

Congress of the United States
House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

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MEMORANDUM

May 13, 2021

To: Members of the Committee on Oversight and Reform

Fr: Committee Staff

Re: Hearing on “Unsustainable Drug Prices (Part III): Testimony from AbbVie CEO Richard Gonzalez”

On Tuesday, May 18, 2021, at 10:00 a.m., the Committee on Oversight and Reform will hold a hybrid hearing in **room 2154 of the Rayburn House Office Building and on the Zoom video platform** to examine the pricing and business practices of AbbVie Inc., which manufactures the anti-inflammatory medication Humira and the cancer medication Imbruvica. The hearing will also evaluate the need for reforms that will lower the price of prescription drugs in the United States.

I. THE COMMITTEE’S DRUG PRICING INVESTIGATION

In January 2019, under the direction of then-Chairman Elijah E. Cummings, the Committee launched a wide-ranging investigation into the drug industry’s pricing and other business practices. The purpose of the investigation was to determine why drug companies are increasing prices so dramatically, how drug companies are using the proceeds, and what steps can be taken to reduce prescription drug prices.

On September 30, 2020, and October 1, 2020, the Committee held two hearings with executives from Celgene Corporation, Bristol Myers Squibb Company, Teva Pharmaceutical Industries Ltd., Amgen Inc., Mallinckrodt Pharmaceuticals, and Novartis AG. Chairwoman Carolyn B. Maloney released five staff reports detailing findings from the Committee’s investigation.¹

¹ House Committee on Oversight and Reform, *Press Release: Committee Begins Releasing Staff Reports on Skyrocketing Drug Prices as Six CEOs Testify This Week* (Sept. 30, 2020) (online at <https://oversight.house.gov/news/press-releases/committee-begins-releasing-staff-reports-on-skyrocketing-drug-prices-as-six-ceos>); House Committee on Oversight and Reform, *Press Release: Committee Releases Additional Staff Reports on Skyrocketing Drug Prices for Day 2 of Landmark Hearings with CEOs* (Oct. 1, 2020) (online at <https://oversight.house.gov/news/press-releases/committee-releases-additional-staff-reports-on-skyrocketing-drug-prices-for-day>).

As part of its investigation, the Committee requested documents and information from AbbVie related to its business and pricing practices for the drugs Humira and Imbruvica.² AbbVie resisted the Committee's efforts to collect and review these documents. In September 2020, Chairwoman Maloney notified Committee Members of her intent to issue a subpoena to AbbVie due to the company's lack of cooperation with the Committee's investigation.³ After this notice, AbbVie finally began to produce long overdue materials in response to the Committee's requests.

II. ABBVIE'S SALES OF HUMIRA AND IMBRUVICA

A. Humira

Humira is the best-selling drug in the world.⁴ It is approved to treat moderate to severe rheumatoid arthritis and other inflammatory diseases.⁵

Since launching Humira in 2003, AbbVie (and its predecessor company Abbott Laboratories) have raised its price 27 times. Humira is now priced at \$2,984 per syringe, or \$77,586 annually—a 470% increase from when the drug entered the market.⁶

In 2020, AbbVie's worldwide net revenues from Humira were nearly \$19.8 billion, including \$16 billion in U.S. net sales.⁷

B. Imbruvica

AbbVie sells Imbruvica in the United States in partnership with Janssen Biotech, Inc., a subsidiary of Johnson & Johnson. The Food and Drug Administration (FDA) first approved Imbruvica in November 2013 to treat mantle cell lymphoma. Since November 2013, FDA has granted approval for Imbruvica to be marketed for the treatment of four other forms of cancer.⁸

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>).

³ Memorandum from Chairwoman Carolyn B. Maloney, Committee on Oversight and Reform, to Members of the Committee on Oversight and Reform (Sept. 1, 2020) (online at <https://oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/2020-09-01%20AbbVie%20Subpoena%20Memo.pdf>).

⁴ IQVIA Institute for Human Data Science, *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).

⁵ Food and Drug Administration, *Humira® (adalimumab) Injection, For Subcutaneous Use* (Dec. 2018) (online at www.accessdata.fda.gov/drugsatfda_docs/label/2018/125057s410lbl.pdf).

⁶ IBM Micromedex Redbook, *Wholesale Acquisition Cost for Humira*. The annual calculation is for a patient that injects Humira every other week.

⁷ *Id.*

⁸ 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).

AbbVie and Janssen have raised the price of Imbruvica nine times since launching the drug in 2013. Today, Imbruvica is priced at \$181,529 per year for a patient taking three pills per day, as compared to \$99,776 per year at launch.⁹

In 2020, AbbVie and Janssen collected more than \$4.3 billion in U.S. net revenues for Imbruvica, nearly nine times the amount collected in 2014.¹⁰

III. NEED FOR REFORMS TO LOWER PRESCRIPTION DRUG PRICES

High drug prices have negatively impacted patients and families in the United States. In 2019, out-of-pocket spending on prescription drugs reached \$82 billion.¹¹ A study by the Kaiser Family Foundation found that nearly a quarter of people taking prescription drugs report that it is difficult for them to afford their medications.¹² Nearly nine in ten Americans, including 85% of Republicans, support allowing Medicare to negotiate directly with manufacturers for lower drug prices.¹³

On April 22, 2021, Energy and Commerce Committee Chairman Frank Pallone, Jr., Ways and Means Committee Chairman Richard E. Neal, and Education and Labor Committee Chairman Robert C. “Bobby” Scott reintroduced H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act. This proposal would empower the Secretary of Health and Human Services to negotiate lower prescription drug prices for Medicare beneficiaries and make those negotiated prices available to commercial health insurance plans.¹⁴

On April 29, 2021, Chairwoman Maloney joined a bipartisan, bicameral group of Members and Senators to introduce legislation that would target anticompetitive practices employed by large drug companies.

- The Preserve Access to Affordable Generics and Biosimilars Act (H.R. 2891) prohibits drug companies from entering into anticompetitive pay-for-delay agreements—arrangements that allow a drug company to pay the manufacturer of a generic or biosimilar competitor not to bring their product to market.
- The Affordable Prescriptions for Patients Through Promoting Competition Act (H.R. 2783) prohibits “product hopping”—an anticompetitive practice where drug

⁹ IBM Micromedex Redbook, *Wholesale Acquisition Cost for Imbruvica*.

¹⁰ AbbVie Inc., *2020 Form 10-K Annual Report* (Feb. 19, 2021) (online at <https://investors.abbvie.com/static-files/b1ca3ffe-226e-499d-992e-344f42d470d1>).

¹¹ IQVIA Institute for Human Data Science, *Medicine Spending and Affordability in the United States* (Aug. 4, 2020) (online at www.iqvia.com/insights/the-iqvia-institute/reports/medicine-spending-and-affordability-in-the-us).

¹² Kaiser Family Foundation, *Public Opinion on Prescription Drugs and Their Prices* (Oct. 16, 2020) (online at www.kff.org/slideshow/public-opinion-on-prescription-drugs-and-their-prices/).

¹³ Kaiser Family Foundation, *What’s the Latest on Medicare Drug Price Negotiations?* (Oct. 17, 2019) (online at www.kff.org/medicare/issue-brief/whats-the-latest-on-medicare-drug-price-negotiations/).

¹⁴ H.R. 3.

companies seek to extend their exclusivity on an expiring patent by switching doctors and patients from the old version of their product to a new version.

- The Stop Stalling Access to Affordable Medications Act (H.R. 2883) prohibits drug companies from overwhelming FDA with meritless “citizen petitions” to block or delay generic competitors.¹⁵

IV. WITNESSES

Mr. Richard Gonzalez

Chairman of the Board and Chief Executive Officer
AbbVie Inc.

Dr. Aaron Kesselheim

Associate Professor of Medicine
Harvard Medical School

Mr. Tahir Amin

Co-Founder and Co-Executive Director
Initiative for Medicines, Access, and Knowledge

Mr. Craig Garthwaite

Herman Smith Research Professor in Hospital and Health Services
Kellogg School of Management at Northwestern University

Staff contacts: Amish Shah, Miles Lichtman, Katie Teleky, Kelly Hennessy, and Cameron MacPherson at (202) 225-5051.

¹⁵ House Committee on the Judiciary, *Press Release: Bipartisan Legislative Package Introduced to Lower Prescription Drug Costs* (Apr. 29, 2021) (online at <https://judiciary.house.gov/news/documentsingle.aspx?DocumentID=4536>).