Attachments-Additional Questions for the Record

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

Justin McCarthy

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?

   Pfizer is deeply concerned about drug shortages and their impact on the healthcare system and patient access to medically significant and necessary therapies. We plan to invest approximately $5 billion over the next five years in capital projects in the United States, including the strengthening of Pfizer's manufacturing presence in the United States. We have been hiring in manufacturing at Pfizer, including Kalamazoo, Michigan; Andover, Massachusetts; McPherson, Kansas; and Rocky Mount, North Carolina.

   While we have seen a reduction in the overall number of drug shortages in recent years, we must do more to address the root causes of the problem. New strategies and policies are necessary to achieve a healthy marketplace. Pfizer is committed to partnering with FDA and stakeholders to bring thoughtful solutions to the table, both for the short- and long-term. Some potential policy solutions include:

   - Creating a structured benefit/risk decision tool to help FDA staff balance the competing public health risks associated with a manufacturing concern and with shortages of medically necessary products and treatments, while also providing greater transparency to manufacturers and the public regarding compliance criteria interpretation or application.

   - Urging FDA to further align with the International Conference for Harmonisation (ICH) on current Good Manufacturing Practices (cGMP) guidelines and ensure consistent implementation with minimal variability by region.

   - Accelerating and building upon synergistic inspectional approaches and greater mutual recognition of inspections across mature regulatory authorities, including harmonized inspection guidance, common criteria for classification of observations, alignment on documentation requirements, mutual reliance on inspections, and/or recognition of third-party inspections.

- Ensuring a stable, sufficient, and redundant supply of essential medications for modern medicine and public health by allowing different payment mechanisms (separate inpatient and outpatient payments, and new add-on ambulance payments for drugs) for "critical medications" in shortage or at risk of becoming in shortage to stabilize the market by incentivizing more market entrants and longer-term contracts.

2. Do you have processes in place to minimize the negative effects of drug shortages should one of your manufacturing facilities offline?

   Pfizer's priority is to provide patients with a consistent and reliable supply of high-quality medicines, and if a drug shortage occurs we work diligently every day to meet our goal of full recovery.

   Pfizer prepares for potential shortages by proactively understanding supply chain risks and undertaking appropriate actions where possible. In situations that may result in supply disruptions, Pfizer forms rapid-response multi-disciplinary teams to review the root cause of the disruption and to develop remediation plans. Pfizer works proactively with the FDA Office of Drug Shortage to propose and discuss regulatory options that can avoid or minimize potential supply disruptions. Pfizer also works closely with FDA Drug Shortages staff to increase production of certain products when other suppliers may have supply constraints.

   While Pfizer is making significant investments to address supply challenges, we also must raise awareness of ongoing commercial and economic challenges and how they impact supply.

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?

   Value based agreements (VBAs) are in the early stages of development in the United States. Many payers and manufacturers have tested different concepts, but to date VBAs have not achieved scale. There are multiple reasons why VBAs represent a small fraction of manufacturer/payer contracts (e.g. access to data, difficult and costly to administer, etc.). There are certain aspects of the current United States regulatory landscape that are perceived by many as not only complicating VBA implementation but also, in some cases, limiting their rapid uptake. Stakeholders have frequently identified two key regulatory hurdles as limiting the expanded adoption of VBAs: i) the Anti-Kickback Statute and ii) the Medicaid Best Price calculation requirement.

   While these regulations serve important roles within the current volume-based

reimbursement system they do not contemplate innovative value-based arrangements which have resulted in a lack of clarity on how to account for these under the current regulatory framework. Ultimately, an expansion of VBAs will require reforms to existing regulations that enable more flexibility in designing VBAs.

Offering protection for appropriately structured arrangements under a new Safe Harbor under the Anti-Kickback Statute is one potential solution to facilitate more VBAs. And since federal healthcare programs are subject to the Anti-Kickback Statute, a safe harbor could promote the proliferation of VBAs in Medicare and Medicare Advantage. This Safe Harbor should be crafted to accommodate the key variables that we often experience with these innovative arrangements. Additionally, VBAs should be either partially or fully exempt from Best Price and Average Manufacturer Price reporting, or at minimum, CMS should be authorized to adopt exemptions from Best Price and Average Manufacturer Price for innovative pricing models. This may impact other programs, such as 340B, and we would be pleased to provide further thoughts in that respect.

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

Value based agreements (VBAs) provide a framework for manufacturers to be compensated based on a product's value to patients and the overall healthcare system. There are many different types of VBAs, but the optimal structure of a VBA includes clinical and/or financial performance metrics for a product. Based on the outcomes achieved, payers use this information to inform how they cover and pay for products.

Products that perform better should be covered in a more favorable manner which often includes lower out-of-pockets costs for patients which is a benefit to patients in the near-term. In the long term, patients can also benefit from other savings either directly, (e.g. reducing spending on other medications, lowering medical costs from reduced hospitalizations, doctor's visits, etc.), or indirectly through lower premiums based on reductions in total cost of care. VBAs can be implemented in federal and state programs so that the benefits described above can accrue to the federal programs, thereby benefitting taxpayers. If the VBA is structured to align the cost of pharmaceuticals to the value to the system, then both patients and taxpayers will benefit because the price paid will also align with the value to the system.