June 6, 2019

The Honorable Richard E. Neal
Ways and Means Committee
U.S. House of Representatives
1102 Longworth House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Kevin Brady
Ways and Means Committee
U.S. House of Representatives
1139 Longworth House Office Building
Washington, DC 20515

The Honorable Greg Walden
Committee on Energy and Commerce
U.S. House of Representatives
2322 Rayburn House Office Building
Washington, D.C. 20515

RE: Solicitation for Feedback on Draft Medicare Part D Legislation

Dear Chairmen Neal and Pallone and Ranking Members Brady and Walden:

Sanofi appreciates the opportunity to provide feedback on the bipartisan draft legislation that seeks to improve the Medicare Part D prescription drug program for beneficiaries and taxpayers.

At Sanofi, we work passionately every day to understand and address the health care needs of patients around the world. We bring medicines to patients and are dedicated to solving patients' most serious health challenges in numerous therapeutic areas, including diabetes, cardiovascular disease, immunology, oncology, multiple sclerosis (MS), rare diseases, and rare blood disorders. We are also devoted to preventing diseases through the research, development, and delivery of vaccines. Additionally, we contribute to improving the health of people around the world through our broad portfolio of consumer health products.

When Medicare Part D began in 2006, it brought to the public a long awaited and necessary drug benefit that helped to improve the lives of millions of Medicare beneficiaries. Its design fostered market competition, a plethora of plan and drug choices, government protections to help manage risk, and a model to support continued innovations. Even today in 2019 Medicare Part D still brings beneficiaries tremendous value, however, certain trends are concerning. Medicare beneficiaries are facing high out-of-pocket costs for many medications even as manufacturer net prices are flat or declining.

We applaud the Committee's interest in revisiting Medicare Part D through legislation so that it can be improved to lower costs both for the patients and for the Medicare program. As requested, Sanofi offers some preliminary feedback on:

- **How the Part D program can better address the problem of high cost drugs for Medicare beneficiaries and taxpayers and whether Congress should eliminate the distinction between the initial coverage phase and the coverage gap discount program.**

- **What improvements and potential changes should the Committee consider with respect to low-to-moderate income Part D beneficiaries and out-of-pocket costs below the catastrophic level.**

- **What share of costs attributed to the beneficiary, Part D plans, and manufacturers under the current system 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.**

Our responses to these questions fall into the topic areas of **improving patient affordability and improving Medicare spending**. We ask that the Committee consider the following when addressing any modifications to the current draft legislation.

A. Improving Patient Affordability

1. **Establish a maximum out of pocket amount (MOOP) for patients.**
2. **Require drug rebates to be passed to patients at the point of sale.**
3. **Adjust patient out of pocket cost parameters prior to the catastrophic phase such that patient costs are more evenly predictable throughout the year and are more affordable.**
4. **Allow coupons in Medicare Part D.**
5. **Avoidance of negative policy changes.**

1. Establish a maximum out-of-pocket amount (MOOP) for patients.

Sanofi supports the draft legislation to establish an out-of-pocket maximum for beneficiaries. Reducing out-of-pocket costs for patients is our top priority. The policy is a simple, visible approach to help address concerns over catastrophic drug spending by Medicare beneficiaries. The number of beneficiaries reaching the catastrophic phase has more than doubled since the program's inception. By establishing a maximum out-of-pocket amount, one in ten beneficiaries would be relieved of such expenses,[1] but more should be done to address affordability for beneficiaries who do not reach the catastrophic phase of the benefit as they too have challenges with out-of-pocket costs.

2. Require drug rebates to be passed to patients at the point of sale.

[1] http://files.kff.org/attachment/Issue-Brief-No-Limit-Medicare-Part-D-Enrollees-Exposed-to-High-Out-of-Pocket-Drug-Costs-Without-a-Hard-Cap-on-Spending

One way to address patient out-of-pocket costs is to require rebates to be passed to the patients at the point of sale. The current Part D system does not work to ensure that manufacturer rebates commensurately result in lowering the cost of medications for Part D beneficiaries in the form of lower deductibles, co-payments, or coinsurance amounts. Sanofi provides rebates to PBMs and health plans to improve patient access to and affordability of Sanofi medicines. We want these price concessions, which have grown in recent years and have resulted in substantially lower net prices, to benefit patients at the point of sale. Passing along rebates to patients at the point of sale should result in coinsurance and deductibles to be applied net of the discounts that manufacturers provide.

3. **Adjust patient out of pocket cost parameters prior to the catastrophic phase such that patient costs are more evenly predictable throughout the year and are more affordable.**

Establishing a MOOP and implementing a rebate pass through policy for patients at the point of sale will make great strides in helping patients, but it doesn't address the fact that patients can face co-insurance rates in Part D up to 50% in the initial coverage limit and 25% in the coverage gap[2]. High out of pocket costs can result in abandonment of prescriptions, sicker patients and higher medical spending[3].

Sanofi supports the concept of improving the predictablity of patient out-of-pocket expenses throughout the Part D benefit year by merging the intial coverage phase and the coverage gap phase with the understanding that patient access and afforability will be adequately balanced and not immeasurably compromised.

Improvement in patient affordability could be accomplished by establishing tighter per prescription out-of-pocket parameters such as making all prescriptions subject to a reasonable out-of-pocket maximum amount. Alternatively, Sanofi is also in favor of reducing the beneficiary share of drug costs in the coverage gap from 25% to 10%. Such affordability improvement policies should be applied for the benefit of all standard beneficiaries, not solely standard low-to-moderate income Part D beneficiaries**.**

4. Allow coupons in Medicare Part D

Sanofi supports a policy change that would allow manufacturers to voluntarily offer co-pay assistance to Medicare beneficiaries. The Medicare program could limit the allowance of such coupons to when manufacturers keep list price increases to a set limit or engage in list price reductions. Coupons help patients afford the medicines their doctors have prescribed and determined is the best for them. In the commercial market, 330,000 people used a Sanofi

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[2] Page 231 Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter

[3] How Much Does Medication Nonadherence Cost the Medicare Fee-for-Service Program? Jennifer T. Lloyd, PhD,* Sha Maresh, DrPH,* Christopher A. Powers, PharmD,† William H. Shrank, MD, MSHS,‡ and Dawn E. Alley, PhD*. Medication nonadherence for diabetes, heart failure, hyperlipidemia, and hypertension resulted in billions of Medicare FFS expenditures, millions in hospital days, and thousands of emergency department visits that could have been avoided. If the 25% of beneficiaries with hypertension who were nonadherent became adherent, Medicare could save $13.7 billion annually, with over 100,000 emergency department visits and 7 million inpatient hospital days that could be averted.

co-pay assistance card in 2018 resulting in more than $340m of patient savings and we believe those savings should be extended to Medicare beneficiaries as well.

5. Avoidance of negative policy changes

There are a few policy proposals that Sanofi believes should be avoided.

First, Sanofi is strongly opposed to policies that would disallow manufacturer discounts in the Part D coverage gap to count towards patient's true out-of-pocket costs (TrOOP). Patients would be exposed to the coverage gap for a longer duration, shifting costs to them and manufacturers that pay significant discounts in that phase of the benefit. To the extent manufacturer coverage gap discounts are in addition to payer negotiated discounts, manufacturers would be paying duplicative discounts for an extended period.

Secondly, as changes are made to the draft legislation such that manufacturer's coverage gap liabilities in a given annual benefit period are shifted to other parts of the benefit, we would like to see those shifts be applied to relieve beneficiary out-of-pocket burdens as opposed to reductions in plan liability for a given year.

B. Improving Medicare Spending

There are a few ways Medicare program costs can be reduced:

a. Allow health plans to take on more risk

The draft legislation sets up Medicare's share of responsibility for catastrophic costs to be phased down gradually until 2023 where Medicare would be responsible for 20%. Given the Medicare Part D program has been operational since 2006, insurance plans have had several years to gain experience predicting and managing Part D costs. It is reasonable at this juncture in the evolution of Part D that health plans can begin to manage more risk. However, we have concerns about possible corresponding patient access compromises that plans could impose on innovative medicines as a result.

Thus, Sanofi supports shifting the risk in the catastrophic phase to plans as long as, depending upon the amount of risk that is shifted, it is balanced with new access protections that could involve new minimum access safeguards, appeals protections, increased CMS oversight responsiblities to ensure broad and robust formulary availability across plans, and/or drug access transparency metrics.

b. Incentivize adherence-friendly formulary management and value arrangements

Medicare can be improved by incentivizing Part D plans to design adherence-friendly formularies and allowing manufacturers and plans to engage in value arrangements that optimize outcomes and result in reduced hospital spending. The Congressional Budget Office (CBO) has determined that improved medication adherence can result in overall federal savings. In CBO's estimate of the rebate safe harbor rule, CBO predicted an increase drug spending of $10 billion that would return a reduction in Medicare Part's A and B spending of

$20 billion for a net savings of about $10 billion.[4] Plans should be better incentivized and held more accountable for formulary design and management that encourages drug adherence.

Value arrangements, when properly structured, can lead to creative arrangements between plans and manufacturers to better ensure patient access to medication and promote behaviors that lead to better patient outcomes. Patients benefit through lower access barriers, lower out-of-pocket costs, and wrap-around services that promote adherence and ultimately better health. These arrangements can often employ a variety of financial arrangements that account for factors such as patient adherence, education, clinical endpoints or support services that may result in better clinical outcomes for patients. The uniqueness of these financial terms may make these arrangements difficult to protect under existing safe harbor or statutory exceptions. New statutory and regulatory language is needed.

Thank you for the opportunity to provide feedback. We look forward to working with you further to help ensure the sustainablibty and longevity of the Medicare Part D program to benefit the program pariticipants.

Sincerely,

Adam Gluck
Head of US External Affairs

[4] https://www.cbo.gov/system/files/2019-05/55151-SupplementalMaterial.pdf