Attachments—Additional Questions for the Record

Subcommittee on Health
Hearing on
"Lowering Prescription Drug Prices: Deconstructing the Drug Supply Chain"
May 9, 2019

Jeffrey Hessekiel

The Honorable Michael C. Burgess, M.D.

1. Something I find particularly concerning about our drug supply chain is the possibility of drug shortages. These can occur because of natural disasters, manufacturing issues, or business decisions. What are each of your respective companies doing to prevent drug shortages?

Exelixis takes seriously our responsibility to ensure that patients who are prescribed our medications have access to them immediately, and we recognize that a shortage can be devastating for the vulnerable population that we serve. Since cabozantinib was first approved by the FDA in 2012, Exelixis has not experienced any drug shortages, and we have put thorough policies and procedures in place to ensure a continuous drug product supply.

To ensure that we never have a supply interruption or shortage, we have built safety stock levels for each stage of our supply chain. We target a two year safety stock for our raw ingredients, active drug substance and finished product, and store these materials at multiple locations to further mitigate risk. Additionally, as our production volumes have grown, we have selected secondary or back up suppliers in different geographical locations who, once qualified, will further bolster our global supply chain network.

The Honorable John Shimkus

1. Given that most of the witnesses on the panel have referenced the role of creating value in the health care supply chain, please comment on: Existing areas where Congress or the Administration may have needlessly added to the cost that patients or the government pays for a particular product, service, or intervention. For example, do you have recommendations on how reforms to existing laws like Stark and the Anti-Kickback Statute could accelerate value-based contracting within Medicare and Medicare Advantage?

If they align the costs of cancer treatments with the value they provide to patients, value-based care arrangements have the potential to reduce treatment costs and generate patient outcomes data that providers may use to help improve patient quality of care.

In order to accelerate value-based contracting, Exelixis recommends policymakers develop a new safe harbor under the Anti-Kickback Statute specifically for value-based contracting arrangements. As Exelixis described in comments to the HHS Office of Inspector General last October, the lack of modern safe harbors to the Anti-Kickback Statute creates uncertainty and potential liability for the contracting parties, which inhibits the development of innovative value-

or outcomes-based contracting arrangements. A new safe harbor that provides flexibility in determining "value" and protects rebate arrangements that meet pre-defined criteria would encourage those developments by providing manufacturers and payors with regulatory clarity. By employing a broad definition of "value," leveraging any of a number of quality measures (including burden of illness, Clinical Outcome Assessments (COAs), Quality Adjusted Life Years (QALY), compliance, adherence, and persistence), payors and manufacturers will have the ability to negotiate individual value-based contracts for different diseases that reflect the value the product provided to the patient. Exelixis believes value should not be defined only in terms of cost-based measures, but should also include patient-reported outcomes. Because patients with advanced cancer, unfortunately, may have a limited life expectancy and care is unavoidably costlier as the disease progresses, cost-based definitions of value may disincentivize the creation of value-based arrangements for this vulnerable population. Furthermore, most value-based contracting arrangements must be implemented as rebate arrangements, because the outcomes data on which value-based rebates are paid are collected after the time of sale. Reforms to the Anti-Kickback Statute that address value-based contracting must clarify whether rebates that will reduce barriers and increase uptake of value-based contracting arrangements are acceptable. Finally, in implementing value-based contracting arrangements, Exelixis strongly encourages all relevant HHS agencies (e.g., OIG, CMS, FDA) to work collaboratively to harmonize regulatory policies. For example, depending on how a value-based arrangement is structured, there is a risk that any significant (or full) rebate based on the failure of the drug to meet an agreed upon measure of "value" could trigger reporting an artificially low Best Price for a product. This, in turn, could increase the manufacturer's Medicaid rebates on all Medicaid utilization, meaning that failure of a drug to reach a specified outcome for even a single patient could trigger outsized financial liability for the manufacturer. Exelixis urges regulators to collaborate to avoid creating unintended barriers to value-based arrangements.

Additionally, as detailed in Exelixis' comments on the Energy & Commerce Committee's draft Medicare Part D legislation, Exelixis strongly supports a policy change to permit manufacturers of certain clinically unique drugs, such as cancer medications, to provide copayment assistance to patients under Part D, as is permitted for patients with commercial insurance. While the current prohibition on manufacturer copayment assistance seeks to give patients "skin in the game" and protect the Medicare program from inappropriate utilization and resulting costs, neither of these arguments are applicable to the majority of cancer drugs. Instead, high beneficiary copays often lead to cancer patients delaying or forgoing treatment due to an inability to pay. Limited cost sharing assistance for those medicines with no generic alternative will increase patient access to lifesaving drugs by reducing the burden of out-of-pocket costs that patients face, with no added costs to the government. Exelixis believes that this reform is an important first step to enhance access, as the Committee continues to develop proposals to accelerate value-based contracting.

2. How do we ensure that these value-based reforms benefit patients and protect taxpayers?

Value-based contracting arrangements enable payors to align costs with the value an individual therapy provides, tying payment to their clinical value to patients. This approach better aligns the interests of taxpayers and patients than current payment policies that would restrict coverage of, and payment access to, expensive medicines like cancer therapies. To further ensure that the cost savings generated through value-based contracts benefit patients, Exelixis recommends requiring that at least a defined percentage, if not all, of savings generated through rebates be passed on to patients at the point-of-sale.

The Honorable Gus M. Bilirakis

1. Mr. Hessekiel – Often when discussing high drug prices, we tend to focus on what is wrong without mentioning what is going right to ensure we achieve the desired result in a way that does not undermine the progress that has already been made or produce other negative unintended consequences.

    - Can you share with us what is currently working and how we might double-down on these efforts?

The United States has established robust policies and incentive structures that have attracted investment in biopharmaceutical companies, which has enabled these companies to become global leaders in discovering innovative treatments and cures. Developing and commercializing new medicines is a difficult and expensive endeavor. But, the United States' strong intellectual property protections and dynamic market have made it possible for innovators — even relatively smaller companies, like ours — to take on substantial financial risks at the outset, betting on the small chance of ultimate success.

I was honored to be invited to testify on behalf of small and medium-sized biopharmaceutical companies that discover the majority of new drugs today. Since the inception of our company 25 years ago, investors have risked more than $3 billion supporting our research and development efforts, with over $2.1 billion spent before the company ever sold a single dose of medicine

We strongly urge Congress not to undermine, disrupt, or even destroy the biopharmaceutical innovation cycle that makes it possible for companies like ours to take on the overwhelming challenges and the inherent risks of failure at each step of the discovery, development, regulatory, and commercialization process. While other countries have implemented price controls or have weaker intellectual property protections, these countries continue to lag behind the United States in developing lifesaving medicines for patients. We request that you consider how weakening incentives for companies to invest in research and development would impact smaller companies the hardest, as companies like ours do not have an established suite of commercialized products or the capital structure needed to continue these substantial investments.

Additionally, the Orphan Drug Act and FDA User Fee Act are two programs that have worked well in accomplishing their intended purposes, and have resulted in a substantial increase in research and development investments and faster approvals of new drugs that treat patients with rare diseases. Congress can build upon these successful efforts by tailoring forthcoming drug pricing legislation to incentivize research and development investments, while discouraging companies who do not make significant investments from setting high list prices. The Senate Finance Committee has proposed a change to the manufacturer discount in the Medicare Part D benefit that would treat all biopharmaceutical companies the same, regardless of differences in their commitment to research and development. We encourage policymakers to consider an alternative approach, which would base manufacturer discounts in the Part D program on the amount of money invested in research and development relative to revenue. We believe that this proposal would address Congress' legitimate concerns with rising prescription drug costs on the federal government and patients, while also preserving the existing biopharmaceutical innovation cycle that delivers lifesaving treatments to patients.