

Testimony of Justin McCarthy
House Energy and Commerce Health Subcommittee
May 9, 2019

Chairwoman Eshoo, Ranking Member Burgess and Members of the Subcommittee, thank you for inviting me to testify today. It is an honor to be part of this panel. My name is Justin McCarthy, and I currently lead the Pfizer team which is responsible for reimbursement and market access for our innovative medicines. I have been in healthcare my entire career having been trained as a pharmacist prior to joining Pfizer.

At Pfizer, our purpose is to create breakthroughs that change patients' lives. We currently have over 100 programs in our R&D pipeline and are hoping to bring a wave of innovative new medicines to the market addressing the most challenging diseases and conditions, including cancer, hemophilia, sickle cell disease, and gene therapies that have the potential for treating and curing diseases in a single dose.

However, these innovations will not change people's lives unless they can access them and afford them. That is why we believe our future success will rest not only on the scientific innovations we bring to patients but also on the commercial innovation and solutions we create to enhance access and affordability to our medicines. To achieve this, I believe we need to work in partnership with governments and others in the healthcare sector to identify and implement solutions that relieve patient affordability burdens.

This hearing and others held by Congress, as well as the Administration's focus, has been a catalyst for this much needed collaboration. I am especially pleased to testify before this Committee as it is the one which helped create the modern-day biopharmaceutical industry with the passage of the Hatch Waxman Act, the Prescription Drug User Fee Act and its subsequent reauthorizations as well as the 21st Century Cures Act.

These laws have and continue to deliver tangible improvements in speeding new medicines to market. It would have been difficult to imagine just a few years ago that FDA could approve a drug based on real world evidence. But that is exactly what happened recently when FDA approved a new use for our breakthrough breast cancer medicine, Ibrance, thanks in large part to provisions in the 21st Century Cures Act.¹

We need to bring that innovation mindset to address what I see as three trends that have emerged over the past several years which are exacerbating the impact of medicine costs to patients.

¹ The FDA expanded the indications for IBRANCE® (palbociclib) in combination with an aromatase inhibitor or fulvestrant to include men with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced or metastatic breast cancer.

First, the current system of rebates has increasingly led to perverse market incentives leading to a disconnect between negotiated net prices and prices people pay at the pharmacy counter. This evolution is creating misaligned incentives and market distortions that are driving up costs for consumers.

Second, the growth in high deductible plans and co-insurance are depriving patients of negotiated discounts and putting healthcare out of reach for many consumers. In fact, more than half of commercially insured patients' out-of-pocket spending for branded prescription drugs is now based upon the full list price, not on the negotiated price. And this trend is even more acute for medicines because patients pay higher out of pocket costs for medicines (14%) than for other healthcare costs (2%)

Just last week, a Kaiser/LA Times survey reported that almost half of those with a plan with at least a \$3,000 individual deductible or a \$5,000 family deductible had trouble meeting their deductible and co-insurance. And more than half of these people lacked savings equal to their high deductibles.

The third factor is that scientific advances have led to the growth of specialty medicines such as cancer immunotherapies, biologics, gene therapies, precision medicines, that weren't contemplated when the Part D design was implemented.

These factors are all coming together to create an affordability crisis for patients. Our healthcare system needs to be simpler and more transparent, and it needs to incentivize innovation while simultaneously ensuring access. And most importantly, we need to put patients first.

Pfizer intends to be a productive participant in policy making and finding meaningful solutions in the government and commercial marketplace. As such, we would like to propose four ideas to drive reductions in costs for patients and the government:

First: Shift Away from Rebates to Upfront Discounts and Pass the Savings to the Patient:

Although the traditional drug distribution and payment system helped constrain overall spending on medicines historically, the underlying mechanics now need to work better for patients. Today's healthcare system has evolved over time with changes in drug insurance benefit designs, as well as changes in the size, role, and structure of the supply chain. The current system of rebates has increasingly led to perverse market incentives culminating with a clear disconnect between list prices and prices people pay at the counter. We believe the Administration's proposed rebate rule is an important first step, but it is only a partial solution and broader reforms are needed. I encourage Congress to consider additional options that will address the distortions in the system and benefit patient affordability.

Research shows that the billions of dollars in negotiated rebates, discounts, and fees do not always directly benefit the patients who are using these medicines. These are the most vulnerable patients with serious medical conditions and they should not be shouldering the burden of subsidizing premiums for everyone. By applying the discounts and fees paid by the pharmaceutical manufacturer to the price paid by patients at the pharmacy, patients can benefit directly. In 2019, Pfizer expects to pay billions in rebates and fees to ensure Medicare Part D and commercial plan patients have access to our medicines.

Though actuarial modeling suggests that moving rebates to discounts at the point of sale will lead to increased premiums in Part D, it is important to put those potential premium increases in context. The average basic Part D premium is \$32.50 in 2019, about a dollar less than in 2018. If the proposed rule was finalized, monthly premiums for Part D beneficiaries would increase between \$2.70 and \$5.64 in 2020, depending on the assumptions made in estimates released by HHS. Additionally, plans will have strong incentives to minimize costs and the lower premium estimates assume that plans would more aggressively manage formulary costs to minimize premium increases.

Contrary to what some analysis has said, the rebate rule is not a windfall to Pfizer or the pharmaceutical industry. We are committing to convert all our rebates to point of sale discounts to benefit what patients pay at the pharmacy counter. In addition to not withholding any negotiated rebates, we also fully expect that plans and PBMs will be able to negotiate even greater discounts above the level of our current rebates. If rebate reform was implemented, our modeling suggests that our largest price concessions to any one plan would become completely transparent to all other plans thereby putting downward pressure on our net prices.

Our modeling also shows that beneficiaries will pay less in out-of-pocket costs for their medicines. For Pfizer alone, 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. Notably, research also shows that sharing discounts at the pharmacy counter could reduce total health care spending, not just drug spending.

In contrast to rebates, point of sale discounts in Medicare Part D will be transparent. As such, plans and PBMs will have additional information enabling them to negotiate for lower net prices in any contract going forward. Nonetheless, despite the potential negative financial risk to the company, the move to point of sale discounts will be good for patients and the broader health care system. In fact, Pfizer believes that rebate reform should apply to all parts of Medicare, Medicaid, as well as to the products that fall within the pharmacy and medical benefits in the commercial market. It is important to avoid a bifurcated market that would continue the misaligned incentives currently in place that drive high list prices.

Eliminating rebates in the commercial markets and replacing them with upfront discounts will provide those patients with reduced out-of-pocket costs, and will in turn improve access, adherence, and overall patient outcomes. In addition, applying the changes to the commercial market will increase the likelihood, in our view, that rebate reform will achieve the goal of reducing 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 while a price reduction applies to all markets, manufacturers will need to compete in the commercial market based on the current rebating system which incentivizes higher list prices and bigger rebates.

To ensure we are working towards this goal, we hope Congress will consider legislation that encourages elimination of rebates and the de-linking of fees based on the list price of a medicine in the commercial markets. These policies will ensure that patients who take these medications benefit from the negotiated discounts at the pharmacy counter. Consistent transparency in discounting is expected to lead to increased competition among manufacturers as each manufacturer competes for formulary position.

The Administration's timeline to implement these system changes can be achieved. If finalized, successful implementation of rebate reform will require coordination among all stakeholders (manufacturers, PBMs, wholesalers, pharmacies, and HHS), and additional guidance from the Administration regarding certain operational aspects of implementation. For example, the Proposed Rule would require rebates to be processed through a chargeback mechanism at the point of sale, however the Rule does not specify which entities will be permitted, and will have the capability, to process the point-of-sale price reductions.

To ensure Pfizer is ready to implement the proposed changes in the Rule, we are taking steps to enhance our processes, systems, contracts and other administrative operations.

We will work with other leaders in the healthcare sector to advance these reforms, and we're committed to lowering list prices if Congress passes legislation to extend the rebate rule to the commercial market.

Second: Capping Seniors' Out-of-Pocket Medicine Costs

Thousands of patients today are benefiting from specialty medicines that are a result of significant scientific and clinical advances. Today's innovative medicines treat highly complex conditions, such as cancer and rare diseases. In fact, among new medicines currently in clinical development across the industry, 74 percent are potentially first-in-class, meaning they represent entirely new ways of treating disease and other health issues.

Specialty medicines can provide great value to some of the hardest-to-treat diseases and may offer a more targeted treatment, meaning they can be more effective than other available options. But no one can benefit from a medicine, or any other health care treatment, that they can't afford. In some ways our health care system has not kept up with these advances, and one key example is health insurance benefit design. The primary purpose of any insurance – and health insurance should be no exception – is to protect people from a loss or risk, and to spread the cost of that protection among a large group of people. Yet, patients are increasingly being required to take on a bigger share of their medicines' costs, and that is particularly true when it comes to innovative and expensive treatments.

The Medicare Part D program – that provides insurance benefits for outpatient pharmacy medicines for people with Medicare – is a prime example of the trend in shifting costs on to patients. Part D plans can charge between 25 percent and 33 percent coinsurance for specialty tier drugs before enrollees reach the coverage gap. In the gap, they now pay 25 percent co-insurance for all brands. Then once they hit the catastrophic threshold (\$5,100 in total drug costs in 2019), they pay 5 percent coinsurance. There is no maximum out-of-pocket cap.

This makes the Medicare Part D program an outlier among most other insurance programs that provide coverage for medicines. Further, all other Medicare-covered services have some form of cap or other supplemental protection (like Medigap) available against out-of-pocket costs.

A recent analysis by the Kaiser Family Foundation examined expected annual 2019 out-of-pocket costs for more than 2 dozen specialty tier medicines and found that median annual out-of-pocket costs ranged from \$2,622 for to \$16,551. For many of those medicines, most of that spending occurred above the catastrophic threshold.²

This significant cost-sharing burden is taking a serious toll on their ability to access needed medicines. In fact, there is evidence that at least a quarter of new Medicare Part D prescriptions are abandoned at the pharmacy counter if beneficiaries are asked to pay \$50 or more, which unfortunately is often the case. This number can exceed 50% for new prescriptions. This is bad not only for patients, but also for overall healthcare system cost.

I think most would agree that cost-sharing requirements should not be so large as to inappropriately restrict or interfere with the proper use of medications, which can lead to negative health outcomes and additional costs to the health care system. Multiple studies have repeatedly shown that higher cost-sharing leads to reduced or delayed initiation of treatment, and lower adherence rates, which, in turn, may result in worse outcomes for patients as well as higher overall Medicare spending. Examples of studies showing the impact of poor adherence on outcomes and spending include:

- Medicare patients with Parkinson’s disease, adults with Crohn’s disease, children with cystic fibrosis and patients with rheumatoid arthritis have all been shown to achieve health care savings through improved use of medicines.³
- Advanced melanoma patients with high adherence to immunotherapy experienced both lower all-cause and melanoma-related costs as compared to patients with low adherence.⁴

² Henry J. Kaiser Family Foundation. Medicare Part D Enrollees with Serious Health Conditions Can Face Thousands of Dollars in Out-of-Pocket Costs Annually for Specialty Drugs. January 29, 2019.

<https://www.kff.org/medicare/press-release/medicare-part-d-enrollees-with-serious-health-conditions-can-face-thousands-of-dollars-in-out-of-pocket-costs-annually-for-specialty-drugs/>

³ YJ Wei et al. Antiparkinson Drug Adherence and Its Association with Health Care Utilization and Economic Outcomes in a Medicare Part D Population. *Value in Health* 2014 17(2), 196-204. BG Feagan et al. Healthcare Costs for Crohn's Disease Patients Treated with Infliximab: A propensity Weighted Comparison of the Effects of Treatment Adherence. *J Med Econ.* 2014;17(12):872-80. AL Quittner et al Pulmonary Medication Adherence and Health-Care Use in Cystic Fibrosis. *CHEST Journal* 2014, 146(1), 142-151. Grabner, et al. “Costs Associated with Failure to Respond to Treatment among patients with Rheumatoid Arthritis Initiating TNFi Therapy: a retrospective claims analysis.” *Arthritis Research & Therapy* (2017) 19:92.

⁴ K Gupte-Singh et al. Adherence to Cancer Therapies and the Impact on Healthcare Costs among Patients with Advanced melanoma in the USA. Proceedings of the 22nd Annual International Meeting International Society of Pharmacoeconomics and Outcomes Research; 2017 May; Boston, MA. Abstract available at:

<https://www.ispor.org/ScientificPresentationsDatabase/Presentation/70971?pdfid=49558>

- For patients with multiple sclerosis, initiation of disease modifying therapy was associated with significant reductions in health care resource utilization (emergency room or urgent care visits, and hospital inpatient stays) and non-prescription medical costs (up to \$5,700).⁵

In fact, in 2012 the Congressional Budget Office credits Medicare policies that increase use of medicines with savings on other Medicare costs, recognizing that a 1% increase in number of prescriptions filled results in a 0.20% reduction in spending on medical services. Since then, research has shown that offsets may be 3 to 6 times greater for beneficiaries with chronic conditions.

It is critically important, therefore, that we review cost-sharing burdens in the Medicare prescription drug program and take steps to modernize the benefit to ensure seniors don't have to make the difficult decision of forgoing their needed prescriptions.

We need to start by adding a reasonable out-of-pocket maximum to the Part D benefit. However, we can and should go further and fundamentally restructure the Part D benefit design so that it is simpler for beneficiaries and more sustainable for the government.

To help mitigate the additional cost to the government of modernizing the Part D benefit to relieve the significant cost sharing burden many Medicare enrollees face today, we support policies advocated by organizations across the ideological spectrum that would require both the health plan and the pharmaceutical industry to shoulder more of the expense of insuring seniors in the program. For example, one concept that holds promise is changing the benefit design by adding an out-of-pocket cap, removing the Medicare coverage gap, and restructuring the catastrophic benefit so that the costs of drug benefits would be paid by a combination of Part D plans, drug manufacturers, and federal government reinsurance.

We are confident that we can achieve these policy changes in such a way that impact to beneficiary premiums is minimal and are ready to work together with Congress to find ways to modernize the Part D benefit to provide much-needed relief for Medicare enrollees.

⁵ Nicholas J et al. Comparison of Disease-modifying Therapies for the Management of Multiple Sclerosis: Analysis of Healthcare Resource Utilization and Relapse Rates from US Insurance Claims Data. *PharmacoEconomics Open*. 2017. Available at: <https://link.springer.com/article/10.1007/s41669-017-0035-2>

Third: Knocking Down Barriers to Lower-Cost Biosimilars:

Medicines are the only segment of the healthcare system with a built-in cost containment mechanism. When a medicine's patent expires, lower-cost generics are made available, often at just 5% of the cost of the original branded product.

This system is working well for generic drugs. In fact, 9 out of 10 drugs sold in the U.S. today are lower-cost generics. However, the system is not yet working in the biologics space where the adoption of biosimilars is facing resistance.

Building on the success of the generic market, establishing a robust biosimilars market can help to lower the overall healthcare costs in the United States, and Pfizer is committed to bringing these more affordable treatment options to patients.

With more than 10 years of global in-market experience and six approved products in major markets, Pfizer is proud to be a leader in biosimilars and at the forefront of this vital healthcare segment. Pfizer is the leading biosimilars company worldwide by revenue, and in the U.S., we are the industry leader with five FDA-approved biosimilars.

As a major producer of biosimilars, Pfizer appreciates the actions Congress took through the Biologics Price Competition and Innovation Act (BPCIA) of 2009 to provide an abbreviated pathway for biosimilars to gain FDA approval. And Biosimilars have the potential to save the U.S. billions in health care costs, providing a solution that will lower health care costs for both patients and American taxpayers, as well as improve public health. That's why we must incentivize the use of biosimilars, which today can be as much as 40% less expensive than the branded biologic for Medicare patients.

Unfortunately, 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. I can't think of a more concerning example of a broken U.S. healthcare system that is directly impacting the pocketbooks of Americans.

For instance, Pfizer produces a biosimilar which have struggled to gain market share. The primary barrier to its uptake is an anticompetitive contracting scheme that relies on rebates. 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 the reference product while effectively blocking the biosimilar from coverage.

In addition to exclusionary contracting, we have also witnessed misleading marketing practices that mischaracterize important elements of biosimilar criteria. This creates doubt and confusion among patients, and it must end. Interestingly, the rebate reform I referenced earlier would go a long way toward removing the perverse incentives that lead to such exclusionary contracts.

At Pfizer, we believe there are several solutions that could help incentivize patients and providers to adopt biosimilars and share in the savings associated with their use. We believe that increasing the adoption of biosimilars will reduce costs to the Medicare program. Let me touch on two:

A Shared Savings Biosimilars Model

Congress could direct the CMS Innovation Center (CMMI) to create a biosimilar “shared savings” approach in which Medicare savings associated with prescribing a biosimilar, as compared to a reference biological, would be shared with providers. Currently, providers in Medicare Part B are reimbursed for administering biosimilars at average sales price (ASP)+6% (less under sequestration), of which the federal government pays 80% and beneficiaries pay 20% coinsurance. To increase biosimilar utilization under the program, providers could share in the difference in total ASP between the biosimilar and its reference biologic, for each administration.

For example, in the first year of a biosimilar being on the market, providers would receive, as an additional payment, 100% of the difference between the ASP of the biosimilar and the ASP of its reference biologic. In the second year, providers would receive 75% of the difference and in the third year and through the budget window, providers would receive 50% of the difference.

Reduced Patient Cost Sharing for Biosimilars

Congress could direct CMS to establish \$0 cost sharing for all beneficiaries who utilize biosimilars in Medicare Part B. These savings would go directly into the pockets of patients who use these medicines, as well as to taxpayers who will benefit from the lower costs. This reduction in cost sharing would apply to patients who have no supplemental coverage, and patients with supplemental coverage that have deductibles or other cost sharing and could be time-limited.

Fourth: Accelerate the Shift to Value Based Care

Pfizer supports the move to value-based healthcare and is prepared to stand behind the benefits that our medicines deliver to patients and to the United States healthcare system.

This will require thinking about the value of healthcare interventions, including medicines, in a more comprehensive way, and designing new approaches to reimbursing participants in the system with regard to that value. It will also require the evolution of insurance designs that remove barriers to high-value treatments.

Further, we believe that we can help our healthcare system operate more efficiently and deliver better value to patients and payers when we also think through ways to address the so-called social determinants of health.

The U.S federal government is already trying to create a healthcare system where hospitals are rewarded for keeping patients from being readmitted, and where physicians get paid more to prevent disease than they do to simply treat it.

We strive to create a system where companies like Pfizer get paid based on the number of strokes we prevent or the number of cancer patients who go into full remission, rather than the number of pills we sell.

In such a system, if our medicines do not produce all the results we expect, we would be paid less. And if they do produce those results, we would be paid more. If done correctly, these arrangements – focused on the appropriate therapeutic areas – can align the interests of patients, health plans and biopharmaceutical companies around one shared goal: ensuring positive health outcomes for the patient.

To make this a reality, we need Congress' help to address impediments that are slowing down the facilitation of these arrangements in the current system for the good of patients. Congress should clarify the Anti-Kickback Statute, the government price reporting requirements, and other laws to encourage interactions between manufacturers, health plans, PBMs, providers (e.g. pharmacists) and beneficiaries that allow for value-based purchasing arrangements, more comprehensive medication adherence incentives, and medication synchronization programs.

For example, offering patients incentives can be an extremely effective mechanism in promoting medication adherence. Current law only allows incentives for a very limited selection of preventive clinical services, and only individuals who are asymptomatic and not currently suffering from an injury, illness, or medical condition qualify.

We believe that broadening this definition to include incentives for interventions that help those already suffering from illness—as well as adherence programs to improve a beneficiary’s ability to obtain medical items and services—will promote industry innovation and lower costs to the healthcare system.

We also see the value in pharmacy programs that combine medication synchronization with medication reviews and counseling to help identify and address gaps in patient care and increase adherence and persistence. These programs ultimately help to drive savings to the health care system

The complexities inherent in value-based contracting arrangements and the lack of clarity with respect to the existing Anti-Kickback Statute (AKS) safe harbors cannot be overstated. There is currently no safe harbor to the AKS that specifically addresses value-based arrangements. Instead, manufacturers and health plans must evaluate such arrangements under existing safe harbors, such as the discount or personal services safe harbors, which were not written with value-based contracts in mind.

Manufacturers also must navigate complex government price reporting regulatory requirements that do not sufficiently provide guidance for the potential price fluctuations over time that are associated with value-based arrangements, where a rebate or refund might be paid years after the patient started their drug therapy. Finally, value-based arrangements present operational challenges, such as issues associated with: (1) the logistics of collecting patient outcomes data relevant for a drug; (2) adjudicating disputes over outcome metrics; and (3) developing agreements and procedures for how to handle cases in which patient adherence affects outcomes.

As much potential as value-based arrangements offer, they function within the constraints of health insurance designs that don’t always serve patients as well as they could. As already discussed, high cost-sharing for medicines can have a negative impact on adherence and outcomes. Applying the principles of value-based insurance design which promote the use of high-value care through lower cost-sharing can serve both patients and payers well.

Consider that many employers now are utilizing high-deductible plans coupled with health savings accounts. While these plans typically have lower premiums, patients are required to spend thousands of dollars out of pocket before their insurance coverage kicks in for needed medicines, creating a major affordability challenge for some patients.

The law allows insurers to cover certain preventive medicines before patients hit their deductible, but many medications are not allowed to be covered on a pre-deductible basis, creating cost barriers to care for patients, especially those with chronic conditions like diabetes, asthma, and mental health disorders. We believe the law should be changed to allow insurers to exempt more preventive medicines (including those that prevent chronic conditions from worsening) from the deductible. Ensuring patients can access their medicines can lead to significant downstream cost savings to the system by reducing hospitalizations and emergency care.

Finally, there needs to be a greater recognition of the role that social factors play in determining health. We are encouraged by the steps that CMS has taken to allow Medicare Advantage plans to provide nonmedical benefits that address the social determinants of health for people with chronic disease. For example, beneficiaries can now receive expanded meal delivery, transportation for non-medical needs like grocery shopping, and in-home services such as safety modifications in order to improve their health and/or overall function. We think efforts like these should be expanded to benefit even more patients.

In closing, across Pfizer, we share a passion to significantly improve patients' lives. And for all of us, our work is personal. I joined Pfizer because I truly believe we are a science-based company focused on bringing the next wave of innovations to patients to make a difference in their lives. Our success is directly connected to how strong our science is.

Today, more than 784 million people around the world used a Pfizer medicine or vaccine to improve their health and, in many cases, save their lives. We estimateⁱ that Pfizer vaccines protected more than 65 million babies and elderly patients; our medicines helped reduce the risk of heart attack or stroke for more than 48 million cardiovascular patients; and oncologists used our therapies to treat more than 1.2 million people battling cancer. These are humbling numbers. More important, they represent real people; real people who rely on our innovations. We also have a bold ambition to bring 15 breakthroughs to patients in the next 5 years.

That is why we come to work every day. It's why the researchers in our labs in California, Connecticut, Massachusetts and New York work day-in and day-out to discover the next treatment or cure. It's why our manufacturing colleagues, who make some of the most complex molecules in existence, in Georgia, Kansas, Michigan, Missouri, North Carolina, Ohio, Pennsylvania and Wisconsin – work to ensure the reliable supply and highest standards of quality of our products.

These potentially lifesaving medicines will not reach the people who need them the most if our patients, your constituents, cannot afford them. Our system needs to be simpler and more transparent, and it needs to incentivize innovation while simultaneously ensuring access.

We are actively working together across the healthcare sector to identify and implement solutions that relieve patient affordability burdens. Where we can, we all need to come together to find systemic solutions to these persistent problems.

We all want America to remain as the leader when it comes to innovative medicines, and to ensure that people have access to them at that moment when they need it the most. No patient should have to wait.

Again, thank you for the opportunity to testify today and I look forward to answering your questions.

ⁱ Patient counts are estimates derived from multiple data sources.