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Before the

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Hearing on "Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain"

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Chairwoman Eshoo, Ranking Member Burgess, and Members of the Subcommittee, thank you for the opportunity to appear before the House Energy & Commerce Subcommittee on Health to discuss issues related to the prescription drug supply chain in the United States.

I am Jeff Hessekiel, Executive Vice President and General Counsel at Exelixis, an innovative, research-focused, biotechnology company that is on a mission to help cancer patients recover stronger and live longer. At Exelixis, we focus exclusively on the most difficult-to-treat cancers, and we have established a broad drug discovery and development platform that has helped bring new cancer therapies to patients in need. As befitting our name, which is the Greek word for evolution, after a long, almost 25-year journey, we are proud to have grown into a stable company with just over 500 employees, based in Alameda, California.

Like the other company representatives on this panel, I am here today to have a frank and open discussion with you and the members of the Subcommittee about the root causes of high prescription drug costs and how drug prices are set in the U.S. health care system. It is possible for us to work together to promote the affordability of new and innovative therapies for patients without undermining the development of the next generation of medicines upon which we, and our children, will rely in the future.

I am also here today for another important reason – to highlight the important role that emerging biopharmaceutical companies, like my employer Exelixis, play in the drug development ecosystem. The voices of small and medium-sized innovative biotech companies are rarely heard in the national debate over prescription drug pricing, yet emerging biotech companies like Exelixis are playing an increasingly larger role in discovering innovative medicines. They are the engines of discovery in the fast growing areas of oncology and orphan drugs. According to a recent report by the IQVIA Institute, of the 59 new drug launches in 2018, 38 were patented by emerging biopharma companies, and 74 percent of those were also registered for FDA approval by these companies.[1] Emerging commercial biotechs like Exelixis account for the greatest share of late-stage pipeline activity; in 2018, emerging biopharma companies accounted for 72 percent of all late-stage clinical pipeline activity, up from 61 percent one decade ago.[2]

Before considering fundamental changes to an innovation system that has so often placed medical miracles in a bottle or pill, it is critical to understand the overwhelming challenges and the inherent risks of failure at each step of the discovery, development, regulatory and commercialization process. Please consider how future changes may impact America's most productive sources of medical innovation – small and medium-sized research-focused biotech businesses. In most cases, these innovations have only emerged thanks to the willingness of entrepreneurial scientists and investors to risk billions of dollars on medical long-shots. Sometimes those bets pay off to the benefit of public health, but far more often, the process is marked by repeated failures and "near-death" business experiences. For Exelixis, this is not a

[1] The Changing Landscape of Research and Development: Innovation, Drivers of Change, and Evolution of Clinical Productivity, IQVIA Institute for Human Data Science (April 23, 2019) (Landscape Report), *available at* https://www.iqvia.com/institute/reports/the-changing-landscape-of-research-and-development (accessed May 7, 2019).

[2] *Id.* at 15.

theoretical matter. Since the inception of our company, investors have risked more than $3 billion supporting our R&D efforts, with over $2.1 billion of that investment spent before the company ever sold a single dose of medicine. At one point, less than 5 years ago, negative clinical results from two pivotal trials drove our share price down to just over $1, and our debt liabilities were several magnitudes larger than our existing cash position. As of today, however, the bet that long-term investors made in Exelixis has paid-off. More importantly, that boom and bust cycle eventually put important new medical therapies in the hands of American oncologists.

Small and mid-sized biotechs, like Exelixis, are very concerned that, unless we speak up – and are heard – well-intended, but narrowly-considered, law and policy changes could do permanent harm to the prolific American system of pharmaceutical discovery and innovation, which is increasingly driven by companies like ours.

Our Commitment to Fighting Cancer

Cancer continues to be one of the most challenging diseases for researchers around the world. In the United States in 2010, care for cancer survivors cost an estimated $137.4 billion.[3] In 2019, there will be an estimated 1,762,450 new cancer cases diagnosed and 606,880 cancer deaths in the United States.[4]

Simply put, Exelixis fights cancer. Our flagship molecule, cabozantinib (the active ingredient in our products CABOMETYX® and COMETRIQ®) has been approved by the FDA to treat patients with forms of liver, kidney and thyroid cancer.[5] Moreover, it has shown the potential to treat over 20 other forms of solid cancer tumors and so is the subject of more than 80 clinical trials, including at cancer centers and academic institutions across the country, including in Massachusetts; North Carolina; Connecticut; New York; Pennsylvania; California; and in other states and countries. CABOMETYX® and COMETRIQ® are taken daily by patients who are prescribed the treatment. Our drugs are covered by Part D for Medicare patients.

Our success in bringing cabozantinib to market for patients and achieving financial stability is only recent. For most of the company's 24-year history, Exelixis operated without product revenue, taking significant risks to sustain formidable research facilities and clinical trials. Along

[3] National Cancer Institute, National Cancer Trends Progress (2019), Financial Burden of Cancer Care, *available at* https://progressreport.cancer.gov/after/economic_burden (accessed May 7, 2019).

[4] The American Cancer Society (ACS) Cancer Facts & Figures 2019, *available at* https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2019.html. (accessed May 7, 2019). ACS expects that 74,000 new cases of kidney cancer will be diagnosed in 2019, and 15,000 people will die from this cancer this year. The ACS also estimates that 42,000 new cases of liver cancer will be diagnosed, and 32,000 people will die from this cancer in 2019. For thyroid cancer, there will be 52,000 new cases diagnosed, and 2,000 people will die in 2019.These statistics evidence the urgent need for biotechnology companies like Exelixis to continue their work so that patients battling these devastating diseases can remain at home and with their families as they receive the treatment they need.

[5] 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).

the way, Exelixis accumulated a nearly $2 billion deficit, although the company's dedication to battling cancer never waned.

We began our work in the late 1990s and early 2000s, focusing on early stage scientific research. The first goal was to study human genes and gain biological insights that could inform better, safer drug development. Over the next decade, we shifted our strategy to focus on the discovery and investigation of discrete drug candidates, alone and with partners, to diversify risk and pursue a "multiple shots on goal" approach. By 2002, we had decided to focus our internal operations exclusively on cancer. We used unique, industry-leading high throughput drug discovery processes to identify compounds with therapeutic potential and then advance them rapidly through preclinical and early clinical development. As is typical, the large majority of those drug candidates failed. But some succeeded, of which the most promising was cabozantinib.

Our history demonstrates the tough financial reality of the biopharma business. Clinical research is much more expensive than lab research, so Exelixis' notable success identifying and advancing promising drug candidates in its labs then resulted in unsustainable clinical research costs. In 2008, Exelixis' R&D spending grew to $257.4 million, nearly twice the $132.1 million the company spent in the labs in 2002. Nearly everything Exelixis had was poured into research and development, as we spent between 73 percent and 87 percent of operating expenses on R&D (nearly $2.3 billion). Even though we were a public company, it was becoming increasingly difficult to secure the additional capital necessary to fund our extensive research and development budgets.

Although FDA approved cabozantinib as COMETRIQ® in 2012 for a small number of patients with a rare thyroid cancer, this product revenue stream was not nearly significant enough to fund our operations and debt service. Then, the company suffered a catastrophic event in late 2014 after two phase 3 registrational cabozantinib clinical trials failed in prostate cancer. That turn of events forced us immediately to restrict spending, reduce our workforce by more than 70 percent, and focus our limited resources and financial reserves on two important and difficult-to-treat indications – kidney and liver cancer. It was our last shot goal. Fortunately for seriously ill cancer patients and our company, cabozantinib demonstrated positive results in two large global pivotal trials in these indications. It is the only drug of its kind to improve overall survival in a statistically significant manner for both kidney and liver cancer.

Today, Exelixis is financially secure thanks to revenues generated as a result of the value and promise of cabozantinib. This enabled us to pay off all our debt in 2017; in 2018 our annual net income was $690 million and our revenue was $854 million. In the United States, we commercialize cabozantinib ourselves. Outside of the U.S., we have licensed cabozantinib to global pharmaceutical companies.

However, our recent financial success has in no way dulled our ambition. We are reinvesting the cabozantinib revenue stream to grow the company and deliver the next generation of Exelixis medicines to help patients recover stronger and live longer.

In 2018, we moved our headquarters to Alameda, California. We are building a research campus equipped with new, state-of-the-art research laboratories, and we intend to invest increasingly substantial amounts on research and development in the years to come. We are proud to be "home-grown" in the United States, a part of the Alameda community, and able to bring new, high-quality jobs to the vibrant community we have adopted as our new home.

Policy Proposals

I appreciate that this Subcommittee has invited me here today for more than a great business success story. Before I speak to drug pricing specifically, I would like to comment on the important topic of transparency. I hope that my presence here, and the information that I am sharing, demonstrates Exelixis' commitment to candor. Ours is not the only company that feels this way. As Congress considers various legislative proposals that would mandate additional transparency in pharmaceutical pricing, we urge you to consider the following:

- First, transparency and reporting requirements should not be limited to a single stakeholder in the supply chain, but should be required for all participants, including drug and device manufacturers, pharmacy benefit managers (PBMs), insurers, hospitals, and physicians. We believe that transparency is a prerequisite for good policymaking; but transparency should be required in all corners so that lawmakers, regulators and, most importantly the patients served by the healthcare system, have the information necessary to make informed decisions.

- Second, reporting requirements should mandate disclosure of objective data and metrics, including what portion of a company's overall spend is dedicated to research and development, as opposed to other expenses, such as sales and marketing. Similarly, companies should have to disclose prices. However, companies should NOT be forced to provide notice to purchasers ahead of price increases. That requirement can enable drug purchasers to game the system, and it does nothing to help patients.

- And, finally, as you consider new drug manufacturer reporting and transparency requirements, we urge you to consider provisions that explicitly preempt the increasing number of state laws covering the same subject matter. It is significantly burdensome and expensive for small businesses, like ours, to comply with a patchwork of inconsistent state reporting laws.

The Subcommittee has asked for input to better understand: (1) the root causes of prescription drug costs; (2) how prices are set; and (3) how each stakeholder in the supply chain can lower prices so that Americans can afford the care that they need. I will do my best to address each of these issues from Exelixis' perspective.

(1) Factors to Consider In Addressing the Cost of Innovative Prescription Drugs

As related above, drug discovery and development imposes significant serial risks and requires tremendous capital investment. This is particularly the case for oncology research. As Exelixis' experience illustrates, R&D at cancer drug companies can exceed hundreds of millions annually

and can total billions of dollars cumulatively before a drug may even be brought to market. Failure and attrition is more common than success.

The factors that most influence the high cost of innovative prescription drugs in the United States are: (1) the tremendous cost of investment in drug discovery research and the clinical trial testing and, perhaps even more importantly, (2) the aggregate cost of all the failed experiments and trials along the way that, while unsuccessful themselves, were a necessary and unavoidable part of the scientific journey that eventually produced an innovative medical product fit for sale. In 2018, the median time from a patent was first filed to its FDA approval was 13.6 years[6] and, when one includes the cost of necessary failures, the R&D cost of transforming the breakthrough to an actual medicine was approximately $2.6 billion.[7] Those facts are directly relevant to the price charged for that medicine once it finally makes it to market.

I respectfully request that when you consider the issue of high drug prices, you permit me to explain why, at least as the system in our country is currently structured, it is essential to look deeper than list price. The list price of Exelixis' flagship product CABOMETYX® is $18,365 per month. However, to understand our business, please do not stop your analysis there. This is not the net price that Exelixis realizes for its medicine. Exelixis has a firm voluntary commitment that NO patient prescribed an Exelixis medicine will go without it due to lack of insurance coverage or inability to pay. If a patient with a prescription does not have insurance or cannot afford our product, we will provide financial assistance, if permitted, or will provide the patient with the drug for free. Exelixis also provides mandatory and voluntary discounts and rebates to public and private insurers and safety net providers, which affect the net price that Exelixis actually recoups on product sales. On a net basis, Exelixis realizes only approximately 73 percent of the list price.

Some may argue that, when a drug company successfully commercializes a medicine, it has already paid for the research and development costs that led to that medicine's discovery and approval, so those costs should not be taken into consideration and need not be passed on. Putting aside the critical concerns of recouping those costs to pay debt or return shareholder equity, Exelixis believes that the revenue collected through sale of approved products should be applied predominantly to the R&D that will lead to the next generation of medicines. In the case of Exelixis, this has meant that, since our inception, we have committed at least 73 percent or more of our operating expenses to developing new medicines. During the launch phase of our newly approved drugs, our sales, general and administrative expenses have increased; however, we plan to have our R&D investment grow again substantially in 2019 to an even greater portion of our overall spend and into the foreseeable future as our more recently discovered drug candidates advance into clinical development.

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[6] Landscape Report, p. 9.

[7] DiMasi JA, Grabowski HG, Hansen RA, "Innovation in the pharmaceutical industry: new estimates of R&D costs," *Journal of Health Economics* 2016; 47:20-33, summary *available at* https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291?via%3Dihub (accessed May 7, 2019). Full article on file with Exelixis.

This cycle of high at-risk investment, return of capital, and reinvestment, is often referred to as the biopharmaceutical innovation cycle. As Congress considers policies that could substantially interfere with this innovation cycle, I strongly urge you to consider the effect that these policies would have on small, innovative businesses, like Exelixis, that are driving the lion's share of medical innovation. Rather than diminishing resources available to small businesses, we should be encouraging such businesses to invest further in the next generation of lifesaving cancer treatments, including potential cures.

(2) How Are Prices Set?

Turning to how prices for drug products are set, at Exelixis, like other commercial-stage drug manufacturers, before we set the launch price of a medicine, and also when we consider increasing the price of a medicine after its launch, we rely on extensive blinded market research with physicians in the therapeutic areas for which the drug may be indicated. We also conduct similar research with formulary managers, and with government and private payers. Our goal is to determine how compelling these stakeholders find the clinical data for the product and the product's safety profile, especially as compared to the competitive approved products already on the market and late-stage investigational products in the same therapeutic category that may soon be approved for sale. The results of that market research permit us to understand the product's relative value proposition as perceived by the stakeholders who may ultimately prescribe or make decisions concerning coverage or reimbursement of the product.

In addition, we consider the market's current commercial context – what are the existing price points for the products with which our product will likely compete? And also, what net price for the product is Exelixis likely to realize after discounts and rebates?

Finally, we consider Exelixis' research and development costs related to the product to date, and the future anticipated costs that are likely to be incurred to fully investigate the therapeutic promise of the product for patient health. We evaluate the remaining period of market exclusivity that Exelixis can likely rely upon, during which the company will have its opportunity to recoup the investments that were necessary to transform the product from a scientific breakthrough to a medicine offered for the benefit of cancer patients.

We believe that our approach to product pricing is responsible and appropriately considers both the specific value of our product relative to its competitors, as well the realities of the necessary risks and rewards that drive the discovery of new, lifesaving medicines.

(3) Making Drugs Affordable to Patients in Need

Lastly, I turn to the most important question – how can drug prices be brought down? As to this point, I hope my remarks have offered some insights, at least regarding why innovative medicines to treat the most serious, life-threatening diseases in the United States – like cancer – cost so much to payors. My goal is to convince you to pause before forcing fundamental changes that would disrupt, or even destroy, the biopharmaceutical innovation cycle. Yes, other countries have implemented price controls or government-mandated pricing to keep drug prices artificially low. However, those countries are not, nor have they ever been the source of humanity's most

critical medicines and medical advances; that has been the United States. And Americans – each and every one of us and our loved ones – have benefitted immeasurably from that innovation. This Committee's landmark 21st Century Cures Act legislation reflected that uniquely American vision. Setting price controls or requiring manufacturers to lower list prices in the U.S. or forfeit their intellectual property is not a viable solution if we expect medical innovation to continue in the future. Taking such steps would weaken incentives for companies to invest in discovering lifesaving new medicines, in the end slowing the innovation cycle and access to vital medicines for patients. This would be acutely felt by small drug makers, like Exelixis, that do not have an established suite of commercialized products or capital structure needed to continue investing in R&D.

At least when it comes to the most critical medicines, we have a serious patient affordability problem. We agree with Chairwoman Eshoo's statement at this Subcommittee's last hearing on the drug supply chain, on December 13, 2017, that "the system is crying out for reform." Manufacturers like Exelixis already assist financially qualified patients with commercial insurance to access their prescribed medicines and we are ready to contribute financially to solving this problem for Medicare Part D patients as well. I believe that other stakeholders in the supply chain, such as payors and PBMs, would also step up, given the opportunity to help ensure that Americans with the most serious illnesses can access treatments without delay.

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,[8] 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."[9] The financial distress faced by cancer patients is disproportionately higher based on age, race and income, and patients face an even greater risk of financial toxicity when they have an advanced-stage cancer.[10]

And THAT problem is absolutely solvable. At Exelixis, we are doing everything that we can, and support further changes to the law, to ensure that our products are affordable for patients in need. Patients prescribed Exelixis' medicines are fighting the most threatening and debilitating cancers, and require personalized treatment options. Even when prescribers have access to the full array of cancer treatments,[11] we recognize that out-of-pocket costs represent a significant

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[8] 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. (accessed May 7, 2019).

[9] 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/ (accessed May 7, 2019).

[10] *Id.*

[11] Given that there may be limited – or in some cases, only one – clinically appropriate treatment for a patient available, we strongly support maintaining CMS' current policies regarding the Part D protected classes, as this structure recognizes that physicians must be able to access the full array of available innovative therapies to determine the optimal cancer treatment for a patient. We oppose any proposals that would impose utilization management or formulary restrictions on protected class drugs, particularly those treating cancer.

burden for patients who are diagnosed with cancer and their caregivers. The bulk of out-of-pocket costs usually occur within 1-2 months of a cancer diagnosis,[12] and patients can face the additional burden of loss of work or productivity and insurance coverage that imposes added costs on a patient battling a deadly disease.

Very soon after receiving the emotionally crippling diagnosis of cancer or cancer progression, Part D patients learn that the Medicare Part D coverage model imposes burdensome financial challenges as well. These patients usually find themselves subject to the Part D specialty tier, cost-sharing in the donut hole, and continued 5 percent out-of-pocket (OOP) cost-sharing the catastrophic portion of their coverage benefit. For cancer patients, these costs create almost immediate financial stress for patients and their families and caregivers.[13] One study of lower-income cancer patients taking oral oncology drugs found that proactive financial assistance programs helped achieve greater medication adherence: financial assistance was associated with an 8 percent increase in adherence over the course of the 2014-15 measurement period.[14] Even for patients and their families living well above the federal poverty level, annual OOP costs regularly total more than a third of their annual income.[15]

Especially for patients facing life-threatening diseases, including cancer, high out-of-pocket costs are concerning because as a patients' out-of-pocket costs increase, the likelihood that they will abandon or delay initiation of an appropriate treatment increases dramatically.[16] Studies demonstrate that the rate of prescription abandonment specifically for oral anti-cancer agents, are as high as 60 percent for individuals with Part D, compared to 40 percent for commercially insured patients.[17] At Exelixis, we want to ensure no patient who can benefit from our medicines is forced to abandon it. 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. We do all that we can, within the constraints of the U.S. system, to mitigate the impact of cost-shifting insurance benefit design on the patients we serve.

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[12] ACS, The Costs of Cancer: Addressing Patient Costs (April 11, 2017), *available at* https://www.fightcancer.org/policy-resources/costs-cancer (accessed May 7, 2019).

[13] *Id.*

[14] Express Scripts, "Financial Assistance programs Increase Adherence to Oral Oncology Drugs" (Jan. 12, 2016), *available at* http://lab.express-scripts.com/lab/insights/adherence/patient-assistance-programs-increase-adherence-to-oral-oncology-drugs. Accessed May 2019.

[15] Doshi *et al.*, Association of Patient Out-of-Pocket Costs with Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents, Journal of Clinical Oncology (Nov. 2017); *see also* Starner, *et al.*, Specialty Drug Coupons Lower Out-Of-Pocket Costs and May Improve Adherence at the Risk of Increasing Premiums, 33 Health Affairs 1761, 1762 (Oct. 2014) (finding in a survey of literature focused on biologic anti-inflammatory drugs and multiple sclerosis drugs that when monthly out-of-pocket costs for prescription drugs exceeded $150-$200, rates of new therapy abandonment approximately doubled, the odds of being adherent were reduced 39 percent, and the risk of discontinuation increased 27 to 58 percent.

[16] Doshi *et al.*, Association of Patient Out-of-Pocket Costs with Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents, Journal of Clinical Oncology (Nov. 2017).

[17] *Id.* at 47, Chart 1.

Current Office of Inspector General (OIG) guidance, however, prevents Exelixis 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, which can lead to them becoming non-adherent to their needed therapy solely due to financial reasons. For patients diagnosed with advanced cancer, there is no merit to the policy argument that Medicare beneficiaries should have financial "skin in the game" with respect to their medications. These patients may have only one appropriate treatment, which does not have a generic or biosimilar alternative. Patient advocacy groups have stated that in these cases, "copayment cards cannot influence the choice of drug because there is no choice available."[18] While we recognize that there are products or drug classes as to which the co-payment assistance prohibition makes sense, we believe there is an urgent need for, at a minimum, an oncology exception (if not a catastrophic disease exception) to the policy.

The amounts that cancer patients pay at the pharmacy are at the heart of the affordability problem. Exelixis strongly urges Congress to allow Medicare Part D cancer patients to obtain the same cost-sharing assistance from manufacturers as commercial patients by eliminating the prohibition on allowing manufacturer copayment assistance for Part D beneficiaries. 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."[19] Alternatively, at a minimum, Congress should direct the U.S. Department of Health and Human Services (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.

At least for cancer patients, we can and should improve affordability in these ways. We also believe this Committee should continue to promote market-based reforms that will improve affordability through stronger competition for today's patients, while ensuring we continue to spur the next generation of treatments for tomorrow's patients. We appreciate this Committee's work to promote more robust generic and biosimilar entry once patents and exclusivities for innovator drugs have expired, and your efforts to move toward a health care payment system – including a drug payment system – that is based on value rather than volume. We believe this work, along with more transparency and data to empower patients and providers on cost and value from all sectors of the supply and payment chain, are essential and responsible approaches to improving access and affordability for American patients.

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[18] Susan G. Komen response to Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs, 83 Fed. Reg. 22692, p. 3.

[19] A "*clinically unique medication*" is 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. Exelixis Response Letter - OIG-0803-N RFI re Anti-Kickback Statute & Beneficiary Inducements CMP (10-25-18), *available at* https://www.regulations.gov/document?D=HHSIG-2018-0002-0157.

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We hope this information is helpful to you as you frame new approaches to drug pricing and payment in the United States. As you proceed, it is critical to ensure that America's most innovative companies, like Exelixis, are permitted to continue driving innovation forward for patients with cancer and helping those patients access our medications when they require financial assistance so they can realize the full benefit of their prescribed therapies.

Thank you for the invitation to speak with you today. I look forward to your questions.