Written Testimony Before the U.S. Senate Committee on Finance

Congressional Hearing On

"DRUG SHORTAGES: Examining Supply Challenges, Impacts, and Policy Solutions from a Federal Health Program Perspective"

December 5, 2023

Marta E. Wosińska, Ph.D.
Senior Fellow
Schaeffer Initiative on Health Policy
The Brookings Institution[1]

[1] The views I express in this testimony are my own and do not necessarily reflect the views of other Brookings staff members, officers, or Trustees of the Institution.

Chairman Wyden, Ranking Member Crapo, and members of the Committee, thank you for inviting me here today. My name is Marta Wosińska, and I am an economist and a Senior Fellow in Economic Studies at the Brookings Institution, where I am affiliated with the Schaeffer Initiative on Health Policy. My research explores the economics and regulation of prescription drug markets. Much of my work focuses on the topic of this hearing – drug shortages.

I would like to begin by thanking Chairman Wyden and Ranking Member Crapo for holding this hearing. As I will discuss, the persistence of drug shortages is primarily rooted in economics, driven by how we pay for and buy generic drugs. This is not the first time we have had cancer drug shortages and it will not be the last unless Congress steps in to address the economics through CMS. Getting at drug shortages through CMS is critical because CMS is much better positioned than FDA to address the economics driving the issue.

But as I will discuss, CMS needs support from Congress, this Committee in particular.

In this testimony, I focus on low-cost generic sterile injectable (GSI) drugs. These drugs are the staple of hospital care, with almost every inpatient stay involving treatment with at least one GSI drug. Shortages of these drugs can affect patients in emergency rooms, ICUs, cancer clinics, and outpatient elective surgery departments.

I begin this testimony by describing why GSI drugs are the most likely drugs to experience shortages. I then describe how federal healthcare programs affect GSI drug profitability, followed by a specific set of recommendations for how this Committee can support CMS in addressing drug shortages. I conclude with a discussion of other areas where Congress can make the greatest impact.

My testimony is based on over a decade of research and extensive engagement with stakeholders on all sides of the issue: manufacturers, wholesalers, group purchasing organizations (GPOs), hospital executives, clinicians, and hospital pharmacists. Much of what I describe in this testimony is contained in a recent analysis published through The Hamilton Project at the Brookings Institution.

In short, I recommend that the Senate Finance committee takes three actions:

- Establishing a CMS pay for performance program that would shift hospital purchase decisions towards more reliable manufacturers
- Enabling Medicaid rebate exemptions for certain drugs
- Strengthening the authority that CMS used for the domestic N95 rule.

There are also many actions that other Congressional Committees should take, the most important of which I describe in this testimony and summarize here:

- Properly funding the CMS efforts
- Allowing FDA to disclose the culprit of each shortage
- Supporting FDA's efforts to improve signals about manufacturing quality and reliability
- Supporting the HHS supply chain coordinator role
- Supporting forgivable loans (not tax credits) for strengthening key drug infrastructure
- Supporting well-targeted buffering mechanism proposals.

Where and why are shortages occurring?

Drug shortages occur when demand exceeds available supply. Drug shortages can result from a rapid demand increase, as we saw with ventilator drugs during the early months of COVID and what we currently see with Ozempic and related diabetes drugs as their use for weight-loss skyrockets. Shortages

can also occur when supply disruptions are significant enough that available inventories or ramping up production on existing lines do not suffice.

Supply disruptions due to manufacturing quality problems dominate as a cause of drug shortages. The share of other causes varies over time, but generally manufacturing quality problems have been followed by increases in demand, natural disasters, product discontinuations, and disruptions in availability of inputs, not necessarily always in this order.

GSI drugs have persistently represented the largest share of drugs in shortage, many lasting months if not years. Although no detailed statistics exists, it is well understood that GSI shortages primarily result from manufacturing quality problems at facilities where the final product is made.

Unlike shortages caused by natural disasters or pandemics, shortages caused by manufacturing quality problems are essentially self-inflicted and thus avoidable. They result not from external shocks, but from choices in how hospitals buy GSI drugs and the underinvestment in reliability of manufacturing operations that results.

As I describe in next section, GSI drug reimbursement mechanisms across all payers give hospitals incentives to use the lowest price GSI available. These reimbursement mechanisms rest on the assumption that two versions of the same generic drug are therapeutically equivalent (TE) and therefore can be readily substituted. This assumption is not without merit – these products met bioequivalence requirements at the time of FDA approval. But reliability of production is much more than meeting bioequivalence at the time of approval.

These reimbursement mechanisms also rest on the presumption that FDA can assure that all approved products are made to exact specifications. However, FDA is not able to continually monitor facilities, instead relying on manufacturers to report problems. If problems are identified, whether by FDA or the manufacturer, FDA may find itself in a bind – to prevent disruptions in production of medically necessary drugs, FDA will be compelled to allow product release from noncompliant facilities that make large share of medically necessary drugs, often GSIs. That FDA does everything to mitigate an impending shortage is expected by Congress and by the American public, even though those actions send the wrong signal to manufacturers.

The price pressures, coupled with inconsistent FDA oversight, create a dynamic for manufacturers where there is little room for and return on investing in facilities, staffing and oversight. This is particularly problematic with GSI drugs because there is less room for error in the final production stage than in production of oral dose products – the drugs are injected into the body, often directly into the blood stream, and therefore they must be sterile and free of particulates. This lower margin for error requires that the final fill-and-finish manufacturing stage be done in specialized facilities with employees following complex manufacturing processes and controls.

Running such complex operations in a cost-cutting environment challenges the reliability of GSI facility operations. If problems with systems or product batches are uncovered, often after FDA inspections, companies may need to discard or recall large batches of compromised product, and temporarily or permanently shut down lines or entire facilities. Any of these scenarios can result in shortages.

How do federal programs affect profitability of GSI drugs?

There are two ways in which CMS programs affect profitability of GSI drugs: by enhancing price competition and by penalizing input cost passthrough.

Reimbursement mechanisms

Most hospital payment arrangements for GSI drugs encourage hospitals to minimize spending on them. Medicare, the largest payer for hospital stays, bundles reimbursement for GSI drugs with other hospital services provided during an inpatient stay, which incentivizes hospitals to keep cost for the inputs to the service low. Such incentives also exist in outpatient settings. In some outpatient settings, payment rate is based on the average cost across manufacturers, providing incentives to buy the lowest cost version. In other outpatient settings, GSI drugs are bundled if the daily drug cost is under $135 and otherwise separately payable on average cost. Other payers create similar reimbursement schemes.

These reimbursement mechanisms incentivize hospitals to find the lowest price available at a given time. Hospitals typically do that by pooling their bargaining power through GPOs. The contracts GPOs negotiate for GSI drugs typically have terms of one to three years. Those contracts generally neither provide a purchase guarantee to the manufacturer nor do they fix the price over the contract term. Instead, the contracts frequently include best-price guarantees that allow the contract price to drop if the GPO finds a better price elsewhere. GPO contract participation is voluntary for hospitals so hospitals can buy off contract.

One place where GPO contracts are not used is 340B hospitals because of a prohibition in place since the ACA. 340B hospitals will still hold GPO contracts for their inpatient use, but will use the 340B vendor, Apexus, to obtain 340B drugs at 340B prices. The GPO prohibition need not be a disadvantage to hospitals from a cost perspective because 340B discounts can be larger than the GPOs discounts.

Whether or not GPOs are involved, hospital purchasing practices encourage cost cutting on the part of manufacturers. In a highly competitive environment with limited demand stability, companies have little incentive to buffer supply chains through dual sourcing or maintaining buffer inventory. The instability of demand means that manufacturers switch between products more often – a risk factor in complex sterile facilities. To cut costs, companies have opened operations in lower cost environments such as India. Some companies have continued to invest in US based facilities, but other facilities have closed. Less profitable products continually are discontinued.

Inflation rebates & discount programs

Even if product price can stay above marginal cost, well-intentioned rebate and discount programs may push a product into unprofitable space. Consider for example a GSI drug selling for $2 per unit with input and production costs totaling at $1.80. Suppose that this product experiences a $1 cost increase. If the manufacturer were to pass on the full cost increase, which is what we would expect in a highly competitive market, the resulting price increase would be 50% (i.e., the full $1), well above the CPI. This means an inflation rebate – which requires manufacturers to rebate the price increase – could make the product unprofitable depending on the market share to which that penalty applies. This could lead a manufacturer to phase out the product or drop it entirely.

Medicare and Medicaid differently handle inflation rebates for competitive generics markets.

In its concern about drug shortages, Congress exempted drugs facing fierce price competition from Medicare inflation drug rebates. Specifically, all multiple source drugs are exempt from Part B inflation rebates and all multiple source generics are exempt from Part D inflation rebates. In addition, Congress directed CMS to reduce the newly required Medicare inflation rebates for single-sourced drugs in shortage. Elsewhere, I have written how CMS should use the flexibilities afforded under the IRA to balance amelioration of shortages of non-exempt drugs with the risk that waiving rebates might exacerbate shortages.

In contrast, Medicaid inflation rebates cover all drugs. The Medicaid inflation rebate affects manufacturers of the same product asymmetrically – products on the market in 2016 have a benchmark set for that year but more recent products have a benchmark set near their market entry date when the market dynamics and equilibrium prices may have also been different. The program includes no exceptions or waivers.

If the Medicaid share of the market is sufficiently low, profit losses from Medicaid sales can potentially be absorbed. However, Medicaid rebates become the basis for the 340b price. This means that for GSI drugs that have large presence in the 340b program, such as cancer drugs, the Medicaid inflation provision can have significant profitability implications that go beyond Medicaid.

The mechanism by which Medicaid inflation rebates affect GSI drug break even, does not directly cause shortages. Instead, the effect is indirect: as manufacturers find certain products to be unprofitable, they phase them out and ultimately drop production entirely. The products are more likely to be unprofitable and therefore dropped when there are many competitors. If a product is dropped when its share is low, there will be no shortage, but fewer competitors will be left in the market, making it less resilient to a future shock.

How should the Senate Committee on Finance support CMS's role in addressing shortages?

Solutions to drug shortages need to reflect the nature of those shortages. For shortages caused by external events, such as pandemics or natural disasters, any actions are largely limited to buffering strategies such as identifying ways to scale up production and creating buffer inventories. But for shortages where triggers are economic, it is imperative that the root causes be addressed.

Here I present three proposals that the Senate Finance committee should undertake to support CMS in addressing the economic drivers of GSI drugs. As I will describe below, these proposals can also support a government response to offshoring, which also has its roots in economics.

Establish a CMS pay-for-performance program to shift hospital purchase decisions

To address the root cause of persistent GSI drug shortages, hospitals must reorient the overt emphasis on low prices in favor of manufacturing quality and reliability.

As the largest payer for hospital stays and outpatient visits, CMS is well positioned to influence how hospitals buy. Specifically, CMS should encourage hospitals to place more weight on reliability of manufacturing supply through a pay-for-performance program under Medicare. Below, I summarize key elements of such a program, referring readers for more detail to a June 2023 report from The Hamilton Project at the Brookings Institution.

Under the proposed pay-for-performance program, hospitals would be scored on their behavior on two measures: do they buy from reliable manufacturers and do they buffer their inventory. Hospitals would be measured on their performance retroactively, on their behavior *before* the first signal of each shortage that occurs. The scorecard would then feed into an end-year sliding-scale payment adjustment based on a hospital's performance relative to its peers. Hospitals should largely expect to cover their participation costs, with top performing hospitals exceeding those cost.

Under the proposal, hospitals would not need to take the responsibility for identifying which manufacturer's products are less likely to be in shortage, instead relying on their GPOs to do this work for them. GPOs already conduct such assessments but have strong financial incentives to continue

heavily weighing low-cost producers because otherwise hospitals buy off contract. But if hospitals weigh reliability more, they will not only encourage GPOs to assess reliability, but be willing to buy higher priced but more reliable on-contract products. By putting at least two GPOs in each hospital peer group, GPOs would be incentivized to perform better on predicting reliability and securing product through quantity commitments.

One nuance in the proposal is that GPOs cannot play the envisioned role for outpatient drugs in 340B hospitals because of the GPO prohibition I described in the previous section. Unless this prohibition is lifted or waived for high-risk shortage drugs of which GSI drugs are part, 340B hospitals would have the first-line responsibility for assessing which drug manufacturers selling 340B products are more reliable.

To start purchasing from reliable manufacturers, hospitals could leverage current but underutilized programs that vet manufacturers on reliability. Greater interest from hospitals in identify which manufacturers are reliable would also drive development and utilization of tools to identify reliability of different suppliers and the vulnerability of specific products to shortages – some of which exist today but are underutilized. The program would also incentivize greater adoption of currently underutilized programs hold buffer inventory through wholesalers or manufacturers (as in the case of Civica Rx or through a GPO private label program).

The proposed pay-for-performance program would build on a long history of such programs in Medicare. If there is one lesson learned from those programs is that the financial incentive must be sufficiently large to change behavior. For this reason, the proposed program should not be budget neutral. The June 2023 Hamilton Project proposal identifies ways to assess the level of necessary support.

There are important reasons why I propose a pay-for-performance proposal instead of the oft recommended “add-on payment,” which would add a fixed reimbursement percentage to what CMS reimburses or a “payment adjustment” program that reimburses CMS share of a difference between two alternatives. One reason add-on payments are not workable is that such payments require separately billable items, which is not the case with inpatient setting where the majority of GSI drugs are used. Second, both add-on and payment adjustment programs require clear identification of where the additional payment applies. However, CMS is not well positioned to identify which manufacturers are more reliable.

To address the latter shortcoming, some propose waiting for FDA to develop a system of metrics on which CMS could rely. However, even with funding (which FDA does not currently have), that system will likely take several years to develop. In addition, the FDAs proposed system of metrics will focus on measures of facility reliability and not product reliability. However, products from the same facility can be at different risk of shortages because of their upstream supply chains and other factors not currently envisioned in FDA’s quality management maturity program.

In turn, GPOs already have various tools at their disposal and therefore a pay-for-performance program can be implemented before FDA’s quality metrics system is ready. FDA’s ratings can be added to the pay-for-performance program later. But even there the proposed pick-right measures should continue to exist in the pay-for-performance program because facility reliability is not the only predictor of product supply reliability.

Currently, CMS does not have the authority to stand up the pay-for-performance program I described here, but this Committee can change that.

Create Medicaid rebate exemptions for certain drugs

As I described above, well-intentioned rebate programs can have adverse impact on the profitability and therefore availability of products in highly competitive markets. To address this issue, I recommend that this committee authorizes Medicaid drug rebate exemptions for multisource drugs. GSI drugs, due to their shortage risk, are at the front of the list for exemptions.

Strengthen the provision on which the N95 domestic mask rule relies

As I described above, payment adjustments are not well suited for identifying which manufacturer is more reliable in supplying a product. However, payment adjustments can be helpful in other settings where eligibility for the adjustment can be easily ascertained. For example, payment adjustments can be a straightforward way to incentivize hospitals to purchase products that the HHS in collaboration with DOD and State Department may deem important from a national security perspective, giving specific guidance to CMS to which products it apples.

I recommend this Committee strengthens Sections 1886(d)(5)(I) and 1833(t)(2)(E) of Social Security Act because the authorities that enable adjustment payments have significant shortcomings. Below, I identify those shortcomings using two examples where CMS has leaned on that authority: domestic production of N95 masks and a now-abandoned hospital buffer inventory of select essential drugs.

First, the IPPS authority can only reimburse the IPPS share of the expense, meaning that a typical hospital purchasing domestic N95 masks will only be reimbursed for about half of the added spending. Under these circumstances, a rational economic agent (such as hospital), would choose the less expensive non-domestic N95 mask, even before the hospital considers administrative burdens to file paperwork. I have not seen statistics on the uptake of the N95 mask rule, but my analysis suggest that it should be very limited if non-domestic masks have been widely available.

Another problem with the IPPS provision is the seeming inability to target IPPS supplemental payments. Recently a colleague and I argued against CMS implementing the buffer inventory proposal because the proposal would provide insufficient incentives to hospitals that currently suffer most from shortages (see above), instead buffering hospitals that already have much greater ability to procure product during shortages. If CMS could target the program to independent clinics and smaller, independent, and often rural, hospitals face inventory program, the program would get closer to reaching its primary goal.

For OPPS, payment adjustment also needs to be prorated. There also appears to be the added complication that any such reimbursement programs be budget neutral. However, there appears to be room for targeting.

To address these shortcomings, I recommend that Congress allows CMS to target the IPPS authority. Additionally, Congress should consider allowing CMS to pay more than IPPS and OPPS share because properly subsidizing products in the program is key to their uptake.

As indicated above, these payment adjustments are not a substitute for a pay-for-performance program described above. In fact, the proposed pay-for-performance program may be necessary for supplementing the payment-adjustment program described in this section because the payment-adjustment, even if reimbursing the full cost differential, falls short of accounting for administrative costs. CMS could work payment adjustment program participation rate into the pay-for-performance program, with it adding further incentives to participate in the payment adjustment program.

Where do the CMS recommendations fit in the broader response plan to shortages?

I consider empowering CMS with a pay-for-performance program authority as the most important step that Congress can take to address the persistent shortages that have plagued our healthcare system for well over a decade.

There are other opportunities for Congressional involvement that may fall outside the jurisdiction of this Committee, but which I highlight here for context. Some of those efforts complement and support the pay-for-performance program I described. Other efforts are concerned with risks that have not thus far caused shortages but may.

Efforts to support the CMS pay-for-performance program

In addition to appropriations to set up the pay-for-performance program, Congress should support FDA's efforts to improve signals about manufacturing quality and reliability, with it aiding hospital and GPO decision-making. There are a variety of steps FDA can take, all of which are within FDA's current authorities. However, FDA cannot take these steps without additional Congressional appropriations.

To further support hospital decision-making, Congress should also authorize public disclosure of which manufacturer had a production disruption that triggered a given shortage. Because the proposed scorecard creates measures based on multiple shortages—in recent years around 30 to 40 a year—the pay-for-performance proposal minimizes inadvertent disclosure of what could be considered business-confidential data. Congress should formalize disclosure by CMS of the shortage trigger, however, so that there is a feedback mechanism to hospitals for when they picked right and when they did not.

Efforts to address other supply chain vulnerabilities

To address the deterioration of the domestic GSI infrastructure, Congress should set up partially forgivable loans. The proposed loan program does not direct manufacturers to specific technologies, instead focusing on establishing a path to quality operations. To reinforce quality outcome goals, part or entire loan is forgiven if the company achieves agreed-on milestones that reflect manufacturing quality principles of proper employee processes and controls.

The main alternative, tax credits, which are within this Committee's authority, are not well suited to address this problem for two reasons. First, it is difficult to identify eligibility criteria that will yield the desired outcome: neither do all companies have the same path for enhancing quality nor is purchasing equipment sufficient because most failures ultimately are human error. Second, tax credits provide meaningful incentives only if there is sufficient taxable profit. But manufacturers that could benefit from such investments have very low profitability and sometimes are making no profits at all.

Tax credits for building new facilities on US soil have a different concern: there are simply so many foreign facilities to potentially move that it would be fiscally irresponsible to allow for such credits without prioritizing carefully. Not only could the expense be immense, but onshoring without a broader strategy could be ineffectual. For example, if the US government subsidizes an API facility in the US but all the key starting materials and reagents still come from a country with high geopolitical risk, then the investment did little to lower that risk. In this example not the whole upstream chain needs to be on-shored, but consideration needs to be given to alternate sources of key starting materials and reagents.

The enormity and complexity of US drug supply chains means that the US government must take a strategic approach in its dealing with broader drug supply chain and medical product supply chain

issues. This requires assessing which drugs and medical products are essential, which of these are vulnerable and how. For more information on what such a strategic framework could look like, I refer readers to the following Health Affairs Forefront article: A Framework For Prioritizing Pharmaceutical Supply Chain Interventions | Health Affairs.

These strategic efforts are broader than pandemic and CBRN threats preparedness and therefore fall outside of ASPR's authority. The recently announced position of an HHS supply chain coordinator is an encouraging step that can only yield results with a statutory mandate and resources.

Lastly, I will comment on the role of buffer inventories. Such inventories are generally recognized as an important buffering strategy therefore many proposals have been put forward. What those proposals generally do not address is the panic buying that ensues at the first sign of a potential shortage. Such panic buying has two effects. First, stockpiling during a shortage amplifies the shortage. Second, the "bank run" on product is uneven, usually with the large hospital systems able get to the product first. For this reason, any government funded stockpile should have allocation mechanisms in place, even if they are simply historical allocations. Otherwise, providers most likely to currently suffer from shortages will continue to suffer.

Conclusion

To address the root cause of persistent GSI drug shortages, hospitals must be encouraged to reorient the overt emphasis on low prices in favor of manufacturing quality and reliability. Without significant progress on that front, we will continue to experience shortages of these drugs. The CMS pay-for-performance program is our best chance for changing the tide.

Beyond persistent GSI drug shortages, Congress must empower the administrative branch of the government to be strategic in its approach to secure drug and medical product supply chains, prioritizing supply chains for greatest impact. Without a strategic approach to prioritize the immense yet vulnerable supply chains, the United States will be vulnerable to potentially wide-reaching shortages.

Contact: mwosinska@brookings.edu