EXELIXIS

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June 6, 2019

The Honorable Richard E. Neal
Chairman
House Committee on Ways and Means
1102 Longworth House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Chairman
House Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Kevin Brady
Ranking Member
House Committee on Ways & Means
1139 Longworth House Office Building
Washington, DC 20515

The Honorable Greg Walden
Ranking Member
House Committee on Energy & Commerce
2322 Rayburn House Office Building
Washington, DC 20515

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

Thank you for the opportunity to submit comments on the House Ways & Means and Energy & Commerce Committees' draft Medicare Part D legislation. As Congress works to find policy solutions that will address the accessibility of prescription drugs, Exelixis wishes to draw particular attention to the urgent concerns of cancer patients in Part D, who in many cases struggle simultaneously with a devastating cancer diagnosis and the dire financial implications of the cost sharing imposed upon them by the current structure of the benefit program.

Exelixis is a research-focused, biotechnology company of approximately 500 employees that is focused exclusively on difficult-to-treat cancers. We invented our flagship molecule, cabozantinib (the active ingredient in our products CABOMETYX® and COMETRIQ®), which is a market leading medicine approved by the FDA to treat patients with forms of liver, kidney and thyroid cancer.[1] For Medicare beneficiaries, Cabometyx and Cometriq are covered under Part D. Behind Cabometyx, we have established a broad drug discovery and development platform that is helping to bring this and other new cancer therapies to patients in need.

Exelixis was privileged to be invited to represent small and medium-sized biotechnology companies during the May 9, 2019 House Energy & Commerce Subcommittee on Health

[1] Cabozantinib was first approved by the FDA as Cometriq to treat a rare form of medullary thyroid cancer (MTC) in late 2012. After conducting additional clinical trials, Exelixis submitted a separate New Drug Application for approval of cabozantinib as Cabometyx to treat advanced renal cell carcinoma (RCC or kidney cancer). Cabozantinib is currently being tested, alone and in combination with other therapies, as a treatment for over 20 forms of cancer.

hearing on the prescription drug supply chain.[2] Although in our industry, companies of our size and smaller deliver the lion's share of pharmaceutical innovation, having patented almost two-thirds of new drugs launched in 2018, our unique challenges have often been overlooked in the national debates on health care policy, innovation, and pricing. We commend the Committees for establishing an open and transparent process. As you craft and advance policy proposals, we urge you to consider the perspectives of emerging biotech companies, like Exelixis, that strive to balance the entrepreneurial risks of investing in innovation with a fundamental commitment to helping our patients access the medicines we discover, develop, and manufacture for them.

Exelixis wholeheartedly supports reforms to the Medicare Part D programs that will help lower out-of-pocket costs for beneficiaries in need and, therefore, we are pleased that the draft bill includes an out-of-pocket cap for Part D beneficiaries. Even so, we believe that patients diagnosed with advanced cancer or other life-threatening conditions for which there are limited treatment options should not be burdened with significant costs before reaching the out-of-pocket maximum. At Exelixis, we are doing everything that we can to ensure that our products are accessible to patients in need. Through our patient assistance programs, we provide free drug to financially needy uninsured and underinsured patients, as well as copayment assistance to commercially-insured patients. For Part D beneficiaries, we urge Congress to go further than the proposed out-of-pocket cap and allow manufacturers of "clinically unique medications"[3] to cover the cost-sharing obligations of Part D beneficiaries before they reach their out-of-pocket maximum, as we are able to do for patients with commercial insurance. Finally, should your efforts in support of a broader out-of-pocket cap falter, we ask that you not close this debate without at least first providing for this less ambitious, but very essential reform, freeing manufacturers to provide this much-needed financial assistance. For Part D beneficiaries battling deadly diseases like cancer, the concept of patient "skin in the game" makes no sense.

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[2] Exelixis Testimony, Energy & Commerce Subcommittee on Health Hearing on "Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain" (May 9, 2019), *available at* https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/Exelixis%20Jeff%20Hessekiel%20EC%20Health%20Subcommittee%20Hearing%20Testimony%2005.09.2019%20FINAL.pdf.

[3] *See* Exelixis Comments to OIG's "Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP," (Oct. 25, 2018), *available at* https://www.regulations.gov/document?D=HHSIG-2018-0002-0157. Our comments defined a "clinically unique medication" as a treatment: (1) for a disease -- such as cancer-- where available treatment options are clinically differentiated, such that lack of access to a particular therapy could severely undermine a patient's quality of care and put the patient at risk of adverse clinical outcomes; (2) for which payor prior authorization is required; and (3) that does not have any therapeutically equivalent generic alternatives.

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(1) Establish an Out-of-Pocket Cap for Part D Beneficiaries

Exelixis supports establishing an out-of-pocket maximum for Part D beneficiaries. We appreciate that the draft bill would achieve this objective by eliminating patient cost-sharing during the catastrophic coverage phase. We encourage the Committees to retain this provision in future drafts.

Unlike individuals covered by nearly all other insurance plans, Medicare beneficiaries are not protected by an annual out-of-pocket cap on spending. The cost-sharing obligations of Part D beneficiaries decrease after he or she has met the deductible and incurred out-of-pocket costs before the catastrophic phase,[4] but by no means does it go away. Due to the unavoidably high costs of recently-approved cutting edge medicines to treat diseases like cancer, the relatively smaller five percent cost-sharing obligation during the catastrophic phase can translate into significant and even devastating out-of-pocket costs for patients.

Moreover, because much of the cost-sharing in Part D is "front loaded," seniors are forced to bear substantial costs before catastrophic coverage kicks in. According to the Kaiser Family Foundation, in 2015, non-low-income subsidy (LIS) Part D beneficiaries with cancer who reached the catastrophic phase had an average of $3,413 in out-of-pocket drug costs, with one-tenth of such beneficiaries incurring more than $6,000 in out-of-pocket drug costs.[5] The combination of the "front loaded" structure of the benefit with the open-ended nature of cost-sharing during catastrophic coverage can put the health of this especially vulnerable population at greater risk of reduced adherence to the medicines they need. In order to provide certainty and protect Part D beneficiaries from unlimited out-of-pocket drug costs, Exelixis encourages the Committees to retain the out-of-pocket cap in future drafts of this legislation.

(2) Even with an Out-of-Pocket Cap, Manufacturers of "Clinically Unique Medications" Should Be Allowed to Cover Patients' Cost-Sharing Obligations

Although the draft bill addresses the catastrophic phase, the Committees have requested input on additional changes that could help beneficiaries manage out-of-pocket costs before they reach catastrophic coverage. In response, Exelixis strongly urges the Committees to

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[4] During the catastrophic phase, the cost-sharing obligation for beneficiaries who do not receive low income subsidies is generally the greater of five percent or a small fixed copay ($2 for generic/preferred multiple source drugs, or $5 for other drugs, both annually adjusted for inflation).

[5] No Limit: Medicare Part D Enrollees Exposed to High Out-of-Pocket Drug Costs With No Hard Cap on Spending, Kaiser Family Foundation (Nov. 7, 2017), *available at* https://www.kff.org/medicare/issue-brief/no-limit-medicare-part-d-enrollees-exposed-to-high-out-of-pocket-drug-costs-without-a-hard-cap-on-spending/.

lift the current prohibition and permit manufacturers of certain clinically unique drugs, such as cancer medications, to provide copayment assistance to patients during earlier phases of the Part D benefit, as we do for commercial patients.

Very soon after receiving the emotionally debilitating diagnosis of cancer or cancer progression, Part D patients learn that the Part D coverage model imposes significant and burdensome financial challenges. Beneficiaries must reach the $5,100 true out-of-pocket (TrOOP) threshold before they enter the catastrophic phase. This can be unaffordable and particularly onerous on patients with cancer. The National Cancer Institute has recognized the increased burden on cancer patients and their families resulting from the "financial toxicity" experienced by patients with health insurance paying higher premiums than in the past, along with higher copayments, deductibles, and coinsurance,[6] all of which exacerbate the stress that comes with a medical diagnosis that can devastate a cancer patient and his or her family and can "diminish the quality of life and impede delivery of the highest quality care."[7] Additionally, for cancer patients, these out-of-pocket costs usually occur in the 2-3 months following diagnosis, creating immediate financial stress for patients and their caregivers. This can leave beneficiaries unable to afford their lifesaving therapies solely due to financial reasons, or cause them to become non-adherent to these therapies.[8]

Exelixis already provides copayment assistance to patients with commercial insurance to help them access their prescribed medicines, and we are prepared to contribute financially to solving this problem for Medicare Part D patients as well. Current Office of Inspector General (OIG) guidance, however, prevents manufacturers from offering copayment assistance to Medicare beneficiaries, leaving some of the most vulnerable cancer patients unable to access the specific therapy prescribed by their physician.

Exelixis strongly urges Congress to create a limited exception to the manufacturer copayment assistance prohibition. This exception would apply only to "clinically unique medications."[9] Although concerns that copayment assistance could cause overutilization or drive inappropriate utilization leading to higher government costs may be reasonable in other

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[6] Financial Toxicity (Financial Distress) and Cancer Treatment, National Cancer Institute, *available at* https://www.cancer.gov/about-cancer/managing-care/track-care-costs/financial-toxicity-pdq.

[7] Zafar, et al., Financial Toxicity, Part 1: A new Name for a Growing Problem, Oncology (February 2013), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4523887/.

[8] As patients' out-of-pocket costs increase, the likelihood that they will abandon or delay initiation of an appropriate treatment increases dramatically. *See* Doshi et al., Association of Patient Out-of-Pocket Costs with Prescription Abandonment and Delay in Fills of Novel Anticancer Agents, J. Clin. Onc. (Nov. 2017).

[9] *See* supra note 3.

therapeutic areas, these concerns are entirely absent with respect to oncology drugs and medications with similar characteristics, where patients may only have one clinically appropriate treatment available, without a generic alternative or biosimilar. In these instances, there is simply no merit to the argument that beneficiaries should have financial "skin in the game."

Specifically, to accomplish this result, Congress should develop a new or revised anti-kickback statute (AKS) and beneficiary inducement civil monetary penalty (CMP) safe harbor that would permit manufacturer copay assistance to Part D beneficiaries for "clinically unique medications." Alternatively, Congress should direct the U.S. Department of Health and Human Services (HHS) to develop new or revised regulatory AKS and CMP safe harbors protecting manufacturer copay assistance to Part D beneficiaries for "clinically unique medications," or issue sub-regulatory guidance confirming that such copay assistance does not run afoul of the AKS and CMP laws. At a minimum, Congress should direct HHS to create a Center for Medicare & Medicaid Innovation (CMMI) demonstration, under which AKS and beneficiary inducement CMP requirements could be waived and the benefits of cost-sharing assistance for the Medicare Part D population could be evaluated.

(3) Should A New Part D Out-of-Pocket Cap Not Take Effect, Copayment Assistance for "Clinically Unique Medications" Across Part D Will Be Crucial

Finally, we note that if future drafts of the Part D legislation do not eliminate cost-sharing during the catastrophic phase, then the current situation for Part D beneficiaries that rely on these clinically unique medications will remain dire and unaddressed. Should this prove to be the case, Exelixis urges Congress to take action to permit manufacturers of clinically unique medications to cover all the cost-sharing obligations of Part D patients, including during the catastrophic phase.

Patients diagnosed with advanced cancer often face crippling out-of-pocket costs, particularly in the months immediately following their diagnosis. These financial burdens not only exacerbate the stress of having been diagnosed with a catastrophic disease, but can also impact whether a patient initiates or continues a clinically appropriate therapy. Exelixis is committed to doing what it can, within the bounds of the law, to ensure that patients in need of our medicines have access at a price that they can afford. We strongly urge Congress to act now and allow manufacturers to provide similar support to Part D patients, as we currently are permitted to do for patients with commercial insurance. At least for beneficiaries with cancer and other life-threatening conditions, we can and should do more to improve affordability.

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Thank you for the opportunity to comment on the draft legislation, and for your consideration of our comments. Exelixis looks forward to continuing to work with you to address patient affordability of Part D drugs. Should you have any questions, please contact Jim Fenton, Executive Director U.S. Government Affairs, at jfenton@exelixis.com or 650.837.7735.

Sincerely,

Michael M. Morrissey, Ph.D.
President and Chief Executive Officer
Exelixis, Inc.