June 6, 2019

The Honorable Richard Neal
2309 Rayburn House Office Building
Washington DC 20515

The Honorable Frank Pallone
2107 Rayburn House Office Building
Washington DC 20515

The Honorable Kevin Brady
1011 Longworth House Office Building
Washington DC 20515

The Honorable Greg Walden
2185 Rayburn House Office Building
Washington DC 20515

Re: Part D Discussion Draft and Related Questions

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:

Astellas Pharma US, Inc. (Astellas) appreciates the opportunity to submit comments to the Committees on the discussion draft released on May 23, 2019. Astellas is an innovative company with global headquarters in Tokyo, Japan and has a growing presence in the Americas. In the U.S., our fundamental goal is to improve the health of individuals by developing and marketing treatments for unmet medical needs in the therapeutic areas of oncology, urology, cardiology, and infectious disease.

In recent years, we have witnessed the emergence of revolutionary scientific innovations that are turning many serious diseases into manageable conditions. Yet, while we embrace the surge of new scientific discoveries, such efforts are moot unless patients have access to these life-saving innovations. As long as patients are struggling to afford their out-of-pocket costs and are unable to access medicines that may save their lives, the promise of these new therapies remains unfulfilled. Astellas appreciates the Committees' attention to Medicare Part D and we look forward to a productive collaboration that modernizes this important program.

Our responses to the specific issues raised by the Committees and our feedback on the discussion draft itself are below.

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.*

Annual Out-of-Pocket Cap

Astellas believes that including an annual out-of-pocket cap for beneficiaries at the catastrophic threshold is a key step towards strengthening and improving the Part D program. Despite the benefit's tremendous success, Part D has remained largely unchanged since its inception in 2006. During this time, we have seen incredible innovation and scientific discovery that has improved and extended the lives of millions of seniors. As a result, there are now legitimate concerns that Part D, while still being an invaluable asset for seniors, is falling short in providing protection for seniors who rely on specialty treatments to battle conditions like cancer and other deadly diseases.

The current Part D benefit design is lagging behind the rapid pace of medical innovation, resulting in many seniors facing high out-of-pocket costs. For example, over 40 percent of the oncology treatments covered by Part D require more than $250 in out-of-pocket payments for each prescription.[1] A 2019 study by the Kaiser Family Foundation found that the median out-of-pocket cost for Part D beneficiaries on 28 specialty tier drugs ranged from $2,622 to $16,551 per year.[2] This is problematic because high cost sharing has been linked to reduced adherence to medicines, risking the health of this vulnerable population.[3]

Astellas strongly supports the Committee's efforts to introduce an annual out-of-pocket spending cap for Part D beneficiaries. It is unjust to burden seniors with unlimited, uncapped spending merely because they are able to manage their medical condition at home with prescription therapies, rather than through costly medical procedures and hospital care.

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.*

Shift in Liability

The Medicare Payment Advisory Commission (MedPAC) has stated that "When competing plans bear risk, they have incentives to offer benefits that are attractive to beneficiaries and yet

[1] "Medicare Part D Must Evolve to Help People Fight Cancer." STAT, 17 Apr. 2019, www.statnews.com/2019/04/18/medicare-part-d-evolve-fight-cancer/.
[2] jcubanski, Juliette Cubanski Follow, et al. "The Out-of-Pocket Cost Burden for Specialty Drugs in Medicare Part D in 2019." The Henry J. Kaiser Family Foundation, 1 Feb. 2019, www.kff.org/medicare/issue-brief/the-out-of-pocket-cost-burden-for-specialty-drugs-in-medicare-part-d-in-2019/.
[3] Eaddy, Michael T, et al. "How Patient Cost-Sharing Trends Affect Adherence and Outcomes: a Literature Review." P & T : a Peer-Reviewed Journal for Formulary Management, MediMedia USA, Inc., Jan. 2012, www.ncbi.nlm.nih.gov/pmc/articles/PMC3278192/.

manage spending so that premiums remain affordable."[4] MedPAC has also noted that "sponsors have been less successful at cost containment when they were at less risk for benefit spending."[5]

Astellas believes that recent changes to the Part D benefit that reduced plan liability to just 5 percent of beneficiary costs in the coverage gap were misguided. CMS recently noted that it is "concerned about the impact these changes will have on drug costs under Part D in 2019 and future years, particularly as plan liability in the gap significantly decreases for brand name drugs beginning in 2019."[6]

Brand manufacturers took on responsibility for a share of Part D program costs in 2011 as part of the Coverage Gap Discount Program in order to close the donut hole for non-low income subsidy (LIS) beneficiaries, and have taken on an increasingly larger share in recent years. If these contributions are recalibrated within the benefit, we believe manufacturer liability should be optimized to address patients' affordability challenges and should not be used to replace Part D plans' role as the entity bearing risk and providing the insurance benefit.

3) *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.*

Distributing Patient Costs throughout the Year

In addition to implementing an out-of-pocket cap, we urge the Committees to consider reforms that give patients the option of spacing their out-of-pocket costs for specialty medicines over time, instead of burdening them with unreasonably high payments upfront. A recent study found that Part D beneficiaries with rheumatoid arthritis (RA), multiple sclerosis, or chronic myeloid leukemia (CML)—whose average annual out-of-pocket spending ranged from $3,900 to $6,300—incurred 25 to 40 percent of these costs in January alone and between 54 and 66 percent of these costs in the first three months of the year.[7]

Allowing beneficiaries to distribute their out-of-pocket costs throughout the year would enable seniors to better plan for the cost of their treatments and thus, help them to adhere to their prescribed drug regimens year-round.

LIS Cost-Sharing

[4] MedPAC. Report to the Congress: Medicare and the Health Care Delivery System. June 2015.
[5] Ibid
[6] CMS. Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, April 2, 2018
[7] 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.

Astellas believes it is crucial that any potential changes to Part D avoid increasing brand medicine cost sharing for beneficiaries who receive low-income subsidies. MedPAC has proposed lowering LIS copayments for generic drugs while increasing copayments for brands as much as twofold to drive generic utilization.[8] The evidence does not support a need for this policy, and in fact, MedPAC notes that use of generic drugs is already high among all Part D enrollees, including the LIS population, and that generics may not always be medically appropriate substitutes for brand medicines in a therapeutic class. Moreover, such increases in out-of-pocket expenses would fall on those least able to pay them.

On average, LIS beneficiaries tend to be in poorer health than non-LIS patients[9] and fill more prescriptions than other Part D beneficiaries.[10] Taking multiple medications for several conditions increases the likelihood that one or more medicines will be a brand for which there is no generic equivalent or medically appropriate substitute. This makes LIS beneficiaries particularly vulnerable to any copay increase for brand medicines, hence our strong opposition.

4) Comments on discussion draft:

Astellas urges the Committees against taking action to exclude coverage gap discounts from the calculation of a patient's True Out-of-Pocket Costs (TrOOP). Excluding manufacturer coverage gap discounts from the calculation of TrOOP spending would exacerbate, rather than mitigate, beneficiary affordability challenges. Prolonging the amount of time spent in the coverage gap would directly harm a significant number of patients. Higher out-of-pocket costs would likely have the unintended consequence of increasing prescription abandonment, medication nonadherence, and premature discontinuation of therapy, leading to poorer health outcomes and higher costs elsewhere in the Medicare program.

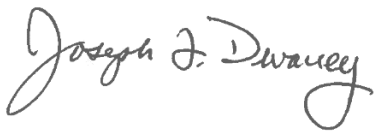
About 1.1 million non-LIS beneficiaries reached catastrophic coverage in 2016, and that number is estimated to reach 1.2 million in 2019.[11] If the calculation of TrOOP were changed to exclude manufacturer coverage gap discounts, about 65 percent (780,000) of these beneficiaries would remain in the coverage gap[12] as the average annual out-of-pocket spending by non-LIS beneficiaries needed to reach the catastrophic threshold increased by over 110% from $2,400 under current law to $5,100.[13] Patients with chronic illnesses—particularly those with

[8] MedPAC. Report to the Congress: Medicare and the Health Care Delivery System. Chapter 6: Improving Medicare Part D. June 2016.
[9] Medicare Payment Advisory Commission, "Report to Congress: Medicare Payment Policy," March 2012.
[10] Medicare Payment Advisory Commission, "A Data Book: Health care spending and the Medicare program" June 2018. Section10, p. 173.
[11] MedPAC. Report to the Congress: Medicare Payment Policy. Chapter 14: The Medicare prescription drug program (Part D): Status report. March 2019.; Xcenda. Analysis for PhRMA of the 2015 Medicare Part D Event Research Identifiable Files, 10% Sample. Modeling of patient completed by Xcenda based on standard benefit parameters for 2019. Part D and Medicare Advantage Part D Non-LIS enrollment estimates from the Congressional Budget Office April 2018 Medicare baseline.
[12] PhRMA analysis of Xcenda data.
[13] PhRMA analysis of Part D benefit parameters (from CMS Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, April 2, 2018).

congestive heart failure, diabetes, hypertension, high cholesterol, and kidney and liver failure—would be the most affected by the TrOOP change, while the relatively healthy would be unaffected. This proposed change to TrOOP would accelerate the trend towards less meaningful coverage for sicker beneficiaries, which may threaten the future of Medicare Part D as a successful, market-based coverage model.

Astellas is committed to ensuring our medicines are priced fairly—in a way that reflects the innovation and value they deliver to patients, healthcare systems and society. We also believe in collaborating with payers and the federal government to enact impactful solutions to help ensure patients have adequate access to their prescribed therapies. We appreciate the Committees' attention to modernizing the Part D benefit and look forward to the opportunity to work with the Committees to strengthen and improve this important program.

Sincerely,



Joseph Devaney
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