Robert W. Jones
Senior Vice President
U.S. Government Relations

Pfizer Inc
1275 Pennsylvania Ave, NW, Suite 600
Washington, DC 20004
Tel 202 624-7518 Robert.Jones@pfizer.com

June 6, 2019

The Honorable Richard E. Neal
Chairman
Ways and Means Committee
U.S. House of Representatives

The Honorable Kevin Brady
Ranking Member
Ways and Means Committee
U.S. House of Representatives

The Honorable Frank Pallone, Jr.
Chairman
Energy and Commerce Committee
U.S. House of Representatives

The Honorable Greg Walden
Ranking Member
Energy and Commerce Committee
U.S. House of Representatives

Dear Chairman Pallone, Chairman Neal, Ranking Member Walden, and Ranking Member Brady,

Pfizer appreciates the opportunity to comment on the bipartisan draft legislation to improve the Medicare Part D prescription drug program that was released on May 23, 2019. We commend the Committees for their efforts to address a significant problem for Medicare beneficiaries enrolled in the Part D program – the growing burden of out-of-pocket costs for prescription medicines. Not only are Medicare beneficiaries at risk from high out-of-pocket costs, but the overall financial health of the Medicare program suffers. As you know, based on a large body of research showing that better use of medicines can reduce spending on other medical services, the Congressional Budget Office (CBO) credits Medicare policies that increase use of medicines with savings on other Medicare costs. [1] Thus, we think it's time to modernize the benefit design to both provide needed relief to Medicare beneficiaries but also to improve the long-term sustainability of the program.

Pfizer, one of the world's largest research-based biopharmaceutical companies, intends to be a productive participant in policy-making and finding meaningful solutions for improving access to medicines in the government and commercial marketplaces, while recognizing the need to reduce the total costs of health care.

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.

[1] According to CBO, every 1 percent increase in the utilization of prescription medicines decreases Medicare spending in Parts A and B by 0.20 percent.

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. New specialty medicines have the promise to reduce total cost of care over a patient's lifetime, but no one can benefit from a medicine, or any other health care treatment, that they can't afford. 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, specialty treatments. Part of the problem is that the health insurance system has not kept up with these advances in drug therapies. Health insurance benefit designs can and should be structured in new ways that ensure insurance does what it is supposed to do – protect people from a loss or risk and spread the cost of that protection among a large group of people – while at the same time effectively manage costs to the system.

The vast majority of Medicare beneficiaries have modest, fixed incomes. In 2016, half had incomes below $26,200 and one quarter were living on less than $15,250. Medicare Part D beneficiaries who are not eligible for low-income subsidies (LIS) face multiple affordability challenges today due to the way the benefit is structured and how cost sharing is calculated. These challenges include high cost sharing, the lack of an out-of-pocket maximum, and an uneven distribution of out-of-pocket costs throughout the benefit year.

The increased use of complex, multi-tiered formularies and growing prevalence of coinsurance expose patients to a disproportionately high share of the cost of their medicines. Today, the majority (95 percent) of Part D prescription drug plans use formularies with five coverage tiers, and 5 percent are now using a sixth tier. Relative to the fixed-dollar copays commonly applied to medicines on the preferred drug tier, the increased use of coinsurance-based non-preferred and specialty tiers results in higher and less predictable cost sharing for beneficiaries who rely on innovative and breakthrough medicines.

This significant cost-sharing burden is taking a serious toll on Medicare beneficiaries' 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 per prescription, which unfortunately is often the case. This abandonment rate can exceed 50% for new prescriptions. This is bad not only for patients, but also for overall healthcare system cost.

As Pfizer testified before the Energy & Commerce Committee last month, we believe it is critically important to 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.

It is in that spirit that we agree with the Committees' proposal to add an out-of-pocket maximum to the Part D benefit. This is a long over-due patient protection that is common in the vast majority of other commercial and government health insurance programs and is increasingly important as many chronic conditions are increasingly treated with drug therapies.

The Committees' draft legislation includes a second provision to shift the manner in which the government subsidizes the cost of the benefit for Medicare beneficiaries and the Part D plans that administer the benefit. Currently, the Federal Government subsidizes 74.5% of the cost of basic drug benefits, and it pays plans those subsidies in two forms: 1) capitated direct subsidy payments based on plan bids and 2) open-ended reinsurance on individual enrollees for drug spending above

the catastrophic threshold. The Committees' proposal would shift more of the subsidies into the capitated direct subsidy payments by reducing the government's share of liability for spending in the catastrophic phase of the benefit from 80 percent to 20 percent over four years. We understand the rationale behind this shift: the fastest growing part of the Part D budget is occurring in the catastrophic phase of the benefit and this shift would provide stronger incentives for plans to be even more efficient than they are today and drive robust negotiations with pharmaceutical manufacturers like Pfizer. Overall, that will help slow government spending for Part D.

We also expect that this shift in incentives will result in greater discounts being required of pharmaceutical companies, and more pressure for health insurance plans and pharmaceutical companies to find new, innovative solutions for covering and paying for valuable prescription drug benefits.

However, in the drive for efficiency, cost savings, and better value we urge the Committees to be cautious about making changes that would harm patient access to medicines. All existing legislative, regulatory, and sub-regulatory patient protections will be just as important – if not more important – in a scenario that puts more risk on plans in the initial benefit phase. Examples include robust formulary review and anti-discrimination requirements, appeals processes, transition requirements, preserving the six protected classes, improved communication and information requirements to beneficiaries about their benefits, and revisions to the risk adjustment system, to name a few. We encourage the Committees to fortify existing and adopt new safeguards to ensure access is not comprised for the sake of costs under any Part D reform effort that increases plan liability.

The Committee also requested feedback on other potential approaches to modernizing the Part D benefit. Pfizer agrees that 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.

One concept that is under discussion and 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 liability for drug benefits would be borne by a combination of Part D plans, drug manufacturers, and federal government reinsurance.

The coverage gap – also more commonly known as the "doughnut hole" – has been a consistent source of confusion and frustration for Medicare beneficiaries in Part D since the start of the program in 2006. As you well know, the doughnut hole is now "closed" effective this year, which means beneficiaries are responsible for 25% (on average) of the cost of their medicines from the time they meet their deductible to the time they enter the catastrophic phase of the benefit. Yet the vast majority of beneficiaries are unlikely to realize that because of the "ups and downs" of what they are required to pay as they move through those phases. First, if they have a deductible, they pay the full cost of the drug until the deductible is satisfied. Then in the initial coverage period most people use drugs that are on flat co-pay tiers. Once they enter the coverage gap phase they will be faced with payments that are a percentage of the negotiated price of the drug (25%). For seniors and people with disabilities living on modest, fixed incomes, this is at best confusing and at worst could negatively impact how they fill and adhere to the medicines prescribed by their doctors because of the uncertainty of what they must pay from month to month.

Thus, eliminating the coverage gap, adding a maximum out-of-pocket cap, and shifting liability for spending that occurs in the catastrophic phase of the benefit would go a long way towards simplifying and rationalizing the benefit design for Medicare beneficiaries.

As we have stated previously, 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 that would require both the health plan and the pharmaceutical industry to shoulder more of the risk and expense of insuring seniors in the program. We recognize, as do the Committees, that any shift in pharmaceutical company liability to the catastrophic phase of the benefit would change that liability from a capped burden (in the coverage gap) that ends once drug spending reaches a set threshold, to a burden limited only by the calendar year.

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.

We also believe that this type of restructuring – if we get the balance right - fundamentally will help to improve the health and lives of Medicare beneficiaries, as well as save costs throughout the Medicare program.

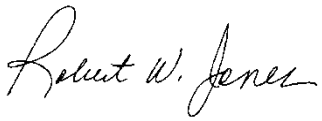
Finally, the Committees also asked for suggestions for other improvements to help address affordability in Part D. As we have stated previously, Pfizer supports reforms that would create a system in which transparent, upfront discounts benefit patients, rather than a system driven by rebates that may not be used to directly benefit patients. 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, particularly for new, single-source drugs.

We believe the Administration's proposed Part D rebate rule is an important first step, but it is only a partial solution and broader reforms are needed. We encourage Congress to expand its proposal to address and distortions in the system and improve?? patient affordability. For example, 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 larger rebates.

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.

Thank you again for the opportunity to provide input on the draft legislation as you consider ways to improve the Part D benefit. We look forward to continuing this discussion with you and your staff over the coming weeks.

Sincerely,



Robert W. Jones
Senior Vice President
US Government Relations