Responses to Questions for the Record to Hearing on:

Legislative Solutions To Bolster Preparedness And Response For All Hazards And Public Health Security Threats

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Questions for the Record

The Honorable Cathy McMorris Rodgers

Mr. Okon, at the hearing Ranking Member Pallone suggested that you contend that drug companies aren't making enough money and that we should oppose price controls and rebate penalties. Ranking Member Pallone continued that he believes that these issues do not actually present a financial problem for drug companies but rather they pose a financial problem for patients who can't afford the drugs, since they won't be able to access drugs because of high prices. I'm afraid that this surface level perspective ignores the root causes of drug supply issues, especially regarding generic drug shortages, and seems to suggest it's better to have fewer drugs at prices that Congress or the administration deem acceptable than have more drugs and supply channels at prices that can rise and fall with greater demand and less political control.

1) Could you please elaborate on the financial challenges manufacturers face and how if the root causes of these problems are not addressed, patients – as we are beginning to unfortunately see – will not have access to needed drugs at *any* price.

My Response:

Unfortunately, and I say this with all due respect, Ranking Member Pallone is confusing high-cost cancer drugs – often priced at tens of thousands of dollars – with low-cost generic injectable cancer drugs. To put this in perspective, the CMS allowable Medicare Part B reimbursement is a little over $14 per vial for a list of the drugs experiencing shortages. **If we are going to truly solve this increasing drug shortage problem, it is essential to understand the difference between expensive brand drugs and these very inexpensive (cheap) generic drugs that are essential in treating a variety of cancers, including curative cancers.**

As I explained in some detail in my written testimony, the nature of the Medicare Part B reimbursement system is such that generic drug manufacturers are constrained in their pricing flexibility. So, when they are required to upgrade their manufacturing equipment, facilities, and plants, they have little pricing power to fund any upgrades and investments. Now, they are further constrained by the Medicaid and Medicare (Inflation Reduction Act) inflation caps. These caps may work by constraining the price increases for expensive brand drugs but are counterproductive with cheap generic drugs.

What compounds this pricing inflexibility on these very inexpensive drugs are mandatory government program discounts and rebates, including 340B drug discounts and Medicaid rebates. These drive down the prices of these drugs further such that they are, at best, financially unattractive to make, and at worst drive manufacturers out of the market.

Let me add the unfortunate and really tragic problem with these shortages. Because key, but inexpensive, cancer drugs, such as cisplatin and carboplatin, are in short supply, at best, oncologists have to go to "plan B' therapies, which are not as effective but are more expensive. So, patients are getting less than optimal therapies and have higher costs. And in cases with certain cancers, patients are simply not getting the treatment they deserve and is required.

It is also important to understand that these cancer drugs in short supply are not simple pills and tablets. They are sterile injectable drugs requiring a more complicated and expensive manufacturing process. The low return from these drugs often requires manufacturers to run equipment 24/7 with little manufacturing redundancy. As a result, their facilities are more prone to inspections that find faults in the sterile processes and other defects. These manufacturers have higher costs but very tight margins, if the drugs have any margins at all.

If we don't address the underlying root cause of what is now a chronic problem of drug shortages, Americans with cancer and other serious diseases will die. And the underlying root cause is financial. It does not require a PhD in economics or finance to understand that if these very inexpensive drugs lose money to manufacture then no one will make them. Unfortunately, there is too much denial that the root cause is financial.

2) How do price controls affect drug supply chains and ultimately the incentives for more resilient supply chains?

My Response:

I touched on this in my previous answer, as well as in my written testimony, but price controls in all of human history have led to restricted access to products and, at worst, shortages. That is exactly what we are experiencing – and have been experiencing for 12 years – with these essential, inexpensive generic cancer drugs. Price controls, which are exacerbated by mandatory government discounts and rebates, tightly constrain any pricing power of generic drug manufacturers of these products and further erode any margins. As a result, we have very little redundancy in the manufacturing of these drugs because in most cases they have very tight margins or are simply unprofitable. We are held hostage to a very tight supply chain that is now mostly overseas. We are starting to understand the importance of bringing electronic chip manufacturing back to the United States and providing financial incentives for chip manufacturers. We need to do the exact same thing with generic drugs, especially these critical drugs for treating cancer.

3) Can you please elaborate on the challenges that cancer care providers face and how price controls exacerbate the financial pressure on providers and the manufacturers they rely on for drug supply.

My Response:

This is a living nightmare for oncologists who have to make decisions on how to treat their patients. This requires deciding on alternative, but suboptimal and more expensive treatments. When practices receive any of the drugs in short supply, they have to determine which patients get those drugs. I literally have hundreds of stories from oncologists on how these drug shortages are harming patients. I included several of these in my written testimony.

There is no amount of early warning signals, by either manufacturers or the FDA, that alleviate these shortages. In fact, additional regulation – which translates into additional costs – aimed at manufacturers can actually worsen the situation by disincentivizing manufacturers from staying in the market. These are mere band-aids that can actually mask the underlying financial problem. As I related in my written testimony, this is like putting a band-aid on a mole that has been biopsied and diagnosed as stage IV melanoma.

As I have previously stated, price controls in the market for inexpensive generic drugs are financial disincentives that are simply strangling the number and quality of manufacturers willing to manufacture these drugs.

4) Can you please elaborate on the role of mandatory rebates play in drug supply and shortages.

My Response:

It's not only rebates but mandatory discounts from 340B that simply drive down the prices of these inexpensive drugs to levels that are simply not financially viable. In some cases, these drugs end up being net-priced at pennies. There is already denial by policymakers that mandatory discounts and rebates are fueling the high prices set by drug manufacturers of expensive brands. This denial, unfortunately, extends to the reality that mandatory government discounts and rebates drive generic drug prices to unsustainable levels, as witnessed by drug shortages.

5) What additional considerations should policymakers keep in mind when discussing different types of drugs, for example, the different rules and market incentives for generic and brand drugs, in order to have a more thoughtful discussion of drug shortages?

My Response:

I want to make it abundantly clear that brand drug manufacturers have the primary hand in setting drug prices. However, mandatory government discounts and rebates are fueling drug list prices higher resulting in documented wide differences in list to net prices. The more these discounts and rebates have increased in both scope and magnitude, the higher we have seen list prices rise and the gap between list and net prices widen. So, until policymakers face the realities of this situation, we face a growing problem. For example,

the 340B program in hospitals is allowing the largest health systems to mark up drugs in the commercial market – as well as for patients with no insurance – five times on average. Not five percent but five times. This report uses hospitals' own data to document that large 340B health systems can make more money on drugs than brand drug manufacturers.

In the generic injectable drug market, if policymakers don't face the reality of the corrosive effect of discounts and rebates, drug shortages will continue. These drugs, and how incentives and disincentives are viewed, need to be treated separately from expensive brand drugs. We need to bring down the cost of expensive brand drugs, which are almost never in short supply. However, policymakers need to take immediate action to strip away tight price controls, discounts, and rebates to fundamentally fix the drug shortage crisis.

6) Can you please share more about the reimbursement and pricing challenges generic manufacturers face, and how this contributes to drug shortages?

My Response:

I believe in my previous answers I have addressed this question. The solution is basically that we need to remove the disincentives facing generic drug manufacturers and increase the incentives. We need a balance that uses market forces of supply and demand to keep these drugs inexpensive but available.

The Honorable Earl L. "Buddy" Carter

1. According to the FDA, upwards of 62% of drug shortages are caused by drug safety issues, largely stemming from foreign facilities. Bloomberg recently reported that major healthcare systems and the Department of Defense are engaging with Valisure, an independent laboratory, to test the quality of generic drugs.

Just last week, the FDA announced it will allow in cancer drugs from a foreign facility in India that is under an import ban, and one in China that hasn't been expected since 2019 and is not even approved by the FDA to make the drug in question. Shouldn't independent drug testing be done, especially when the FDA bends the rules to let drugs in from bad manufacturers? Aren't immuno-compromised cancer patients further at risk if they are being given medicines that are not safe, are not efficacious?

My Response:

My short answer is yes. It is scary to import drugs that have not been adequately tested as safe to administer to immunocompromised cancer patients. Oncologists rely on the safety of the drugs they are administering as determined by the FDA. It is unfortunate that importing these drugs has to be a desperate move because policymakers have not fixed the underlying root cause of drug shortages. Government over-regulation, price controls, and mandatory discounts and rebates have greatly distorted the free-market

forces of supply and demand. This has resulted in drug shortages of key generic injectable cancer drugs. The political pressures presented by these shortages, fueled by extensive media reporting, are resulting in desperation moves to band-aid the drug shortage crisis. Yet, policymakers are doing nothing to address the underlying financial root cause.

2. What can we learn from the challenges faced during the pandemic and how might Buy American policies be used or modified to better support U.S.-based manufacturers and consequently improve our resilience to future health security threats? What incentives and funding do you recommend is needed to strengthen and support domestic manufacturing of pharmaceuticals and essential medical supplies?

My Response:

Unfortunately, we are now increasingly reliant on manufacturers in other countries with cheap labor to produce critical generic injectable cancer drugs. This is a terrible position and a true national security threat. If there is one lesson we need to take away from the COVID pandemic, we need to be much more self-reliant in producing key goods and services in the United States. I am not advocating for a total nationalistic perspective because we are dependent on a robust global economy. However, like we are doing with electronic chip production, we need to bring more generic drug manufacturing back to the United States. We have made many inroads in reducing cancer deaths but have a long road to go. That is dependent on the availability of innovative therapies as well as mainstay generics and biosimilars.

A simple approach is to provide tax incentives for generic drug manufacturers, in addition to stripping away burdensome regulations and creating safe harbors from mandatory government discounts and rebates.

I think we can be more creative and innovative in developing value-based manufacturing programs that reward manufacturers for ongoing quality production of inexpensive generic injectable drugs. Value-based programs are increasingly being used by payers, including Medicare, and we should apply a similar approach to rewarding quality manufacturing. I welcome the opportunity to discuss this in greater detail.

3. A report about drug supply chain resiliency by Duke University's Margolis Health Policy Center recommends that Congress "promote guaranteed federal purchase contracts, virtual stockpiles, and surge capacity for essential medicines for which disruptions would be particularly harmful." My bill, the Essential Medicines Strategic Stockpile Act, that I have led with Rep. Lisa Blunt Rochester would enable HHS to implement a pilot program to contract with drug distributors to maintain a strategic reserve of essential generic drugs. The distributors would utilize their expertise to ensure an informed and appropriate buildout of the reserve. Additionally, the program would utilize the commercial markets' highly efficient perpetual inventory model to cycle the products to prevent any expiration and provide greater visibility to market imbalances.

While I recognize this would not solve drug shortages, it would certainly help to have an essential medicines stockpile, to complement the SNS, of essential drugs, such as oncology drugs. Tell me how you can see this pilot program helping to ensure all Americans have access to generic drugs at risk of shortage, such as oncology drugs currently in shortage.

My Response:

I think your bill, which envisions an HHS pilot program to create a national stockpile of drugs, relying on the expertise of drug distributors, certainly has merit. However, until we solve the existing drug shortages, it is difficult to create any type of stockpile. As with oil, we need available products to create a stockpile.

The one concern I have with some of the proposals involving early warning signals and stockpile ideas is the potential to view these as fixes. As I stated, nearly 12 years ago, and have restated now here, in written testimony, and my oral remarks to members during the hearing, the root causes of these shortages are financial. Unfortunately, there is denial about this, which is very disconcerting. The underlying root cause of drug shortages needs to be addressed by Congress or we will face additional drug shortages.

I appreciate the opportunity to respond to these questions for the record.

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