

July 6, 2023

Chair McMorris Rodgers
House Energy and Commerce Committee
U.S. House of Representatives

Ranking Member Crapo
Senate Finance Committee
U.S. Senate

Chair McMorris Rodgers and Ranking Member Crapo,

We appreciate the opportunity to comment on your June 12th [request for information](#) (RFI) about drug shortages. We are buoyed by your focus on economic factors underpinning many of the drug shortages the U.S. has been experiencing for over a decade. As you note, the problem is complex and calls for solutions that extend well beyond Food and Drug Administration (FDA) action.

In addressing your RFI, we rely in part on research we have been conducting on causes of and solutions to persistent drug shortages. The report that resulted can be found on The Hamilton Project website here: [Federal Policies to Address Persistent Generic Drug Shortages - The Hamilton Project](#).

Causes of persistent drug shortages

Generic sterile injectable (GSI) drugs are a staple of hospital care. Shortages of GSI drugs can affect patients in emergency rooms, ICUs, cancer clinics, and outpatient elective surgery departments. As your letter indicates, these shortages can have substantial adverse impacts on health outcomes through treatment delays, the use of inferior alternatives, and an increased risk of medication errors.

Despite the importance of these drugs, the U.S. healthcare system has been experiencing persistent GSI drug shortages for over a decade, mostly caused by production disruptions due to manufacturing quality problems. Unlike shortages caused by natural disasters or pandemics, shortages caused by manufacturing quality problems are a form of self-inflicted wound. That is, they result not from external shocks, but from how hospitals buy GSI drugs and the underinvestment in reliability of manufacturing operations that results (see your question #2).

At the root of the problem is tremendous price pressure. GSI drug reimbursement mechanisms across all payers give hospitals incentives to use the lowest price GSI available. In the inpatient setting, payers – whether commercial or government – bundle inputs such as drugs with a procedure or within a hospital day or stay. In the outpatient setting, payers will reimburse with a differential level of add-on, but even there, the reimbursement generally remains the same across generic versions of the same GSI drug (see your question #5).

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 with their FDA approval. Because of the therapeutic equivalence designation hospitals can create intense price competition among manufacturers. That competition is enhanced by concentrating buying power through group purchasing organizations (GPOs). The resulting GPO contracts commit manufacturers to a price but rarely carry a minimum quantity agreement. Despite existence of GPO contracts, hospitals can and do buy off contract if faced with a sufficiently attractive (low) price (see question # 2).

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 and therefore rely on manufacturers to report potential problems voluntarily. If problems are found during inspections, FDA faces a too-important-to-fail problem with some facilities. To prevent disruptions in production of medically necessary drugs, FDA often allows continued product release from noncompliant facilities that make a large share of such 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 (see your question #3).

Despite FDA's inability to ensure that manufacturers consistently follow good manufacturing practices, hospitals are not doing enough to secure reliable supply. Hospitals are concerned about drug shortages because shortages disrupt patient care and create costs for hospitals through increased staffing and more costly treatment alternatives. But costs to hospitals are extremely low in comparison to the patient harm that results. The immense gap between the social and private costs of having an unreliable supply chain is a key reason why hospitals are not willing to pay more for supply reliability.

The resulting price pressures, coupled with incomplete FDA oversight, create a dynamic for manufacturers where there is little economic incentive to invest in facilities to ensure reliable supply, but strong incentive to overuse existing equipment and to skimp on proper staffing and oversight. 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.

Solutions to drug shortages

Solutions to drug shortages depend on the type of trigger that causes them. For shortages caused by external events, such as pandemics or natural disasters, 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.

To address the root cause, hospitals must reorient the overt emphasis on low prices in favor of manufacturing quality and reliability (see questions #2 and #8).

With support of Congress, CMS could be well positioned to promote such a shift in hospital purchasing through a pay-for-performance program through Medicare. Under the program we propose, hospitals would be scored on resilience-focused procurement and inventory practices during *non-shortage* times. The scorecard would then feed into an end-year payment adjustment based on a hospital's performance relative to its peers. The program should not be budget neutral so that hospitals can expect their participation to be worth their effort. Hospitals performing at the top of their peer group should expect to more than cover their participation costs. This, by extension, would create competition among GPOs for best ways to assess and assure reliable supply (see your question #8).

To support hospital decision-making, we propose ways for FDA to improve information about manufacturer quality and reliability. FDA should enhance the information it makes public on the lagging indicators of manufacturer quality that reflect compliance with good manufacturing practices. To create leading indicators of quality, we recommend that FDA focus the development of its Quality Management Maturity (QMM) program on GSI facilities. QMM metrics, in particular, play an important role in the pay-for-performance program we propose.

To address existing efforts to improve manufacturing infrastructure, we also propose targeted low-interest loans for GSI infrastructure upgrades. We note however that capital investments are not sufficient to ensure manufacturing quality, and therefore it is important to add an incentive mechanism for establishing the proper employee processes and controls needed in a quality operation. We propose this be accomplished by partly forgiving the loan when a company achieves agreed-upon milestones that reflect QMM principles. In addition,

greater loan forgiveness could be tied to setting aside, contractually, a certain percentage of capacity to manufacture older GSI drugs that are more vulnerable to shortage (see your question #6).

In this context, we caution about onshoring as a strategy to lower shortage risk due to geopolitical disruptions. We note that location of production need not equate quality. In fact, many, if not most, drug shortages have been caused by problems in U.S.-based facilities. For this reason, we strongly recommend that any efforts to support a domestic drug manufacturing base come with strings attached for manufacturing quality and reliability (see your question #3).

Other considerations

Thus far, we have addressed the root causes of persistent drug shortages and offered proposals for how to address those root causes. We also want to comment on several other questions posed in the RFI.

On question #11, we note that a Center for Medicare and Medicaid Innovation (CMMI) model is a poor substitute for the Medicare drug shortage program we propose. By design, CMMI models are time-limited and often voluntary. We need systemic market change, and a time-limited proposal would not likely get the necessary commitment from participants, including manufacturers' support for QMM. To the extent CMS needs testing during roll-out, it can do so through a staged roll-out supported by continuous program evaluation.

On question #14, we understand there is great interest in addressing drug shortages through greater transparency in drug supply chains. We generally support such efforts. In fact, our proposal calls for improving transparency in areas that would enable hospital buyers to select more reliable manufacturers.

We note, however, that not all information sharing is equally useful and, in some cases, could be counterproductive. Proposals for expeditious sharing of 483s with limited redaction could trigger across-the-board panic buying, without giving FDA any time to work with manufacturers to increase production. Yes, currently some players appear, for whatever reason, to get an unfair head start, but having everyone run out of the gate early is not the solution we need. For this reason, we recommend that any legislative efforts on transparency consider *who* wants what information and *how* it will be used, including what might be unintended consequences of those uses.

Finally, on question #9, we would also like to note that the Inflation Reduction Act (IRA) Medicare inflation rebates are not likely to contribute to drug shortages. The IRA [exempts](#) from inflation rebates almost all drugs at high risk of shortage: Part A drugs, Part B generics and multisource brands, Part D multisource drugs, and any drugs for which average annual charges per person are less than \$100. For brands and the rare single-source Part D generics, IRA granted CMS broad authority to waive inflation rebates in shortage or, in the case of the single-source Part D generics, in anticipation of shortage. One of us has written how CMS should implement those provisions so to balance the intent of the law with manufacturer incentives around shortages: [Drug shortages and IRA inflation rebates: Considerations for CMS | Brookings](#). We invite you to review that analysis.

Thank you again for inviting comments through your RFI. We welcome further discussion of the issues.

Marta E Wosińska, PhD
Senior Fellow
Schaeffer Initiative on Health Policy
The Brookings Institution

Richard G Frank, PhD
Director and Senior Fellow
Schaeffer Initiative on Health Policy
The Brookings Institution