>	<b>\$ 2,545,770,789.23</b>	<b>0.87%</b>	<b>\$ 2,523,529,912.88</b>	<b>26.65%</b>	<b>\$1,867,224,548.99</b>	<b>\$ 656,305,363.89</b>

Although companies selling drugs with very small patient populations sometimes set higher prices to recover their costs, Acthar’s price is much higher than other Medicare Part D drugs with similar patient populations. A recent study examined the most expensive Medicare drugs and number of beneficiaries and found that Acthar is a “conspicuous outlier” compared to other Medicare drugs. The study concluded that “although it was prescribed for about 3,000 Medicare Part D beneficiaries in 2016, it was priced like a drug with at most a tenth as many potential beneficiaries.”<sup>73</sup>

Since 2015, an increasing share of Mallinckrodt’s sales for Acthar have come from Medicare. Around the time of acquisition, Medicare accounted for approximately 25% of Acthar’s overall business.<sup>74</sup> But that grew quickly. A July 2017 draft strategic plan reported that Medicare contributed 50% of Acthar vials sold for the year to date, driven by rheumatology, nephrology, and pulmonology patients.<sup>75</sup> Documents provided to the Committee indicate that, in 2018, Medicare accounted for 55% of Acthar vials sold and constituted more than 60% of Mallinckrodt’s net sales from Acthar.<sup>76</sup> Figure 7 below shows the contribution of sales through Medicare Part D to Mallinckrodt’s overall Acthar net sales.

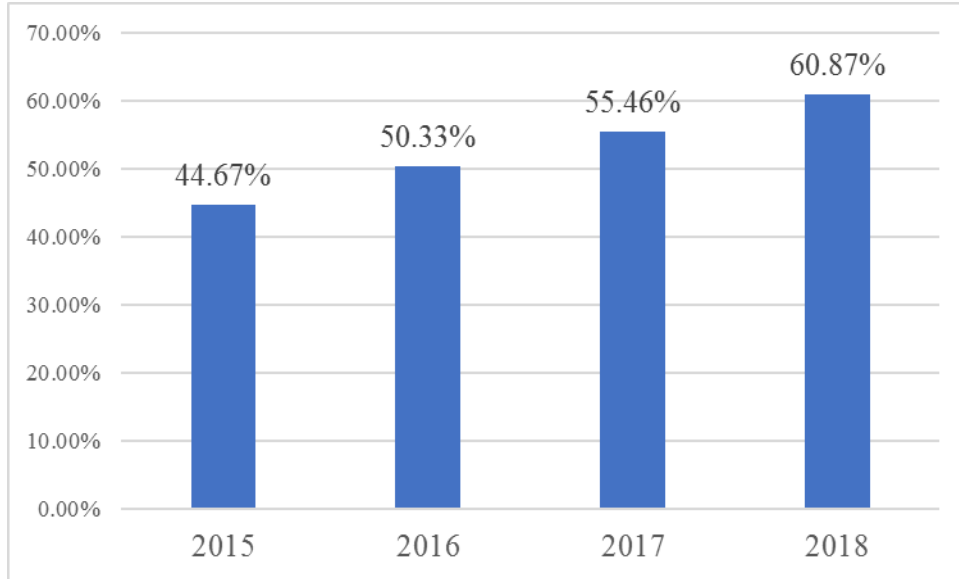
<sup>73</sup> Daniel Hartung et al., *Repository Corticotropin Versus Glucocorticoid for Nephrotic Syndrome: When Will We See the Evidence?*, American Journal of Kidney Diseases (Feb. 11, 2019) (online at <https://pubmed.ncbi.nlm.nih.gov/30765104/>).

<sup>74</sup> MNK\_InCamera-000000135183, at Page 5.

<sup>75</sup> MNK\_InCamera-000000030207, at Slide 12. The presentation reported that nearly 60% of patients with commercial insurance were under contract for Acthar, but the company expected flat or declining patients with commercial insurance through the end of the year due to payer pressure until an “indication flexible contracting strategy” could be executed.

<sup>76</sup> MNK\_InCamera-000000142895, at Page 2.

Figure 7: Medicare Part D Contributions to Mallinckrodt’s Total Acthar Net Sales<sup>77</sup>



Long-term planning documents indicate that Mallinckrodt expects Medicare to contribute an even greater percentage of its sales in future years—estimating that competition and other pressures would reduce the share of commercial payers and could result in Medicare accounting for as much as 70%-75% of Acthar’s sales by 2025.<sup>78</sup>

A 2018 draft business narrative explained that one reason that Medicare’s costs for Acthar continue to escalate is because Medicare plans are required to approve payment for Acthar despite skepticism about the drug’s clinical value. The document noted that “Acthar currently has higher than average approval rates in Medicare Part D business, with approvals in the 85% range,” which compares to average commercial rates of approximately 45% among the same plan sponsors.<sup>79</sup>

The document acknowledged that these approvals were not based on greater clinical acceptance, but on regulatory limitations on Medicare:

However, these approvals are not based on plan sponsor clinical acceptance of Acthar, but rather limitations in the effectiveness of utilization management techniques, such are [sic] cost differentials. In addition a regulated and uniformed appeals process that ultimately results in the approval of any product with and [sic] FDA approval.<sup>80</sup>

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<sup>77</sup> *Id.*

<sup>78</sup> MNK\_INCamera-000000045618, at Slide 10; *see also* MNK\_INCamera-000000067071, at Slide 3.

<sup>79</sup> MNK\_InCamera-000000063852, at Slide 3.

<sup>80</sup> *Id.*

The narrative concluded, “If plan sponsors were granted the ability to manage Part D exactly as they manage commercial books of business this would have a significant impact on Acthar.”<sup>81</sup>

Mallinckrodt’s pricing practices for Acthar have strained local governments. Several cities have complained that the exorbitant price of Acthar has impacted their entire budgets. For example:

- In 2017, the City of Rockford, Illinois sued Mallinckrodt alleging federal antitrust violations and unconscionable trade practices.<sup>82</sup> In an interview with *60 Minutes*, the Mayor of Rockford said that Acthar financially crippled the city after two children of city employees were prescribed the drug. He said that because the city spent close to \$500,000 on Acthar for these two children, he had to squeeze other essential city functions, such as “hiring police and firefighters, keeping firetrucks and other equipment on the street.” According to this report, the city’s “health care budget was going bust,” and the city was “bleeding money.” The mayor described the effect of the drug’s exorbitant prices as “exploiting children” and “abusing taxpayers.”<sup>83</sup>
- The Director of Human Resources and Risk Management for Marietta, Georgia also complained that the exorbitant cost of Acthar was impacting the city’s budget. In 2017, he emailed CEO Mark Trudeau to complain that one citizen’s Acthar prescription cost the city \$500,000 per year, impacting premiums for all employees. He wrote, “We can’t sustain this. We have gone over budget and have had to raise the premiums on all of our employees and pre-age 65 retirees because of this one drug. This is maddening.”<sup>84</sup> He implored Mr. Trudeau to help “alleviate the burden on the employees (and incidentally, the taxpayers) of the City of Marietta.”<sup>85</sup> In February 2020, the city filed a class action complaint against Mallinckrodt—on behalf of third-party payers and their beneficiaries—on the grounds that the city had paid \$2 million to cover the cost of Acthar for an employee and that Mallinckrodt is being unjustly enriched.<sup>86</sup>

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<sup>81</sup> *Id.*, at Slides 3-4.

<sup>82</sup> *City of Rockford v. Mallinckrodt ARD, Inc.*, 360 F. Supp. 3d 730 (N.D. Ill. 2019).

<sup>83</sup> *60 Minutes: The Problem with Prescription Drug Prices*, CBS News (May 6, 2018) (online at [www.cbsnews.com/video/the-problem-with-prescription-drug-prices/](http://www.cbsnews.com/video/the-problem-with-prescription-drug-prices/)).

<sup>84</sup> MNK\_InCamera-000000127175.

<sup>85</sup> *Id.*

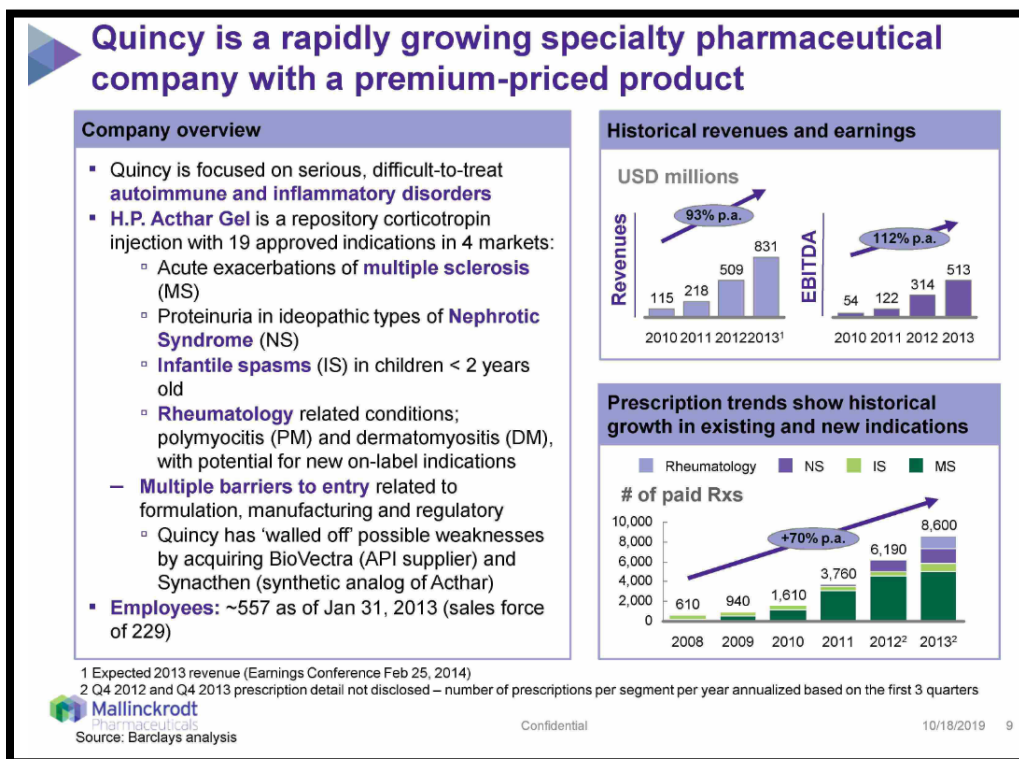
<sup>86</sup> Complaint (Feb. 6, 2020), *City of Marietta v. Mallinckrodt ARD LLC*, N.D. Ga. (No. 1:20-cv-00552); see also Mallinckrodt plc, *2019 Form 10-K* (Feb. 26, 2020) (online at <https://mallinckrodt.gcs-web.com/static-files/d761443c-4f66-4d85-8aea-3b299f918b05>).

## VI. TACTICS TO MAXIMIZE PROFITS

Mallinckrodt acquired Questcor in part because it expected to be able to charge high prices for Acthar without competition, while significantly expanding Acthar’s use beyond its original orphan patient population. In the years following acquisition, Mallinckrodt engaged in an aggressive physician marketing campaign to maximize profits from Acthar.

### A. Stifling Competition by Acquiring Competitor

Documents reviewed by the Committee show that when Mallinckrodt acquired Questcor, it expected little to no competition for Acthar. In researching whether to acquire Questcor, Mallinckrodt’s market assessment concluded that Acthar “will face limited/no competition in future.”<sup>87</sup> Mallinckrodt’s transaction team explained that there were “multiple barriers to entry related to formulation, manufacturing, and regulatory” and that Questcor had also “walled off” possible competition, in part by acquiring the supplier of the active pharmaceutical ingredient for Acthar.<sup>88</sup>



Mallinckrodt assured investors that Acthar would not face generic competition. In investor presentations after acquisition, Mallinckrodt noted, “Current regulatory guidelines drive

<sup>87</sup> MNK\_InCamera-000000128172, at Slide 22.

<sup>88</sup> MNK\_InCamera-000000128109, at Slide 9; *see also* MNK\_InCamera-000000128172, at Slide 7; MNK\_InCamera-000000142572, at Slide 23 (noting that Questcor created an “integrated supply chain” with a single partner for distribution and a sole source supplier of the finished product).

complicated development and make a generic unlikely.”<sup>89</sup> A presentation prepared for Mallinckrodt’s board of directors prior to acquisition highlighted several factors that made competition unlikely, including “Biologic formulation that is hard to replicate,” “Undisclosed composition with impurities that would need to be replicated in a generic version,” and a complex manufacturing process that would make a generic challenging to create.<sup>90</sup>

In a 2017 discussion with investors, Mallinckrodt’s Executive Vice President and Chief Scientific Officer Steven Romano explained that FDA standards for placebo-controlled trials make it “essentially impossible” to develop a competitor to Acthar.<sup>91</sup>

Mallinckrodt executives noted that Questcor had walled off potential competition by acquiring the rights to market Synacthen, Acthar’s closest competitor drug, in 2013.<sup>92</sup> Documents show that Mallinckrodt viewed Questcor’s acquisition of Synacthen as an advantage of the deal, even though the FTC had launched an investigation in 2014 into the Synacthen acquisition as potentially anti-competitive.<sup>93</sup>

FTC alleged that Questcor “stifled competition” by acquiring the Synacthen assets in order to prevent other bidders from developing the alternative drug to sell at a “significant discount to Acthar’s price,” in violation of antitrust laws.<sup>94</sup> FTC Chairwoman Edith Ramirez alleged that “to maintain its monopoly pricing, [Questcor] acquired the rights to its greatest competitive threat, a synthetic version of Acthar, to forestall future competition.”<sup>95</sup> FTC also noted that the “supracompetitive price that Questcor charges for Acthar and its restriction of Acthar’s output are direct evidence of this monopoly power” and that “Questcor has encountered

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<sup>89</sup> MNK-COR-00001291.

<sup>90</sup> MNK\_InCamera-000000142599, at Slide 19.

<sup>91</sup> MNK\_InCamera-000000124567, at Page 8.

<sup>92</sup> See, e.g., MNK\_InCamera-000000128109, at Slide 9; MNK\_InCamera-000000128172, at Slide 7. Synacthen is “a synthetic analog of Acthar” and has “similar therapeutic properties.” MNK\_InCamera-000000131709, at Slide 8.

<sup>93</sup> MNK\_InCamera-000000131709, at Slide 8; MNK\_InCamera-000000142572, at Slide 14; MNK\_InCamera-000000128172, at Slide 7; see also MNK\_InCamera-000000142542, at Slide 7.

<sup>94</sup> Federal Trade Commission, *Press Release: Mallinckrodt Will Pay \$100 Million to Settle FTC, State Charges it Illegally Maintained its Monopoly of Specialty Drug Used to Treat Infants* (Jan. 18, 2017) (online at [www.ftc.gov/news-events/press-releases/2017/01/mallinckrodt-will-pay-100-million-settle-ftc-state-charges-it](http://www.ftc.gov/news-events/press-releases/2017/01/mallinckrodt-will-pay-100-million-settle-ftc-state-charges-it)); see also Complaint (Jan. 25, 2017), *FTC v. Mallinckrodt ARD, Inc.* D.D.C. (No. 1:17-cv-00120) (online at [www.ftc.gov/system/files/documents/cases/170118mallinckrodt\\_complaint\\_public.pdf](http://www.ftc.gov/system/files/documents/cases/170118mallinckrodt_complaint_public.pdf)). Several government and third-party payers brought charges against Mallinckrodt alleging anti-competitive behavior through the Synacthen acquisition. See, e.g., *United Ass’n. of Plumbers & Pipefitters Local 322 of S. N.J. v. Mallinckrodt ARD, LLC, et al.*, No. 20-188 (RBK/KMW) (D.N.J. Aug. 18, 2020); *City of Rockford v. Mallinckrodt ARD, Inc.*, 360 F.Supp. 3d 730 (N.D.Ill. 2019).

<sup>95</sup> Federal Trade Commission, *Press Release: Mallinckrodt Will Pay \$100 Million to Settle FTC, State Charges it Illegally Maintained its Monopoly of Specialty Drug Used to Treat Infants* (Jan. 18, 2017) (online at [www.ftc.gov/news-events/press-releases/2017/01/mallinckrodt-will-pay-100-million-settle-ftc-state-charges-it](http://www.ftc.gov/news-events/press-releases/2017/01/mallinckrodt-will-pay-100-million-settle-ftc-state-charges-it)).

no competitive constraint on its ability to repeatedly and profitably increase Acthar's price and earn extremely high margins."<sup>96</sup>

Mallinckrodt settled the FTC case for \$100 million in 2017 while admitting no wrongdoing.<sup>97</sup>

## **B. Expanding Sales at High Orphan Price**

Internal documents show that after acquiring Questcor, Mallinckrodt sought to drive revenue growth for Acthar by maintaining its premium price while expanding sales volumes across its non-orphan indications. Mallinckrodt did this primarily through aggressive marketing to providers and patients, even though clinical trials demonstrating effectiveness for many of those indications were lacking.

Documents reviewed by the Committee show that Mallinckrodt aimed to drive revenue by expanding sales volumes for Acthar's non-orphan indications through an aggressive sales push. In pre-acquisition analysis, Mallinckrodt executives projected that Acthar revenue would grow exponentially if the company maintained the drug's high price while expanding sales volume in current and new on-label indications.<sup>98</sup>

Investor presentations and internal documents set forth Mallinckrodt's strategy to "drive prescription volume growth" in currently marketed indications and indications not yet in play.<sup>99</sup> Company talking points prepared immediately after the acquisition in September 2014 emphasized, "We believe that the sales potential for Acthar hasn't even scratched the surface."<sup>100</sup>

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<sup>96</sup> Complaint (Jan. 25, 2017), *FTC v. Mallinckrodt ARD Inc.* D.D.C. (No. 1:17 cv-00120) (online at [www.ftc.gov/system/files/documents/cases/170118mallinckrodt\\_complaint\\_public.pdf](http://www.ftc.gov/system/files/documents/cases/170118mallinckrodt_complaint_public.pdf)).

<sup>97</sup> Mallinckrodt News Release, Jan. 18, 2017, *Mallinckrodt and Federal Trade Commission Resolve Questcor Matter* (online at [www.mallinckrodt.com/about/news-and-media/2238262](http://www.mallinckrodt.com/about/news-and-media/2238262)).

<sup>98</sup> See, e.g., MNK\_InCamera-000000128109, at Slides 11-12; MNK\_InCamera-000000142599, at Slide 18. Analysts forecasted that the lead indication for Acthar would become rheumatology and that rheumatology would grow by a compound annual growth rate of 150%. MNK\_InCamera\_000000128172, at Slide 16. The company expected rheumatology to become the largest market, estimating approximately 250,000 combined patients with these conditions in need of treatment. MNK\_InCamera-000000131709, at Slide 13.

<sup>99</sup> MNK-COR-00001446.

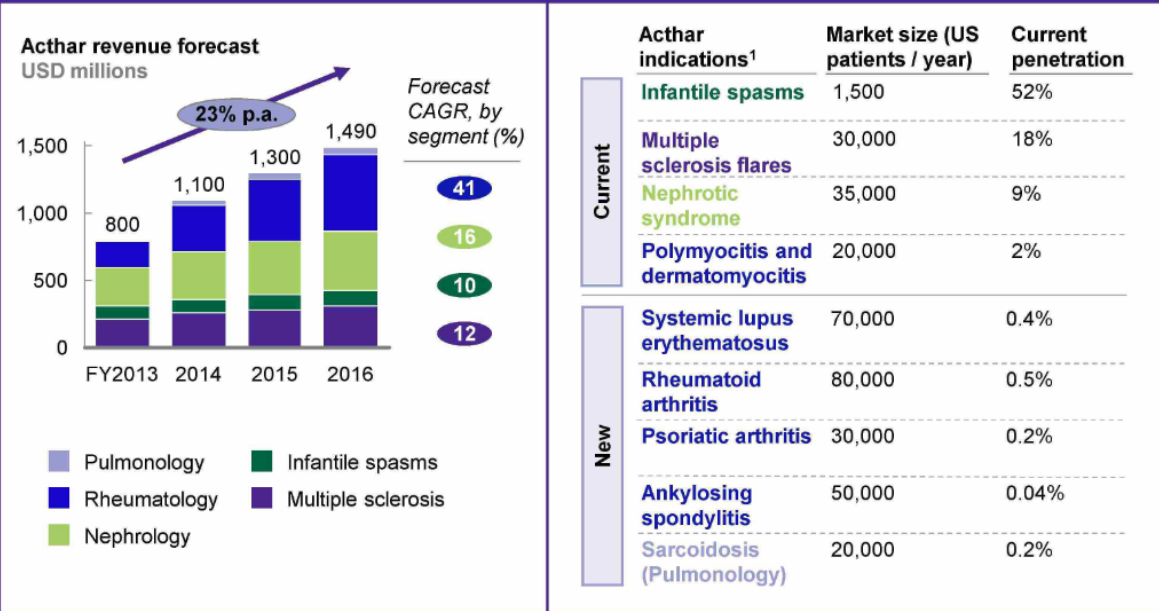
<sup>100</sup> MNK\_InCamera-000000135171, at Page 8.





## Acthar revenue growth will be driven by new on-label indications and 'headroom' in current indications

Expansion into on-label rheumatology indications will provide ~XX% of Acthar growth over the next 3 years



<sup>1</sup> In 2010, the Acthar label was updated in connection with FDA approval of the sNDA for Acthar in the treatment of IS (with Orphan designation); prior to this update, the label included over 50 approved indications; now there are 19 listed indications

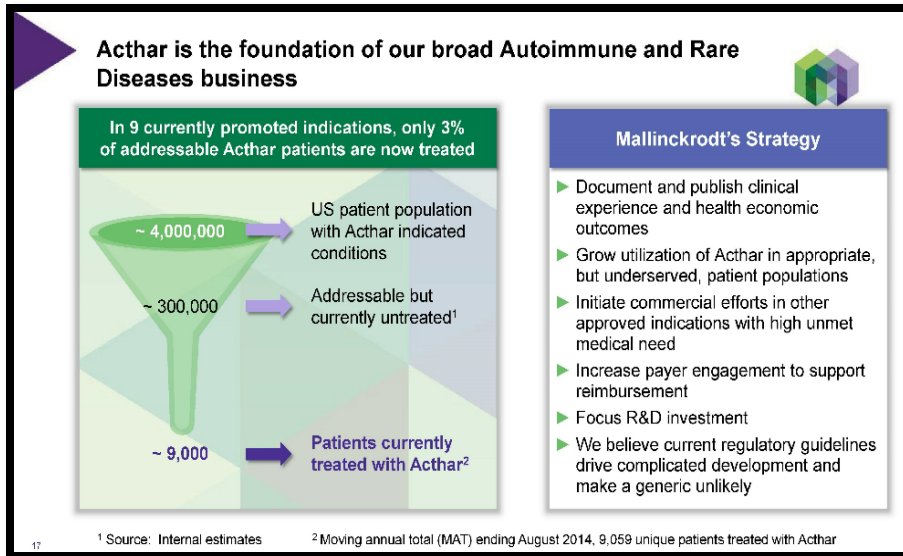


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In an October 2014 briefing with investors, Gary Phillips, then-Senior Vice President and President of Mallinckrodt's Autoimmune and Rare Disease Unit, used the graphic below to summarize Acthar's marketing strategy as targeting four million potential patients the company believed suffered from "Acthar-related conditions."<sup>101</sup>

<sup>101</sup> MNK-COR-00001275, at Slide 17.



Although Mallinckrodt and Questcor had used Acthar’s small patient population as justification for its high price, the presentation contained no indication that Mallinckrodt would *reduce* the price of Acthar if it reached a larger patient population.

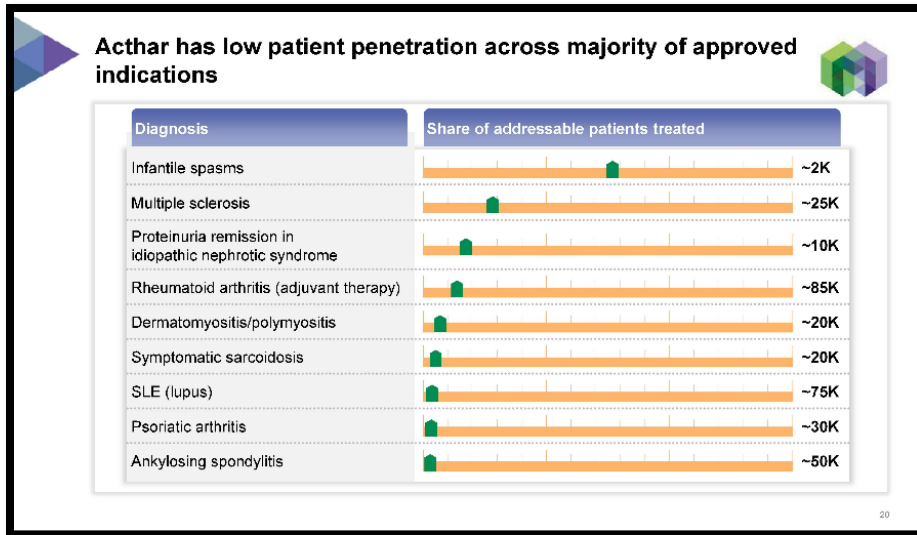
Mr. Phillips pointed out that Acthar’s potential growth was based on its ability to reach additional patient populations in current indications and to initiate commercial efforts in other indications, specifically highlighting rheumatology and pulmonology.<sup>102</sup> In the same briefing, Mr. Trudeau highlighted the “untapped opportunity in marketed indications and additional, but unaddressed, approved indications.”<sup>103</sup>

An investor presentation in 2015 emphasized the strategy of increasing “patient penetration” and prescriber growth across all approved indications, yet again showed no indication that Mallinckrodt would reduce the price as Acthar reached larger patient populations.<sup>104</sup>

<sup>102</sup> *Id.*

<sup>103</sup> MNK-COR-00001447.

<sup>104</sup> MNK-COR-00001333, at Slide 20.



Other documents confirm that, in the years following the acquisition, Mallinckrodt’s long-term strategy for Acthar continued to be driving more prescriptions and increasing volume across non-orphan indications. For example, in a 2017 presentation, Hugh O’Neill, Executive Vice President and then-President of Autoimmune and Rare Diseases, stated that Acthar’s strategy continued to be increasing “new patient and prescriber growth for all promoted Acthar indications.”<sup>105</sup>



<sup>105</sup> MNK\_InCamera-00000051322, at Slide 10. This strategic goal is repeated frequently. See, e.g., MNK\_InCamera-000000118343, at Slide 5.

### C. Marketing to Physicians

Before Mallinckrodt acquired Acthar, a consultant emphasized that Acthar’s growth potential to non-orphan indications was “directly linked to, and driven by, size and aggressiveness of specialty sales force.”<sup>106</sup>

Mallinckrodt appears to have adopted this strategy, aggressively targeting prescribers to drive growth. A 2018 study by researchers at Oregon State University and Oregon Health and Science University found more than half of Medicare’s expenditure for Acthar in 2015 was attributable to 300 prescribers. The study found that that 90% of physicians who frequently prescribed Acthar received at least one payment from Mallinckrodt, and the payments by Mallinckrodt to these physicians were larger than in other cases (almost a third of frequent prescribers received more than \$1,000).<sup>107</sup>

A separate analysis based on Medicare data from 2016 found a similarly aggressive marketing push by Mallinckrodt. The analysis noted that more than 80% of doctors who filed Medicare claims in 2016 for Acthar received “money or other perks” from Mallinckrodt. The analysis found that Mallinckrodt and Questcor “paid 288 prescribers more than \$6.5 million for consulting, promotional speaking and other Acthar-related services between 2013 and 2016.”<sup>108</sup>

From 2013 to 2018, spending on Acthar in the Medicare program was driven by an approximately 73% increase in prescriptions per beneficiary.<sup>109</sup>

Mallinckrodt’s aggressive sales push contradicts the company’s public statements that acknowledge Acthar’s limited application and that, for most indications, the drug should be used only when all other treatments have failed.<sup>110</sup> For example, in an investor call in 2017, CEO Mark Trudeau acknowledged: “Acthar is the drug that has a number of indications, but has very

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<sup>106</sup> MNK\_InCamera-000000131863, at Slide 23.

<sup>107</sup> Daniel Hartung et al., *Industry Payments to Physician Specialists Who Prescribe Repository Corticotrophin*, Journal of the American Medical Association Network Open (June 29, 2018) (online at <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2686039>). See also Daniel Hartung et al., *Trends and Characteristics of US Medicare Spending on Repository Corticotrophin*, Journal of the American Medical Association Internal Medicine (Nov. 1, 2017) (online at <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2653010>); *Something Weird’s Going On with the Doctors Prescribing One of Pharma’s Most Controversial Blockbuster Drugs*, Business Insider (Mar. 21, 2017) (online at [www.businessinsider.com/acthar-risks-including-doctors-prescribing-and-efficacy-questions-2017-3](http://www.businessinsider.com/acthar-risks-including-doctors-prescribing-and-efficacy-questions-2017-3)).

<sup>108</sup> *Medicare Spent \$2 Billion for One Drug as the Manufacturer Paid Doctors Millions*, CNN (June 29, 2018) (online at [www.cnn.com/2018/06/29/health/acthar-mallinckrodt-medicare-claims-doctor-payments/index.html](http://www.cnn.com/2018/06/29/health/acthar-mallinckrodt-medicare-claims-doctor-payments/index.html)).

<sup>109</sup> Center for Medicare and Medicaid Services, *Medicare Part D Spending Dashboard & Data* (online at [www.cms.gov/Research-Statistics-Data-and-Systems/Research-Statistics-Data-and-Systems](http://www.cms.gov/Research-Statistics-Data-and-Systems/Research-Statistics-Data-and-Systems)) (accessed Sept. 1, 2020). Average prescription per beneficiary was measured as the total number of Acthar claims in a given year divided by the number of beneficiaries receiving Acthar through Medicare Part D over the same period.

<sup>110</sup> See, e.g., Mallinckrodt Pharmaceuticals, *About Acthar* (online at [www.mallinckrodt.com/about/acthar/](http://www.mallinckrodt.com/about/acthar/)) (accessed Sept. 30, 2020) (“Aside from treatment of IS, Acthar Gel is often prescribed by doctors predominantly as a later-line treatment to a small subset of patients suffering from various devastating diseases for whom other approved FDA treatment options have failed.”).

limited application. And frankly, we would agree with that.”<sup>111</sup> He added, “Our positioning for Acthar outside of infantile spasms, is that this drug should be used for patients that are highly refractory, meaning they’ve tried and failed on virtually everything else.”<sup>112</sup>

In September 2019, Mallinckrodt paid \$15.4 million to settle DOJ claims that Questcor had paid illegal kickbacks to doctors from 2009 through 2013 to induce prescriptions for the treatment of complications from multiple sclerosis. The government alleged that Questcor sales representatives who were marketing Acthar provided lavish meals and entertainment to doctors to induce Acthar Medicare referrals and that this behavior “cheats taxpayers and the patients who rely on government health care programs for essential care.”<sup>113</sup>

## VII. RESEARCH EXPENSES DO NOT JUSTIFY PRICE OF ACTHAR

When discussing Acthar price increases, Mallinckrodt executives frequently cite the company’s significant R&D investment in Acthar. Mallinckrodt’s pricing decisions were not needed to recoup past R&D expenditures, as Acthar has been on the market for nearly 70 years. Documents reviewed by the Committee indicate that Mallinckrodt’s R&D is not likely to provide the clinically relevant information necessary to support Acthar’s effectiveness and use over lower-cost treatments. Instead, Mallinckrodt’s R&D efforts appear designed to support Mallinckrodt’s aggressive marketing strategy and justify Acthar’s use with skeptical physicians and payers. Mallinckrodt’s R&D is based on a reverse business model—while other drug companies argue that high drug prices are needed to recover the costs of their R&D investment, Mallinckrodt set a high price and then claimed that additional R&D would support that price.

### A. Acthar’s Unique FDA Approval History

FDA’s initial approval of Acthar predated the 1962 enactment of the “Drug Efficacy Amendment” to the Federal Food, Drug, and Cosmetic Act, which introduced the requirement that drug manufacturers demonstrate proof of effectiveness, in addition to the required proof of safety.<sup>114</sup>

In 2010, FDA approved Acthar for the treatment of infantile spasms and reassessed the evidence in support of each of the previously-approved indications.<sup>115</sup> FDA’s review at that time

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<sup>111</sup> MNK\_InCamera-000000125930, at Page 4.

<sup>112</sup> *Id.*

<sup>113</sup> Department of Justice, *Press Release: Drug Maker Mallinckrodt Agrees to Pay \$15.4 Million to Resolve False Claims Act Allegations for “Wining and Dining” Doctors* (Sept. 4, 2019) (online at [www.justice.gov/usao-edpa/pr/drug-maker-mallinckrodt-agrees-pay-154-million-resolve-false-claims-act-allegations](http://www.justice.gov/usao-edpa/pr/drug-maker-mallinckrodt-agrees-pay-154-million-resolve-false-claims-act-allegations)).

<sup>114</sup> 21 U.S.C. 9 § 301 et. seq.

<sup>115</sup> Food and Drug Administration, *Orphan Drug Designations and Approval* (online at [www.accessdata.fda.gov/scripts/opdlisting/oodp/detailedIndex.cfm?cfgridkey=20031681](http://www.accessdata.fda.gov/scripts/opdlisting/oodp/detailedIndex.cfm?cfgridkey=20031681)); Mallinckrodt plc, *2019 Form 10-K* (Feb. 26, 2020) (online at <https://mallinckrodt.gcs-web.com/static-files/d761443c-4f66-4d85-8aea-3b299f918b05>); see also Food and Drug Administration, *Full Prescribing Information for H.P. Acthar Gel* (Oct. 2010) (online at [www.accessdata.fda.gov/drugsatfda\\_docs/label/2010/022432s000lb1.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022432s000lb1.pdf)); Mallinckrodt plc, *Acthar*

was less robust than it would be for a new drug application today—while the review included a medical and scientific review of Acthar and each indication and an evaluation of available clinical and non-clinical literature available, FDA did not require additional clinical trials.<sup>116</sup>

As a result of this review, FDA removed approximately 30 indications from Acthar’s label and approved the safety and efficacy of Acthar in two indications—treatment of infantile spasms and acute exacerbations in multiple sclerosis. FDA allowed Mallinckrodt’s label to state that it “may be used” for 17 other disorders and diseases.<sup>117</sup>

Due to this history, only two of Acthar’s indications—infantile spasms and multiple sclerosis—are supported by clinical trials of safety and efficacy presented to FDA. The lack of such trials for Acthar’s other uses and its expensive price tag have contributed to physician and payer skepticism of the drug across therapeutic areas.<sup>118</sup>

## **B. Research Expenditures Insignificant Compared to Revenue from Acthar**

To justify the price of Acthar, Mallinckrodt claims that it has invested \$500 million into the drug.<sup>119</sup> Yet, documents reviewed by the Committee show that Mallinckrodt spent a much smaller amount—\$363 million—on R&D between 2014-2018,<sup>120</sup> while the rest of its investment

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*Gel—Clinical Benefits to Appropriate Patients* (Mar. 27, 2019) (online at [www.mallinckrodt.com/globalassets/images/acthar/h.p.-acthar-gel-clinical-value-presentation-03-27-19.pdf](http://www.mallinckrodt.com/globalassets/images/acthar/h.p.-acthar-gel-clinical-value-presentation-03-27-19.pdf)).

<sup>116</sup> Mallinckrodt plc, *2019 Form 10-K* (Feb. 26, 2020) (online at <https://mallinckrodt.gcs-web.com/static-files/d761443c-4f66-4d85-8aea-3b299f918b05>).

<sup>117</sup> Food and Drug Administration, *Approved Label for H.P. Acthar Gel* (Oct. 2010) (online at [www.accessdata.fda.gov/drugsatfda\\_docs/label/2010/022432s0001b1.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022432s0001b1.pdf)).

<sup>118</sup> See, e.g., MNK\_InCamera-000000051322, at Slide 9 (noting that one of physicians’ biggest issues is Acthar’s “low level of clinical data” and that payers’ biggest issues are “broad indications and high price” and “Limited prospective & cost offset data makes justification difficult”); MNK\_InCamera-000000046209, at Slide 9 (noting “Brand Perception as overpriced steroid” and “Lack of Acceptance of Academic Opinion Leaders” across therapeutic areas); MNK\_InCamera-00000000089, at Slide 5 (noting that physicians are “skeptical of Acthar data”).

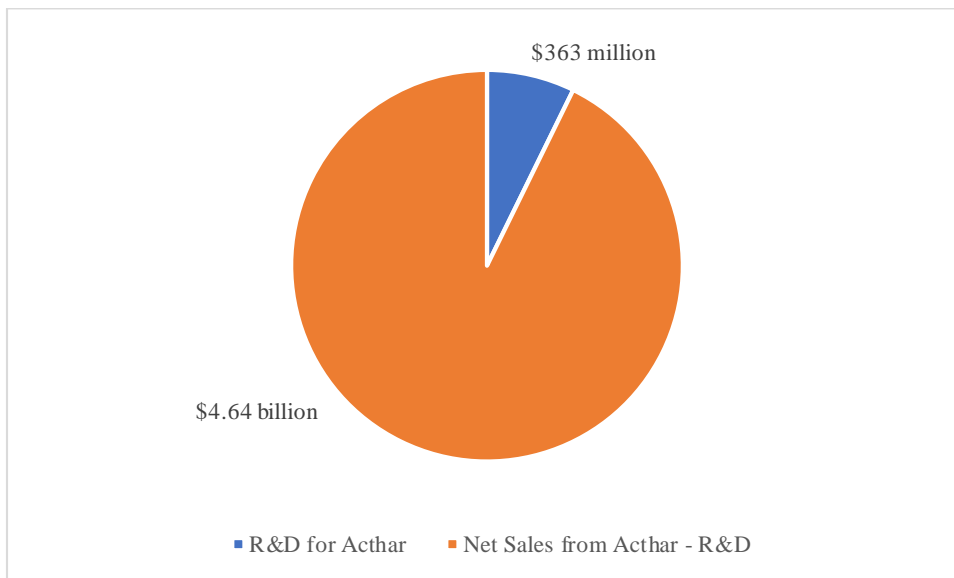
<sup>119</sup> Mallinckrodt Pharmaceuticals, *About Acthar* (online at [www.mallinckrodt.com/about/acthar/](http://www.mallinckrodt.com/about/acthar/)) (accessed Sept. 30, 2020) (“Since acquiring Acthar Gel in 2014, Mallinckrodt has invested more than \$660 million into the drug, specifically: building on substantial clinical experience as well as previously completed and largely independent clinical case series and smaller trials; modernizing manufacturing; expanding medical affairs and research activities; and initiating seven well-designed, company-sponsored randomized, controlled clinical studies, targeting combined enrollment of nearly 1,100 patients.”). Mallinckrodt’s pricing pledge commits to increasing the company’s overall R&D spending in absolute dollars by at least 50% by 2021. Mallinckrodt Pharmaceuticals, *Pledge on Drug Pricing and Innovation* (online at [www.mallinckrodt.com/pledge](http://www.mallinckrodt.com/pledge)) (accessed Sept. 30, 2020). While Mallinckrodt often claims that it is investing in Acthar while Questcor did not, Questcor expanded its R&D budget 20-fold after increasing Acthar’s price. See Terence Burnham, Samuel Huang, and Andrew Lo, *Pricing for Survival in the Biopharma Industry: A Case Study of Acthar Gel and Questcor Pharmaceuticals*, *Journal of Investment Management* (Sept. 22, 2017) (online at [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3040369](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3040369)).

<sup>120</sup> MNK-COR-00001704. This document indicates total Acthar Science and Technology investments of \$363.3 million, which includes Acthar’s clinical testing, spending on clinical trials, and other R&D activities, and Acthar manufacturing investments of approximately \$165.6 million. Another document reviewed by the Committee states that \$313 million was spent on Acthar R&D between 2014 and 2018. MNK-COR-00001894. See Letter from

went to “modernization efforts.”<sup>121</sup> This expenditure is less than 7.3% of the net revenue it received from Acthar during the same period.

Figure 8 below shows total U.S. revenue from Acthar as compared to R&D costs, from the time when Mallinckrodt acquired Acthar in 2014 through 2018.

Figure 8: R&D for Acthar vs. Net Sales



Internal communications undermine Mallinckrodt’s claims that Acthar’s high price was needed to fund future R&D. In October 2017, the company’s executives drafted a letter to the editor of a medical journal to respond to an article about Medicare spending on Acthar. In a comment on a draft of the letter, Steven Romano, Executive Vice President and Chief Scientific Officer, wrote, “I also suggest we don’t say that the revenues are needed for reinvestment. Naturally we commit a certain amount of revenues to fund RD [sic], but I wouldn’t link Acthar to that directly.”<sup>122</sup>

Contrary to this caution, the final version of the letter stated:

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Hogan Lovells, on behalf of Mallinckrodt Pharmaceuticals, to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Sept. 11, 2020).

<sup>121</sup> The company uses the term “modernization” to refer to clinical trials and R&D investments, as well as manufacturing investments. *See, e.g.*, Letter from Hogan Lovells, on behalf of Mallinckrodt Pharmaceuticals, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Feb. 4, 2019); MNK-COR-00001704; Mallinckrodt Pharmaceuticals, *About Acthar* (online at [www.mallinckrodt.com/about/acthar/](http://www.mallinckrodt.com/about/acthar/)) (accessed Aug. 13, 2020).

<sup>122</sup> MNK\_InCamera-000000000931, at Page 1.

Revenue generated from sales of Acthar enable Mallinckrodt to conduct additional research and, importantly, generate the evidence to fill the gap identified by [researchers].<sup>123</sup>

### **C. Research Motivated by Marketing and Reimbursement Strategy**

Mallinckrodt frequently touts its research investments to support the value of Acthar, including sponsoring seven clinical studies, conducting health economics and outcomes research, and funding more than 40 investigator-initiated research programs.<sup>124</sup> However, documents reviewed by the Committee indicate that Mallinckrodt was primarily motivated to invest in R&D to support its aggressive marketing and revenue goals and overcome physician and payer skepticism about Acthar’s effectiveness for most of its marketed uses.

Mallinckrodt has long acknowledged that the lack of clinical evidence related to Acthar is a danger to its business. Mallinckrodt’s 2016 annual reports admitted, “Clinical trials demonstrating the efficacy for Acthar are limited.” The report also warned:

The absence of such clinical trial data could cause physicians not to prescribe Acthar, which could negatively impact our business, financial condition, results of operations and cash flows.<sup>125</sup>

After acquiring Acthar, Mallinckrodt recognized that it needed to strengthen the “value proposition” of the drug by developing scientific evidence to support it.<sup>126</sup> For example, Hugh O’Neill, then-President of the Autoimmune and Rare Disease Unit, wrote in his notes for a 2017

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<sup>123</sup> Tunde Otulana, *Uses of H.P. Acthar Gel in the Clinical Setting*, *Journal of the American Medical Association Internal Medicine* (Apr. 2018) (online at <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2677015>). In media talking points prepared to respond to questions about Acthar’s 2017 price increase, the company claimed that R&D investments justified Acthar’s price: “The single digit price increase will help Mallinckrodt continue to ensure the clinical value Acthar brings as a later line treatment option for patients suffering from a number of complex and devastating diseases through the company’s investments in R&D.” MNK\_InCamera-000000125058, at Page 1.

<sup>124</sup> Mallinckrodt plc, *Acthar Gel—Clinical Benefits to Appropriate Patients* (Mar. 27, 2019) (online at [www.mallinckrodt.com/globalassets/images/acthar/h.p.-acthar-gel-clinical-value-presentation-03-27-19.pdf](http://www.mallinckrodt.com/globalassets/images/acthar/h.p.-acthar-gel-clinical-value-presentation-03-27-19.pdf)). Mallinckrodt notes often that evidence of safety and efficacy does not need to come just from clinical trials, but can come in other forms, such as clinical experience and published literature. Mallinckrodt’s investor presentations frequently describe five goals for Acthar’s R&D investment—expand evidence base, strengthen clinical profiles, generate compelling value proposition, defend integrity of product, and establish differentiation from steroids. *See, e.g.*, MNK-COR-00001353; MNK\_InCamera-000000051322, at Slide 11.

<sup>125</sup> Mallinckrodt plc, *2016 Form 10-K* (Nov. 29, 2016) (online at [www.sec.gov/Archives/edgar/data/0001567892/000156789216000098/mnk10-k93016.htm](http://www.sec.gov/Archives/edgar/data/0001567892/000156789216000098/mnk10-k93016.htm)); Mallinckrodt plc, *2016 Form 10-K* (Nov. 29, 2016) (online at [www.sec.gov/Archives/edgar/data/0001567892/000156789216000098/mnk10-k93016.htm](http://www.sec.gov/Archives/edgar/data/0001567892/000156789216000098/mnk10-k93016.htm)); Mallinckrodt plc, *2015 Form 10-K* (Nov. 25, 2015) (online at <https://mallinckrodt.gcs-web.com/static-files/5c5e81b9-73a1-4133-83de-bc2bce5adac>).

<sup>126</sup> MNK\_InCamera-000000135171, at Slide 3.



Investor Day presentation that Mallinckrodt had expanded Acthar clinical studies “in order to provide the data necessary to address questions on the brand.”<sup>127</sup>

Mallinckrodt was aware that some physicians were frustrated with the limited clinical evidence related to Acthar. The company noted that one of its consistent challenges was the perception of Acthar as an “overpriced steroid” and that Acthar has not been accepted among academic leaders across therapeutic areas.<sup>128</sup> When the Acthar Competitive Strategy team conducted physician research in 2018, it reported that almost all physicians said that Acthar’s “clinical data lacked rigor,” that there were not trials comparing Acthar “head-to-head” with steroids,<sup>129</sup> and that some physicians reported “Frustration/anger over ‘unwarranted price’ vs. clinical evidence.”<sup>130</sup>

Internally, Mallinckrodt described R&D (and modernization) as a way to “legitimize the brand” and respond to patient and physician skepticism.<sup>131</sup> In response to a question about Acthar’s price during a Q4/FY 2017 earnings Q&A, Mallinckrodt stated:

Patient penetration and uptake for Acthar is much more closely tied to data than to price—the more data that exists, the higher likelihood of prescribing. Where the data set is less robust, we see less penetration. That’s why we continue to invest [hundreds of millions] in data generation.<sup>132</sup>

A 2018 presentation described Mallinckrodt’s Phase IV clinical trials as driving “positive impact on HCP [Health Care Practitioner] demand” and supporting “growth in demand and payer coverage.”<sup>133</sup>

Similarly, in describing the actions necessary to deliver on the Autoimmune and Rare Disease Unit’s 2019 budget, a presentation identified two priority actions as “Data generation and increased dissemination to justify the utilization of Acthar” and “Increased referral growth in multiple indications based on new data generation.”<sup>134</sup>

Mallinckrodt executives also recognized that the lack of clinical evidence was a barrier to reimbursement by insurers and other payers. For example, Mallinckrodt’s pre-acquisition analysis noted that the insurance company Aetna would no longer be covering Acthar beyond infantile spasms because of Aetna’s conclusion that “there is no clinical evidence that the [sic]

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<sup>127</sup> MNK\_InCamera-000000023124, at Slide 6.

<sup>128</sup> MNK\_InCamera-000000046209, at Slide 9. *See also* MNK\_InCamera-000000028645, at Slide 13.

<sup>129</sup> MNK\_InCamera-000000000089, at Slide 5.

<sup>130</sup> *Id.*, at Slides 5-6.

<sup>131</sup> MNK\_InCamera-000000028645, at Slide 13.

<sup>132</sup> MNK\_InCamera-000000038586, at Page 2.

<sup>133</sup> MNK\_InCamera-000000067071, at Slides 2 and 4.

<sup>134</sup> MNK\_InCamera-000000028645, at Slide 7.

Acthar is more effective than steroids.”<sup>135</sup> A July 2017 market access plan noted that “payers” were telling Mallinckrodt that Acthar is an “Old drug/old FDA label—high cost steroid,” that “Pricing is egregious,” and that “Evidence base and clinical support is lacking.”<sup>136</sup>

**Here is what payers are telling us:**

- ▶ Old drug/old FDA label – high cost steroid
- ▶ Public scrutiny and negative perception of Acthar
- ▶ Pricing is egregious; payers want 30-50% rebates
- ▶ Evidence base and clinical support is lacking and doesn't support access
- ▶ Concerned about managing utilization and risk of opening access without clearly defined patient population, UM criteria and expected outcomes
- ▶ Worried about adverse selection
- ▶ Payers need to offer competitive programs that control specialty drug spend for clients

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In a 2018 draft business narrative, the company emphasized that “Acthar will continue to face access barriers based on payer perceptions of insufficient evidence to justify price.” The presentation noted that payers perceive a “value gap in Acthar because it is priced significantly higher than both FDA approved and unapproved alternative therapies across indications” and that “for many indications, payers believe that Acthar lacks sufficient clinical evidence to support coverage at its current price.”<sup>137</sup>

Documents reviewed by the Committee demonstrate that Acthar’s R&D was motivated in large part by a need to justify its cost to payers. For example, in an earnings call with investors in 2017, CEO Mark Trudeau said:

[W]e believe that it’s the result of the positioning and creation of the data, both the clinical data and the health economic data, that has enabled us to go into payers, position the drug appropriately and get open access to our drug on now almost 60% of commercial covered lives.<sup>138</sup>

<sup>135</sup> MNK\_InCamera-000000128172, at Slide 9.

<sup>136</sup> MNK\_InCamera-000000030207, at Slide 10.

<sup>137</sup> MNK\_InCamera-000000063852, at Page 3.

<sup>138</sup> MNK\_InCamera-000000124567, at Page 10.

A 2018 market access presentation emphasized that the key to engaging payers and protecting coverage is to “proactively reinforce efficacy with any/all new data” and to “reinforce clinical evidence to build medical acceptance consensus.”<sup>139</sup>

#### **D. Research Provides Limited Clinically Valuable Information**

In 2019, a team of researchers at Oregon State University and Oregon Health and Science University investigated the quality of the evidence likely to emerge from all studies of Acthar for kidney disease. The review of 75 trials concluded that the study designs would not provide clinically relevant information on efficacy. Specifically, the studies were all either dose-finding (comparing Acthar doses) or placebo-controlled, and the enrollment sizes were small. No studies compared Acthar to a corticosteroid treatment. The researchers noted that “the continued emphasis on small studies that lack a control arm receiving [a steroid] or another [Acthar]-free active treatment is perplexing.” The researchers concluded that “it is highly unlikely that compelling data supporting the use of rACTH [Acthar] over gluco-corticoid [*i.e.* steroid] treatment for any renal indication will emerge soon.”<sup>140</sup>

In another research paper, the same Oregon researchers concluded more broadly that Mallinckrodt’s research will not produce clinically relevant data to justify its use, stating: “Given the preponderance of small and uncontrolled single-arm studies, we have serious doubts that these studies will provide scientific evidence sufficient to justify use of Acthar at its current price.”<sup>141</sup>

An article by Duke rheumatologists noted that the way Acthar studies are designed—mostly small, nonrandomized trials—was not likely to produce clinically helpful information. In the article, the rheumatologists criticized the limited studies comparing Acthar to the steroid prednisone:

Most importantly, it [Acthar] has not been tested head-to-head with prednisone except for a few small studies on ACTH for infantile spasms. Given this lack of data, we simply have no way to know how the efficacy of Acthar compares with prednisone for the vast majority of indications listed on the drug label.<sup>142</sup>

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<sup>139</sup> MNK\_InCamera-000000117110, at Slide 28.

<sup>140</sup> Daniel Hartung et al., *Repository Corticotropin Versus Glucocorticoid for Nephrotic Syndrome: When Will We See the Evidence?*, *American Journal of Kidney Diseases* (Feb. 11, 2019) (available at <https://pubmed.ncbi.nlm.nih.gov/30765104/>).

<sup>141</sup> Daniel Hartung, Dennis Bourdette and David Cohen, *Uses of H.P. Acthar Gel in the Clinical Setting—Reply*, *Journal of the American Medical Association Internal Medicine* (Apr. 2018) (online at <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2677031>).

<sup>142</sup> Megan Elizabeth Bowles Clowse and Daniel Leverenz, *Do Not Get Us Started on Acthar*, *Duke Forge Blog* (Sept. 10, 2018) (online at <https://forge.duke.edu/blog/do-not-get-us-started-acthar>).

The rheumatologists ended the article by emphasizing that “patients, insurers, prescribers and the FDA should mandate large-scale, randomized, prednisone-controlled trials of Acthar prior to allowing further prescriptions for rheumatic indications.”<sup>143</sup>

In defending its investment into Acthar, Mallinckrodt specifically highlights six company-sponsored controlled trials relating to the drug’s efficacy.<sup>144</sup> According to a researcher of pharmacoepidemiology at Oregon Health and Science University who applied the same methodology to evaluate these trials: “These studies will likely not provide the clinically relevant information necessary to support Acthar’s effectiveness and use over lower-cost treatments.”<sup>145</sup> Of these trials, two provide no comparison to alternative treatment, and the other four do not compare Acthar to continued treatment with a steroid—which would be necessary to evaluate the effectiveness of the drug compared to alternative less-expensive treatments.<sup>146</sup>

This analysis is supported by Mallinckrodt’s own internal documents. A Mallinckrodt presentation reviewing the Autoimmune and Rare Disease Unit’s science and technology portfolio describes the primary “opportunity drivers” of its studies as, among other things, developing a “refined marketing message” and driving “depth” and “breadth” in the prescriber physician base.<sup>147</sup>

Mallinckrodt was not always forthcoming about data that might negatively impact the company’s bottom line. For example, in discussing updates to the “Acthar Statement” for the website in 2017, senior executives debated whether to cite a prospective article on the use of Acthar in patients with sarcoidosis, an inflammatory disease. The article found 40ml of Acthar to be as effective as the regular 80ml dose and that patients suffered fewer side effects with the lower dose. A senior executive wrote in an email that Mallinckrodt may be able to use the results promotionally, but needed to develop talking points about the lower dose:

[W]e are urgently working through talking points as most customers use the higher dose. I just wanted to share, as an astute investor may have questions about the financial implications of using 40 units for patients vs. 80 units ... i.e. Do you lose half the value you once recognized for sarcoidosis patients?<sup>148</sup>

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<sup>143</sup> *Id.*

<sup>144</sup> Mallinckrodt Pharmaceuticals, *About Acthar* (online at [www.mallinckrodt.com/about/acthar/](http://www.mallinckrodt.com/about/acthar/)) (accessed Aug. 27, 2020). Although the website explains that the company has sponsored seven clinical trials, the footnote links to only six trials.

<sup>145</sup> Email from Daniel Hartung, Associate Professor, Pharmacy Practice, College of Pharmacy, Oregon State University, to Committee Staff (Sept. 17, 2020).

<sup>146</sup> *Id.*

<sup>147</sup> MNK\_InCamera-00000013271, at Slides 13, 15, and 17. For the eight Acthar studies described at this Autoimmune and Rare Disease Unit meeting, the strategic objective for seven of them was listed as to “Expand evidence base” and/or “strengthen clinical profiles,” and in only one study, the Acthar ALS program, to “Expand Acthar into novel areas of unmet clinical needs.”

<sup>148</sup> MNK\_InCamera-000000012255, at Page 1 (ellipses in original).

Another executive asked, “So the half dose was just as effective AND better tolerated, right? (and thus cheaper as well.)” The first executive replied, “The implication of half the dose is definitely half the price.”<sup>149</sup> The executives ultimately decided not to cite the study at the time and stated instead, “We might as well not cause more issues for ourselves.”<sup>150</sup>

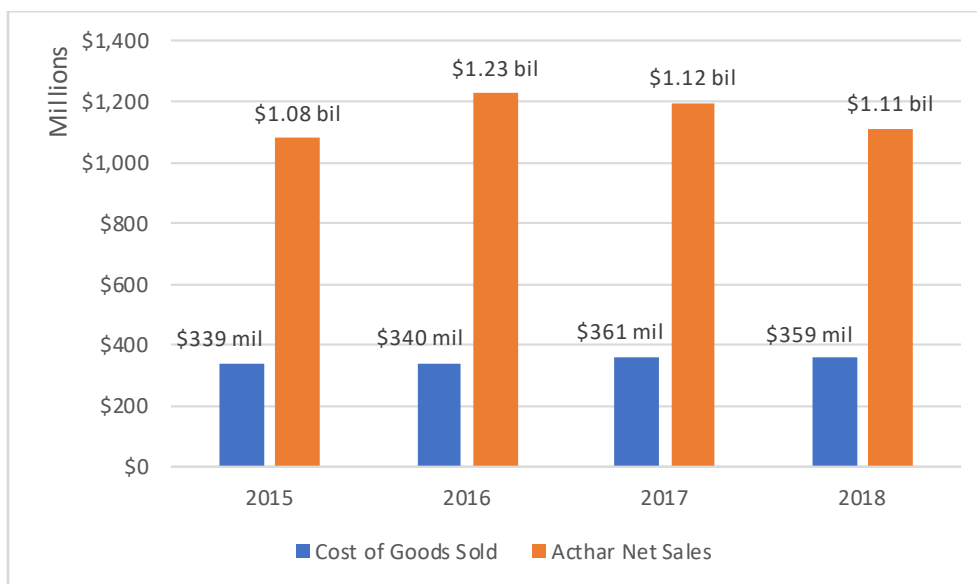
## VIII. OTHER COSTS DO NOT JUSTIFY ACTHAR’S PRICE

### A. Manufacturing Costs and Pharmacy Benefit Manager Rebates

Pharmaceutical companies frequently cite rising costs of manufacturing or other commercial expenses to justify their pricing practices.<sup>151</sup> However, internal data produced by Mallinckrodt do not support this justification for the price of Acthar. Manufacturing costs have remained relatively stable since Mallinckrodt acquired Acthar and are minimal compared to net revenue.<sup>152</sup>

Figure 9 below shows Acthar net revenue compared to costs of goods sold.

Figure 9: Acthar Cost of Goods Sold v. Total Acthar Net Sales 2015-2018



<sup>149</sup> *Id.*

<sup>150</sup> MNK\_InCamera-000000012417, at Page 1.

<sup>151</sup> See, e.g., *Big Pharma’s Go-To Defense of Soaring Drug Prices Doesn’t Add Up*, The Atlantic (Mar. 23, 2019) (online at [www.theatlantic.com/health/archive/2019/03/drug-prices-high-cost-research-and-development/585253/](http://www.theatlantic.com/health/archive/2019/03/drug-prices-high-cost-research-and-development/585253/)); *Drug Makers Try to Justify Prescription Prices to Senators at Hearing*, New York Times (Feb. 26, 2019) (online at [www.nytimes.com/2019/02/26/us/politics/prescription-drug-prices.html](http://www.nytimes.com/2019/02/26/us/politics/prescription-drug-prices.html)).

<sup>152</sup> See MNK-COR-00001947, at Page 2.

The pharmaceutical industry often attributes price increases to rebates or discounts to payers and pharmacy benefit managers (PBMs).<sup>153</sup> In defending its price increases, Mallinckrodt has stated that it provides “discounts to the drug’s list price to both public and private payors” and that its average rebates have increased each year.<sup>154</sup> In December 2016, Mallinckrodt CEO Mark Trudeau noted that, in the two and a half years since owning Acthar, “list price adjustments have averaged mid-single price digits,” but “net price for all payers after contracting, discounting, and government rebates, reduced that price change impact by roughly a third.”<sup>155</sup>

Internal documents reviewed by the Committee indicate that Mallinckrodt executives sought to perpetuate the narrative of attributing price increases to PBMs and rebates. Responding to a report about drug price inflation in January 2017, a senior executive emailed colleagues that she was “searching for messages” and asked Executive Vice President Hugh O’Neill if they could argue that, “with our most recent increase, the list price of Acthar grew by 6.9% but with the contractual discounts included in our payer strategy, the net effective increase is Y.Y%”<sup>156</sup>

**From:** [REDACTED]  
**Sent:** Monday, January 23, 2017 7:47 AM  
**To:** O’Neill, Hugh M  
**Subject:** FW: Pharmaceuticals - Quantifying “real” price growth vs. list price growth

Have we recently done an analysis like this about Acthar price growth under our ownership? Not necessarily to try to make a point that price has ‘declined’ but to have another data point that would say, ‘with our most recent increase, the list price of Acthar grew by 6.9%, but with the contractual discounts included in our payer strategy, the net effective increase is Y.Y%?’

May not make a difference but I’m searching for messages. M

Mr. O’Neill replied, “we have the data and can certainly pull it together.”<sup>157</sup> Another executive replied that the company looked into this previously and it did not help the narrative because “it was still showing a net increase as a result of rebate payments not being as high as originally estimated.”<sup>158</sup>

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<sup>153</sup> See, e.g., *Drug Makers Try to Justify Prescription Prices to Senators at Hearing*, New York Times (Feb. 26, 2019) (online at [www.nytimes.com/2019/02/26/us/politics/prescription-drug-prices.html](http://www.nytimes.com/2019/02/26/us/politics/prescription-drug-prices.html)).

<sup>154</sup> MNK\_InCamera-000000024471, at Page 1.

<sup>155</sup> MNK-COR-00001430.

<sup>156</sup> MNK\_InCamera-000000124918, at Page 2.

<sup>157</sup> *Id.*, at Page 1.

<sup>158</sup> *Id.*

**From:** [REDACTED]  
**Sent:** Monday, January 23, 2017 9:00 AM  
**To:** O'Neill, Hugh M; [REDACTED]  
**Cc:** [REDACTED]  
**Subject:** RE: Pharmaceuticals - Quantifying "real" price growth vs. list price growth

Hugh,

We will absolutely look into this. We did last fall and it was still showing a net increase as a result of rebate payments not being as high as originally estimated. [REDACTED] and I will take another look.

Also, if you trend the ASP that is published it was still showing a positive. This is a data point that some of the analysts will call out.

[REDACTED]

Internal data indicate that Acthar's average net price—the price of the drug after subtracting rebates, distributor fees, and pharmacy price concessions—continued to increase each year the drug was on the market, meaning any rebates or discounts from the list price of the drug were outpaced by the company's price increases.<sup>159</sup>

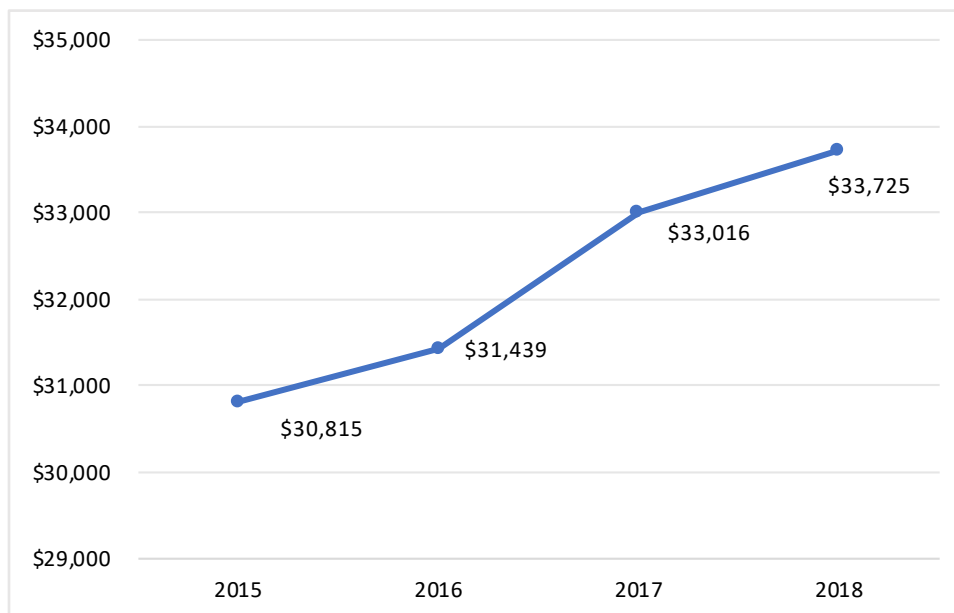
Figure 10 below shows Acthar's average net price per vial—excluding rebates, fees and other negotiated discounts—under Mallinckrodt's ownership, from 2015 to 2018.<sup>160</sup>

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<sup>159</sup> MNK-COR-00001947. Mallinckrodt did not include Medicaid rebates as part of this calculation.

<sup>160</sup> *Id.*

Figure 10: Average Net Price Per Vial of Acthar



## **B. Patient Assistance Programs**

In responding to criticism about its pricing, Mallinckrodt has highlighted the generosity of its patient assistance programs to help defray the costs of price increases. Yet, a review of these programs reveals that they are not as generous as they appear, serve the company’s own strategic and business interests, and are not always reliable for patients and constitute a small fraction of Mallinckrodt’s revenue from Acthar.

According to information reviewed by the Committee, from 2014 to 2018, Mallinckrodt spent approximately \$125 million in charitable activities relating to Acthar or “disease states for which Acthar is an FDA approved treatment,” including approximately \$109 million in donations to 501(c)(3) independent charitable co-pay foundation funds for government-insured patients.<sup>161</sup> Mallinckrodt’s expenditures on patient assistance includes the costs of administering a free goods program for the uninsured (excluding the costs of drugs provided) and co-pay assistance for patients with commercial insurance, as well as the costs of an injection training program.<sup>162</sup>

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<sup>161</sup> Letter from Hogan Lovells, on behalf of Mallinckrodt Pharmaceuticals, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Mar. 29, 2019). Approximately \$109 million was donated to independent 501(c)(3) patient assistance organizations. Letter from Hogan Lovells, on behalf of Mallinckrodt Pharmaceuticals, to Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform (Sept. 11, 2020).

<sup>162</sup> Letter from Hogan Lovells, on behalf of Mallinckrodt Pharmaceuticals, to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Mar. 29, 2019), at Page 1. Although companies often claim to have donated significant amounts of their drugs for free, the cost is often not as significant. For example, while Mallinckrodt has stated that the value of Acthar donated was \$1 billion, this was the commercial value of the product and not the actual cost. In one exchange, Mallinckrodt’s Senior Vice President of Investor Strategy wrote, “I dont [sic] believe even the theoretical numbers have ever been ‘\$1 billion+’.” MNK\_InCamera-00000001867, at Pages 3-4.



The total cost of these programs accounted for approximately 2.5% of Mallinckrodt’s \$5 billion in Acthar net revenues from the same period.

Documents reviewed by the Committee indicate that the company views patient assistance programs as an important part of its business growth strategy and key to retaining patients. Before acquisition, a presentation by a Questcor Vice President highlighted that patient assistance and co-pay assistance “are a critically important component of Acthar strategy.”<sup>163</sup>

Mallinckrodt executives recognized that the company’s profits would suffer if patients’ out-of-pocket costs forced them to abandon the drug. For example, one internal document describing market trends in 2018 stated, “For patients on specialty pharmaceuticals, out of pocket costs are unaffordable and they must rely on financial assistance provided by manufacturers or foundations.”<sup>164</sup>

To ensure that it continued collecting significant revenue from insurers, Mallinckrodt used its patient assistance programs to reduce out-of-pocket costs. One internal strategic planning document noted that “rising *patient* OOP [out-of-pocket] cost, decreasing external support leads to increases in Rx abandonment.”<sup>165</sup> The document acknowledged that “Co-pays are challenging for patients and result in withdrawals” and noted that “fortifying our patient’s experience getting and staying on drug via superior patient services” was a “critical growth driver.”<sup>166</sup>

The federal Anti-Kickback Statute prohibits pharmaceutical manufacturers from subsidizing the co-pay and other cost-sharing obligations incurred by Medicare Part D patients.<sup>167</sup> A DOJ suit alleges that Questcor—now part of Mallinckrodt—violated the law by using a foundation to funnel co-pay subsidies to Medicare patients on Acthar from 2010 to 2014. According to the government, this scheme was designed to enable Mallinckrodt to raise the price of Acthar and collect higher payments from Medicare without losing sales due to patients’ higher out-of-pocket posts.<sup>168</sup>

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<sup>163</sup> MNK\_InCamera-000000128699, at Slide 3.

<sup>164</sup> MNK\_InCamera-000000063852, at Page 2.

<sup>165</sup> MNK\_InCamera-000000051322, at Slide 6.

<sup>166</sup> *Id.*, at Slides 3, 9, and 10.

<sup>167</sup> See 42 U.S.C. § 1320a-7b(b); Department of Health and Human Services, Office of Inspector General, *Special Advisory Bulletin: Patient Assistance Programs for Medicare Part D Enrollees*, 70 Fed. Reg. 70623 (Nov. 22, 2005) (online at [www.govinfo.gov/content/pkg/FR-2005-11-22/pdf/05-23038.pdf](http://www.govinfo.gov/content/pkg/FR-2005-11-22/pdf/05-23038.pdf)); Department of Health and Human Services, Office of Inspector General, *Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs*, 79 Fed. Reg. 31120 (May 30, 2014) (online at <https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/independent-charity-bulletin.pdf>).

<sup>168</sup> See Complaint in Intervention (June 4, 2019), *United States ex rel. Strunck et al. v. Mallinckrodt ARD, Inc.*, E.D. Pa. (No. 12-CV-0175); *United States ex rel. Strunck et al. v. Mallinckrodt ARD, Inc.*, Nos. 12-175 13-1776, 2020 WL 362717 (E.D. Pa. Jan. 21, 2020) (denying Mallinckrodt’s motion to dismiss allegations that it violated the federal Anti-kickback statute).

The health insurance company Humana Inc. has also recently sued Mallinckrodt claiming, among other things, that Mallinckrodt artificially inflated demand for the drug by using a charitable foundation to subsidize patient copays.<sup>169</sup> Mallinckrodt denies these allegations.<sup>170</sup>

Patient assistance programs are not always reliable for patients. Qualifying for the programs depends on several factors (such as income requirements and insurance coverage decisions), so patients may fall in and out of eligibility. Mallinckrodt received complaints from patients who once received patient assistance and relied on Acthar to manage their conditions and were then told that the funds were no longer available for their disease or that there was no more assistance available to them.<sup>171</sup>

For example, the adult child of a 90-year-old patient contacted Mallinckrodt's medical information line to complain that, after two years of receiving assistance, the patient was no longer eligible. The complaint stated that "the medicine is priced way above her means of being able to pay—or anyone else for that matter" and that "she is unable to afford the astronomical copay required."<sup>172</sup> In other cases, patients reported being out of medicine and behind on treatment because they were waiting for co-pay assistance to come through.<sup>173</sup>

## IX. CONCLUSION

Mallinckrodt's pricing and business practices for Acthar 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>174</sup>

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

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<sup>169</sup> Demand for Jury Trial (Apr. 24, 2020), *Humana, Inc. v. Mallinckrodt ARD LLC*, C.D.Ca. (No. 2:19-cv-06926-DFS-MRW). Humana's complaint alleges that it overpaid for Acthar by \$700 million because of the company's "complex, multipart scheme involving monopoly, bribery, racketeering, fraud, and other deceptive and unfair practices." See also *Humana Sues Drugmaker Mallinckrodt Over Alleged Price Gouging*, MedCityNews (Aug. 12, 2019) (online at [www.medicitynews.com/2019/08/humana-sues-drugmaker-mallinckrodt-over-alleged-price-gouging/](http://www.medicitynews.com/2019/08/humana-sues-drugmaker-mallinckrodt-over-alleged-price-gouging/)).

<sup>170</sup> *Humana, Inc. v. Mallinckrodt ARD LLC*, CV 19-06926 DFS (MRW), 2020 WL 3041309 (C.D. Ca. Mar. 9, 2020). In March 2020, the Court granted in part and denied in part the company's motion to dismiss Humana's claims. The Court denied the company's motion to dismiss Humana's RICO and other fraud-based claims.

<sup>171</sup> See, e.g., MNK-COR-00001949, at Pages 5, 8.

<sup>172</sup> MNK-COR-00001949, at Page 5.

<sup>173</sup> MNK-COR-00001949, at Page 13. In another example, a patient complained about trying to get patient assistance but needed two more denials from insurance before eligibility for the program. See MNK-COR-00001949, at Page 10.

<sup>174</sup> See State of California, Office of Statewide Health Planning and Development, *Prescription Drug Wholesale Acquisition Cost (WAC) Increases* (Aug. 17, 2020) (online at <https://oshpd.ca.gov/visualizations/prescription-drug-wholesale-acquisition-cost-increases/>).