CAROLYN B. MALONEY
CHAIRWOMAN

ONE HUNDRED SIXTEENTH CONGRESS

JAMES COMER
RANKING MINORITY MEMBER

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House of Representatives
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MEMORANDUM

September 1, 2020

To: Members of the Committee on Oversight and Reform

Fr: Chairwoman Carolyn B. Maloney

Re: Notice of Intent to Issue a Subpoena to AbbVie Inc.

This memorandum provides Committee Members with notice of my intent to issue a subpoena to AbbVie Inc. for documents related to the Committee's ongoing investigation of drug company pricing practices, which was initiated under our former Chairman, Rep. Elijah E. Cummings.

I. BACKGROUND

On January 14, 2019, Chairman Cummings announced that the Committee would be conducting an investigation of the pricing practices of 12 drug companies that sell 19 of the most expensive medications for patients, consumers, and taxpayers in the United States. In his announcement, Chairman Cummings stated:

> For years, drug companies have been aggressively increasing prices on existing drugs and setting higher launch prices for new drugs while recording windfall profits. The goals of this investigation are to determine why drug companies are increasing prices so dramatically, how companies are using the proceeds, and what steps can be taken to reduce prescription drug prices.[1]

As part of this investigation, Chairman Cummings wrote to AbbVie Chief Executive Officer (CEO) Richard Gonzalez to request information and communications on price increases, investments in research and development, and corporate strategies to preserve market share and pricing power for two drugs: Humira and Imbruvica.[2]

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[1] Committee on Oversight and Reform, *Press Release: Oversight Committee Launches Sweeping Drug Price Investigation* (Jan. 14, 2019) (online at https://oversight.house.gov/news/press-releases/oversight-committee-launches-sweeping-drug-price-investigation).

[2] Letter from Chairman Elijah E. Cummings, Committee on Oversight and Reform, to Richard A. Gonzalez, Chairman and Chief Executive Officer, AbbVie Inc. (Jan. 14, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2019-01-14.EEC%20to%20Gonzalez-AbbVie%20re%20Drug%20Pricing.pdf).

- **Humira:** Humira is the best-selling drug in the world.[3] It is approved to treat moderate to severe rheumatoid arthritis and other inflammatory diseases.[4] In 2019, AbbVie's United States net revenues from Humira were nearly $14.9 billion.[5] That same year, AbbVie's worldwide net revenues from Humira were nearly $19.2 billion.[6] The Initiative for Medicine, Access, and Knowledge (I-MAK) found that AbbVie has filed 247 patent applications on Humira with the intention of delaying competition for 39 years. According to I-MAK, 89% of these patent applications were filed after Humira was brought to market.[7] The company has raised the price of Humira on 18 occasions between January 1, 2009, and January 14, 2019.[8]

- **Imbruvica:** In 2019, AbbVie's total net revenues for Imbruvica were more than $4.6 billion, including $3.8 billion in United States net revenues and $844 million in collaborative net revenues from its partnership with Johnson & Johnson's Janssen Biotech, Inc.[9] The Food and Drug Administration (FDA) first approved Imbruvica in November 2013 to treat mantle cell lymphoma.[10] FDA granted the approval to Pharmacyclics and Janssen, which entered into a co-development agreement in 2011.[11] In 2015, AbbVie acquired Pharmacyclics for $21 billion.[12] Since November 2013, FDA has granted approval for Imbruvica to be marketed for the treatment of four other forms of cancer.[13]

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[3] IQVIA Institute, *Medicine Spending and Affordability in the United States* (Aug. 2020) (online at www.fdanews.com/ext/resources/files/2020/08-04-20-MedicineSpendingAffordabilityUS.pdf?1596568064).

[4] Food and Drug Administration, *Humira® (adalimumab) Injection, For Subcutaneous Use* (Dec. 2018) (online at www.accessdata.fda.gov/drugsatfda_docs/label/2018/125057s410lbl.pdf).

[5] AbbVie Inc., *2019 Form 10-K Annual Report* (Feb. 21, 2020) (online at https://investors.abbvie.com/static-files/19b29be9-9b2a-4915-9a85-1e6344a06863).

[6] *Id.*

[7] I-MAK, *Overpatented, Overpriced: Special Humira Edition* (online at www.i-mak.org/wp-content/uploads/2018/09/i-mak.humira.report.final_.0917.pdf).

[8] IBM Micromedex Redbook, Wholesale Acquisition Cost and Average Wholesale Price History for Humira Prefilled Syringe Kit 40 mg/0.8 mL.

[9] AbbVie Inc., *2019 Form 10-K Annual Report* (Feb. 21, 2020) (online at https://investors.abbvie.com/static-files/19b29be9-9b2a-4915-9a85-1e6344a06863).

[10] Food and Drug Administration, *Imbruvica® (ibrutinib) Capsules, For Oral Use; Imbruvica® (ibrutinib) Tablets, For Oral Use* (Feb. 2018) (online at www.accessdata.fda.gov/drugsatfda_docs/label/2018/210563s000lbl.pdf).

[11] Janssen Biotech, Inc., *Press Release: Janssen Biotech, Inc. Announces Collaborative Development and Worldwide License Agreement for Investigational Anti-Cancer Drug, PCI-32765* (Dec. 8, 2011) (online at www.jnj.com/media-center/press-releases/janssen-biotech-inc-announces-collaborative-development-and-worldwide-license-agreement-for-investigational-anti-cancer-drug-pci-32765).

[12] AbbVie Inc., *AbbVie to Acquire Pharmacyclics, Including Its Blockbuster Product Imbruvica®, Creating an Industry Leading Hematological Oncology Franchise* (Mar. 4, 2015) (online at https://news.abbvie.com/news/abbvie-to-acquire-pharmacyclics-including-its-blockbuster-product-imbruvica-creating-an-industry-leading-hematological-oncology-franchise.htm).

[13] Food and Drug Administration, *Imbruvica® (ibrutinib) Capsules, For Oral Use; Imbruvica® (ibrutinib)*

Over the course of the Committee's investigation, AbbVie repeatedly failed to comply with the Committee's requests and provided inadequate responses regarding Humira and Imbruvica. AbbVie has produced only limited documents about its pricing practices and strategies to preserve market share and pricing power for both products.

On June 21, 2019, Chairman Cummings wrote a second letter to AbbVie and the other 11 drug companies to warn that they had failed, up to that point, to provide adequate responses to the Committee's requests. In these letters, Chairman Cummings provided the companies with a deadline of July 18, 2019, to comply with the Committee's requests.[14]

On September 27, 2019, Chairman Cummings sent a third letter—only to AbbVie—indicating that the company's responses continued to be "woefully inadequate." He explained that the documents produced following his letter on June 21, 2019, were "grossly inadequate and incomplete." He pointed out that, up to that date, the company had produced "primarily external newsletters with publicly-available information and widely-distributed emails notifying AbbVie's sales force about changes to Humira's formulary position." Chairman Cummings requested a "complete set" of documents by October 18, 2019, warning: "If AbbVie fails to provide a complete response by this date, the Committee will consider issuing a subpoena."[15]

After receiving Chairman Cummings' letter on September 27, 2019, AbbVie committed to ensuring that its productions would be more substantive.[16] However, the company's two subsequent productions—on February 28, 2020, and July 31, 2020—failed to show marked improvement over previous productions. Again, a significant portion of these productions included nonresponsive press articles—including nearly one-third of the February 28, 2020, production and approximately 10% of the July 31, 2020, production.

In addition to these three letters from Chairman Cummings, Committee staff have communicated these deficiencies to AbbVie's counsel on more than a dozen occasions.

In total, AbbVie has produced fewer than 7,000 documents to the Committee—a significant portion of which were non-substantive or duplicative. The volume and quality of AbbVie's responses are inconsistent with the expected recordkeeping and decision-making processes of a large multi-national corporation regarding two of its most profitable drugs. In addition, the volume and quality of AbbVie's responses are particularly poor in comparison to

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Tablets, For Oral Use (Feb. 2018) (online at www.accessdata.fda.gov/drugsatfda_docs/label/2018/210563s000lbl.pdf).

[14] Letter from Chairman Elijah E. Cummings, Committee on Oversight and Reform, to Richard A. Gonzalez, Chairman and Chief Executive Officer, AbbVie Inc. (June 21, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2019-06-21.EEC%20to%20Gonzalez-AbbVie%20re%20Drug%20Pricing.pdf).

[15] Letter from Chairman Elijah E. Cummings, Committee on Oversight and Reform, to Richard A. Gonzalez, Chairman and Chief Executive Officer, AbbVie Inc. (Sept. 27, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/2019-09-27.EEC%20to%20ABBVie%20re%20Production.pdf).

[16] Telephone Conference between Counsel to AbbVie, and Staff, Committee on Oversight and Reform (Dec 4, 2019).

the documents produced by other companies that are the subject of the Committee's investigation—particularly given that the Committee is examining two of AbbVie's most profitable products.

II. NEED FOR SUBPOENA

After more than 18 months, AbbVie has demonstrated its unwillingness to comply voluntarily with the Committee's investigation. I am attaching a copy of the subpoena, which I provided to the Ranking Member earlier today as part of our consultation process.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. The Supreme Court has made clear that Congress has broad authority to inquire about a wide array of topics that could be the subject of legislation and appropriations:

> The power of inquiry has been employed by Congress throughout our history, over the whole range of the national interests concerning which Congress might legislate or decide upon due investigation not to legislate; it has similarly been utilized in determining what to appropriate from the national purse, or whether to appropriate. The scope of the power of inquiry, in short, is as penetrating and farreaching [sic] as the potential power to enact and appropriate under the Constitution.[17]

This broad investigative authority extends to drug companies' actions in raising the prices of prescription drugs. Congress has legislated on this issue in the past, is actively considering current legislative proposals, and is likely to continue legislating on this issue in the future.[18] For example, in December 2019, the House of Representatives passed H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act.[19] Among other reforms, the bill would give Medicare the power to negotiate directly with drug companies—authority that President Trump suggested in the past that he supports.[20]

Congress has also considered a wide array of other legislation to limit the ability of drug manufacturers to delay generic competition, cap executive compensation for companies that

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[17] *Barenblatt v. U.S.*, 360 U.S. 109, 111 (1959).

[18] *See, e.g.*, CREATES Act, Pub. L. No. 116-94, §610 (2019); H.R. 3, The Elijah E. Cummings Lower Drug Costs Now Act; H.R. 448, Medicare Drug Price Negotiation Act; H.R. 1046, Medicare Negotiation and Competitive Licensing Act of 2019.

[19] H.R. 3, The Elijah E. Cummings Lower Drug Costs Now Act.

[20] As a candidate, President Trump repeatedly expressed support for empowering Medicare to negotiate directly with drug companies to lower prescription drug prices. At a public event in Farmington, New Hampshire on January 25, 2016, then-candidate Trump claimed that Medicare could save $300 billion if it negotiated discounts and stated: "We don't do it. Why? Because of the drug companies." At a town hall in Exeter, New Hampshire on February 4, 2016, he stated: "When it comes time to negotiate the cost of drugs, we are going to negotiate like crazy." *Donald Trump Says Medicare Should Negotiate Prices*, Associated Press (Jan. 26, 2016) (online at www.statnews.com/2016/01/26/trump-negotiate-drug-prices/); *Trump Vows to Take On 'Powerful' Drug Companies, Drive Down Prices*, Wall Street Journal (Feb. 4, 2016) (online at https://blogs.wsj.com/washwire/2016/02/04/trump-vows-to-take-on-powerful-drug-companies-drive-down-prices/).

steeply raise prices, or require greater transparency for research and development expenditures. As a result of its investigation, including a review of the subpoenaed documents, the Committee may make recommendations on the merits of these legislative proposals and help tailor them to ensure their efficiency and effectiveness towards their intended goals.

We will not be holding a business meeting to consider this subpoena. As you know, when Republican Committee Chairmen held the gavel from 2011 to 2018, they never held a vote on any of their more than 150 subpoenas. Chairman Cummings tried a different approach, explaining at our organizational meeting last year that he hoped to hold votes on subpoenas when possible. However, Chairman Cummings was clear that this was a two-way street. He warned Republican Members "not to reflexively oppose any and every subpoena" for political reasons, and he stated, "If that happens, we will revisit this policy."[21]

Unfortunately, in this case, Republican Committee Members have made clear that they do not support this investigation. To this end, on April 5, 2019, they sent multiple letters attacking Chairman Cummings' integrity, and they urged each drug company not to cooperate with the Committee's investigation.

For example, in their letter to AbbVie CEO Richard Gonzalez, then-Ranking Member Jim Jordan and then-Committee Member and now-White House Chief of Staff Mark Meadows directly questioned "Chairman Cummings' motives" for conducting the investigation, declared their belief that that the Committee "should not pursue" the investigation, raised baseless and inaccurate accusations about Chairman Cummings' safeguarding of sensitive information, and claimed that they were doing so because, as they wrote, "we feel obliged to inform you about these matters."[22]

On April 17, 2019, Chairman Cummings sent a letter responding to then-Ranking Member Jordan:

> You personally may have no interest in bringing down drug prices for your constituents, you honestly may believe it is more important to protect drug company profits and stock prices than the budgets of American families, and you may even disagree with President Trump that drug companies are "getting away with murder," but your efforts to interfere with this investigation represent a new low for a Member of this Committee.[23]

If you have any questions or would like more information, please contact Committee staff at (202) 225-5051.

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[21] Committee on Oversight and Reform, Organizational Meeting, 116th Cong. (Jan. 29, 2019).

[22] Letter from Ranking Member Jim Jordan, Committee on Oversight and Reform, and Ranking Member Mark Meadows, Subcommittee on Government Operations, to Richard A. Gonzalez, Chairman and Chief Executive Officer, AbbVie Inc. (Apr. 5, 2020) (online at https://republicans-oversight.house.gov/wp-content/uploads/2019/04/Pharma-Letters.pdf).

[23] Letter from Chairman Elijah E. Cummings to Ranking Member Jim Jordan, Committee on Oversight and Reform (Apr. 17, 2019) (online at https://oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/2019-04-17.EEC%20to%20Jordan%20re%20Prescription%20Drug%20Investigation.pdf).