Ways and Means Committee

United States House of Representatives

February 5, 2024

Dear Chairman Smith, Ranking Member Neal, and members of the Committee,

The Duke-Margolis Institute for Health Policy ("Duke-Margolis" or "the Institute") appreciates the opportunity to provide comments and recommendations regarding the pressing issue of chronic drug shortages.

The Duke-Margolis Institute's mission is to improve health, health equity, and the value of health care through practical, innovative, and evidence-based solutions. Duke-Margolis has conducted years of research and stakeholder engagement aimed at promoting drug supply chain reliability and preventing drug shortages, most recently including the work of the Duke-Margolis ReVAMP Drug Supply Chain Consortium that was founded in 2023. Through the Consortium, we're working to generate effective policy solutions that promote a reliable drug supply chain to improve patient outcomes by reducing the frequency and severity of drug shortages.

The recommendations herein do not necessarily represent the views of Consortium Members and are not intended to limit the ability of Consortium members to provide their own comments on behalf of their independent organizations, but are informed by the Institute's work with Consortium Members.

Since the Duke-Margolis ReVAMP Consortium's founding, we have published 3 major work products that outline promising recommendations to improve drug supply chain reliability. We recommend that Congress take action on these 3 areas:

1. **Advance Federal Coordination**. Congress should provide requisite authorities and funding to the HHS Supply Chain Resilience and Shortage Coordinator to lead a cross-cutting effort to reduce drug shortages, including funding for the establishment of a public-private partnership tasked with developing supply chain reliability measurement and tracking mechanisms.
2. **Improve Quality Management and Supply Chain Reliability Practices.** Congress should provide dedicated funding for FDA's Quality Management Maturity Program, and Congress should direct the establishment of a product-level Drug Supply Chain Reliability pilot program. Development of both of these initiatives could be led by the public-private partnership mentioned above.
3. **Enable Demand-Side Reforms for Reliability.** Congress should authorize and provide funding for CMS to establish a reliable drug supply payment adjustment to cover the cost to hospitals, outpatient clinics, physician offices, and other settings of shifting to more reliable purchasing practices, including:
    i. Purchasing through committed contracts
    ii. Purchasing from manufacturers that demonstrate reliability.

In this document, we summarize key recommendations in each of these three areas. We focus first and foremost on demand-side reforms for reliability, as those relevant policy actions are most squarely within the Ways and Means Committee's purview.

Impact and Root Causes of Chronic Drug Shortages

Drug shortages are a pressing and chronic issue. As of last week, over 100 drugs were on the U.S. Food and Drug Administration's (FDA) drug shortage list. About a third of these are essential medicines, and about 75% have been in shortage for over a year. Over 60% of drugs in shortage are sterile injectable drugs, a category of medicines commonly used to treat life-threatening conditions such as cancer and sepsis in hospitals and clinics across the country every day. Drug shortages are associated with higher mortality rates, medication errors, delays in life-saving cancer treatment and other critical medical procedures, and significant financial costs to the health care system.

The majority of drug shortages are caused by manufacturing quality issues. Many prescription drugs, especially more complex drugs such as sterile injectables, require specialized manufacturing facilities to ensure sterility, purity, and other critical product attributes. Too frequently, manufacturing quality issues are detected – for example, when a manufacturer runs final product testing on a batch of drug product, they may find a sterility, particulate, or other manufacturing quality issue. This may necessitate shutting down the production line, scrapping batches that have already been produced, and other remediation activities and delays. All of this may lead to the drug not being available in adequate quantities for patients.

Ultimately, this poor performance in manufacturing reflects problems in health care purchasing and payment. Payers and providers lack insights into manufacturers' supply chains and quality management practices and generally have not invested enough on their own into gaining further insights. Drug purchasers choose suppliers based primarily on price, not reliability. Contracting practices that are currently prevalent often enable purchasers to switch suppliers whenever a lower short-term price is available from another supplier—an understandable path to short-term cost savings, but one that contributes to manufacturer uncertainty about what volume they should produce. Reimbursement from the Centers for Medicare and Medicaid Services (CMS) in the hospital and outpatient settings is generally the same regardless of which generic supplier a healthcare institution chooses, creating further incentive for choosing the lowest-price option.

Manufacturers of these older generic medicines therefore compete by offering the lowest possible price, and resulting low margins make it difficult for the manufacturers to invest in equipment upgrades, risk management plans, and other steps that would ensure better quality management and reliability.

Chronic drug shortages occur most frequently in older, inexpensive, generic drugs. The FDA Drug Shortages Task Force report found that drugs in shortage have a median price of less than $9/dose, have been on the market for a median of 35 years, and usually have generic versions on the market. In addition, a report from IQVIA in 2023 found that over half of drugs in shortage are priced at less than $1 per extended unit. While generic medicines represent about 90% of prescriptions filled in the U.S., they represent less than 20% of U.S. prescription drug spending. Ensuring affordability of medicines for patients is an incredibly important priority. However, that priority is most important when considering new branded drugs that still have patent protection and tend to be more expensive. ***For older generic medicines, the primary barrier to patient access is availability, not affordability***.

Policy Solutions to Chronic Drug Shortages

Enable Demand-Side Reforms for Reliability

Since the root causes of chronic shortages are economic incentive issues, effective solutions should enable a shift to a new market equilibrium that places much more value on reliability in drug purchasing.

Duke-Margolis staff recently authored an article in Health Affairs entitled "Demand-Side Reforms to Prevent Drug Shortages: Medicare's Role In A Successful National Strategy." The article lays out policy options to prevent drug shortages, which we summarize here in the following paragraphs.

We propose a "reliable drug supply payment adjustment" that would adjust Medicare payments to hospitals based on whether they engage in reliable drug purchasing practices when buying certain essential generic medicines. We lay out two major criteria for what purchases could qualify for the payment adjustment.

The first is committed contracting. Committed contracting involves a commitment by the purchaser to buy a certain volume and by the manufacturer to supply that volume. In truly committed contracting models, meaningful financial penalties exist for both sides if their commitments are not met. Common provisions of committed contracting models include strong failure-to-supply language, fixed volumes with take-or-pay agreements, longer-term commitments, limited ability for price challenges, and centralized buffer inventories. This type of contract exists now, but the model is not very widely implemented. Increasing their use can help stabilize the market.

The second important criterion is purchasing from reliable suppliers. Developing evaluation tools such as FDA's Quality Management Maturity Program can provide clear and standardized information regarding the manufacturers that are investing in reliable production practices. There is more work to be done in developing and implementing these supply chain measurement and evaluation tools, and, as discussed further below, we recently outlined some steps that can be taken to advance such tools in a policy brief on this topic.

For a targeted list of essential generic medicines, we propose payments to hospitals for purchases that meet the "process measures" above. These payments would help to cover the cost of shifting to a new market equilibrium. Payments to support this shift toward reliability would likely be relatively affordable and cost-effective since the base prices of generic medicines are quite low on average.

These payments also may not need to be permanent. Incentive payments may be appropriate at first to cover the cost of shifting to more reliable purchasing, but as the market adjusts, CMS could transition to requiring certain practices that prove to be effective in preventing shortages. There is precedent for this approach to improving the way hospitals and health systems do business – for example, CMS issued incentive payments to hospitals for adopting Electronic Health Records in the early 2010s, and then gradually transitioned to reducing reimbursement rates for those who had *not* adopted EHRs as they became the industry standard and embedded in bundled payment rates.

"Outcomes measures", such as the hospital "Drug Shortage Scorecard" proposal from Brookings, could retroactively reward hospitals if they bought from manufacturers who actually delivered a reliable supply of a shortage drug. This would encourage providers, and the GPOs and wholesalers that act on their behalf, to expand the robustness of their supplier vetting and put committed contracts in place

with more reliable suppliers. Questions on this scorecard approach remain, including how often shortages can be fairly and accurately tied to missteps by a specific manufacturer(s), expectations for higher payments to address payment uncertainty, feasibility of program administration, and a need for coordination between CMS and FDA. However, if these questions could be addressed, outcomes-based payment programs would provide strong incentives for drug purchasers to use reliable suppliers. To support this, CMS and FDA could pilot the creation of a sample scorecard under a memorandum of understanding.

Improve Quality Management and Supply Chain Reliability Practices

As we've described, changes to payment and contracting for essential generic medicines will be most effective if payments can be carefully targeted and tied to accurate measures of supply chain reliability.

FDA's Quality Management Maturity Program is designed to evaluate manufacturing facilities based on their sustained commitment to quality management practices that can prevent drug shortages over time. This can be a critical tool in helping purchasers to identify more reliable suppliers. Congress should support the rapid development and implementation of QMM by allocating dedicated funding to it. While QMM has great potential, some refinements to the program are needed as well. In December, Duke-Margolis issued a policy brief on this topic, recommending that QMM be focused initially on essential, vulnerable drugs and the facilities that produce those drugs.

That issue brief also includes a recommendation for Congress to direct the development and piloting of a product-level Drug Supply Chain Reliability (DSCR) Program, building on FDA's QMM Program. The QMM Program assesses quality management practices at the manufacturing facility level. The insights generated by the program will be valuable for purchasing and contracting decisions. However, other important factors that contribute to supply chain reliability beyond the facility level and beyond the quality management domain, such as a manufacturer's backup raw material suppliers, manufacturing flexibilities and redundancies, inventory buffers, and risk management plans, are also necessary to consider. A DSCR Program that includes QMM evaluations as a primary input, but also encompasses other product-level aspects of supply chain reliability, will provide actionable information to purchasers looking to ensure their suppliers will deliver the drugs patients need, in adequate quantities, when they're needed.

Advance Federal Coordination

Drug supply chains are complex, and, as described above, effective solutions will require coordination across multiple federal agencies – CMS and FDA, but also ASPR, DoD, and others beyond HHS. Duke-Margolis last year published a white paper on this topic, including outlining a framework that could be used to guide the priorities of the recently announced HHS Supply Chain Resilience and Shortage Coordinator position. Congress should provide this Coordinator with the requisite authorities and funding to lead a cross-cutting effort to improve drug supply chain reliability, including producing measurable reductions in the frequency and severity of shortages of critical drugs. This cross-cutting effort should include the establishment of a public-private partnership that works to develop improved measures of supply chain reliability to help accomplish the goals laid out above. A public-private partnership model would ensure engagement from private sector stakeholders including manufacturers, health care providers, group purchasing organizations, wholesalers, and others in the development and implementation of necessary reforms to improve drug supply chain reliability.

Conclusion

Many of the most important and effective policy solutions that can help to address the economic root causes of drug shortages lie within the purview of this committee, and of the Senate Finance Committee, which has also held recent hearings on this topic. The Duke-Margolis Institute appreciates the bipartisan, bicameral efforts underway to address this critical challenge and the opportunity to contribute to the solution by providing this comment.

We thank the Committee for its efforts, and look forward to continued collaboration to prevent chronic drug shortages.

Sincerely,

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