Written Testimony on Hearing:

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

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One Page Summary of Written Testimony

- There is a shortage of critical cancer drugs that is a growing crisis. These drugs, notably carboplatin, cisplatin, and fluorouracil, although decades old, are mainstay treatments for many different types of cancers, including curable cancers. As a result of these drug shortages, Americans with cancer are facing treatment delays, potentially receiving inferior treatments, and even having their treatments stopped.
- This is not a new crisis. I testified to Congress nearly 12 years ago on shortages of injectable generic drugs used to treat cancer. This crisis is more severe and is due to denial and inaction about the root cause: financial. It is increasingly unprofitable to manufacture these sterile injectable drugs, which are not like making simple pills and tablets.
- Solutions proposed to deal with the crisis of drug shortages include early warnings and regulations from generic drug manufacturers, which may well backfire because the market is already over-regulated.
- The fundamental financial problems for generic drug manufacturers are that the Medicare Part B drug reimbursement system based on average sales price, also used by commercial payers, caps drug prices; mandatory 340B drug pricing discounts and Medicare rebates erode drug prices; and Inflation Reduction Act (IRA) drug price inflation caps further put downward pressure on injectable generic drug prices. These products at best are so unprofitable that there is little to no margin to invest in manufacturing upgrades. At worst, there is little manufacturing redundancy as manufacturers leave the market.
- Price caps, discounts, rebates, and regulation need to be stripped from the market or shortages will worsen. Congress needs to stop band-aiding the problem and fix the fundamental financial problem, as well as bring manufacturing back to the United States.

Chairman Guthrie, Ranking Member Eshoo, and members of the Health Subcommittee of the House Committee on Energy & Commerce, I appreciate the opportunity to submit this written testimony and to be asked to appear as a witness at this extremely important hearing. I frame this written testimony, opening statement, and answers to questions from the perspective of cancer treatment.

I am the Executive Director of the Community Oncology Alliance (COA), an organization dedicated to advocating for the complex care and access needs of patients with cancer and the community oncology practices that serve them. COA is the only non-profit organization in the United States dedicated solely to independent community oncology practices, which serve the majority of Americans receiving treatment for cancer. Since its grassroots founding 20 years ago, COA's mission has been to ensure that patients with cancer receive quality, affordable, and accessible cancer care in their own communities where they live and work, regardless of their racial, ethnic, demographic, or socioeconomic status.

My wife Susan practiced as a certified oncology nurse for 10 years, administering cancer therapies to patients with solid tumors. Like many Americans, we have had family and friends with cancer, living with it and dying from the disease. **I want to make it very clear that my overriding goal is to ensure that every American with cancer has access to the highest quality, most affordable cancer care close to home.**

Through my time leading COA, including interactions with physicians, researchers, manufacturers, and health policy experts, as well as extensive previous experience founding and running health care delivery companies, I have gained a firsthand understanding of the underlying

economics of our cancer care delivery system. I am testifying to share this knowledge to help Congress better understand and fix what is a true public health emergency that needs to be urgently addressed.

Testimony Background

The focus of my testimony is on describing the problem of and providing legislative solutions to the current public health threat; namely, the shortage of critical cancer drugs that we are now facing. This is a growing crisis for cancer patients. As I am sure you have heard, given all the extensive national and local news coverage of this crisis, there is a severe shortage of low-cost generic drugs used to treat cancer. These drugs, notably carboplatin, cisplatin, and fluorouracil, although decades old, are mainstay treatments for many different types of cancers, including curable cancers. As a result of these drug shortages, Americans with cancer are facing treatment delays, potentially receiving inferior treatments, and even having their treatments stopped. What is especially heartbreaking, and simply unimaginable in this country, are our fellow Americans with potentially curable cancers who may miss the treatment and the cure because of shortages. Our inaction in fundamentally solving the cancer drug shortage problem, which has existed for years but is now the most severe that we have ever faced, has already likely signed a death sentence for some Americans.

If I sound angry in this written testimony and my remarks during the hearing, I am angry. Frustration and outright anger do not begin to describe how I feel in reading heartbreaking story after heartbreaking story of patients with cancer not being able to receive treatment due to shortages of decades old, low-cost generic drugs. My anger and frustration is exacerbated by the

fact that nearly 12 years ago I testified to Congress on the then current cancer drug shortage crisis.[1] Also testifying was Scott Gottlieb, MD, who went on to become the FDA Commissioner.[2] Although we did not know each other before testifying, independently we arrived at the same conclusion: *The fundamental root cause of cancer drug shortages is financial*. And, as I relate in this testimony, the fundamental root cause of the current cancer drug shortages remains financial, just more pronounced than 12 years ago.

Unfortunately, solutions advanced in pronouncements from organizations, congressional letters to the FDA, and recent legislation introduced all deal with symptoms of the problem but none address the financial root cause at the heart of cancer drug shortages. Imagine being very diligent about staying out of the sun and getting regular skin checkups. If you had a suspicious looking mole, had it biopsied, and found out that you had melanoma, you would not be in denial and simply put a band-aid on the mole. You would have the underlying cancer treated. The problem is with many of the "solutions" being advanced is that they involve tracking early warning signs of shortages and placing even more regulations on generic drug manufacturers, which can actually have unintended consequences of exacerbating the problem. At best, these are mere band-aids. Congress is simply in denial of the financial problems that are at the root cause of these drug shortages. That denial is now costing Americans hope and even their lives.

[1] "Testimony on: Drug Shortages Crisis" to the United States House of Representatives Committee on Oversight and Government Reform Subcommittee on Health Care, District of Columbia, Census, and the National Archives", Ted Okon, Community Oncology Alliance, November 27, 2011.
[2] "The Causes of Drug Shortages and Proposals for Repairing these Markets" Testimony to the United States House of Representatives Committee on Oversight and Government Reform Subcommittee on Health Care, District of Columbia, Census, and the National Archives", Scott Gottlieb, MD, American Enterprise Institute, November 27, 2011.

Before describing aspects of the underlying financial problem and proposing specific solutions, I want to note that following my previous testimony on cancer drug shortages nearly 12 years ago, a concerned then Representative Bill Cassidy, MD introduced the *Patient Access to Drugs in Shortage Act* (H.R. 6611) in the 112th Congress. So, there has been legislation to address some of the root financial causes of cancer drug shortages introduced over 11 years ago. However, neither this legislation nor any other similar to it have been acted upon. Like an untreated cancer, the problem of cancer drug shortages is much worse and unnecessarily now costing lives.

The Fundamental Financial Problem

This is very simple and does not require a PhD in economics: If a generic drug manufacturer cannot make a profit on a drug they will simply stop making the drug. If a manufacturer makes a very small margin on the drug it will cut costs, however possible. That includes running the manufacturing facility 24/7, cutting corners on quality, and not investing in new equipment and facilities. Cost cutting makes drug manufacturing facilities more prone to equipment failures and/or the kinds of problems that result in FDA inspections shutting down plants. Unfortunately, given many of the drugs in short supply are money losers, we have seen more and more manufacturers leave the market. Today, not only is there no manufacturing redundancy at the manufacturer level but there is little to no redundancy in the market as a whole.

Let me also explain why we are dealing with shortages of sterile injectable drugs, which are physician-administered intravenously or by other injectable means (referred to herein as "injectable" drugs). These are not pills or tablets. The manufacturing involved in producing sterile injectable drugs is far more involved and exacting, as well as capital intensive, than making pills

or tablets. That is why, except for specific and short-lived supply or demand issues, shortages have not hit the pill or tablet market to the same degree as the sterile injectable market.

Before discussing the specific financial causes, let me address the belief by some that the current shortages were caused by the pandemic and resultant supply chain disruptions. Certainly, the "perfect storm" of the pandemic, supply chain disruptions, and record high inflation may have been the fuse that lit the current generic drug manufacturing problem *but the root cause remains financial.* That is proven by the fact that cancer drug shortages have been around for well over a decade, before COVID, supply chain problems, and high inflation. These drug shortages are just now more pronounced due to the current environment and worsening financial picture, which I will describe.

I also want to be crystal clear that this testimony and solutions I propose do not let pharmaceutical brand manufacturers off the hook for the high costs of drugs. They play a role in our health care system, and we cannot deny that. However, Congress must understand that we are facing drug shortages for low cost, often money-losing, injectable generic drugs, not headline-making new and expensive brands. Injectable generics are a different part of our drug supply system that is adversely impacted by the bad economics of generic drug manufacturing, which desperately needs special consideration and immediate action.

Until we cure the fundamental financial cause of these drug shortages many Americans with cancer will be unable to access the treatments and cures that they deserve. That is simply unacceptable in this country!

The Reimbursement Problem

As background, the Medicare Modernization Act of 2003 (MMA) changed Medicare Part B drug reimbursement from average wholesale price (AWP) set by the manufacturer to average sales price (ASP), a market-based price. Oncology facilities administering chemotherapy are reimbursed by Medicare at ASP plus 4.3 percent, which is intended to cover drug cost, overhead, staff, and materials. In actuality, reimbursement is lower than ASP plus 4.3 percent due to manufacturer-to-distributor prompt payment discounts included in the ASP calculation. It is also important to understand there is a perpetual lag of 6 months in updating ASPs each quarter, which results in providers subsidizing Medicare for drug price increases.

The old AWP-based reimbursement system allowed generic drug manufacturers to compete on the margins they established by setting a drug's AWP and then selling the drug at a discounted price. The ASP-based system changed generic drug manufacturers' means of competing to solely on actual sales price. That and the 6-month lag in updating Medicare reimbursement rates have resulted in a system that is effectively price capped. There has been steady downward pricing pressure on most generics since 2005, the year ASP was first implemented.

It is important to understand that ASP-based reimbursement is also used by commercial payers, in addition to Medicare. Additionally, ASP masks the true decline in net prices for manufacturers because they do not reflect other discounts and rebates exempt from the calculation of ASP.

Part of the motivation for replacing the AWP reimbursement system was to stop drug "arbitrage" – setting the AWP higher and selling at a discounted price. Ironically, the old AWP system actually allowed generic drug manufacturers pricing profitability. They could compete by

adjusting their margins. The ASP-based system essentially price caps generic drugs. Then, when subject to mandatory government discounts and rebates, they have products that are barely profitable or even priced at a loss. And, just as ironically, the ASP-based system of reimbursement was the fuse that led to the explosive growth in what was once a little obscure government discount program – the 340B Drug Pricing Program – that has further eroded generic drug margins.

340B Drug Discount and Medicaid Rebate Problems

Generic manufacturers have felt additional pricing pressure from an increasing volume of 340B discounts, which they are required to extend to 340B-eligible hospitals and other entities who qualify for the program. Over the last two decades, as more independent community oncology practices facing lower reimbursements and financial pressures have been acquired by 340B hospitals, the scope and magnitude of these discounts have increased. Furthermore, Medicaid best price rebates exert further downward pricing pressure on true net prices realized by generic drug manufacturers.

History has clearly documented that repeated and misguided cancer care payment cuts have forced independent cancer care providers to close or merge with expensive hospital systems.[3] When independent practices close, medical care almost always shifts to much more expensive hospitals, which typically are 340B hospitals. This has caused the 340B program to grow by over 1,600 percent from 2005 – the first year of implementation of the ASP-based reimbursement system – through 2021. Thus, mandatory 340B discounts, coupled with Medicaid rebates, severely push down low-cost generic drugs to pennies, if that, making them increasingly not financially viable.

[3] "2020 Community Oncology Alliance Practice Impact Report", Community Oncology Alliance, April 24, 2020.

I understand that there are many in Congress who do not want to touch the 340B program. However, 340B is simply out of control in the hospital market. Investigative reports by the New York Times[4] and the Wall Street Journal[5] demonstrate how 340B funds intended to help patients and communities in need are simply not helping the disadvantaged. Rather, 340B has become a veritable printing press for hospitals. Additionally, 340B discounts incentivize the use of more expensive drugs, which is resulting in hospitals shunning biosimilars[6], which have the potential to bring down the high price of biologics**. I want to state for the record that COA supports the 340B program as it is intended to be used; that is, support patients and communities in need.** However, although the federal grantees – community health, hemophilia, and HIV centers, etc. – are using the program to support those in need, more hospitals are simply not.

Although some may be in denial, the reality is that mandatory 340B discounts and Medicaid rebates are major contributors to making the manufacturing of injectable generic drugs a losing proposition. And I will add that Congress expanding Medicaid rebates to generics exceeding the inflation rate was a terrible move that further compounded this problem.

IRA Inflation Price Cap Problem

While COA has acknowledged that one of the positives in the IRA is the inflation cap where brand drug manufacturers rebate any price increases above the current inflation rate, the unintended consequence of this portion of the law is that it puts further downward pressure on the price caps that generic drug manufacturers already face with the ASP-based reimbursement system. This

[4] "How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits", New York Times, September 24, 2022.
[5] "Many Hospitals Get Big Drug Discounts. That Doesn't Mean Markdowns for Patients", Wall Street Journal, December 20, 2022.
[6] "The Role Of Financial Incentives In Biosimilar Uptake In Medicare: Evidence From The 340B Program", Health Affairs, May, 2023.

inflation cap makes it virtually impossible for a generic drug manufacturer to increase the price of their products above the inflation rate to pay for manufacturing plant or machine upgrades and investments that are critical to avoiding drug shortages. This cap further contributes to the financial unattractiveness and instability in the injectable generic drug market.

Unfortunately, the IRA provision extending Medicare rebates to generic drugs exceeding the inflation rate doubles down on the Medicaid inflation cap rebate. These misguided policy moves are contributing to systematically destroying the injectable generic drug market.

Legislative Solutions

In order to fundamentally fix the chronic problem of drug shortages, I propose the following solutions.

Changes to the Reimbursement System

The Energy & Commerce Committee needs to include similar provisions as in H.R. 6611 (1112th Congress) in a legislative package to fundamentally fix the drug shortages problem. This legislative solution provides market incentives for injectable generic drugs with three or fewer active manufacturers. For a single source drug, Medicare reimbursement would be based on wholesale acquisition cost (WAC) rather than ASP. WAC will provide stable market-based pricing. It is the manufacturer's list price and is a real price, unlike AWP. WAC is used by the Centers for Medicare & Medicaid Services (CMS) to reimburse for new drugs that do not yet have an ASP at market launch.

Exemption from 340B Discounts and Medicaid Rebates

As in H.R. 6611, exempting low-cost injectable generic drugs from 340B discounts and Medicaid rebates is essential to achieving pricing stability and financial viability. These are low-cost generics so the overall impact on 340B and Medicaid is very small. Additionally, these discounts and rebates are meaningless when a drug is in short supply and cannot be procured. Pricing changes and exemptions only occur when there are three or fewer manufacturers of these low-cost drugs. If the market is functioning correctly, there are no changes.

Exemption from the IRA Inflation Price Cap

In order to give generic drug manufacturers more pricing flexibility as incentive to invest in manufacturing facilities and to stay in the market, they should be exempted from the IRA inflation price cap.

Make Each Generic Drug a Unique Product

Another issue is that injectable generic drugs have been totally commoditized by CMS because all similar generics products are placed in the same reimbursement category. As with pill and tablet generic drugs, they are treated as interchangeable commodities. The result is that manufacturers have virtually no pricing latitude to increase prices to pay for plant and product manufacturing upgrades. Each injectable generic drug needs to have its own product code and treated as a unique product. Not only will this allow generic drug manufacturers more latitude in pricing flexibility but this is a necessary requirement to implementing the next solution.

Move Generic Manufacturing Facilities Back to the United States Via Value-Based Incentives

Drug manufacturers need to be incentivized to manufacture injectable generic drugs in the United States. We simply should not be relying on countries outside the United States for our supply of critical generic drugs used to treat cancer.

One obvious incentive is to use tax breaks. However, another way is to create "value" incentives for manufacturing plants that run according to "quality" standards to be rewarded with value-based payments. Manufacturers should be rewarded for investing in plant upgrades and hitting pre-agreed quality metrics. This is a creative approach to rewarding manufacturing excellence and follows the trend in health care of moving to value-based payments.

The scope of this testimony is such that these are just outlines of legislative solutions. COA welcomes the opportunity to work with the Energy & Commerce Committee in greater detail to turn these conceptual solutions into comprehensive legislation.

Conclusion

If Congress does not address the basic fundamental financial root cause of generic drug shortages, the crisis will only worsen. We simply cannot regulate our way out of this mess, which some are suggesting we do with band-aids and more regulation. Let me be very clear that the current market is already too regulated, which is part of the problem. If we place any additional regulation and reporting onus on generic drug manufacturers we risk toppling what is already a house of cards. Band-aids will not solve the underlying financial problem. Not only are we in denial if we try to band-aid an ailing system but regulation will likely have negative unintended consequences and do nothing to solve the underlying financial issues behind drug shortages. Congress has to

understand that Americans are paying a high cost for artificially low prices for drugs that are not even available right now to treat cancer.

Just so the urgency of this crisis is not lost on any member of Congress, as well as the Administration, please consider the following very real stories provided by oncologists of their patients struggling with this current crisis.

Male patient, 72-years-old, with stage III Merkel cell high grade cancer requires pre-op carboplatin and etoposide due to the size and location of the cancer. With no carboplatin available, treatment cannot be switched to the second option because he has a liver transplant. So, he received the 3rd treatment option of attenuated intensity chemotherapy. Chemotherapy treatment has been delayed and has resulted in an increase in the tumor size.

Female patient, 46-years-old, with stage IIa poorly differentiated ER+, PR+, Her2+ breast cancer requires pre-op docetaxel, carboplatin, trastuzumab, and pertuzumab, which is the standard of care. She was not able to receive the carboplatin because it is not available. This is a curative intent regimen but the lack of carboplatin could lead to a higher risk of recurrence of disease and death.

Female patient, 32-years-old, with BRCA1+, stage IIIc (T3N1M0) triple negative invasive ductal carcinoma who needed to receive indicated treatment of carboplatin, paclitaxel, doxorubicin, cyclophosphamide, and pembrolizumab. Carboplatin has had to be held due to shortages resulting in a suboptimal regimen for this young mother of three children with an aggressive breast cancer.

Unfortunately, there are already way too many of these heartbreaking stories across the country now on a daily basis.

It is beyond unfortunate and unthinkable that now we have to resort to desperate measures to address drug shortages, including importation of these short-supply drugs from China and any other country that will provide them urgently, as well as rely on other means to procure these critical drugs.

COA stands ready to work with Congress on these recommendations and others. We want to provide meaningful input on ensuring that Americans with cancer have access to the highest quality, most appropriate treatments. We implore Congress to put aside politics and simple solutions, which are more feel-good sound bites, to fundamentally fix a deteriorating cancer drug shortages crisis.

I end by emphasizing again that we are all concerned about high drug prices but we are now paying an inordinately high cost for low priced drugs that are simply not available.

I appreciate the opportunity to provide this testimony.

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