Senate Finance Committee Hearing

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

February 26, 2019

Questions for:

Giovanni Caforio, M.D.

Chairman of the Board and Chief Executive Officer

Bristol-Myers Squibb Co.

Responses Submitted on April 5, 2019

Senator Grassley:

At the hearing, you testified that Bristol-Myers Squibb does not withhold samples from generic manufacturers in order to block generic versions of your drug from entering the market. You also expressed your support for the "Creating and Restoring Equal Access to Equivalent Samples Act," also known as the CREATES Act.

As you know, the FDA has a list on its website which identifies reference listed drug (RLD) access inquiries where brand manufacturers may have prevented generic companies from obtaining samples of products necessary to support FDA approval. Celgene is on this FDA list. According to your testimony, Bristol-Myers Squibb is in the process of acquiring Celgene.

- **Are you aware that Celgene is on the FDA list and that Celgene had multiple access inquiries?**

  Yes.

- **Will you ensure that Bristol-Myers Squibb/Celgene will not block access to samples once the Celgene acquisition is final?**

  As Dr. Caforio testified at the hearing, BMS does not withhold samples from generic manufacturers in order to block generic versions of the drug from entering the market. BMS believes it is important to ensure generics are made available whenever that is permissible under our system, and supports the administration's focus on increasing the approval of generics. As part of that system, it is important that

generic companies perform the needed testing to ensure product quality and patient safety. BMS cannot comment on Celgene's practices in this area, but once the transaction closes, BMS' practices with regard to generic samples will govern the combined portfolio.

To all witnesses:

The Department of Health and Human Services' proposed rule, "Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees", envisions that drug manufacturers will offer upfront discounts rather than the back-end rebates that are now commonly provided. Some observers argue that a 1996 court case called into question whether manufacturers could offer upfront discounts, resulting in today's rebate-based system. I've heard differing opinions as to whether the issues related to the initial court case are still relevant. If the HHS proposed rule is finalized, can you assure the Committee that your company will offer upfront discounts? If not, why?

BMS supports the HHS proposed rule to eliminate safe harbor protection for back-end rebates under Medicare Part D and the rule's objective to ensure that patients benefit from price reductions that BMS provides on its drugs. As the proposed rule notes, there is uncertainty as to the strategic behavior changes that will occur if the rule is enacted, and therefore uncertainty as to precise mechanisms that will be available to meet the objectives of the rule. However, there is some risk that manufacturers would have to defend themselves against antitrust litigation if they were to offer upfront discounts instead of rebates if the proposed rule were finalized. In particular, there may be risk of claims being crafted under the Robinson-Patman Act, 15 U.S.C. § 13. Any such claims would have to meet significant substantive requirements and be subject to important statutory defenses. Nonetheless, even if meritless, Robinson-Patman claims can be expensive and time consuming for manufacturers to defend against.

In light of the potential for antitrust litigation, BMS recommends that the Committee consider how best to address this risk as it considers the HHS proposal. Congress, could, for example, enact legislation that immunizes from liability under the Robinson-Patman Act drug manufacturers who offer upfront discounting under Medicare Part D in accordance with the fraud and abuse safe harbor created by the HHS rule.

Please describe how you expect your company to respond to the HHS proposed rule to eliminate safe harbor protection for back-end rebates in Medicare Part D that is referenced above if it is finalized. Assuming you are confident that antitrust laws do not prevent your company from offering upfront discounts, specifically, do you envision that your company lowers the list price of a drug to the current after-rebate net price, offer discounts equal to the current rebate amount, or a combination of both?

BMS supports the HHS proposed rule to eliminate safe harbor protection for back-end rebates in Medicare Part D, and we believe it would lead to lower out-of-pocket costs. This question rightly supposes that the goals of the proposed rule could be achieved through lower list prices, negotiated discounts at the point-of-sale, or some combination of these two approaches. While it is unclear how Part D plans and PBMs will react to the proposed rule, at this time, BMS envisions that we would offer point-of-sale discounts to Part D plans equivalent on average to the current contracted rebate amount and will continue to assess the possibility of lowering list price on a product-by-product basis. Our ability to lower list prices, however, is constrained by the fact that the HHS proposed rule does not apply to the commercial insurance market, where we anticipate back-end rebates to continue for the foreseeable future.

Please also see the answer to the previous question.

To what extent are the back-end rebates your company currently offers contingent on the amount of market share realized for your drugs as a result of Part D plan formulary placement and other techniques?

The back-end rebates BMS currently offers pursuant to its Medicare Part D agreements are not contingent on the amount of market share realized for any of BMS' drugs as a result of Part D plan formulary placement or any other performance requirement.

Please provide a breakdown of percentage of sales that go to each payer (including Medicare, Medicaid, private pay, other) and a similar percentage by volume of the total number of each drug compared to total volume. Please provide this data for the most recent year available.

This information is not available publicly and is competitively sensitive.

Do your companies hire consultants or lobbyists to promote products at state Medicaid Pharmacy & Therapeutics Committees? To whom do you disclose advocacy activities surrounding state Medicaid programs, if at all?

BMS does not hire consultants or lobbyists to promote its products at state Medicaid P&T Committees. BMS complies with the applicable lobbying laws across all 50 states, Puerto Rico, and the District of Columbia. Many states require engagement with its Medicaid officials to be reported. We disclose required lobbying activities to each state in accordance with the individual state lobbying disclosure and ethics laws.

1. **Please describe how the costs of patient assistance programs are accounted for within your company's financial statements. Please also describe the types of market information, such as prescribing and use patterns that your company collects from different types of patient assistance programs and patient hub services.**

For purposes of responding to this request, BMS interprets "patient assistance programs" and "patient hub services" as BMS programs or services supporting education, access and/or treatment adherence for eligible patients who are prescribed a BMS medicine. Costs associated with these programs are accounted for in our financial statements as marketing, selling and administrative expenses or gross-to-net sales adjustments, depending on the type of assistance offered.

Data captured through the administration of patient support programs allows our program administrators to validate information provided directly from patients and providers in support of the specific program(s) for which assistance is being requested. This data capture includes, but may not be limited to: (1) information that supports determination of patient eligibility; (2) validation of licensed provider/prescriber; (3) prescription related information necessary to execute patient assistance available through program(s) (*i.e.*, dosage and units being prescribed/dispensed); and, (4) insurance information.

2. **Please provide a list of all contributions since January 1, 2014, that your company has made to any tax exempt organizations working on issues related to drugs within your product lines, including but not limited to patient groups, disease awareness groups, medical or professional societies, universities or hospitals, industry associations or leagues. For each contribution, please provide the name of the organization that received the donation, the date the donation was made, the amount of the donation, and a description of the purpose of the contribution (i.e., was the contribution for the general fund, a specific purpose to a specific program, or continuing medical education). Please also note whether the contribution was unrestricted or restricted; if it was restricted, please explain all restrictions. Finally, if your company maintains a foundation or other separate charitable arm, please provide the name of all such entities, and list all donations made from that entity or entities.**

BMS refers the Committee to the Corporate Giving page on the BMS website (https://www.bms.com/about-us/responsibility/corporate-giving.html). This page includes comprehensive information about BMS' Corporate Giving policies and practices. It also includes comprehensive lists of IME Grants, Charitable Donations and Corporate Giving for calendar years 2016, 2017 and 2018. These grants are made for a variety of appropriate purposes, not limited to issues related to drugs within the BMS product line.

BMS supports the BMS Patient Assistance Foundation (BMSPAF), a non-profit organization that helps patients in the United States who need temporary help obtaining various BMS medications. In 2018, BMS donated over $1 billion worth of BMS medicines to the BMSPAF, and the BMSPAF provided free medicine to more than 75,000 patients.

BMS also supports the Bristol-Myers Squibb Foundation, a non-profit organization that promotes health equity and seeks to improve the health outcomes of populations disproportionately affected by serious diseases by strengthening healthcare worker capacity, integrating medical care and community based support services, and mobilizing communities to fight against disease. BMS views the activities of the BMS Foundation as outside the scope of this question.

Pay for delay agreements cost consumers and taxpayers billions in higher drug costs every year. The FTC has gone after drug companies that enter into these settlements where the brand pays the generic company to keep its lower cost alternative off the market. I'm the lead republican sponsor of S. 64, the "Preserve Access to Affordable Generics and Biosimilars Act," which would help put an end to these deals.

- **Do you agree that these pay-off agreements keep drug costs high for patients because they delay competition?**

  BMS agrees that patent settlement agreements that have substantial payments going from innovators to generics, and are solely intended to delay competition, are anticompetitive.

- **Has your company ever entered into these kinds of settlements with a generic company?**

  BMS has not entered into patent settlements that have substantial payments going from innovator to generics and are solely intended to delay competition.

- **Do you support the pay for delay bill?**

  In general, the ability to settle patent litigation, like any litigation, reflects a balancing of considerations by the involved parties and often leads to earlier generic entry than patent expiration. The current system provides the government with the ability to monitor and review these settlements, and has worked well.

  With regard to S. 64, BMS supports the goals of the legislation but has objections to the legislation as currently drafted. For example, the legislation should be revised: (1) only to apply prospectively and not retroactively to agreements already entered into; (2) eliminate the presumption that all settlements are presumptively anticompetitive; (3) eliminate restrictions on the arguments companies would be permitted to advance to defend agreements; and (4) include "exclusions" for certain types of agreements, such as those containing exclusive licenses, to name a few. BMS would be happy to follow up and provide further details to the committee.

Rebate Traps/Walls

I'm increasingly concerned about the effect of so-called "rebate traps" or "rebate walls" on patients' access to quality, lower cost medicine. I understand there is ongoing litigation challenging these practices as anti-competitive.

1. **Does your company engage in the bundling of rebates over multiple products? If so, why? And what benefit does the consumer gain from that?**

   BMS does not have any Medicare Part D or any other payer contracts with bundling of rebates.

2. **Does your company view these practices as anticompetitive or harmful to patients' access to quality, lower cost medicine?**

   BMS believes that clinical treatment decisions should be made by physicians in consultation with patients. As noted, BMS does not have bundled payer agreements and without insight to the specific terms of other manufacturers' bundling agreements, it is difficult to assess the impact on patient access and healthcare costs. BMS does not support agreements that create barriers to patients' access to quality, lower cost medicines.

3. **If a policy were adopted to eliminate rebates, or to require that rebate savings be passed on to the consumer, would that in and of itself solve the issue of rebate "traps" and "walls"? And would consumers benefit from such a policy?**

   BMS believes that requiring PBMs and payers to pass manufacturer rebates on to patients has the potential to lower patient out-of-pocket costs, and therefore benefit consumers. However, it is unclear how payers will adjust their benefit plan designs in response to this change and whether it would completely solve the issue of rebate "traps" and "walls." It is possible, for example, that in response to such changes, PBM and payer business models might evolve, and thus we recommend implementing safeguards to protect consumers' access to medicines.

Drug Pricing

a) **When setting the list price of a drug, does your company consider regulatory costs or compliance? If so, how specifically do those factors affect the list price of a drug? Please provide at least one specific example, if applicable, from your current product portfolio.**

   BMS does not consider these costs in setting list price.

b) When setting the list price of a drug, does your company consider the risk of liability or litigation? If so, how specifically do those factors affect the list price of a drug? Please provide at least one specific example, if applicable, from your current product portfolio.

BMS does not consider the risk of liability or litigation in setting list price.

Senator Roberts:

1. What role do you see Value Based Arrangements (VBAs) playing in the effort to reduce prescription drug costs? What potential do these arrangements have to find the "sweet spot" between controlling costs to patients and encouraging innovation of new drugs?

Manufacturers and payers have been participating in Value Based Agreements (VBAs) with increasing frequency. These agreements can potentially reduce overall healthcare costs by reducing costs for medicines, and importantly, improving outcomes for patients and reducing overall healthcare costs. Although there are many types of VBAs, and the goals and impact of these arrangements differ by specific medicines and therapeutic areas, we believe that as the sophistication of these payer and manufacturer arrangements increase, and the capture, integrity and timeliness of healthcare data improves, these agreements will evolve to the "sweet spot" between controlling costs and encouraging the innovation of new medicines.

2. How can VBAs help lower what patients pay out-of-pocket?

VBAs may lower patient out-of-pocket costs where, as a result of the VBA, the drug is placed on a preferred or lower formulary tier. In addition, as explained above, VBAs can potentially reduce overall healthcare costs, including patient out-of-pocket costs, by improving outcomes for patients through the reduction or elimination of the need for additional medicines and/or healthcare services.

3. Can Congress do more to allow for and encourage the use of VBAs?

Yes. Congress can do more to allow for and encourage the use of VBAs. For example, Congress could adopt an exception to the Anti-Kickback Statute and enact measures to avoid unintended consequences under Medicaid price reporting.

Senator Cornyn:
For all witnesses:

We continue to hear that rebates negotiated off of the list price of a drug are both good and bad. Pharmacy benefit managers and plans have argued that rebates are used to lower premiums across the board and that it is the best way to seek a price concession on otherwise expensive drugs. Your industry argues that these payers are insisting on higher rebates that can only be achieved by raising list prices. But patients often lose under this system, with out of pocket costs being tied to list price. Insulin patients appear to be routinely impacted by this perversity in the system.

- **Please explain to the committee how your company would reduce list prices if rebates were no longer a part of the equation?**

  BMS supports the HHS proposed rule to eliminate safe harbor protection for back-end rebates in Medicare Part D, and we believe it would lead to lower out-of-pocket costs. The goals of the proposed rule could be achieved through lower list prices, negotiated discounts at the point-of-sale, or some combination of these two approaches. While it is unclear how Part D plans and PBMs will react to the proposed rule, at this time, BMS envisions that we would offer point-of-sale discounts to Part D plans equivalent on average to the contracted rebate amount and will continue to assess the possibility of lowering list prices on a product-by-product basis. BMS would likely follow a similar approach if back-end rebates were eliminated from the commercial insurance market.

- **What assurance can you provide that you would in fact lower your prices?**

  Please see answer to previous question.

- **What actions should be taken to ensure that patients are actually seeing the benefits of lower out of pocket costs?**

  In order to ensure that patients receive the full benefits of manufacturer discounts, we support the proposed rule's requirement that manufacturer discounts be passed on to patients at the point-of-sale. In addition, we recommend implementing safeguards to protect consumers' access to medicines, to prevent increases in patients' out-of-pocket costs, and to ensure that patients' costs at the point-of-sale fully reflect manufacturer discounts.

- **If rebates are driving high list prices for drugs as drug manufacturers' claim, why do you think that Part B drugs, which have no PBM rebates, are also seeing significant price increases? Whose fault is that?**

The price increases for BMS Part B drugs have been largely in line with Medical CPI. We cannot comment on the Part B price increase practices of other manufacturers.

Senator Young:
For all witnesses:

1. Re-evaluating Business Strategies in Foreign Countries

Since taking office, President Trump has made reducing drug prices one of his highest priorities – and has repeatedly spoken about his frustration with the U.S. subsidizing the costs of pharmaceuticals for the rest of the world. He has gone so far as to issue proposals, like the International Pricing Index (IPI) Model, in an attempt to bring down prescription drug prices.

Questions for All Companies:

With the increased scrutiny of the industry and of the drug supply chain as a whole in the United States …

- **Have any of your companies re-evaluated your business strategy in foreign countries?**

  Please see answer below.

- **If not, then why?**

  Please see answer below.

- **If a proposal, like IPI, were implemented, would it force your companies to potentially "walk away from the negotiating table when other countries demand low prices subsidized by America's seniors," as HHS Senior Advisor for Drug Pricing Reform John O'Brien has said?**

  Please see answer below.

- **What are some of your ideas on how we can ensure Americans aren't shouldering the full cost of pharmaceuticals?**

  BMS reviews its business strategies within and outside of the U.S. on a regular basis. BMS believes that all patients deserve access to life changing medicines. Because of these ethical considerations, BMS would not walk away from discussions about access to our medicines in foreign countries. We believe that the most likely outcome of IPI is further delays in access to life extending and

innovative medicines within the referenced countries, resulting in, for example, lower cancer survival rates.

The IPI proposal imposes price controls in the U.S. based on the policies of foreign countries with socialized health care systems that often deny their citizens access to innovative medicines. Patients in many of the countries included in the reference basket wait significantly longer for new, life extending and innovative medicines to reach them. Outside of the U.S., reimbursement of new medicines can often take more than 2 years. In Greece, for example, only 8% of new cancer therapies are available, and on average it requires 32 months for these products to be available to patients. In comparison, in the U.S., 96% of new cancer drugs are available within 3 months of market approval. Eventually, the industry often accepts foreign prices which do not recognize the value and cost effectiveness of our medicines because patients can wait no longer.

BMS is committed to working with Congress and the Administration to advance better, more effective ways to lower drug prices for patients. As an alternative to the IPI model, finalizing the proposed rebate rule would lower seniors' out-of-pocket costs at the pharmacy counter. Regulatory reforms at the FDA are leading to more medicine approvals and greater competition in the market. Value-based arrangements (VBAs) and indication-based pricing (IBP) can reduce the payer risk of exposure to failed outcomes, more closely associate drug costs and value, and make prescription medicines more affordable for patients.

2. <u>Foreign Countries' Pricing and Reimbursement</u>

President Trump and Secretary Azar have both repeatedly described their frustrations with "foreign freeloading" of U.S. drugs in the last year.

"When foreign governments extort unreasonably low prices from U.S. drug makers, Americans have to pay more to subsidize the enormous cost of research and development. . . It's unfair and it's ridiculous, and it's not going to happen any longer."

<u>Questions for All Companies:</u>

- **Do you agree that because of foreign countries' pricing and reimbursement systems, U.S. patients and innovators are shouldering the burden for financing medical advances?**

  Please see answer below.

- **How do foreign countries' pricing and reimbursement systems affect our prescription drug costs?**

  Please see answer below.

- **Are foreign governments taking note of the concerns being raised by the Trump Administration and have they responded in any way?**

  Please see answer below.

- **Has there been any noticeable change in any of our trade agreements since these concerns have been raised by the Trump Administration?**

  Drug pricing in markets outside of the U.S. must take into account significant differences in economic status, cultural beliefs and values, as well as differences in the local processes for setting prices, which vary significantly from market-to-market. Countries vary significantly in their per capita gross domestic product (GDP), their willingness to invest in, and provide rapid access to, healthcare innovation, their focus on a single best average treatment for a population versus focusing on patient heterogeneity and preserving consumer choice and provider autonomy, and their tolerance and acceptability for optimal patient care.

  The countries selected for international comparison through the IPI model are not economically comparable with the U.S. Many of the countries in the IPI model, most notably Greece, the Czech Republic, and Italy, do not have comparable economies as measured in per capita gross domestic product (GDP). The significant difference in drug costs between the U.S. and other countries referred to by CMS in the IPI proposal is also seen with the comparative cost of physician services, hospital care, diagnostics, and medical devices. For example, according to a recent report by the OECD, hospital services in the U. S. cost ~150% more than in Japan, France, Germany, Finland and Spain; ~170% higher than in UK, Greece, and Italy.

  Through the USMCA and other trade actions, the Trump Administration has taken steps to crack down on foreign violations of U.S. intellectual property rights. There remain, however, several practices that undermine U.S. intellectual property and violate existing trade deals. We need to continue to negotiate better trade deals with better enforcement that protect American medical innovations.

3. **Medicaid Closed Formulary Proposals**

In an attempt to bring down drug costs, various states have been exploring whether to exclude certain drugs from its Medicaid program. For example, the state of Massachusetts' recently asked CMS for permission to create a closed formulary where the state Medicaid program would pick at least one drug per therapeutic class. CMS denied their waiver request citing violation of federal law, but this proposal does bring up important questions on how to contain drug prices in state Medicaid programs.

Questions for All Companies:

- **If the principles of the Medicare Part D program – including the necessary patient protections – were applied to state Medicaid programs, do you think it lower drugs costs while ensuring access to patients?**

  It is unlikely that applying Part D principles to Medicaid would lower drug costs. Medicaid is already a lower cost channel and patients have little to no copay obligations.

4. **Medicaid "Best Price"**

In the Trump Administration's Blueprint, they suggested that because drug manufactures have to give Medicaid the "best price" on drugs, there is no incentive to offer deeper discounts to other payers - both government and commercial - than what is already offered under the Medicaid Drug Rebate Program.

Questions for All Companies:

- **Does the Medicaid "best price" requirement encourage manufacturers to increase initial prices?**

  For BMS, Medicaid "best price" is not a consideration in determining initial product pricing.

- **What, if any, changes would you suggest we make to the program?**

  As clarification, prices offered to Medicare Part D plans are excluded from Medicaid "best price," and therefore, manufacturers can offer deeper discounts to Part D without impacting Medicaid best price.

  More generally, BMS recommends the creation of an exemption from best price and AMP for select value based purchasing arrangements and greater clarity on best price and AMP reporting on issues related to such arrangements.

5. **Outcomes-Based Contracts**

In almost all of your testimonies, you highlight your support of outcomes-based contracts and how we need to be shifting our system toward that approach.

Questions for All Companies:

- **How will these contracts lower drug costs for patients in both the near-term and long-term?**

  The goal and design of outcome-based contracts will vary depending on the specific drug and the therapeutic area/disease state which is being evaluated. In

general, outcome-based contracts are designed to demonstrate the efficacy, safety, clinical superiority, cost savings and/or improvement in overall patient health outcomes. To the extent that outcomes-based contracts demonstrate improvement in clinical outcomes and/or reduction in overall healthcare costs and facilitate access to appropriate medicines, patients will benefit from improved outcomes and reduced out-of-pocket costs, and federal healthcare programs will benefit from lower overall healthcare costs.

- **How will they lower overall healthcare costs for our federal programs?**

  Please see answer to previous question.

- **What have the preliminary results looked like so far?**

  Eliquis has demonstrated a better safety profile than alternate therapies (less bleeding events) as proven through outcomes-based contracts using real world data. Oncology patients have higher rates of diagnostic testing done to monitor disease progression (as recommended by guidelines), through our testing based value-based contract.

6. **<u>Transparency/Point of Sale</u>**

   In almost all of your testimonies, you express your support for the Trump Administration's proposal to allow manufacturers to provide PBMs up-front discounts that are passed onto patients at the point-of-sale.

   <u>Questions for All Companies:</u>

   - **Do you feel like this proposal will make the transactions within the drug supply chain more transparent?**

     To the extent that discounts provided by manufacturers to PBMs and payers are passed through to the patients at the point-of-sale, transactions within the drug supply chain will be more transparent.

   - **If so, would this transparency bring down drug costs –overall and for specialty drugs?**

     In terms of bringing down drug costs, the result of passing discounts through to patients at the point-of-sale will likely vary depending on the individual drug. We anticipate that patients who are prescribed high-cost, highly-discounted drugs, primarily specialty drugs, and are subject to high co-insurance costs, will experience the greatest reduction in drug costs.

7. **<u>The Relationship between Wholesalers and Manufacturers</u>**
When talking about the pharmaceutical supply chain, a lot of focus has been placed on the Pharmacy Benefit Manager. But there's another side of the equation that I'd like to ask about –

<u>Questions for All Companies:</u>

- **How do wholesalers negotiate pricing with manufacturers?**

  Wholesalers and manufacturers negotiate distribution service agreements that include terms and fees. The fees are typically a percentage of list price.

- **What impact does this have on drug costs?**

  It is BMS' understanding that the fees negotiated by wholesalers and manufacturers do not have a material impact on drug costs.

- **What incentives or disincentives do they have to contain price increases?**

  This question is best answered by wholesalers.

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%.

Senator Menendez:
For all witnesses:

Part 1: When new products enter the market, do drug companies set high initial rebates and then provide deep rebates in order to gain access to insurance plan's formularies?

BMS does not. We cannot comment on the pricing practices of other manufacturers.

Part 2: If CMS finalizes the rebate rule, do you anticipate future products entering the market with significantly lower initial list prices?

If CMS were to finalize the rebate rule, the impact on list prices of future products would likely differ by product depending on such factors as the clinical profile of the product, competition, market dynamics, and the channel into which the product is primarily sold. As noted above, the goals of the proposed rule could be achieved through lower list prices, negotiated discounts at the point-of-sale, or some combination of these two approaches.

Senator Carper:
For all witnesses:

a. **What are your recommendations for lowering prices for the 40 percent of drugs that do not offer rebates in Medicare Part D?**

   BMS believes that market-based reforms are the best way to lower costs and maintain the appropriate incentives for innovation. BMS supports policies that enable payers to negotiate innovative and flexible ways to pay for medicines, including value-based purchasing arrangements. Additionally, we need to ensure generics are available whenever permissible under our system. BMS notes also that even manufacturers pay coverage gap discounts for all Part D drugs regardless of whether a payer rebate is provided for that drug.

b. **In the health insurance plans that you offer your employees, do you ask your insurers to pass through the full manufacturer rebates to the beneficiaries?**

Based on the contract negotiated with the PBM with which BMS has contracted, BMS has elected to reinvest the rebates we would otherwise have received from the PBM to reduce the per claim cost for brand drugs across the entire population of members we cover. BMS provides health care coverage to approximately 10,000 active employees, 4,000 retirees and 18,000 spouses and other dependents.

Under this reinvested model, those rebate dollars are applied to reduce the negotiated rate our enrollees pay for brand drugs. This means that the PBM charges the plan a lower negotiated rate for all branded drugs (not just those associated with specific rebates), benefiting a broader portion of our covered population. Since our health plan benefit design uses a coinsurance for member cost sharing, this lower negotiated drug cost enabled by the application of the rebate value, reduces the coinsurance amount our members pay for their medications at the pharmacy counter.

c. The systems for pricing and distributing drugs are opaque and difficult to understand. What are your recommendations for increasing transparency in how your companies set the list prices for drugs, and for improving transparency in the supply chain for prescription drugs? Would you support federal standards for transparency in setting the list prices for drugs?

BMS intends to provide added transparency around the list prices for its medicines. We are creating pricing pages for all of our advertised medicine websites to include list price and additional information on out-of-pocket costs and support programs. Any DTC TV ads will direct patients to the site through a web link. Our plan is to have this information available by April 15, 2019. We solicited feedback from the patient community to ensure the resources we provide about pricing are meaningful to patients. The research suggests patients may misinterpret list price information in a television advertisement without additional context.

BMS is complying with the recently enacted California drug price transparency legislation and would like to work with the Committee on similar legislation at the federal level, or legislation similar to the SPIKE Act (S. 474), both of which are intended to require manufacturers to disclose price increases above a certain threshold.

d. In nearly every sector of the health care industry, Medicare, Medicaid, employers, and insurers are moving away from fee-for-service payments to reimbursements based on value and performance. Prescription drugs and medical devices were the glaring exceptions to this trend until recently. How many of your drugs are included in value-based contracts and how many patients are benefiting from them? How do these value-based contracts work to lower drug prices for both patients and taxpayers?

Currently, BMS has value-based contracts for two products. Approximately 39 million patients are eligible for potential coverage under those contracts.

The goal and design of outcome-based contracts will vary depending on the specific drug and the therapeutic area/disease state which is being evaluated. In general, outcome-based contracts are designed to demonstrate the efficacy, safety, clinical superiority, cost savings and/or improvement in overall patient health outcomes. To the extent that outcomes-based contracts demonstrate improvement in clinical outcomes and/or reduction in overall healthcare costs, patients will benefit from improved outcomes and reduced costs, and the federal programs will benefit from lower overall healthcare costs.

e. Last year, Senator Portman and I did an investigation on the pricing of an opioid overdose reversal drug called EVZIO, manufactured by Kaléo. Kaléo increased the price of EVZIO from $575 in 2014 to $4,100 in 2017. We found that the best price Medicare was able to get for EVZIO, about $4,000, was much higher than the price other federal programs and private insurers were able to get. It seemed that Kaléo was able to get this higher price of $4,000 from Medicare by helping doctors fill out paperwork showing that the drug was medically necessary, even though there are cheaper alternatives on the market. As a result of the investigation, Kaléo announced it will bring a generic version of the drug to market at only $168 per pack. Are any of your companies providing medical necessity paperwork to doctors in order to get your drugs covered by Medicare?

BMS offers patient support programs that help eligible patients who are prescribed our medicines obtain access to those medicines. This includes assisting patients in navigating the insurance approval process. Consistent with longstanding OIG guidance and common industry practices, BMS does provide the template forms required by insurers for use in making coverage determinations, but BMS does not provide medical necessity content. That content must be independently provided by the prescribing health care provider.

f. In 2017, the Rand Corporation estimated that biosimilar drugs, which are competitors to complex, biologic drugs, could save the United States more than $50 billion over the next decade. Some of you have also argued that increasing the use of biosimilar drugs would help lower drugs costs for consumers and taxpayers. What is delaying the uptake of biosimilar drugs in the United States? What policies do you recommend to increase the development of biosimilar drugs?

BMS does not have a biosimilar or a branded product with biosimilar competition, and consequently, is not in a position to offer first-hand insight.

Senator Cardin:

1. **The United States is one of the only countries in the world to allow prescription drug manufacturers to advertise directly to consumers through magazines, billboards, radio, and television commercials. While I will not argue that it is beneficial to educate consumers about an unfamiliar disease and encourage them to seek medical help, most commercials from all of your companies recommend asking about a specific brand name drug, not a medical condition. Furthermore, even if your advertisements follow all FDA rules and list medication side effects, they also almost always list these while a smiling, apparently healthy person is walking on a beach.**

   Researchers say that this type of imagery, combined with viewing hours of drug commercials each month, leads consumers to underestimate the risks associated with medications. For the past decade, studies have shown that aggressive direct-to-consumer advertising is associated with rising drug prices and an increase in inappropriate drug prescriptions.

   ***For Mr. Gonzalez, Dr. Soriot, Dr. Caforio, Ms. Taubert, Mr. Frazier, Dr. Bourla, and Dr. Brandicourt*:**

   a. **Since researchers have concluded that consumers are misunderstanding the benefits and risks described in your ads, what further policies could help you and your colleagues ensure that you are educating patients in a clear manner?**

      BMS engages in DTC TV advertising selectively and only when we think it will help educate patients. Our DTC TV advertising is submitted to the FDA for advisory comments prior to being broadcast in accordance with FDA guidance. BMS believes that our DTC advertising clearly and appropriately communicates the benefits and risks of our medicines.

      BMS believes responsible DTC communications play a critical role in educating patients and families about treatment options and encourages them to have an informed discussion with their physician about the best treatment for their needs. BMS would be open to considering any additional policy proposals that further facilitate the achievement of this goal.

Pharmaceutical Companies Continue to Raise Prices

1. **As you are well aware, high prescription drug prices are the number one concern for Americans and their families. According to the Organization for Economic Cooperation and Development, the average American spends around <u>$1,208</u> annually on prescription drugs. There have been several instances where brand name or even generic drugs that have been on the market for years continue to increase in price.**

One of the most well-known examples is Mylan's increase of the price of EpiPen from less than $100 in 2007 to more than $600 in 2016. Another example, is the ever-increasing price of insulin. Sanofi increased the price of a vial of Lantus from $88.20 in 2007 to $307.20 in 2017. And those are just a small sample of price increases.

***For Mr. Gonzalez, Dr. Soriot, Dr. Caforio, Ms. Taubert, Mr. Frazier, Dr. Bourla, and Dr. Brandicourt*:**

a. **Why don't we see price decreases for drugs that have been on the market for years without new formulations or added benefit?**

Although list prices for a drug without new formulations or added benefits may not decrease over time, in our experience, net prices generally decrease over time and/or volume decreases significantly as generics enter the market.

Pay for Delay

1. **Pay for delay is a tactic that more and more branded drug manufacturers have been using to stifle competition from lower-cost generic manufacturers. This allows you to sidestep competition by offering patent settlements that pay generic companies not to bring lower-cost alternatives to market.**

These "pay-for-delay" patent settlements benefit both brand-name pharmaceutical companies by helping them avoid costly patent litigation and general manufacturers by rewarding them a hefty sum to delay entering the market with a cheaper drug alternative. However, these deals do not benefit consumers. According to an FTC study, these anticompetitive deals cost consumers and taxpayers $3.5 billion in higher drug costs every year.

***For Mr. Gonzalez, Dr. Soriot, Dr. Caforio, Ms. Taubert, Mr. Frazier, Dr. Bourla, and Dr. Brandicourt*:**

Does your company partake in pay-for-delay settlements?

No.

a. **Why would a pharmaceutical company enter into a pay-for delay agreement?**

As stated above, BMS does not enter into any pay-for-delay settlements. We cannot comment on the actions and motivations of other manufacturers.

b. Do you think these agreements stifle competition and prevent generic alternatives to your branded medications?

BMS agrees that patent settlement agreements that have substantial payments going from innovators to generics, and are solely intended to delay competition, are anticompetitive. In contrast, agreements that do not contain such substantial payments and properly balance litigation considerations often lead to earlier generic entry than patent expiration.

Drug Rebate Rule

1. **In January, the Department of Health and Human Services' (HHS) Office of Inspector General (OIG) promulgated a new regulation to remove regulatory safe harbor protections under the Anti-Kickback Statute (AKS) for rebates on prescription drugs rebates paid by manufactures to PBMs under Medicare Part D and for Medicaid managed care organizations (MCOs). The OIG proposal attempts to ban most rebates by eliminating their regulatory protections.**

   The rule is predicted to increase net drug costs in its early years. The CMS actuaries estimate it would cost $196 billion over 10 years. Despite this high price tag, the beneficiary benefits are limited. The proposed rule notes that under the CMS Actuary's analysis, the majority of beneficiaries would see an increase in their total out-of-pocket payments and premium costs; reductions in total cost sharing will exceed total premium increases.

   I wanted to ask a question about the Administration's rebate rule, which I understand that many of the drug manufacturers, and your main trade association, strongly support. According to an analysis of the rule by the Office of Actuaries at CMS, drug manufacturers are likely to initially retain 15 percent of the current rebates as higher net drug prices.

   ***For Mr. Gonzalez, Dr. Soriot, Dr. Caforio, Ms. Taubert, Mr. Frazier, Dr. Bourla, and Dr. Brandicourt*:**

   a. Given that estimate, can you provide the Committee with any assurances that prices will not increase under this proposed rule?

   BMS supports HHS' proposed rule because BMS believes it will lower patient costs at the point-of-sale and ensure patients realize the benefit of manufacturer discounts. We do not anticipate that manufacturer average net prices will increase as a result of this rule.

Senator Brown:

According to an article recently published in the Journal of the American Medical Association, medical marketers spend nearly $30 billion dollars in 2016, up from $17 billion in 1997. Direct-to-Consumer (DTC) advertising had the biggest percentage increase: from $2.1 billion, or 11.9% of all medical marketing, in 1997 to $9.6 billion, or 32% of total spending, in 2016.

1. **All witnesses: Can each of you please provide what your ratio of spending on sales and marketing to research and development is today?**

   BMS does not disclose sales and marketing investments separately. In 2018, BMS marketing, selling and administrative expenses were $4.6 billion, which is inclusive of sales and marketing, and R&D expenses were $6.3 billion. That ratio is approximately 7 to 10.

Price-Gouging

Sanofi, as I understand it, has made a pledge to the public to limit its price increases to the national health expenditures growth projection.

1. **Mr. Gonzalez, Mr. Soriot, Dr. Caforio, Ms. Taubert, Mr. Frazier, Dr. Bourla: Would your company commit to a cap on annual price increases as part of your PhRMA membership criteria?**

   It is BMS' understanding that a cap on annual price increases as part of PhRMA membership would raise significant antitrust concerns.

2. **All witnesses: What policies would you propose to help ensure lower <u>launch</u> prices for new drugs?**

   BMS does not believe that government policies should govern launch pricing of new drugs. Payers, providers, patients, and the marketplace should freely assess the value of new innovative therapies relative to their improvement in outcomes and impact to total cost of care. At BMS, we believe the prices of our medicines reflect the value they bring to patients, healthcare providers, payers, and society as a whole.

Transparency

In many of your testimonies, you mentioned that the current system of pharmacy benefit manager (PBM) back-end rebates do not rarely results in a scenario where the PBM passes

on savings to consumers at the point of sale (POS). The Administration recently proposed a rule to eliminate the anti-kickback statute safe harbor protections for these drug rebates.

1. **All witnesses: do you agree that greater transparency should be required to understand how manufacturers and PBMs are negotiating prices and rebates to ensure that savings are passed down to beneficiaries?**

   Yes, BMS agrees that manufacturer's net prices should be transparent to and passed through to beneficiaries. BMS also believes that this transparency should be required for all entities in the healthcare market.

PBMs

An *Axios* article from March 7, 2019 highlights the fact that, while "pharmaceutical companies put a lot of the blame for high drug prices on pharmacy benefit managers," many large pharmaceutical companies "rely on PBMs to manage their own health care benefits."

1. **All witnesses: in your role as an employer, does your company contract with a pharmaceutical benefit manager (PBM) to administer the prescription drug benefits for your employees and negotiate lower drug costs on your behalf?**

   Yes.

2. All witnesses: for those of you who do use a PBM to help manage the prescription drug benefit for your employees, how do you utilize the rebates your PBM negotiates to lower health care costs or drug costs for your employee plans and what does your company do with that savings? Specifically, do the savings go toward lowing premiums?

   BMS uses a PBM for our self-funded Pharmacy Benefit Program, which is part of our overall healthcare plan. The PBM offers the option of direct point-of-sale rebates, however, based on the contract negotiated with the PBM, BMS has elected to reinvest the rebates we would otherwise have received from the PBM to reduce the per claim cost for brand drugs. Under this reinvested model those rebate dollars are applied to reduce the negotiated rate our enrollees pay for branded drugs. This means that the PBM charges the plan a lower negotiated rate for all branded drugs (not just those associated with specific rebates). Since our health plan benefit design uses a coinsurance for beneficiary cost sharing, this lower negotiated drug cost enabled by the application of the rebate value, reduces the coinsurance amount our members pay for their medications at the pharmacy counter. Under this model, a greater number of participants benefit from the value of the rebates.

3. All witnesses: for those of you who do use a PBM to help manage the prescription drug benefit for your employees, does your PBM offer point-of-sale rebates to your employees?

   Please see answer to previous question.

Senator Whitehouse:
For all witnesses:

1. **Please describe any policy changes you support that would result in your company lowering the list prices of its drugs.**

   BMS supports the HHS proposed rule to eliminate safe harbor protection for back-end rebates in Medicare Part D, and we believe it would lead to lower out-of-pocket costs. The goals of the proposed rule could be achieved through lower list prices, negotiated discounts at the point-of-sale, or some combination of these two approaches. While it is unclear how Part D plans and PBMs will react to the proposed rule, at this time, BMS envisions that we would offer point-of-sale discounts to Part D plans equivalent to the contracted rebate amount and will continue to assess the possibility of lowering list price on a product-by-product basis. Our ability to lower list prices, however, is constrained by the fact that the HHS proposed rule does not apply to the commercial insurance market, where we anticipate back-end rebates to continue for the foreseeable future.

2. **How much does your company's research and development portfolio rely on taxpayer-funded research conducted by the National Institutes of Health (NIH)? How many of your company's products are based, at least in part, on NIH research, and how many are the result of research funded solely by your company?**

   Government institutions such as NIH and NCI do critically important basic research. However, the most significant investment behind any molecule is the clinical development program, which is usually when a pharmaceutical company comes into the development process. On average it takes 10 to 15 years and about $2.5 B to bring a medicine to patients, depending on the asset, therapeutic area, number of indications, and other factors. This is highly dependent on the stage of the molecule/asset when it comes to BMS. There is also considerable risk of failure given the complexity of clinical development. Only about 12% of drugs that make it to Phase 1 clinical trials result in an approved product.

3. **In each of the last five years, how much has your company spent on research and development versus the advertising and marketing of your products?**

BMS does not publicly disclose specific advertising and marketing expenditures. The figures below are for marketing, sales and administrative expenses, which includes advertising and marketing expenditures.

2018 spend:
Marketing, selling and administrative expenses: $4.6 billion
Research and development expenses: $6.3 billion

2017 spend:
Marketing, selling and administrative expenses: $4.8 billion
Research and development expenses: $6.5 billion

2016 spend:
Marketing, selling and administrative expenses: $5.0 billion
Research and development expenses: $5.0 billion

2015 spend:
Marketing, selling and administrative expenses: $4.8 billion
Research and development expenses: $5.9 billion

2014 spend:
Marketing, selling and administrative expenses: $4.8 billion
Research and development expenses: $4.5 billion

4. **During the hearing, you mentioned that your company would be likely to lower the list prices of its drugs if the recent proposal by the Trump administration to change the current system of rebates was extended to the private market.**

   a. **If the policy was extended to the private market, how large would the list price reductions be relative to the size of the rebates your company is currently providing?**

      While it is unclear how health plans and PBMs would react if the HHS proposed rule's policy were extended to the private market, at this time, BMS envisions that we generally would offer point-of-sale discounts to health plans equivalent on average to the contracted rebate amount and would continue to assess the possibility of lowering list price on a product-by-product basis. In the absence of list price reductions, the policy requirement that manufacturer discounts be passed on at the point-of-sale would accomplish the goal of reducing patient out-of-pocket costs.

   How will this proposal affect how your company sets the list prices for new drug products?

b. If the proposal is finalized and not extended to the private market, will your company make any list price reductions? If so, how large would the reductions be relative to the size of the rebates your company is currently providing?

While it is unclear how health plans and PBMs would react if the HHS proposed rule were finalized and not extended to the private market, at this time, BMS envisions that we would offer point-of-sale discounts to Part D plans equivalent on average to the contracted rebate amount and would continue to assess the possibility of lowering list price on a product-by-product basis. In the absence of a list price reduction, the proposed rule's requirement that manufacturer discounts be passed through to patients at the point-of-sale would accomplish the goal of reducing patient out-of-pocket costs.

Senator Hassan:
For all witnesses:

In June of 2018, the Medicaid and CHIP Payment and Access Commission (MACPAC) unanimously recommended under Recommendation 1.1 in their annual report to Congress that Congress remove the statutory requirement that manufacturers blend the average manufacturer price (AMP) of a brand drug and its authorized generic. [1]

This requirement created an unintended loophole. Rather than use the price of the authorized generic, drug companies can sell its authorized generic to a corporate subsidiary at an artificially lower price, and use that lower price to bring down the AMP, which in turn lowers the rebate obligation.

Does your company engage in this practice? Has your company ever engaged in this practice in the past?

No. BMS does not have any authorized generics with its own corporate subsidiary.

Senator Cortez Masto:

1. ***Question to Dr. Giovanni Caforio, Bristol Meyers Squibb***

Dr. Caforio, your company has entered a merger agreement to acquire Celgene, which makes the cancer drug Remlivid. The price of Remlivid was hiked nearly 20% in 2017, 5% last year, and another 3.5% just last month.[i] **Remlivid was also high on a list of**

[1]MACPAC: Improving Operations of the Medicaid Drug Rebate Program: https://www.macpac.gov/wp-content/uploads/2018/06/Improving-Operations-of-the-Medicaid-Drug-Rebate-Program.pdf

brands whose manufacturers have refused to provide generic companies with the samples they need to submit an FDA application. Celgene refused 13 such inquiries, despite FDA's assurance that they were safe to share.[ii,iii] Today Remlivid stands as a $70,000 sole source drug with no competition.[iv] You mention increasing access to generics as a priority in your testimony. In a case were Remlivid falls under your purview, what specific actions will you take to promote generic competition of that drug?

BMS believes it is important to ensure generics are made available whenever that is permissible under our system, and supports the administration's focus on increasing the approval of generics. As part of that system, it is important that generic companies perform the needed testing to ensure product quality and patient safety.

Until the transaction closes, BMS and Celgene will continue to operate as separate companies. BMS thus does not know and cannot comment on Celgene's practices as they relate to generic manufacturers. Once the transaction closes, BMS' practices with regard to generic manufacturers, including the provision of samples, will govern the combined portfolio.

2. ***Questions to all witnesses***

As a portion of your revenue, for what percentage of the drugs in your portfolio do you offer no rebates? Based on the drugs in your pipeline, do you foresee that portion growing? For those drugs is your list price equal to your net price?

Although the level of rebates varies by product and channel, BMS pays rebates for all products in our portfolio.

Do you invest more in R&D than you generate in US sales revenue? Please include specific figures.

BMS invested $6.3 billion in R&D in 2018, which includes the discovery and development of new medicines.

U.S. sales for 2018 were $12.5 billion.

Do you invest more in R&D than you spend on marketing and administration? What company functions do you consider to be included in administration? Please include specific figures.

BMS does not publicly disclose specific marketing and administration expenditures. The figures below are for marketing, sales and administrative expenses, which includes marketing and administration expenditures.

2018 spend:
Marketing, selling and administrative expenses: $4.6 billion
Research and development expenses: $6.3 billion

2017 spend:
Marketing, selling and administrative expenses: $4.8 billion
Research and development expenses: $6.5 billion

2016 spend:
Marketing, selling and administrative expenses: $5.0 billion
Research and development expenses: $5.0 billion

2015 spend:
Marketing, selling and administrative expenses: $4.8 billion
Research and development expenses: $5.9 billion

2014 spend:
Marketing, selling and administrative expenses: $4.8 billion
Research and development expenses: $4.5 billion

Do you invest more in R&D than you spend on marketing and sales? What company functions do you consider to be included in sales? Please include specific figures.

BMS does not publicly disclose the functions included in sales nor specific marketing and sales expenditures. Please see the answer to the prior question for R&D and marketing, selling and administrative expenses.

Why do you advertise for the drugs you manufacture? What factors do you consider in choosing which drugs you advertise?

BMS believes responsible DTC communications plays a critical role in educating patients and families about treatment options, and encourages them to have an informed discussion with their physician about the best treatment for their needs. As a company, BMS engages in DTC TV advertising selectively and only when we think it will help educate patients. Currently BMS is engaging in DTC TV advertising for one product (Eliquis).

[i] https://www.reuters.com/article/us-celgene-results/celgene-profit-tops-expectations-will-limit-future-price-hikes-idUSKBN1KG1IC

[ii] https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm?utm_campaign=FDA%20publishes%20list%20of%20inquiries%20from%20generic%20drug%20applicants%20about%20RLD%20access&utm_medium=email&utm_source=Eloqua

[iii] https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away

[iv] https://twitter.com/megtirrell/status/1016769284025016320