June 6, 2019

By Electronic Delivery: PartDImprovements@mail.house.gov

Re: Improving the Medicare Part D Prescription Drug Program for Beneficiaries

Dear Ways and Means Committee Chairman Richard E. Neal and Energy and Commerce Committee Chairman Frank Pallone, Jr., and Ranking Members Kevin Brady and Greg Walden:

On behalf of AstraZeneca Pharmaceuticals LP (AstraZeneca), I am pleased to submit the following comments on the draft legislation, *Improving the Medicare Part D Prescription Drug Program for Beneficiaries,* and related questions released by the Energy and Commerce and Ways and Means Committees for public input. We would like to express our support for the Committees' work on improving access and affordability of drug therapies for Medicare Part D patients. We appreciate the opportunity to provide our suggestions on how to reform the Part D program to ensure its continued success. We look forward to continued engagement on these important issues.

I. Introduction

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialization of prescription medicines, primarily for the treatment of diseases in three main therapy areas: Oncology; Cardiovascular, Renal & Metabolic; and Respiratory. AstraZeneca is also selectively active in the areas of autoimmunity, neuroscience, and infection. AstraZeneca operates in over 100 countries and our innovative medicines are used by millions of patients worldwide.

As described below, we look forward to continuing to work with the Committees to develop and test market-based policies that will improve care and affordability and reduce costs in the Part D program. We believe medicines are part of the solution to controlling healthcare costs, and this contribution to reducing overall healthcare costs should be considered when discussing drug pricing and reforms to Medicare Part D.

However, we recognize that the current state of drug pricing in the U.S. healthcare system is not sustainable and patients are facing increasingly high out-of- pocket costs. This is particularly true in the Part D program, where Medicare beneficiaries without low-income subsidies (LIS) face unique challenges. As PhRMA notes in its comments to the draft legislation, many non-LIS Medicare Part D beneficiaries have plan benefit designs with high co-insurance based on list price; no annual or monthly out-of-pocket limit; and variable cost-sharing throughout the plan year, with most out-of-pocket costs "front-loaded" in the first months of the plan year or first months of therapy.

A significant body of research shows that higher cost-sharing is associated with reduced medication adherence and in turn, sub-optimal outcomes. A recent study found that when patients have cost-sharing amounts that exceed $250, 71% of prescriptions were abandoned. Even for cancer patients, the abandonment rate was approximately 60% for oral oncology drugs with cost-sharing amounts exceeding

$250. Given the high rates of co-insurance for specialty products in Part D, cost-sharing amounts that exceed $250 are common, particularly in the early months of therapy or the plan year.[1]

Although the Part D program works well for the vast majority of beneficiaries, for non-LIS patients taking specialty products, the status quo is clearly unacceptable. We believe that this issue must be addressed urgently, and we appreciate the Committees' request for input on this topic. We have arranged our comments below to respond to the three questions posed by the Committees on the draft legislation.

II. Question 1: [Feedback on] How the Part D program is addressing the problem of high cost drugs and how the program could better address the costs of these drugs? Specifically, whether or not Congress should consider changing or eliminating the distinction between the initial coverage phase and the coverage gap discount program.

We have three specific suggestions on how the program could better address the costs of drugs: reforming the current rebate system so that patient cost-sharing is based on net prices; creating an annual out-of-pocket cap and assessing the most effective way to address uneven out-of-pocket costs over the plan year; and encouraging the use of value-based agreements in Part D. With respect to the second question on eliminating the distinction between the initial coverage phase and the coverage gap phase, we offer our suggestions on how to simplify the Part D benefit design.

Rebate reform: As a science-led, patient-focused company, the fact that many patients struggle with out-of-pocket costs despite the discounts and rebates we and other manufacturers provide stands counter to our mission of improving patient health.

An important step to addressing affordability in Part D is to evolve the current system of paying for and delivering drug therapies to one in which patients more directly benefit from the discounts and rebates manufacturers provide to Part D plans. Specifically, we believe that patient cost-sharing should be aligned to a product's net price as opposed to its list price, as is the case today. We therefore support regulatory and legislative efforts to require that cost-sharing amounts reflect the rebates and discounts provided to plans. As PhRMA notes in its comments, a short-term solution would be a change in the definition of "negotiated price" to require that this price, on which patient cost-sharing is based, reflects the concessions offered by manufacturers. We also support the recent proposal to create a new safe harbor for discounts provided to Part D plans and pharmacy benefit managers so long as the value of those discounts is passed to the patient at the point-of-sale.

Value-based Agreements: Value-based agreements allow us to reimburse the healthcare system if our medicines do not deliver as intended. This solution demonstrates our willingness to stand behind the value of our medicines. AstraZeneca is working closely with payers and health systems to explore innovative solutions to improve access and affordability that demonstrate the value our medicines bring to patients and the healthcare system. Our value-based agreements aim to manage the totality of treatment costs and keep people healthy and out of the hospital. For several years, AstraZeneca has

[1] Doshi JA, Pengxiang L, Pettit AR, et al. Reducing Out-of-Pocket Cost Barriers to Specialty Drug Use Under Medicare Part D: Addressing the Problem of "Too Much Too Soon." *American Journal of Managed Care*. 2017;23(3 Suppl):S39-S45; Amundsen Consulting. Medicare Part D Abandonment: Deep Dive into Branded Product Abandonment. November 2017.

been exploring these types of solutions through value-based agreements where we are willing to work with healthcare stakeholders to tie payment to patient outcomes.

To date, we have entered into approximately 40 value-based agreements across our therapeutic areas with a variety of payers, making AstraZeneca a leader in the field. While most of these agreements have been focused on securing patient access to our medicines and delivering better patient outcomes, where payers are willing, we are also looking to more directly address patient out-of-pocket affordability through these innovative arrangements. Our ambition is that these agreements will evolve to enable reimbursement back to a payer to be shared with the patient when medicines do not perform as expected.

As an example where a value-based agreement directly reduced out-of-pocket costs for patients, we recently announced the initiation of a value-based agreement for University of Pittsburgh Medical Center (UPMC) Medicare patients who are prescribed BRILINTA. This value-based contract, effective as of January 1, 2019, is groundbreaking in two ways. First, the contract lowers the out-of-pocket costs for a UPMC Medicare Part D patient to approximately $10 for a 30-day supply. Second, what UPMC pays for BRILINTA will vary based on patient outcomes, tying the cost of the medicine to its real-world clinical performance.

We are currently exploring another value-based agreement in Medicare Part D. In addition to having a significant outcomes-based component, this arrangement would reduce patient out-of-pocket costs. This type of agreement allows patients to access their medicines at a lower out-of-pocket cost and payers to control their overall healthcare costs through paying for outcomes.

We strongly believe that value-based agreements offer a significant opportunity to improve the efficiency of the Part D program. There are steps the government can take to encourage the timely adoption of value-based agreements, including in public sector programs like Medicare Part D. For example, at this time, the current Anti-Kickback Safe Harbor (AKS) regulations do not expressly address value-based agreements. Accordingly, manufacturers must seek to structure value-based agreements to meet the requirements of existing safe harbors from the AKS, such as the discount safe harbor and personal services safe harbor, that were created for purposes other than value-based agreements. Although we believe that value-based agreements can strongly benefit patients and the healthcare system overall, the lack of clarity in application of the safe harbors to value-based agreements creates regulatory uncertainty that discourages broader implementation of value-based agreements in public-sector programs.

In addition to the risk of AKS liability, value-based agreements present other regulatory challenges that manufacturers must navigate. For example, manufacturers must manage complex government price reporting calculations that may not account for price fluctuations over time that may be associated with a value-based agreement. In a future system, the default approach should be that pricing and reimbursement for drug therapies are tied to patient outcomes and the value the particular therapy provides. As such, it is imperative that manufacturers and payers—including Medicare Part D plans—engage in value-based agreements.

Policies to encourage these arrangements and to reduce or eliminate existing challenges will be essential to their long-term success. To that end, we appreciate the support of Senators Warner and Cassidy for value-based agreements, as demonstrated by their requests for input on the Patient Affordability Value and Efficiency (PAVE) Act. This draft legislation would promote the development of

value-based agreements by offering increased flexibility for manufacturers to enter into such arrangements, including with Medicare Part D plans by addressing AKS and government pricing concerns. We encourage the Committees to consider similar legislation as it develops policies to improve the Part D program.

Simplifying the Part D benefit design: We believe that the Part D benefit design should be updated to better address patient needs. For example, as a patient moves through the Part D benefit, their cost-sharing liability may vary substantially, causing confusion and lack of predictability. In both the initial coverage phase and the coverage gap, patients are responsible for an average of 25%of costs. However, in the initial coverage phase, patients are more likely to have set cost-sharing set by formulary tier, whereas in the coverage gap, they are more likely to pay a co-insurance, leading to confusion and variation in out-of-pocket costs.

The coverage gap discount program was originally designed to eliminate the "donut hole" that left Part D patients with 100% liability in the coverage gap under the original Part D benefit design. Currently, patients are responsible for 25% of costs in the coverage gap. Now that patients pay 25% of costs in the coverage gap - the same percentage as in the initial coverage phase - it is less clear that a distinct coverage gap phase is necessary.

Additionally, last year we saw significant change to the Medicare Part D Coverage Gap Discount Program in the Bipartisan Budget Agreement of 2018. This measure included a provision that increased required manufacturer contributions within the Part D coverage gap, upping the manufacturers' share of cost in the Part D coverage gap from 50% to 70%, and reducing plan liability to 5%.

Coverage gap liability for plans of only 5% raises concerns that plans do not face sufficient risk to create an incentive for them to manage costs as robustly as they would if they had greater liability. Changes to the coverage gap phase of the Part D benefit should address this issue by increasing plan liability.

To summarize, any change in the coverage gap program should be designed to reduce confusion as patients move from the initial coverage phase to the coverage gap phase. It should also ensure that plans have incentives to manage costs throughout the Part D benefit. Elimination of the coverage gap entirely and shifting liability of plans and manufacturers to the catastrophic phase, if carefully designed, could accomplish these goals.

Out-of-pocket caps: We applaud the Committees for including an annual out-of-pocket cap in the draft legislation. We believe this is an important step in addressing the affordability challenges faced by non-LIS Medicare beneficiaries. Currently, Part D beneficiaries pay 5% coinsurance for all their medicines once they reach the catastrophic phase of the Part D benefit. For beneficiaries on high-cost or multiple medications, even a 5% financial liability can be cost-prohibitive. Providing a predictable limit on costs could assist in limiting beneficiary exposure to costs and allow beneficiaries to better budget for these expenses. Medicare Advantage plans already apply a maximum out-of-pocket (MOOP) limit on annual patient cost-sharing for services covered under Parts A and B. It is therefore reasonable to expect a similar MOOP limit to be extended to Medicare Part D to offer a true catastrophic benefit for patients.

However, as noted above, patient adherence declines significantly as cost-sharing exceeds $250. An annual cap may result in a patient paying their entire annual liability in the first one to two months of therapy or the plan year, and then paying no cost-sharing the rest of the year. While this is certainly an improvement over the current construct, many patients may still be unable to afford their medications

even with an annual out-of-pocket limit. An annual cap would therefore not address the concern of high out-of-pocket costs early in the course of therapy or the plan year. We therefore urge the Committees to explore options to create a monthly cap, a per-prescription maximum copayment, or to otherwise "smooth" cost-sharing more evenly over the plan year.

III. Question 2: What share of costs should be attributed to the beneficiary, Part D plans, and manufacturers under the current system and how this share should change if the liability were shifted for the manufacturer from the current coverage gap discount program to the catastrophic phase of the Part D benefit?

It is important that Part D remain the market-based program as it was designed and has proven successful. In order to keep all stakeholders invested in the program, it needs to function as an insurance benefit by requiring insurers to bear risk. Shifting too much of the cost to manufacturers or patients, leaving plans with nominal risk, runs the risk of loss of competition between plans to provide the best choice of options to beneficiaries and of reduced plan incentives to manage costs.

We therefore agree that the Part D benefit design needs to be modernized to better meet patient and program needs. We are generally aligned with the Committee's proposal to increase plan liability in the catastrophic phase. We also believe, that if carefully designed, shifting manufacturer liability from the coverage gap to the catastrophic phase of the benefit could help better align incentives and simplify the Part D benefit design. It is imperative that any liability assumed by manufacturers in the catastrophic phase should go directly to reducing cost-sharing for Part D patients through the creation of an annual or monthly out-of-pocket cap, and not to reducing risk that should be held by Part D plans.

Finally, we would emphasize that shifting additional risk to plans must be balanced against the need to protect patient access to needed therapies. The Committees' draft legislation includes a provision that would significantly increase plan liability in the catastrophic phase of coverage to 80%, versus 15% today. While we are aligned with increasing plan risk in the catastrophic phase for the reasons described above, we urge the Committees to consider potential impacts to coverage and access and include policies to mitigate these effects in any reform to the Part D benefit design.

Patients who reach catastrophic coverage are among the most vulnerable in Medicare and putting plans at significantly more risk for the costs of these patients could result in increased efforts to limit access. We agree with PhRMA's suggestion that reforms that result in increased Part D plan liability in the catastrophic phase should be coupled with additional patient safeguards, such as improved appeals processes and prohibitions on requiring patients to change therapy in the middle of the plan year.

IV. What improvements the Committees should consider with respect to low-to-moderate income Part D beneficiaries and out-of-pocket costs below the catastrophic level?

We believe that our suggestions in response to question one regarding rebate reform and value-based agreements will help reduce out-of-pocket costs for low-to-moderate income patients and costs below the catastrophic level. Additionally, a monthly out-of-pocket cap would help these patients by addressing uneven costs over the plan year as well.

Furthermore, we support PhRMA's comments regarding the need for Congress to address the out-of-pocket "cliff," in which the catastrophic threshold will increase substantially in 2020, resulting in higher costs to patients. We urge Congress to address this issue to avoid negative impacts to patients.

We also support PhRMA's comments regarding the potential harm that could occur if coverage gap discounts were excluded from the calculation of True Out-of-Pocket Costs (TrOOP), which is the amount used to calculate whether a patient reaches catastrophic coverage. If manufacturer coverage gap payments were excluded from TrOOP calculations, patients would take longer to reach catastrophic coverage, resulting in higher costs to patients.

Finally, we urge the Committees not to change cost-sharing for LIS patients as part of any reform to Part D. Proposals to increase cost-sharing for branded products for these patients fail to acknowledge the already high rate of generic use in this population, as well as the harm this could cause this vulnerable population by making it more difficult to afford needed therapies. We believe the proposals we have outlined in our comments offer more efficient and patient-oriented solutions than excluding coverage gap payments from counting towards TrOOP or raising copayment amounts for LIS patients.

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We greatly appreciate the opportunity to provide these comments and look forward to continued engagement with the Committees on reforming the Part D program. If you have any questions or would like any additional information, please contact me at 202-350-5542 or via e-mail at Christine.Bloomquist@astrazeneca.com.

Sincerely,

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