**Testimony of**

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**Presented before the United States Senate**

**Committee on Finance**

**December 5, 2023**

*Summary of Testimony:*

- Civica is a non-profit generic drug company created by US health systems and philanthropies to address drug shortages.
- Civica currently delivers 80+ drugs, all chosen by US hospitals because they are at risk of shortage, with more than 140 million containers delivered over five years.
- The "Civica model" is designed to ensure a resilient supply and relies on:
    - Long-term purchase and supply contracts that add stability to the market. Civica contracts directly with hospitals, rather than through middlemen that may contribute to price and supply instability.
    - Maintaining approximately 6-month buffer inventory of every drug
    - US sourcing whenever possible, with the EU and Canda as a second choice. We don't source finished drugs or API from China unless there is no other source.
    - Intensive quality oversight of suppliers.
    - A single cost-plus price, available to every purchaser.
- The Civica model works, as demonstrated by the fact that we are able to supply hospitals at or above committed volumes even though 20 of our top 25 drugs are currently in national shortage.
- The Committee should take steps to incentivize or encourage systemic changes that lead to generic injectable drug purchasing strategies that include:
    - Measures to ensure adequate buffer inventory.
    - Measures to ensure that generic sterile injectable drugs are priced sustainably; and
    - Measures to create market demand from manufacturers that are less likely to have quality failures.
- In addition, consideration should be given to targeted grant or forgivable loan programs that ensure reserve U.S. finished-dosage-form manufacturing capacity for essential medicines.

*Full Testimony*

Chairman Wyden, Ranking Member Crapo, and Members of the Committee,

Thank you for the opportunity to speak with you today on the pressing issue of drug shortages, and on policies to prevent and mitigate future shortages.

My name is Allan Coukell. I am a pharmacist by training, and I lead public policy for Civica – also known as Civica Rx, which is a non-profit generic drug company created specifically to prevent drug shortages.

**The problem of drug shortages**

Drug shortages have been a chronic and ongoing problem in the U.S. for well over a decade. At any given time, hundreds of drugs appear on the FDA drug shortages list. Currently, we are seeing an acute exacerbation of shortages as a number of manufacturers have experienced quality problems, causing them to permanently or temporarily leave the market. Cancer drugs and penicillin and cephalosporin antibiotics are among those products of highest current concern, but shortages cut across therapeutic categories of generic drugs. Sterile injectable drugs are predominantly affected, though not exclusively, due to the complexity of manufacturing and the low profit margins associated with these products.

Drug shortages disrupt patient care, causing procedures to be canceled or delayed. They require treatment regimens to be adjusted to alternate products, potentially increasing the risk of medication error or resulting in suboptimal care. They require commitment of enormous pharmacy and hospital staff time in attempting to source drugs that are in shortage. And, while the low cost of drugs is the ultimate driver of supply failures, once a shortage occurs, prices spike, adding to costs.

**About Civica**

Civica is the only pharmaceutical company established specifically to address generic sterile injectable drug shortages.

We were founded as a non-profit, non-stock organization by a group of U.S. health systems and philanthropies who, after more than a decade of chronic shortages, recognized that the market was not self-correcting and that a different approach is required.

They created Civica with the mission if delivering a safe, stable, and affordable supply of essential medicines to U.S. patients.

Civica marked its 5th anniversary in September. In that time, our hospital membership has grown to 55 health systems, accounting for one-third of licensed beds in the United States, and we have supplied more than 148 million containers of generic sterile injectable drugs – more than 80 different drug products.

With substantial support from the U.S. government, we recently completed construction of our own state-of-the-art sterile injectable manufacturing facility in Petersburg, Virginia.

Civica's member health systems have taken steps to mitigate the risk of shortages by changing the way they purchase essential drugs. But many other hospitals have yet to develop or implement a systemic strategy for shortage prevention. Civica's unique model may offer a guide to what such a strategy should look like.

**The model**

The drugs that Civica delivers are those that are in shortage or at high-risk of being in shortage.

They are chosen by a committee of physicians and pharmacists from Civica member hospitals.

They are typically old, low-cost, but essential medicines. They are not the products with the highest return on investment; they are the products required to deliver care every day in hospitals across the country.

Because our mission is to prevent shortages, several features of the "Civica model" are different from the traditional generic drug supply chain and may suggest potential improvements to the larger US system. In particular:

- Civica enters long-term purchase and supply contracts that add stability to the market.

- We target a 6-month buffer inventory of every drug to ensure continuity of supply.
- We emphasize US sourcing whenever possible, with the EU and Canda as a second choice. We don't source finished drugs or API from China unless there is no other source.
- Civica performs an intensive quality audit of potential suppliers, supplemented by ongoing review of key metrics, to reduce the risk of a failure to supply.
- Every drug is sold on a cost-plus basis, with the same price available to any purchaser. Our prices remain stable even when the drug is in short supply.

Lastly, Civica has built a new, state-of-the-art sterile injectable manufacturing facility in Petersburg, Virginia, and is developing its own generic drug applications to further ensure supply of essential generic medications.

**Success of the model**

The Civica model has demonstrated benefits. In fact, 20 of our top 25 drugs are currently in shortage nationally,[1] but we are able to supply without interruption.

When a tornado recently hit a generic drug manufacturing facility in Rocky Mount, North Carolina, the Civica portfolio included 21 products that overlapped with products produced in that plant. We immediately let member hospitals know that we could supply double their committed volume for all 21 drugs.

And a recently published peer-reviewed study in the journal *NEJM Catalyst* showed that:

(1) *Supply from Civica was more consistent* than from a traditional wholesaler model, and

(2) Sourcing from Civica produced *net cost savings* to the health system.[2]

**Policy responses**

[1] ASHP Drug Shortage list as of 28 NOV 2023

[2] Dredge C, Scholtes S. "Vaccinating Health Care Supply Chains Against Market Failure: The Case of Civica Rx." NEJM Catal Innov Care Deliv 2023;4(10). DOI: 10.1056/CAT.23.0167

When considering policy responses to drug shortages, it is important to recognize that chronic drug shortages have now become a built-in outcome of the current system. Market trends and the resumption of FDA inspections after COVID mean shortages are more likely to increase than to abate in the years ahead.

The immediate cause of most shortages of sterile injectable drugs is quality problems in the manufacture of the finished dosage form. But it is widely acknowledged that the root cause is the low cost of these products, which reduces the incentive or ability for manufacturers to invest in quality or in newer manufacturing facilities and pushes production offshore to low-wage markets where quality problems proliferate, and the FDA presence is less consistent.[3]

Therefore, policy responses should focus on changing the current system that causes shortages because it favors low prices over resiliency of supply. While Civica member hospitals have taken direct action to reduce their risk of shortages, many others have yet to take steps.

Using its authority over provider reimbursement and quality, we urge the Committee to support providers in purchasing generic essential medicines, taking into account:

- Measures to ensure adequate buffer inventory,
- Measures to ensure that generic sterile injectable drugs are priced sustainably,
- Measures to create market demand from manufacturers that are less likely to have quality failures; and
- Support for domestic manufacturing.

Buffer inventory

Production of injectable medicines is relatively inelastic. If a particular facility stops producing, others take many months to ramp up production (assuming other companies already have approval to produce the drug). Therefore, a system that operates on just-in-time inventory will always be at high risk of shortages.

[3] For example, see FDA "Drug Shortages: Root Causes and Potential Solutions," 2019; Brookings "Federal Policies to Address Persistent Generic Drug Shortages," 2023; Duke Margolis, "Advancing Federal Coordination to Address Drug Shortages" 2023.

However, the resources required to establish and maintain access to a buffer stock of essential medicines will generally be greater than the resources required to establish and maintain access to these medicines without such a buffer stock.

Congress should incentivize supply chain stakeholders to maintain buffer inventory. Civica's experience is that a 6-month reserve is the appropriate quantity to create added resiliency, as it allows suppliers to deliver additional batches in the event of a supply interruption.

The cost of a holding a buffer inventory can be calculated on a straightforward basis, by taking into account the weighted cost of capital for the inventory held, along with the cost of the storage facility itself.[4]

Congress could incentivize manufacturers, wholesalers, or providers to hold extra inventory. The most practical approach would be to provide incentives for hospitals, health systems and other providers to contract with manufacturers or wholesalers who actually hold the buffer stock. This maximizes the effectiveness of inventory allocation in a shortage situation and does not require providers to directly maintain or operate storage facilities, with the attendant cost, complexity, and risk of outdated inventory.

The Centers for Medicare & Medicaid Services, in its draft Inpatient Payment rule, recently proposed a very similar approach to providing supplemental payments to hospitals for this purpose. While CMS did not move the provision forward in the final rule, the Committee should consider how, with minor improvements, it could be an effective approach.

<u>Drug Shortage Prevention and Mitigation Strategies</u>

Civica's hospital members have made investments and purchase commitments to reduce the impact of drug shortages, but all hospitals and health systems should have a drug shortage prevention strategy and review it on a regular basis. Elements of such a strategy could include:

- Identification of a priority list essential drugs that are at risk of shortages;
- Maintenance of buffer inventory to mitigate a supply disruption, including a contract for maintenance of inventory on behalf of the hospital;

[4] Weighted cost of capital is a measure of the cost companies pay to finance their operations.

- Contracting procedures for those drugs that take into account:
    - Supplier quality,
    - Diversity of supply, and
    - Committed volume to bring stability to the market.

The Committee should encourage and incentivize the development and implementation of such strategies, including through the use of Medicare payment policies.

"Insurance" against future shortages

Drug shortages are relatively predictable and therefore targeted investments can create backup domestic manufacturing capacity as "insurance" against future shortages. This can be accomplished at modest cost.

Shortages occur across drugs in all therapeutic classes, but predominantly affect generic sterile injectable products. A variety of predictive factors can be considered, but the strongest risk factor for a future shortage is whether the drug has been in shortage previously. Therefore, it is possible to create a priority list of products that are essential medicines at high risk of shortages.

Current low market prices – often below $4 for a vial – make it financially infeasible for US manufacturers to develop many of these products and find commercial sales at today's prices. However, it takes a manufacturer roughly two years to develop a generic injectable product and obtain FDA approval. Therefore, starting that process after a shortage begins does not result in a timely response.

In contrast, if Congress were to create a targeted program to support domestic manufacturers to develop essential products that are at high risk of shortage (doing all the required studies and obtaining FDA approval of an ANDA), domestic manufacturers would then be ready to manufacture on short notice once a shortage starts. In this way, Congress could create an insurance policy against future shortages at the cost of a one-time investment of $3 million to $4 million per drug.

The Committee has previously created grant programs to encourage the growth of other sectors and could use its authority to ensure that the United States has domestic manufacturers who are ready on short notice to produce essential drugs.

**Conclusion**

Thank you again for your attention to this important topic and for the opportunity to be with you today. I welcome your questions.