Responses to Questions for the Record

Drug Pricing in America:
A Prescription for Change, Part II

Senator Ron Wyden

Abbvie Responses

Senator Wyden:
For all witnesses:

Proposed Rebate Rule

As has been done in many other settings, drug manufacturers said during the hearing that one reason list prices for drugs are high is that pharmaceutical benefit managers (PBMs) demand larger and larger rebates in order for the drug to receive favorable placement on a formulary. You and your colleagues who testified during the hearing stated if the Administration's proposal on changes to the anti-kickback safe harbor for pharmaceutical rebates took effect, your company would likely lower list price.

Like many Oregonians, I am skeptical drug manufacturers would voluntarily lower their prices. Therefore, would you support legislation that would 1) make similar changes the Administration has put forward related to Part D and Medicaid managed care, 2) change the rebate system in a similar way to the proposal for the commercial market, and 3) require drug makers to lower the list price of their drugs equal to the amount of rebates provided today?

Response: There has been significant discussion over the past several months about proposals to eliminate rebates from Medicare Part D, Medicaid and the Commercial market culminating in the Administration's publication of a proposed rule to "expressly exclude[e] from safe harbor protection under the Anti-Kickback Statute (AKS) rebates on prescription drugs paid by manufacturers to pharmacy benefit managers (PBMs), Part D plans, and Medicaid managed care organizations. The proposal would create a new safe harbor protecting discounts offered to patients at the pharmacy counter. Finally, the proposal would create new safe harbor protection for fixed fee services arrangements between manufacturers and PBMs."

AbbVie is encouraged by the goals of the proposed rule to ensure manufacturer discounts are reflected in and reduce patient cost sharing under Part D. While we believe the rule is an important step in the right direction, we also believe more should be done to help reduce the out-of-pocket cost burden on Medicare Part D patients.

As for what the elimination of rebates might mean to the overall health care system or pharmaceutical companies, it is premature to comment on these items until the Administration's rule is finalized, implementation timelines are solidified and there are specific details regarding how a new system without rebates will be structured and function.

Medicaid Drug Rebate Program

The Medicaid Drug Rebate Program (MDRP) requires manufacturers to provide a basic rebate and an additional inflationary rebate for both brand and generic drugs. The inflationary rebate is an increasingly substantial part of total rebates due in large part to large increases in drug prices that exceed inflation. Under current law, this inflationary rebate is capped at 100 percent of Average Manufacturer Price (AMP). This is the case even when manufacturers continue to raise their prices well above inflation.

1. **Please provide a list of all of your pharmaceutical products that have reached the Medicaid AMP rebate cap in any of the 20 quarters from January 1, 2014 through December 31, 2018.**
2. **For each drug listed in response to question 1, please also provide a list of which quarters and years each drug hit the cap.**

Response to previous two questions:

PRODUCT NAME	NDC 11	QTR/YEAR of AMP CAPs
Androgel 1%, 2.5 G Unit Dose, 30'S	00051-8425-30	Q1 2015
Androgel 1%, 5.0 G Unit Dose, 30'S	00051-8450-30	Q1 2015
Androgel 1.62% 2.5Gm Unit Dose	00051-8462-30	Q2 2017, Q1 2018 - Q3 2018
Androgel 1.62% 1.25Gm Unit Dose	00051-8462-31	Q2 2017, Q1 2018 - Q3 2018
Androgel 1.62% Pump	00051-8462-33	Q2 2017, Q1 2018 - Q3 2018
Biaxin, Filmtab Tablets, 500 Mg, 60'S	00074-2586-60	Q3 2016 - Q4 2016
Biaxin XL, Filmtab Tab, 500 Mg, 10 X10'S	00074-3165-11	Q1 2014 - Q4 2015
Biaxin XL 500Mg(1X14)	00074-3165-14	Q1 2014 - Q4 2015
Biaxin XL, Filmtab Tabs, 500Mg, 4X14'S	00074-3165-41	Q1 2014 - Q4 2015
Biaxin XL, Filmtab Tablets, 500 Mg, 60'S	00074-3165-60	Q1 2014 - Q4 2015
Biaxin OS, 250Mg/5Ml, 100ML	00074-3188-13	Q2 2014 - Q3 2014, Q1 2016 - Q2 2018
Biaxin OS 250Mg/5Ml, 50ML	00074-3188-50	Q2 2014 - Q3 2014, Q1 2016 - Q2 2018
Biaxin Filmtab Tablets, 250 Mg, 60'S	00074-3368-60	Q1 2014, Q3 2014, Q1 2015 - Q3 2015
Cardizem LA , Tablets, 120 Mg, 30'S	00074-3045-30	Q1 2014 - Q3 2014
Cardizem LA , Tablets, 120 Mg, 90'S	00074-3045-90	Q1 2014 - Q3 2014
Cardizem LA , Tablets, 180 Mg, 30'S	00074-3061-30	Q1 2014

PRODUCT NAME	NDC 11	QTR/YEAR of AMP CAPs
Cardizem LA , Tablets, 180 Mg, 90'S	00074-3061-90	Q1 2014
Cardizem LA , Tablets, 240 Mg, 30'S	00074-3062-30	Q1 2014
Cardizem LA , Tablets, 240 Mg, 90'S	00074-3062-90	Q1 2014
Cardizem LA , Tablets, 300 Mg, 30'S	00074-3063-30	Q1 2014
Cardizem LA , Tablets, 300 Mg, 90'S	00074-3063-90	Q1 2014
Cardizem LA , Tablets, 360 Mg, 30'S	00074-3064-30	Q1 2014 - Q2 2014
Cardizem LA , Tablets, 360 Mg, 90'S	00074-3064-90	Q1 2014 - Q2 2014
Cardizem LA , Tablets, 420 Mg, 30'S	00074-3069-30	Q1 2014
Cardizem LA , Tablets, 420 Mg, 90'S	00074-3069-90	Q1 2014
Depacon 500Mg (100Mg/1ML) 10X5ML SDV	00074-1564-10	Q1 2016, Q4 2016 - Q4 2017
Depakene 250Mg 100Cap	00074-5681-13	Q1 2014, Q3 2014 - Q4 2018
Depakene OS 250Mg/5ML, 16Oz	00074-5682-16	Q3 2014 - Q4 2018
Depakote ER 250Mg 10X10Tab	00074-3826-11	Q1 2015, Q4 2018
Depakote ER 250Mg 100Tab	00074-3826-13	Q1 2015, Q4 2018
Depakote, Sprinkle Capsule, 125 Mg,10X10	00074-6114-11	Q1 2015 - Q4 2018
Depakote Sprinkle Capsule, 125Mg, 100	00074-6114-13	Q1 2015 - Q4 2018
Depakote 125Mg 100Tab	00074-6212-13	Q1 2014, Q3 2014 - Q4 2018
Depakote 250Mg 100Tab	00074-6214-13	Q1 2014, Q3 2014 - Q4 2018
Depakote 250Mg 500Tab	00074-6214-53	Q1 2014, Q3 2014 - Q4 2018

PRODUCT NAME	NDC 11	QTR/YEAR of AMP CAPs
Depakote 500Mg 100Tab	00074-6215-13	Q1 2014, Q3 2014 - Q4 2018
Depakote 500Mg 500Tab	00074-6215-53	Q1 2014, Q3 2014 - Q4 2018
Depakote ER 500Mg 10X10Tab	00074-7126-11	Q4 2014 - Q1 2015, Q1 2017 - Q3 2017, Q4 2018
Depakote ER 500Mg 100Tab	00074-7126-13	Q4 2014 - Q1 2015, Q1 2017 - Q3 2017, Q4 2018
Depakote ER 500Mg 500Tab	00074-7126-53	Q4 2014 - Q1 2015, Q1 2017 - Q3 2017, Q4 2018
Humira 40Mg/0.8ML (2 Syringes)	00074-3799-02	Q2 2016 - Q4 2018
Humira Ped Crohns Starter Pack, 40 Mg	00074-3799-03	Q2 2016 - Q4 2018
Humira Ped Crohns Starter Pack, 40 Mg	00074-3799-06	Q2 2016 - Q4 2018
Humira 40Mg/0.8 ML (2 Pens)	00074-4339-02	Q2 2016 - Q4 2018
Humira, Crohn's, 40Mg/0.8 ML (6 Pens)	00074-4339-06	Q2 2016 - Q4 2018
Humira, Psoriasis, 40Mg/0.8ML (4 Pens)	00074-4339-07	Q2 2016 - Q4 2018
Humira, Single Dose Syringe, 10 Mg/0.2ML	00074-6347-02	Q2 2016 - Q4 2018
Humira 20Mg/0.4ML (2 Syringes)	00074-9374-02	Q2 2016 - Q4 2018
K-Tab, Filmtabs, 8Meq, 600Mg, 100Ct	00074-3058-41	Q3 2018
K-Tab, Filmtabs, 8Meq, 600Mg, 1000Ct	00074-3058-46	Q3 2018
Marinol 2.5 Mg Capsules, 60'S	00051-0021-21	Q2 2016
Marinol 5 Mg Capsules, 60'S	00051-0022-21	Q3 2018
Marinol 10 Mg Capsules, 60'S	00051-0023-21	Q2 2014, Q3 2017
Mavik, Tablets, 1 Mg, 100'S	00074-2278-13	Q4 2014, Q2 2015

PRODUCT NAME	NDC 11	QTR/YEAR of AMP CAPs
Niaspan, Tablets, 500 Mg, 90'S	00074-3074-90	Q1 2014, Q2 2015, Q1 2016 - Q3 2016, Q1 2017 - Q4 2018
Niaspan, Tablets, 750 Mg, 90'S	00074-3079-90	Q1 2014, Q4 2014, Q2 2015 - Q2 2016, Q4 2016 - Q4 2018
Niaspan, Tablets, 1000 Mg, 90'S	00074-3080-90	Q1 2014, Q1 2015 - Q2 2015, Q1 2016 - Q3 2016, Q1 2017 - Q4 2018
Niaspan, Tablets, 500Mg, 90'S	00074-3265-90	Q4 2017 - Q4 2018
Niaspan, Tablets, 750Mg 90'S	00074-3274-90	Q1 2018 - Q4 2018
Niaspan, Tablets, 1000Mg 90'S	00074-3275-90	Q4 2017 - Q4 2018
Prometrium 100 Mg Capsules, 100'S	00032-1708-01	Q2 2016 - Q4 2018
Prometrium 200 Mg Capsules, 100'S	00032-1711-01	Q2 2016 - Q4 2018
Simcor 500Mg/20Mg, 90Tab	00074-3312-90	Q3 2014
Simcor 1000Mg/20Mg, 90Tab	00074-3455-90	Q1 2014, Q3 2014
Tarka ER 2Mg/180Mg, 100Tab	00074-3287-13	Q2 2015 - Q4 2015, Q2 2016 - Q4 2016, Q2 2017 - Q4 2017, Q2 2018 - Q4 2018
Tarka 1Mg/240Mg, 100Tab	00074-3288-13	Q2 2015 - Q4 2015, Q2 2016 - Q4 2018
Tarka ER 2Mg/240Mg, 100Tab	00074-3289-13	Q1 2014, Q2 2015 - Q4 2015, Q2 2016 - Q4 2016, Q2 2017 - Q4 2017, Q2 2018 - Q4 2018
Tarka ER 4Mg/240Mg, 100Tab	00074-3290-13	Q1 2014, Q1 2015 - Q3 2015, Q1 2016 - Q2 2016, Q4 2016 - Q2 2017, Q4 2017 - Q3 2018
Tricor, Tablets, 145Mg, 90Ct Btl	00074-3189-90	Q3 2018
Tricor, Tablets, 48 Mg, 90'S	00074-6122-90	Q4 2014 - Q1 2015
Tricor, Tablets, 145 Mg, 90'S	00074-6123-90	Q3 2018

PRODUCT NAME	NDC 11	QTR/YEAR of AMP CAPs
Trilipix, Delayed Release Cap, 45Mg 90Ct	00074-3161-90	Q2 2017 - Q4 2017, Q2 2018 - Q4 2018
Trilipix, Delayed Release Cap, 135Mg 90S	00074-9189-90	Q3 2018 - Q4 2018
Trilipix, Delayed Release Cap, 45 Mg 90S	00074-9642-90	Q3 2014 - Q4 2014, Q2 2015 - Q3 2015, Q1 2016, Q3 2016 - Q4 2016, Q2 2017 - Q4 2017, Q2 2018 -Q4 2018
Zemplar, Capsules, 2 Mcg, 30S	00074-4314-30	Q3 2014 - Q1 2015, Q3 2015 - Q4 2015, Q2 2016 -Q4 2016, Q2 2017, Q4 2017 - Q4 2018
Zemplar, Capsules, 4 Mcg, 30'S	00074-4315-30	Q2 2014 - Q4 2015
Zemplar, Capsules, 1 Mcg, 30'S	00074-4317-30	Q4 2014, Q2 2015, Q4 2015, Q2 2016, Q1 2018 - Q4 2018

Medicaid Drug Rebate Program Compliance

I am concerned about recent reports and legal settlements surrounding drug manufacturers' failure to comply fully with the requirements of the MDRP. For example, an analysis by the U.S. Department of Health and Human Services Office of Inspector General found that between 2012 and 2016 taxpayers may have overpaid by as much as $1.3 billion for 10 potentially misclassified drugs. That is why I introduced the Right Rebate Act with Chairman Grassley to prevent drug manufacturers from manipulating Medicaid to increase their profits. However, I continued to be concerned about oversight and manufacturer compliance with the requirements of the Medicaid Drug Rebate Program. Accordingly, please describe the following:

1. **Your company's current compliance plan and procedures used to ensure compliance with the requirements of the Medicaid Drug Rebate Program including internal audits or other checks you use to identify compliance vulnerabilities.**

   Response: AbbVie has established and maintains a comprehensive compliance plan and procedures to ensure MDRP compliance, the core components of which include policies and procedures relating to MDRP issues, routine internal and external monitoring and auditing, and a dedicated governance team to monitor and address any potential MDRP issues.

2. **Any past or ongoing issues of non-compliance.**

Response: We are not aware of past or ongoing issues of non-compliance with MDRP legal requirements.

3. **Any corrective actions taken to address identified problems or issues of non-compliance with the MDRP and how such steps were communicated to the Centers for Medicare & Medicaid Services.**

   Response: We are not aware of past or ongoing issues of non-compliance with MDRP legal requirements.

4. **Any steps taken to improve compliance and ensure that all Medicaid drug rebates owed to the federal government and the states are paid in full.**

   Response: AbbVie conducts periodic reviews of its compliance plan and updates its policies, procedures, and monitoring plans as needed to ensure Company's continued implementation of MDRP legal requirements.

Bonus Payments Tied to Specific Drugs

I am concerned by the potential for employee financial incentives to encourage high launch prices and price increases for prescription drugs.

1. **Is your salary, bonus or other compensation tied to sales or revenue targets of a single product your company sells? Has it ever been? If yes, please state the product or products to which your salary, bonus or other compensation was tied.**
2. **Is your salary, bonus or other compensation tied to either revenue or net income of the company as a whole? Has it ever been? If yes, please explain what assumptions about price increases are used when the compensation committee sets revenue or net income goals. Does the compensation committee provide any guidance to executives in regards to the amount of revenue that the company will generate from price increases versus volume growth?**

   Response to previous two questions: To determine Mr. Gonzalez's 2018 annual incentive compensation (sometimes referred to as a bonus), net revenues, income before taxes, and Humira sales were three of several quantitative financial metrics that were considered in addition to qualitative factors. At most, a single quantitative financial metric had the potential to impact up to 3% of Mr. Gonzalez's total compensation, subject to additional qualitative and relative analyses. No other compensation element, beyond the annual incentive compensation, includes Humira sales, revenue, or net income as a performance metric. While some specific details have differed somewhat, the foregoing has generally been true in prior years as well.

AstraZenenca Responses

VI. Senator Wyden

1. Proposed Rebate Rule. As has been done in many other settings, drug manufacturers said during the hearing that one reason list prices for drugs are high is that pharmaceutical benefit managers (PBMs) demand larger and larger rebates in order for the drug to receive favorable placement on a formulary. You and your colleagues who testified during the hearing stated if the Administration's proposal on changes to the anti-kickback safe harbor for pharmaceutical rebates took effect, your company would likely lower list price. Like many Oregonians, I am skeptical drug manufacturers would voluntarily lower their prices.

   Therefore, would you support legislation that would 1) make similar changes the Administration has put forward related to Part D and Medicaid managed care, 2) change the rebate system in a similar way to the proposal for the commercial market, and 3) require drug makers to lower the list price of their drugs equal to the amount of rebates provided today?

   Assuming the HHS rebate rule is finalized largely as proposed, AstraZeneca intends to comply with its requirements and use point-of-sale discounts. Our goal is to maintain net prices broadly in line with today, recognizing our ability to do so may be dependent on external factors and market response such as how plans evolve their benefit design and the total degree of transparency under the new model.

   AstraZeneca would plan to reduce list prices, pending reforms across all payers, including in the commercial sector in addition to Part D, as the current construct does not allow for two separate list prices (i.e., one list price for Part D and a different list price for the commercial sector). Therefore, we also support efforts to eliminate rebates in the commercial sector and recommend that Congress explore such legislation. While eliminating rebates is an important step, benefit designs must also be evaluated.

2. Medicaid Drug Rebate Program. The Medicaid Drug Rebate Program (MDRP) requires manufacturers to provide a basic rebate and an additional inflationary rebate for both brand and generic drugs. The inflationary rebate is an increasingly substantial part of total rebates due in large part to large increases in drug prices that exceed inflation. Under current law, this inflationary rebate is capped at 100 percent of Average Manufacturer Price (AMP). This is the case even when manufacturers continue to raise their prices well above inflation.

a. **Please provide a list of all of your pharmaceutical products that have reached the Medicaid AMP rebate cap in any of the 20 quarters from January 1, 2014 through December 31, 2018.**

Please see Appendix B.

b. **For each drug listed in response to question 1, please also provide a list of which quarters and years each drug hit the cap.**

Please see Appendix B.

3. Medicaid Drug Rebate Program Compliance. I am concerned about recent reports and legal settlements surrounding drug manufacturers' failure to comply fully with the requirements of the MDRP. For example, an analysis by the U.S. Department of Health and Human Services Office of Inspector General found that between 2012 and 2016 taxpayers may have overpaid by as much as $1.3 billion for 10 potentially misclassified drugs. That is why I introduced the Right Rebate Act with Chairman Grassley to prevent drug manufacturers from manipulating Medicaid to increase their profits. However, I continued to be concerned about oversight and manufacturer compliance with the requirements of the Medicaid Drug Rebate Program.

Accordingly, please describe the following:

a. **Your company's current compliance plan and procedures used to ensure compliance with the requirements of the Medicaid Drug Rebate Program including internal audits or other checks you use to identify compliance vulnerabilities.**

All aspects of AstraZeneca's compliance with the requirements of the Medicaid Drug Rebate Program, including Statutory Pricing (average manufacturer price (AMP) and Best Price) and Medicaid Rebate payments, are covered by AstraZeneca's compliance framework. This compliance plan includes a robust review process, including Sarbanes-Oxley testing, self-auditing, and formal audits by internal and external audit.

b. **Any past or ongoing issues of non-compliance.**

Since the implementation of AstraZeneca's compliance framework, we are not aware of any compliance issues that have been identified via this internal and external audit process.

c. **Any corrective actions taken to address identified problems or issues of non-compliance with the MDRP and how such steps were communicated to the Centers for Medicare & Medicaid Services.**

As noted above, to date, no compliance issues have been identified via this internal and external audit process.

d. **Any steps taken to improve compliance and ensure that all Medicaid drug rebates owed to the federal government and the states are paid in full.**

AstraZeneca has a comprehensive compliance framework that includes Sarbanes-Oxley testing, self-auditing, and formal audits by internal and external audit. Additionally, as it relates to Medicaid drug rebates owed to the federal government and states, AstraZeneca performs additional reviews of claims-level data, ensuring the completeness and accuracy of both the payments made by manufacturers as well as claims submitted to manufacturers. This process has identified duplicate pharmacy claims submitted to State Medicaid Agencies resulting in overpayment by both States and manufacturers. Clearly, these overpayments disadvantage both the States and manufacturers like AstraZeneca.

4. Bonus Payments Tied to Specific Drugs. I am concerned by the potential for employee financial incentives to encourage high launch prices and price increases for prescription drugs.

a. **Is your salary, bonus or other compensation tied to sales or revenue targets of a single product your company sells? Has it ever been? If yes, please state the product or products to which your salary, bonus or other compensation was tied.**

The CEO's compensation as well as the compensation of other senior leaders is directly based on three areas of performance that are generally weighted equally: development and delivery of innovative science, our aggregate sales, and other important financial metrics.

AstraZeneca understands that executive pay is a closely scrutinized issue. As part of our compensation decisions, we are mindful of the sensitivity of this issue as we determine how best to incentivize, reward and retain executives capable of leading a global pharmaceutical company in a highly competitive market.

b. **Is your salary, bonus or other compensation tied to either revenue or net income of the company as a whole? Has it ever been? If yes, please explain what assumptions about price increases are used when the compensation committee sets revenue or net income goals. Does the compensation committee provide any guidance to executives in regards to the amount of revenue that the company will generate from price increases versus volume growth?**

The CEO's compensation as well as the compensation of other senior leaders is directly based on three areas of performance that are generally weighted equally: development and delivery of innovative science, our aggregate sales, and other important financial metrics. AstraZeneca's Remuneration Committee does not provide any guidance on price increases.

5. Provision of Rebates in Exchange for Formulary Placement. In today's system, drug makers receive a limited time window to sell their drug without competition. After that period has expired, low-cost generics should become available. However, drug makers often prevent access to these cheaper generic drugs in Medicare. Researchers have found that 72 percent of Medicare Part D plans charged lower cost-sharing for a brand name drug compared to its generic equivalent. This means seniors were charged less out of pocket for brand name drugs compared to generics that are on average four times cheaper than the brand-named drug. This happens because drug makers pay a rebate to the Part D plans in order to give the more expensive drug better treatment than a generic. As a result, Medicare spending increases due to the current structure of the Part D benefit.

   a. **Has your company ever paid a rebate to a Part D plan so that a brand name drug would get preferential treatment (i.e. lower cost-sharing or less utilization management) compared to a cheaper generic?**

      In certain instances, AstraZeneca enters into arrangements under which a branded agent is discounted at or below the net cost of the generic(s) in the market, therefore benefiting the plan and the beneficiary. AstraZeneca typically enters into these types of arrangements for medicines already existing on formulary. These arrangements benefit patients by ensuring greater affordability for the branded medicine and by ensuring continuity of treatment if a patient has already been prescribed a branded medicine. These arrangements also support competition because they provide the opportunity for multiple competitors and medicine options to compete on price and other factors. We have had several such arrangements in Medicare Part D (see Appendix C).

   b. **If so, please provide:**

      (i) **A list of the drugs for which your company has done this since January 1, 2014.**

      A list providing this information is attached as Appendix C.

      (ii) **The number of Part D plans in which this type of rebate was given for each drug in each year.**

      A list of the relevant Part D plans is included in Appendix C.

6. Net Prices. During your testimony, you stated, "the estimates for 2018 show that across our medicines, our average rebate is nearly 50 percent of our gross revenues in the U.S. Despite this, in recent years, in our primary cap portfolio, we have seen flat to declining net effective prices for most of our medicines."

Please describe how the company's year-over-year aggregate net price is calculated.

The analysis discussed during the hearing on February 26, 2019 was completed by brand; the change in Net Price was calculated at the brand level, and then weighted based on Net Sales for each brand as a percent of Total Net Product Sales for 2018.[2]

Please also specifically address the following questions:

a. **How many products are included in the calculation of the average net price change? What was the median net price change?**

The analysis discussed during the hearing on February 26, 2019 included 26 brands that represent 98% of annual Net Product Sales in the United States for the period ending December 31, 2018.

The Median Price Change (prior to weighting) was a Net Price decrease of 1%.

b. **Is net price weighted? If so, how? For example, in determining the aggregate net price does the company assign different weights to different products based on volume or other factors? Are "on patent" and "off patent" drugs weighted identically? Are other statistical weights used or are all products treated equally?**

The analysis discussed during the hearing on February 26, 2019 was completed by brand; the change in Net Price was calculated at the brand level, and then weighted based on Net Sales for each brand as a percent of Total Net Product Sales for 2018 irrespective of whether the medicines are on or off patent.

c. **Does the figure that you provided during your testimony account for U.S. prices, international prices, or both? Generally speaking, when your company reports net price changes, does it differentiate between U.S. and international prices?**

The analysis discussed during the hearing on February 26, 2019 referred to 26 brands that represent 98% of annual Net Product Sales in the United States for the period ending December 31, 2018.

d. **Please list the five drugs your company sold in the U.S. that had the greatest year-over-year net price increase in 2018, noting the increase for each drug by dollar figure and percentage. Please list the five drugs your company sold in the U.S. that had the**

[2] Net Product Sales reflect the invoiced amount less movements in estimated accruals for rebates and chargebacks given to managed-care and other customers. Cash discounts for prompt payment are also deducted from sales. Average Net Price per Unit excludes product returns, and the figures were arrived at using the conventional Net Price calculation, that is, before deducting cost of goods sold, royalties, and variable selling expenses.

lowest year-over-year net price increase (and/or the greatest decrease) in 2018, noting the increase (or decrease) for each drug by dollar figure and percentage.

In 2018, we experienced a Weighted Average Net price decline in our hyper-competitive respiratory and diabetes therapeutic areas, with declines of 2.4% and 1.9%, respectively. Our Weighted Average Net prices in oncology remained flat. Brand-specific pricing information is competitively sensitive information.

e. **For 2018, what was the average net price change in the U.S. market for (1) drugs with no competition, (2) drugs with only branded competition, and (3) drugs with generic competition?**

For 2018, the Weighted Average Net price change in the United States market for:

- Medicines with no competition was an increase of 0.6%;
- Branded "on patent" medicines without generic equivalents was a decrease of 4.7%;
- "Off patent" medicines with generic equivalent competition was an increase of 4.6%.

With respect to the last category of medicines described above, we note by way of context that once generic options enter the market, our market share rapidly erodes, as many PBMs, insurers, and government agencies to which AstraZeneca offers rebates and discounts replace our branded medicines on their formularies with these generic competitors. Accordingly, the mix of business for medicines with generic competition shifts towards programs whereby health plans/PBMs chose to list our branded medicines on their formularies given a lower net cost versus generics, and to individual patients who chose to pay for branded agents over generic agents, resulting in a higher average net effective price across all distribution channels.

f. **You state that "the estimates for 2018 show that across our medicines, our average rebate is nearly 50 percent of our gross revenues in the U.S." For each product, please disclose the gross revenue and the amount of rebates paid.**

The table below reflects our Product Sales in the U.S. for the period ending December 31, 2018, including the proportion of Gross Sales allocated to estimated amounts we expect to pay to third-party managed care organizations, hospitals, long-term care facilities, group purchasing organizations and various federal or state programs. The percentage of Gross Product Sales column reflects our effective rebate rate per channel, a combination of mix of business in that channel and related rebate rate.

	USD (in millions)		% of Gross Product Sales
Gross Product Sales	$	16,538,000	
Chargebacks	$	(2,224,000)	**-13%**
Regulatory – Medicaid and state programs	$	(1,304,000)	**-8%**
Contractual – Managed-care and Medicare	$	(4,600,000)	**-28%**
Cash and other discounts	$	(286,000)	-2%
Customer returns	$	(119,000)	-1%
U.S. Branded Pharmaceutical Fee	$	(140,000)	-1%
Other	$	(989,000)	-6%
Net Product Sales	$	6,876,000	

Brand-specific pricing information is competitively sensitive information.

Bristol-Myers Squibb Responses

Senator Wyden:
For All Witnesses:

<u>Proposed Rebate Rule</u>

As has been done in many other settings, drug manufacturers said during the hearing that one reason list prices for drugs are high is that pharmaceutical benefit managers (PBMs) demand larger and larger rebates in order for the drug to receive favorable placement on a formulary. You and your colleagues who testified during the hearing stated if the Administration's proposal on changes to the anti-kickback safe harbor for pharmaceutical rebates took effect, your company would likely lower list price.

Like many Oregonians, I am skeptical drug manufacturers would voluntarily lower their prices. Therefore, would you support legislation that would 1) make similar changes the Administration has put forward related to Part D and Medicaid managed care, 2) change the rebate system in a similar way to the proposal for the commercial market, and 3) require drug makers to lower the list price of their drugs equal to the amount of rebates provided today?

BMS supports the extension of rebate reforms to the commercial market. However, given the significant market change in the proposed Part D safe harbor change, we urge

the Committee to pursue an implementation timeline that will allow manufacturers, PBMs, plans, retail pharmacies, wholesalers, and other impacted parties to address the many operational challenges for the industry. We anticipate that the implementation of the safe harbor change in Part D will provide important learnings, but in order to extend these changes to the commercial market, industry will need additional lead time to do so.

Given the many payers and channels in the healthcare market, an individual drug has multiple net price points. Moreover, the goals of the proposed rebate rule can be achieved not only through lower list prices, but also through negotiated discounts at the point-of-sale, or through some combination of the two approaches. We believe the goals of the proposed rule can be best achieved by giving manufacturers the full range of options in their negotiations with plans and PBMs. Consequently, BMS would not support legislation that required drug makers to lower the list price of their drugs equal to the amount of rebates provided today.

There may be instances where a reduction in product list price is warranted, but with or without a list price change, in order for patients to benefit fully from the changes, regulations would need to ensure that manufacturer discounts are passed through to patients at the point-of-sale and that patient out-of-pocket costs are based on product net price.

Medicaid Drug Rebate Program

The Medicaid Drug Rebate Program (MDRP) requires manufacturers to provide a basic rebate and an additional inflationary rebate for both brand and generic drugs. The inflationary rebate is an increasingly substantial part of total rebates due in large part to large increases in drug prices that exceed inflation. Under current law, this inflationary rebate is capped at 100 percent of Average Manufacturer Price (AMP). This is the case even when manufacturers continue to raise their prices well above inflation.

1. **Please provide a list of all of your pharmaceutical products that have reached the Medicaid AMP rebate cap in any of the 20 quarters from January 1, 2014 through December 31, 2018.**

   Please see answer to question 2 below.

2. **For each drug listed in response to question 1, please also provide a list of which quarters and years each drug hit the cap.**

Product	Quarter
BARACLUDE TAB 0.5MG	Q3 2014, Q4 2014, Q1 2015, Q2 2015, Q3 2015, Q4 2015
BARACLUDE TAB 1MG	Q3 2014, Q4 2014, Q1 2015, Q2 2015, Q3 2015, Q4 2015
COUMADIN TAB 4MG	Q1 2014, Q2 2014, Q3 2014, Q4 2014, Q1 2015, Q2 2015, Q3 2015, Q4 2015, Q1 2016, Q2 2016, Q3 2016, Q4 2016, Q1 2017, Q2 2017, Q3 2017, Q4 2017, Q1 2018, Q2 2018, Q3 2018, Q4 2018

COUMADIN TAB 4MG (1BTLX1000) US	Q3 2014, Q4 2014, Q1 2015, Q2 2015
COUMADIN TAB 1MG	Q1 2014, Q2 2014, Q3 2014, Q4 2014, Q1 2015, Q2 2015, Q3 2015, Q4 2015, Q1 2016, Q2 2016, Q3 2016, Q4 2016, Q1 2017, Q2 2017, Q3 2017, Q4 2017, Q1 2018, Q2 2018, Q3 2018, Q4 2018
COUMADIN TAB 2MG	Q1 2014, Q2 2014, Q3 2014, Q4 2014, Q1 2015, Q2 2015, Q3 2015, Q4 2015, Q1 2016, Q2 2016, Q3 2016, Q4 2016, Q1 2017, Q2 2017, Q3 2017, Q4 2017, Q1 2018, Q2 2018, Q3 2018, Q4 2018
COUMADIN TAB 5MG	Q1 2014, Q2 2014, Q3 2014, Q4 2014, Q1 2015, Q2 2015, Q3 2015, Q4 2015, Q1 2016, Q2 2016, Q3 2016, Q4 2016, Q1 2017, Q2 2017, Q3 2017, Q4 2017, Q1 2018, Q2 2018, Q3 2018, Q4 2018
COUMADIN TAB 7.5MG	Q1 2014, Q2 2014, Q3 2014, Q4 2014, Q1 2015, Q2 2015, Q3 2015, Q4 2015, Q1 2016, Q2 2016, Q3 2016, Q4 2016, Q1 2017, Q2 2017, Q3 2017, Q4 2017, Q1 2018, Q2 2018, Q3 2018, Q4 2018
COUMADIN TAB 10MG	Q1 2014, Q2 2014, Q3 2014, Q4 2014, Q1 2015, Q2 2015, Q3 2015, Q4 2015, Q1 2016, Q2 2016, Q3 2016, Q4 2016, Q1 2017, Q2 2017, Q3 2017, Q4 2017, Q1 2018, Q2 2018, Q3 2018, Q4 2018
COUMADIN TAB 2.5MG	Q1 2014, Q2 2014, Q3 2014, Q4 2014, Q1 2015, Q2 2015, Q3 2015, Q4 2015, Q1 2016, Q2 2016, Q3 2016, Q4 2016, Q1 2017, Q2 2017, Q3 2017, Q4 2017, Q1 2018, Q2 2018, Q3 2018, Q4 2018
COUMADIN TAB 3MG	Q1 2014, Q2 2014, Q3 2014, Q4 2014, Q1 2015, Q2 2015, Q3 2015, Q4 2015, Q1 2016, Q2 2016, Q3 2016, Q4 2016, Q1 2017, Q2 2017, Q3 2017, Q4 2017, Q1 2018, Q2 2018, Q3 2018, Q4 2018
COUMADIN TAB 6MG	Q1 2014, Q2 2014, Q3 2014, Q4 2014, Q1 2015, Q2 2015, Q3 2015, Q4 2015, Q1 2016, Q2 2016, Q3 2016, Q4 2016, Q1 2017, Q2 2017, Q3 2017, Q4 2017, Q1 2018, Q2 2018, Q3 2018, Q4 2018
COUMADIN TAB 6MG US	Q1 2014, Q2 2014, Q3 2014, Q4 2014, Q1 2015
AVAPRO TAB 75MG	Q1 2014, Q2 2014, Q3 2014, Q4 2014, Q1 2015, Q2 2015, Q3 2015
AVAPRO TAB 150MG	Q1 2014, Q2 2014, Q3 2014, Q4 2014, Q1 2015, Q2 2015, Q3 2015, Q4 2015, Q1 2016
AVAPRO TAB 300MG	Q1 2014, Q2 2014, Q3 2014, Q4 2014, Q1 2015, Q2 2015, Q3 2015, Q4 2015, Q1 2016
AVALIDE TAB 150/12.5MG	Q1 2014, Q2 2014, Q3 2014, Q4 2014
AVALIDE TAB 300/12.5MG	Q1 2014, Q2 2014

Medicaid Drug Rebate Program Compliance

I am concerned about recent reports and legal settlements surrounding drug manufacturers' failure to comply fully with the requirements of the MDRP. For example, an analysis by the U.S. Department of Health and Human Services Office of Inspector General found that between 2012 and 2016 taxpayers may have overpaid by as much as $1.3 billion for 10 potentially misclassified drugs. That is why I introduced the Right Rebate Act with Chairman Grassley to prevent drug manufacturers from manipulating Medicaid to increase their profits. However, I continued to be concerned about oversight and manufacturer

compliance with the requirements of the Medicaid Drug Rebate Program. Accordingly, please describe the following:

1. **Your company's current compliance plan and procedures used to ensure compliance with the requirements of the Medicaid Drug Rebate Program including internal audits or other checks you use to identify compliance vulnerabilities.**

   The Company routinely assigns new employees working in the government pricing area formal training on U.S. government pricing and contracting. This training includes an overview of the Medicaid Program obligations and requirements. BMS also maintains policy and procedural documents which govern compliance relative to the Medicaid Drug Rebate Program. In addition, BMS periodically holds informal training sessions as part of departmental and other internal meetings, where compliance training is provided on topics relevant to the Medicaid Drug Rebate Program. BMS has also identified key controls related to the Medicaid Drug Rebate Program which are independently tested as part of the Company's Sarbanes-Oxley controls. As part of these controls, all Medicaid pricing submissions are reviewed and approved by the appropriate Company management. In addition, BMS Global Internal Audit and Assurance periodically conducts internal audits of the Company's operations, which include activities that support the Medicaid Drug Rebate Program.

2. **Any past or ongoing issues of non-compliance.**

   There are no ongoing issues of non-compliance with the Medicaid Drug Rebate Program, nor were there any within the past 5 years. (BMS interprets the question as asking for a reasonable period in the past, and has selected 5 years).

3. **Any corrective actions taken to address identified problems or issues of non-compliance with the MDRP and how such steps were communicated to the Centers for Medicare & Medicaid Services.**

   There are no ongoing issues of non-compliance with the Medicaid Drug Rebate Program, nor were there any within the past 5 years. (BMS interprets the question as asking for a reasonable period in the past, and has selected 5 years).

4. **Any steps taken to improve compliance and ensure that all Medicaid drug rebates owed to the federal government and the states are paid in full.**

   In addition to the compliance and audit activities already outlined, the BMS Government Pricing team conducts regular cross-functional information sharing meetings in order to facilitate communication within the organization, to gather all relevant pricing and contracting information, and to provide education that is

focused on ensuring compliance with our Medicaid reporting obligations. The Government Pricing team also conducts quarterly Medicaid Best Price review meetings with key members of the pricing and contracting organization and requires that leaders of key functions within the pricing and contracting organization sign-off on quarterly Medicaid Best Price information prior to the Company's final. Additionally, the Company has made significant investments in the systems which are used to support the calculation and payment of Medicaid rebates to help ensure greater compliance, standardization and automation of our processes. BMS also maintains a Compliance and Ethics hotline and encourages all employees to raise potential compliance concerns so that they can be investigated and addressed.

More specifically with regard to the payment of Medicaid drug rebates, based on the current portfolio of active drugs, all BMS drugs are classified as Innovator Single Source or Innovator Multiple Source drugs which are subject to the higher basic rebate calculation. When BMS launches a new drug that is subject to Medicaid reporting, the drug classification is reviewed as part of the Medicaid submission approval process.

To the extent that BMS has questions on MDRP compliance or on interpretative approaches to MDRP price reporting, we communicate with the Centers for Medicare & Medicaid Services.

Bonus Payments Tied to Specific Drugs

I am concerned by the potential for employee financial incentives to encourage high launch prices and price increases for prescription drugs.

1. **Is your salary, bonus or other compensation tied to sales or revenue targets of a single product your company sells? Has it ever been? If yes, please state the product or products to which your salary, bonus or other compensation was tied.**

   No, Dr. Caforio's salary and bonus are not tied to sales or revenue targets for a single product. Dr. Caforio's compensation is tied in part to the revenue of the Company as a whole. Please see answer to question 2 below.

2. **Is your salary, bonus or other compensation tied to either revenue or net income of the company as a whole? Has it ever been? If yes, please explain what assumptions about price increases are used when the compensation committee sets revenue or net income goals. Does the compensation committee provide any guidance to executives in regards to the amount of revenue that the company will generate from price increases versus volume growth?**

   Dr. Caforio's compensation is tied in part to the revenue of the Company as a whole. The revenue metric is based on the overall Company target for the applicable

performance period (annual for annual bonus and longer-term, 3 years for Performance Share Units), which typically includes assumptions concerning both price changes and volume growth. Over the last few years, BMS' revenue growth has been primarily attributable to increased volume arising from increased demand for our products rather than price increases

Dr. Caforio's compensation is reviewed and recommended by the Compensation and Management Development Committee, which is a Committee consisting of only independent directors, and approved by at least three-fourths of the independent directors of our Board of Directors. The Compensation Management and Development Committee annually completes a thoughtful and rigorous evaluation of the Company's executive compensation program to ensure that the program is aligned with our mission and delivers shareholder value, while not encouraging excessive or inappropriate risk-taking by our executives. When determining metrics and setting incentive plan targets each year and for 3 year performance period, the Committee is aware of the risks associated with drug pricing, among other risks, and ensures our plans do not incentivize risky behavior in order to meet targets and goals.

Net Prices

In your testimony you stated, "for this reason, the average net pricing across our U.S. portfolio of medicines increased by 5 percent of the last year-over-year for the last five years. Importantly, it did not increase at all in 2018 and we expect that it will not increase in 2019." Please describe how the company's year-over-year aggregate net price is calculated. Please also specifically address the following questions:

Dr. Caforio testified that BMS' average net pricing across the Company's U.S. portfolio increased by *five percent or less* year-over-year for the last five years. Please see the answer to Question 2 below for a description of how year-over-year net price is calculated.

1. **How many products are included in the calculation of the average net price change? What was the median net price change?**

   Approximately 20 products are included in the calculation of the average net price change. The median net price change over the last 5 years is 3.4% based on the following net price change per year:

2018	2017	2015	2014	2016
(0.3%)	1.6%	3.4%	4.0%	5.2%

2. **Is net price weighted? If so, how? For example, in determining the aggregate net price does the company assign different weights to different products based on volume or other factors? Are "on patent" and "off patent" drugs weighted identically? Are other statistical weights used or are all products treated equally?**

   Net price is weighted according to the product's sales relative to total BMS sales. Year-over-year change in Net Price = Change in List Price + Change in effective discount rate across all channels. Patent and off-patent drugs are treated equally in the calculation.

3. **Does the figure that you provided during your testimony account for U.S. prices, international prices, or both? Generally speaking, when your company reports net price changes, does it differentiate between U.S. and international prices?**

   The figure included in Dr. Caforio's testimony accounted for U.S. prices. Yes, BMS discloses by region (*i.e.*, U.S, Europe, Rest of World) in our quarterly 10Q and Annual 10K filings. However, the only net price changes specifically outlined (*i.e.*, in % terms) is for the U.S.

4. **Please list the five drugs your company sold in the U.S. that had the greatest year-over-year net price increase in 2018, noting the increase for each drug by dollar figure and percentage. Please list the five drugs your company sold in the U.S. that had the lowest year-over-year net price increase (and/or the greatest decrease) in 2018, noting the increase (or decrease) for each drug by dollar figure and percentage.**

   This question calls for information that BMS does not disclose publicly and considers to be competitively sensitive.

5. **For 2018, what was the average net price change in the U.S. market for (1) drugs with no competition, (2) drugs with <u>only</u> branded competition, and (3) drugs with generic competition?**

   This questions calls for information that BMS does not disclose publicly and considers to be competitively sensitive.

6. **You stated that average net price increased 5 percent in 2017, but did not increase in 2018, and that you do not expect it to increase in 2019. What factors contributed to the change from 2017 to 2018? What would the net price increase have been if your company excluded the impact of drugs like Reyataz and Sustiva, which lost exclusivity in the United States at the end of 2017, and Daklinza, which the company reported losing revenue on?**

Dr. Caforio testified that BMS' average net pricing across the Company's U.S. portfolio increased by *five percent or less* year-over-year for the last five years. Average U.S. net price remained unchanged from 2017 to 2018 (*i.e.*, 0% net price increase from 2017 to 2018), because discounts across all channels increased at a rate higher than list price increased. If drugs which lost exclusivity, like Reyataz, Sustiva and Daklinza, were excluded, the net price change would still be 0%.

Johnson and Johnson Responses

Senator Wyden:
For All Witnesses:

Proposed Rebate Rule

As has been done in many other settings, drug manufacturers said during the hearing that one reason list prices for drugs are high is that pharmaceutical benefit managers (PBMs) demand larger and larger rebates in order for the drug to receive favorable placement on a formulary. You and your colleagues who testified during the hearing stated if the Administration's proposal on changes to the anti-kickback safe harbor for pharmaceutical rebates took effect, your company would likely lower list price.

Like many Oregonians, I am skeptical drug manufacturers would voluntarily lower their prices. Therefore, would you support legislation that would 1) make similar changes the Administration has put forward related to Part D and Medicaid managed care, 2) change the rebate system in a similar way to the proposal for the commercial market, and 3) require drug makers to lower the list price of their drugs equal to the amount of rebates provided today?

We support reforms to the rebate system that restructure incentives to ensure patients benefit from a competitive marketplace and see lower out-of-pocket costs.

Depending on whether elimination of rebates applies to the entire market or only to those related to federal health plans and assuming rebates are not replaced by high fees or other costs that offset the amount saved, we expect to lower list prices or offer discounts for pass-through at the point of sale. In either case, we would need to renegotiate our agreements with customers.

The degree to which we can convert current rebates to list price reductions or point-of-sale discounts will depend upon the details of the final regulation and the reactions of other stakeholders in the supply chain. We are concerned that PBMs may seek to replace rebate revenue with new and increasing fees or may seek to shift costs among supply chain participants through service fees.

Medicaid Drug Rebate Program

The Medicaid Drug Rebate Program (MDRP) requires manufacturers to provide a basic rebate and an additional inflationary rebate for both brand and generic drugs. The inflationary rebate is an increasingly substantial part of total rebates due in large part to large increases in drug prices that exceed inflation. Under current law, this inflationary rebate is capped at 100 percent of Average Manufacturer Price (AMP). This is the case even when manufacturers continue to raise their prices well above inflation.

1. Please provide a list of all of your pharmaceutical products that have reached the Medicaid AMP rebate cap in any of the 20 quarters from January 1, 2014 through December 31, 2018.
2. For each drug listed in response to question 1, please also provide a list of which quarters and years each drug hit the cap.

Janssen has numerous current products, and products that have since been sold to third parties, that have reached the Medicaid AMP rebate cap in at least one of the 20 quarters from 1Q 2014 through 4Q 2018. The fact that these products reaching the 100% AMP cap is based on confidential metrics reported under the Medicaid Drug Rebate Program. The Medicaid AMP rebate cap is reached when AMP is less than or equal to the Unit Rebate Amount (URA). URA is calculated based on AMP and Best Price– which are confidential under the Medicaid Drug Rebate statute at 42 U.S.C. § 1396r-8(b)(3)(D). There are exceptions in the statute that permit the Secretary and State Medicaid agencies to disclose the information only in certain situations, including disclosure to CBO. Thus, if there was legislation proposing to amend the 100% AMP cap, CBO would be able to access the drugs and underlying data to estimate the cost/savings to the government of such a legislative change.

The product-specific information requested is confidential and competitively sensitive. As such, potentially responsive information is not available for public disclosure.

Medicaid Drug Rebate Program Compliance

I am concerned about recent reports and legal settlements surrounding drug manufacturers' failure to comply fully with the requirements of the MDRP. For example, an analysis by the U.S. Department of Health and Human Services Office of Inspector General found that between 2012 and 2016 taxpayers may have overpaid by as much as $1.3 billion for 10 potentially misclassified drugs. That is why I introduced the Right Rebate Act with Chairman Grassley to prevent drug manufacturers from manipulating Medicaid to increase their profits. However, I continued to be concerned about oversight and manufacturer compliance with the requirements of the Medicaid Drug Rebate Program. Accordingly, please describe the following:

1. Your company's current compliance plan and procedures used to ensure compliance with the requirements of the Medicaid Drug Rebate Program including internal audits or other checks you use to identify compliance vulnerabilities.

2. Any past or ongoing issues of non-compliance.
3. Any corrective actions taken to address identified problems or issues of non-compliance with the MDRP and how such steps were communicated to the Centers for Medicare & Medicaid Services.
4. Any steps taken to improve compliance and ensure that all Medicaid drug rebates owed to the federal government and the states are paid in full.

We comply with the obligations we undertake when participating in U.S. federal, state or local government contracts and government pricing programs such as the Medicaid Drug Rebate Program. We have an established compliance framework along with organizational structure and accountabilities designed to assure compliance. Our framework includes testing and monitoring and an obligation to correct any identified discrepancies. As such, any discrepancies have been timely addressed and corrected.

The other information requested is confidential. As such, potentially responsive information is not available for public disclosure.

Bonus Payments Tied to Specific Drugs

I am concerned by the potential for employee financial incentives to encourage high launch prices and price increases for prescription drugs.

1. Is your salary, bonus or other compensation tied to sales or revenue targets of a single product your company sells? Has it ever been? If yes, please state the product or products to which your salary, bonus or other compensation was tied.

At no time during her employment with the Johnson & Johnson Family of Companies has Ms. Taubert's salary, bonus or other compensation been tied to sales or revenue targets of a single product.

2. Is your salary, bonus or other compensation tied to either revenue or net income of the company as a whole? Has it ever been? If yes, please explain what assumptions about price increases are used when the compensation committee sets revenue or net income goals. Does the compensation committee provide any guidance to executives in regards to the amount of revenue that the company will generate from price increases versus volume growth?

We structure performance-based compensation to reward an appropriate balance of short-term and long-term financial and strategic business results, with an emphasis on managing the business for long-term results. Our compensation program's emphasis on long-term value reduces the possibility that our executives make excessively risky business decisions that could maximize short-term results at the expense of long-term value.

Ms. Taubert's base salary is tied to performance, market data, responsibilities, time in position, internal equity, and experience. Ms. Taubert's bonus and long-term incentive

compensation has been and is awarded based on her individual performance and the company's performance.

The compensation committee does not provide guidance to executives regarding the amount of revenue that the company will generate from price increases versus volume growth.

Provision of Rebates in Exchange for Formulary Placement

In today's system, drug makers receive a limited time window to sell their drug without competition. After that period has expired, low-cost generics should become available. However, drug makers often prevent access to these cheaper generic drugs in Medicare. Researchers have found that 72 percent of Medicare Part D plans charged lower cost-sharing for a brand name drug compared to its generic equivalent. This means seniors were charged less out of pocket for brand name drugs compared to generics that are on average four times cheaper than the brand-named drug. This happens because drug makers pay a rebate to the Part D plans in order to give the more expensive drug better treatment than a generic. As a result, Medicare spending increases due to the current structure of the Part D benefit.

1. Has your company ever paid a rebate to a Part D plan so that a brand name drug would get preferential treatment (i.e. lower cost-sharing or less utilization management) compared to a cheaper generic?
2. If so, please provide:
    a. A list of the drugs for which your company has done this since January 1, 2014.
    b. The number of Part D plans in which this type of rebate was given for each drug in each year.

In negotiations with PBMs and payers, Janssen may offer multiple different rebate options. The PBM or payer has sole discretion over how formularies are structured. In some cases, a PBM or payer may establish a formulary that puts a branded drug in a preferential position.

The information requested is confidential and competitively sensitive. As such, potentially responsive information is not available for public disclosure.

Net Prices

Your testimony stated that "while our 2018 aggregate list price increase was 6.3 percent, for the second year in a row discounts and rebates outweighed that increase, and aggregate net price – in other words, the real price – decreased by 6.8 percent." According to your testimony, the net price "represents the year-over-year change in the average net price, which is WAC less rebates, discounts, and returns." Please describe how the company's year-over-year aggregate net price is calculated. Please also specifically address the following questions:

Average net price change represents the year-over-year change in the average net price, which is Wholesale Acquisition Cost less rebates, discounts, and returns.

1. How many products are included in the calculation of the average net price change? What was the median net price change?

   We believe weighted average net price change is the appropriate metric for evaluating list price changes across the portfolio. There are 99 products (brands) included in the average net price change calculation. The 2017–2018 weighted average net price change is -6.8%. The non-weighted average 2017–2018 net price change is -3.7%. The 2017–2018 median net price change is -1.9%. It is important to note that non-weighted average or median net price change treats all medicines—whether used by many patients or by very few—equally, so those figures are not useful or valuable in understanding the actual change experienced.

2. Is net price weighted? If so, how? For example, in determining the aggregate net price does the company assign different weights to different products based on volume or other factors? Are "on patent" and "off patent" drugs weighted identically? Are other statistical weights used or are all products treated equally?

   Annual net price change vs. prior year is calculated at the product level and weighted across the company's U.S. product portfolio using net trade sales. All products, both "on patent" and "off patent," are included.

3. Does the figure that you provided during your testimony account for U.S. prices, international prices, or both? Generally speaking, when your company reports net price changes, does it differentiate between U.S. and international prices?

   The figure provided, -6.8%, accounts for 2018 net price change for our U.S. pharmaceutical business only. We disclose this figure in our annual Janssen U.S. Transparency Report.

4. Please list the five drugs your company sold in the U.S. that had the greatest year-over-year net price increase in 2018, noting the increase for each drug by dollar figure and percentage. Please list the five drugs your company sold in the U.S. that had the lowest year-over-year net price increase (and/or the greatest decrease) in 2018, noting the increase (or decrease) for each drug by dollar figure and percentage.

   The information requested is confidential and competitively sensitive. As such, potentially responsive information is not available for public disclosure.

5. For 2018, what was the average net price change in the U.S. market for (1) drugs with no competition, (2) drugs with <u>only</u> branded competition, and (3) drugs with generic competition?

   The information requested is confidential and competitively sensitive. As such, potentially responsive information is not available for public disclosure.

6. Your company noted in its annual financial filing with the Securities and Exchange Commission that "Immunology was negatively impacted by lower sales of REMICADE® (infliximab) due to increased discounts/rebates and biosimilar competition," and "Strong sales of long-acting injectables INVEGA TRINZA®/TREVICTA®(paliperidone palmitate) and INVEGA SUSTENNA®/XEPLION® were partially offset by cannibalization of RISPERDAL CONSTA® (risperidone) and generic competition for CONCERTA®/methylphenidate," and "Lower sales of INVOKANA®/INVOKAMET® (canagliflozin) in the U.S. was primarily due to an increase in price discounts, higher rebates and market share decline driven by competitive pressure. Lower sales of XARELTO® (rivaroxaban) were driven by an increase in discounts and rebates, partially offset by an increase in market share." What were the year-over-year net price changes for each of these drugs?

   The information requested is confidential and competitively sensitive. As such, potentially responsive information is not available for public disclosure.

7. Please define the following terms that were used on page 20 of your company's annual report for the year ending December 31, 2018 regarding sales of various pharmaceutical products: strong uptake, market growth, and share gain. Please also define "reduction in sales," as used in the sentence "Biosimilar versions of REMICADE® have been introduced in certain markets outside the U.S., resulting in a reduction in sales of REMICADE® in those markets."

   "Strong uptake" means that we are seeing significant utilization of a medicine that was recently introduced into the market or approved for a new indication.

   "Market growth" refers to increase in utilization of medicines overall for a particular disease state or in a particular class of medicines.

   "Share gain" means that within a class of medicines or therapeutic area, a particular medicine is being selected and utilized more than it had been previously and now represents a greater percentage of utilization within that class relative to competitor medicines.

   "Reduction in sales" in the sentence you reference means that revenues for REMICADE® are lower than they have been in previous years. Please note that our 2018 Annual Report goes on to state, "In the U.S., a biosimilar version of REMICADE® was introduced in 2016, and additional competitors continue to enter the market. Continued infliximab biosimilar competition in the U.S. market will result in a further reduction in U.S. sales of REMICADE®."

Merck Responses

Senator Wyden:
For All Witnesses:

Proposed Rebate Rule

As has been done in many other settings, drug manufacturers said during the hearing that one reason list prices for drugs are high is that pharmaceutical benefit managers (PBMs) demand larger and larger rebates in order for the drug to receive favorable placement on a formulary. You and your colleagues who testified during the hearing stated if the Administration's proposal on changes to the anti-kickback safe harbor for pharmaceutical rebates took effect, your company would likely lower list price.

Like many Oregonians, I am skeptical drug manufacturers would voluntarily lower their prices. Therefore, would you support legislation that would 1) make similar changes the Administration has put forward related to Part D and Medicaid managed care, 2) change the rebate system in a similar way to the proposal for the commercial market, and 3) require drug makers to lower the list price of their drugs equal to the amount of rebates provided today?

We believe we must change the system to ensure that patients receive the benefit of the significant rebates and discounts that manufacturers like Merck pay to PBMs and plans. The proposed rule is a positive step in that direction. Based on our initial assessment of the proposed rule, we believe that it will remove misaligned incentives within the system, drive more transparency in the system, and most importantly, lower beneficiaries' out-of-pocket costs. Merck supports the earliest possible implementation of the proposed rule that can be achieved without creating disruption for the beneficiaries who rely on Medicare for their drug coverage. We are committed to working with the PBMs and health plans and other intermediaries to make this happen.

We do not support legislation to require manufacturers to lower their list price equal to the amount of rebates today. First, different purchasers receive different levels of discounts, based on individualized negotiations and the formulary positioning of Merck's products. So, there is not a uniform "rebate amount" that could reduce the list price. Moreover, we expect that the robust negotiations that occur today will continue in the highly competitive Part D market, and we expect to realize the same level of net price that we do today. In fact, we expect that there could be additional pricing pressure under the new system, which could lead to lower net prices.

Over time, we expect that our list prices will go down if the misaligned incentives across the system are addressed. We are currently working with other stakeholders in the system to solve the operational challenges that will enable these changes.

But, it is also important to note that if the rule is implemented, Medicare beneficiaries' out-of-pocket costs will be reduced, independent of any lowering of list prices, since their cost-sharing will be based on the net price. Nonetheless, we believe the rebate rule will align incentives in a way that will restrain list prices.

As we stated when we reduced the list price of several of our products in July 2018, we have continued to look for opportunities to reduce our list prices. We think the proposed rule would help create those opportunities, but it can't happen overnight. All the players in the ecosystem will need to adjust to the new model. We are actively working to support the move to a contracting model in Part D that would change the incentives to support lower list prices.

Lowering list prices is not an easy thing to do in our health care system:

- One of the key challenges to lowering list prices is the contractual arrangements that companies have with PBMs and health plans, which are intended to ensure access to our products. These contracts are often multi-year and are most often written to provide a discount off of the list price, which is paid as a rebate later.
- To reduce the list price without significant financial consequences, all of these contracts would need to be modified to maintain the same net price. Unless the entire system changes, one manufacturer runs the risk of being disadvantaged and losing formulary status or being required to pay the same percentage discount on a lower list, which could be unsustainable.
- In addition, drugs flow through a complex supply chain, from the manufacturer, to the wholesaler, to a pharmacy or hospital who dispenses the drug to patients. For any product but even more so for a high volume primary care product that is flowing through to all pharmacies and hospitals, there is not a mechanism in place to readjust the value of the inventory being held by all those parties.

If the proposed rule is implemented as written, it would only apply to our contracts with PBMs and health plans for Medicare Part D and Managed Medicaid. If PBMs and health plans maintain the rebate model in the commercial market, we would still have commercial contracts based on rebates, which would be subject to the existing constraints to lowering list price. We also would still need a mechanism to revalue drug in the distribution channel in a financially viable manner.

Medicaid Drug Rebate Program

The Medicaid Drug Rebate Program (MDRP) requires manufacturers to provide a basic rebate and an additional inflationary rebate for both brand and generic drugs. The inflationary rebate is an increasingly substantial part of total rebates due in large part to large increases in drug prices that exceed inflation. Under current law, this inflationary rebate is capped at 100 percent of Average Manufacturer Price (AMP). This is the case even when manufacturers continue to raise their prices well above inflation.

1. *Please provide a list of all of your pharmaceutical products that have reached the Medicaid AMP rebate cap in any of the 20 quarters from January 1, 2014 through December 31, 2018.*
2. *For each drug listed in response to question 1, please also provide a list of which quarters and years each drug hit the cap.*

Merck conforms to all statutory, regulatory, and sub-regulatory guidance regarding its participation in the Medicaid Drug Rebate Program, including the payment of Medicaid rebates. The information requested by this question, however, is confidential, proprietary, and commercially and competitively sensitive. Merck would be happy to explore other means to share this information with the Committee in a confidential fashion.

Medicaid Drug Rebate Program Compliance

I am concerned about recent reports and legal settlements surrounding drug manufacturers' failure to comply fully with the requirements of the MDRP. For example, an analysis by the U.S. Department of Health and Human Services Office of Inspector General found that between 2012 and 2016 taxpayers may have overpaid by as much as $1.3 billion for 10 potentially misclassified drugs. That is why I introduced the Right Rebate Act with Chairman Grassley to prevent drug manufacturers from manipulating Medicaid to increase their profits. However, I continued to be concerned about oversight and manufacturer compliance with the requirements of the Medicaid Drug Rebate Program. Accordingly, please describe the following:

1. *Your company's current compliance plan and procedures used to ensure compliance with the requirements of the Medicaid Drug Rebate Program including internal audits or other checks you use to identify compliance vulnerabilities.*

Merck's government price reporting team – in consultation with in-house attorneys, outside counsel, and third-party vendors as appropriate – maintains comprehensive and detailed government price reporting policies, procedures, and reasonable assumptions for compliance with all price reporting programs, including the Medicaid Drug Rebate Program (MDRP). Merck's policies are evaluated and updated, as needed, on an annual basis by the government price report team, in-house attorneys, and outside counsel to ensure that they are consistent with current regulations and applicable guidance from the Centers for Medicare and Medicaid Services (CMS). Additionally, Merck's reasonable assumptions are evaluated and updated, as needed, on a monthly basis for Average Manufacturer Price and on a quarterly basis for Best Price by the government price reporting team, in-house attorneys, and outside counsel. Merck has a long history of transparency and communication with CMS regarding its MDRP compliance and reasonable assumptions, and company compliance personnel regularly oversee Merck's price reporting operations. Merck evaluates any new guidance issued by CMS to ensure that its price reporting calculations and processes are in compliance with the law.

2. *Any past or ongoing issues of non-compliance.*

Merck maintains comprehensive and detailed reasonable assumptions for its MDRP participation. In situations in which Merck is uncertain about a calculation approach that is not

clearly addressed in CMS rules or guidance, the company documents its approach in assumptions and/or discloses its intended approach to CMS. Additionally, given the complexity of the calculations, Merck may identify calculation mistakes or other issues that require correction. This may happen, for example, to the extent that Merck believes that any new CMS rules or guidance call into question a reasonable assumption that the company has previously maintained. In such cases, if Merck has any concern about its program compliance, it promptly communicates with CMS to seek the agency's guidance and potentially restate its prior MDRP reports.

3. *Any corrective actions taken to address identified problems or issues of non-compliance with the MDRP and how such steps were communicated to the Centers for Medicare & Medicaid Services.*

As noted above, to the extent that Merck believes that any of its existing calculation or compliance processes for MDRP participation are not in keeping with current CMS rules or guidance, the Company would promptly engage with the agency to identify any necessary remedial steps and the appropriate way forward, including filing pricing restatements.

4. *Any steps taken to improve compliance and ensure that all Medicaid drug rebates owed to the federal government and the states are paid in full.*

As noted above, Merck takes its government price reporting obligations very seriously, and the Company maintains robust, ongoing legal and compliance oversight of its price reporting team and its operations. As discussed above, we routinely review our policies, procedures, and reasonable assumptions to ensure compliance with current law. Merck also has an annual training requirement for government price reporting compliance. If Merck were to identify any potential noncompliance issue associated with the underpayment of rebates to the State Medicaid Programs, Merck immediately would identify this issue to CMS and would work with the agency to ensure the implementation of any appropriate remedy (including restating pricing metrics and reconciling rebate amounts with the states).

Bonus Payments Tied to Specific Drugs

I am concerned by the potential for employee financial incentives to encourage high launch prices and price increases for prescription drugs.

1. *Is your salary, bonus or other compensation tied to sales or revenue targets of a single product your company sells? Has it ever been? If yes, please state the product or products to which your salary, bonus or other compensation was tied.*

My salary, bonus, or other compensation is not tied to sales or revenue targets of a single product that Merck sells. In 2011, a very small percentage of my annual bonus was tied to the net sales of 3 new products (DULERA, SIMPONI and VICTRELIS).

2. *Is your salary, bonus or other compensation tied to either revenue or net income of the company as a whole? Has it ever been? If yes, please explain what assumptions about price*

increases are used when the compensation committee sets revenue or net income goals. Does the compensation committee provide any guidance to executives in regards to the amount of revenue that the company will generate from price increases versus volume growth?

Yes, a portion of my annual bonus is tied to revenue and pretax income (*i.e.*, a variation of net income) of the company as a whole, with each contributing 40 percent (for a total of 80 percent) to the aggregate incentive target, and research and development productivity constituting the other 20 percent of the target. The final bonus that I receive is then calculated based on the company's actual performance for those three metrics.

The Compensation and Benefits Committee of the Board sets annual targets for revenue and pretax income based upon the company's annual plan, as approved by the full Board of Directors.

The company's annual plan includes U.S. pricing assumptions informed by several variables, including volume, price, and discount rates, which for 2019 are fully consistent with our July 19, 2018 commitment to not increase net price across our product portfolio in the U.S. by more than inflation annually.

Neither the Board of Directors as a whole, nor the Compensation and Benefits Committee specifically, provides guidance to executives with regard to the amount of revenue that the company will generate from price increases versus volume growth.

Net Prices

In your testimony, you stated, "last year we pledged that we will not increase our average net prices for our portfolio by more than the rate of inflation annually," and that "From 2010 to 2017, Merck's average net price increase across our portfolio each year has been in the low to mid-single digits. In fact, our average net price declined in 2017 by almost 2 percent. In 2017, the average discount for our medicines and vaccines was more than 45 percent lower than the list price." Please describe how the company's year-over-year aggregate net price is calculated. Please also specifically address the following questions:

Net Price Change represents the year-over-year change in average net price, which is Wholesale Acquisition Cost (WAC) less rebates, discounts, and returns. The annual percent change vs. prior year was calculated at a product level and weighted across the company's U.S. Product Portfolio. U.S. Product Portfolio includes human health pharmaceutical and vaccine products marketed by the company, excluding partnered products. The product sales utilized in the analysis represent ~97 percent of the total U.S. Product Portfolio in 2010, increasing each year to approach 99.8 percent of coverage in 2017.

1. *How many products are included in the calculation of the average net price change? What was the median net price change?*

In 2017, 78 products were included. The median net price change was 0 percent.

2. *Is net price weighted? If so, how? For example, in determining the aggregate net price does the company assign different weights to different products based on volume or other factors? Are "on patent" and "off patent" drugs weighted identically? Are other statistical weights used or are all products treated equally?*

The Net Price Change percent for each product is weighted by its Net Sales relative to the Total Net Sales of the Product Portfolio for the current year. On and off patent drugs are calculated in the same fashion, and no other "statistical weighting" is applied.

3. *Does the figure that you provided during your testimony account for U.S. prices, international prices, or both? Generally speaking, when your company reports net price changes, does it differentiate between U.S. and international prices?*

Only U.S. prices are used in the report.

4. *Please list the five drugs your company sold in the U.S. that had the greatest year-over-year net price increase in 2018, noting the increase for each drug by dollar figure and percentage. Please list the five drugs your company sold in the U.S. that had the lowest year-over-year net price increase (and/or the greatest decrease) in 2018, noting the increase (or decrease) for each drug by dollar figure and percentage.*

The product-specific information requested is competitively sensitive and Merck therefore cannot produce it in a public setting in which it could be accessed by competitors. However, Merck does report similar information in an aggregated format in its annual price transparency report, which we proactively make available on our corporate responsibility website:

https://s3.amazonaws.com/msd18-assets/wp-content/uploads/2019/02/28155345/2018-US-PRICING-TRANSPARENCY-REPORT_02.2019.pdf

The report sets forth the average annual list price changes across the Merck portfolio as well as other price related information concerning Merck medicines and vaccines. The report shows that in 2018 the average annual list price across the Merck portfolio increased by 5.5 percent – the lowest increase since 2010 – as compared with a 6.6 percent increase in 2017. In 2018, the Company's gross U.S. sales were reduced by 44.3% as a result of rebates, discounts and returns. The below chart reflects additional information about the price changes for Merck products.

	2010	2011	2012	2013	2014	2015	2016	2017	2018
US Product Portfolio[1] % Change vs. Prior Year[2]									
List Price Change (WAC)[3]	7.4	9.5	9.2	9.6	10.5	9.8	9.6	6.6	5.5
Net Price[4]	3.4	5.1	6.2	5.5	3.7	5.5	5.5	(1.9)[5]	2.99
	2010	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**
US Product Portfolio									
Avg. Discount[6] (%)	27.3	28.9	29.9	32.1	37.0	38.2	40.9	45.1	44.3

5. *For 2018, what was the average net price change in the U.S. market for (1) drugs with no competition, (2) drugs with only branded competition, and (3) drugs with generic competition?*

The product-specific information requested is competitively sensitive and Merck therefore cannot produce it in a public setting in which it could be accessed by competitors. However, Merck does report similar information in an aggregated format in its annual price transparency report, which we proactively make available on our corporate responsibility website:

https://s3.amazonaws.com/msd18-assets/wp-content/uploads/2019/02/28155345/2018-US-PRICING-TRANSPARENCY-REPORT_02.2019.pdf

The report sets forth the average annual list price changes across the Merck portfolio as well as other price related information concerning Merck medicines and vaccines. The report shows that in 2018 the average annual list price across the Merck portfolio increased by 5.5 percent – the lowest increase since 2010 – as compared with a 6.6 percent increase in 2017. In 2018, the Company's gross U.S. sales were reduced by 44.3% as a result of rebates, discounts and returns. The below chart reflects additional information about the price changes for Merck products.

	2010	2011	2012	2013	2014	2015	2016	2017	2018
US Product Portfolio[1] % Change vs. Prior Year[2]									
List Price Change (WAC)[3]	7.4	9.5	9.2	9.6	10.5	9.8	9.6	6.6	5.5
Net Price[4]	3.4	5.1	6.2	5.5	3.7	5.5	5.5	(1.9)[5]	2.99
	2010	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**
US Product Portfolio									
Avg. Discount[6] (%)	27.3	28.9	29.9	32.1	37.0	38.2	40.9	45.1	44.3

6. *In Merck's most recent pricing transparency report, the company notes that the "the average annual net price across our portfolio declined by 1.9 percent, reflecting specific in-year dynamics, including the impact of loss of patent protection for three major medicines." Please identify these medicines, and the net price change for each of them on a dollar and percentage basis for 2017. What was Merck's average net price increase/decrease in 2017 for drugs excluding these three medications?*

This information is confidential, proprietary and commercially sensitive. Merck's average net price increase/decrease in 2017 excluding the three drugs referred to is -0.6 percent.

7. *In Merck's pricing transparency report, the company states that its net price is "represents the year-over-year change in average net price, which is WAC less rebates, discounts and returns," while its average discount is "weighted … [and] calculated by dividing annual rebates, discounts and returns by annual gross sales." Please clarify whether the company's average net price is weighted for purposes of complying with its publically stated pledge.*

Yes, the average net price is weighted.

Pfizer Responses

Senator Wyden:
For All Witnesses:

Proposed Rebate Rule

As has been done in many other settings, drug manufacturers said during the hearing that one reason list prices for drugs are high is that pharmaceutical benefit managers (PBMs) demand larger and larger rebates in order for the drug to receive favorable placement on a formulary. You and your colleagues who testified during the hearing stated if the Administration's proposal on changes to the anti-kickback safe harbor for pharmaceutical rebates took effect, your company would likely lower list price.

Like many Oregonians, I am skeptical drug manufacturers would voluntarily lower their prices. Therefore, would you support legislation that would 1) make similar changes the Administration has put forward related to Part D and Medicaid managed care, 2) change the rebate system in a

similar way to the proposal for the commercial market, and 3) require drug makers to lower the list price of their drugs equal to the amount of rebates provided today?

Pfizer would support legislation that reforms the current system of rebating to one in which payers are required to use manufacturer provided discounts to ensure that the patient gets the benefit of the discount at the point of sale. We support this reform across all segments of the market where private sector negotiations result in lower net prices including Medicare Part D, Medicaid managed care and the commercial markets.

We realize that the transition away from rebates toward a point-of-sale discount model will result in a lowering of our net prices. Despite this potential negative financial impact, we support efforts to eliminate rebates because we believe the new model will be good for patients.

As currently written, the proposed rule only applies to the Medicare and Medicaid managed care segments of the market. It will be important to have any rebate reform apply to both government programs and the commercial market as that will also lead to a lowering of list prices as well. A bifurcated market will make it more challenging for manufacturers to reduce list price since the commercial market covers more than fifty percent of Americans with insurance and represents over half of the business for most manufacturers.

If the proposed rule is modified to apply to all market segments, we would evaluate the best options to arrive at a net price that ensures patients have access to our medicines. Decisions would be made on a product by product basis given that each therapeutic class has its own set of competitive and access dynamics. To ensure these benefits reach patients, it will be important for policymakers to ensure that plans do not create new barriers or restrictions that hinder patient access and undermine the spirit of the rule.

Medicaid Drug Rebate Program

The Medicaid Drug Rebate Program (MDRP) requires manufacturers to provide a basic rebate and an additional inflationary rebate for both brand and generic drugs. The inflationary rebate is an increasingly substantial part of total rebates due in large part to large increases in drug prices that exceed inflation. Under current law, this inflationary rebate is capped at 100 percent of Average Manufacturer Price (AMP). This is the case even when manufacturers continue to raise their prices well above inflation.

1. Please provide a list of all of your pharmaceutical products that have reached the Medicaid AMP rebate cap in any of the 20 quarters from January 1, 2014 through December 31, 2018.
2. For each drug listed in response to question 1, please also provide a list of which quarters and years each drug hit the cap.

   Given the highly confidential nature of the information requested, we would need to discuss the scope of this request with your staff.

Medicaid Drug Rebate Program Compliance

I am concerned about recent reports and legal settlements surrounding drug manufacturers' failure to comply fully with the requirements of the MDRP. For example, an analysis by the U.S. Department of Health and Human Services Office of Inspector General found that between 2012 and 2016 taxpayers may have overpaid by as much as $1.3 billion for 10 potentially misclassified drugs. That is why I introduced the Right Rebate Act with Chairman Grassley to prevent drug manufacturers from manipulating Medicaid to increase their profits. However, I continued to be concerned about oversight and manufacturer compliance with the requirements of the Medicaid Drug Rebate Program. Accordingly, please describe the following:

1. Your company's current compliance plan and procedures used to ensure compliance with the requirements of the Medicaid Drug Rebate Program including internal audits or other checks you use to identify compliance vulnerabilities.
2. Any past or ongoing issues of non-compliance.
3. Any corrective actions taken to address identified problems or issues of non-compliance with the MDRP and how such steps were communicated to the Centers for Medicare & Medicaid Services.
4. Any steps taken to improve compliance and ensure that all Medicaid drug rebates owed to the federal government and the states are paid in full.

It is Pfizer's policy to comply with all legislation, regulations, provisions, requirements, terms and conditions of the MDRP.

In order for its outpatient drugs to be covered by the Medicaid program, a manufacturer must enter into a national rebate agreement with the Secretary of HHS. This agreement generally requires manufacturers to offer Medicaid agencies the mandated discounts for covered prescription drugs. Pfizer is responsible for calculating and reporting to the federal government on a monthly and quarterly basis various metrics for each of Pfizer's products and, ultimately, for paying corresponding rebates based on Medicaid recipients' purchases of the company's covered drugs. In return for these rebates, state Medicaid agencies must pay for all of the drug company's covered drugs (with certain limited exceptions). If the price of the manufacturer's drug rises faster than the inflation rate, states may require an additional rebate. Pfizer and/or its predecessor entities have signed a Rebate Agreement with HHS for all Pfizer labeler codes and Pfizer remains vigilant of its obligations under the Medicaid Drug Rebate Program.

The Company has robust policies and procedures to ensure compliance with government price calculations, certification and reporting under MDRP including Pfizer's certification, reporting, payment obligations, records retention and audit obligations. The Company's policies and procedures are also meant to impart to Pfizer employees an understanding of the government pricing metrics calculated under the MDRP. Consistent with Pfizer's policies and procedures and available CMS guidance, if Pfizer becomes aware of any instances of non-compliance with the MDRP, Pfizer reports and/or communicates with CMS. Based on

our current information and belief, Pfizer complies with CMS regulations and interacts with CMS to take corrective action as instructed.

Bonus Payments Tied to Specific Drugs

I am concerned by the potential for employee financial incentives to encourage high launch prices and price increases for prescription drugs.

1. Is your salary, bonus or other compensation tied to sales or revenue targets of a single product your company sells? Has it ever been? If yes, please state the product or products to which your salary, bonus or other compensation was tied.

   No. Dr. Bourla's salary, bonus, or other compensation is not nor has ever been tied to the sales or revenue targets of a single product.

2. Is your salary, bonus or other compensation tied to either revenue or net income of the company as a whole? Has it ever been? If yes, please explain what assumptions about price increases are used when the compensation committee sets revenue or net income goals. Does the compensation committee provide any guidance to executives in regards to the amount of revenue that the company will generate from price increases versus volume growth?

   Dr. Bourla, along with over approximately 48,000 other colleagues, participates in Pfizer's annual bonus plan, Pfizer's Global Performance Plan (GPP), which is funded annually based on Pfizer's performance measured against three financial metrics: revenue, adjusted earnings per share and cash flow from operations and has been since 2008.

   Therefore, any annual bonuses through Pfizer's GPP, determined by the Compensation Committee of the Board of Directors and ratified by the independent members of the Board, is in part based on company revenue and net income as adjusted earnings per share is derived from net income. In determining Dr. Bourla's bonus, the Compensation Committee also takes into account other factors such as his individual performance against his annual performance objectives and overall company performance (e.g. pipeline). Neither Dr. Bourla's salary nor other compensation is tied to revenue or net income of the company as a whole.

   In setting the corporate financial goals for compensation purposes, the Compensation Committee uses the company's annual budget as the starting point and it is adjusted accordingly based on the final business plan discussion which accounts for various factors, including access, rebates, losses of exclusivity and expected price adjustments.

   The Compensation Committee does not provide any guidance with regard to the amount of revenue that the company will generate from price increases versus volume growth.

Net Prices

In your testimony, you stated "in 2018, the average net price of Pfizer's medicines in the United States declined 1% percent." Please describe how the company's year-over-year aggregate net price is calculated.

The Net Sales Price impact vs. the Prior Year reflects the year-over-year change in average net selling price (calculated as net sales / units) multiplied by the current year's units. This calculation is performed at a product NDC level, and then aggregated up to the product and then the total business level.

The company's aggregate year-over-year impact of price on growth is the summation of the sales price impact vs. prior year from all products in dollars, divided by the prior year's total net revenues. In 2018, the year-over-year impact on price on growth for the U.S. pharmaceutical business was negative one percent.

Please also specifically address the following questions:

1. How many products are included in the calculation of the average net price change? What was the median net price change?

   For 2018, there are a total of 399 products included in the U.S. portfolio; median net price impact on growth is negative four percent.

2. Is net price weighted? If so, how? For example, in determining the aggregate net price does the company assign different weights to different products based on volume or other factors? Are "on patent" and "off patent" drugs weighted identically? Are other statistical weights used or are all products treated equally?

   Aggregate change in net price is weighted based on product volume (units) and mix. All products - both "on patent" and "off patent" - are treated identically.

3. Does the figure that you provided during your testimony account for U.S. prices, international prices, or both? Generally speaking, when your company reports net price changes, does it differentiate between U.S. and international prices?

   The figure of negative one percent price impact on growth provided during the testimony is for the United States. Generally speaking, when we respond to inquiries on the impact of price on growth, we have responded on a global basis, a U.S. only basis, or both, dictated by how the inquiry is posed.

4. Please list the five drugs your company sold in the U.S. that had the greatest year-over-year net price increase in 2018, noting the increase for each drug by dollar figure and percentage.

   The following products had the greatest positive impact of sales price on growth in the United States in 2018: Prevnar, Lyrica, Chantix, Pristiq, Relpax

Please list the five drugs your company sold in the U.S. that had the lowest year-over-year net price increase (and/or the greatest decrease) in 2018, noting the increase (or decrease) for each drug by dollar figure and percentage.

The following products had the greatest negative impact of sales price on growth in the United States in 2018: Xeljanz, Viagra, Inflectra, Ibrance, Celebrex

5. For 2018, what was the average net price change in the U.S. market for (1) drugs with no competition, (2) drugs with only branded competition, and (3) drugs with generic competition?

   2018 impact of price on growth from branded products in the United States was two percent. 2018 impact of price on growth from remainder of portfolio (excluding Branded Products) in the United States was negative five percent.

6. Pfizer has lost exclusivity for several products in recent years, including Viagra, Zyvox, Relpax, Tygacil and Pristiq. For each of these products, please provide the percentage and dollar change in the average net price from (1) the last full year in which Pfizer maintained product exclusivity to the (2) first full year in which generic competition was present in the market.

   Pfizer has lost exclusivity on several products in recent years, including:

   •2014: Detrol, Rapamune, Celebrex

   •2015: Zyvox

   •2016: Relpax, Tygacil

   •2017: Viagra, Pristiq

   In all but one case, the net price impact of the branded products listed above was negative the year after exclusivity was lost reflecting market dynamics and the competitive environment.

Sanofi Responses

Senator Wyden:
For All Witnesses:

Proposed Rebate Rule

As has been done in many other settings, drug manufacturers said during the hearing that one reason list prices for drugs are high is that pharmaceutical benefit managers (PBMs) demand larger and larger rebates in order for the drug to receive favorable placement on a formulary. You and your colleagues who testified during the hearing stated if the Administration's proposal on changes to the anti-kickback safe harbor for pharmaceutical rebates took effect, your company would likely lower list price.

Like many Oregonians, I am skeptical drug manufacturers would voluntarily lower their prices. Therefore, would you support legislation that would 1) make similar changes the Administration has put forward related to Part D and Medicaid managed care, 2) change the rebate system in a similar way to the proposal for the commercial market, and 3) require drug makers to lower the list price of their drugs equal to the amount of rebates provided today?

If (1) the proposed changes to the anti-kickback statute safe harbors were codified, and (2) Congress implemented similar changes to the commercial insurance market, Sanofi would lower the list prices of its prescription medications for products in competitive categories for which there is currently a material difference between list price and net price on the assumption that patient access and affordability would be improved. Sanofi also supports policy changes that would de-link other payments in the pharmaceutical supply chain from list price.

We support extending the intent behind the anti-kickback statute safe harbor proposed rule to the commercial market so that incentives are aligned across the marketplace. Together, we believe these changes would facilitate Sanofi's ability to lower our list prices. However, we recommend a step-wise approach, implementing changes to the commercial market after the safe harbor rule is implemented on January 1, 2020. Such an approach would provide an opportunity for stakeholders and the government to identify unintended consequences, and address them, prior to extending these policies to the commercial market.

We want to ensure that the new system achieves its goal of improving affordability for patients. For instance, CMS should monitor and evaluate how the new system affects formulary access, utilization management, and patient cost-sharing, particularly with respect to medicines with a lower list price. We also have concerns that changes to the rebate system may lead to new fees, which simply require manufacturers to pay previous rebate values in new ways, rather than creating savings for patients.

Without a better understanding of how these policy changes ultimately would affect the competitive marketplace, patient access, and affordability, we are unable to quantify the amount of any potential list price reduction.

We support legislation that would incentivize manufacturers to lower list prices by connecting better patient access and affordability to such pricing actions. The U.S. market-based approach to drug pricing has been successful in reducing net prices, but in the current system, that value is not being passed on to patients. We expect that the reforms we note above would address that issue while preserving a market-based approach that promotes competition and ensures patients have affordable and sustainable access to innovative medicines.

Medicaid Drug Rebate Program

The Medicaid Drug Rebate Program (MDRP) requires manufacturers to provide a basic rebate and an additional inflationary rebate for both brand and generic drugs. The inflationary rebate is an increasingly substantial part of total rebates due in large part to

large increases in drug prices that exceed inflation. Under current law, this inflationary rebate is capped at 100 percent of Average Manufacturer Price (AMP). This is the case even when manufacturers continue to raise their prices well above inflation.

1. **Please provide a list of all of your pharmaceutical products that have reached the Medicaid AMP rebate cap in any of the 20 quarters from January 1, 2014 through December 31, 2018.**
2. **For each drug listed in response to question 1, please also provide a list of which quarters and years each drug hit the cap.**

Sanofi takes steps to ensure that it complies with all applicable laws related to the Medicaid Drug Rebate Program, including that it is paying rebates to the state Medicaid programs in accordance with law. Sanofi sells NDCs in 29 product families for which it pays Medicaid rebates at 100% of AMP. Respectfully, Sanofi's view is that the detailed information requested by this question is confidential and proprietary. We would be happy to work with the Committee to provide this information in a way that mitigates against competitive harms that could arise from public disclosure of this information.

Medicaid Drug Rebate Program Compliance

I am concerned about recent reports and legal settlements surrounding drug manufacturers' failure to comply fully with the requirements of the MDRP. For example, an analysis by the U.S. Department of Health and Human Services Office of Inspector General found that between 2012 and 2016 taxpayers may have overpaid by as much as $1.3 billion for 10 potentially misclassified drugs. That is why I introduced the Right Rebate Act with Chairman Grassley to prevent drug manufacturers from manipulating Medicaid to increase their profits. However, I continued to be concerned about oversight and manufacturer compliance with the requirements of the Medicaid Drug Rebate Program. Accordingly, please describe the following:

1. **Your company's current compliance plan and procedures used to ensure compliance with the requirements of the Medicaid Drug Rebate Program including internal audits or other checks you use to identify compliance vulnerabilities.**

Sanofi takes steps to ensure that it complies with all applicable laws related to its participation in the Medicaid Drug Rebate Program (MDRP). These steps include, for example, documenting Medicaid rebate calculation methodologies, processes, and reasonable assumptions as appropriate. Sanofi's government price reporting personnel also hold weekly meetings with the Sanofi legal department, including with support from outside counsel as needed, to ensure that compliance questions are discussed and addressed in a timely manner. Sanofi's MDRP compliance is tested through several audits, including biannual Sarbanes-Oxley Act audits, biannual external audits, conversations with an external consultant government pricing advisory team, and annual calculation audits of Average Manufacturer Price and Best Price.

2. **Any past or ongoing issues of non-compliance.**

Given the complexity of the MDRP and applicable law and guidance, Sanofi routinely reviews its calculation methodologies and reasonable assumptions. In the normal course of business, questions may arise as to specific Sanofi compliance processes for the MDRP. When such questions arise, Sanofi takes prompt steps to engage with CMS about appropriate next steps, including a restatement of any of the components of the Medicaid rebate calculation if needed. Such restatements are administrative in nature and expressly contemplated by the CMS regulations.

3. **Any corrective actions taken to address identified problems or issues of non-compliance with the MDRP and how such steps were communicated to the Centers for Medicare & Medicaid Services.**

As noted above, in the event that Sanofi identifies any compliance questions that it believes warrant review by CMS, Sanofi promptly engages with CMS. This may occur, for example, in the event of statutory or regulatory changes, or if CMS releases new sub-regulatory guidance.

4. **Any steps taken to improve compliance and ensure that all Medicaid drug rebates owed to the federal government and the states are paid in full.**

Sanofi's government price reporting team routinely works with in-house and outside counsel regarding compliance with the Medicaid Drug Rebate Act and CMS rules. As part of this continuing compliance, the company assesses its calculation processes and reasonable assumptions for purposes of calculating Average Manufacturer Price, Best Price, and Unit Rebate Amount. In certain cases, moreover, Sanofi engages directly with CMS to seek the agency's view of Sanofi's reasonable assumptions or compliance processes. In any instance in which Sanofi would determine that the State Medicaid Programs were underpaid rebates, Sanofi would engage with CMS to determine the appropriate way forward, including restating pricing metrics and paying additional rebates to the states.

<u>Bonus Payments Tied to Specific Drugs</u>

I am concerned by the potential for employee financial incentives to encourage high launch prices and price increases for prescription drugs.

1. **Is your salary, bonus or other compensation tied to sales or revenue targets of a single product your company sells? Has it ever been? If yes, please state the product or products to which your salary, bonus or other compensation was tied.**

2. **Is your salary, bonus or other compensation tied to either revenue or net income of the company as a whole? Has it ever been? If yes, please explain what assumptions about price increases are used when the compensation committee sets revenue or net income goals. Does the compensation committee provide any guidance to executives in regards to the amount of revenue that the company will generate from price increases versus volume growth?**

The Sanofi Board of Directors, acting on the recommendation of the Compensation Committee, sets the compensation for the Chief Executive Officer (CEO). That compensation structure includes fixed compensation, variable compensation, options, performance shares, and benefits in kind.

Sanofi's overall compensation policy is designed to motivate and reward performance by ensuring that a significant portion of compensation is contingent on the attainment of financial, operational, and extra-financial criteria aligned with the corporate interest and with the creation of shareholder value. Therefore, in 2017 (the most current year in which public information is available), as Sanofi's CEO, Dr. Brandicourt was eligible for up to 250 percent of his target fixed compensation in variable compensation. Several factors are considered in determining his variable compensation; 40 percent is based on financial indicators, and 60 percent is based on specific individual objectives, including external growth, product launches, operational transformation, organization and staff relations, and new product pipeline.

Dr. Brandicourt's compensation package also includes equity-based compensation, which is medium-term and aims to align the interests of the CEO with those of the shareholders and other stakeholders. In 2017, he received a set number of options to subscribe for shares, based on performance conditions measured over a three year period, as well as performance shares based on business net income, return on assets, and total shareholder return.

Net Prices

In your testimony, you stated, "we have increased transparency by providing, each year, information about our list and net prices across all of our medicines," and that "in 2018, the average aggregate list price increase across all Sanofi medicines in the U.S. was 4.6 percent…the price actually paid to Sanofi, declined by 8 percent. So declining average aggregate net price in [2018] represents the third consecutive year in which the amount paid by payers across all of our medicines went down." Please describe how the company's year-over-year aggregate net price is calculated. Please also specifically address the following questions:

Sanofi calculates the aggregate net price as follows: Brand net sales are divided by common units for the appropriate period. This amount – "net price per unit" – is then compared to the prior period. This amount establishes any increase or decrease for the brand for the period being calculated. Once this is done for all brands, the increase/decrease is weighted by gross sales (i.e., volume) to show the aggregate net price impacts for Sanofi's portfolio of medicines.

1. **How many products are included in the calculation of the average net price change? What was the median net price change?**

This analysis is done on 79 separate products, covering 76 brands. Some brands have multiple product forms with different prices; Sanofi separates these product forms when calculating average net price.

The median net price change in 2018 was zero percent across all products. Removing products with no net price change, the median net price change in 2018 is -1.0%. This calculation is not weighted by gross sales.

2. **Is net price weighted? If so, how? For example, in determining the aggregate net price does the company assign different weights to different products based on volume or other factors? Are "on patent" and "off patent" drugs weighted identically? Are other statistical weights used or are all products treated equally?**

All products are weighted by gross sales (i.e., volume), irrespective of whether Sanofi has any current patents related to the product. No other statistical weights were used.

3. **Does the figure that you provided during your testimony account for U.S. prices, international prices, or both? Generally speaking, when your company reports net price changes, does it differentiate between U.S. and international prices?**

The data Dr. Brandicourt provided regarding average aggregate list price and average aggregate net price accounted for U.S. prices. Sanofi's annual pricing report[10] and related reporting on net price consider U.S. prices only.

4. **Please list the five drugs your company sold in the U.S. that had the greatest year-over-year net price increase in 2018, noting the increase for each drug by dollar figure and percentage. Please list the five drugs your company sold in the U.S. that had the lowest year-over-year net price increase (and/or the greatest decrease) in 2018, noting the increase (or decrease) for each drug by dollar figure and percentage.**

Products with Greatest Average Net Price Increases in 2018[11]

Product	YOY Percentage Change	YOY U.S. Dollar Change by Unit
Renvela[12]	40%	1.00
Imovax[13]	15%	30.10
Caprelsa[14]	12%	1536.60
Hectorol[15]	11%	0.03

[10] https://mediaroom.sanofi.com/-/media/Project/One-Sanofi-Web/Websites/Global/Sanofi-COM/mediaroom/pdf/2019/Prescription_Medicine_Pricing_2019.pdf

[11] We have excluded products that were discontinued/divested in 2018, have no sales in 2018, or if the reason for net price increase was due to changes in prior accounting estimates or assumptions (as opposed to changes in rebates and discounts).

[12] Sanofi did not take any list price increases on Renvela in 2018. The net price increase is due to (1) changes in prior accounting estimates/assumptions, and (2) increasing use of generics in class, resulting in (i) change in the mix of business, and (ii) a reduction in rebate payments.

[13] Sanofi took a 5 percent list price increase on Imovax in 2018.

[14] Sanofi took a 5 percent list price increase on Caprelsa in 2018.

Zaltrap[16]	9%	0.60

Products with Greatest Average Net Price Decreases in 2018[17]

Product	YOY Percentage Change	YOY U.S. Dollar Change by Unit
Renvela AG	-74%	-1.57
Zolpidem CR	-68%	-0.26
Leflunomide	-63%	-0.59
Clolar	-48%	-894.26
Priftin	-26%	-0.54

5. **For 2018, what was the average net price change in the U.S. market for (1) drugs with no competition, (2) drugs with only branded competition, and (3) drugs with generic competition?**

(1) Drugs with no competition[18]: 0.0%
(2) Drugs with only branded competition[19]: -2.1%
(3) Drugs with AB-rated generic/follow-on biologic/biosimilar competition: -13.5%

6. **In its most recent pricing report, Sanofi states that it "increased the price of 35 of our 76 prescription medicines" in the United States. This statement appears to be in regards to list price. How many of these medicines had their net price increase?**

Seventeen of the 35 prescription medicines with list price increases also had average net price increases.

7. **In its most recent pricing report, Sanofi states that "in 2018, 55 percent of our gross sales were given back to payors as rebates, including $4.5 billion in mandatory rebates to government payors and $7.3 billion in discretionary rebates." For each product, please disclose the gross sales and the amount of rebates paid.**

Product-level rebate information is confidential and proprietary information for competitive reasons and falls within the definition of "trade secret" under the Trade Secrets Act,

[15] Sanofi reduced the list price of Hectorol by 47% in October 2018. The net price increase was due to a reduction in rebate payments.
[16] Sanofi did not take any list price increases on Zeltrap in 2018.
[17] We have excluded products that were discontinued/divested, have no sales in 2018, or if the reason for net price decline was due to changes in prior accounting estimates or assumptions (as opposed to changes in rebates and discounts).
[18] We define a product as having no competition if there are no other products in the therapeutic class.
[19] We define a product as having only branded competition if there is no generic, follow-on biologic, or biosimilar product in the therapeutic class.

18 U.S.C. § 1905, Exemption 4 of the Freedom of Information Act, 5 U.S.C. § 552(b)(4), and the Defend Trade Secrets Act of 2016, 18 U.S.C. § 1836. Public disclosure of this information would cause significant harm to Sanofi and Sanofi's customers, and competitors would gain unfair competitive advantage if they were to obtain this information through public disclosure.

We note that Congressional and Executive agencies have historically expressed concern that disclosure of such information could inhibit competition. For example, in 2007 when then-Chairman Waxman asked several Medicare Part D prescription drug plans ("PDPs") to submit to the House Oversight and Government Reform Committee information on the negotiated price discounts, rebates and other price concessions that they obtained from drug manufacturers, the CBO issued a report concluding that public disclosure of that information could reduce the rebates that PDPs received and thus raise Medicare costs.[20] Specifically, the CBO found that the disclosure of rebate data could cause the variation in rebates among purchasers to decline. Because PDPs generally secure rebates that are somewhat larger than the average rebates observed in commercial health plans, the disclosure of Part D rebates to competitors could create pressure to reduce those rebate amounts, which in turn could increase costs for the Medicare program and, on average, the costs for Medicare beneficiaries.[21] Specifically, the CBO found that the disclosure of rebate data could cause the variation in rebates among purchasers to decline. Second, CBO concluded that disclosure of rebates could facilitate tacit collusion among the manufacturers of competing brand-name drugs, reducing the rebates to PDPs and thus increasing net drug prices.[22] Similarly, the Federal Trade Commission ("FTC") has cited concerns regarding the anti-competitive effects of disclosing net pricing and other price-sensitive information. In the context of the healthcare industry generally, the FTC noted:

> [Price transparency] can actually harm competition and consumers. Some types of information are not particularly useful to consumers, but are of great interest to competitors. We are especially concerned when information disclosures allow competitors to figure out what their rivals are charging, which dampens each competitor's incentive to offer a low price, or increases the likelihood that they can coordinate on higher prices.[23]

Moreover, in describing its concerns about a New York state bill that would have required pharmacy benefit managers ("PBMs") to disclose their rebate arrangements with drug manufacturers, the FTC explained that disclosure of this information could "facilitate collusion, raise prices, and harm the patients the Bill is supposed to protect."[24] The FTC further explained that, without knowledge of such competitor rebate information:

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[20] CBO, Letter to the Hon. Joe Barton and the Hon. Jim McCrery (March 12, 2007), *available at* https://www.cbo.gov/system/files?file=2018-10/03-12-drug-rebates.pdf; *see also* CBO, Increasing Transparency in the Pricing of Health Care Services and Pharmaceuticals (June 5, 2008), *available at* https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/06-05-pricetransparency.pdf.
[21] *Id.*, at 3.
[22] *Id.,* at 4.
[23] FTC, Office of Policy Planning, *Price Transparency or TMI?* (July 2, 2015), *available at* https://www.ftc.gov/news-events/blogs/competition-matters/2015/07/price-transparency-or-tmi.
[24] FTC, Office of Policy Planning, Bureau of Competition and Bureau of Economics, Letter to Hon. James L. Seward re: New York Senate Bill 58, at 5 (March 31, 2009), *available at* https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-james-l.seward-concerning-new-york-senate-bill-58-pharmacy-benefit-managers-pbms/v090006newyorkpbm.pdf.

> [M]anufacturers have powerful incentives to bid aggressively for formulary position, because preferential formulary treatment may yield increased sales. Unprotected disclosures thus may raise the price that New York consumers pay for pharmaceutical coverage by undermining competition among pharmaceutical companies for preferred formulary treatment.[25]

For these reasons, in public settings, we have provided rebate information at an aggregate level only, to prevent reverse engineering by competitors to learn our net pricing information for specific products. We would be happy to work with the Committee to provide this information in a way that mitigates against competitive harms that could arise from public disclosure of this information.

[25] *Id. See, also,* FTC, Office of Policy Planning, Bureau of Competition, and Bureau of Economics, to Assemblyman Greg Aghazarian re: California Assembly Bill No. 1960 (September 7, 2004) (concluding that, if manufacturers learn the exact amount of the rebates offered by their competitors through required PBM disclosures, then tacit collusion among manufacturers is more feasible, which may lead to higher prices for PBM services and drugs), *available at* https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-comment-hon.greg-aghazarian-concerning-ca.b.1960-requiring-pharmacy-benefit-managers-make-disclosures-purchasers-and-prospective-purchasers/v040027.pdf.