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Building resiliency into medical supply chains



By Sascha Matuszak

The crippling severity the coronavirus outbreak has had on peoples' daily lives and on the world's economy is a direct result of a fragmented and thinly stretched global medical supply chain. If the nations of the world all had access to accurate and swift testing, ventilators and hospital beds, generic drugs to help ease symptoms, and a variety of other materials, such as syringes, facemasks, and gloves, the effect of the virus would be significantly less than it is right now—not just for humans, but for the world economy as well. The uncertainty that comes with a lack of testing requires nations to institute lockdowns, because nobody knows where the virus is, who has it or where concentrations of the virus might be. Lockdowns have the major multinational firms of the world clamoring for billions of dollars to keep them afloat.

The current grim debate in the United States—considering whether to use mitigation or suppression to combat the disease and how to achieve some sort of balance between human life and national economic well-being—would be a moot point if the medical supply chains were robust and flexible.

What led to this?

All of this was foreseen

Medical professionals, manufacturers of medical devices and pharmaceutical companies have been raising the alarm over the lack of supply chain resiliency in the medical field for years.

One of the loudest and most consistent voices calling for change belongs to Dr. Michael T. Osterholm, regents professor, McKnight Presidential Endowed Chair in Public Health and director of **Center for Infectious Disease Research and Policy** at the University of Minnesota. His book, *Deadliest Enemy: Our War against Killer Germs*, published in March 2017, foresaw the situation the world currently finds itself in. Perhaps more damning, especially for the current administration, is a 2017 **opinion piece in *The New York Times***^[1] calling for President Trump to not cut funding to the National Institutes of Health in order to fund more military expenditures.



“We already spend far more on our military than any other country in the world,” wrote Osterholm and colleague and co-author of the book, Mark Olshaker. “To help pay for the increases, President Trump wants to cut back many federal programs, including those that prepare us to wage war against microbes, the greatest and most lethal enemy we are ever likely to face. This is where ‘defense spending’ needs to increase, significantly.”

Osterholm has become one of the more prominent faces on national television, but he is not alone.

A 2018 study, “**Impact of the Global Medical Supply Chain on SNS Operations and Communications: Proceedings of a Workshop**,”^[2] addressed many of the issues Osterholm raises and pointed out the structure of the medical supply chain and how inflexible and nonresilient global medical supply chains truly are. The study cites Allison Neale, director of public policy for Henry Schein, a global distributor of health care products and services to office-based physicians, dentists and veterinarians and the private-sector lead of the global Pandemic Supply Chain Network in its discussion of supply chain weak links:

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...many raw materials are imported from very limited geographic areas; for example, she said, 90 percent of the latex for sterile gloves is produced in Malaysia (MRB, 2016), and a significant portion of surgical hand instruments are manufactured in Pakistan. Local or national disruptions in raw material production or export from such key locations—resulting from any of the destabilizing factors known as the ‘four Ps’: powerful weather, pandemic, port closures, and political instability—would have serious repercussions worldwide, she observed.

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This inflexibility is compounded by cost-saving procedures that value leaner supply chains with just-in-time capabilities over warehouses and stockpiles. In the discussion that followed, experts described the Strategic National Stockpile as more of an inventory management system than an actual stockpile.

As recent as October 2019, Janet Woodcock, director of the Center for Drug Evaluation and Research, testified before the U.S. Food and Drug Administration (FDA) that medical supply chains were dispersed, inflexible and vulnerable to shocks and surges. In her testimony, **Safeguarding Pharmaceutical Supply Chains in a Global Economy**,^[3] Woodcock advised the FDA to locate and research all of the facilities that produce the following sets of drugs:

- “All drugs on the U.S. market, including brand and generic drugs under approved applications, over-the-counter (OTC) drugs, and compounded medications.
- “Drugs on the World Health Organization (WHO) Essential Medicines List that are marketed in the United States.
- “Drugs on the medical countermeasures (MCM) lists. **These include drugs we would use to counter biological, chemical, nuclear, or radiation threats and influenza.**” [emphasis added]

There are many more examples of U.S.-based and international organizations ringing alarm bells that went unheeded. Medical supply chains remain dispersed across the globe, concentrated in nodes of production and lacking in stockpiles and inventory. Medical professionals across the planet do not have the equipment they need to combat the coronavirus, and people are dying.

So, what now?



After the world has finished dealing with the coronavirus, the work to introduce resilience into the medical supply chain will still need to be done.

A 2011 [study on drug shortages](#)^[4] in the U.S. found that one of the biggest problems was a lack of an early warning system:

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Ideally, there would be an early warning system for impending drug product shortages that would provide ample opportunity to prepare for all implications of the shortage. Manufacturers are required to give the FDA six months' advance notice only when they plan to stop producing a single-source, medically necessary drug. However, even this requirement has been criticized as being 'soft,' since 'medically necessary' is not statutorily defined; therefore, the manufacturer is free to decide whether or not notification is required. Also, the manufacturer isn't penalized in any way if it fails to provide the required notification. Manufacturers are required to notify the FDA of quality problems; however, drug shortages or discontinuations are often caused by a business decision or other factors that don't require FDA notification.

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In a [February 2020 statement](#)^[5] from the FDA, Commissioner of Food and Drugs Stephen M. Hahn lists four proposals that could help strengthen the supply chain, including the need for an early warning system for medical devices as well as drugs:

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The FDA does not have the same authorities for medical device shortages as it does for drugs and biological products. For instance, medical device manufacturers are not required to notify the FDA when they become aware of a circumstance that could lead to a device shortage or meaningful disruption in the supply of that device in the U.S., nor are they required to respond to inquiries from the FDA about the availability of devices. ... Among other things, the FDA proposes to require that firms notify the agency of an anticipated meaningful interruption in the supply of an essential device; require all manufacturers of devices determined to be essential to periodically provide the FDA with information about the manufacturing capacity of the essential devices they manufacture; and authorize the temporary importation of devices where the benefits of the device in mitigating a shortage outweigh the risks presented by the device that could otherwise result in denial of importation of the device into the U.S.

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Legislation has been introduced in the House of Representatives and the U.S. Senate that could give the FDA regulatory powers to enforce an early warning system. The House version of the [Medical Supply Chain Security Act](#)^[6] was introduced by Rep. Mike Gallagher (R-WI) and Rep. Mark Pocan (D-WI) on March 2, 2020. The bill would:

- “Require that manufacturers report imminent or forecasted shortages of life-saving or life-sustaining medical devices to the FDA just as they currently do for pharmaceutical drugs. This new information on devices would be added to the FDA's annual report to Congress on drug shortages.
- “Allow the FDA to expedite the review of essential medical devices that require pre-market approval in the event of an expected shortage reported by a manufacturer.



- “Give new authority to the FDA to request information from manufacturers of essential drugs or devices regarding all aspects of their manufacturing capacity, including sourcing of component parts, sourcing of active pharmaceutical ingredients, use of any scarce raw materials, and any other details the FDA deems relevant to assess the security of the U.S. medical product supply chain.”

As further evidence that this problem was foreseen and could have been addressed, a 2013 report, **Building New Strengths in the Healthcare Supply Chain**^[7] from McKinsey & Company, outlines the problems in the medical supply chain, as well as five capabilities private companies should develop to strengthen their supply chains. Unfortunately, the authors concede, strengthening supply chains requires a holistic effort over time that can be costly and time-consuming.

When this pandemic passes, companies and governments will have another chance to listen to the experts and take the necessary steps to build resilient supply chains.

Takeaways

- The medical supply chains that wrap around the globe are not resilient enough to meet the demand in normal times, let alone in times of crisis. Numerous experts have raised the alarm bells and are doing work to improve medical supply chains. Companies in the medical device and drugs sectors cannot rely on supply chains to work as they did before the coronavirus outbreak.
- Companies with the medical device and drugs sectors can act now to emerge from this crisis in a better position. Supply chain mapping, coordination and collaboration with federal agencies and diversification of suppliers are three things that would help build supply chain resilience.

and Communications: Proceedings of a Workshop (Washington, D.C.: National Academies Press, July 18, 2018), <https://bit.ly/2UfFmPL>.

3 Janet Woodcock, “Safeguarding Pharmaceutical Supply Chains in a Global Economy,” testimony before House Committee on Energy and Commerce, Subcommittee on Health, October 30, 2019, <https://bit.ly/2xrBYrX>.

4 C. Lee Ventola, “The Drug Shortage Crisis in the United States: Causes, Impact, and Management Strategies,” *Pharmacy & Therapeutics Journal* 36, no. 11 (November 2011), 740–742, 749–757, <https://bit.ly/33J3Kwe>.

5 Stephen M. Hahn, “Coronavirus (COVID-19) Supply Chain Update,” news release, February 27, 2020, <https://bit.ly/2JiHAYA>.

6 Mike Gallagher, “Gallagher, Pocan Introduce Bill to Strengthen Medical Supply Chains,” news release, March 2, 2020, <https://bit.ly/2UFxxSm>.

7 Thomas Ebel, Katy George, Erik Larsen, Ketan Shah, and Drew Ungerman, *Insights into Pharmaceuticals and Medical Products: Building New Strengths in the Healthcare Supply Chain—Pharmaceuticals and Medical Products Operations*, January 2013, <https://mck.co/3bsImxQ>.

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