Testimony of

Allan Coukell, BSc(Pharmacy)

Chief Government Affairs & Public Policy Officer

Civica, Inc. (Civica Rx)

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United States Senate Special Committee on Aging

"Made in America: Restoring Trust in Our Medicines"

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Summary of Testimony:

- Civica is a non-profit generic drug company created by US health systems and philanthropies to prevent and mitigate drug shortages.
- Civica currently delivers more than 50 injectable medications,[1] each chosen by US hospitals because they are at risk of shortage, with more than 240 million vials of medicine delivered to date.
- Civica prioritizes domestic manufacturing, both in sourcing from contract suppliers and in our own U.S. sterile injectable fill-finish manufacturing facility located in Petersburg, Virginia. We also conduct direct quality oversight of our suppliers.
- Civica has a "no China" policy in our supply chain, both for finished drugs and for active pharmaceutical ingredient, unless there is no other supply available.
- Despite this commitment to domestic production, the financial model for producing generic drugs is challenging with many generic drugs selling below the marginal cost of domestic production.
- There isn't a single "silver bullet" policy that will restore domestic manufacturing, but a key component of any successful effort will be ensuring market prices that allow for domestic production. Targeted investments can also create new manufacturing capacity at an affordable cost.
- Onshoring active ingredient production cannot succeed unless a manufacturer has FDA approval to turn that API into a finished drug product and a viable domestic market.

[1] In nearly 80 distinct presentations.

Full Testimony

Chairman Scott, Ranking Member Gillibrand, and Distinguished Members of the Committee,

Thank you for the opportunity to speak with you today on the issue of "Made in America" pharmaceuticals.

My name is Allan Coukell. I am a pharmacist by training, and I lead public policy for Civica, Inc., also known as Civica Rx, which is a non-profit generic drug company created specifically to mitigate and prevent drug shortages by ensuring a reliable supply of quality essential medicines for U.S. patients.

Civica currently provides more than 50 drugs to 60 health systems, accounting for 1400 hospitals around the country. Over the past seven years, we have delivered more than 240 million vials, serving about 90 million American patients. To provide these medications, we work with a range of manufacturing partners, giving preference to U.S. sourcing whenever possible. Civica has a rigorous quality oversight process for its suppliers involving in-person facility audits and ongoing quality reviews.

We also have our own newly built pharmaceutical manufacturing facility located in Petersburg, Virginia, funded partly with U.S. government support from ASPR/BARDA. It is a state-of-the-art sterile injectable finished dosage form manufacturing facility with the ability to make 90 million vials and 50 million prefilled syringes per year, as well as to fill and assemble autoinjector pens used for insulin and other products. We have dozens of generic drug products in development for this facility.

Civica has a "no China" policy in our supply chain, both for finished drugs and for active pharmaceutical ingredients (API), unless there is no other supply available.

The drugs that Civica supplies are chosen by pharmacists and physicians from US health systems because they are at risk of being in shortage. These are the products that are the bedrock of emergency and in-patient health care– products like antibiotics, anesthetics, blood thinners, sedatives, and pain medications. These tend to be long-established, low-cost drugs. Most of them are on one or more essential drugs lists.

As this committee knows, generic medications account for 90 percent of prescriptions in this country, but less than 15 percent of drug spending.[2] While branded drugs are mostly produced domestically, generic drugs are more likely to be produced offshore – increasingly in low-cost manufacturing environments such as China and India. Our dependence on foreign-made active ingredients is even greater than our dependence on foreign finished drug products – a point I will return to.

It is precisely because generic drugs are so inexpensive – and because U.S. systems for drug procurement are so efficient at pushing prices down – that manufacturing has been steadily exiting the US for decades. Make no mistake: low prices are the principal barrier to onshoring generic drug manufacturing.

Let me provide a real-world example. There is a widely prescribed antinausea medication that typically sells for under $0.40 per vial. That is an astonishingly low price for a medicine that can only be produced in an expensive manufacturing facility after a complex process of scientific development, quality oversight, time-consuming testing and analytics, facility inspection and regulatory approval. Even the packaging is subject to strict regulatory requirements. While each of these steps is necessary to ensure patient safety, it would be difficult or impossible at that price for a US manufacturer to compete. Numerous injectable drugs sell for less than $1.

Creating a sustainable market

Generic drugs are the foundation of inpatient medical care. They also cost less in the United States than they do in other OECD countries.[3] In discussing how we create a sustainable market for domestic production, we must be comfortable that it is worth paying slightly more for a reliable and safe supply of quality domestic medication.

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[2] Association for Accessible Medicines. *The U.S. Generic & Biosimilar Medicines Savings Report* (Sept. 2024), *available at* https://accessiblemeds.org/resources/blog/2024-savings-report./

[3] For every dollar the other countries on average pay for generic drugs, in the U.S., consumers pay 67 cents. Andrew W. Mulcahy, et al. *"International Prescription Drug Price Comparisons: Current Empirical Estimates and Comparisons with Previous Studies,"* July 1, 2022, https://aspe.hhs.gov/reports/international-prescription-drug-price-comparisons

The good news is that – at least for the sterile injectable drugs that I am focused on today – it should be possible to substantially increase domestic supply at a manageable cost and in a reasonable timeframe. Indeed, while I focused a moment ago on products selling for less than a dollar, there are others at higher prices that don't need support. Therefore, a policy that puts a floor price on domestic drugs would achieve the desired goal.

One possible approach, developed as a bipartisan discussion draft by the Senate Finance Committee, would be to provide extra payments to hospitals that take into account quality and supply resiliency, along with domestic sourcing, when purchasing generic drugs. Since generic drug spending accounts for only 1 to 2 percent of total hospital expenditures, such a program would have a negligible impact on overall health spending but could help to incentivize hospitals to purchase from domestic and/or more resilient suppliers.

The Senate Finance discussion draft was framed in response to drug shortages, but the general approach can also be applied to onshoring. Stakeholders generally recognize that that framework, in its 2024 form, needs to be streamlined. Nevertheless, this approach is directionally correct in that it offsets the incremental costs associated with choosing domestic, higher quality suppliers and holding a buffer inventory to mitigate supply disruptions.

Targeted investments as an insurance policy

In combination with long-term market fixes, Congress should invest in an insurance policy so that domestic manufacturers can develop low-cost products now so the drugs can be ready when they are needed. It takes two to three years to develop a generic drug for an existing manufacturing facility, but companies cannot invest in products if they won't recover their costs. We should support companies to develop these products now and obtain FDA approval, rather than waiting for the day when the foreign supply fails. The FY26 Senate Labor HHS Appropriations bill has report language instructing the Administration for Strategic Preparedness and Response (ASPR) Industrial Base and Supply Chain Management office (IBMSC) to fund generic drug development. Congress should direct funding to ASPR to implement the policy.

Creating new manufacturing facilities

The above policies would support manufacturing of domestic drugs in existing facilities. The cost to onshore a drug into an existing facility is two orders of magnitude less than the cost to create a new manufacturing facility where none currently exists. However, in some cases entirely new manufacturing facilities will be required. New facilities are capital intensive – typically in the hundreds of millions of dollars – and the facility startup costs can be as high, or higher, than the capital costs. And, because of the complex development and approval process mentioned previously, more than four years may elapse from the start of construction to the first commercial sales.

No single facility can produce every drug. For example, in the injectable drug space, liquid-fill vials require different equipment than powder-fill vials. Some drugs, such as penicillin-type antibiotics, require their own dedicated facilities. Many cancer drugs also must be separated from facilities where other products are produced.

At current market prices, if new facilities need to be built to enable domestic production, it will require government support for capital investment – combined with some assurance of sustained demand in the face of low-cost foreign production.

Active pharmaceuticals ingredient (API) facilities are different from the facilities that produce finished dosage forms, such as vials and tablets. They require different equipment and expertise. While policymakers interested in onshoring drug production often focus on API (because that is where our dependence on China is greatest), it does no good to produce domestic API unless there is a U.S. facility with an FDA-approved finished dosage form.

Removing harmful market distortions

Generic drugs are beyond doubt the single most effective cost-saving strategy ever deployed in American healthcare.[4] They reduce prices as much as 95 percent below the pre-

[4] The Association of Accessible Medicines, the generic industry trade association, calculates savings of $445 billion from generics and biosimilars in 2023 and $3 trillion over the prior decade alone.

competition prices of branded drug products.[5] And yet government policies distort the market by introducing mandatory rebates that disincentivize production and prevent prices from rising the way they sometimes need to in a properly functioning market. Congress should remove the market distortions from mandatory rebates on generic drugs, allowing prices to rise to sustainable levels.

Regulatory reforms

Finally, I would like to address the potential for regulatory reform to support domestic manufacturing. Building and qualifying a new pharmaceutical manufacturing facility is a multi-year process. Even developing a new drug for an existing facility is typically a two- to three-year undertaking, The first federal oversight is typically an FDA inspection that occurs in the months after a drug application is filed with the agency. There are opportunities to de-risk this by allowing FDA inspection to occur earlier, and the agency has recently announced a program to enable such earlier engagement.[6]

However, most or all generic drug facilities are multi-product facilities, meaning they are not breaking even until they have multiple different FDA-approved products. The financial viability for a new generic drug facility typically depends not only on the first product approved, but on having a portfolio of approved drugs, each with a typical FDA review time of one year. By shortening the review time for drugs manufactured on already-approved lines and allowing manufacturers to submit drug stability data on a rolling basis, this cycle could be reduced by as much as nine months. This change would have a major impact for new domestic facilities.

Conclusion

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

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[5] Ryan Conrad & Randall Lutter, *Generic Competition and Drug Prices: New Evidence Linking Greater Generic Competition and Lower Generic Drug Prices* (2019), *available at* https://www.fda.gov/media/133509/download?attachment.

[6] Food and Drug Administration. FDA Announces New FDA PreCheck Program to Boost U.S. Drug Manufacturing. 07 August 2025. https://www.fda.gov/news-events/press-announcements/fda-announces-new-fda-precheck-program-boost-us-drug-manufacturing