Senate Committee on Finance Questions for the Record

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

February 26, 2019

Responses to Questions for:
Kenneth C. Frazier
Chairman and Chief Executive Officer
Merck & Co., Inc.

Senator Grassley:

At the hearing, you testified that Merck 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.
However, 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. Cubist Pharmaceuticals is on this FDA list. According to news reports, Merck bought this company in 2014. If this is accurate, this would appear to contradict your testimony at the hearing that Merck has not withheld samples of their products to delay generic competition.

- *Could you please explain in detail the discrepancy between your testimony and the FDA list?*
- *Has Merck ever blocked access to samples?*

Merck does not block generic companies from accessing samples. Your inquiry references FDA's website for reference listed drugs, or RLDs, which lists inquiries the Agency has received from potential generic companies for samples of RLDs. Importantly, FDA's website also provides the following statement in describing the various inquiries related to the RLDs listed: "We note that FDA has not independently investigated or confirmed the access limitations described in the inquiries received."

As FDA's website details, ENTEREG® (alvimopan) has a restricted distribution requirement mandated by its FDA-approved Risk Evaluation and Mitigation Strategy (REMS). ENTEREG is the only Merck product subject to an FDA-approved REMS. Under this program, ENTEREG is available only to hospitals that perform surgeries that include a bowel resection and dispensed by pharmacies that are enrolled in the E.A.S.E. ENTEREG REMS Program. This program is designed to ensure that ENTEREG is used in accordance with the FDA-approved label.

Merck acquired ENTEREG from Cubist Pharmaceuticals in 2015. Since acquiring ENTEREG, whenever Merck has received a request from a generics company to supply ENTEREG, we have directed them to the draft FDA Guidance which outlines how the generics company can obtain a letter from FDA stating that their study protocols contain the appropriate safety protections for products subject to this type of REMS. If provided with a copy of such a letter from FDA, Merck is happy to work with generics companies on supply arrangements. To date, we have not received any such letters. FDA's website also details that the Agency has not issued any Safety Determination Letters for samples of ENTEREG.

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?

Merck is aware that some in the industry have asked whether the antitrust laws as interpreted in the *In re Brand Name Prescription Drugs Antitrust Litigation* would limit the ability of manufacturers to offer point-of-sale discounts (as opposed to rebates). But, the U.S. antitrust laws, including the Robinson-Patman Act, apply to price discrimination in any context (including rebates), and nothing about *In re Brand Name Prescription Drugs Antitrust Litigation* changes this fact. As a result, Merck commits that, if the OIG's Proposed Rule is finalized, we will modify our contracts to comply with the new safe harbors and will provide discounts in a manner consistent with the new regulations.

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?

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.

If this 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.

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?

Our contracts typically provide rebates to Part D plans in exchange for a specified formulary status. We are aware of only one current agreement that makes a Part D rebate contingent on reaching a certain market share.

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.

The table below provides a proxy for volume by reporting percentages based on gross sales from 2018, given that there is no standard unit of volume measure that can be applied across our diverse product line (*e.g.*, tablet products, injectable products, vaccines).

Segment	Gross/Volume
CML+Specialty Pharm	28%
Hospital / GPO / 340B	23%
Medicare Part D	19%
Medicare Part B	12%
Medicaid	12%
Federal	6%

Notes: CML refers to private commercial payers; Medicare Part B also encompasses Part B products sold through Medicare Advantage Plans; Medicaid includes fee for service and managed Medicaid; Federal includes the VA, DoD, Coast Guard, Public Health Service and other similar purchasers.

Do your companies hire consultants or lobbyists to promote products at state Medicaid Pharmacy & Therapeutics Committees?

No. While Merck does contract with lobbyists who may interact with individuals associated with state Medicaid programs, they do not promote products at state Pharmacy & Therapeutics Committees.

To whom do you disclose advocacy activities surrounding state Medicaid programs, if at all?

Merck requires employees to adhere to state ethics law requirements for disclosing advocacy activity. Additionally, employees who attend Medicaid program meetings must comply with state public meeting law requirements pertaining to their attendance and participation.

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 this question, we are interpreting "patient assistance programs" to include the Merck Patient Assistance Program (Merck PAP), which provides free product to qualifying patients, Merck donations to independent patient assistance foundations, and Merck's patient coupon programs which help eligible privately insured patients afford their prescribed medications. Merck also makes available patient hub support programs to assist patients with accessing their prescribed medications.

With respect to the company's financial statements, for Merck PAP and Merck's donations to independent patient assistance foundations, the costs are recorded to the "Selling, general and administrative" category on our Consolidated Statement of Income. The co-pay assistance made available to patients through Merck's coupon programs is treated as a reduction to Merck's gross sales for the applicable products and is included in the "Sales" line of our Consolidated Statement of Income. The expenses associated with administering Merck's coupon programs are recorded in the "Selling, general and administrative" category on our Consolidated Statement of Income. Similarly, the expenses associated with administering Merck's patient hub support programs are recorded in the "Selling, general and administrative" category of our Consolidated Statement of Income.

Merck receives different types of market information in connection with the different programs identified above. For market information associated with the Merck PAP, the Merck PAP reviews data, such as patient insurance status and household income, to determine an individual's eligibility for PAP program enrollment. Merck PAP also tracks the number of prescriptions associated with the PAP for budgeting and planning purposes, but Merck PAP does not collect information associated with the courses of therapy for individual patients. With respect to Merck's donations to independent patient assistance foundations Merck does not receive any market information. Merck receives only a final report that confirms donations were received and spent in their totality for their intended purpose.

With respect to Merck's patient coupon programs, Merck may receive certain market information to assist it with evaluating whether its coupons programs are functioning consistent with their intended purpose and whether the vendor is meeting its contractual obligations. The information also may be used to assist Merck with budgeting and planning. For example, Merck may receive information about: the product filled; the product dispensing date and site; the prescriber; the number of patients enrolled in the coupon program; the number of coupons redeemed; the patient out-of-pocket costs associated with the use of a Merck coupon**;** and the benefit amount Merck pays on behalf of privately-insured patients using a coupon.

With respect to Merck's patient hub support programs, Merck may receive certain market information to assist it with evaluating whether its hub support programs are functioning consistent with their intended purpose and whether the vendor is meeting its contractual obligations. The information also may be used to assist Merck with budgeting and planning. For example, Merck may receive aggregate information about: call type, frequency, and vendor response times; the number of patients enrolled in the program; patient enrollment demographic and diagnosis information; patient benefit investigations; insurance coverage information for the applicable product; and pharmacy product fulfillment information.

Merck's third-party contractors may receive additional, patient-specific information that is not shared directly with Merck.

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.*

The information concerning our Philanthropic grants and charitable contributions, including contributions made through the Office of Corporate Responsibility, our company's Foundation, U.S. Global Human Health, and the MSD for Mothers Program can be found here: https://www.msdresponsibility.com/ethics-transparency/transparency-disclosures/. Please note the website does not include grants or contributions from Merck's Research Laboratories or Merck's Manufacturing Division.

In addition, the information concerning our grants of more than $500 provided by the company's Global Human Health division to U.S. organizations in support of independent, accredited educational programs for health care professionals, as well as grants to patient organizations and other medical education or scientific societies and organizations in the United States, Europe, the Middle East, Africa and Canada can also be found at the website referenced above.

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?*

Patent settlement agreements challenged by the FTC as anti-competitive, in which brands pay generic companies to stay out of the market when it would otherwise be lawful for them to enter the market, could delay patient access to lower cost alternatives. In contrast, patent settlement agreements in which the brand, while not conceding the invalidity or non-infringement of the patents, but in the face of the uncertainties and costs associated with protracted litigation, settles cases in a manner that allows a generic to enter the market *prior to* expiry of the brand's patents could actually accelerate patient access to lower cost alternatives. Still, brands do not enter into such agreements lightly because they believe in the rights of patent holders to vigorously enforce their intellectual property rights in court. At the end of the day, these settlements do not delay entry or cause the loss of any lawful competition because entry prior to the expiry of these patents would be unlawful infringement unless and until the generic manufacturers prevailed in court.

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

Merck has not entered into patent settlement agreements with generic companies to delay their entry past when it would otherwise be lawful for them to enter the market. Merck has been party to a number of patent settlement agreements that provide for generic market entry prior to patent expiry, including some that have provided some level of exclusivity for a limited time. These agreements allowed generic products to enter the market earlier than would have otherwise been the case. The FTC has not challenged as anti-competitive any of these types of agreements involving Merck.

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

Merck does not support S. 64 in its present form. Merck believes that the development of the law through the judicial process is the most effective way to address the balance between antitrust law and patent law raised by settlement agreements. S. 64 upsets the careful balance embodied in a rule-of-reason analysis by creating a presumption that "anything of value" or an "exclusive license" are anticompetitive, thus denying an antitrust defendant the ability to present and rely on countervailing evidence of pro-competitive effects, such as the impact on competition by the entry of the generic product before the expiration of the patent or statutory exclusivity term. As noted by the Supreme Court in *FTC v. Actavis*:

> Given these factors, it would be incongruous to determine antitrust legality by measuring the settlement's anticompetitive effects solely against patent law

policy, rather than by measuring them against procompetitive antitrust policies as well.[1]

S. 64 also seeks to insulate the FTC's fact finding from judicial review. Finally, the retroactive application of the provisions of the bill to June 2013 is unworkable. While there had been a split between the Circuit Courts over the proper analysis of reverse payment settlements, the Supreme Court's opinion in *Actavis* in 2013 settled that split by holding that patent settlements including those with reverse payments were subject to a rule-of-reason analysis. That decision did not provide hard and fast rules for the balance between antitrust and patent principles. To impose a process that alters that balance, and to do so retroactively, is imprudent and unfair.

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?*

Merck understands this question to refer to certain concerns about contracting practices applied to contracts between manufacturers and PBMs or health plans. Merck offers rebates to payers on bundles of products within certain product families (*e.g.*, JANUVIA and JANUMET, ASMANEX TWISTHALER and ASMANEX HFA). These bundled discounts benefit patients by ensuring that multiple therapies are maintained on a PBM or health plan formulary, thus ensuring wider patient access to our medicines at lower costs to the payer. Merck also offers discounts with respect to multiple bundled products outside of the PBM and health plan contracts, such as in the vaccine and hospital markets.

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

No. Merck believes the rebates it offers to payers on pharmaceutical products are procompetitive. Merck does not believe that its rebating practices are harmful to patients.

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?*

Merck is very supportive of current efforts to change the system. We believe these efforts will remove misaligned incentives within the system, drive more transparency in the system and, most importantly, benefit patients by lowering out-of-pocket costs. It is difficult to predict whether these changes will solve all of the issues seen today, but Merck is committed to working toward additional solutions if issues remain after these changes are implemented.

[1] *FTC v. Actavis*, 570 U.S. 136, 148 (2013).

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.*

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.*

In setting the list price for a drug, we do not specifically consider the regulatory costs or compliance or the risk of liability or litigation.

Merck approaches pricing from the perspective of value. This approach looks at the value that a medicine provides through multiple lenses with the goal of reflecting its benefit to patients and to society, while at the same time paying an appropriate return on invested capital to our investors, to ensure that we are able to sustain R&D. While each individual situation varies based on factual circumstances and market dynamics, generally, we consider:

- *Value provided to patients* – to what extent does a new medicine or vaccine establish a new standard of care that has the potential to significantly extend and improve patient lives?
- *Value provided to health care systems* – to what extent does a new medicine or vaccine reduce the costs associated with hospitalization and other costly complications of disease if not appropriately (or optimally) treated?
- *Unmet need* – does a new medicine or vaccine address a critically unmet medical need, where few or no treatments exist?
- *Access* – what is the ability of various customers around the world – including national, regional or local institutional payers, physicians, employers and patients – to pay for our products?
- *R&D sustainability* – given the long-term risk and cost of capital, can we appropriately compensate our investors to ensure continued investment in the kind of risky and capital-intensive research and development that will bring forward medically-important breakthroughs?
- *Competition* – what are the costs of other treatments currently on the market relative to the value provided by Merck's products?

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?*

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

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

For more than 10 years, Merck has worked with payers and health care providers to advance alternative pricing and contracting arrangements and Merck has publicly shared information about value-based agreements (VBAs) it entered into with the payers Aetna and Cigna. We are continuously reviewing ways in which the company may enter into VBAs for our products, which we define as a contractual framework aimed at achieving a mutually agreed upon value objective that that drives greater value from health care spending. Merck is interested, where business and customer objectives align, to implement VBAs across the health care market, including Medicare Part D, Managed Medicaid, and Fee-For-Service Medicaid.

By aligning payments for medicines more directly with their value in improving meaningful health outcomes and/or reducing the need for other health care services (such as hospitalizations), VBAs make pharmaceutical manufacturers accountable for the results their products achieve in a concrete way and can help improve patients' health and maximize the benefits of health care spending. A recent Avalere survey of payers found that 44 percent of payers engaged in outcomes-based contracts experienced improvements in patient outcomes.[2]

VBAs also can increase patient access to new therapies which could ultimately improve patient outcomes. A payer that might otherwise decline to cover a new medicine (or that would only cover the medicine with significant utilization management restrictions or high cost sharing) due to uncertainties about the expected percentage of its patient population who would benefit might increase access to the medicine if the manufacturer shared the risks of the medicine's performance. These agreements may make medicines more accessible to patients who will benefit from them and increase competition in relevant therapeutic classes.[3] Researchers have found that value-based arrangements can improve patient access to medicines.[4]

While Merck has had some experience with VBAs, these efforts have not been as robust as they could be due to the challenges involved in developing and implementing them. In addition to infrastructure and data limitations, challenges include regulatory limitations such as government pricing frameworks (*e.g.*, Medicaid Best Price (BP) rules, Medicare's Average Sales Price (ASP)) and federal fraud and abuse laws.

Accordingly, we support opportunities that would enable greater experimentation in the design, structure, and implementation of VBAs. Further innovation in this space is needed to support overall sponsor and plan learning, and to determine the range of potential benefits to diverse health systems and beneficiaries. To fully achieve these goals, however, the impacts of the current regulatory framework, including government pricing requirements, the federal Anti-

[2] Avalere Health. Outcomes-Based Contracts: Payer Perspectives Avalere Policy 360. July 19, 2018.
[3] Staley L. A Drug's Worth: Why Federal Law Makes It Hard to Pay for Pharmaceutical Performance. *Boston University Law Review*.2018;98(1):303-334. ("Tying reimbursement to health outcomes presents new opportunities for competition with rival manufacturers… [A] manufacturer that can demonstrate sustained health benefits in post-market studies may distinguish itself from competitors.").
[4] See, for example, description of Entresto and Repatha contracts in: Seely E and Kesselheim A. "Outcomes-Based Pharmaceutical Contracts: An Answer to High U.S. Drug Spending?" Commonwealth Fund. Issue Brief. September 2017.

Kickback Statute (AKS), and overall environmental barriers, must be analyzed and addressed as appropriate. Policy solutions such as the Patient Affordability Value and Efficiency Act (PAVE), introduced by Senators Warner and Cassidy, could provide necessary regulatory flexibility for properly structured VBAs.

Senator Enzi:

Dr. Bourla, Mr. Frazier

1) *More than ten years ago, I worked on a bipartisan basis with my good friends Ted Kennedy and Orrin Hatch to develop a biosimilars approval pathway. One of the difficult things was accounting for the differences between biosimilars and generics. I have said before that if a drug was a three bedroom, two bath home, a biologic would be a skyscraper. The size and complexity of the items are just that different. I understand that it is much harder to build a skyscraper without blueprints than a house. Even though the science has come a long way since then, there aren't as many biosimilars on the market as we might have hoped. Do you think the incentives in the law appropriately account for the differences between biosimilars and generics?*

In general, biosimilars competition thus far has resulted in moderation of prices, but actual utilization of the biosimilars remains modest at best. We fear that an environment where market entry of biosimilars brings value to the market, but little or none of that value accrues to the biosimilar patient or the health care system, will not be sustainable.

Merck remains an advocate for rigorous biosimilarity standards globally, and we believe that all biosimilar product applicants should be required to demonstrate equivalence (*i.e.*, biosimilarity) in safety (including immunogenicity) and efficacy, and no differences in purity and potency profiles between the originator reference product and the biosimilar candidate. We believe the FDA has instituted such a standard with its Totality of the Evidence approach, "including structural and functional characterization, nonclinical evaluation, human PK and PD data, clinical immunogenicity data, and comparative clinical study(ies) data."[5]

We are urging Congress to pursue policies to encourage and support biosimilar uptake and utilization in order to realize these potential savings for the system and patients. These policies could include reduced cost sharing in Medicare Part B.

2) *I know there are proposals to essentially pay more for biosimilars to make them more attractive, but that is not exactly what we were intending when we wrote the law. Can you talk about adverse incentives in the market and any barriers to market penetration that we might address to help improve patient access to these lower cost products?*

Merck introduced a biosimilar to the market 18 months ago at a 35 percent discount to the originator product, yet we have captured only a tiny fraction of the market. Uptake of the product was limited, we believe due to physician confusion regarding interchangeability and

[5] U.S. Food & Drug Administration, Scientific Considerations in Demonstrating Biosimilarity to a Reference Product Guidance for Industry (Apr. 2015), https://www.fda.gov/downloads/drugs/guidances/ucm291128.pdf.

extrapolation, and a lack of physician, patient, and payer incentives. While we believe that the prescribing physician must always have the authority to designate exactly which biological product is dispensed to the patient, we believe there are market barriers that hamper appropriate adoption of biosimilars. Merck encountered the following market barriers that hampered uptake of RENFLEXIS®:

- We have observed cases where Medicare Advantage plans seem to be imposing utilization management controls that require providers to first use the reference biologic before providing coverage for the biosimilar. This is a significant disincentive to biosimilar uptake in that setting, and we believe is contrary to policy objectives to promote the uptake of biosimilars.
- Some providers may be hesitant to adopt biosimilar products due to overall confusion and the current lack of standardized definitions of biosimilarity (including the concepts of extrapolation and interchangeability). Currently, we lack standardized definitions of interchangeability as it relates to clinical significance, and concerns about the clinical appropriateness of switching stable patients to a biosimilar product have been contentious issues for some prescribers. Further, prescribers may be comfortable with a single switch (*i.e.*, moving a stable patient from a reference product treatment protocol to a biosimilar), but may have concerns about switching a patient multiple times, absent the interchangeability designation. We believe that regulatory clarification of these terms and concepts could help mitigate concerns for providers and support biosimilar product adoption.

We suggest the following policy changes to help encourage and support prescriber biosimilar utilization:

- Consider options to reduce or eliminate patient cost sharing in Medicare Part B for biosimilars. While some Part B beneficiaries are already able to reduce their 20 percent cost sharing via supplemental coverage, we believe eliminating cost sharing will encourage many physicians to use biosimilars for their patients. A similar approach in Part D and in Medicaid for small-molecule generics has driven generic utilization up to 90 percent.[6]
- Create pathways for MA and Part D plans to receive bonus payments and/or enhanced star ratings for achieving metrics related to access to biosimilars. This will incentivize plans to implement policies that drive additional utilization of biosimilars.
- Consider alternative reimbursement methodologies that adjust the current Part B reimbursement formula. The current structure in Part B to reimburse at ASP + 6 percent of the reference product's ASP ensures there is no reimbursement downside to physicians for using biosimilars. But so far, the evidence does not suggest the current reimbursement rate sufficiently incentivizes providers to use biosimilar products. Congress should consider alternatives to further incentivize physician adoption of biosimilars.

[6] Department of Health & Human Services, Office of Inspector General, Generic Drug Utilization in the Medicare Part D Program (Nov. 2007), https://oig.hhs.gov/oei/reports/oei-05-07-00130.pdf.

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?*

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

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

As we stated when we reduced the list price of several of our products in July 2018, we will continue to look for opportunities to reduce our list prices. We think the proposed rule will help create those opportunities, but it can't happen overnight. We are currently working with other stakeholders in the system to solve the operational challenges that will enable these changes.

It is important to note that if the proposed 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. Further actions to ensure patients actually see the benefit of lower out of pocket costs might include prohibitions on changes in benefit design by payers/PBMs that could allow payers/PBMs to defeat the intent of delivering savings to patients.

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?

While the misaligned incentives of Part D are partly responsible for PBMs favoring high list prices, that is not the sole dynamic associated with price increases. There may be unique reasons for price increases on specific products given their individual circumstances, including competitive dynamics and the costs of clinical research and manufacturing improvements. In addition, while PBMs generally do not manage Part B benefits, this does not mean that discounts are not provided or applied on these products. Providers and commercial health plans do receive discounts, the average of which is passed along to patients through ASP-based reimbursement.

The 20 percent coinsurance paid by a patient is based on the ASP, which reflects the average discounts received by providers and payers.

Biosimilar Competition/Insulin

Biosimilars have been much anticipated as a solution to the drug pricing crisis. In particular, the FDA is moving to make insulin a biologic that would be subject to biosimilar competition in the future.

But we are hearing from all of you that the biosimilar market doesn't work and the benefit of these cheaper but equally effective alternatives are really not available to U.S. patients.

- *Can a biosimilar version of insulin be part of the solution for diabetes patients?*

- *If so, what changes need to be made to the system so that patients and the taxpayer can realize the benefit of biosimilars? (Merck gave up on pursuing a biosimilar to Sanofi's Lantus[7])*

We believe there is potential for significant savings to national health care systems if high quality biosimilars – including insulins – can be brought to the market and compete with those biologics that have exhausted their intellectual property protections.

Biosimilar products are still the subject of a great deal of confusion, particularly among providers, regarding the scientific, regulatory, and clinical basis for extrapolation and interchangeability decisions made by the FDA. Merck has urged the FDA to expand its work in educating providers and other stakeholders on these topics.

Beyond that, we believe Congress should consider policy changes to help encourage and support prescriber biosimilar utilization. In our Blueprint comments to HHS we recommended incentives targeting patients, health plans, and providers that we believe can move the needle in stimulating uptake. One idea is for Congress to consider options to reduce or eliminate patient cost sharing in Medicare Part B for biosimilars.

As to the Lantus biosimilar, after a comprehensive assessment of the current and future market environment for insulin glargine, including biosimilars, which included an assessment of anticipated pricing and cost of production, we made the business decision to terminate our agreement on the commercialization of the Lusduna pen and vial. There is already one other biosimilar glargine on the market and others on the way. So, we concluded this space was, or soon will be, adequately covered. This will allow us to allocate resources to other products in development.

[7] Arlene Weintraub, Merck Ditches Biosimilar Lantus, But Will That Ease the Path for Mylan's Rival Insulin Product?, FiercePharma (Oct. 12, 2018), https://www.fiercepharma.com/pharma/merck-ditches-biosimilar-lantus-but-will-ease-path-for-mylan-s-rival-insulin-product.

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

Merck continually reevaluates its business strategies in all markets, seeking in particular to make its vaccines and medicines accessible to patients while realizing their full value in foreign markets with regulatory schemes that do not recognize the full value of these products and artificially reduce prices. Nevertheless, in most markets there are very limited options for adjusting prices to recognize the full value of our medicines and vaccines. One-sided and onerous pricing and reimbursement schemes most often leave little room for negotiation.

With regard to "walking away from the negotiating table," Merck always reserves that option. However, we recognize the serious and negative implications on patient health and access, the company's ultimate mission, and other possible repercussions that would result from denying patient access to our medicines. Moreover, foreign governments can resort to compulsory licensing, essentially seizing patent rights, where a company refuses to market a product, which also makes it difficult to withdraw from a foreign market.

Regarding ideas to ensure Americans aren't shouldering the full cost of pharmaceuticals, we believe appropriate U.S. trade strategies are a promising avenue to dealing with unreasonable foreign government action. Positive actions in the U.S. can also reduce prices in the U.S., including removing misaligned incentives that cause PBMs to favor more expensive products and lead to higher out-of-pocket costs for U.S. patients, like the Administration's proposal regarding the rebate safe harbor. One potential proposal would be to create a special USTR negotiator specifically for drug pricing issues.

2. ***Foreign Countries' Pricing and Reimbursement***

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."

Questions for All Companies:

- *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?*
- *How do foreign countries' pricing and reimbursement systems affect our prescription drug costs?*
- *Are foreign governments taking note of the concerns being raised by the Trump Administration and have they responded in any way?*
- *Has there been any noticeable change in any of our trade agreements since these concerns have been raised by the Trump Administration?*

We agree that foreign countries' pricing and reimbursement systems result in their not paying enough to support the biopharmaceutical innovation from which they benefit. This causes the U.S. to shoulder more than its fair share of financing medical advances. These pricing and reimbursement systems do not necessarily, however, affect prescription drug costs in the U.S. in any direct or algorithmic fashion. Rather, Merck approaches pricing from the perspective of value. This approach looks at the value that a medicine provides through multiple lenses with the goal of reflecting its benefit to patients and to society, while at the same time paying an appropriate return on invested capital to our investors, to ensure that we are able to sustain R&D. While each individual situation varies based on factual circumstances and market dynamics, generally, we consider:

- *Value provided to patients* – to what extent does a new medicine or vaccine establish a new standard of care that has the potential to significantly extend and improve patient lives?
- *Value provided to health care systems* – to what extent does a new medicine or vaccine reduce the costs associated with hospitalization and other costly complications of disease if not appropriately (or optimally) treated?
- *Unmet need* – does a new medicine or vaccine address a critically unmet medical need, where few or no treatments exist?
- *Access* – what is the ability of various customers around the world – including national, regional or local institutional payers, physicians, employers and patients – to pay for our products?
- *R&D sustainability* – given the long-term risk and cost of capital, can we appropriately compensate our investors to ensure continued investment in the kind of risky and capital-intensive research and development that will bring forward medically-important breakthroughs?

- *Competition* – what are the costs of other treatments currently on the market relative to the value provided by Merck's products?

Prices in other countries often reflect different value systems and criteria. It is important to note that all components of the health care system, including hospital services, physician services, physician salaries, and medical devices are considerably less expensive in foreign countries than in the U.S. That said, we agree that foreign countries' pricing and reimbursement systems result in their not sufficiently supporting biopharmaceutical innovation. While foreign governments are generally aware of concerns raised by the Trump Administration, we are not aware of any substantive response.

There has been some change in trade agreements, but more work needs to be done. U.S. free trade agreements address discriminatory approaches to pricing and reimbursement and ensure fair treatment for innovative medicines through commitments established by trade partners. Free trade agreements can help advance innovation, versus approaches proposed by the Administration such as the International Pricing Index that have the potential to stifle investment in R&D by driving down prices across markets.

Here are three examples:

- A 2004 U.S. Department of Commerce study examining OECD countries found that foreign price controls restrict the ability to innovate in our sector and identified trade agreements as a key lever. We strongly encourage the Trump Administration to update this report to reflect the impact of continued price controls in OECD countries.
- The pharmaceutical pricing and reimbursement provisions in the U.S. Mexico Canada Agreement commit governments to provide transparency and due process protections in national pharmaceutical reimbursement processes and decisions. This is a step in the right direction, but more is needed to ensure that many countries, such as Canada, appropriately recognize the value of innovative medicines.
- The Trump administration has worked to ensure adherence to commitments in pricing and reimbursement in the Korea-U.S. Free Trade Agreement, and direct advocacy by the U.S. has also made an impact in Japan to mitigate some approaches.

There is clearly more work to be done in these areas, and trade tools such as a new U.S.-Japan Free Trade Agreement, are critical.

3. <u>Medicaid Closed Formulary Proposals</u>

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.

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

- *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?*

There are important differences in the population covered under Medicaid and the coverage options available that need to be considered. Medicaid beneficiaries remain some of the sickest and most complex populations of patients, with sometimes inconsistent relationships with health care providers and other complicating factors that make accessing medical care already difficult. Many Medicaid patients have complex diseases for which there are not always therapeutically equivalent drugs available, so access to the specific drug providers prescribe is crucial.

Part D is a highly competitive, successful program that has come in at nearly half the cost that was originally projected. It also has extremely high rates of beneficiary satisfaction – generally around 90 percent. While Part D offers multiple plan options and levels of benefits such that patients can shop for plans that cover their medicines at varying levels of cost-sharing, patients in Medicaid do not have access to alternative coverage options. So, if a medicine they need is not available, they do not have the ability to switch plans or otherwise obtain access to the medicine.

As a result, the use of restrictive formularies is likely to result in adverse effects on beneficiary outcomes and increased costs when applied in Medicaid. While the patient protections that exist in Part D may provide beneficiaries with an option to appeal formulary decisions, it would be complicated to navigate for Medicaid patients and their providers, who may have limited resources to take on the additional responsibility and may take time that patients with complex conditions may not have.

Medicaid is already receiving the best price based on the statutory rebate and states have flexibility to exert utilization management controls to negotiate supplemental rebates. Given this, we believe that applying the principles of Medicare Part D in Medicaid is not likely to result in lower drug costs without significantly impacting access.

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

We can speak only to Merck's practices, and Merck does not consider the Medicaid Best Price requirement when setting initial prices. Merck approaches pricing from the perspective of value. This approach looks at the value that a medicine provides through multiple lenses with the goal of reflecting its benefit to patients and to society, while at the same time paying an appropriate return on invested capital to our investors, to ensure that we are able to sustain R&D. While

each individual situation varies based on factual circumstances and market dynamics, generally, we consider:

- *Value provided to patients* – to what extent does a new medicine or vaccine establish a new standard of care that has the potential to significantly extend and improve patient lives?
- *Value provided to health care systems* – to what extent does a new medicine or vaccine reduce the costs associated with hospitalization and other costly complications of disease if not appropriately (or optimally) treated?
- *Unmet need* – does a new medicine or vaccine address a critically unmet medical need, where few or no treatments exist?
- *Access* – what is the ability of various customers around the world – including national, regional or local institutional payers, physicians, employers and patients – to pay for our products?
- *R&D sustainability* – given the long-term risk and cost of capital, can we appropriately compensate our investors to ensure continued investment in the kind of risky and capital-intensive research and development that will bring forward medically-important breakthroughs?
- *Competition* – what are the costs of other treatments currently on the market relative to the value provided by Merck's products?

We recognize the value that the Medicaid program provides for patients who need it, and we do not believe the "best price" requirement encourages manufacturers to increase initial prices.

Merck believes that the exclusion of value-based arrangements (VBAs) from the calculations of Best Price, Average Manufacturer Price, and Average Sales Price would facilitate VBA implementation, which would further align prices with the value that pharmaceutical products bring to the market.

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?*
   - *How will they lower overall healthcare costs for our federal programs?*
   - *What have the preliminary results looked like so far?*

For more than 10 years, Merck has worked with payers and health care providers to advance alternative pricing and contracting arrangements and Merck has publicly shared information about value-based agreements (VBAs) it entered into with the payers Aetna and Cigna. We are continuously reviewing ways in which the company may enter into VBAs for our products, which we define as a contractual framework aimed at achieving a mutually agreed upon value

objective that that drives greater value from health care spending. Merck is interested, where business and customer objectives align, to implement VBAs across the health care market, including Medicare Part D, Managed Medicaid, and Fee-For-Service Medicaid.

By aligning payments for medicines more directly with their value in improving meaningful health outcomes and/or reducing the need for other health care services (such as hospitalizations), VBAs make pharmaceutical manufacturers accountable for the results their products achieve in a concrete way and can help improve patients' health and maximize the benefits of health care spending. A recent Avalere survey of payers found that 44 percent of payers engaged in outcomes-based contracts experienced improvements in patient outcomes.[8]

VBAs also can increase patient access to new therapies which could ultimately improve patient outcomes. A payer that might otherwise decline to cover a new medicine (or that would only cover the medicine with significant utilization management restrictions or high cost sharing) due to uncertainties about the expected percentage of its patient population who would benefit might increase access to the medicine if the manufacturer shared the risks of the medicine's performance. These agreements may make medicines more accessible to patients who will benefit from them and increase competition in relevant therapeutic classes.[9] Researchers have found that value-based arrangements can improve patient access to medicines.[10]

While Merck has had some experience with VBAs, these efforts have not been as robust as they could be due to the challenges involved in developing and implementing them. In addition to infrastructure and data limitations, challenges include regulatory limitations such as government pricing frameworks (*e.g.*, Medicaid Best Price (BP) rules, Medicare's Average Sales Price (ASP)) and federal fraud and abuse laws.

Accordingly, we support opportunities that would enable greater experimentation in the design, structure, and implementation of VBAs. Further innovation in this space is needed to support overall sponsor and plan learning, and to determine the range of potential benefits to diverse health systems and beneficiaries. To fully achieve these goals, however, the impacts of the current regulatory framework, including government pricing requirements, the federal Anti-Kickback Statute (AKS), and overall environmental barriers, must be analyzed and addressed as appropriate. Policy solutions such as the Patient Affordability Value and Efficiency Act (PAVE), introduced by Senators Warner and Cassidy, could provide necessary regulatory flexibility for properly structured VBAs.

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[8] Avalere Health. Outcomes-Based Contracts: Payer Perspectives Avalere Policy 360. July 19, 2018.

[9] Staley L. A Drug's Worth: Why Federal Law Makes It Hard to Pay for Pharmaceutical Performance. *Boston University Law Review*.2018;98(1):303-334. ("Tying reimbursement to health outcomes presents new opportunities for competition with rival manufacturers. . . . [A] manufacturer that can demonstrate sustained health benefits in post-market studies may distinguish itself from competitors.").

[10] See, for example, description of Entresto and Repatha contracts in: Seely E and Kesselheim A. "Outcomes-Based Pharmaceutical Contracts: An Answer to High U.S. Drug Spending?" Commonwealth Fund. Issue Brief. September 2017.

6. ***Transparency/Point of Sale***
   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.

   Questions for All Companies:
   - *Do you feel like this proposal will make the transactions within the drug supply chain more transparent?*
   - *If so, would this transparency bring down drug costs –overall and for specialty drugs?*

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 proposal, 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.

7. ***The Relationship between Wholesalers and Manufacturers***
   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 -

   Questions for All Companies:
   - *How do wholesalers negotiate pricing with manufacturers?*
   - *What impact does this have on drug costs?*
   - *What incentives or disincentives do they have to contain price increases?*

There are many entities supporting the distribution and dispensing of pharmaceutical products. Wholesalers purchase pharmaceutical products directly from manufacturers and subsequently sell those products to sites of care for dispensing. Downstream customers of the wholesalers include retail and specialty pharmacies, hospitals, clinics, and others. Those entities that purchase from the wholesalers ultimately dispense or administer the drug to patients.

Many manufacturers typically offer a "prompt pay" discount to wholesalers in exchange for timely payment of invoices (2 percent for payment within 30 or 35 days is fairly standard in the industry).

Manufacturers also contract with wholesalers for services that support the appropriate storage and distribution of product to appropriate customers within the supply chain. These "Distribution Service Agreements" provide wholesalers with an opportunity to earn fees based on performance against pre-defined metrics that are part of a set of standard services. These services include managing inventory levels, achieving defined service levels, consolidating receipt of inventory to a central location, and administering contract pricing and chargebacks. Although these distribution service fees manufacturers pay to wholesalers are commonly administered as a percent of the list price, they are negotiated at arm's length and are based on fair market value for the services rendered.

The terms of wholesaler agreements with their downstream customers vary; however, in general, the prices they offer to their customers are set relative to a product's list prices. In general, fees paid to wholesalers by manufacturers are modest and wholesaler economics (including both buy and sell side) are not likely to influence the setting of a product's list price.

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:

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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.

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?*

Merck approaches pricing from the perspective of value. This approach looks at the value that a medicine provides through multiple lenses with the goal of reflecting its benefit to patients and to society, while at the same time paying an appropriate return on invested capital to our investors, to ensure that we are able to sustain R&D. While each individual situation varies based on factual circumstances and market dynamics, generally, we consider:

- *Value provided to patients* – to what extent does a new medicine or vaccine establish a new standard of care that has the potential to significantly extend and improve patient lives?
- *Value provided to health care systems* – to what extent does a new medicine or vaccine reduce the costs associated with hospitalization and other costly complications of disease if not appropriately (or optimally) treated?
- *Unmet need* – does a new medicine or vaccine address a critically unmet medical need, where few or no treatments exist?
- *Access* – what is the ability of various customers around the world – including national, regional or local institutional payers, physicians, employers and patients – to pay for our products?
- *R&D sustainability* – given the long-term risk and cost of capital, can we appropriately compensate our investors to ensure continued investment in the kind of risky and capital-

intensive research and development that will bring forward medically-important breakthroughs?

- *Competition* – what are the costs of other treatments currently on the market relative to the value provided by Merck's products?

When the company launched ZEPATIER® into the Hepatitis C market, Merck chose a low list price strategy, while competitors had a higher price with significant rebates. Unfortunately, we were unable to gain reasonable formulary status or resulting sales in certain market segments with this strategy. Positive actions in the U.S., such as the Administration's proposal regarding the rebate safe harbor could provide incentives for lower initial list prices in the future.

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

Over time, we expect that list prices will go down if you remove the misaligned incentives in the system. 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. But we believe the rebate rule will align incentives in a way that will restrain list prices.

If this 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.

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?

Assuming the 40 percent reference is correct, we believe that the Administration's rebate safe harbor proposal will lead to lower prices even for products which currently may offer no or minimal rebates in Medicare Part D. We believe the increasing transparency of prices will spur heightened competition even in classes and for products where rebating has been limited in the current system. Similarly, the fact that price concessions will be made directly available to patients will also create a price-reducing dynamic since price concessions will make products more affordable to patients, resulting potentially in greater adherence and appropriate use of prescribed medicines, clearly benefiting patients and encouraging manufacturers to offer price concessions. Additionally, assuming policy changes are made to further incentivize value-based contracts, we believe that value-based contracts can also help to restrain initial list prices by tying those prices to the value that the products bring to patients and the health care system.

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?

Merck offers a generous health care benefit for our 24,000 U.S. employees. There is no deductible for medications covered under our pharmacy benefit, and employees never have to pay more than $50 for a retail prescription for a covered medication, and in most cases pay less. We contract with a PBM for management of the prescription drug benefits for our employees, and the benefit does not offer point-of-sale rebates to our employees. Merck uses savings generated by rebates to lower overall costs for employees while ensuring low out-of-pocket costs.

b. 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?

We are open and transparent about the factors we consider in setting prices. Merck approaches pricing from the perspective of value. This approach looks at the value that a medicine provides through multiple lenses with the goal of reflecting its benefit to patients and to society, while at the same time paying an appropriate return on invested capital to our investors, to ensure that we are able to sustain R&D. While each individual situation varies based on factual circumstances and market dynamics, generally, we consider:

- *Value provided to patients* – to what extent does a new medicine or vaccine establish a new standard of care that has the potential to significantly extend and improve patient lives?
- *Value provided to health care systems* – to what extent does a new medicine or vaccine reduce the costs associated with hospitalization and other costly complications of disease if not appropriately (or optimally) treated?
- *Unmet need* – does a new medicine or vaccine address a critically unmet medical need, where few or no treatments exist?
- *Access* – what is the ability of various customers around the world – including national, regional or local institutional payers, physicians, employers and patients – to pay for our products?
- *R&D sustainability* – given the long-term risk and cost of capital, can we appropriately compensate our investors to ensure continued investment in the kind of risky and capital-intensive research and development that will bring forward medically-important breakthroughs?
- *Competition* – what are the costs of other treatments currently on the market relative to the value provided by Merck's products?

c. 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?

Merck has been party to value-based discounting arrangements for four of its products. It is difficult to assess exactly how many patients have benefitted from them, however, since that information is not in Merck's possession under the arrangements.

Merck agrees that value-based discounting strategies can benefit patients and the Federal health care programs by ensuring that payment aligns with the value or outcomes that a manufacturer's products bring to the system. If, for example, a value-based agreement demonstrates that a manufacturer's product helps patients to achieve meaningful clinical outcomes (or even to avoid more serious illness complications or comorbidities), the product would have demonstrated a savings to patients and taxpayers (for example, by avoiding hospitalization or further treatment for a particular condition). There are, however, significant impediments under current law regarding adopting this type of contract – including under the Anti-Kickback Statute and manufacturer government price reporting obligations – and Merck supports legislative or regulatory reforms to increase the proliferation of value- or outcomes-based discounting.

d. *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?*

In the United States, Merck provides limited reimbursement support for patients in connection with the purchase of certain of Merck's products following a physician's prescribing decision (in accordance with Department of Health and Human Services Office of Inspector General guidance). In certain cases, this support includes identifying – for patients and physicians – the appropriate forms and insurance processes attendant to securing insurance coverage for our products. But it is Merck's policy never to interfere with the physician-patient relationship or the decision about whether to seek insurance coverage.

e. *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?*

Merck agrees that we can significantly reduce spending on pharmaceuticals, especially for patients, by ensuring that we have a viable market for biosimilars in the United States. We

believe, like with traditional small molecule medicines, generic competition after a reasonable period of exclusivity will create headroom for patients to afford the newest, most innovative medicines. In addition to the RAND data that you referenced, other research shows that generics and biosimilars are expected to drive savings of $105 billion through 2022 in the U.S.[11]

We suggest the following policy changes to help encourage and support prescriber biosimilar utilization:

- Consider options to reduce or eliminate patient cost sharing in Medicare Part B for biosimilars. While some Part B beneficiaries are already able to reduce their 20 percent cost sharing via supplemental coverage, we believe eliminating cost sharing will encourage many physicians to use biosimilars for their patients. A similar approach in Part D and in Medicaid for small-molecule generics has driven generic utilization up to 90 percent.[12]
- Create pathways for MA and Part D plans to receive bonus payments and/or enhanced star ratings for achieving metrics related to access to biosimilars. This will incentivize plans to implement policies that drive additional utilization of biosimilars.
- Consider alternative reimbursement methodologies that adjust the current Part B reimbursement formula. The current structure in Part B to reimburse at ASP + 6 percent of the reference product ASP ensures there is no reimbursement downside to physicians for using biosimilars. But so far, the evidence does not suggest the current reimbursement rate sufficiently incentivizes providers to use biosimilar products. The Administration should consider alternatives to further incentivize physician adoption of biosimilars.

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.

[11] IQVIA, Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022 (Apr.19, 2018), https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022.
[12] Department of Health & Human Services, Office of Inspector General, Generic Drug Utilization in the Medicare Part D Program (Nov. 2007), https://oig.hhs.gov/oei/reports/oei-05-07-00130.pdf.

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?*

Merck believes that direct-to-consumer (DTC) advertising can be an important and helpful way to inform patients about diseases that may be relevant to them and therapeutic options they may want to discuss with their physician. Data demonstrate that DTC can have a positive impact on patient health in terms of diagnosis, treatment, and adherence to prescribed therapies. We recognize that DTC is one channel amongst many to help educate patients. Print materials, telephone, websites, and other channels are also used to provide more in-depth information to patients. The ultimate decision to prescribe a product for any specific patient remains with the physician following discussion with their patient.

Merck adheres to FDA regulations and guidelines governing DTC promotion and has a long-standing policy to voluntarily submit new DTC broadcast advertising campaigns to FDA for pre-review. Merck also follows the PhRMA Guiding Principles for DTC Advertisements About Prescription Medicines. We are currently considering what additional information we can make available to consumers to ensure that they can make informed health care decisions.

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 $1,208 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?*

List prices do not generally decline largely owing to many of the misaligned incentives that the Administration's rebate safe harbor proposal is designed to address. Specifically, rebate contracts for commercial and Medicare Part D payers/PBMs are designed as set percentages from the list price. Lowering list prices while maintaining these same percentage discounts/rebates usually precludes the commercial viability of reducing list prices.

We do in fact see price decreases for products that have been on the market for years – extremely large ones. They occur at the time of patent expiry, and often reduce prices by over 90 percent. This is unlike any other part of the health care system we are aware of, where prices drop massively after a specified period. If these massive one-time price reductions occurred more gradually, it would be far more obvious that prices were decreasing. Even putting this aside, net prices on many products drop dramatically over time as competition from new products increases. For instance, the average net price of our anti-diabetes medicine Januvia is less today than it was when it was launched in 2007.

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:

   a. *Does your company partake in pay-for-delay settlements?*

Merck has not entered into patent settlement agreements with generic companies to delay their entry past when it would otherwise be lawful for them to enter the market. Merck has been party to a number of patent settlement agreements that provide for generic market entry prior to patent expiry, including some that have provided some level of exclusivity for a limited time. These agreements allowed generic products to enter the market earlier than would have otherwise been the case. The FTC has not challenged as anti-competitive any of these types of agreements involving Merck.

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

Parties enter into settlements of patent litigation for all the same reasons parties settle other civil litigation. These include allocation of risk in the dispute, avoidance of litigation costs, or beneficial access to technology from cross-licensing of the litigant's patents. Merck would be speculating as to why litigants would enter into settlements with large unjustified reverse payments.

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

Merck believes that the patent settlements it has made did not stifle competition nor unlawfully prevent generic alternatives to our patented medications.

Patent settlement agreements in which a brand settles cases in a manner that allows a generic to enter the market *prior to* expiry of the brand's patents could actually accelerate patient access to lower cost alternatives. These settlements do not delay entry or cause the loss of any lawful competition because entry prior to the expiry of these patents would be unlawful infringement unless and until the generic manufacturers prevailed in court.

Merck works within the statutory framework set by Hatch-Waxman and BPCIA to protect its intellectual property. We believe that patent holders have a valid right to enforce legitimate patents and that the courts are an appropriate venue to resolve such disputes.

Our patents are a direct result of the investment we have made in R&D. When others seek to commercialize our innovations, Merck has engaged in litigation to enforce our patents.

Merck is a strong supporter of bringing more generics to the market. It is important to remember that generics all started as a branded medication. A period of patent protection is provided for all new medicines as an incentive to research-based biopharmaceutical companies for the costly and risky research that is undertaken to develop them. Following the loss of patent protection, the medicines become low-cost generics that are available for many years, often decades into the future.

Merck is proud that more than 40 million Americans annually benefit from our science in the form of generic medicines. Several of our discoveries − including cholesterol-lowering, heart disease, osteoporosis, and asthma treatments − are now widely available to a patient as generics, including some for about $20 per year, bringing billions of dollars in savings to consumers and the health care system.

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?

Over time, we expect that list prices will go down if the misaligned incentives across the system are addressed. 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.

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?***

In 2018, Merck incurred $9.8 billion in research and development costs globally, the vast majority of which was conducted in the U.S. Since 2010, Merck has invested nearly $70 billion in R&D to create new medicines and vaccines that address the greatest health challenges of our time – including antimicrobial resistance, Ebola, HIV, and cancer – to save and improve lives around the world. In 2018, Merck spent about $2.3 billion in the U.S. market on direct marketing and selling expenses. This number includes all sales and marketing expenses, including creative development of resources and headcount related to all marketing and sales activity in the U.S. market.

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?***

In July 2018, Merck pledged to not increase the average net price across our portfolio by more than inflation annually.

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

Merck approaches pricing from the perspective of value. This approach looks at the value that a medicine provides through multiple lenses with the goal of reflecting its benefit to patients and to society, while at the same time paying an appropriate return on invested capital to our investors, to ensure that we are able to sustain R&D. While each individual situation varies based on factual circumstances and market dynamics, generally, we consider:

- *Value provided to patients* – to what extent does a new medicine or vaccine establish a new standard of care that has the potential to significantly extend and improve patient lives?
- *Value provided to health care systems* – to what extent does a new medicine or vaccine reduce the costs associated with hospitalization and other costly complications of disease if not appropriately (or optimally) treated?
- *Unmet need* – does a new medicine or vaccine address a critically unmet medical need, where few or no treatments exist?
- *Access* – what is the ability of various customers around the world – including national, regional or local institutional payers, physicians, employers and patients – to pay for our products?
- *R&D sustainability* – given the long-term risk and cost of capital, can we appropriately compensate our investors to ensure continued investment in the kind of risky and capital-intensive research and development that will bring forward medically-important breakthroughs?
- *Competition* – what are the costs of other treatments currently on the market relative to the value provided by Merck's products?

We believe the proper objective should be that launch prices appropriately reflect the true value of the medicine and are not distorted by any misaligned incentives in Medicare Part D or any other sector. We believe the Administration's proposed rebate safe harbor, and similar changes in commercial plans, would address the misaligned incentives in the marketplace that favor high list prices and high rebates in competitive markets. In addition, addressing the misaligned incentives for the 340B program would allow for more flexibility in list prices.

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. We believe there should be greater transparency of the financial arrangements between manufacturers and PBMs. In particular, 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 Administration's 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.

2. ***Mr. Frazier and Dr. Bourla: Senator Thune asked if this administration rule would lead you to lowering list prices. Both of you answered that you would be likely to lower your prices. However, if this rule were finalized tomorrow as proposed, would any of your companies be <u>required</u> to lower the list price of any of your drugs?***

Under the proposed rule, there is no requirement to lower list prices. However, over time, we expect that our list prices will go down if the misaligned incentives across the system are addressed. 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.

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?*
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?*

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?*

Merck offers a generous health care benefit for our 24,000 U.S. employees. There is no deductible for medications covered under our pharmacy benefit, and employees never have to pay more than $50 for a retail prescription for a covered medication, and in most cases pay less. We contract with a PBM for management of the prescription drug benefits for our employees, and the benefit does not offer point-of-sale rebates to our employees. Merck uses savings generated by the PBM on rebates to lower overall costs for employees while ensuring low out-of-pocket costs.

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.

Over time, we expect that our list prices will go down if the misaligned incentives across the system are addressed. 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 of the players in the ecosystem will need to adjust to the new model.

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.

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?

The U.S. leads the world in biomedical research thanks to a robust biomedical ecosystem comprised of important and unique contributions from the National Institutes of Health (NIH), academic institutions, and the biopharmaceutical industry. Historically, the NIH's focus has been on basic biomedical science and research concerning public health (including in the recent budget funding for drug and alcohol abuse prevention, reducing health care disparities, and other important causes). Through this basic research, NIH seeks to understand the fundamental biological processes and leverage that understanding to determine which processes are involved

in the development and progression of disease. There is significant basic research that in some respects contributes to all new medicines. Most of this is considered "pre-competitive" since the individual contributions are in themselves too small or too broad to lead directly to a new therapy, which takes considerable work to invent and develop.

Merck also conducts basic research. However, where we use intellectual property that others have created, we are diligent in recognizing and agreeing on terms to use that property (including financial compensation), which may include with agencies of the U.S. government such as NIH. After this stage of basic research, our company's further role is to then engage in the most risky and costly part of discovery – to invent something that's never existed in the history of the world that will alter the targets that come from basic research and unlock treatments and cures for disease. This invention is then followed by extensive clinical trial programs to demonstrate safety and effectiveness.

On occasion, we will rely on work by government agencies that is more advanced; however, we take the same approach of respecting intellectual property rights and agreeing on terms of use of that property. For example, Merck, along with Instituto Butantan, has licensed certain rights from National Institute of Allergy and Infectious Diseases (NIAID), part of NIH, for the development of live attenuated tetravalent vaccines (LATV).

All parts of the ecosystem are needed to continue to lead in biomedical research: the portion of NIH's entire $33 billion budget that it devoted to biomedical research in 2017 as well as the $70 billion the biopharmaceutical industry spent in 2017 – $10 billion of which was spent by Merck – to invent and bring to market new treatments and cures.

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?

In 2018, Merck incurred $9.8 billion in research and development costs globally, the vast majority of which was conducted in the U.S. Since 2010, Merck has invested nearly $70 billion in R&D to create new medicines and vaccines that address the greatest health challenges of our time – including antimicrobial resistance, Ebola, HIV, and cancer – to save and improve lives around the world. In 2018, Merck spent about $2.3 billion in the U.S. on direct marketing and selling expenses. This number includes all sales and marketing expenses, including creative development of resources and headcount related to all marketing and sales activity in the U.S. market.

For the remaining years, we spent the following:

- In 2017, Merck invested $10.3 billion in R&D and $2.5 billion in U.S. marketing and selling expenses.
- In 2016, Merck invested $10.3 billion in R&D and $2.5 billion on U.S. marketing and selling expenses.
- In 2015, Merck invested $6.8 billion in R&D and $2.4 billion on U.S. marketing and selling expenses.
- In 2014, Merck invested $7.3 billion in R&D and $2 billion on U.S. marketing and selling expenses.

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?

It is hard to predict an exact amount of list price reduction if the rule were implemented as described. However, we believe that removing the misaligned incentives from the system should result in downward pressure on list prices. It is also important to understand that different purchasers receive different levels of discounts, based on the access provided for patients. 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.

b. How will this proposal affect how your company sets the list prices for new drug products? Standard answer on how we set launch prices; connect to question.

Merck approaches pricing from the perspective of value. This approach looks at the value that a medicine provides through multiple lenses with the goal of reflecting its benefit to patients and to society, while at the same time paying an appropriate return on invested capital to our investors, to ensure that we are able to sustain R&D. While each individual situation varies based on factual circumstances and market dynamics, generally, we consider:

- *Value provided to patients* – to what extent does a new medicine or vaccine establish a new standard of care that has the potential to significantly extend and improve patient lives?
- *Value provided to health care systems* – to what extent does a new medicine or vaccine reduce the costs associated with hospitalization and other costly complications of disease if not appropriately (or optimally) treated?
- *Unmet need* – does a new medicine or vaccine address a critically unmet medical need, where few or no treatments exist?
- *Access* – what is the ability of various customers around the world – including national, regional or local institutional payers, physicians, employers and patients – to pay for our products?
- *R&D sustainability* – given the long-term risk and cost of capital, can we appropriately compensate our investors to ensure continued investment in the kind of risky and capital-intensive research and development that will bring forward medically-important breakthroughs?
- *Competition* – what are the costs of other treatments currently on the market relative to the value provided by Merck's products?

We do not expect this approach to change based on the Trump Administration's proposed rule.

c. *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?*

We expect that the robust negotiations that occur today will continue in the highly competitive Part D and commercial markets, 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, but predicting the size of any such reductions is difficult.

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.[13]

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. Merck does not engage in the practice of selling authorized products to a subsidiary and then blending the pricing data for the products. Merck does engage with third parties who act as our authorized generic partners. Merck has disclosed the methodology used to account for these transactions in AMP to CMS.

Senator Cortez Masto:

1. ***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?

Since Merck's entire product portfolio is covered within at least one government program that requires a mandated rebate or discount (such as Medicaid, 340B, Federal Supply Schedule), there are no Merck products that are not rebated or discounted. Merck also offers voluntary rebates or discounts on many of its products. We would expect similar rebates and discounts to be paid for our drugs in the pipeline, barring fundamental changes in the marketplace.

[13] 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

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

In 2018, Merck incurred $9.8 billion on research and development costs globally, the vast majority of which was conducted in the U.S. Since 2010, Merck has invested nearly $70 billion in R&D to create new medicines and vaccines that address the greatest health challenges of our time – including antimicrobial resistance, Ebola, HIV, and cancer – to save and improve lives around the world. In 2018, Merck had $18.2 billion in U.S. sales revenue.

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.

In 2018, Merck incurred $9.8 billion in research and development costs globally, the vast majority of which was conducted in the U.S. Since 2010, Merck has invested nearly $70 billion in R&D to create new medicines and vaccines that address the greatest health challenges of our time – including antimicrobial resistance, Ebola, HIV, and cancer – to save and improve lives around the world. In 2018, Merck spent about $10.1 billion on marketing, selling, and administration globally ($2.6 billion of which is directly attributed to the U.S. market). This number includes all sales and marketing expenses, including creative development of resources and headcount related to all marketing and sales activity, as well as administrative expenses associated with business support functions, including information technology, human resources, facilities, finance, legal, and others.

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.

In 2018, Merck incurred $9.8 billion on research and development costs globally, the vast majority of which was conducted in the U.S. Since 2010, Merck has invested nearly $70 billion in R&D to create new medicines and vaccines that address the greatest health challenges of our time – including antimicrobial resistance, Ebola, HIV, and cancer – to save and improve lives around the world. In 2018, Merck spent about $6.9 billion on direct marketing and selling expenses globally ($2.3 billion of which is directly attributable to the U.S. market). This number includes all sales and marketing expenses, including creative development of resources and headcount related to all marketing and sales activity in the U.S. market.

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

Merck believes that direct-to-consumer (DTC) advertising can be an important and helpful way to inform patients about diseases that may be relevant to them and therapeutic options they may want to discuss with their physician. Data demonstrate that DTC can have a positive impact on patient health in terms of diagnosis, treatment, and adherence to prescribed therapies. We recognize that DTC is one channel amongst many to help educate patients. Print materials, telephone, websites, and other channels are also used to provide more in-depth information to

patients. The ultimate decision to prescribe a product for any specific patient remains with the physician following discussion with their patient.

Merck adheres to FDA regulations and guidelines governing DTC promotion and has a long-standing policy to voluntarily submit new DTC broadcast advertising campaigns to FDA for pre-review. Merck also follows the PhRMA Guiding Principles for DTC Advertisements About Prescription Medicines. We are currently considering what additional information we can make available to consumers to ensure that they can make informed health care decisions.