

Opening Remarks

National Academy of Science, Engineering and Medicine Study

Martin VanTrieste, President & CEO, Civica Rx

Background: September 21, 2020 was the first day for this NASEM study, which was ordered by Congress as part of the CARES corona-virus relief package and is expected to take many months. Martin's remarks include a focus on: (1) the generic drug supply chain and dependence of the United States on critical drugs sourced or manufactured outside of the United States, (2) recommendations to improve the resiliency of the medical supply chain.

Introduction

I would like to thank the Academy for asking me to participate today, and for the opportunity to help [your work to improve the resilience of the US drug supply chain](#).

My name is Martin VanTrieste. I am the President and CEO of Civica, Inc.

I am also a 37-year veteran of the pharmaceutical industry.

I started my career in R&D as a formulation pharmacist in a pilot plant at Abbott Laboratories. I worked in manufacturing and quality at Abbott, where I became the VP of Quality for the Hospital Products Division.

I then joined Bayer as the Head of Global Quality for Biologics and subsequently Amgen as their Chief Quality Officer.

I retired a few years ago and then was persuaded to leave retirement to help establish and lead a unique organization.

Background on Civica

Civica was created to serve patients by making quality medications available and affordable.

We were established by U.S. health systems – now more than 50 of them – and three philanthropies as a non-profit 501(c)(4) social welfare organization.

That means we don't make any profit on the drug we make or sell. Our larger mission is to reduce chronic drug shortages.

That means creating a more resilient drug supply chain that can meet patient needs in ordinary times and under extreme circumstances, such as a pandemic.

We have designed Civica's supply chain in a way that may hold lessons for the larger US system. I will return to this point in a moment, but first let me talk about some problems with the status quo.

Generic drug supply chain

Several things characterize today's generic drug industry:

- Manufacturing is global, with heavy reliance on production of drug ingredients and chemical building blocks from low-cost economies – especially India and China.
- Despite long supply chains, most parts of the system operate with “just in time” inventory
- Purchasers treat generic drugs as commodities, relentlessly pursuing the lowest-cost product with no economic value placed on quality or reliability of supply.

Facing low margins and uncertain sales prospects, companies are discouraged from investing in quality and incentivized to move production out of the U.S. to economies with lower labor costs, lower regulatory compliance costs and where they may receive direct or indirect support from foreign governments for to build new facilities.

We have also seen well-documented quality problem – in the domestic market, but also in overseas plants where the FDA has much less ability to inspect.

Because of these factors, the vulnerability of the supply chain has been obvious for years – long before the current pandemic.

At any given time over the past decade, the United States has dozens or hundreds of drugs in short supply – a chronic problem of drug shortages.

Pandemic impact

During the early weeks of the pandemic, demand surged for drugs used to manage patients with COVID-19

We saw numerous countries move to protect their own domestic markets by restricting exports. There were also issues with transportation and production issues – for example a prolonged lock-down in India prevented employees from getting to work in manufacturing plants.

It could have been worse if, for example, the global pandemic had been more sustained.

In addition, we should think about other risks, such as national security concerns. For example, Chinese officials have already suggested that the drug supply could be used as leverage in a trade dispute.

Improving supply chain resilience

How, then, can we take steps to improve the resilience of our supply chain?

One tool is stockpiling.

Civica was able to supply without interruption because we maintain a physical reserve stockpile of several months’ supply.

That is not typical. Suppliers, manufacturers, wholesalers and distributors and health systems typically operate on a “just in time” basis. It has been estimated that from manufacturer to provider, total inventory across the entire system at any one time is about 30 days.

Stockpiles of essential drugs – and of their active ingredients, which are less costly and have longer expiry dates than finished drugs – can help.

But deeper solutions require investments that support short, simple supply chains that we can be confident will be able to respond to US needs in a global emergency.

To do that, we have to move away from short-term contracts for the cheapest possible drugs and ensure we are supporting adequate domestic capacity.

The Civica model

Several elements of the Civica model are relevant here.

Civica relies on:

1. Long-term purchase commitments from health systems that provide the certainty that allow us and our suppliers to invest in quality systems, capacity and staff.
2. Use of backup suppliers to create redundant capacity, plus we maintain a physical reserve of averaging at least 6 months' supply, and
3. A preference to purchase or manufacture in the U.S., sourcing from other highly regulated economies as a next preference and avoiding Chinese ingredients in our drugs.

How to improve resilience:

A resilient market does not mean that we should isolate the US drug supply from the global market.

Indeed, diversity of supply is a good thing

But we need to recognize that in an emergency, every country will look out for its own interests first.

Restoring American pharmaceutical manufacturing won't happen overnight, and no single policy alone will achieve it.

But the following measures would help. The United States should:

1. Create an essential drugs list so we know which products are priorities for domestic production
 - a. Set targets, including ability ramp up production when needed.
2. Ensure adequate stockpiles of essential medicines.
 - a. Ideally, move away from a static government warehouse to a dynamic stockpile that is managed by the private sector entities that already run the drug supply chain. Should be structured around a "flow-through" inventory, in which newer stock is constantly added as older stock is shipped to an end user. That reduces the cost of the stockpile by reducing the problem of expired inventory.
 - b. Also, create an API stockpile. API is less expensive than finished drug and it lasts much longer.
3. Recognize that if we want US capacity, we will have to make it economically viable to manufacture here.
 - a. We should use US government purchasing power to prioritize American-made drugs and to pay more for them.
 - b. Create funding to support new manufacturing processes and safer synthesis of key ingredients
 - c. Create tax incentives for US manufacturing facilities
4. And, as the FDA has recommended, we should create a public-facing quality scorecard that will allow purchasers to support quality manufacturing.

Conclusion

This has been a short overview, and I look forward to your questions and discussion.

In concluding, though, let me emphasize that it is entirely within reach to create a system that will ensure quality medicines are **available** and affordable for all, regardless of age, gender, race, ethnicity, disability or other health conditions.