Congress of the United States
Washington, DC 20515

January 14, 2019

Richard A. Gonzalez
Chairman and Chief Executive Officer
AbbVie Inc.
1 North Waukegan Road
North Chicago, IL 60064

Dear Mr. Gonzalez:

The Committee on Oversight and Reform is investigating the actions of drug companies in raising prescription drug prices in the United States, as well as the effects of these actions on federal and state budgets and on American families.

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 drug companies are using the proceeds, and what steps can be taken to reduce prescription drug prices.

Research and development efforts on groundbreaking medications have made immeasurable contributions to the health of Americans, including new treatments and cures for diseases that have affected people for centuries. But the ongoing escalation of prices by drug companies is unsustainable. As President Trump has said, drug companies are "getting away with murder."[1]

Approximately 94% of widely-used brand-name drugs on the market between 2005 and 2017 more than doubled in price during that time, and the average price increase in 2017 was 8.4%—four times the rate of inflation—according to an analysis conducted by AARP.[2] A recent

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[1] *Trump on Drug Prices: Pharma Companies Are "Getting Away with Murder,"* Washington Post (Jan. 11, 2017) (online at www.washingtonpost.com/news/wonk/wp/2017/01/11/trump-on-drug-prices-pharma-companies-are-getting-away-with-murder/?noredirect=on&utm_term=.bf515b3ac693).

[2] AARP, *Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans: 2017 Year-End Update* (Sept. 2018) (online at www.aarp.org/content/dam/aarp/ppi/2018/09/trends-in-retail-prices-of-brand-name-prescription-drugs-year-end-update.pdf).

Associated Press analysis found that more than 4,400 brand-name drugs increased in price in the first seven months of 2018 alone, compared to 46 price decreases.[3]

The Centers for Medicare and Medicaid Services projects that spending on prescription drugs will increase more rapidly than spending on any other health care sector over the next ten years.[4] The federal government bears much of the financial burden of escalating drug prices through Medicare Part D, which provides drug coverage to approximately 43 million people.[5] The government is projected to spend $99 billion on Medicare Part D in 2019.[6]

A review by the Inspector General of the Department of Health and Human Services found that ten of the most expensive brand-name drugs accounted for $15.6 billion of spending in the catastrophic coverage phase of the Medicare Part D benefit in 2015.[7] The Inspector General has also found that Part D payments for brand-name drugs increased by 62% from 2011 to 2015—after taking into account manufacturer rebates—even though the number of prescriptions fell by 17%.[8]

These price increases are negatively affecting patients, including those on Medicare. The percentage of Medicare Part D beneficiaries who paid at least $2,000 out-of-pocket for their drugs nearly doubled from 2011 to 2015.[9] A survey conducted by the Kaiser Family Foundation last year found that one in five Americans had not filled a prescription due to costs.[10]

In 2016, the 20 most expensive drugs to Medicare Part D accounted for roughly $37.7 billion in spending.[11] The Committee is examining your company's pricing practices with respect to the following drugs:

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[3] *Drug Prices Going Up Despite Trump Promise*, Associated Press (Sept. 24, 2018) (online at www.apnews.com/b28338b7c91c4174ad5fad682138520d).

[4] Centers for Medicare and Medicaid Services, Office of the Actuary, *CMS Office of the Actuary Releases 2017-2026 Projections of National Health Expenditures* (Feb. 14, 2018) (online at www.cms.gov/newsroom/press-releases/cms-office-actuary-releases-2017-2026-projections-national-health-expenditures).

[5] Kaiser Family Foundation, *Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing* (May 17, 2018) (online at www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing/).

[6] Congressional Budget Office, *Medicare—CBO's April 2018 Baseline* (online at www.cbo.gov/sites/default/files/recurringdata/51302-2018-04-medicare.pdf) (accessed Dec. 30, 2018).

[7] Department of Health and Human Services, Office of the Inspector General, *High-Price Drugs Are Increasing Federal Payments for Medicare Part D Catastrophic Coverage* (Jan. 2017) (online at https://oig.hhs.gov/oei/reports/oei-02-16-00270.pdf).

[8] Department of Health and Human Services, Office of the Inspector General, *Increases in Reimbursement for Brand-Name Drugs in Part D* (June 2018) (online at https://oig.hhs.gov/oei/reports/oei-03-15-00080.pdf).

[9] *Id.*

[10] Kaiser Family Foundation, *Data Note: Americans' Challenges with Health Care Costs* (Mar. 2, 2017) (online at www.kff.org/health-costs/poll-finding/data-note-americans-challenges-with-health-care-costs/).

[11] Centers for Medicare and Medicaid Services, *Medicare Part D Drug Spending Dashboard & Data* (online at www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.html) (accessed Dec. 30, 2018) (data reflect drug spending for the Part D

Drug	Disease/ Condition	2016 Part D Spending	2016 Average Spending per Beneficiary	One Year Change in Ave. Spending/Unit 2015-2016	Five Year Annual Growth Rate in Ave. Spending/Unit 2012-2016
Humira (2002)	Arthritis	$490,135,622	$31,669	21.90%	17.97%
Humira Pen (2014)	Arthritis	$1,638,715,583	$34,024	21.89%	18.00%
Imbruvica* (2013)	Lymphoma	$978,350,728	$65,424	9.07%	6.71%

Source: Centers for Medicare and Medicaid Services—Medicare Part D Drug Spending Dashboard
*Imbruvica is co-marketed by AbbVie and Johnson & Johnson

To assist the Committee with this investigation, please provide the following information and documents on behalf of your company by February 4, 2019:

1. For each drug identified above, for each calendar year from 2009 through the present, and separated by each of the commercial, Medicare Part B, Medicare Part D, Medicaid, and VA sales channels:

   a. total gross sales;
   b. number of units sold;
   c. total sales net of rebates, discounts, and all other price concessions, including the type, amount, and recipient of each discount or concession;
   d. cost of goods sold;
   e. highest, lowest, and average percent rebate negotiated per unit, including supplemental Medicaid rebates, and the dollar value of the rebate;
   f. highest, lowest, and average negotiated price per unit;
   g. average net effective price per unit; and
   h. a description of the sources of information and methodology for responding to requests (a) through (g);

2. For each drug identified above, separated by year since the drug entered the company's development pipeline:

   a. amount spent by your company on pre-clinical testing, Phase 1, Phase 2, Phase 3 clinical trials, and/or post-market surveillance;
   b. amount spent by your company on direct-to-consumer advertising;
   c. amount of Research and Development tax credits claimed annually by your company;
   d. total amount of tax deductions taken for charitable activities related to each drug identified above; and
   e. a description of the sources of information and methodology for responding to requests (a) through (d);

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program during the benefit year, but do not reflect manufacturer rebates and price concessions, which CMS is prohibited from publicly disclosing).

3. For each drug identified above:

   a. a list of the company's patents or patent applications that claim the drug's active ingredient(s), methods of use, or indication, and any other patents that the company would seek to enforce in litigation related to the drug;
   b. whether each identified patent was originally obtained under the Patent and Trademark Law Amendments Act (the Bayh-Dole Act) or otherwise developed under federally-sponsored research;
   c. whether each identified patent or patent application was filed before or after the drug received marketing approval from the Food and Drug Administration; and
   d. the number of patents for each approved indication of the drug;

4. If your company acquired the sales rights to any of the drugs identified above from another company, including as part of a larger acquisition:

   a. the name of the company;
   b. the total acquisition price of the transaction;
   c. the price of the drug at the time of acquisition; and
   d. all documents and communications regarding any planned price increase(s) after acquisition, including documents regarding payer price sensitivity;

5. For each drug identified above, a list of each business unit, component, or division within your company involved in the commercialization or pricing of the drug, and organizational charts for those entities;

6. For each drug identified above, a list of all third-party entities that have been contracted to provide services related to marketing, commercialization, pricing, or lifecycle management of the drug, and a description of the services provided by the third-party entity;

7. For each of the past five years:

   a. the total compensation paid or projected to be paid to the ten highest-paid employees, broken down by salaries, bonuses (cash and equity), and benefits; a description of the reasons for the year to-year changes in compensation; and all related communications and approval documentation regarding the compensation;
   b. a list of all other employees who were paid, or are projected to be paid, more than $1,000,000 in total compensation; the total compensation paid or projected to be paid to these employees, broken down by salaries,

bonuses (cash and equity), and benefits; and a description of the reasons for the year to-year changes in these amounts; and

c. compensation policies, procedures, and practices as they relate to pricing strategies for each drug identified above; and all related communications and approval documentation regarding the compensation;

8. The dates, times, locations, and attendees of any meetings between representatives of your company and officials at the Centers for Medicare and Medicaid Services, the Department of Health and Human Services, the Office of Management and Budget, or the Executive Office of the President from January 20, 2017, to the present;

9. All internal and external presentations, analyses, or other documents prepared for or provided to the Board of Directors, any subcommittee of the Board of Directors, or any corporate officers, regarding pricing strategies or lifecycle management of each drug identified above;

10. For each drug identified above, from January 1, 2009 through the present, all documents, including communications, related to:

a. pricing strategies or lifecycle management;
b. your company's reporting to the public of return on investment, profitability, or sales, including draft talking points for investor presentations and earnings calls;
c. the potential impact on sales revenue under a single dosage or single tablet regimen;
d. utilization or pricing strategies as they relate to any discount coupon, drug donation, or co-pay assistance programs, or any other manufacturer-affiliated or independent patient assistance or prescription assistance programs, foundations, or charities; and
e. Risk Evaluation and Mitigation Strategies or other limited, restricted, or specialty distribution networks as they relate to increasing patient utilization or limiting prospective generic applicants' access to each drug identified above;

11. All communications between employees or officers of your company and employees or officers of any other pharmaceutical company regarding the price of each drug identified above, or the price of any other drugs that are approved for the same indication;

12. All contracts with pharmacy benefit managers related to each drug identified above;

13. All co-marketing or co-development agreements related to Imbruvica;

14. A list of all federally-funded research studies associated with development of each drug identified above, including federally-funded research conducted by third-party entities, and a list of related licensing and royalty agreements; and

15. All complaints received by your company regarding the price or coverage of each drug identified above.

For purposes of this request, the term "drug" includes any line extension, reformulation, combination product, follow-on product, authorized generic, or other pharmaceutical product that contains the same active ingredient (including in combination with other ingredients) as the drug identified in the chart above. For purposes of this request, the term "your company" includes AbbVie Inc. and its subsidiaries and agents.

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.

An attachment to this letter provides additional instructions for responding to the Committee's request. If you have any questions regarding this request, please contact my staff at (202) 225-5051.

Thank you for your attention to this matter.

Sincerely,

Elijah E. Cummings
Chairman

Enclosure

cc: The Honorable Jim Jordan, Ranking Member