

Senate Committee on Finance Questions for the Record

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

February 26, 2019

**Questions for:
Albert Bourla, DVM, Ph.D.
Chief Executive Office
Pfizer**

Senator Grassley:

At the hearing, you testified that Pfizer 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. Pfizer is on this FDA list. This would appear to contradict your testimony at the hearing that Pfizer has not withheld samples of their products to delay generic competition.

- Could you please explain in detail why Pfizer is on the FDA list?
- Could you please explain in detail the discrepancy between your testimony and the FDA list?
- Has Pfizer ever blocked access to samples?

As a patient-focused company and leading manufacturer of innovative, generic, and biosimilar medicines, Pfizer supports innovation and a strong, competitive marketplace. Consistent with these values, Pfizer does not block generic manufacturers from purchasing our products, and it has never been our policy to do so. Generic manufacturers are treated the same as any other customer seeking to purchase our products. Pfizer is not aware of any current, unfulfilled requests from a generic manufacturer to purchase a Pfizer product.

Generic manufacturers seeking to purchase Pfizer products should request the product from Pfizer's authorized distributors or, if the product is not available at a distributor, from Pfizer directly, the same as any other Pfizer customers. Pfizer's website includes a list of our authorized distributors, from which customers (including generic companies) may purchase most Pfizer products. (See <https://www.pfizer.com/products/medicine-distributors>) For products that are not available via our authorized distributors and that are not in extreme drug shortage or unavailable due to a recall, customers can contact Pfizer's Customer Service center at 1-800-TRY-FIRST (1-800-879-3477) to purchase product directly from Pfizer. The telephone number for Pfizer's Customer Service center is also included on our website at <https://www.pfizer.com/contact>. Pfizer makes its products available for sale to appropriately licensed entities at Pfizer's listed price and on Pfizer's standard terms of sale. We do not have any agreements with authorized distributors that block the sale of Pfizer's products to generic manufacturers.

Regarding the FDA List (the List), while Pfizer supports FDA's (the Agency) goal of providing transparency, Pfizer is concerned that the List lacks certain key information and context and, as currently presented, may create the misleading impression that *all* products on the List are the result of bad faith attempts to block generic manufacturer access to samples. The appearance of a product on the FDA List means only that a generic manufacturer informed the Agency at some point in time that it was having difficulty purchasing the listed product. FDA's own disclaimer states that the Agency has not independently investigated or confirmed whether a generic manufacturer actually made a request to purchase product, and to whom.¹ The FDA List also lacks several important pieces of information that would enable a New Drug Application (NDA) holder to investigate its appearance on the List. The List does not include: (1) which generic manufacturer made the request; (2) when and to whom the generic manufacturer made the request (*e.g.*, to a wholesaler or directly to the NDA holder); (3) whether the generic manufacturer that made the inquiry was thereafter able to obtain product; and (4) any reason(s) why a generic manufacturer may not have been able to obtain product (*e.g.*, a recall). Finally, Pfizer notes that FDA does not currently inform an NDA holder in real time when a generic manufacturer notifies the Agency that it is having difficulty obtaining product. Had the Agency informed Pfizer at the time it received the inquiries noted on the FDA List, Pfizer could have then undertaken its own efforts to resolve the issue. Pfizer communicated its concerns about the FDA List to the Agency in May 2018. For your information we have included Pfizer's letter to FDA on this topic and the Agency's response (*See Exhibits 1 and 2 in the Appendix*).

There are three new drug applications owned by Pfizer on the FDA List: Embeda (NDA 022321), Tikosyn (NDA 020931) and Hemabate (NDA 017989). Embeda offers a good example of the List's shortcomings. Pfizer acquired King Pharmaceuticals (the previous NDA holder of Embeda) in March 2011, and two weeks later determined that Embeda needed to be recalled from the U.S. market due to stability issues. After diligently addressing the issues that led to the recall, Pfizer relaunched Embeda to the U.S. market in January 2015, and it is available for purchase via Pfizer's authorized distributors. However, one consequence of the recall was that Embeda was not available in the U.S. market for almost four years which may explain why a generic manufacturer had a problem obtaining it during those years. The FDA List does not specify when the generic manufacturer's inquiry regarding Embeda was made nor does the FDA List indicate that several generic applications for Embeda had been submitted to FDA in 2010 (which means that before the recall, several generic manufacturers were successfully able to purchase Embeda, conduct the necessary testing, and file Abbreviated New Drug Applications (ANDAs)). Pfizer has not identified any recent inquiries from generic manufacturers seeking to purchase Embeda that have not been fulfilled.

The circumstances around Tikosyn also illustrate the List's shortcomings. Pfizer was able to identify a single inquiry made by a generic manufacturer directly to Pfizer to purchase Tikosyn in 2014. At that time, Tikosyn was subject to an FDA imposed Risk Evaluation and Mitigation Strategies (REMS) with Elements to Assure Safe Use ("ETASU") that restricted distribution, so Pfizer responded by asking the manufacturer to obtain written confirmation from the FDA that

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(<https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm>)

Pfizer's provision of the product to the generic manufacturer would not be considered a violation of its REMS. The generic manufacturer did not contact Pfizer further, and Pfizer never received any written correspondence from the Agency. FDA subsequently removed the REMS for Tikosyn in 2016, and multiple generic versions of Tikosyn are now approved, the first generic approval occurring in June 2016. This context is not reflected in FDA's List.

Finally, with respect to Hemabate, this product was previously subject to certain restrictions on distribution (*i.e.*, it was sold only to customers with medical and surgical intensive care centers) to ensure its safe and appropriate use. This distribution approach was established by the previous NDA holder (Pharmacia) and it continued following Pfizer's acquisition of Pharmacia in 2003. Pfizer discontinued this approach in early 2018 after determining that it was no longer necessary, and this product is now available through our authorized distributors. During the time when Hemabate was under restricted distribution, it was not available at Pfizer's authorized distributors, but had a generic manufacturer approached Pfizer's Customer Service center directly, we would have been able to address the inquiry. Pfizer's Customer Service was not able to identify any specific requests from a generic manufacturer to purchase Hemabate that have not been fulfilled.

We hope that this information explains the apparent discrepancy between Mr. Bourla's testimony and the appearance of these Pfizer products on the FDA List, and demonstrates Pfizer's diligence on these issues and commitment to a competitive marketplace.

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?

Yes, if finalized, price concessions negotiated with intermediaries, including Pharmacy Benefit Managers (PBMs) and plan sponsors, will be provided as discounts that will be applied at the point of sale. These discounts will lower patient out-of-pocket costs since the net price will be used to determine the cost to the patient when they are in the deductible, co-insurance, and coverage gap phases of their benefits.

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?

If finalized, the rule will result in lower out-of-pocket patient costs at the pharmacy counter and help address the perverse incentives in the system that have been contributing to higher list prices for medicines. We realize that the transition away from rebates toward a point-of-sale discount model will result in a lowering of our net prices. Despite this potential negative financial impact, we support efforts to eliminate rebates because we believe the new model will be good for patients.

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

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

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?

Pfizer's contracts with Part D Health Plans and PBMs negotiating on their behalf do not make rebates contingent on 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.

Pfizer's prescription pharmaceutical products are sold principally to wholesalers, and therefore the Company does not have sufficient visibility into wholesaler distribution at the channel level to provide responses as requested. We welcome the opportunity to discuss with your Committee staff the confidential information requested and what we maintain in the ordinary course of business.

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

No.

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

Pfizer is committed to the principle of transparency — the disclosure of activities reflecting participation in efforts of public interest. These activities include such areas as funding for educational activities, the status of Pfizer's U.S. pharmaceutical post-marketing commitments, Pfizer's pipeline of experimental medicines, the registration and reporting of results of clinical trials, political contributions in the United States and payments to U.S. health care professionals. The information we report includes grants to support independent medical education, support for fellowship, scholarship and visiting professorship programs, grants to patient organizations, medical and scientific associations, and academic or other medical centers, charitable contributions, healthcare-related support to civic organizations and healthcare-related non-promotional sponsorships to organizations. For descriptions of types of support, please visit <https://www.pfizer.com/purpose/independent-grants/transparency-in-grants>. Any Medicaid specific advocacy funding we provide would be captured in these reports.

1. Please describe how the costs of 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.

Pfizer's patient assistance program is a charitable free drug program that provides commercially-available Pfizer medicines free of charge to financially-eligible uninsured and underinsured patients. Separate from the Pfizer patient assistance program, Pfizer also offers patient support programs, which are limited access reimbursement support offerings to patients to assist with obtaining access to and coverage of a prescribed Pfizer medicine.

The product and administrative costs for the patient assistance program are charged against Pfizer's Selling, General and Administrative Expenses line in the income statement.

Pfizer gathers data in the course of providing free drugs to patients via the patient assistance program. We can bucket data collection in several ways:

- 1) Transactional data– Utilized to determine patient *eligibility* to receive free access to a physician-prescribed therapy.
- 2) Operational data– The operational data is utilized to *provide free access to medicines* to the eligible patient and the following is reported at an aggregated level:
 - i. Program utilization trends
 - ii. Application Processing trends
 - iii. Patient coverage trends

- iv. Channel utilization (distribution versus pharmacy)
- v. Fulfillment and order processing days
- vi. Call metrics

Pfizer gathers the following two categories of data when providing patient support programs:

- 1) Transactional – Utilized to assist in accessing prescribed therapy and to determine insurance coverage for the patient. This information contains data such as the outcome of a benefits investigation, information to determine the financial need and eligibility for patient support, and disposition of the patient case (*i.e.*, sent to a specialty pharmacy for fulfillment, sent to Pfizer patient assistance program, triaged to other financial options, or rejected/denied).
 - 2) Operational – These fields could include primary and secondary payers, out-of-pocket costs borne by the patient, turnaround time to obtain insurance approval, prior authorization requirements, number of cases requiring appeals, and other data elements on access dynamics. In addition to these elements, Pfizer will collect relevant adverse events as required by Pfizer drug safety.
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.

Information about Pfizer's charitable giving is listed on Pfizer.com. Please see the annual reports dating back to 2008 available at <https://www.pfizer.com/purpose/independent-grants/transparency-in-grants>, which include the recipient name, the contribution amount and the annual quarter in which it was made, and a description of the relevant program or project. This data is updated each quarter. Data from Q4 2018 is currently being analyzed and will be available at the end of March 2019. The annual reports include various funding types and recipient types. However, in collating this data, Pfizer does not characterize the organizations as working on issues related to drugs within product lines, or contributions as restricted or unrestricted. Consequently, the requested data is not available in that format.

Note that information regarding charitable contributions from the Pfizer Foundation is not included in these reports, so Pfizer has included a Pfizer Foundation Grant Summary as Exhibit 3. The Pfizer Foundation has been working to expand health care access to

people around the world for nearly sixty-five years. The impact of this work is significant and far-reaching, helping underserved individuals from diverse backgrounds in remote corners of the globe. Through the Pfizer Foundation's global health strategy, we provide grant and investment funding to support organizations and social entrepreneurs in an effort to improve health care delivery in low- and middle-income countries and increase access to health care for underserved communities.

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?

Pfizer wants to work with you on this issue because we agree that gaming the patent system is unacceptable. The Company's patent settlements do not involve "pay for delay." On the contrary, when Pfizer settles patent litigation with generic firms, it does so on terms that generally enable entry of generic competition earlier than the expiration of its patents and that do not involve unlawful reverse payments. Pfizer's patent settlements thus involve lawful compromises that accelerate patient access to lower cost generics relative to the expiration of its patents.

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

No. On the contrary, when Pfizer settles patent litigation with generic firms, it does so on terms that generally enable entry of generic competition earlier than the expiration of its patents and that do not involve unlawful reverse payments. Pfizer's patent settlements thus involve lawful compromises that appropriately resolve patent disputes and accelerate patient access to lower cost generics relative to the expiration of its patents. While Pfizer has been the target of plaintiff lawyer driven class action lawsuits challenging certain of its settlements with generic companies, we believe these lawsuits are without merit and are vigorously asserting the pro-competitive nature of these settlements in court.

- Do you support the pay for delay bill?

Pfizer agrees that gaming the patent system is unacceptable. We hope to work with you on legislation that prohibits anticompetitive patent settlements that is prospective, clearly defines violations and what is deemed to be an improper settlement and does not presume all patent settlement agreements are per se illegal and anticompetitive. Laws or actions to restrict certain kinds of pharmaceutical patent settlements could prevent some pro-consumer settlements that bring generics to market prior to patent expiration—patent settlements often include an agreement that enables generics to enter the market earlier than the date of patent expiration, speeding patient access to more affordable generic options.

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?

Pfizer does currently bundle rebates over multiple products. Pfizer does offer bundling arrangements to obtain formulary positions that allow patients to access our medicines that otherwise might be restricted.

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

Pfizer does not believe bundling is inherently anticompetitive and in certain circumstances can be procompetitive. However, Pfizer does not tie bundled rebates to blocking lower cost competitive agents and believes that when a firm with monopoly power uses such practices to block lower cost alternatives the conduct is anticompetitive.

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?

A policy that moves rebates to discounts would not in and of itself eliminate the ability of a market leader to block a lower priced medicine. In both Medicare and Commercial, the Health Plan is still responsible for the majority of the drug cost and would therefore receive the majority of the discount. The Health Plan or PBM would still need to transition patients from the higher priced market leader to the lower priced product in order to realize the savings from the discount. Based on internal analysis, Pfizer expects that moving from a rebate to a discount model will weaken a market leader's ability to restrict other less expensive products, but it would not eliminate the possibility.

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.

The Food and Drug Administration is the primary regulatory body for the pharmaceutical industry and is largely focused on the safety, quality, and efficacy of medicines. The price of a new medicine is most directly influenced by the value that the medicine may bring to patients and society. Inherent in the value any product Pfizer brings to the market are the quality, safety, delivery, efficacy, and reliability of our medicines. These regulatory and compliance factors are part of the underlying investments to identify a product's value and are amongst the many factors we consider when we determine a launch price or make a decision to change a price.

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

Liability and litigation are not primary considerations when setting the list price of a medicine; the value that a product may bring to patients and society is the most important factor considered.

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?

Value based agreements (VBA) provide a framework for manufacturers to be compensated based on a product’s value to patients and the overall healthcare system. Although there are different constructs for VBAs, the basic premise is that the net price for a product will ultimately be derived based on an agreed upon performance metric (e.g. clinical, financial, adherence, etc.). Therefore, VBAs can play a role in reducing prescription drug costs by ensuring that net prices are linked to value.

As we shift to a system that rewards value, manufacturers will be incentivized to focus research and development (R&D) investments in disease areas where there are unmet needs, to focus on best in class or first in class medicines, and to design trials that provide the necessary evidence to demonstrate the value of a medicine beyond the regulatory standards of safety and efficacy to include the evidence to support reimbursement. If manufacturers deliver medicines of value, the system will reward the manufacturer which encourages innovation of new drugs.

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

Value based agreements (VBA) provide a framework for manufacturers to be compensated based on a product’s value to patients and the overall healthcare system. There are many different types of VBAs including those based on clinical and/or financial performance metrics for a product. Based on the outcomes achieved, payers use this information to inform how they cover products. Products that perform better should be covered in a more favorable manner which often includes lower out-of-pockets costs for patients which is a benefit to patients in the near-term. In the long term, patients can also benefit from other savings either directly, (e.g., reducing spending on other medications, lowering medical costs from reduced hospitalizations, doctor’s visits, etc.), or indirectly through lower premiums based on reductions in total cost of care.

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

VBAs are in the very early stages of development in the United States. Many payers and manufacturers have tested different concepts, but to date VBAs have not achieved scale. There are multiple reasons why VBAs represent a small fraction of manufacturer/payer

contracts (e.g. access to data, difficult and costly to administer, etc.). There are certain aspects of the current U.S. regulatory landscape that are perceived by many as not only complicating VBA implementation but in some cases limiting their rapid uptake. Stakeholders have frequently identified two key regulatory hurdles as limiting the expanded adoption of VBAs: i) the Anti-Kickback Statute and ii) the Medicaid Best Price calculation requirement. While these regulations serve important roles within the current volume-based reimbursement system they do not contemplate innovative value-based arrangements which have resulted in a lack of clarity on how to account for these under the current regulatory framework. Ultimately, an expansion of VBAs will require reforms to existing regulations that enable more flexibility in designing 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?

The Biologics Price Competition and Innovation Act (BPCIA) created an abbreviated pathway for the licensure of biosimilars, including interchangeable biologic products, and created the framework biosimilar applicants and reference product sponsors use to resolve patent disputes. There are currently seven biosimilars on the market in the United States, and there are a number of biosimilars currently in development. The FDA has approved a total of 18 biosimilars to date. Nevertheless, the success of the BPCIA lies in the increased use of these products, which will provide savings to both the patient and the taxpayer.

To date, there have been two key policies that have helped support the biosimilars marketplace: 340B pass-through status for biosimilars and the separate billing/J code policy for biosimilars.

The separate billing/J code policy for biosimilars has aided in the prompt reimbursement of biosimilars for physicians, which is critical in supporting uptake of biosimilars. The separate billing/J code also provides Congress and CMS with transparency on the average sales price of the biosimilar versus the reference biologic. Below is a table outlining the latest Medicare published average sales prices for the reference biologic Remicade and both of the biosimilars on the market for Remicade, Pfizer's Inflectra and Merck's

Renflexis.² It is important to note that the average sales price (ASP) for both biosimilars is lower than the ASP of the reference biologic. Yet, the market share of the Inflectra biosimilar remains at six percent in open systems (which excludes the VA and Kaiser, which are closed systems where the insurer is the payer, the prescriber and the provider).

	HCPCS Code	Q4 2018 CMS ASP	Q1 2019 CMS ASP	Q2 2019 CMS ASP
Remicade (reference biologic)	J1745	\$743.71	\$723.10	\$677.60
Inflectra (biosimilar)	Q5103	\$569.01	\$529.37	\$502.72
Renflexis (biosimilar)	Q5104	\$599.20	\$575.64	\$552.00

The 340B pass-through policy for biosimilars has been another positive policy to support uptake of biosimilars in 340B hospitals. The 340B pass-through policy provides a temporary “level playing field” for the biosimilar and the reference biologic. Under the reimbursement model of ASP + x%, providers are incentivized to use a higher cost product to drive a higher “+x%” reimbursement. As in the case of biosimilars, when the biosimilar has a lower ASP the reimbursement is lower to the healthcare provider/340B hospital. The pass-through policy provides temporary reimbursement parity for lower cost biosimilars. This policy has encouraged 340B hospitals to adopt biosimilars and gain experience and confidence in using them.

Despite these current policies, other adverse incentives that favor higher-cost originator biologics are keeping biosimilars from reaching patients. In many cases, payers decline to include lower-cost biosimilars or generics in their formularies because they would risk losing the rebates they could receive by covering higher-cost medicines.

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?

Ninety percent of the medicines Americans take are generics and competition from these drugs keeps prices low in most cases. The biologics market, where some of the most expensive drugs exist, needs similar competition. The market today has already seen demonstrated savings as high as forty percent relative to the branded product. In Europe, biosimilars have obtained a market share of over sixty percent on some products. However, in the United States, our biosimilar, Inflectra, has captured only six percent, despite the fact that its average selling price (ASP) is more than twenty-five percent lower than the originator product. With more competition, Pfizer hopes even further

² <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/2019ASPFiles.html>

savings can be realized. We believe some of the adverse incentives and barriers to market penetration include:

1. **The Rebate Trap:** Brand-name biologic companies are using maneuvers to block biosimilar competition such as higher rebates and exclusionary contracts.
2. **Misinformation:** We believe that some physician and patient-directed materials created by brand companies mischaracterize biosimilars, creating doubt and confusion about the safety and efficacy of biosimilars. As defined by statute, an approved biosimilar must be highly similar to and have no clinically meaningful differences from the reference product and must have the same mechanism of action (to the extent the mechanism(s) of action of the reference product are known) as the reference product. Thus, by definition, biosimilars are safe and efficacious treatments relative to the reference product and must work in the same way as the reference product. Any information disseminated by reference product sponsors to suggest or imply otherwise should be promptly addressed by the FDA.
3. **Need for incentives:** Legislative ideas to promote biosimilar uptake could include a shared savings biosimilar model; reduced patient cost sharing for biosimilars.

Although the biosimilar market in the United States is still relatively new, Pfizer's experience has been that anticompetitive conduct by brand-name biologic manufacturers, combined with the lack of policy measures to support appropriate uptake of biosimilars, have contributed to a slow uptake. Therefore, we encourage you to consider measures to help incentivize the use of biosimilars, which can substantially lower Medicare costs with demonstrated savings to date as high as nearly forty percent relative to the branded biologic.

In addition to stopping anticompetitive behavior (either through government enforcement or in the courts through private litigation), some key policy initiatives we believe will support the uptake of biosimilars in the United States include:

- **Waiver of Part B Patient Coinsurance for Biosimilars for a certain period of time.** CMS should waive Part B patient coinsurance amounts for biosimilars. Cost-sharing changes could be applied at the Healthcare Common Procedure Coding System (HCPCS) level. This would not change the overall payment for a biosimilar; however, it would change the beneficiary's payment percentage.
- **CMS should pursue a CMMI model** designed to increase access to biosimilars, including a "shared savings" model whereby Medicare

savings associated with prescribing a biosimilar, as compared to a reference biological, would be shared with providers.

- **CMS should maintain the current biosimilar pass-through status** as this provides biosimilars with a “level playing field” with their higher priced reference biologic competitors.
- **CMS should create payment incentives for plans** by contracting with a measure developer for a biosimilar use measure for the STARS program, which would correct other adverse incentives for biosimilar uptake for Medicare Advantage plans.

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?

If finalized, the rule would result in lower out-of-pocket patient costs at the pharmacy counter and help address the perverse incentives in the system that have been contributing to higher list prices for medicines.

In 2019, Pfizer expects to pay billions of dollars in rebates to ensure patients with pharmacy benefits coverage in Medicare Part D and patients in commercial plans have access to our medicines. If the proposed rule to share rebates with consumers at the point of sale is finalized, we estimate that seniors taking Pfizer medicines could save \$270 on average per year, and up to \$574 per year for certain Pfizer medicines, through lower cost sharing – and that would outweigh any premium increases.

As currently written, the proposed rule only applies to the Medicare and Medicaid managed care segments of the market. It will be important to have rebate reform changes apply to both government programs and the commercial market. A bifurcated market will make it more challenging for manufacturers to reduce list price since the commercial

market covers more than fifty percent of Americans with insurance and represents over half of the business for most manufacturers.

If the proposed reform is modified to apply to all market segments, we would evaluate the best options to arrive at a net price that ensures patients have access to our medicines. Decisions would be made on a product by product basis given that each therapeutic class has its own set of competitive and access dynamics.

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

If the rule is finalized consistent with the aforementioned concerns, Pfizer is confident patients will benefit from savings of any price concessions at the point of sale.

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

We strongly support ensuring that patients receive the benefit of rebates at the pharmacy counter and look forward to working with Congress and HHS on this issue. We encourage Congress to ensure that plans do not impose new barriers or restrictions to access that undermine the spirit of the rule and prevent patients from benefitting from the savings.

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?

There are rebates involved with infusion medicines (Medicare Part B drugs), and Pfizer is willing to engage with your staff in general terms to explain the relationship and negotiations between manufacturers and payers such as insurers and PBMs for drugs in this space.

Pfizer also believes there are other ways to reform the Part B payment system to move away from incentivizing the use of more costly drugs. One solution we support for reforming Part B is a Competitive Acquisition Program (CAP) to allow vendors to deliver and bill Medicare for drugs, starting in a few cities. We believe this will inject competition into the program.

Biosimilars are another solution. Pfizer is fully committed to the goals set by Congress to bring new biosimilars to market, ensuring that patients have access to a wide range of treatment options at a competitive, affordable price. The market today has already seen demonstrated savings as high as forty percent relative to the branded product. With more competition, we hope even further savings can be realized.

Rebate Traps

Pfizer's biosimilar to Janssen's Remicade has struggled to gain market share, despite being priced at a significant discount to the biologic.

- Please explain the market challenges you are seeing with this product. How does the practice of drug companies "bundling" the prices of product portfolios and rebates associated with these drugs limit competition and access to lower-cost biosimilars?

As more fully laid out in Exhibit [4], the primary barrier to Inflectra's uptake is an anticompetitive contracting scheme that targets both the payer (*i.e.*, insurer) channel and the healthcare provider (*i.e.*, hospitals, clinics and doctors) channel. The centerpiece of the scheme is the "rebate trap" that uses pricing penalties (*i.e.*, the loss of significant rebates) to coerce insurers to enter into exclusive deals that cover Remicade while effectively blocking Inflectra from coverage. Multi-product bundling is just one aspect of the conduct. Despite bringing a lower-cost version of Remicade to market, this biosimilar has captured less than ten percent of the market.

- Do you attribute this to exclusionary contracts or "paying for position" to keep your product off formularies? Please explain this practice and how it keeps lower-cost drugs out of the hands of patients.

Pfizer attributes low uptake to an anticompetitive contracting scheme as described above in response to Question 1.

This is particularly concerning not only because of the direct impact regarding the healthcare system's spend, but also because it could become the playbook by which innovator biologics thwart entry by biosimilars in the future. This could inhibit significant competition to biologics going forward and act as a disincentive for companies to invest in developing biosimilars.

Senator Daines:

As an advocate for improving Montanans' access to low-cost medications, I've been a champion of the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act, which would combat anticompetitive practices used by some brand-name pharmaceutical companies to block or delay competing generic drugs from entering the market.

During the hearing when I asked if your company had ever withheld samples from generic manufacturers, you answered emphatically no. Yet, according to the Food and Drug Administration (FDA), generic drug makers have made inquiries with the agency claiming they were unable to access samples provided by Pfizer and AstraZeneca that are needed to conduct studies to produce low-cost generic drugs.

- Do you agree that denying generic drug manufacturers access to samples keeps drug costs high for patients due to lack of competition?
- Has your company refused to sell samples or placed any barriers in the way of generic drug makers acquiring samples?
- Are you aware of any outstanding requests for samples?
- How does your company work to prevent abuses in the sample system?

As a patient-focused company and leading manufacturer of innovative, generic, and biosimilar medicines, Pfizer supports innovation and a strong, competitive marketplace. Consistent with these values, Pfizer does not block generic manufacturers from purchasing our products, and it has never been our policy to do so. Generic manufacturers are treated the same as any other customer seeking to purchase our products. Pfizer is not aware of any current, unfulfilled requests from a generic manufacturer to purchase a Pfizer product.

Generic manufacturers seeking to purchase Pfizer products should request the product from Pfizer's authorized distributors or, if the product is not available at a distributor, from Pfizer directly, the same as any other Pfizer customers. Pfizer's website includes a list of our authorized distributors, from which customers (including generic companies) may purchase most Pfizer products. (See <https://www.pfizer.com/products/medicine-distributors>) For products that are not available via our authorized distributors and that are not in extreme drug shortage or unavailable due to a recall, customers can contact Pfizer's Customer Service center at 1-800-TRY-FIRST (1-800-879-3477) to purchase product directly from Pfizer. The telephone number for Pfizer's Customer Service center is also included on our website at <https://www.pfizer.com/contact>. Pfizer makes its products available for sale to appropriately licensed entities at Pfizer's listed price and on Pfizer's standard terms of sale. We do not have any agreements with authorized distributors that block the sale of Pfizer's products to generic manufacturers.

Regarding the FDA List (the List), while Pfizer supports FDA's (the Agency) goal of providing transparency, Pfizer is concerned that the List lacks certain key information and context and, as currently presented, may create the misleading impression that *all* products on the List are the result of bad faith attempts to block generic manufacturer access to samples. The appearance of a product on the FDA List means only that a generic manufacturer informed the Agency at some point in time that it was having difficulty purchasing the listed product. FDA's own disclaimer states that the Agency has not independently investigated or confirmed whether a generic manufacturer actually made a request to purchase product, and to whom.³ The FDA List also lacks several important pieces of information that would enable a New Drug Application (NDA) holder to investigate its appearance on the List. The List does not include: (1) which generic manufacturer made the request; (2) when and to whom the generic manufacturer made the request (*e.g.*, to a wholesaler, directly to the NDA holder); (3) whether the generic manufacturer that made the inquiry was thereafter able to obtain product; and (4)

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(<https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm>)

any reason(s) why a generic manufacturer may not have been able to obtain product (*e.g.*, a recall). Finally, Pfizer notes that FDA does not currently inform an NDA holder in real time when a generic manufacturer notifies the Agency that it is having difficulty obtaining product. Had the Agency informed Pfizer at the time it received the inquiries noted on the FDA List, Pfizer could have then undertaken its own efforts to resolve the issue. Pfizer communicated its concerns about the FDA List to the Agency in May 2018. For your information we have included Pfizer's letter to FDA on this topic and the Agency's response (*see* Exhibits 1 and 2 in the Appendix).

There are three new drug applications owned by Pfizer on the FDA List: Embeda (NDA 022321), Tikosyn (NDA 020931) and Hemabate (NDA 017989). Embeda offers a good example of the List's shortcomings. Pfizer acquired King Pharmaceuticals (the previous NDA holder of Embeda) in March 2011, and two weeks later determined that Embeda needed to be recalled from the U.S. market due to stability issues. After diligently addressing the issues that led to the recall, Pfizer relaunched Embeda to the U.S. market in January 2015, and it is available for purchase via Pfizer's authorized distributors. However, one consequence of the recall, was that Embeda was not available in the U.S. market for almost four years which may explain why a generic manufacturer had a problem obtaining it during those years. The FDA List does not specify when the generic manufacturer's inquiry regarding Embeda was made nor does the FDA List indicate that several generic applications for Embeda had been submitted to FDA in 2010 (which means that before the recall, several generic manufacturers were successfully able to purchase Embeda, conduct the necessary testing, and file Abbreviated New Drug Applications (ANDAs)). Pfizer has not identified any recent inquiries from generic manufacturers seeking to purchase Embeda that have not been fulfilled.

The circumstances around Tikosyn also illustrate the List's shortcomings. Pfizer was able to identify a single inquiry made by a generic manufacturer directly to Pfizer to purchase Tikosyn in 2014. At that time, Tikosyn was subject to an FDA imposed Risk Evaluation and Mitigation Strategies (REMS) with Elements to Assure Safe Use ("ETASU") that restricted distribution, so Pfizer responded by asking the manufacturer to obtain written confirmation from the FDA that Pfizer's provision of the product to the generic manufacturer would not be considered a violation of its REMS. The generic manufacturer did not contact Pfizer further, and Pfizer never received any written correspondence from the Agency. FDA subsequently removed the REMS for Tikosyn in 2016, and multiple generic versions of Tikosyn are now approved, the first generic approval occurring in June 2016. This context is not reflected in FDA's List.

Finally, with respect to Hemabate, this product was previously subject to certain restrictions on distribution (*i.e.*, it was sold only to customers with medical and surgical intensive care centers) to ensure its safe and appropriate use. This distribution approach was established by the previous NDA holder (Pharmacia) and it continued following Pfizer's acquisition of Pharmacia in 2003. Pfizer discontinued this approach in early 2018 after determining that it was no longer necessary, and this product is now available through our authorized distributors. During the time when Hemabate was under restricted distribution, it was not available at Pfizer's authorized distributors, but had a

generic manufacturer approached Pfizer's Customer Service center directly, we would have been able to address the inquiry. Pfizer's Customer Service was not able to identify any specific requests from a generic manufacturer to purchase Hemabate that have not been fulfilled.

We hope that this information explains the apparent discrepancy between Mr. Bourla's testimony and the appearance of these Pfizer products on the FDA List, and demonstrates Pfizer's diligence on these issues and commitment to a competitive marketplace.

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?

Pfizer's purpose is breakthroughs that change patients' lives; all aspects of Pfizer's business model are infused with this purpose. It is Pfizer's priority to make our medicines and vaccines available and accessible to all patients who need them, regardless of where they live.

Proposals to implement international reference pricing for the U.S. market would have far-reaching consequences to patient access, innovation and our business strategies both in the United States and in foreign countries.

If the United States were to implement the proposed International Price Indexing (IPI) model, we believe that a change of this scale could be very disruptive, challenging our ability to reach patients both inside and outside of the United States in a timely manner while fulfilling commitments to our shareholders and further investing in R&D.

- If not, then why?

Pfizer agrees that more must be done to address foreign pricing differentials. We want to continue to work with policymakers on solutions to ensure other countries appropriately recognize the value of innovation. Pfizer supports the concept of

“shared value for innovation” because it promotes global fairness. This means that all nations recognize the importance and benefits of medicines to patients and society and the significant investments required to develop them, and that all patients should benefit, no matter where they live.

If foreign countries were to increase their support for shared value for innovation, American patients would benefit based on increased innovation, drug launches, competition and more access to new medicines.

- 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?

While the IPI could lead to potential situations in which a company would ‘walk away’ as noted by John O’Brien, pricing is not the only determinant of reimbursement negotiations in foreign countries, many of which employ access controls, restricting patients’ ability to receive new innovative medicines.

We have concerns with the IPI model. The use of reference pricing is strongly associated with market and patient access delays in countries that have adopted reference pricing, among other cost-containment mechanisms. Pfizer works with governments and health systems around the world to support patients’ access to the medicines they need. We strongly believe that flexibility in our ability to set global prices improves access to medicines.

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

Pfizer believes that developed countries have an important role to play in supporting global innovation ecosystems. As such, we would encourage the United States Government to continue to elevate the innovation agenda in multilateral discussions, with an emphasis on rewarding innovation in healthcare delivery, science policy and pharmaceutical breakthroughs (*e.g.*, through the G7). U.S. trade negotiations, such as those with Japan, also provide important opportunities for the United States to secure robust commitments that ensure countries protect intellectual property, provide fair market access for U.S. companies, and appropriately recognize the value of innovation.

Pfizer also believes that there are other ways to reform the Part B payment system to move away from incentivizing the use of more costly drugs. One solution we support for reforming Part B is a Competitive Acquisition Program (CAP) to allow vendors to deliver and bill Medicare for drugs, starting in a few cities. We believe this will inject competition into the program.

Biosimilars are another solution. Pfizer is fully committed to the goals set by Congress to bring new biosimilars to market, ensuring that patients have access to a wide range of treatment options at a competitive, affordable price. The market today has already seen demonstrated savings as high as forty percent relative to the branded product. With more competition, Pfizer hopes even further savings can be realized.

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?

Pfizer agrees that more must be done to address foreign pricing differentials. Wealthy countries should reimburse innovative medicines based on fair value. As stated above, “foreign free-loading” has a significant impact on the U.S. biopharmaceutical industry’s investments in continued innovation. If the United States secures agreements that ensure countries protect intellectual property, provide fair market access for U.S. companies, and appropriately recognize the value of innovation, this will help ensure U.S. patients continue to have access to innovative medicines.

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

The U.S. health care system offers patients more choice and faster availability of innovative medicines. While government-run health systems aim to provide care to their people, they are often challenged to provide fast and easy access to the latest innovations. These governments often have to make choices between paying for healthcare and other government priorities.

The United States allows companies and providers to set prices that reflect the benefits to patients and societies. This includes ensuring that healthcare professionals and patients have choices for individualized care, that there is competition among companies, and that their expectations for access to the latest medical advances are met.

Some developed countries rely on price controls and other government regulations to set the prices of healthcare, including medicines. This may result in some lower prices but can also result in restrictions on who is eligible to receive a covered medicine. A recent op-ed in the Wall Street Journal pointed out that of the forty-five new drugs that FDA approved in 2015, all were covered by Medicare in the United States in 2017, but only 19 in France, 13 in Canada and 11 in Australia.⁴

However, prices are not always higher in the United States. Nine out of ten drugs that patients pick up at the pharmacy are generics, and these drugs are less expensive than they are in Europe, Japan, China or many countries around the world. The U.S. system is the most efficient system for delivering lower-cost generics to patients.

Pfizer supports the concept of “shared value for innovation” because it promotes global fairness. This means that all nations recognize the importance and benefits of medicines to patients and society and the significant investments required to develop them, and that all patients should benefit, no matter where they live.

If foreign countries were to increase their support for shared value for innovation, American patients would benefit based on increased innovation, drug launches, competition and more access to new medicines.

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

Pfizer believes that other governments are indeed taking note of the Administration’s focus on healthcare spending.

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

The Trump Administration recently signed the U.S.-Mexico-Canada Agreement (USMCA), which includes important commitments that will help companies like Pfizer continue to innovate to bring new therapies to patients. For example, the agreement includes a commitment to provide ten years of regulatory data protection for biologics. This commitment had not been included in any trade agreement negotiated prior to USMCA and is an important achievement. The Trump Administration is also pursuing new bilateral trade negotiations with Japan, the EU, and the UK; because the negotiations have not yet concluded, however, it is premature to comment on how those agreements may compare to other U.S. trade deals.

⁴ <https://www.wsj.com/articles/how-to-reduce-prescription-drug-prices-first-do-no-harm-11550100537>

3. **Medicaid Closed Formulary Proposals**

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

Questions for All Companies:

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

Pfizer supports efforts to ensure patients have access to medicines. Studies suggest that allowing more choice of medications has positive results for patients: lowering the chances of drug interactions and adverse events and increasing the efficacy of treatment.⁵ Years of research have also shown that limiting formularies correlates to poor medication adherence outcomes.⁶ Studies featuring Medicaid recipients with severe health conditions indicate that in many instances, these restrictions can result in negative health outcomes and other outcomes (such as increased incarceration rates) without generating program savings or other intended benefits (and sometimes increasing overall state costs).⁷

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

⁵ See, e.g., DiMasi, “Competitiveness in follow-on drug R&D: a race or imitation?” 10 Nat. Rev. Discov. 23-27 (Jan. 2011); Turner et. al, “Parsing Interindividual Drug Variability: An Emerging Role For Systems Pharmacology,” Wiley Interdiscip. Rev. Syst. Biol. Med. 221-41 (2015); Mullins et. al, “Persistence, Switching, And Discontinuation Rates Among Patients Receiving Sertraline, Paroxetine, And Citalopram,” 25 Pharmacotherapy 660-67 (2005).

⁶ See, e.g., Happe et. al, “A Systematic Literature Review Assessing The Directional Impact Of Managed Care Formulary Restrictions On Medication Adherence, Clinical Outcomes, Economic Outcomes, And Health Care Resource Utilization,” 20 Manag. Care Spec. Pharm. 677-84 (2014).

⁷ See, e.g., USC Schaffer, “Medicaid Access Restrictions on Psychiatric Drugs: Penny-Wise or Pound Foolish?” (Feb. 2015), <http://healthpolicy.usc.edu/documents/USC%20Issue%20Brief%20No.%202%20Final.pdf> (indicating increased incarceration rates associated with certain access restrictions); Lu, et. al, “Unintended Impacts of a Medicaid Prior Authorization Policy on Access to Medications for Bipolar Illness,” 48 Medical Care 4 (Jan. 2010) (finding that while a prior authorization policy in Maine Medicaid was associated with a marked decrease in rates of initiation of bipolar treatments associated with reduction in initiation of nonpreferred agents, the policy had no discernable impact on rates of switching therapy among patients currently on treatment); Farley, et al., “Retrospective Assessment of Medicaid Step-Therapy Prior Authorization Policy for Atypical Antipsychotic Medications,” 30 Clinical Therapeutics 1524 (April 2008) (showing, for a group of Medicaid patients with schizophrenia who were subject to a prior authorization policy for atypical antipsychotic medications, significant increases in per member per month outpatient expenditures far exceeded the associated savings in atypical antipsychotic expenditures).

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?

Medicaid Best Price is not a factor in setting our launch prices.

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

Pfizer encourages HHS to consider how to address the challenges that Medicaid Best Price poses for value-based agreement (VBAs). Specifically, we recommend that:

- To allow for innovative approaches and risk sharing, a poor outcome should not set a new price for Medicaid. This would allow manufacturers to share more risk with commercial health plans.
- Approaches to reporting VBAs should be as simple as possible. This would help avoid creating operational challenges for companies that may prevent development of innovative approaches.
- Manufacturers should continue to have flexibility to make reasonable assumptions in their price reporting, so that reporting approaches can evolve to reflect changes in the dynamic market and contracting environment

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?

Value based agreements (VBA) provide a framework for paying for medicines based on their value to patients and the overall healthcare system. There are many different types of VBAs including those based on clinical and/or financial performance metrics for a product. Based on the outcomes achieved, payers use this information to inform how they cover products. Products that perform better should be covered in a more favorable manner which often includes lower out-of-pocket costs for patients which is a benefit to patients in the near-term. In the long term, patients can also benefit from other savings either directly, (e.g. reducing spending on other medications, lowering medical costs from reduced hospitalizations, doctor’s visits, etc.), or indirectly through lower premiums based on reductions in total cost of care.

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

VBA's can be implemented in federal programs so that the benefits described above can accrue to the federal programs.

- What have the preliminary results looked like so far?

VBA's are in the very early stages of development in the United States. Many payers and manufacturers have tested different concepts but to date, VBA's have not achieved scale. There are multiple reasons why VBA's represent a small fraction of manufacturer/payer contracts (e.g. access to data, difficult and costly to administer, etc.). There are certain aspects of the current U.S. regulatory landscape that are perceived by many as not only complicating VBA implementation but in some cases limiting their rapid uptake. Stakeholders have frequently identified two key regulatory hurdles as limiting the expanded adoption of VBA's: i) the Anti-Kickback Statute and ii) the Medicaid Best Price calculation requirement. While these regulations serve important roles within the current volume-based reimbursement system they do not contemplate innovative value-based arrangements which has resulted in a lack of clarity on how to account for these under the current regulatory framework. Ultimately, an expansion of VBA's will require reforms to existing regulations that enable more flexibility in designing VBA's.

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?

Pfizer acknowledges that providing discounts pursuant to the safe harbor for point-of-sale price discounts will enhance transparency of net pricing strategies and potentially drive downward pressure on net prices. Nonetheless, Pfizer believes that the proposed safe harbors are good for patients and lay the groundwork for the systemic change needed to create a simpler, more cost effective, and more transparent U.S. healthcare system, and we are fully committed to operating in this new system. We are concerned, however, that plans and PBMs could impose new formulary restrictions and utilization barriers to make up for lost rebates that undermine the spirit of the rule and create new access challenges to patients. For patients to receive the benefits of the rule, we urge policymakers to ensure that no new access barriers are created as a way to compensate for lost rebate.

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

Only through such transparency can Pfizer and other industry players ensure that discounts and other price reductions directly benefit the patient, which is a critical factor driving Pfizer's support for the Proposed Rule.

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?

Wholesalers pay list price for our products. They may receive prompt pay discounts, which would reduce their net price. Wholesalers also can earn bona fide service fees based on performing services that are important to pharmaceutical manufacturers.

- What impact does this have on drug costs?

These discounts and fees are relatively consistent across products and do not significantly impact drug costs.

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

As a result of the competitive nature of their business, wholesalers do have an incentive to contain price increases.

Senator Wyden:

For All Witnesses:

Proposed Rebate Rule

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

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

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

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

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

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

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

Medicaid Drug Rebate Program

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

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

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

Medicaid Drug Rebate Program Compliance

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

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

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

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

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

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

Bonus Payments Tied to Specific Drugs

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

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

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

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

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

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

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

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

Net Prices

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

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

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

Please also specifically address the following questions:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

•2014: Detrol, Rapamune, Celebrex

•2015: Zyvox

•2016: Relpax, Tygacil

•2017: Viagra, Pristiq

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

Senator Menendez:

Pfizer CEO, Albert Bourla

During the hearing, when I asked whether your company engaged in tactics to delay generic production of your products, you answered “no”. However, Pfizer appears on the FDA’s list of companies who have access complaints against them. Can you explain the discrepancy between your answer and the FDA list? The FDA list can be found here: <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandA>

As a patient-focused company and leading manufacturer of innovative, generic, and biosimilar medicines, Pfizer supports innovation and a strong, competitive marketplace. Consistent with these values, Pfizer does not block generic manufacturers from purchasing our products, and it has never been our policy to do so. Generic manufacturers are treated the same as any other customer seeking to purchase our products. Pfizer is not aware of any current, unfulfilled requests from a generic manufacturer to purchase a Pfizer product.

Generic manufacturers seeking to purchase Pfizer products should request the product from Pfizer's authorized distributors or, if the product is not available at a distributor, from Pfizer directly, the same as any other Pfizer customers. Pfizer's website includes a list of our authorized distributors, from which customers (including generic companies) may purchase most Pfizer products. (See <https://www.pfizer.com/products/medicine-distributors>) For products that are not available via our authorized distributors and that are not in extreme drug shortage or unavailable due to a recall, customers can contact Pfizer's Customer Service center at 1-800-TRY-FIRST (1-800-879-3477) to purchase product directly from Pfizer. The telephone number for Pfizer's Customer Service center is also included on our website at <https://www.pfizer.com/contact>. Pfizer makes its products available for sale to appropriately licensed entities at Pfizer's listed price and on Pfizer's standard terms of sale. We do not have any agreements with authorized distributors that block the sale of Pfizer's products to generic manufacturers.

Regarding the FDA List (the List), while Pfizer supports FDA's (the Agency) goal of providing transparency, Pfizer is concerned that the List lacks certain key information and context and, as currently presented, may create the misleading impression that *all* products on the List are the result of bad faith attempts to block generic manufacturer access to samples. The appearance of a product on the FDA List means only that a generic manufacturer informed the Agency at some point in time that it was having difficulty purchasing the listed product. FDA's own disclaimer states that the Agency has not independently investigated or confirmed whether a generic manufacturer actually made a request to purchase product, and to whom.⁸ The FDA List also lacks several important pieces of information that would enable a New Drug Application (NDA) holder to investigate its appearance on the List. The List does not include: (1) which generic manufacturer made the request; (2) when and to whom the generic manufacturer made the request (*e.g.*, to a wholesaler, directly to the NDA holder); (3) whether the generic manufacturer that made the inquiry was thereafter able to obtain product; and (4) any reason(s) why a generic manufacturer may not have been able to obtain product (*e.g.*, a recall). Finally, Pfizer notes that FDA does not currently inform an NDA holder in real time when a generic manufacturer notifies the Agency that it is having difficulty obtaining product. Had the Agency informed Pfizer at the time it received the inquiries

8

(<https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm>)

noted on the FDA List, Pfizer could have then undertaken its own efforts to resolve the issue. Pfizer communicated its concerns about the FDA List to the Agency in May 2018. For your information we have included Pfizer's letter to FDA on this topic and the Agency's response (see Exhibits 1 and 2 in the Appendix).

There are three new drug applications owned by Pfizer on the FDA List: Embeda (NDA 022321), Tikosyn (NDA 020931) and Hemabate (NDA 017989). Embeda offers a good example of the List's shortcomings. Pfizer acquired King Pharmaceuticals (the previous NDA holder of Embeda) in March 2011, and two weeks later determined that Embeda needed to be recalled from the U.S. market due to stability issues. After diligently addressing the issues that led to the recall, Pfizer relaunched Embeda to the U.S. market in January 2015, and it is available for purchase via Pfizer's authorized distributors. However, as a consequence of the recall, Embeda was not available in the U.S. market for almost four years which may explain why a generic manufacturer had a problem obtaining it during those years. The FDA List does not specify when the generic manufacturer's inquiry regarding Embeda was made nor does the FDA List indicate that several generic applications for Embeda had been submitted to FDA in 2010 (which means that before the recall, several generic manufacturers were successfully able to purchase Embeda, conduct the necessary testing, and file Abbreviated New Drug Applications (ANDAs)). Pfizer has not identified any recent inquiries from generic manufacturers seeking to purchase Embeda that have not been fulfilled.

The circumstances around Tikosyn also illustrate the List's shortcomings. Pfizer was able to identify a single inquiry made by a generic manufacturer directly to Pfizer to purchase Tikosyn in 2014. At that time, Tikosyn was subject to an FDA imposed Risk Evaluation and Mitigation Strategies (REMS) with Elements to Assure Safe Use ("ETASU") that restricted distribution, so Pfizer responded by asking the manufacturer to obtain written confirmation from the FDA that Pfizer's provision of the product to the generic manufacturer would not be considered a violation of its REMS. The generic manufacturer did not contact Pfizer further, and Pfizer never received any written correspondence from the Agency. FDA subsequently removed the REMS for Tikosyn in 2016, and multiple generic versions of Tikosyn are now approved, the first generic approval occurring in June 2016. This context is not reflected in FDA's List.

Finally, with respect to Hemabate, this product was previously subject to certain restrictions on distribution (*i.e.*, it was sold only to customers with medical and surgical intensive care centers) to ensure its safe and appropriate use. This distribution approach was established by the previous NDA holder (Pharmacia) and it continued following Pfizer's acquisition of Pharmacia in 2003. Pfizer discontinued this approach in early 2018 after determining that it was no longer necessary, and this product is now available through our authorized distributors. During the time when Hemabate was under restricted distribution, it was not available at Pfizer's authorized distributors, but had a generic manufacturer approached Pfizer's Customer Service center directly, we would have been able to address the inquiry. Pfizer's Customer Service was not able to identify any specific requests from a generic manufacturer to purchase Hemabate that have not been fulfilled.

We hope that this information explains the apparent discrepancy between Mr. Bourla's testimony and the appearance of these Pfizer products on the FDA List, and demonstrates Pfizer's diligence on these issues and commitment to a competitive marketplace.

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?

Launch pricing is driven by a multitude of factors, the most important being the medicine's impact on patients and their health. We also may consider other factors like the medicine's potential to reduce other healthcare costs, such as hospital stays; the availability of other treatments and generic options; affordability for patients, insurers and governments; and investments to maintain the quality, safety, delivery and reliability of our medicines.

Given the consolidation that has taken place in the U.S. market, the vast majority of retail prescriptions are managed by a few large PBMs. Pharmaceutical manufacturers must successfully negotiate with these PBMs to gain access to their formularies or risk having their products disadvantaged or even excluded from coverage.

The system has evolved in a manner where rebates play a significant role in how the PBM business is transacted and in the decisions regarding product placement on formularies. PBMs often win or lose business on the basis of rebate guarantees and are therefore incentivized to favor products with high list prices and deep rebates assuming comparable safety and efficacy. Because the PBMs have enormous leverage and depend on rebates to attract and retain clients, many manufacturers will enter the market with higher list prices and deeper rebates in order to ensure patients have access to their medicines.

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

Launch pricing will be driven by product value and competitive intensity of the specific therapeutic category. Importantly, if finalized, the rule could result in lower out-of-pocket patient costs at the pharmacy counter and help address the perverse incentives in the system that have been contributing to higher list prices for medicines.

Senator Carper:

For all witnesses:

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

It is unclear if the forty percent of drugs that do not offer rebates in Medicare Part D are brand medicines or generics. However, Pfizer pledges to bring more affordable treatment options to the market. Our mid- to late-stage

pipeline contains five biosimilar candidates expected to launch in the next two to three years. Ninety percent of medicines Americans take are generics, and competition from these drugs keeps prices low in most cases. We need to bring similar competition to the biologics market, where some of the most expensive drugs exist. The market today has already seen demonstrated savings as high as forty percent relative to the branded product. With more competition, we hope even further savings can be realized

Pfizer's plan design is generous and corresponding employee cost sharing for prescription drugs is already very limited – in fact, for many products, Pfizer employees experience no cost sharing at all. Given this, the terms of contract with our PBM for our employee benefits does not include a requirement to pass on rebates to Pfizer employees at the point of sale.

- bb. 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?

Pfizer supports system-wide price transparency that is thoughtful, purpose-driven, and that can result in improved patient care, an enhanced understanding of the comparative value of all medical services, and a more patient-centered use of healthcare resources.

We would be interested in exploring with the Committee ways to ensure transparency across the health care system, including hospitals, plans, PBMs, etc., so that we can make informed judgments about the root of cost inflators in the system. We are also committed to ensuring that patients, healthcare professionals and payers understand our commitment to pricing our medicines responsibly.

Regarding a federal transparency standard, we believe that an appropriately crafted, balanced piece of federal legislation that applies to all stakeholders in the health care system and preempts future state laws could be beneficial for patients. However, Pfizer believes that mandating disclosure of research and development, manufacturing, or marketing costs to assess the value of medicines is inconsistent with purpose-driven transparency.

- cc. 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?

Patient outcomes should determine our reimbursement and Pfizer pledges that we will aggressively pursue value-based arrangements. We should not be rewarded for treatments that do not work.

Currently, Pfizer has value-based contracts for twelve drugs in our portfolio.

The agreements are in place with commercial and Medicare payers with millions of covered lives. In addition, Pfizer has a multi-product innovative agreement that has been offered to the majority of states for the Medicaid program, but currently only a small number of states comprising less than five million lives have taken or are actively considering the offer.

dd. How do these value-based contracts work to lower drug prices for both patients and taxpayers?

Value based agreements (VBA) provide a framework for manufacturers to be compensated based on a product's value to patients and the overall healthcare system. There are many different types of VBAs but the optimal structure of a VBA includes clinical and/or financial performance metrics for a product. Based on the outcomes achieved, payers use this information to inform how they cover products. Products that perform better should be covered in a more favorable manner which often includes lower out-of-pockets costs for patients which is a benefit to patients in the near-term. In the long term, patients can also benefit from other savings either directly, (e.g. reducing spending on other medications, lowering medical costs from reduced hospitalizations, doctor's visits, etc.), or indirectly through lower premiums based on reductions in total cost of care.

VBAs can be implemented in federal and state programs so that the benefits described above can accrue to the federal programs thereby benefitting taxpayers.

ee. 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?

Consistent with industry practice, Pfizer provides a sample statement of medical necessity and appeals letters through our patient support programs for patients, their caregivers and prescribing physicians to help guide these individuals in gaining access to certain Pfizer medicines after a physician has determined that a Pfizer product is right for a patient and a prescription has been written. These sample letters are generally PDF documents that describe the type of information payers require to approve access/coverage of a particular medication based upon the payers' formulary requirements, such as step therapy (therapeutic agents that must be tried first), proof of diagnosis or other common utilization management techniques that payers determine. Pfizer does not customize these letters, and patients, caregivers and physicians are advised that they are responsible for the accuracy of the information that they submit to the payer to obtain coverage and/or reimbursement. Sample letters are available from Pfizer's third-party call centers which specialize in product access triage with payers, field based reimbursement specialists and Pfizer product websites. Pfizer sales representatives do not provide this information to physicians.

- ff. 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?

Pfizer believes that some of the adverse incentives and barriers to market penetration include:

1. **The Rebate Trap:** Brand-name biologic companies are using maneuvers to block biosimilar competition such as higher rebates and exclusionary contracts.
2. **Misinformation:** Some physician and patient-directed materials created by brand companies mischaracterize biosimilars, creating doubt and confusion about the safety and efficacy of biosimilars. As defined by statute, an approved biosimilar must be highly similar to and have no clinically meaningful differences from the reference product and must have the same mechanism of action (to the extent the mechanism(s) of action of the reference product are known) as the reference product; thus, by definition, biosimilars are safe and efficacious treatments relative to the reference product and must work in the same way as the reference product. Any information disseminated by reference product sponsors to suggest or imply otherwise should be promptly addressed by FDA.

3. Need for incentives: Legislative ideas to promote biosimilar uptake could include a shared savings biosimilar model; reduced patient cost sharing for biosimilars. More detail is provided below.

Although the biosimilars market in the United States is still relatively new, our experience has been that anticompetitive conduct by brand-name biologic manufacturers, combined with the lack of policy measures to support appropriate uptake of biosimilars, have contributed to a slow uptake. Therefore, we encourage you to consider measures to help incentivize the use of biosimilars, which can substantially lower Medicare costs with demonstrated savings to date as high as nearly forty percent relative to the branded biologic.

Some key policy initiatives we believe will support the uptake of biosimilars in the United States are the following:

- **Waiver of Part B Patient Coinsurance for Biosimilars for a certain period of time:**
 - CMS should waive Part B patient coinsurance amounts for biosimilars. Cost-sharing changes could be applied at the HCPCS level. This would not change the overall payment for a biosimilar; however, it would change the beneficiary's payment percentage.
- **CMS should pursue a CMMI model** designed to increase access to biosimilars, including a "shared savings" model whereby Medicare savings associated with prescribing a biosimilar, as compared to a reference biological, would be shared with providers.
- **CMS should maintain the current biosimilar pass-through status** as this provides biosimilars with a "level playing field" with their higher priced reference biologic competitors.
- **CMS should create payment incentives for plans** by contracting with a measure developer for a biosimilar use measure for the STARS program, which would correct other adverse incentives for biosimilar uptake for Medicare Advantage plans.

Senator Cardin:

1. The United States is one of the only countries in the world to allow prescription drug manufacturers to advertise directly to consumers through magazines, billboards, radio, and television commercials. While I will not argue that it is beneficial to educate consumers about an unfamiliar disease and encourage them to seek medical help, most commercials from all of your companies recommend asking about a specific brand name drug, not a medical condition. Furthermore, even if your advertisements follow all FDA

rules and list medication side effects, they also almost always list these while a smiling, apparently healthy person is walking on a beach.

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

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

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

Pfizer wants patients to have access to our drugs and part of this is making sure patients have the information they need. Pfizer believes that direct-to-consumer (DTC) advertising should be, first and foremost, a tool through which we can provide patients with useful information to inform them about their medical conditions, and the potential benefits and risks of available treatment options so they can have a discussion with their doctors and take an active role in managing their health.

The Office of Prescription Drug Promotion at the FDA, which has responsibility for reviewing prescription drug advertising and promotional labeling to ensure that the information contained in them is not false or misleading, studies advertising so that regulations are grounded in evidence on how best to ensure ads are accurate, balanced and not misleading. The FDA's website describes in detail the many ways that its Office of Prescription Drug Promotion ensures that DTC advertising is not misleading.⁹

DTC advertising is of significant educational importance to patients, especially as the provision of health care becomes more patient-centric. Over the last two decades, consumer research sponsored by the industry and the FDA has underscored that clear, relevant communication allows DTC advertising, when executed thoughtfully, to have a positive impact on public health. For example, in 2004, a study by FDA found that "DTC ads help patients have better discussions with their physicians and provide greater awareness of treatments. The study demonstrated that when a patient asked about a specific drug, eighty-eight percent of the time they had the condition that the drug treated. And eighty percent of physicians believed their patients understood what condition the advertised drug treats."

⁹ <https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm090142.htm>

More recently, according to a 2017 survey, conducted by Princeton Survey Research Associates International on behalf of PhRMA, Americans overwhelmingly reported that DTC advertisements help inform people about new treatments (88%), alert people to symptoms that are related to a medical condition they may already have (81%), and allow people to be more involved in their health care (79%).¹⁰ Similarly, a research survey published in 2017 with 4,481 U.S. adults and sponsored by a working group of pharmaceutical companies has shown DTC advertising conveys useful information.¹¹ DTC ads raise awareness about medications and effectively communicate potential risks and benefits, but they also increase concern about potential side effects.

Pfizer believes that PhRMA, individual companies, academics and FDA should continue to study DTC advertising to ensure that pharmaceutical consumer communications are achieving their intended goals to educate, inform information-seeking consumers and facilitate better discussions with healthcare professionals.

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?

There are a number of reasons that the price of medicines can change over time. While these reasons often include more obvious changes such as discovery of new indications and new formulations, they can also include less

¹⁰ 2017 Direct to Consumer Advertising Survey Results. Presented by Princeton Survey Research Associates International, Prepared for PhRMA. <https://www.phrma.org/report/2017-direct-to-consumer-advertising-survey-results>

¹¹ DIA, Therapeutic and Regulatory Science, <https://journals.sagepub.com/doi/abs/10.1177/2168479017708226>
<https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm090276.htm#Completed>

obvious changes such as improvements in the manufacturing and supply chain and market-based factors.

Pfizer has reduced the price of many of our older off-patent medicines in the United States, and we are committed to bringing more affordable treatment options to the market to induce competition, including generic and biosimilar medicines. Competition is the best way to promote affordable access to quality, safe and effective medicines; competition means more and better medicines, more options for patients, and more affordable drugs.

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?

No. On the contrary, when Pfizer settles patent litigation with generic firms, we do so on terms that generally enable entry of generic competition earlier than the expiration of its patents and that do not involve unlawful reverse payments. Pfizer’s patent settlements thus involve lawful compromises that appropriately resolve patent disputes and accelerate patient access to lower cost generics relative to the expiration of its patents. While Pfizer has been the target of plaintiff lawyer driven class action lawsuits challenging certain of its settlements with generic companies, we believe these lawsuits are without merit and are vigorously asserting the pro-competitive nature of these settlements in court.

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

Pfizer does not enter into these types of settlements and cannot speculate on why others might.

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

Pfizer's patent settlements do not "stifle competition" or "prevent generic alternatives." On the contrary, when Pfizer settles patent litigation with generic firms, it does so on terms that generally enable entry of generic competition earlier than the expiration of its patents and that do not involve unlawful reverse payments. Pfizer's patent settlements thus involve lawful compromises that accelerate patient access to lower cost generics relative to the expiration of its patents.

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?

If finalized, the rule could result in lower out-of-pocket patient costs at the pharmacy counter and help address the perverse incentives in the system that have been contributing to higher list prices for medicines. In 2019, Pfizer expects to pay billions of dollars in rebates to ensure patients with pharmacy benefits coverage in Medicare Part D and patients in commercial plans have access to our medicines. If the proposed rule to share rebates with consumers at the point of sale is finalized, we estimate that seniors taking Pfizer medicines could save \$270

on average per year, and up to \$574 per year for certain Pfizer medicines, through lower cost sharing.

Importantly, we believe any reform should apply to all market segments as this could also lead to further reduction in list prices. A bifurcated market in which we eliminate rebates in government programs but maintain rebates for commercial plans will make it difficult for manufacturers to reduce list prices because a single list price applies to all markets.

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 order to fulfill Pfizer's mission to create breakthrough medicines that change patients' lives, we invest in several areas to ensure an innovative pipeline, top-quality manufacturing, and education of patients and physicians to ensure they have the information they need to make knowledgeable decisions about patient care.

In 2018, Pfizer spent approximately \$6.9 billion on direct sales and marketing and approximately \$8 billion on research and development globally.

Biosimilars/Rebate Traps

In many of your testimonies, you mention that encouraging the development of generics and biosimilars will help bring down the cost of drugs. However, while 17 biosimilars are now approved in the US, only 7 are actually on the market and available to patients. There are growing concerns about rebate traps, which are ways of gaming the system to ensure a biosimilar is not able to enter the market.

- 1. Dr. Bourla:** In your testimony, you mention "Adverse incentives that favor higher cost originator biologics are keeping biosimilars from reaching patients. In many cases, payers decline to include lower cost biosimilars or generics in their formularies because they would risk losing the rebates they can get by covering higher cost medicines." Your company has filed lawsuits challenging rebate traps as antitrust violations. **What do you think should be done about these rebate practices?**

Anticompetitive conduct should be stopped through government enforcement of the antitrust laws and in the courts. Brand-name biologic companies should not be permitted to abuse the rebate system to effectively block lower-cost biosimilars from coverage

For more details, see Pfizer's Exhibit 4 attached.

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?**

We are unable to answer this question as it requires analysis under the antitrust laws.

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

At Pfizer, we are committed to our purpose: breakthroughs that change patients' lives. Pfizer's more than 90,000 colleagues around the world come to work every day focused not only on creating breakthrough medicines, but also on making sure those medicines get into the hands of the patients who need them.

The launch prices for our medicines reflect the value that they bring to patients and society. The relationship between the price of a medicine and a patient's out-of-pocket cost is not always clear. Out-of-pocket costs continue to rise due to insurance designs that place a disproportionate burden on consumers who use medicines than other interventions. Consumers on average pay fifteen percent of medicine costs but only two percent of hospitalization and other healthcare costs. We encourage Congress to continue its efforts to understand the complexity of the pricing and reimbursement system in the United States, and to identify ways in which patient out-of-pocket expenditures can be reduced.

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?**

Pfizer is committed to working toward greater transparency along the supply chain, so patients can better understand what they are paying for and why. We believe pricing transparency policies should seek to inform consumers about the costs of healthcare items and services across the industry and should promote a definition of value that considers impact to health and costs over time and across all industry stakeholders.

Pfizer believes that the proposed safe harbors lay the groundwork for the systemic change needed to create a simpler, more cost effective, and more transparent U.S. healthcare system, and we are committed to operating in this new system.

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 required to lower the list price of any of your drugs?**

As long as rebate reform extends to both the commercial market and government programs, there could be a reduction in list prices. The commercial market covers more than fifty percent of Americans with insurance, and the safe harbor will not affect it at all. However, in Medicare, the rebate rule will make list prices less relevant because the entire rebate will be converted to a point of sale discount so that patient out-of-pocket costs, when they are in the deductible, coinsurance, and coverage gap phases of the benefit, will be based off the lower net price. If we ensure that rebates paid out to commercial plans find their way to patients, the patients will see savings of hundreds of dollars.

PBMs

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

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

Yes, we contract with a PBM to administer our prescription drug benefits and we work with them to establish criteria for negotiating lower drug costs on our employees’ 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 lowering premiums?

Pfizer's medical and prescription drug coverage is generous in terms of what we subsidize as an employer; therefore we work to ensure that our employees benefit from our investment in our workforce and any savings in the form of affordable plan premiums and substantially lower cost sharing responsibilities for prescription drugs.

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?

Pfizer's plan design is generous and corresponding employee cost sharing responsibility for prescription drugs is already very limited – in fact, for many products, Pfizer employees experience no cost sharing at all. Given this, the terms of contract with our PBM for our employee benefits does not include a requirement to pass on rebates to Pfizer employees at the point of sale.

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.

Pfizer would support legislation that reforms the current system of rebating to one in which payers are required to use manufacturer provided discounts to ensure that the patient gets the benefit of the discount at the point of sale. We support this reform across all segments of the market where private sector negotiations result in lower net prices including Medicare Part D, Medicaid managed care and the commercial markets. It is important to understand that even if rebates are prohibited, manufacturers will still negotiate discounts with plans consistent with safe harbors in exchange for formulary access, though those discounts will be reflected in lowered drug prices at the pharmacy counter rather than retrospective payments benefitting plans or their PBM instead of the beneficiaries who are underwriting premiums for others.

To ensure these benefits reach patients, it will be important for Congress and the Administration to ensure that plans do not create new barriers or restrictions that hinder patient access and undermine the spirit of the rule.

2. How much does your company's research and development portfolio rely on taxpayer-funded research conducted by the National Institutes of Health (NIH)?

The biopharmaceutical industry is one of the most research-intensive industries in the United States. In 2017, NIH had a budget of \$39.2 billion, only a fraction of which, \$3.2 billion, was dedicated to drug discovery. The industry invested over \$90 billion in R&D—almost 30 times more. For Pfizer alone, we invested approximately \$8 billion in R&D last year.

NIH's strength is its focus on important basic scientific research and the industry does derive important insights from basic scientific research conducted by NIH-funded researchers and scientists worldwide. There is, however, a large gap between understanding basic scientific principles and the discovery, development, and delivery of medicines to patients. For example, the initial NIH-funded basic science discovery of cell division and cell signaling proteins in yeast led researchers to identify similar proteins in humans. This early research later informed the thinking of Pfizer scientists and helped pave the way for the discovery and development of targeted cancer drugs like palbociclib a new treatment for breast cancer.¹

The discovery of cell division in yeast is a long way from discovering and developing a drug that prevents cancer tumors from growing. As stated above, the government plays a role in advancing basic science such as identifying cellular pathways underlying disease. However, the ability to translate knowledge about biological processes into a medicine or vaccine, with appropriate drug-like properties and a clinically meaningful benefit, remains the primary function of the biopharmaceutical industry. The drug discovery and development process involves harnessing existing knowledge of underlying disease biology to chart and execute a research agenda that often encompasses ten to fifteen years of discovery research, preclinical testing, clinical development (for dosing, safety, and efficacy) and pharmaceutical science to ensure the quality of the compound to be delivered. Disciplines like medicinal chemistry, process and formulation chemistry and formulation, drug metabolism, pharmacokinetics and safety sciences are practiced at a scale and expertise in the biopharmaceutical industry that extends well beyond government and academic research endeavors to deliver life-savings therapies for patients.

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?

We have not identified readily available information in response to this request that is maintained in the ordinary course of business. We would need to discuss the scope and terms of this question with your staff to respond appropriately.

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 order to fulfill Pfizer's mission to create breakthrough medicines that change patients' lives, we invest in several areas to ensure an innovative pipeline, top-quality manufacturing, and education of patients and physicians to ensure they have the information they need to make knowledgeable decisions about patient care.

Over the last five years, Pfizer spent approximately \$34 billion on advertising and marketing and approximately \$40 billion on R&D globally. Advertising and marketing expenses include advertising, promotion and field selling.

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?

The size of any list price reductions relative to the size of rebates Pfizer is currently providing would depend on all components of the final rule and how the point of sale discount model that replaces rebates will function.

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

At Pfizer, we are committed to our purpose: breakthroughs that change patients' lives. Pfizer's more than 90,000 colleagues around the world come to work every day focused not only on creating breakthrough medicines, but also on making sure those medicines get into the hands of the patients who need them.

Launch pricing is driven by a multitude of factors, the most important being the medicine's impact on patients and their health. We also may consider other factors like the medicine's potential to reduce other healthcare costs, such as hospital stays; the availability of other treatments and generic options; affordability for patients, insurers and governments; and investments to maintain the quality, safety, delivery and reliability of our medicines.

- 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?

Because there is no specific requirement for plans and PBMs to shift away from negotiating contracted rebates in the commercial market, it is possible that a bifurcated market, with the same perverse incentives and the same mechanism to drive list prices higher, will result. If reform does extend to the commercial marketplace, it could result in lowering of list prices. However, we cannot speculate on the amounts until we see the specifics of the rule and the changes that are made to the supply chain.

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.¹²

¹²MACPAC: 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>

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?

Pfizer has a number of Authorized Generics (AGs) arrangements, both with affiliates and non-affiliates. CMS's Medicaid Covered Outpatient Drugs Final Rule, 81 Fed. Reg. 5170 (Feb. 1, 2016) (the "Final Rule") included an extensive discussion of when a primary manufacturer should include or exclude sales of AGs to secondary manufacturers in its average manufacturer price (AMP). Pfizer has developed reasonable assumptions that it believes are consistent with the guidance CMS set forth in the Final Rule for purposes of determining when to include or exclude sales of AGs in its AMP calculation. Pfizer disclosed its assumptions with respect to its approach both in written correspondence and in an onsite meeting with CMS representatives. In addition, Pfizer disclosed its assumptions to the OIG in response to a January 2018 survey.

Senator Cortez Masto:

1. *Question to Dr. Bourla, Pfizer*

According to public filings, in 2015 Pfizer collected US revenues that were more than double the amount you invested in R&D.¹ Is this still true - do you collect more in revenue in the US alone than you invest in R&D?

The biopharmaceutical industry is one of the most research-intensive industries in the United States. In 2017, NIH had a budget of \$39.2 billion, only a fraction of which, \$3.2 billion, was dedicated to drug discovery. The industry invested over \$90 billion in R&D—almost 30 times more. For Pfizer alone, we invested approximately \$8 billion in R&D last year.

Pfizer's number one priority is always the care of our patients, and we are proud of the investments Pfizer makes to insure we continue to bring new, innovative cures to patients. These responsibilities require investments in R&D, manufacturing and other areas to accomplish our mission of creating breakthrough medicines that change people's lives.

In 2018, Pfizer spent approximately \$20 billion on global R&D and manufacturing. This includes investing in state-of-the-art labs so we can attract the finest scientists in the world and continuing to invest in innovative, high-tech manufacturing to ensure the high quality of our products.

Pfizer's revenues in the United States in 2018 totaled approximately \$25 billion.

2. *Questions to all witnesses*

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

Approximately one third of Pfizer's revenue comes from products that are not Medicare Part D eligible. This product group includes generics, vaccines, and physician administered products. Of the remaining two thirds of our revenue, 92 percent comes from products that offer Medicare Part D or commercial rebates. The remaining 8 percent is from products that have lost patent exclusivity, have generic alternatives, and offer no rebates. It is not possible to determine at this time whether that portion will increase because rebating on future products will be based on numerous factors, including product value and the competitive intensity of the therapeutic area. For products that do not rebate, there are additional deductions from sales such as prompt payment fees and distribution service fees resulting in the net price being lower than list price.

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

The biopharmaceutical industry is one of the most research-intensive industries in the United States. In 2017, NIH had a budget of \$39.2 billion, only a fraction of which, \$3.2 billion, was dedicated to drug discovery. The industry invested over \$90 billion in R&D—almost 30 times more. For Pfizer alone, we invested approximately \$8 billion in R&D last year.

Pfizer's number one priority is always the care of our patients, and we are proud of the investments Pfizer makes to insure we continue to bring new, innovative cures to patients. These responsibilities require investments in R&D, manufacturing and other areas to accomplish our mission of creating breakthrough medicines that change people's lives.

In 2018, Pfizer's revenues in the United States totaled approximately \$25 billion and Pfizer spent approximately \$20 billion on global R&D and manufacturing. This includes investing in state-of-the-art labs so we can attract the finest scientists in the world and continuing to invest in innovative, high-tech manufacturing to ensure the high quality of our products.

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 order to fulfill Pfizer's mission to create breakthrough medicines that change patients' lives, we invest in several areas to ensure an innovative pipeline, top-quality manufacturing, and education of patients and physicians to ensure they have the information they need to make knowledgeable decisions about patient care.

In 2018, Pfizer spent approximately \$14 billion on selling, informational and administrative expenses and approximately \$8 billion on R&D. Selling, informational and administrative costs are expensed as incurred. Among other things, these expenses include the internal and external costs of marketing, advertising, shipping and handling, information technology and legal defense.

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 order to fulfill Pfizer's mission to create breakthrough medicines that change patients' lives, we invest in several areas to ensure an innovative pipeline, top-quality manufacturing, and education of patients and physicians to ensure they have the information they need to make knowledgeable decisions about patient care.

In 2018, Pfizer spent approximately \$6.9 billion on direct sales & marketing and approximately \$8 billion on R&D globally. Direct sales and marketing expenses include, among other things: direct promotion or sale of the company's products.

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

Pfizer believes that direct-to-consumer (DTC) advertising should be, first and foremost, a tool through which we can provide patients with useful information about their medical conditions, the availability of treatments and the potential benefits and risks of available treatment options so they can have a discussion with their doctors and take an active role in managing their health. Research has confirmed that this communication channel delivers on this goal.¹³

We may consider several factors when making decisions about our consumer communications. Some of these may include the information needs of patients who might benefit from one of our medicines and/or the extent to which a health condition is un- and under-diagnosed and treated.

¹³ See 2017 Direct to Consumer Advertising Survey Results. Presented by Princeton Survey Research Associates International, Prepared for PhRMA, <https://www.phrma.org/report/2017-direct-to-consumer-advertising-survey-results>; DIA, Therapeutic and Regulatory Science, <https://journals.sagepub.com/doi/abs/10.1177/2168479017708226>; <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm090276.htm#Completed>



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May 30, 2018

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Scott Gottlieb, M.D.
Commissioner
Food and Drug Administration
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Re: Reference Listed Drug (RLD) Access Inquiries Website and NDA 022321 for Embeda (morphine sulfate; naltrexone hydrochloride) Extended-Release Capsules; NDA 017989 for Hemabate (carboprost tromethamine) Injection; and NDA 020931 for Tikosyn (dofetilide) Capsules

Dear Dr. Gottlieb:

We write in reference to the newly posted page on the FDA website entitled "Reference Listed Drug (RLD) Access Inquiries."¹ We note that several new drug applications (NDAs) owned by Pfizer Inc. or wholly-owned subsidiaries of Pfizer (collectively, "Pfizer") are included in the list published on this site ("List"):

1. Embeda (morphine sulfate; naltrexone hydrochloride), NDA 022321;
2. Hemabate (carboprost tromethamine), NDA 017989; and
3. Tikosyn (dofetilide), NDA 020931.

We write to the Agency for several reasons. First, we wish to inform the Agency about Pfizer's internal practice for handling drug purchasing inquiries from prospective generic applicants, as well as provide some context for why the Agency may have received inquiries about these particular products, and Pfizer's diligence in addressing these issues. We believe that this information demonstrates Pfizer's commitment to supporting innovation and a competitive marketplace. Second, we wish to provide our suggestions on additional, non-confidential information to add to the List in order to provide context critical to understanding the List and its value. Additionally, we wish to express our concerns that the Agency's announcement surrounding the new webpage and how the information is currently presented

¹<https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm>.

implies that the companies listed have engaged in “gaming” or anti-competitive behavior, which is untrue with respect to Pfizer, and not supported by the facts currently included in the List.

Pfizer was surprised and disappointed to discover that FDA had been informed by prospective generic applicants that they had difficulty obtaining some of our products to conduct the testing necessary to support submission of an abbreviated new drug application (ANDA). However, we note that the Agency included a disclaimer on the webpage stating that “[w]e note that FDA has not independently investigated or confirmed the access limitations described in the inquiries received.”² As discussed in more detail below, without having any additional information about these inquiries, Pfizer is unable to confirm whether those inquiries were made to Pfizer, and if so, whether they were handled in accordance with Pfizer’s practice to make its drug products available to applicants for purchase.

Following publication of the List, Pfizer conducted internal due diligence to identify whether Pfizer was contacted by prospective generic applicants for the listed products, and whether Pfizer was able to provide those customers with the requested drug product. By way of background, our standard approach is to ensure that drug product is available to licensed generic manufacturers at the listed price and on Pfizer’s standard terms of sale.³ The vast majority of Pfizer’s products are available through traditional wholesale channels (i.e., available through one or more of Pfizer’s authorized distributors). If Pfizer receives an inquiry about a product that is available at wholesale, Pfizer will refer a prospective buyer to a publicly-available list of its authorized distributors, and indicate that the prospective buyer should obtain product from an authorized distributor on that list. For the limited number of products that are not available at wholesale, requests made to Pfizer by a generic manufacturer wishing to purchase drug samples should be fulfilled in accordance with Pfizer’s standard practice. If such requests involve a product with a REMS that restricts distribution, Pfizer’s position is that a Safety Determination Letter (SDL) needs to be provided prior to sale. Pfizer developed an internal process to handle such requests in early 2015, upon realizing that such requests come into Pfizer via multiple departments and colleagues.

Tikosyn

The List indicated that the Agency had received four inquiries regarding Tikosyn. To the best of its knowledge, Pfizer is aware of only one request for Tikosyn from a prospective generic applicant. At the time of that request, Tikosyn was approved with a REMS with elements to assure safe use (ETASU) that restricted distribution. When contacted by the applicant, Pfizer requested that the applicant provide us with written confirmation from the Agency that Pfizer’s sale of the product to the applicant would not be considered a violation of our REMS. The applicant did not contact Pfizer further and Pfizer never received any written correspondence from the Agency. The Agency removed the REMS in 2016, and Pfizer notes that the Access Inquiries Webpage indicates that FDA never issued any SDLs for this drug product.

We note despite the inquiries submitted to the Agency identified in the List, ANDAs have been submitted and approved for the drug product. There are three approved ANDAs for the drug product, with the first approved on June 6, 2016,⁴ and two additional ANDAs approved in 2018.⁵ Additionally, the Agency’s

²<https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm>.

³ If a drug product is in critical short supply, Pfizer will ship products to fulfill orders for dispensing to patients before fulfilling orders for product for testing.

⁴ ANDA 207058, see

https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=207058, accessed May 23, 2018.

⁵ ANDA 208625, see

https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=208625, accessed May 23, 2018; ANDA 207746, see

paragraph IV certification list indicates that the first ANDA containing a paragraph IV certification was submitted on May 1, 2014, when the REMS was still in place.⁶ This additional information indicates that applicants were able to obtain product, submit ANDAs, and obtain approval from the approval even while the REMS was in place.

As the REMS has been removed by the Agency, Pfizer now makes Tikosyn available at wholesale through its authorized distributors.

Embeda

The List indicated that the Agency received one inquiry regarding Embeda. We note that despite the inquiry submitted to the Agency, ANDAs containing a paragraph IV certification were submitted to the Agency for Embeda from May 3, 2010, through May 28, 2010, covering five of the six approved strengths of Embeda.⁷ Pfizer acquired King Pharmaceuticals (and with it, Embeda) on March 1, 2011. Two weeks later, Pfizer recalled Embeda from the market due to stability issues with the product. Pfizer spent the next several years diligently addressing the issues that led to the recall, and Pfizer was able to re-launch the product in January 2015. However, as a result of these issues, from March 2011 through January 2015, there was no Embeda product available for sale in the U.S. market.

Pfizer was not able to identify any request from a generic applicant to purchase Embeda. Embeda is now available at wholesale through Pfizer's authorized distributors.

Hemabate

Finally, the List indicated that FDA had received one inquiry for Hemabate, an older drug owned by Pharmacia and Upjohn Co., which was acquired by Pfizer in 2003. Pharmacia, and later Pfizer, limited Hemabate distribution to customers with medical and surgical intensive care facilities to help ensure the drug product was used in accordance with the product's labeling. While this limited distribution may have prevented a prospective generic applicant from acquiring the drug product from a wholesaler, it would not have prevented an applicant from contacting Pfizer directly to buy the drug product. Pfizer ceased the limited distribution of Hemabate to ensure patients and healthcare professionals had appropriate access to the drug product. The product is now available at wholesale through Pfizer's authorized distributors since January 2018. Pfizer was not able to identify any request from a generic applicant to purchase Hemabate.

Proposed Revisions to the List

We encourage the Agency, in accordance with its goal “[t]o help address this issue and to provide transparency regarding these inquiries,”⁸ to add further information to the List. The information Pfizer suggests the Agency include will provide critical context to help clarify to the stakeholders involved, i.e., the American public, the United States Government, and industry, whether an NDA holder may be preventing generic applicants from obtaining the drug products necessary to support submission of an ANDA. Without this information, stakeholders may come away with the false impression that every

https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=A&Appl_No=207746, accessed May 23, 2018.

⁶ See

<https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM293268.pdf>.

⁷ See

<https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM293268.pdf>.

⁸<https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm>.

company on the List has impeded access, as demonstrated by the news coverage of the List and FDA's statements.⁹

We recommend that the List include:

- The date the inquiry was made to FDA, and if furnished by the prospective generic applicant, the date(s) the applicant attempted to acquire the drug product and failed;
- If available, whether the prospective generic applicant directly approached the NDA holder or manufacturer, and was unable to obtain product that way;
- The identity of the NDA holder at the time the inquiry was made;
- Whether there are approved generic products for the drug product, and when those were approved;
- Whether and when an applicant submitted an ANDA with paragraph IV certification; and
- Whether a particular inquiry for a product with a REMS with ETASU restricting distribution included a protocol, and whether the Agency issued an SDL relating to that inquiry.

While the Agency includes a disclaimer on the Access Inquiries Webpage that it has not investigated or confirmed the access limitations described in the inquiries it received,¹⁰ the Agency's statements, both on its website and in public statements, strongly suggest that the Agency endorses the claim that access to biosamples was blocked for all products on the list. In reality, however, the only certain fact about the inquiries on the List is that a prospective applicant complained to FDA that it was unable to obtain the drug product. Neither Pfizer nor the FDA knows whether that is in fact the case, or, if it is, whether there are reasons the applicant did not obtain product that are not the result of "gaming" or anti-competitive tactics by NDA holders. For example, the drug may not be available due to a drug shortage, recall (as in the case of Embeda), or because the generic applicant did not actually try all avenues to obtain the drug product, such as contacting the NDA holder or manufacturer directly.

Including this additional information in the List will shed light on the reasons the generic applicant may have been unable to obtain the drug product, as well as indicate whether generic applicants were able to obtain the drug product, despite the inquiries received by FDA. For example, knowing the dates the inquiries were made could indicate whether the requests came during a time when the drug product was not being marketed, as in a recall situation, or when a REMS with ETASU that restricted distribution was in place that may have triggered the need for a review of the prospective generic applicant's protocol. And, knowing those dates will help industry perform its own due diligence to identify whether a request for drug product was inappropriately denied. Likewise, noting whether the prospective generic applicant stated whether it contacted the NDA holder or manufacturer will indicate whether the applicant reached out to a party that could provide the drug product, and will assist a company in determining whether its policy on providing drug product, such as Pfizer's, was appropriately followed.

Additionally, providing the identity of the NDA holder at the time of the inquiry will help clarify whether the company that currently owns the NDA could potentially be responsible for the failure to provide drug product, or whether that failure, if any, could be attributable to the prior holder of the NDA. For example, without knowing when the inquiry was made or who the NDA holder was at the time of the inquiry,

⁹ See, e.g., Sara Koblitz, *FDA's Version of the Scarlet Letter*, FDA Law Blog (May 23, 2018), <http://www.fdalawblog.net/2018/05/fdas-version-of-the-scarlett-letter/>; Sheila Kaplan, *F.D.A. Names and Shames Drug Makers to Encourage Generic Competition*, The New York Times (May 17, 2018), <https://www.nytimes.com/2018/05/17/health/drug-prices-generics-fda.html>; Sy Mukherjee, *The FDA Is Naming and Shaming Companies Accused of Blocking Cheap Generic Drugs*, Fortune (May 17, 2018), <http://fortune.com/2018/05/17/fda-database-generic-drug-delays/>.

¹⁰ <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm>.

Pfizer cannot tell for two of its products on the List (Embeda and Hemabate) whether those inquiries came before or after Pfizer's acquisition of the companies that originally owned those products. Accordingly, Pfizer cannot adequately respond to allegations that it may have inappropriately restricted access to its drug products.

Including the dates of generic entry would also demonstrate to stakeholders whether generic competition was impeded, or if in fact, one or more generic applicants were able to obtain the product needed in order to obtain approval from the Agency. While we recognize that the Agency may be unable to identify who made the inquiry to FDA, even if that applicant has an ANDA approved later, to the extent that information can be provided, it would demonstrate whether a particular generic applicant was blocked from obtaining product.

Additionally, providing more information related to products with REMS that restrict distribution, e.g., whether an applicant has submitted a protocol to the Agency, and whether a particular inquiry on the List correlates to the issuance of an SDL, will also indicate whether the generic applicant who made the inquiry provided its protocol to the Agency, and whether the Agency determined that the protocol contained safety protections comparable to the REMS. Currently, there is no indication as to whether an applicant who complained about not having access to such drug product took appropriate steps to facilitate its access to the product when there was such a REMS in place for the drug product.

Finally, we also note that the Agency does not inform an NDA holder in real time when an applicant has had difficulty obtaining product. Given Pfizer's policy to provide drug product when requested, if the Agency had informed Pfizer that it had received such an inquiry on a specific date, Pfizer could have then undertaken its own efforts to resolve the issue.

We appreciate the Agency's consideration of the issues raised in this letter, and reiterate our commitment to competition and innovation in the biopharmaceutical industry.

Sincerely,



Peter Honig, M.D., M.P.H.
Senior Vice President, Worldwide Safety and Regulatory

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July 19, 2018

Peter Honig, M.D., M.P.H.,
Senior Vice President, Worldwide Safety and Regulatory
Pfizer Inc.
Email: Peter.Honig@pfizer.com

Dear Dr. Honig:

Thank you for your letter of May 30, 2018, regarding FDA's Reference Listed Drug (RLD) Access Inquiries web page. Your letter informs FDA about Pfizer's internal practice for handling inquiries about samples from prospective generic applicants, provides suggestions about additional information to add to the RLD Access Inquiries web page, and expresses concern about the Agency's announcement surrounding the web page (Letter at 1-2). The Commissioner referred your letter to the Center for Drug Evaluation and Research (CDER) for response.

1. Pfizer's internal practice for handling drug purchasing inquiries from prospective generic applicants

Your letter provides a synopsis of Pfizer's internal practices for handling the inquiries that it receives related to RLD access to its products and the circumstances surrounding the Pfizer products that appear on the RLD Access Inquiries web page (Letter at 2-3). We appreciate the insight provided by Pfizer on its internal processes. As you are aware, inclusion on the list of products on the RLD Access Inquiries web page signifies that FDA has received an RLD access inquiry related to limited distribution of the product. As we state on the web page, FDA has not independently investigated or confirmed the access limitations as described in the inquiries received.

You also state that FDA "does not inform an NDA holder in real time when an applicant has had difficulty obtaining product" and that "if [FDA] had informed Pfizer that it had received such an inquiry on a specific date, Pfizer could have then undertaken its own efforts to resolve the issue." As the web page explains (and as also described in the draft guidance for industry *How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD* (How to Obtain a Letter Guidance)), FDA does notify certain RLD sponsors, after the prospective generic applicant has provided appropriate disclosure authorization to the Agency. However, to the extent that Pfizer has a process for prospective generic applicants to obtain samples, we encourage Pfizer to consider making that process public to help ensure both that interested developers know what process to use, and that Pfizer has access to as much information as possible about any access issues.



2. Suggestions for additional information Pfizer believes FDA should add to the RLD Access Inquiries web page

Your letter also contains a list of six points of information Pfizer recommends be added to the RLD Access web page (Letter at 4):

1. The date the inquiry was made to FDA, and (if furnished by the prospective generic applicant), the date(s) the applicant attempted to acquire the product and failed;
2. If available, whether the prospective generic applicant directly approached the NDA holder or manufacturer, and was unable to obtain product that way;
3. The identity of the NDA holder at the time the inquiry was made;
4. Whether there are approved generic products for the drug product, and when those were approved;
5. Whether and when an applicant submitted an ANDA with a paragraph IV certification; and
6. Whether a particular inquiry for a product with a REMS with ETASU impacting distribution included a protocol, and whether the Agency issued a Safety Determination Letter (SDL) relating to that inquiry.

We note that two of these items (“[t]he identity of the NDA holder at the time the inquiry was made,” and “whether the Agency issued a [Safety Determination Letter] relating to [an] inquiry”) are already included on the RLD Access Inquiries web page. The web page identifies the RLD sponsor associated with each inquiry, and clarifies that this is the RLD sponsor that was listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book) at the time FDA received the inquiry (see footnote on the chart of inquiries). The web page also identifies whether FDA issued a Safety Determination Letter in connection with a particular RLD access inquiry (and explains that receipt of such a letter is preceded by FDA’s review of bioequivalence study protocols to assess whether they contain safety protections comparable to those in the applicable REMS for the RLD).

Two of the other points of information (“[w]hether there are approved generic products for the drug product, and when those were approved” and “[w]hether an applicant submitted an ANDA with a paragraph IV certification”) are already publicly available on FDA’s web site (via the Orange Book or Drugs@FDA and the Paragraph IV Certifications List, respectively).¹ For the remaining points of information, to the extent FDA has access to the information you describe, we will take your feedback (along with feedback from other stakeholders) into account as we

¹ See <https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm>, <https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm> and <https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/UCM293268.pdf>, respectively.



consider whether any changes to the RLD Access Inquiries web page should be made in order to best address and improve transparency about this topic.

3. Concerns relating to the Agency's announcement surrounding the RLD Access Inquiries web page

Your letter also indicates that FDA's presentation of information about this topic "strongly suggest that the Agency endorses the claim that access to biosamples was blocked for all products on the list" (Letter at 4). As you note, however, the RLD Access web page makes clear that FDA has not independently investigated or confirmed the access limitations described in the inquiries the Agency received. The web page is one effort under the FDA's Drug Competition Action Plan to provide transparency about the potential impact of this important issue. If generic companies are unable to purchase the samples they need to support their applications, this slows down, or entirely impedes, the generic drug development process – leading to delays in bringing affordable generic alternatives to patients in need. FDA is committed to advancing policies to help bring more competition to the prescription drug market, and we will continue to consider how we can best advance this goal, including whether any changes to the RLD Access Inquiries web page should be made. We appreciate your feedback on this issue.

Thank you again for contacting us.

Sincerely,

Janet Woodcock, M.D.

Director

Center for Drug Evaluation and Research

PFIZER FOUNDATION GRANT SUMMARY

2015 – 2018

TOTAL: \$45,877,000

GLOBAL HEALTH PROGRAMMING

NOTE: This report includes information for recipient both U.S. and ex-U.S. recipient organizations. Certain Pfizer Foundation grants to non-U.S. grantees are facilitated through U.S.-based donor-advised funds that specialize in vetting and processing grants to non-U.S. grant recipients.

IMPROVING HEALTHCARE DELIVERY AND LOCAL INNOVATION

DATE BOARD APPROVED	PARTNER	DESCRIPTION	AMOUNT
November 2015	Swasth Foundation, Afya Research, Jacaranda Heath, Northstar Alliance, Penda Health, World Health Partners, Clinicas del Azucar, Saluno, APOPO, Ayzh, Last Mile Health, LifeNet International, One Family Health, Operation ASHA and Sevamob	Global Health Innovation Grants support organizations that are advancing innovative health models in low and middle income countries. The goal of this portfolio is to improve healthcare delivery for underserved populations and support local innovation in key countries: India, Kenya, Mozambique, Mexico, Tanzania, India, Liberia, Uganda, Rwanda, and South Africa. The grants support projects that align to the Foundation's 4 strategic elements: primary healthcare delivery, women and children's health, health technologies for low resource settings and innovative financing mechanisms. The Foundation supported \$100,000 grants to fifteen organizations in 10 countries.	1,500,000
December 2016	Swasth Foundation, Afya Research, Jacaranda Heath, Northstar Alliance, Penda Health, World Health Partners, Clinicas del Azucar, Saluno, Ayzh, Last Mile Health, LifeNet International, One Family Health, Operation ASHA and Sevamob, Purple Source, Unjani, AccuHealth, Bive, Salud Cercana, 2020MicroClinic	SECOND CYCLE: The Foundation supported \$100,000 grants to twenty organizations in 10 countries.	2,000,000
March 2018	Swasth Foundation, Afya Research, Jacaranda Heath, Northstar Alliance, World Health Partners, Clinicas del Azucar, Saluno, Ayzh, Last Mile Health, LifeNet International, One Family Health, Operation	THIRD CYCLE: The Foundation supported \$100,000 grants to twenty organizations in 12 countries.	2,000,000

	ASHA and Sevamob, Purple Source, Unjani, Bive, 2020MicroClinic, MUSO, Possible, UE Life Sciences		
March 2018	Acumen	The Foundation provided catalytic funding to Acumen America, an early-stage philanthropic venture fund that invests in companies that are improving the lives of low-income Americans and advancing innovative solutions to issues of poverty in America. Through this grant, Acumen will grow its portfolio of health investments that transform services for the poor in the US, including programs that will increase access to care, including lowering the financial and time burden of health and wellness on low-income individuals, improve quality of care to make care more effective, and improve patient experience of care to drive patient engagement & adherence. Portfolio companies include approaches to use technology to address and reduce health disparities for underserved and multicultural populations.	500,000

IMPACT INVESTING CATALYTIC GRANTS

DATE BOARD APPROVED	PARTNER	DESCRIPTION	AMOUNT
July 2015	PharmAccess	The Foundation provided a grant to support the development and roll out of PharmAccess' innovative healthcare financing, funding which will help scale PharmAccess's mobile health (mHealth) wallet, a mobile health payment platform linked to M-Pesa in Kenya. The goal of the Foundation's grant is to support user roll-out of the platform and increase the number of people who use the platform, demonstrating its usability and collecting data. The Foundation's grant will target 100,000 low income, urban mothers who will be enrolled and receive a financial subsidy through the mHealth wallet to pay for healthcare services and products for their children under 5 years old.	1,500,000
July 2015	PATH	The Foundation provided a grant to support the expansion of PATH's Global Health Innovation Hub in South Africa, in partnership with the South Africa Medical Research Council. The Hub's mission is to accelerate access to the most promising technology innovations by building the capacity of local innovators to develop, manufacture, and deploy global health technologies for vulnerable groups, leveraging PATH's expertise and network in global health and product development. The grant will support activities to build and accelerate local innovations and identify and prioritize local technologies that can deliver global health impact.	350,000

July 2015	UNITUS	The Foundation provided a grant to support the expansion of 'StartHealth', a health technology jump-starter designed to accelerate the pace of development of bottom of the pyramid focused health-tech startups in India	650,000
July 2015	Global Partnerships	The Foundation provided a grant to this impact investment fund, which focuses on providing products and services using market based approaches in Latin America. This includes efforts to pilot and validate high potential health modes for last mile and underserved populations, with a focus on woman and children.	500,000

SUPPORT INNOVATIVE APPROACHES TO ENHANCING NON-COMMUNICABLE DISEASE CARE

DATE BOARD APPROVED	PARTNER	DESCRIPTION	AMOUNT
November 2015	FHI360	The Foundation provided a grant to support the 'Suc Khoe Doi Dao' project that will establish a community-based, integrated NCD prevention and control program in Vietnam.	1,000,000
November 2015	George Institute of Global Health	This partnership will pilot implementation of a novel primary care platform to support communities and healthcare providers in the prevention and management of NCDs in Indonesia and India.	1,000,000
April 2016	PATH	As part of Pfizer Foundation's work to advance oncology care, the Foundation provided support to PATH in Peru to reduce the growing burden of illness and death from breast cancer for underserved populations through early detection linked to service and treatment.	500,000
April 2016	Susan G Komen Breast Cancer Foundation	As part of Pfizer Foundation's work to advance oncology care, the Foundation provided support to Susan G Komen Breast Cancer Foundation in Northeast Brazil to integrate breast cancer patient support, early detection and timely/quality diagnosis into existing primary care services with the goal of improving health access and delivery for underserved women.	500,000
April 2016	Partners in Health	As part of Pfizer Foundation's work to advance oncology care, the Foundation provided support to Partners in Health to increase accessibility of treatment for breast cancer for underserved patients and document and disseminate lessons learned to inform cancer care in Rwanda.	500,000
April 2016	Indiana University Center for Global Health	As part of Pfizer Foundation's work to advance oncology care, the Foundation partnered with AMPATH, through the Indiana University Center for Global Health, to improve breast cancer services for underserved women in Kenya including screening, early diagnosis, treatment and palliative and survivorship care.	500,000
April 2017	FHI360	The Foundation provided additional funding of the 'Abundant Health' project to support routine prevention, screening and management of hypertension and diabetes care in five commune health stations in Tan Phu district in Ho Chi Minh City, Vietnam.	300,000
April 2017	PATH	The Foundation provided additional funding of the 'Community Based Program for	350,000

		Breast Health' project in Peru.	
August 2018	FHI360	The Foundation provided additional funding/phase two of the 'Abundant Health' project to support routine prevention, screening and management of hypertension (HTN) and diabetes (DM) care at the community level.	437,000
August 2018	PATH	The Foundation provided additional funding of the 'Community Based Program for Breast Health' project in Peru.	230,000
August 2018	Indiana University Center for Global Health	The Foundation provided additional funding to AMPATH, through the Indiana University Center for Global Health, to improve breast cancer services for underserved women in Kenya including screening, early diagnosis, treatment and palliative and survivorship care.	250,000
August 2018	George Washington American Cancer Institute	The Foundation additional funding to help improve health outcomes and reduce health disparities for African-American, Latina and LGBT women	150,000

PROVIDING CRITICAL SUPPORT FOR PRESSING US PUBLIC HEALTH NEEDS

DATE BOARD APPROVED	PARTNER	DESCRIPTION	AMOUNT
April 2016	American Cancer Society	As part of Pfizer Foundation's work to advance oncology care, the Foundation partnered with the American Cancer Society in Los Angeles, California and Hamptons Roads, Virginia to develop a patient navigation model that links community health advisors with federally-qualified health center (FQHC) screening and in-hospital navigation.	1,000,000
April 2016	George Washington American Cancer Institute	As part of Pfizer Foundation's work to advance oncology care, the Foundation provided support to George Washington University Cancer Institute to help improve health outcomes and reduce health disparities for African-America, Latina and LGBT women.	1,000,000
December 2017	West Virginia Department of Health and Human Resources	The Foundation provided a grant to support opioid addiction prevention and education programming in West Virginia	500,000
December 2017	New Hampshire Department of Education	The Foundation provided a grant to support opioid addiction prevention and education programming in New Hampshire	500,000
December 2017	Office of Drug Control Policy	The Foundation provided a grant to support opioid addiction prevention and education programming in Kentucky	500,000
December 2017	New Mexico Department of Health	The Foundation provided a grant to support opioid addiction prevention and education programming in New Mexico	500,000
December 2017	Utah Department of Health	The Foundation provided a grant to support opioid addiction prevention and education programming in Utah	500,000

December 2017	Commonwealth of Massachusetts Department of Public Health	The Foundation provided a grant to support opioid addiction prevention and education programming in Massachusetts	500,000
December 2017	Rhode Island Department of Health	The Foundation provided a grant to support opioid addiction prevention and education programming in Rhode Island	500,000
December 2017	Foundation for Appalachian Ohio	The Foundation provided a grant to support opioid addiction prevention and education programming in Ohio	500,000
December 2017	Department of Public Health	The Foundation provided a grant to support opioid addiction prevention and education programming in CT	500,000
December 2017	Delaware Health and Social Services	The Foundation provided a grant to support opioid addiction prevention and education programming in Delaware	500,000

ADDRESSING KEY BARRIERS FOR WOMEN AND CHILDREN

DATE BOARD APPROVED	PARTNER	DESCRIPTION	AMOUNT
July 2015	Save the Children	The Foundation provided a grant to support a pilot program offering an integrated approach to delivering immunization and family planning services. The grant supported development of materials and tools for healthcare workers to engage women on family planning services, including formal evaluation.	500,000
November 2015	CARE	The Foundation provided a grant to support increased access to family planning and immunization in Benin by integrating both services into comprehensive delivery and strengthening of clinical skills and outreach	1,000,000
November 2015	FHI360	The Foundation provided a grant to support to develop a global monitoring and evaluation framework to assess task shifting in the delivery of family planning products and demonstrate the effectiveness and safety of using Community Health Workers to administer products.	1,000,000
November 2015	IRC	The Foundation provided a grant to support increased access to family planning and immunization in Ethiopia and Uganda by integrating both services into comprehensive delivery and male engagement. The project focused on last mile and hard to reach communities.	1,200,000

November 2015	PSI	The Foundation provided a grant to support increased access to and demand for contraception and reproductive health services in Uganda for women and adolescent girls	1,000,000
November 2015	US Fund for UNICEF	The Foundation provided a grant to support expanding national mobile health platforms that improve immunization coverage and delivery in Indonesia, Laos and Uganda in partnership with MOH.	1,000,000
November 2015	World Vision	The Foundation provided a grant to support increased access to family planning and immunization in Kenya by integrating both services into comprehensive delivery, community mobilization and male engagement.	1,000,000
August 2016	World Vision	The Foundation partnered with World Vision in Zimbabwe to identify gaps in immunization coverage for children, adolescents and adults and support efforts to develop a life course approach to immunization with the Ministry of Health. The focus of the project was to increase access to and use of basic childhood immunizations for children from birth to age 5, and HPV immunization for girls as well as maternal immunizations for pregnant women. In addition World Vision worked with the Ministry of Health to address adult immunization needs, barriers and gaps in community service. Activities included training village health workers, health facility staff and community and faith leaders to educate and mobilize their communities around immunization and promote vaccination. This project also supported the development of a national life course approach.	1,000,000
August 2016	US Fund for UNICEF	The Foundation provided a grant to help UNICEF improve immunization coverage in urban underserved communities in Asia (Cambodia, Myanmar, Mongolia and the Philippines), and to support UNICEF in conducting operational research to assess the feasibility of using current newborn immunization delivery programs to support life course immunization strategies and reach female populations with additional immunizations and reproductive health services. A centerpiece of this work is supporting the roll out of technology platforms that track immunization coverage and population registries.	1,000,000
August 2016	UN FOUNDATION	The Foundation partnered with the UN Foundation's Shot@Life program to pilot a life course immunization approach with a focus on rubella. Activities include the development of culturally specific local communication materials on the importance of vaccination and answering concerns parents may have about immunization and life-long impacts, as well as an integrated marketing program featuring social media, digital assets and a U.S based media campaign.	1,000,000
April 2017	IRC	The Foundation provided additional funding to existing programs in Uganda and	800,000

		Ethiopia to advance integrated immunization and family planning program.	
April 2017	Save the Children	The Foundation provided additional funding to existing programs in Malawi to advance integrated immunization and family planning program.	250,000
July 2017	CARE	The Foundation provided additional funding to an existing program in Benin to advance integrated immunization and family planning program.	250,000
July 2017	World Vision	The Foundation provided additional funding to an existing program in Kenya focused on integrated immunization and family planning.	300,000
March 2018	CARE	The Foundation provided additional funding to support work in Benin, where mortality of mothers and children is high. The project works in 20 public health clinics to increase the uptake of two life saving interventions, childhood vaccinations and family planning, through integration of the two services. The project addresses two main challenges at the same time: a weak healthcare system and sociocultural barriers in the community, which both need to be overcome for women and children to have access to quality health services.	1,000,000
March 2018	IRC	The Foundation provided additional funding to permit the IRC to expand their work with health partners in Ethiopia and Uganda to increase the use of immunization and family planning by reaching women with information and services at a critical time – the 12 months following birth.	1,500,000
March 2018	Save the Children	The Foundation provided additional funding to an existing program in Malawi to advance integrated immunization and family planning program with Save the Children.	1,000,000
March 2018	World Vision	The Foundation provided funding for the second phase of this project, Increasing Use of Family Planning (FP) and Immunization Services in Kenya.	1,000,000

DISASTER RELIEF RESPONSE

DATE BOARD APPROVED	PARTNER	DESCRIPTION	AMOUNT
April 2015	American Red Cross	Cyclone Pam	10,000
June 2016	American Red Cross	West Virginia relief efforts	25,000
June 2016	American Red Cross	Ecuador Earthquake	75,000
June 2016	International Medical Corp	Ecuador Earthquake	75,000
Sept-Oct 2016	American Red Cross	West Virginia relief efforts	25,000
Sept-Oct 2016	American Red Cross	Ecuador Earthquake	75,000
Sept-Oct 2016	International Medical Corp	Ecuador Earthquake	75,000
Sept-Oct 2016	American Red Cross	Louisiana flooding	25,000
Sept-Oct 2016	Direct Relief International	Louisiana flooding	25,000
Sept-Oct 2016	One SC Fund	Hurricane Matthew in SC	50,000
Sept-Oct 2016	Direct Relief International	Hurricane Matthew in the US	50,000

Sept-Oct 2016	Project Hope	Hurricane Matthew in Haiti	50,000
Sept-Oct 2016	World Vision	Hurricane Matthew in Haiti	50,000
Sept-Oct 2016	PSI	Zika virus relief efforts	100,000
Sept-Oct 2016	The CDC Foundation	Zika virus relief efforts	500,000
Sept-Oct 2016	The CDC Foundation	Zika virus relief efforts	500,000
Sept-Oct 2016	PAHO Foundation	Zika virus relief efforts	1,000,000
Sept-Oct 2016	Florida State Dept of Health	Zika virus relief efforts	1,000,000
Sept-Oct 2016	Texas Dept of Health	Zika virus relief efforts	1,000,000
December 2016	American Red Cross	Louisiana flooding	25,000
December 2016	Pinebelt Foundation	Mississippi flooding	25,000
December 2016	American Red Cross	Peru and Colombia mudslide	100,000
December 2016	UNICEF	Peru and Colombia mudslide	100,000
Sept-Oct 2017	Americares	Hurricane Harvey - TX and LA	125,000
Sept-Oct 2017	World Vision	Hurricane Harvey - TX and LA	125,000
Sept-Oct 2017	American Red Cross	Hurricane Harvey - TX and LA	250,000
Sept-Oct 2017	One America Appeal	Hurricane Irma - TX and FL	500,000
Sept-Oct 2017	American Red Cross	Hurricane Irma - Puerto Rico/US Virgin Islands	400,000
Sept-Oct 2017	IFRC	Hurricane Irma - Caribbean	100,000
Sept-Oct 2017	American Red Cross	Hurricane Maria - Puerto Rico	250,000
Sept-Oct 2017	American Red Cross	Mexico Earthquake	250,000
Sept-Oct 2017	UNICEF	Mexico Earthquake	250,000
Sept-Oct 2018	American Red Cross	California Wildfires	50,000
Sept-Oct 2018	United Way of North Carolina	Hurricane Florence	100,000
Sept-Oct 2018	Central Carolina Community Foundation	Hurricane Florence	100,000
Sept-Oct 2018	International Medical Corp	Hurricane Florence	200,000
Sept-Oct 2018	American Red Cross	Hurricane Florence	100,000
Sept-Oct 2018	International Medical Corp	Hurricane Michael	100,000
Sept-Oct 2018	Florida Disaster Fund	Hurricane Michael	100,000
Sept-Oct 2018	Save the Children	Indonesia Tsunami	100,000
Sept-Oct 2018	Direct Relief International	Indonesia Tsunami	100,000
Sept-Oct 2018	World Vision	Indonesia Tsunami	100,000
Sept-Oct 2018	Physicians for a Healthy California	California Wildfires	100,000

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA**

PFIZER INC.,

Plaintiff,

v.

JOHNSON & JOHNSON and JANSSEN
BIOTECH, INC.,

Defendants.

Case No.

JURY TRIAL DEMANDED

COMPLAINT

TABLE OF CONTENTS

	<u>Page</u>
Preliminary Statement.....	1
The Parties	9
Jurisdiction, Venue, and Interstate Commerce	10
Factual and Regulatory Background.....	11
A. Biologics.....	11
B. Congress Enacts the Biologics Price Competition and Innovation Act to Spur Price Competition for Biologic Medications.....	11
C. Infliximab	14
D. J&J’s Remicade.....	15
E. Pfizer’s Inflectra.....	15
F. The Importance of Insurance Coverage for Infliximab.....	17
G. The Importance of Access at the Provider Level	19
J&J’s Exclusionary Scheme.....	20
A. J&J Bars Access to Insurer Reimbursement Through Improper Exclusive Contracts and Anticompetitive Bundling Practices	21
1. J&J’s Exclusive Contracts with Health Insurers.....	21
2. J&J’s Bundling Tactics with Health Insurers	26
B. J&J’s Improper Insurer-Level Contracts Deter Hospitals and Clinics from Purchasing Inflectra, Thus Amplifying Foreclosure.....	28
C. J&J Has Further Barred Access Through Exclusionary Contracts with Providers	31
J&J Has Monopoly Power in the Relevant Markets.....	32
J&J’s Conduct Has Stifled Competition in the Relevant Markets, Thereby Maintaining and Enhancing its Monopoly Power and Injuring Pfizer.....	41
Claims for Relief.....	43
First Claim for Relief.....	43
Second Claim for Relief.....	44
Third Claim for Relief	45
Fourth Claim for Relief.....	47
Prayer for Relief.....	48
Jury Trial Demanded.....	49

For its Complaint, plaintiff Pfizer Inc. (“Pfizer”) alleges against defendants Johnson & Johnson and Janssen Biotech, Inc. (collectively, “J&J”), as follows:

PRELIMINARY STATEMENT

1. It is accepted national policy to promote price competition among pharmaceutical manufacturers after an originator firm’s patent protection has expired. This policy extends to biologics, a unique category of medications that are derived from living organisms. As one lawmaker put it when adopting applicable legislation, such competition “is good for patient safety, consumer choice . . . and the healthcare system at large.” This case is about J&J’s efforts to suppress that competition and deprive society of those benefits by, among other things, imposing a web of exclusionary contracts on both health insurers and healthcare providers (e.g., hospitals and clinics) to maintain its stranglehold in respect of an important biologic, brand named Remicade, also known by its generic name, infliximab.

2. For many patients suffering from chronic diseases such as rheumatoid arthritis, plaque psoriasis, and Crohn’s disease, the best—and sometimes the only—option for treatment is infusion therapy with infliximab. As these conditions are chronic in nature, patients often require long-term treatment and multiple infusions per year.

3. J&J owned patents protecting infliximab and has been amply rewarded for its invention: Between 1998 and 2016, Remicade was the only infliximab product on the market. This position allowed Remicade to become J&J’s best-selling drug by far, generating about \$4.8 billion in U.S. sales in 2016 alone. In fact, Remicade is among the best selling drugs in the world. For most uses, at list price Remicade sells for about \$4,000 per infused dose and about \$26,000 for a full year of treatment. When Pfizer introduced its competing biologic Inflectra (infliximab-dyyb) in 2016, J&J deployed improper exclusionary tactics to maintain the dominance of its flagship product.

4. Inflectra received marketing approval under the Biologics Price Competition and Innovation Act (“BPCIA”). Congress recognized the growing importance of biologics, as well as the growing costs associated with them, and passed the BPCIA in 2010. The purpose of the BPCIA, as its name suggests, is to foster meaningful price competition for long-entrenched branded biologic products—with the ultimate goal of lowering healthcare costs. To facilitate price competition, the BPCIA provides an abbreviated FDA approval pathway for “biosimilar” versions of branded biologic drugs. Biosimilars are products that the FDA has determined to have “no clinically meaningful differences” from the already approved biologic (sometimes referred to as the “reference listed drug” or “RLD”) in terms of safety, purity, and potency. Although the BPCIA was enacted in 2010, FDA procedures for implementing the Act did not become effective until a few years later, and biosimilars are only recently beginning to come onto the market, with the first biosimilar approval in 2015.

5. On April 5, 2016, Inflectra received FDA approval as the first biosimilar to Remicade. Pfizer began shipping Inflectra in November 2016 and set its initial list price, often referred to as the wholesale acquisition cost (or “WAC”), at 15 percent below the then-current WAC of Remicade.¹

6. The threat from Inflectra did not go unnoticed by J&J. Within weeks of Inflectra’s launch, J&J began to deploy what it publicly has termed its “Biosimilar Readiness Plan.” The core features of the plan are exclusionary contracts that foreclose Pfizer’s access to an overwhelming share of consumers, coupled with anticompetitive bundling and coercive rebate policies designed to block both insurers from reimbursing, and hospitals and clinics from purchasing, Inflectra or other biosimilars of Remicade despite their lower pricing.

¹ WAC is the manufacturer’s published list price to wholesalers or direct purchasers, not including prompt pay or other discounts, rebates, or reductions in price.

7. J&J's actions with respect to Remicade exclude competition at multiple levels:

8. *Exclusive contracts with insurance company payers.* Insurer decisions regarding reimbursement policies have a dramatic impact on which infliximab product will be stocked by healthcare providers such as hospitals and clinics. Because providers administer infliximab on site (it is an infusion product), they must use their own funds to stock the product, purchasing it for later use and relying upon subsequent reimbursement from insurers to recoup their expenses. Given the cost of biologic drugs generally, and Remicade in particular, there is almost no chance that providers will pay for a product that is not widely covered by insurers for fear of stocking a product that will not be reimbursed after the provider administers it to a patient, as even a single unreimbursed dose may cost the provider in excess of \$4,000.

- Recognizing this, J&J has induced insurers to enter into contracts that require an explicit commitment not to cover Inflectra at all or to do so only in the rarest of circumstances—in effect, to make Remicade the only covered infliximab. As a direct result of these exclusive dealing contractual commitments, Inflectra is either not listed on the insurance company's medical policy—a published listing of the drugs approved for reimbursement under the insurer's medical benefit—or is designated reimbursable only in so-called “fail first” cases. The “fail first” exception, which requires that Remicade has been tried by and failed with respect to a given patient before a biosimilar infliximab can be reimbursed, is medically inappropriate and illusory in practice. If Remicade, which is an infliximab product, does not work for a patient, a physician would turn to a non-infliximab drug, not to Inflectra, which also is an infliximab product and has no clinically meaningful differences from Remicade. The spurious nature of J&J's “fail first” restriction is illustrated by the fact that in early 2017, before J&J's contracts

took hold, the major insurers listed Inflectra at parity with Remicade—indicating that they saw no medical reason to favor one over the other.

- J&J’s “fail first” contractual restrictions therefore have the same practical effect as pure exclusive contracts: both operate to exclude Inflectra from qualifying for reimbursement under the insurers’ plans; both prevent the insurer from freely reimbursing for Inflectra or another biosimilar without breaching the contracts; and both foreclose Inflectra from competing for patients covered by those plans. J&J has entered into such contracts with all or nearly all national health insurance companies. These “biosimilar-exclusion” contracts, on their own, have foreclosed Inflectra’s ability to vie for at least *70 percent* of commercially insured patients in the United States, including a significant number of commercially insured patients who reside in the Philadelphia area. But the foreclosure effects of those insurer contracts go well beyond the immediate impact on patients covered by the affected plans, as discussed below.

9. ***Exclusionary rebates and bundling arrangements with insurance company payers.*** A key to J&J’s ability to coerce insurers into accepting its exclusionary commitments is its denial of rebates to insurers that decline J&J’s exclusivity commitments, thereby imposing a substantial financial penalty. In effect, J&J says to insurers, “If you want to receive attractive rebates on Remicade for all your existing Remicade patients”—rebates which, for some insurers, run into the tens of millions of dollars annually—“you must agree to not reimburse for Inflectra, or to do so in the most limited of circumstances.” In short, insurers that decline J&J’s offer face a substantial financial penalty, and those that accept receive a payoff (multimillion dollar rebate payments) in return for their commitment to exclude biosimilars.

- J&J’s threatened financial penalty is effective because there is a substantial base of patients across the country who are already controlling their diseases with Remicade and thus

are unlikely to switch to a lower-priced biosimilar once available. Although biosimilars have no clinically meaningful differences in safety, purity, and potency from the biologic originator, they are not substitutable without the prescriber's approval (unlike generics for non-biologic drugs approved under the Hatch-Waxman structure, which are substitutable without a new prescription). And, although the FDA's approval permits physicians to switch from the originator to the biosimilar, and Pfizer believes they should consider doing so in appropriate circumstances, as a practical matter, existing-patient Remicade demand is economically incontestable, that is, not a realistic candidate for biosimilar firms to compete for. As the head of J&J's pharmaceuticals business told investors, "the 70% of patients who are [already] stable on Remicade are highly unlikely to switch."² J&J bundles this economically "incontestable" demand for Remicade with the portion of demand that is "contestable" for biosimilar firms—new patients starting therapy with infliximab—by threatening to deny rebates on *all* Remicade prescriptions if *any* infliximab biosimilar prescriptions are reimbursed, effectively meaning insurers would have to forfeit their rebates and pay J&J's ever increasing price for the incontestable patients.

- J&J also bundles rebates on multiple *different* products, such that insurers that refuse to grant exclusivity to Remicade would be forced to pay higher prices and/or forego enhanced portfolio rebates. The net effect of these anticompetitive bundling practices is that the insurers subject to them have no real choice but to agree to J&J's exclusivity conditions. Insurers have made it clear to Pfizer that its net cost for Inflectra would need to be low enough to offset the loss of J&J rebates. Pfizer and other biosimilar firms cannot feasibly make up the difference for the J&J rebates (on the existing Remicade patient base) that insurers would lose if

² Johnson & Johnson, Q3 2016 Results Earnings Call Transcript (Oct. 14, 2016), available at <https://seekingalpha.com/search/transcripts?term=johnson+%26+Johnson+biosimilar>.

they declined J&J's conditions. Insurers have stated a desire to support biosimilars—and the lower per-unit prices they bring—but realistically cannot do so without incurring a substantial financial penalty imposed by J&J and thus potentially placing themselves at a disadvantage relative to insurers accepting J&J's rebates.

10. ***J&J-engineered coverage restrictions impact provider purchasing behavior and thus magnify foreclosure.*** The foreclosure created by J&J's exclusionary insurer-level contracts goes well beyond the patients covered by these health insurers: Inflectra's coverage status has a spillover effect on the purchasing decisions of healthcare providers (as noted, the clinics, hospitals, and other institutions that purchase and administer infliximab) as well as the prescribing decisions of physicians affiliated therewith. Given the widespread gaps in Inflectra's insurance coverage—engineered by J&J—providers have overwhelmingly chosen to stock *only* Remicade (which is essentially universally covered given its long tenure and dominant position) rather than deal with the risk of possible denials of coverage for Inflectra. Thus, providers have declined to purchase Inflectra across the board, even for patients covered by insurance plans that *do* cover the product. To take one example, even though Inflectra is covered by Medicare and other government programs, providers have been unwilling to stock Inflectra even for potential use with such government-insured patients. As a result, not only is the federal government forced to continue reimbursing for Remicade, the more expensive product, but the effective foreclosure of biosimilars is expanded well beyond the 70 percent of commercially insured patients directly foreclosed by J&J's insurer contracts. Indeed, as of September 1, 2017, about *90 percent* of healthcare provider accounts using infliximab had purchased *no Inflectra at all*. J&J has stoked providers' reluctance to purchase Inflectra by touting with providers the very lack of coverage for Inflectra created by J&J's own exclusionary contracts.

11. *Exclusionary rebates and bundling arrangements with healthcare providers.*

Beyond the spillover impact described above, J&J has also extended its practices of multi-product bundling and bundling of contestable and incontestable demand in contracts with healthcare providers.

12. J&J's exclusionary plan has been remarkably effective at stifling competition: Today, almost no national commercial health insurer provides coverage for Inflectra (except under the spurious "fail first" scenario), and the vast bulk of healthcare provider accounts using infliximab (approximately 90 percent) have not purchased Inflectra at all. Despite some coverage by regional and government plans, Inflectra has secured *less than 4 percent* of total infliximab unit sales in the U.S. as of September 1, 2017.

13. The harm to Pfizer and to competition as a whole—and, ultimately, to consumers, businesses, and the U.S. government, who bear the brunt of rising healthcare costs nationwide—is manifest. In response to a new entrant offering lower prices for a product deemed to have "no clinically meaningful differences" from the incumbent's brand, basic economics would predict that market-wide prices would fall. Instead, the opposite has occurred. Since the time the FDA approved Inflectra and J&J implemented its publicly-stated plan to block biosimilars like Inflectra, J&J has *raised* the list price of Remicade by close to 9 percent and increased the amount the U.S. government reimburses for Remicade by more than \$190 per infused dose. J&J's list price increases are not overcome by increased rebates and discounts: Remicade's "average selling price" ("ASP")—which by federal law is an average of a drug's pricing after taking into account discounts, rebates, and other price concessions—actually has *increased* since Inflectra's entry. As of September 2017, Remicade's ASP was more than 10 percent higher than Inflectra's ASP. Pfizer has offered to guarantee clients that Inflectra would be less expensive

unit-for-unit than Remicade during a contract term. Despite Inflectra's lower per-unit prices, and J&J's escalating prices, Remicade has not lost any substantial volume or share of sales to Inflectra, even though FDA determined there to be no clinically meaningful differences between the two products.

14. In July, J&J extolled the success of its scheme, noting that it had not "seen much of an impact" from Inflectra's entrance, and that J&J is "especially well-prepared to manage through the Remicade biosimilars."³ J&J also said it was confident that it could fend off even subsequent biosimilar entrants this year because of its exclusionary contracts: "[W]e have our contracting in place with all the managed care organizations [e.g., health insurers]."⁴ The net result is that patients (along with healthcare providers and the U.S. government) have fewer choices and pay more than they should.

15. Major stakeholders at every level of the healthcare marketplace are suffering as a result of J&J's competition-reducing actions:

- Most importantly, consumers suffer in the form of artificially inflated prices (including higher coinsurance payments, insurance premiums, and taxes), as well as reduced choice.
- Government programs, including Medicare—and ultimately taxpayers—suffer by having to pay artificially higher prices for the vast majority of their infliximab utilization.
- Pfizer, of course, suffers loss of sales, investment, and reputation as a result of J&J's success in securing commitments to disadvantage Inflectra.

16. Pfizer brings this action under the antitrust laws of the United States to challenge J&J's anticompetitive conduct. If J&J's conduct is allowed to continue, its "Biosimilar

³ Johnson & Johnson, Q2 2017 Results Earnings Call Transcript (July 18, 2017), available at <https://seekingalpha.com/search/transcripts?term=johnson+%26+Johnson+biosimilar>.

⁴ *Id.*

Readiness Plan” will become the playbook for biologic originator firms seeking to preserve their dominance in the face of biosimilar competition—thus subverting the competition-enhancing objectives of the BPCIA.

17. Allegations relating to Pfizer’s conduct are based on personal knowledge; other allegations are based on Pfizer’s research, publicly available sources, feedback from customers, and information and belief.

THE PARTIES

18. Plaintiff Pfizer is a corporation organized and existing under the laws of Delaware. Pfizer’s principal place of business in the United States is located at 235 East 42nd Street, New York, New York 10017. Pfizer is a research-based international pharmaceutical company which researches, develops, manufactures, and sells pharmaceutical products across the spectrum, from branded innovator products to generics and over-the-counter medications. Pfizer is also committed to developing biosimilar medications to bring competition, lower prices, and choice to patients.

19. Pfizer has commercialized Inflectra, a biosimilar to J&J’s Remicade, through its partnership with Celltrion, the holder of the drug product’s Biologics License Application. The FDA approved Inflectra as a biosimilar to Remicade on April 5, 2016.

20. Defendant Johnson & Johnson is a corporation organized and existing under the laws of New Jersey. Johnson & Johnson’s principal place of business in the United States is located at One J&J Plaza, New Brunswick, New Jersey 08933. Johnson & Johnson is an international pharmaceutical company—one of the largest in the world—and was the sole supplier of infliximab, marketed as Remicade, between 1998 and 2016, when Inflectra came to market.

21. Defendant Janssen Biotech, Inc. (“Janssen”) is a wholly owned subsidiary of Johnson & Johnson. Janssen is a corporation organized and existing under the laws of Pennsylvania. Janssen’s corporate headquarters are located at 800 Ridgeview Drive, Horsham, Pennsylvania 19044. Janssen co-owns or has licenses to the Remicade patents and performs the marketing for Remicade in the United States.

JURISDICTION, VENUE, AND INTERSTATE COMMERCE

22. This action arises under the antitrust laws of the United States, including Section 1 of the Sherman Act, 15 U.S.C. § 1, Section 2 of the Sherman Act, 15 U.S.C. § 2, Section 3 of the Clayton Act, 15 U.S.C. § 14, and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26.

23. Subject matter jurisdiction is founded on 28 U.S.C. §§ 1331 and 1337(a).

24. Johnson & Johnson may be found, transacts business, and is subject to personal jurisdiction in this judicial district.

25. Janssen may be found, transacts business, and is subject to personal jurisdiction in this judicial district.

26. The violations of law alleged in this Complaint took place, in part, in this judicial district and have injured Pfizer in this district. Venue is therefore appropriate in the Eastern District of Pennsylvania under Section 12 of the Clayton Act, 15 U.S.C. § 22, and under 28 U.S.C. §§ 1391(b) and (c).

27. The creation, marketing, sale, and distribution of Remicade and Inflectra, and the actions complained of in this Complaint, occur in and substantially affect interstate commerce.

FACTUAL AND REGULATORY BACKGROUND

A. Biologics

28. Biologics are treatments derived from living systems such as microorganisms or plant or animal cells. As the FDA explains: “Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. Biologics can be composed of sugars, proteins, or nucleic acids or complex combinations of these substances, or may be living entities such as cells and tissues. Biologics are isolated from a variety of natural sources—human, animal, or microorganism—and may be produced by biotechnology methods and other cutting-edge technologies. Gene-based and cellular biologics, for example, often are at the forefront of biomedical research, and may be used to treat a variety of medical conditions for which no other treatments are available.”⁵ In contrast to most drugs, which are chemically synthesized and whose structure is known, most biologics are complex mixtures that are not easily identified or characterized.⁶

B. Congress Enacts the Biologics Price Competition and Innovation Act to Spur Price Competition for Biologic Medications

29. Congress has made clear that competition in pharmaceuticals is to be encouraged, and, to that end, in 1984 enacted the Hatch-Waxman Act (“Hatch-Waxman”), which established an abbreviated pathway for approval of generic counterparts to non-biologic branded drug products. Before Hatch-Waxman, a generic applicant had to conduct the same kinds of safety and efficacy studies (including large clinical trials and the like) as the originating drug manufacturer. Such a process, which can cost hundreds of millions of dollars and take years to

⁵ See U.S. Food & Drug Administration, *What Are “Biologics” Questions and Answers*, <https://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cber/ucm133077.htm> (last visited Sept. 18, 2017).

⁶ *Id.*

complete, was prohibitive for would-be generic entrants and led to the near absence of generic competition to branded drug products. Hatch-Waxman eliminated this hurdle; it allowed generic firms to rely upon the originator's safety and efficacy studies. Generic applicants need only show that their products use the same active pharmaceutical ingredient as the originator, and that their products are bioequivalent (e.g., that the generic product's uptake into the body is equivalent to the branded drug). A principal goal of Hatch-Waxman was to trigger price competition with originator products, many of which had enjoyed longstanding exclusivity. That goal has been achieved: According to the FDA, the competition spurred by Hatch-Waxman has saved *more than \$1.6 trillion* for patients and the healthcare system.⁷

30. However, for a number of reasons, biologic products generally are not covered by the Hatch-Waxman procedures. Nevertheless, given the success of Hatch-Waxman in spurring competition for non-biologic medicines, Congress and nearly all stakeholders in the healthcare system have recognized the great desirability of having an analogous system for biologics.⁸

31. In 2009, Congress addressed the need for competition in the biologics marketplace by introducing the BPCIA, which was signed into law in 2010. The Act furthers the "FDA's longstanding policy of permitting appropriate reliance on what is already known about a drug, thereby saving time and resources and avoiding unnecessary duplication of . . . testing."⁹

⁷ See Kathleen "Cook" Uhl, *2016: A Record-Setting Year for Generic Drugs*, U.S. Food & Drug Administration (Feb. 24, 2017), available at <https://blogs.fda.gov/fdavoices/index.php/2017/02/2016-a-record-setting-year-for-generic-drugs/> (noting that "2016 was a record-setting year for FDA's generic drug program," and that "[o]ver the last 10 years, generic drugs have saved the U.S. healthcare system about \$1.68 trillion").

⁸ See U.S. Food & Drug Administration, *Implementation of the Biologics Price Competition and Innovation Act of 2009* (Feb. 12, 2016), available at <https://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/ucm215089.htm> ("The goal of the BPCI Act is similar, in concept, to that of the Drug Price Competition and Patent Term Restoration Act of 1984 (a.k.a. the 'Hatch-Waxman Act') which created abbreviated pathways for the approval of drug products under Federal Food, Drug, and Cosmetic Act (FFD&C Act).").

⁹ U.S. Food & Drug Administration, *Implementation of the Biologics Competition and Innovation Act of*

32. A principal purpose of the Act—as reflected in its very name (i.e., the Biologics *Price Competition* and Innovation Act)—was to spur price competition in biologic drug products:

- “We have to find a way to introduce competition into [the biosimilar] market,” including balancing “giving incentives for development of new products but bringing about the benefits of competition in the marketplace.” (Hon. Henry Waxman, United States Representative from California)
- “Legislation to facilitate the development of biosimilars should promote competition and lower prices[.]” (Hon. Anna G. Eshoo, United States Representative from California)
- “We want to foster a robust biosimilar market.” (Hon. Joe Barton, United States Representative from Texas)
- “[C]ompetition [from biosimilars] is good for patient safety, consumer choice, and drive[s] savings for consumers and the healthcare system at large.” (Hon. Gene Green, United States Representative from Texas)

33. The BPCIA provides an abbreviated regulatory approval pathway for the introduction of biosimilars. A biosimilar applicant may rely on the clinical studies of the reference listed drug if it can show: (a) that the proposed biosimilar is “highly similar to the [originator product, or RLD] notwithstanding minor differences in clinically inactive components”; and (b) that “there are no clinically meaningful differences between the [proposed biosimilar] and the [RLD] in terms of safety, purity, and potency.” 42 U.S.C. § 262(i)(2).

34. Although biosimilars have no clinically meaningful differences in safety, purity, and potency from the RLD, they are not automatically substitutable with the RLD (unlike Hatch-Waxman generics). Thus, if a doctor prescribes the RLD, a pharmacist cannot substitute a biosimilar unless that product has been designated as interchangeable by FDA and the relevant

2009, <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm215089.htm> (last visited Sept. 18, 2017).

state law permits substitution of interchangeable biologics.¹⁰ This allows originator firms to retain the bulk of their existing patient bases, which typically is not possible for a branded firm to do when a Hatch-Waxman generic enters (because state substitution laws permit prescriptions for the brand to be automatically substituted with the Hatch-Waxman generic by the pharmacist without the need for physician intervention). This difference enables biologic originator firms to leverage their monopolies over existing patients to extract anticompetitive commitments from insurers and providers.

C. Infliximab

35. Infliximab is a tumor necrosis factor (“TNF”)-inhibiting biologic drug used to treat a range of immune-mediated diseases, including Crohn’s disease, ulcerative colitis, rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis.

36. As a biologic, infliximab is not synthesized in a laboratory, but rather derived from a living organism. Infliximab is a chimeric IgG1 κ monoclonal antibody (composed of human constant and murine variable regions) specific for human tumor necrosis factor-alpha. Infliximab is produced by a recombinant cell line cultured by continuous perfusion and is purified by a series of steps that includes measures to inactivate and remove viruses.

37. Infliximab is an infusion therapy, meaning it is administered intravenously. Thus, infliximab patients must (in most cases) visit clinics, hospitals, or other medical facilities to receive the therapy from healthcare professionals. As a result, patients rarely purchase

¹⁰ The BPCIA does provide for an “interchangeable” designation, but FDA published draft guidelines for establishing interchangeability only this year. U.S. Food & Drug Administration, *Considerations in Demonstrating Interchangeability With a Reference Product (Draft Guidance)* (Jan. 17, 2017). And while Pfizer believes that Inflectra can be safely and effectively substituted for Remicade (indeed, studies have shown that switching patients can be done safely and effectively, and Pfizer has supported and/or taken part in some of these studies), it will be years before Inflectra or any other biologic receives a formal “interchangeability” designation from FDA in the United States. Nonetheless, neither the BPCIA nor FDA contemplates that biosimilars should be prevented from competing in the marketplace—i.e., that consumers should be denied access to them—until they are designated interchangeable.

infliximab themselves at retail pharmacies. Instead, infusion centers, clinics, and hospitals purchase infliximab, and after administration, seek reimbursement from the patient's insurer or a government payer (e.g., Medicare). Infliximab is an important medicine that has provided life-changing benefits to millions of patients.

D. J&J's Remicade

38. J&J introduced the first infliximab product in the United States in 1998, under the brand name Remicade.

39. Remicade is widely used: An estimated 475,000 patients in the U.S. receive at least one dose of Remicade annually. This fact, combined with the cost (approximately \$4,000 per infused dose at list price), makes administering Remicade a major expense item for insurers and healthcare providers.

40. J&J's list price increases for Remicade and other pricing actions have resulted in consistent increases in Remicade's ASP. J&J has increased the price of Remicade without experiencing a loss of sales to other therapies. Instead, Remicade sales have increased steadily since it was introduced. Indeed, J&J has been able to continue raising the price of Remicade notwithstanding the arrival of Inflectra.

41. Since 1998, J&J has made billions of dollars in profit on Remicade.

E. Pfizer's Inflectra

42. Beginning in 2008, Celltrion undertook to develop a biosimilar to Remicade and move it through the intensive FDA review process. The Biologics License Application for Inflectra was filed with FDA in 2014. After rigorous scientific review, FDA approved infliximab-dyyb on April 5, 2016. In the FDA news release announcing its approval of Inflectra, the director of FDA's Center for Drug Evaluation and Research reiterated that approval as a biosimilar reflects a determination of "no clinically meaningful differences" from the originator,

and stated that “[p]atients and the health care community can be confident that biosimilar products are high quality and meet the agency’s rigorous scientific standards.”¹¹

43. J&J claimed patent protection over Remicade—as noted, making it the sole provider of infliximab for nearly two decades—and thus Pfizer and Celltrion were forced to defend against J&J’s patent suit in parallel with FDA’s regulatory review of the Inflectra application. On August 17, 2016, J&J’s patent covering the infliximab antibody was ruled invalid by the United States District Court for the District of Massachusetts, a ruling which confirmed that J&J had no valid right to exclude Pfizer (or other potential biosimilar entrants). The Court held that the antibodies covered by J&J’s Remicade patent had been disclosed and claimed in an earlier patent.¹² Just a few months after the district court ruling, the U.S. Patent and Trademark Office issued a final decision in a re-examination of the same patent, holding that the patent was invalid.¹³

44. After overcoming these hurdles, and after a 180-day notice period required by the BPCIA, Pfizer began selling Inflectra in November 2016.

45. Inflectra is approved for all the same indications as Remicade, except pediatric ulcerative colitis, as to which J&J continues to enjoy an FDA-granted period of exclusivity because of the indication’s status as an “orphan” indication (established on proof that the number of people affected by the disease or condition for which the drug is to be developed is fewer than 200,000 persons), which is scheduled to end in 2018. On that date, Inflectra will be eligible to

¹¹ See U.S. Food & Drug Administration, *FDA Approves Inflectra, A Biosimilar to Remicade* (Apr. 5, 2016), <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm494227.htm>.

¹² Janelle Lawrence, *J&J Remicade Patent Found Invalid in U.S. Victory for Pfizer*, Bloomberg (Aug. 17, 2016), <https://www.bloomberg.com/news/articles/2016-08-17/j-j-patent-on-remicade-expiring-in-2018-invalid-judge-rules>.

¹³ *Id.*

seek approval for pediatric ulcerative colitis. In any event, this indication accounted for less than 5 percent of overall infliximab utilization in 2016.

46. Pfizer introduced Inflectra with a list price 15 percent lower than Remicade's, and, in negotiations with insurers and providers, offered substantial additional pricing concessions in the form of discounts and/or rebates that in some instances were more than 40 percent below Inflectra's list price. The goal and effect was to offer Inflectra for less than J&J was offering Remicade; indeed, for many customers, Pfizer committed to ensure that Inflectra would have a lower net per-unit price than Remicade.

47. Given that it was charging a lower price for Inflectra than J&J was charging for Remicade, Pfizer was optimistic that it would have an opportunity to compete, to secure a reasonable share of the business, particularly for new patients, and to bring the benefits of price competition to consumers, providers, insurers, and the U.S. government. However, due to J&J's exclusionary conduct, competition has been foreclosed. J&J maintains its monopoly and has continued to capture over 96 percent of infliximab sales even while maintaining prices far above competitive levels.

F. The Importance of Insurance Coverage for Infliximab

48. Most patients who are prescribed Remicade have some form of insurance coverage or qualify for patient assistance. The sources of insurance coverage are (a) private insurance, accounting for about 60 percent of patients nationally, and (b) government insurance programs (principally Medicare and Medicaid), accounting for the remaining 40 percent. Insurance coverage and reimbursement are therefore key to the adoption of the product by patients and healthcare providers alike. If a product as expensive as Remicade is not widely reimbursed, it will not be significantly utilized.

49. Because Remicade is not dispensed in a retail pharmacy but rather administered intravenously in a clinic or other institutional setting, it generally is not included under the “pharmacy benefit” of most health plans. In the pharmacy benefit setting, physicians prescribe a drug and the patient procures the medication him or herself at the pharmacy, paying for it with a combination of insurance coverage (either private or government-sponsored) and out-of-pocket payment (usually, a co-pay). In the pharmacy benefit context, neither the prescribing physician nor the institution with which the physician is affiliated bears financial risk with respect to the drug selected, i.e., the drug is not purchased and stocked in advance by providers at their own cost. The pharmacy buys the drug, dispenses it, and is reimbursed.

50. In contrast, “medical benefit” products such as Remicade are administered at a clinic or other healthcare provider site, and the provider *itself* first purchases the drug product for use in the infusion treatment of patients, and then later seeks reimbursement for the drug from a third party payer (a practice commonly referred to as “buy and bill”). When a treatment is administered, the provider must secure payment for the service, including the cost of the product dispensed (which the provider had to pay up front with its own funds). In this context, the provider has a strong interest in utilizing drugs that are widely covered by insurance, particularly by the major national commercial health insurers and significant regional insurers active in its area. If a drug product is not widely covered, such that there is a risk that coverage might be denied, and providers thus would be burdened with a potential financial loss for what they paid for the product, providers are much less likely to purchase that product—a response that is in line with the providers’ economic interests (to be reimbursed).

51. Many of the facilities administering infusion services of the type at issue here are physician-owned. Thus, the physicians themselves have both prescribing authority and a strong financial incentive to avoid products that are not widely covered.

52. Commercial insurers typically publish medical policies enumerating the drug products they will cover under the medical benefit and the terms under which they will do so. For example, medical policies may exclude drugs from coverage, or they may dictate restrictions on use. Drug manufacturers compete, usually with rebates or other price concessions, to obtain coverage under insurer medical policies and to have either fewer restrictions on reimbursement than their competitors—or, at a minimum, to achieve “parity” whereby the competing products have the same restrictions on reimbursement and the patient and/or doctor can choose between them. Securing at least parity placement is critical, especially for new products seeking to gain traction in the marketplace, and particularly with large insurers, which have tens of millions of covered patients.

G. The Importance of Access at the Provider Level

53. As discussed above, providers (hospitals, clinics, etc.) are the market actors that actually purchase infliximab for use with their infusion services for patients. J&J’s agreements and conduct have the effect of foreclosing this essential source of distribution.

54. Providers do not want to risk being unable to secure reimbursement for any drug used to treat a patient after having already paid for the product. Because it can be costly to monitor coverage status across myriad insurers and implement procedures to match product use to a patient’s coverage, gaps in reimbursement policies give “buy and bill” provider accounts reasons to stock only products with universal (or near-universal) coverage. Here, due to J&J’s anticompetitive contracts at the insurer level, J&J has succeeded in preventing biosimilar competitors from achieving the same status.

J&J'S EXCLUSIONARY SCHEME

55. Not content with its nearly two full decades of exclusivity with Remicade, and the billions of dollars of profits that such exclusivity enabled, J&J hatched a multifaceted scheme to ensure that biosimilars would never become viable competitors—a scheme embodied, at least in part, in its “Biosimilar Readiness Plan.” J&J revealed the existence of the plan, and at least some specifics thereof, during a recent investor call and presentation.¹⁴ And a J&J consultant bragged at a recent health conference that his firm helped design the plan to realize J&J’s goal of ensuring that biosimilars never gain a foothold.

56. J&J’s conduct has not gone unnoticed in the industry. For example, an analyst at a prominent securities firm (Bernstein Research) recently summarized key aspects of J&J’s scheme, observing that J&J has: (a) “negotiated with [insurers]” and set up “exclusive contracts . . . in nearly half the market,” thereby making providers unwilling to purchase Inflectra; (b) “offered up deeper discounts to large independent infusion centers [i.e., major providers], which are more economically sensitive”; and (c) “bundled several drugs and medical devices [together] for larger hospitals.”¹⁵ The analyst also noted that a key to J&J’s strategy was the “long ‘tail’ of [patients] remaining on the brand”¹⁶—the incontestable demand—which gives J&J leverage to extract commitments from insurers not to cover Inflectra.¹⁷ Another industry observer,

¹⁴ Johnson & Johnson, Q3 2016 Results Earnings Call Transcript (Oct. 14, 2016), available at <https://seekingalpha.com/search/transcripts?term=johnson+%26+Johnson+biosimilar>.

¹⁵ Aaron Gal, *Biosimilars: So, Why Has Remicade Biosimilar Not Gotten Much Traction in the U.S.*, Bernstein Research, at 1 (July 20, 2017).

¹⁶ *Id.*

¹⁷ While the Bernstein survey suggests that Pfizer has offered only a “‘low single digit’ discount off of the ASP” of Inflectra, that is not accurate. As set forth herein, Pfizer has offered Inflectra at a significant discount (to list price as well as ASP), but continues to be foreclosed by J&J’s anticompetitive contracts. J&J, meanwhile, has raised the price of Remicade since Inflectra’s entry. The Bernstein survey also speculates that with the entry of a third biosimilar in mid-2019, “we would likely [sic] see one of the biosimilars crossing the Rubicon and offering the required discounts.” Gal, *supra* note 15, at 1. However, as set forth herein, J&J’s exclusive contracts and bundling practices foreclose all new biosimilar entrants, including Pfizer, from competing with Remicade on price and, if not stopped, will

commenting on the Bernstein survey, noted that J&J’s “fail first” requirements with insurers “force hospitals and clinics to buy Remicade.” The observer also noted that:

J&J has had yet another advantage—an ability and willingness to bundle different medicines as part of a package deal. By offering discounts and rebates for several drugs, J&J can secure contracts and crowd out rivals. And discounts are also appealing to physicians who run their own infusion centers.¹⁸

57. J&J’s scheme is set forth in more detail below:

A. J&J Bars Access to Insurer Reimbursement Through Improper Exclusive Contracts and Anticompetitive Bundling Practices

1. J&J’s Exclusive Contracts with Health Insurers

58. A centerpiece of J&J’s strategy to block competition from biosimilars has been to secure contractual commitments from commercial insurance companies to exclude biosimilars from coverage under their plans, making Remicade the exclusive infliximab available to patients covered by those plans. Such contractual commitments have taken various forms. Some insurers have entered into contracts with J&J that required them simply to exclude biosimilars from their medical policies and/or drug formularies altogether. Other J&J contracts have imposed a spurious requirement that the biosimilar could be reimbursed only after a patient first tried and failed on Remicade (the “fail first” requirement), which virtually ensures that the biosimilar will never be prescribed and never be reimbursed. If a patient fails on Remicade, it would defy sound medical judgment for a physician to switch to the therapeutically equivalent biosimilar, which works in exactly the same way, rather than another therapy, to which a patient may potentially respond differently.¹⁹ Regardless of their specific form, these contracts all had

allow J&J to continue to maintain the monopoly power it currently exercises with Remicade.

¹⁸ Ed Silverman, *J&J Now Has Two Competitors for A Pricey Blockbuster. Will That Finally Drive Down Prices?*, Stat News (July 25, 2017), <https://www.statnews.com/pharmalot/2017/07/25/merck-samsung-biosimilar-pfizer-johnson/>.

¹⁹ The notion that attempting treatment with a biosimilar after its reference listed drug has first failed would defy medical judgment recently has been reinforced in the European League Against Rheumatism rheumatoid arthritis management recommendations. In those recommendations, “[t]he Task Force

the same effect—to exclude biosimilars from coverage and (as one analyst recently confirmed) grant an “exclusive” to Remicade.²⁰

59. J&J has induced most major health insurers, covering at least 70 percent of commercially insured patients in the United States, to adopt these improper contractual exclusivity restrictions and to impose outright bans on Inflectra’s coverage or so-called “fail first” requirements. These insurers include (in decreasing order of patients covered):

National insurers:

(a) UnitedHealthcare: UnitedHealthcare adopted the “fail first” requirement.

UnitedHealthcare has approximately 30.6 million covered commercial medical patients across all 50 states.

(b) Anthem: Anthem excluded Inflectra from coverage altogether. Anthem has approximately 30.4 million covered commercial medical patients concentrated in 14 states.

(c) Aetna: Aetna adopted a complex set of indication specific conditions which operate in practice as “fail first” requirements. Aetna has approximately 17.9 million covered commercial medical patients in all or nearly all states and territories in the United States.

(d) Cigna: Cigna adopted the “fail first” requirement. Cigna has approximately 13 million covered commercial medical patients across all 50 states.

reiterated its position that if a TNF-inhibitor fails, another TNF-inhibitor—but not a biosimilar of the same molecule!—can be as effective as changing the mode of action.” Smolen, J.S., et al., *EULAR Recommendations for the Management of Rheumatoid Arthritis with Synthetic and Biological Disease-Modifying Antirheumatic Drugs: 2016 Update*, *Annals of the Rheumatic Diseases* 2017:0:1-18 (Mar. 6, 2017).

²⁰ Gal, *supra* note 15, at 1.

Regional insurers:

- (a) ***HealthNet (Centene):*** HealthNet adopted a complex set of indication specific conditions which operate in practice as “fail first” requirements. HealthNet (as part of its acquisition by Centene) has approximately 12 million covered commercial medical patients concentrated in 28 states.
- (b) ***CareFirst/Blue Cross Blue Shield:*** CareFirst adopted the “fail first” requirement. Indeed, CareFirst agreed with J&J that Inflectra would be non-preferred, meaning it cannot be reimbursed unless there are “clinical circumstances that would exclude the use of . . . preferred products,” including Remicade. CareFirst has approximately 3.2 million covered commercial medical patients principally found in Maryland, Virginia, and the District of Columbia.
- (c) ***Blue Cross Blue Shield of North Carolina:*** BCBS of North Carolina adopted the “fail first” requirement. BCBS of North Carolina has approximately 2.7 million covered commercial medical patients concentrated in North Carolina.
- (d) ***Blue Cross Blue Shield of Tennessee:*** BCBS of Tennessee adopted the “fail first” requirement. BCBS of Tennessee has approximately 1.6 million covered commercial medical patients concentrated in Tennessee.
- (e) ***Blue Cross Blue Shield of Louisiana:*** BCBS of Louisiana adopted the “fail first” requirement. BCBS of Louisiana has approximately 1.6 million covered commercial medical patients principally concentrated in Louisiana.
- (f) ***Excellus Blue Cross Blue Shield:*** Excellus BCBS adopted the “fail first” requirement. Excellus has approximately 1.2 million covered commercial medical patients concentrated in New York.

(g) Independence Blue Cross: Independence Blue Cross adopted the “fail first” requirement. Independence Blue Cross is the leading health insurer in Philadelphia.

These contracts alone affect approximately 114 million covered commercial medical patients of the over approximately 214 million patients covered by commercial medical insurance in the United States. Pfizer has reason to believe there are more.

60. While exclusive contracts can—in certain circumstances—be perfectly appropriate, the exclusivity provisions described in Paragraphs 8, 9, and 58 serve no legitimate or procompetitive purpose and were not earned through simple price competition. After Inflectra’s FDA approval in April 2016, and before J&J implemented its exclusionary contracts, health insurers undertook reviews to determine whether there was a *medical* reason not to reimburse Inflectra or to disfavor it relative to other therapies. Following these reviews, several major health insurance companies—including at least Aetna, Anthem, and UnitedHealthcare—classified Inflectra at *parity* with Remicade. This confirmed that there was no medical reason justifying a restrictive reimbursement policy toward Inflectra. It also meant that, for the time being, Inflectra would be reimbursed without restriction. As a result, the stage was set for Inflectra to begin competing head-to-head with Remicade on a level playing field—and for patients to begin receiving the benefits of greater choice and lower prices.

61. But this initial state of affairs was short lived. As a result of J&J’s anticompetitive conduct, insurers began to reverse course and restrict coverage of Inflectra.

62. For example, in October 2016, UnitedHealthcare, the nation’s largest health insurer, with over 30 million covered commercial medical patients, published an update to its medical and site of care policies classifying Inflectra at parity with Remicade for the approved indications (with an effective date of November 1, 2016). This meant that, for UnitedHealthcare,

Inflectra would be reimbursed freely and would not be disfavored relative to Remicade. Just *weeks later*, however, UnitedHealthcare reversed course. UnitedHealthcare classified Remicade as its “preferred” product, and instructed that Inflectra would be eligible for reimbursement only in circumstances so limited as to be practically non-existent. Under UnitedHealthcare’s new policy, Inflectra could be reimbursed only where the following conditions are met: (a) the patient must show a minimal clinical response, or an intolerance or adverse reaction, to Remicade; (b) the physician must attest that Inflectra would not lead to the same adverse responses; and (c) the patient must show no loss of favorable response in established maintenance therapy with Remicade, and must not have developed neutralizing antibodies to any infliximab biosimilar product that has made the therapy less effective. As a practical matter, this meant that Inflectra would not be reimbursed for UnitedHealthcare’s more than 30 million commercial medical members, and that Remicade would be the exclusive infliximab with UnitedHealthcare—despite the lack of any medical basis for denying those members access to a lower-priced alternative to Remicade.

63. UnitedHealthcare’s reversal, of course, did not happen by chance. J&J induced UnitedHealthcare to enter into an exclusive deal by threatening to penalize UnitedHealthcare with the loss of significant rebates unless UnitedHealthcare agreed to deny coverage of Inflectra.

64. J&J has employed the same approach to secure exclusive deals with most or all of the major insurers identified above. In most cases these coercive biosimilar-exclusion contracts were the only economically viable option for insurers—as adopting any alternative would require the insurer to incur a substantial penalty (i.e., foregone rebates to existing Remicade patients) that could not be offset by the per-unit cost savings available on the number of patients likely to use the biosimilar, at least in the near term.

2. J&J's Bundling Tactics with Health Insurers

65. J&J's threatened penalties are effective because they leverage the large base of existing patients already stabilized on Remicade. Given that J&J has offered the only infliximab option in the United States for nearly two decades, its base of existing Remicade patients is substantial, amounting to hundreds of thousands of patients across the country. And, in part driven by J&J's marketing efforts to secure this outcome, existing Remicade patients are likely to stay on Remicade. Thus, the demand for Remicade associated with this existing base of patients is, as a practical and economic matter, incontestable. This is so despite the fact that switching is within the scope of FDA's approval for use of biosimilars and thus appropriate when medically directed—something Pfizer discusses with clients. The situation is different for *new* patients who may be candidates for infliximab. In light of this, Pfizer has focused, among other things, on competing for a substantial share of *new patient starts* (the “contestable” demand) by pricing Inflectra competitively with both insurers and providers on a unit-for-unit basis. The fact that Inflectra's ASP is lower than Remicade's underscores the cost savings it offers.

66. By threatening to withhold attractive rebates on *all* Remicade prescriptions—including those for existing patients as well as new ones—unless an insurer agrees to exclusivity, J&J is able to leverage the incontestable demand for Remicade to exclude competition for the contestable demand, i.e., it bundles the contestable and incontestable demand. Even if Pfizer offers a significantly lower price for Inflectra unit-for-unit, as it has done, insurers will agree to J&J's exclusive deals to avoid losing rebates on the substantial base of existing Remicade patients who are not likely to switch to Inflectra despite the presence of the lower-priced biosimilar. A recent article by two Yale Medical School professors in the *Journal of the*

American Medical Association illustrates how the kind of leverage J&J has over existing, stable Remicade patients allows it to extract commitments to exclude the biosimilar:

If a biosimilar manufacturer intends to upend the preferred position of the brand by offering a substantial price discount to the [insurer], the branded manufacturer can respond by withdrawing the rebate on the [branded] biologic, ***creating a “rebate trap.”*** For any patient continuing the [branded] biologic, a payer’s cost for that patient will double once the rebate is withdrawn Even in [an] optimistic scenario, in which the price of the biosimilar is 60 percent less than the price of the brand after rebates and discounts, if the payer is only able to convert 50 percent of its patient users to the biosimilar [because existing patients will tend to stay on the original branded product], ***the rebate trap ensures that payer total costs actually increase relative to costs prior to biosimilar availability.***

* * *

To avoid the rebate trap, any strategy to reduce spending on biologics through adoption of biosimilars requires a near-complete switch of patient users from the branded biologic to the biosimilar. However, for many chronic diseases, the proportion of patients new to a given biological therapy is less than 20 percent of the total patients taking that drug in a given year. The remainder ***represents a stable base of patients whose disease is well-maintained while they are using current therapy and thus are unlikely to switch [to the biosimilar].***²¹

67. J&J has further insulated its contracts with insurers from competition by bundling rebates for Remicade with rebates on other products in return for commitments not to cover Inflectra. J&J made it no secret that it would leverage other products as part of its “Biosimilar Readiness Plan.” As J&J’s Worldwide Chair for Pharmaceuticals made clear on a recent earnings call, “We are fully prepared to execute our focused biosimilar readiness plan,” including “developing innovative contracts . . . [to] utilize the full breadth of our portfolio.”²² The “full breadth of [J&J’s] portfolio” includes several drugs for which Pfizer does not offer any directly competing alternative. These include drugs such as Simponi (used for rheumatoid

²¹ Aaron Hakim & Joseph S. Ross, *Obstacles to the Adoption of Biosimilars for Chronic Diseases*, *Journal of the American Medical Association* (May 1, 2017), available at <http://jamanetwork.com/journals/jama/article-abstract/2625049> (emphasis added).

²² Johnson & Johnson, Q3 2016 Results Earnings Call Transcript (Oct. 14, 2016), available at <https://seekingalpha.com/search/transcripts?term=johnson+%26+Johnson+biosimilar>.

arthritis, psoriatic arthritis, ankylosing spondylitis, and ulcerative colitis), Simponi Aria (used for rheumatoid arthritis), and Stelara (used for plaque psoriasis, psoriatic arthritis, and Crohn's disease). These products are widely used, with Simponi/Simponi Aria generating for J&J approximately \$1.7 billion in 2016 and Stelara generating for J&J approximately \$3.2 billion in 2016. J&J has threatened insurers with the loss of rebates on these other drugs, as well as Remicade, if they do not agree to exclude Inflectra from coverage.

68. J&J's multi-product bundling, along with its bundling of contestable demand (i.e., new patients) and incontestable demand (i.e., existing Remicade patients), have amplified the anticompetitive effects of J&J's exclusive contracts, and made the exclusivity provided by those contracts even more durable. Insurers have made it clear to Pfizer that its net cost for Inflectra would need to be low enough to offset the loss of J&J rebates. But, because of the combined effect of these bundles, Pfizer cannot offset the financial penalties that J&J threatens to impose on insurers who do not agree to exclusivity. As a result, Pfizer is economically prohibited from competing for coverage by the major insurers—even when their exclusive contracts with J&J expire. J&J can use the same bundling strategies to ensure continuation of the exclusionary pattern.

B. J&J's Improper Insurer-Level Contracts Deter Hospitals and Clinics from Purchasing Inflectra, Thus Amplifying Foreclosure

69. Providers are unwilling to stock a drug product where there is significant uncertainty about whether it will be reimbursed by health insurers; because they administer infliximab onsite, providers must expend funds for the product in the first instance, then seek reimbursement after providing treatment. The provider has theoretical recourse against the patient where coverage is denied, but the prospect of securing payment in full from the patient is bleak, especially for drugs as costly as Remicade. As a result, where a significant portion of a

provider's patients are insured by plans that have agreed to exclude Inflectra—pursuant to the types of contracts described above—the provider is unlikely to offer Inflectra for *any* of its patients, to avoid being caught with no reimbursement.

70. As a recent article in *Bloomberg* stated:


Ascension Health, a nearly 23,000-bed nonprofit hospital system based in St. Louis, spends \$55 million a year on Remicade, more than any other drug. Using Inflectra, part of a new class of medicines called biosimilars, would save it at least \$10 million annually, according to Ascension's chief pharmacist, Roy Guharoy. He met with Pfizer and planned to integrate Inflectra into care more often until learning that insurers preferred to stay with Remicade. "This we did not expect," Guharoy said. "If the insurance companies force us to use the branded product, of course our hands are tied."²³

In short, provider purchases are driven by the coverage stated by commercial insurers.

71. Having created reimbursement concerns through its exclusionary contracts with health insurers, J&J touts the excluded status of Inflectra in its marketing communications, knowing that doing so will discourage providers from stocking the new biosimilar. As this brochure shows, J&J markets the "fail first" requirement as a selling point despite the fact that such a provision is medically inappropriate and despite FDA's determination that there are no clinically meaningful differences between the two products. Thus the brochure touts that Remicade is "Preferred Over Inflectra . . . Inflectra requires trial and failure on Remicade prior to [Inflectra] utilization."

²³ Jared S. Hopkins, *What's Harder Than Making Copycat Biotech Drugs? Selling Them*, Bloomberg (Aug. 15, 2017).

COMMERCIAL REIMBURSEMENT INFORMATION



Effective April 1, 2017

**REMICADE® (infliximab) is
PREFERRED* over the biosimilar
Inflectra® (infliximab-dyyb)
at UnitedHealthcare¹**

PATIENTS **CONTINUE** TO HAVE ACCESS TO REMICADE®

Collected December 2016.


Please read the accompanying full Prescribing Information, including Boxed Warnings, and MEDICATION GUIDE for REMICADE® (infliximab). Provide the MEDICATION GUIDE to your patients and encourage discussion.

The information provided represents no statement, promise, or guarantee of Janssen Biotech, Inc., concerning levels of reimbursement, payment, or charge. Please consult your payer organization with regard to local or actual coverage, reimbursement policies, and determination processes. Information is subject to change without notice. Nothing herein may be construed as an endorsement, approval, recommendation, representation, or warranty of any kind by any plan or insurer referenced herein. This communication is solely the responsibility of Janssen Biotech, Inc.

Indicated trademark is the registered trademark of its owner. Please refer to the product's Prescribing Information for indication(s), recommended dosing, and administration.

* Preferred Over Inflectra®: REMICADE® is a 1st line biologic; Inflectra® requires trial and failure on REMICADE® prior to utilization.

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72. Given the widespread gaps in Inflectra's insurance coverage—caused by J&J—providers using infliximab have overwhelmingly chosen to stock *only* Remicade (which is essentially universally covered given its long tenure and dominant position) rather than deal with the risk of possible denials of coverage for Inflectra. Thus, providers have declined to purchase Inflectra across the board, even for patients covered by commercial or government insurance plans that *do* cover the product. The effective foreclosure of biosimilars thereby is expanded well beyond the 70 percent of commercially insured patients directly foreclosed by J&J's insurer contracts. Indeed, as of September 1, 2017, about 90 percent of healthcare provider accounts using infliximab had purchased *no Inflectra at all*.

C. J&J Has Further Barred Access Through Exclusionary Contracts with Providers

73. To further amplify Inflectra's foreclosure—even beyond the population of patients covered by insurance plans that have agreed to J&J's exclusivity terms, and the spillover effect on providers discussed above—J&J has imposed exclusionary contracts on providers themselves (e.g., clinics, hospitals, etc.).

74. After Inflectra's introduction, J&J began offering certain large providers additional rebates and/or discounts on Remicade, but *only* if the provider committed to buy Remicade for nearly all of its infliximab needs. To be eligible for rebates, J&J required providers to maintain purchase levels for Remicade at very close to the levels of the year *before* Inflectra's launch—when Remicade was the *only* infliximab option. With about 30 percent of prescriptions in any year representing new patients (and a certain percentage of existing patients exiting therapy each year), this condition also requires providers to use Remicade for new patients if they wish to secure payment from J&J, thus bundling contestable and incontestable demand for Remicade. Like its insurer-level contracts, these contracts as a practical matter make Remicade the exclusive infliximab with the participating providers.

75. J&J has also used multi-product bundling in its provider-level contracts. As one analyst reported, "J&J bundled several drugs and medical devices for larger hospitals, making Inflectra less economical."²⁴ Conditioning rebates linked to *other* J&J products upon a promise not to do business with Inflectra only exacerbates the exclusionary nature of J&J's contracts.

76. Pfizer was and is prepared to negotiate with providers to make Inflectra the lower-priced infliximab option on a per-unit basis, and has even offered to guarantee that Inflectra would be less expensive unit-for-unit than Remicade. But as with insurer contracts, to secure the

²⁴ Gal, *supra* note 15, at 1.

right to deal freely as to Inflectra (i.e., principally as to new patients), the providers would lose significant J&J rebates on their existing Remicade patient bases.

77. For Pfizer to make up the J&J rebates/discounts that insurers and providers would lose on their existing Remicade patients, Pfizer would have to price Inflectra below its own average variable cost. This is because the lost J&J rebates/discounts are based on the much larger base of existing Remicade patients, whereas Pfizer would be serving a much smaller group of new patients, at least in the near term.

78. When the total amount of discounts and rebates that J&J offers to insurers and providers under the contracts described herein, including multi-product bundle contracts, is attributed to the portion of Remicade sales that is contestable by a biosimilar like Inflectra, J&J is pricing Remicade below its own average variable cost. As a result, biosimilar competition to Remicade is foreclosed.

79. The combined effect of J&J's multifaceted exclusionary scheme has been to foreclose Inflectra from approximately 90 percent of the provider account distribution channel essential to connecting Inflectra with patients of any kind.

J&J HAS MONOPOLY POWER IN THE RELEVANT MARKETS

80. Monopoly power is the ability of a single seller to raise prices above the competitive price level without losing significant business.

81. For years before Inflectra's entry, J&J's ASP for Remicade increased, yet Remicade did not lose business. Between 2007 and 2017, Remicade's ASP increased more than 62 percent. Despite Remicade's price hikes, unit sales of Remicade have actually grown 15 percent during the period from 2012 to 2016.

82. Inflectra's introduction has done nothing to erode Remicade's monopoly power: Since Inflectra was launched, Remicade's ASP has continued to increase without impacting

Remicade’s market position. Ten months after Inflectra was introduced, Remicade still accounts for over 96 percent of all infliximab sales. Indeed, J&J has confirmed that “biosimilar competition” has had “very little impact” on Remicade.²⁵

83. As noted, infliximab is an infusion-administered TNF-inhibiting immuno-suppressant with FDA approved indications for rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis, Crohn’s disease, and plaque psoriasis (together, the “Relevant Indications”).

84. The broadest appropriate relevant product market is infusion-administered drugs whose approved labeling from the FDA (a) encompasses one or more of the Relevant Indications, and (b) is without restriction for the applicable Relevant Indication, that is to say, the labeling does not specify that the drug may be used for the applicable Relevant Indication only after the patient has not responded to another therapy (the “Relevant Product Market”).²⁶ Remicade enjoys a share of over 60 percent in the Relevant Product Market, nearly the same share it had before Inflectra entered.

85. The following infusion-administered therapies have been approved as unrestricted therapies for the Relevant Indications:

- ***Rheumatoid Arthritis:***
 - Remicade (infliximab) (J&J) (TNF-inhibiting immuno-suppressant)
 - Simponi Aria (golimumab) (J&J) (TNF-inhibiting immuno-suppressant)
 - Inflectra (infliximab) (Pfizer) (TNF-inhibiting immuno-suppressant)
 - Renflexis (infliximab) (Merck) (TNF-inhibiting immuno-suppressant)

²⁵ Johnson & Johnson, Q1 2017 Results Earnings Call Transcript (Apr. 18, 2017), available at <https://seekingalpha.com/search/transcripts?term=johnson+%26+Johnson+biosimilar>.

²⁶ For example, the FDA approved Rituxan for the treatment of moderate to severe active rheumatoid arthritis in adults only after treatment with at least one other TNF antagonist has been used and did not work well enough.

- Orencia IV (abatacept) (Bristol-Myers Squibb) (synthetic recombinant DNA technology immune-suppressant)
- Actemra IV (tocilizumab) (Roche) (interleukin-6 blocker) (IL-6 blocker)
- ***Psoriatic Arthritis:***
 - Remicade (infliximab) (J&J) (TNF-inhibiting immuno-suppressant)
 - Stelara IV (ustekinumab) (J&J) (human interleukin-12 and -23 antagonist)
 - Inflectra (infliximab) (Pfizer) (TNF-inhibiting immuno-suppressant)
 - Renflexis (infliximab) (Merck) (TNF-inhibiting immuno-suppressant)
 - Orencia IV (abatacept) (Bristol-Myers Squibb) (synthetic recombinant DNA technology immuno-suppressant)
- ***Ankylosing Spondylitis:***
 - Remicade (infliximab) (J&J) (TNF-inhibiting immuno-suppressant)
 - Inflectra (infliximab) (Pfizer) (TNF-inhibiting immuno-suppressant)
 - Renflexis (infliximab) (Merck) (TNF-inhibiting immuno-suppressant)
- ***Plaque Psoriasis:***
 - Remicade (infliximab) (J&J) (TNF-inhibiting immuno-suppressant)
 - Stelara IV (ustekinumab) (J&J) (human interleukin-12 and -23 antagonist)
 - Inflectra (infliximab) (Pfizer) (TNF-inhibiting immuno-suppressant)
 - Renflexis (infliximab) (Merck) (TNF-inhibiting immuno-suppressant)
- ***Crohn's Disease:***
 - Remicade (infliximab) (J&J) (TNF-inhibiting immuno-suppressant)
 - Stelara IV (ustekinumab) (J&J) (human interleukin-12 and -23 antagonist)
 - Inflectra (infliximab) (Pfizer) (TNF-inhibiting immuno-suppressant)
 - Renflexis (infliximab) (Merck) (TNF-inhibiting immuno-suppressant)

- Entyvio (vedolizumab) (Takeda) (integrin receptor antagonist monoclonal antibody)
- ***Ulcerative Colitis:***
 - Remicade (infliximab) (J&J) (TNF-inhibiting immuno-suppressant)
 - Inflectra (infliximab) (Pfizer) (TNF-inhibiting immuno-suppressant)
 - Renflexis (infliximab) (Merck) (TNF-inhibiting immuno-suppressant)
 - Entyvio (vedolizumab) (Takeda) (integrin receptor antagonist monoclonal antibody)

These infusion therapies are referred to collectively as the “Relevant Products.”

86. Certain non-infusion drugs are also indicated to treat the Relevant Indications. None of those drugs, however, is a reasonable substitute for the infusion-administered products. None significantly constrains the prices J&J is able to charge for Remicade.

87. The non-infusion products approved for the Relevant Indications include oral medications (e.g., Xeljanz) and self-injectables (e.g., Humira, Enbrel). These products are patient-administered. Infusion drugs, by contrast, must be delivered by healthcare professionals in a clinical setting (e.g., hospitals or infusion centers) during infusion sessions that take upwards of two hours.

88. Physicians are not likely to switch from prescribing their patients infliximab to prescribing those non-infusion products in response to a small but significant non-transitory change in the price of infliximab.

89. Not only are the infusion and non-infusion treatments different kinds of therapies, but they are most often sold to different buyers, on different contracts, and are distributed by different means:

- Infliximab is, as described above, sold primarily to hospitals and clinics and is almost never stocked by retail pharmacies (only rarely being stocked by certain specialty pharmacies). After administering the infusion treatments to their patients, the hospitals and clinics seek reimbursement from the patients' insurers or government payers.
- By contrast, non-infusion drugs such as Xeljanz, Humira, and Enbrel are primarily sold to and distributed in the pharmacy channels. Physicians who prescribe these non-infusion drugs generally do not administer the treatments and do not bear financial risk with respect to the drug selected.
- Non-infusion drugs are also typically covered by insurance through a *pharmacy* benefit plan. These are products that insured patients obtain using their "pharmacy" cards. Such drugs are put out for bid periodically by insurers and/or pharmacy benefit managers. The bidding process generally does not even include infusion and other therapies not stocked in a retail pharmacy.
- By contrast, infusion therapies generally are treated as part of the basic *medical* coverage provided by health insurers. Infusion therapies are thus generally put out for bid separately from self-administered therapies.

90. Beyond the medical reasons physicians may have for prescribing an infusion therapy as opposed to a non-infusion therapy, patients exhibit strong preferences for one form of therapy over another. Patients with active lifestyles often prefer self-administered treatments. Infusion therapy, on the other hand, is often preferred by patients with needle aversions, or by patients who prefer to have their treatments administered by medical professionals.

91. In addition, infusion and non-infusion therapies are offered at very different price points: On an annual basis, Enbrel and Humira (which are self-administered therapies) at list price are at least twice as expensive as Remicade (which is an infusion therapy) for patients stabilized on them.

92. Because of these various factors, a small but significant non-transitory increase in price of infusion therapies would not have a meaningful impact on the demand for non-infusion therapies, and vice-versa.

93. As noted, the Relevant Product Market includes certain segments that qualify themselves as Relevant Markets, in which J&J also possesses monopoly power. For example:

94. ***Specific-use product markets.*** Specific-use product markets are predicated on infusion-administered therapies for the Relevant Indications. A small but significant non-transitory increase in price for an infusion product in each of these specific-use product markets would not cause substitution to non-infusion medicines approved for the same indication. In each category, Remicade has been the dominant infusion-administered therapy. The categories are as follows:

- ***Infusion-administered therapies for Crohn's disease.*** Remicade accounts for over 70 percent of prescriptions to patients of infusion-based drugs indicated for Crohn's disease.
- ***Infusion-administered therapies for rheumatoid arthritis.*** Remicade accounts for nearly 55 percent of prescriptions to patients of infusion-based drugs indicated for rheumatoid arthritis. When combined with the share of its product Simponi Aria, J&J commands an aggregate of nearly 65 percent of prescriptions to patients in this category.

- ***Infusion-administered therapies for ulcerative colitis.*** Remicade accounts for nearly 70 percent of prescriptions to patients of infusion-based drugs indicated for ulcerative colitis.
- ***Infusion-administered therapies for psoriatic arthritis.*** Remicade accounts for over 95 percent of prescriptions to patients of infusion-based drugs indicated for psoriatic arthritis.
- ***Infusion-administered therapies for ankylosing spondylitis.*** Remicade accounts for over 95 percent of prescriptions to patients of infusion-based drugs indicated for ankylosing spondylitis.
- ***Infusion-administered therapies for plaque psoriasis.*** Remicade accounts for over 95 percent of prescriptions to patients of infusion-based drugs for plaque psoriasis.

95. ***Clinic-based product market.*** The Relevant Product Market encompasses a submarket consisting of sales of the Relevant Products to non-hospital clinics (including free-standing clinics and physician offices with infusion chairs) that administer infusion therapies to patients. Such a submarket is properly treated as a relevant submarket among other reasons because J&J is able to price discriminate between hospitals and non-hospital clinics. The U.S. antitrust enforcement agencies and economists recognize that relevant antitrust product markets can be based on categories of customers against whom sellers can exercise price discrimination, i.e., differential pricing.²⁷ Non-hospital clinics are subject to successful price discrimination by J&J. J&J can and does identify and target clinics for differential pricing. There are significant differences in the rebates and discounts J&J makes available to non-hospital clinics as compared

²⁷ See, e.g., U.S. Department of Justice and Federal Trade Commission Horizontal Merger Guidelines (2010), § 3.

to hospital customers. Moreover, a small but significant non-transitory increase in the price of Remicade or other Relevant Products will not induce infusion clinics to switch to self-administered therapies. A very substantial percentage of provider accounts that purchase infliximab are non-hospital clinics.

96. ***Product markets for new and existing patients.*** As described above, J&J has a substantial base of existing Remicade patients, the substantial majority of whom are not likely to switch to another therapy, even a biosimilar, if they have achieved relief with Remicade—even in response to a small but significant non-transitory increase in price for Remicade. By contrast, for new patients who are candidates for infusion-administered therapies for the Relevant Indications, Inflectra *is* a reasonable substitute for Remicade. Thus, there is a distinct product market for sales of Relevant Products to new patients in need of infusion-administered therapies for the Relevant Indications. There is also a distinct product market for patients already stabilized on Remicade—a market dominated by Remicade. As described above, J&J’s scheme has bundled its control over the latter market (for patients stabilized on Remicade) to thwart competition in the former market (for new patients in need of infusion therapy).

97. ***Infliximab product market.*** After discovery, the data may also support an infliximab-only product market. Among other things, J&J has been able to raise prices for Remicade consistently without losing significant sales to other branded drug products. Both J&J and Pfizer consider Remicade and Inflectra to be particularly close substitutes. For example, J&J’s marketing materials focus on comparisons of price and clinical effectiveness between Remicade and infliximab biosimilars, and do not reference any other therapies, and its “Biosimilar Readiness Plan” similarly ignores other therapies, focusing instead on the unique

competitive threat posed by biosimilars. Inflectra's marketing materials likewise focus on Remicade, not on other therapies.

98. **Barriers to entry.** Substantial barriers to entry exist to developing other infusion-administered drug therapies for the Relevant Indications generally, and infusion-administered TNF inhibitors specifically. The development of a new therapy requires tens if not hundreds of millions of dollars and substantial risk, as any new product must survive years of research and development, clinical trials, and FDA approval. If left unchecked, J&J's conduct will serve as an additional barrier to entry, as potential new entrants will recognize that they will be unable to break J&J's "rebate trap" and thus to profitably enter the Relevant Markets—and consequently will not invest the resources necessary to develop biosimilars.

99. While a second biosimilar to Remicade has been approved—called Renflexis, sponsored by Merck and Samsung—the sponsoring firms had to overcome just the kind of substantial burdens noted above, and began the effort long before J&J commenced its scheme to exclude biosimilar competition. J&J itself has expressed confidence in maintaining its Remicade dominance despite the potential entry of Renflexis based on its exclusionary contracting strategy. Pfizer has received marketplace feedback that Renflexis will face the same access challenges from J&J's scheme as Inflectra.

100. J&J's scheme—including coercive contracts bundling the incontestable demand (existing patients) with contestable demand (new patients), and promoting the results of its exclusionary insurer-level contracts to create uncertainty about Inflectra among providers—has led directly, with J&J's active encouragement, to nearly all provider accounts that use infliximab declining to purchase Inflectra *at all*. Even if some portion of a provider's patient base may be covered, providers are unwilling to risk using Inflectra only to ultimately be denied coverage. A

single denied claim can cost a provider in excess of \$4,000, whereas the typical provider savings in product acquisition cost for a covered Inflectra claim is \$200-300. Because Remicade is nearly universally covered, providers have taken the “safe” option and stocked Remicade over Inflectra, thus increasing the already-substantial foreclosure caused by J&J’s exclusionary contracts. Thus, as a practical matter, J&J’s scheme has foreclosed Inflectra from *approximately 90 percent of provider accounts using infliximab*, the essential channel of distribution for infliximab. And, as noted, in terms of sales, Remicade continues to control over 96 percent of infliximab unit sales.

101. ***Geographic market.*** The relevant geographic market for the Relevant Markets alleged herein is the United States of America and its possessions and territories, as these products are marketed and sold on a national basis.

**J&J’s CONDUCT HAS STIFLED COMPETITION IN THE RELEVANT MARKETS,
THEREBY MAINTAINING AND ENHANCING ITS MONOPOLY POWER AND
INJURING PFIZER**

102. J&J’s scheme has led to the near total foreclosure of Inflectra with patients across the country. First, its exclusionary contracts with health insurers alone—including with most of the largest health insurers in the country—have foreclosed Pfizer’s ability to compete for at least 70 percent of patients covered by commercial health insurance plans in the United States. Second, J&J’s exclusionary contracts with certain providers have foreclosed Pfizer’s ability to compete even for patients covered by plans that do provide reimbursement for Inflectra. And, as discussed, the reimbursement challenges (created by J&J) have led most provider accounts to decline to purchase Inflectra at all, with approximately 90 percent of provider accounts that use infliximab across the country not stocking Inflectra at all. As of September 2017, J&J maintained over 96 percent share of infliximab unit sales in the U.S.

103. Despite vigorous efforts to compete—including offering guarantees that Inflectra would be less expensive unit-for-unit than Remicade—Pfizer has been foreclosed from gaining a competitive foothold as a direct result of J&J’s scheme. In the absence of Remicade’s exclusionary practices, Inflectra’s growth in the Relevant Markets would be substantially greater than it has been, and would be substantially larger in the future. J&J’s conduct has deprived Pfizer of (a) past profits; (b) future profits; and (c) the value of invested capital from unrealized efforts to enter and expand in the Relevant Markets. Further, Pfizer’s current and prospective customer relationships and goodwill have been, and will continue to be, impaired. J&J’s conduct, if allowed to continue, will also dampen the incentives of Pfizer and other biosimilar developers to invest the substantial resources needed to bring biosimilars to the market. Thus, the aims of the BPCIA will have been thwarted.

104. J&J’s activities have not only harmed Pfizer, they have caused substantial harm to the competitive process as well as to government payers and to consumers, who have been deprived of the principal benefits of competition—more choices and lower prices. The anticompetitive effects of J&J’s conduct are evident in its pricing of Remicade since Inflectra’s entry. Despite the fact that Pfizer has offered substantial discounts and a lower ASP to compete for business with insurers and healthcare providers, J&J has been able to *increase* the price of Remicade without losing any significant share or volume of sales to Pfizer (or any other competitor). J&J’s prices for Remicade have been increasing by every measure. J&J has increased Remicade list prices twice since FDA approval of Inflectra. These increases alone raised Remicade’s list price nearly 9 percent. Remicade’s actual ASP (which, as noted above, is net of discounts, rebates, and other price concessions) has also increased since Inflectra’s entry—negating any claim that J&J’s rebates qualify as meaningful price competition.

105. There is no efficiency or cost-reducing justification for J&J's coercive and exclusionary insurer- or provider-level contract terms. J&J has not achieved improved production costs, or economies of scale or scope through its contracting strategies. J&J also has achieved no improvements in the Remicade treatment through its contracting strategies.

106. If J&J's conduct is not prohibited, it will be adopted by other originator biologics firms aiming to preserve their dominant positions. As the first major biosimilar approval, this case will be a bellwether for the success of Congress's biosimilars initiative, as embodied in the BPCIA.

CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

Violation of 15 U.S.C. § 2
Monopolization of All Relevant Markets

107. Pfizer repeats and realleges Paragraphs 1 through 106 as set forth herein.

108. J&J has monopolized the Relevant Markets in violation of Section 2 of the Sherman Act.

109. J&J has monopoly power in the Relevant Markets.

110. Through the scheme described above, and other conduct likely to be revealed in discovery, J&J has willfully and unlawfully maintained and enhanced its monopoly power in violation of Section 2 of the Sherman Act. J&J's scheme constitutes exclusionary conduct within the meaning of Section 2 of the Sherman Act.

111. J&J's scheme has stifled competition in the Relevant Markets and thwarted Congress's purpose in enacting the BPCIA.

112. Among other things, given that (a) J&J imposed explicit conditions that insurers and providers eliminate (or almost completely curtail) their dealings with infliximab biosimilars, and (b) J&J's ASP for Remicade has actually *increased* since the biosimilar entered, J&J's

pricing is not the clearly predominant means by which competition has been foreclosed in the Relevant Markets.

113. Even if price were deemed to be the clearly predominant means by which competition has been foreclosed, when the total amount of discounts and rebates that J&J offers to insurers and providers under the contracts described herein, including multi-product bundle contracts, is attributed to the portion of Remicade sales that is contestable by a biosimilar like Inflectra, J&J is pricing Remicade below its own average variable cost.

114. As a result of J&J's conduct, and the harm to competition caused by that conduct, Pfizer has suffered substantial and continuing injuries.

SECOND CLAIM FOR RELIEF
Violation of 15 U.S.C. § 2
Attempted Monopolization of All Relevant Markets

115. Pfizer repeats and realleges Paragraphs 1 through 114 as set forth herein.

116. J&J has attempted to monopolize the Relevant Markets in violation of Section 2 of the Sherman Act.

117. J&J is violating Section 2 of the Sherman Act by attempting to implement the anticompetitive scheme set forth above with the specific intent to monopolize the Relevant Markets. J&J's scheme constitutes exclusionary conduct within the meaning of Section 2 of the Sherman Act.

118. There is a dangerous probability that J&J will succeed in monopolizing the Relevant Markets through its anticompetitive scheme.

119. J&J's scheme has stifled competition in the Relevant Markets and thwarted Congress's purpose in enacting the BPCIA.

120. Among other things, given that (a) J&J imposed explicit conditions that insurers and providers eliminate (or almost completely curtail) their dealings with infliximab biosimilars,

and (b) J&J's ASP for Remicade has actually *increased* since the biosimilar entered, J&J's pricing is not the clearly predominant means by which competition is dangerously likely to be foreclosed in the Relevant Markets.

121. Even if price were deemed to be the clearly predominant means by which competition is dangerously likely to be foreclosed, when the total amount of discounts and rebates that J&J offers to insurers and providers under the contracts described herein, including multi-product bundle contracts, is attributed to the portion of Remicade sales that is contestable by a biosimilar like Inflectra, J&J is pricing Remicade below its own average variable cost.

122. As a result of J&J's conduct, and the harm to competition caused by that conduct, Pfizer has suffered substantial and continuing injuries.

THIRD CLAIM FOR RELIEF

Violation of 15 U.S.C. § 14

Sale on Condition to Exclude Inflectra and Other Infliximab Biosimilars or Impose a Fail First Requirement and to Force Use of Remicade in All Relevant Markets

123. Pfizer repeats and realleges Paragraphs 1 through 122 as set forth herein.

124. J&J has entered into agreements with insurers (which reimburse Remicade) and providers (which purchase Remicade), whereby it has conditioned the availability of discounts, rebates, and/or other price concessions on insurers and/or providers eliminating or drastically curtailing their dealings with Inflectra (or any other infliximab biosimilar).

125. J&J's agreements function as exclusive agreements, what are for all practical purposes sole-source agreements, the effect of which is to foreclose substantially competition from rivals, such as Pfizer, in the sale of the infliximab to medical providers, in violation of Section 3 of the Clayton Act.

126. The essence of the J&J-insurer contracts is to pay the insurers to exclude biosimilar alternatives from their prescription drug or medical benefits coverage, whereby the

insurers either deny coverage altogether or restrict coverage to only the rarest of circumstances. The insurers, as the payers for the treatment, have the ability to exclude selected drugs from coverage and as a result, patients and providers do not have a practical ability to choose Inflectra or other infliximab biosimilars over Remicade where coverage is not available. Moreover, because insurers wield power over providers with the ability to grant or withhold coverage for treatment, and because providers are risk-averse when it comes to buying and stocking medications such as infliximab, the providers are effectively compelled to stock Remicade exclusively.

127. The intent and effect of the insurers' performance of these contracts is to cause providers to forgo alternatives and to drive all treatment sales to J&J. The result of the J&J-insurer contracts thus is the amplification of foreclosure, such that Inflectra and other biosimilars are denied access to approximately 90 percent of provider accounts and foreclosed from competition in the Relevant Markets.

128. Because providers and insurers are the gateway for the distribution and sale of the Relevant Products, there are no viable alternative means of distribution or sale and substantial foreclosure exists. Biosimilar competitors to J&J have no practical alternative means of selling infliximab to patients.

129. These de facto exclusive arrangements are in effect durable long-term agreements because the incentives J&J has exploited are not likely to change. So long as J&J's contracts remain in place, biosimilars will not be able to dent J&J's base of existing patients, and the incentives underlying J&J's contracts will remain. No insurer can practically walk away from and not continue to perform under the J&J agreement due to the above-discussed penalties.

130. The effect of each such agreement is and has been to substantially lessen competition in the Relevant Markets. The aggregate impact of such agreements is and has been to substantially lessen competition or tend to create a monopoly in the Relevant Markets.

131. By imposing such conditional contracts, J&J is directly and proximately foreclosing Pfizer and other competitors from a substantial portion of the Relevant Markets.

132. J&J's conduct has had anticompetitive effects in the Relevant Markets, including, without limitation, the effects described above in Paragraphs 102 through 106.

133. As a result of J&J's conduct, and the harm to competition caused by that conduct, Pfizer has suffered substantial and continuing injuries.

FOURTH CLAIM FOR RELIEF
Violation of 15 U.S.C. § 1
Agreements in Restraint of Trade in All Relevant Markets

134. Pfizer repeats and realleges Paragraphs 1 through 133 as set forth herein.

135. J&J has entered into agreements with insurers and providers of Remicade with the purpose and effect of unreasonably restraining trade and commerce in the Relevant Markets.

136. J&J's solicitation and enforcement of the exclusionary contracts described above constitute unlawful agreements, contracts, and concerted activity that unreasonably restrain trade in the Relevant Markets in violation of Section 1 of the Sherman Act.

137. J&J's conduct has had anticompetitive effects in the Relevant Markets, including, without limitation, the effects described above in Paragraphs 102 through 106.

138. Among other things, given that (a) J&J imposed explicit conditions that insurers and providers eliminate (or almost completely curtail) their dealings with infliximab biosimilars, and (b) J&J's ASP for Remicade has actually *increased* since the biosimilar entered, J&J's

pricing is not the clearly predominant means by which competition has been foreclosed in the Relevant Markets.

139. Even if price were deemed to be the clearly predominant means by which competition has been foreclosed, when the total amount of discounts and rebates that J&J offers to insurers and providers under the contracts described herein, including multi-product bundle contracts, is attributed to the portion of Remicade sales that is contestable by a biosimilar like Inflectra, J&J is pricing Remicade below its own average variable cost.

140. As a result of J&J's conduct, and the harm to competition caused by that conduct, Pfizer has suffered substantial and continuing injuries.

PRAYER FOR RELIEF

141. WHEREFORE, Pfizer respectfully prays that the Court enter judgment against J&J and in favor of Pfizer, as follows:

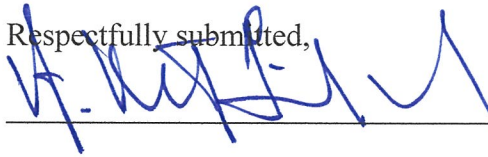
- a. Awarding Pfizer money damages, trebled pursuant to law, in an amount in excess of \$150,000.00 (exclusive of interest and costs);
- b. Awarding Pfizer the costs of the lawsuit, including its reasonable attorneys' fees and court costs;
- c. Declaring J&J's conduct unlawful and in violation of the above-referenced statutes;
- d. Entering appropriate preliminary and permanent injunctive relief barring J&J from continuing to undertake its anticompetitive scheme, including its exclusionary contracts; and
- e. Ordering such other and further relief as the Court may deem just, proper, and equitable.

JURY TRIAL DEMANDED

142. Pfizer demands a trial by jury for all issues triable by jury.

Dated: September 20, 2017
Philadelphia, PA.

Respectfully submitted,



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