

EXECUTIVE SUMMARY

The medical supply chain is an extensive network of systems, components, and processes that collectively work to ensure medicines and other health care supplies are manufactured, distributed, and provided to patients. In the broadest sense, a supply chain includes all activities related to manufacturing, the extraction of raw materials, processing, warehousing, and transportation. Hence, for large multinational companies that manufacture complex products, supply chains are highly complex socioeconomic systems. To strengthen and stabilize the medical supply chain, it is important to understand the various aspects of the medical supply chain, to identify the challenges that resulted in supply chain disruptions during the pandemic, and to consider several strategies to mitigate medical supply chain disruptions for the future.

Over decades, the medical supply chain has assembled substantial global networks; however, the pandemic has exposed structural weaknesses and cracks within these networks. Many medical supply distributors and health systems had adopted a “just-in-time” approach to supplies, by which they stocked only what they immediately needed and trusted supply chains to deliver other items quickly. At the same time, much of America’s manufacturing capacity shifted abroad, where products could be made inexpensively with low labor and energy costs. While American manufacturing’s share of overall output remained constant, its labor share declined as firms automated production lines and relied upon emerging technologies. That production and distribution system worked as planned until difficulties in the global supply chain disrupted those practices and created problems in supply, safety, and security. Today’s problems include a wide array of medical supply and equipment shortages that can be traced to component scarcities, factory closures, backlogged ports, and transportation glitches.

The disruptions caused by the “just-in-time” approach have led to calls for greater domestic manufacturing capability through onshoring or reshoring (bringing production back to the United States) or nearshoring (bringing production back to friendly countries not far from the U.S., such as Canada and Mexico). One of the key areas affected by the pandemic was the manufacturing facilities making active pharmaceutical ingredients (APIs) for the U.S. market—72% of the medical supplies and APIs for making drugs found in the United States have resulted from outsourcing to other countries. While locally sourced API production will likely become an increasingly important part of government policy and pharmaceutical company commercial strategy, diversifying supply chains is expensive, and the cost of reconfiguring them will fall on consumers or governments.

Factors that disrupt medical supply chains include infectious disease outbreaks, geopolitical conflict, economic conditions, and quality-related issues at production sites. These factors can impact daily health care, as well as the profitability of manufacturing companies. In 2021, virtually all U.S. hospitals and health care systems (99%) reported challenges in procuring needed supplies, including shortages of key items and significant price increases.

Most experts agree that stakeholders must come together to develop consistent, meaningful metrics that reflect a sophisticated approach to managing and preventing shortages that pose risks to health care systems and patients. There are several automated technologies available that health care

systems can use to quickly access data and projections: cloud-based, radio-frequency identification (RFID) technology allows for real-time tracking that prevents shortages while enabling health care professionals to view their inventory quickly and accurately; internet-connected medical devices and equipment enable different systems in health care organizations to speak to one another and ensure information is updated across departments, rather than being held up in siloes; and analytics platforms, powered by artificial intelligence (AI), can be embedded in an electronic health record (EHR) to allow users to access benchmarking data so they can analyze their overall performance.

In a recent McKinsey survey of U.S. health system and supply chain executives, three themes emerged as critical to a high-performing medical supply chain function:

- *Engage front-line physicians in supply decisions,*
- *Jointly set goals across facilities and functions, and*
- *Invest in accurate, actionable data and analytics.*

While the pandemic caused major disruptions in health care with severe consequences, it also spurred medical and technological innovations. Telemedicine has become common, medical professionals have urged adoption of new models of care, shifting from cost-efficiency to long-term planning, and public-private partnerships have been formed to deal with current and future crises. Patient care has historically been limited to a person's ability to arrive at a hospital or care facility and restricted by the supply chain's capacity to provide swiftly the correct product for that patient's individual need. Technology has recently enhanced treatment products to allow patients to receive care outside of a traditional care facility. The use of 3D printing and new forms of diagnostics allow for more personalized treatment to be provided while saving manufacturing costs.

Artificial Intelligence (AI) and predictive analytics—while being used nominally right now by physicians and health care organizations—can, should, and will be used to ensure the right items, from the right sources, at the right prices for the right outcomes are ordered at the right times and in the right quantities to prevent shortages and price gouging. This will help to ensure financial stability of medical practices and health care organizations while mitigating patient risk. Although technology is a crucial enabler of resilience through supply chain digitalization, using it as the tip of the spear to address weaknesses may only partially fix the issues. Comprehensive solutions that position technology as a component alongside people and processes can help make the medical supply chain more resilient. Several large health care organizations have developed partnerships with shared goals and vision between physicians and hospital administrations. What is necessary to further these efforts is an investment in evidence tools and the creation of a physician role in the supply chain, which is becoming more common.

The future of the medical supply chain entails transparent communication of supply chain issues and patient needs between suppliers and health care professionals who can work together to create methods that enhance situational awareness. The medical supply chain can gain physician trust by communicating regularly and providing insight into the inner workings of logistics. Physicians can articulate needs, and medical supply chain professionals can provide information about the prices of products and transportation, outcomes, and alternative options for their products. Addressing these issues can improve the relationship between the supply chain, physicians, and health care organizations. Effective supply chain performance directly links to patient outcomes and clinical safety, influencing much more than personal protective equipment (PPE).

Subject: A Primer on the Medical Supply Chain

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1 INTRODUCTION

2

3 The critical medical shortages that resulted from COVID-19 hampered the pandemic response and
4 cascaded into defaults of other aspects of U.S. health care delivery. This informational report was
5 developed to provide members of the House of Delegates (HOD) with some history of medical
6 supply chain shortages, the structure of the medical supply chain, globalization of the U.S. medical
7 supply chain, causes and consequences of failures, U.S. governmental actions to mitigate issues,
8 and onshoring and nearshoring strategies for the U.S. medical supply chain. It also identifies
9 opportunities for physicians and health systems to improve medical supply chain resilience and
10 performance.

11

12 BRIEF HISTORY OF U.S. MEDICAL SUPPLY CHAIN SHORTAGES

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14 Shortages of medical supplies in the United States due to supply chain issues are not new.

15

- 16 • During War II, the supply of quinine that was primarily sourced in the Japanese-occupied
17 East Indies, was cut off. The United States suddenly found itself facing malaria across the
18 globe without sufficient treatment, which resulted in major hospitalizations from malarial
19 infections throughout different battles and theaters.¹
- 20 • In September 2017, Hurricane Maria devastated the territory of Puerto Rico—producer of
21 50% of America’s supply of intravenous saline—catapulting hospitals nationwide into a
22 shortage.²
- 23 • In late 2019, SARS-CoV-2 emerged from China and rapidly evolved into a pandemic,
24 resulting in disrupted production and export of medications and personal protective
25 equipment (PPE) around the world.

26

27 The critical medical shortages that resulted from COVID-19 hampered the pandemic response and
28 cascaded into defaults of other aspects of U.S. health care delivery. What differentiates COVID-19
29 from prior supply chain disruptions is the level of uncertainty and the length of the disruption, as
30 well as its simultaneous global impact. Additionally, unlike most other disruptions, COVID-19 has
31 affected not only the supply of, but also the demand for products and services.

32

33 MEDICAL SUPPLY CHAIN STRUCTURE

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35 The medical supply chain is an extensive network of systems, components, and processes that
36 collectively work to ensure medicines and other health care supplies are manufactured, distributed,
37 and provided to patients. In the broadest sense, a supply chain includes all activities related to

1 manufacturing, the extraction of raw materials, processing, warehousing, and transportation.
2 Hence, for large multinational companies that manufacture complex products supply chains are
3 highly complex socioeconomic systems.

4
5 There are many players in the medical supply chain; however, manufacturers and distributors are
6 particularly prominent.

- 7
- 8 • Manufacturers are the first link in the supply chain and make the medicines and health care
9 supplies patients and physicians rely on. Manufacturers acquire raw materials for
10 production of approved products; conduct research, develop, and process medicines and
11 products; identify what product(s) is needed and if enough supply will be available based
12 on demand; conduct safety trial testing; and package approved products for distribution.
 - 13 • Distributors are the second link in the medical supply chain. Distributors repackage,
14 relabel, and ensure special handling for unique products; obtain medicines and products
15 from manufacturing facilities and distribute to providers, health care facilities or other
16 general areas of need; and manage temperature and climate conditions for safe
17 transportation of medicines and products. Distributors purchase drugs and medical
18 products in bulk from manufacturers and maintain large stocks in strategic locations across
19 the country. Some wholesalers specialize in dealing with a particular range of products,
20 such as biologics or to specific types of customers.
 - 21 • Providers (hospitals, pharmacies, dialysis centers, urgent care, assisted living, and long-
22 term care facilities) submit orders to distributors; refill prescriptions for patients; and
23 identify shortages in inventory and potential distribution challenges.
 - 24 • Patients and communities with unique medical needs that require specific products
25 influence the demand for medicines and products.
- 26

27 To strengthen and stabilize the medical supply chain, it is important to understand the various
28 aspects of the medical supply chain, to identify the challenges that resulted in supply chain
29 disruptions during the pandemic, and to consider several strategies to mitigate medical supply
30 chain disruptions for the future.

31 32 GLOBALIZATION OF U.S. MEDICAL SUPPLY CHAIN

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34 Over decades, the medical supply chain has assembled substantial global networks; however, the
35 COVID-19 pandemic has exposed structural weaknesses and cracks within these networks. Many
36 medical supply distributors and health systems had adopted a “just-in-time” approach to supplies,
37 by which they stocked only what they immediately needed and trusted supply chains to deliver
38 other items quickly. That approach saved money because firms and hospitals did not need to build
39 extended storage facilities or keep full inventories. Rather, they kept their stocks low and refreshed
40 on an “as needed” basis.³ At the same time, much of America’s manufacturing capacity shifted
41 abroad, where products could be made inexpensively with low labor and energy costs.⁴ Further,
42 while American manufacturing’s share of overall output remained constant, its labor share declined
43 as firms automated production lines and relied upon emerging technologies.⁵ That production and
44 distribution system worked as planned until issues in the global supply chain disrupted those
45 practices, creating problems in terms of supply, safety, and security.

46
47 The National Academies of Sciences, Engineering, and Medicine (NASEM) reported that only
48 28% of the manufacturing facilities making active pharmaceutical ingredients (APIs) for the U.S.
49 market were in the United States as of August 2019. This means that 72% of the medical supplies
50 and APIs for making drugs found in the United States had resulted from outsourcing to other

1 countries. A previous shortfall occurred with the anticoagulant heparin, made using pig intestines:
2 China makes 80% of the world's heparin and 60% of the U.S. supply. In 2007, an infectious
3 disease outbreak in Asia decimated pig herds, pushing heparin into short supply and doubling
4 prices. Seeking a rapid, practical solution, the U.S. Food and Drug Administration (FDA)
5 suggested using U.S. bovine heparin and asked manufacturers to submit applications that
6 demonstrated safety, efficacy, quality, and purity. Although the FDA cannot eliminate all possible
7 risk, it can enforce requirements, controls, and best practices to detect problems early while
8 ensuring the availability of safe and effective medications.⁶
9

10 As COVID-19 became a pandemic, different countries took steps to protect their local supplies by
11 limiting or stopping exports entirely. For example, China, which produces roughly 50% of the
12 global supply of masks at 10 million masks daily, ramped up production to 115 million daily
13 during the early phases of COVID-19, yet simultaneously terminated all mask exports, leading to a
14 gradual depletion of global stockpiles. Additionally, Germany banned the export of most of its PPE
15 supplies. In other areas where local production was not significant, essential equipment
16 procurement became vulnerable.
17

18 Virus mitigation measures continue to affect production and limit efforts to return the supply chain
19 to pre-pandemic levels. Several industry players have reduced worker levels due to fears of the
20 further spread of COVID-19 within the workplaces. In China, port terminals temporarily closed
21 because of the country's COVID-19 zero-tolerance policy, creating lengthy shipping backlogs at
22 some of the world's largest ports. While consumer demand can increase in months, more time is
23 required to increase port capacity, build warehouses, and hire employees so that shipping can meet
24 the needs of the demand.
25

26 Problems include a wide array of medical supply and equipment shortages that can be traced to
27 component scarcities, factory closures, backlogged ports, transportation glitches, and COVID-19
28 lockdowns across the global supply chain. According to the FDA, the list of persistently scarce
29 items is long and includes latex and vinyl examination gloves, surgical gowns, laboratory reagents,
30 specimen-collection testing supplies, saline-flush syringes, and dialysis-related products.⁷
31

32 CAUSES AND CONSEQUENCES OF MEDICAL SUPPLY CHAIN FAILURES 33

34 Factors that disrupt medical supply chains include infectious disease outbreaks, geopolitical
35 conflict, economic conditions, and quality-related issues at production sites. These factors can
36 impact daily health care, as well as the profitability of manufacturing companies. Once there is an
37 infectious outbreak, it may be difficult to access treatment and other health services, especially if
38 the outbreak comes with harsh control measures such as quarantines and lockdowns. Such
39 measures may generate an acute surge in the demand for critical medical supplies and equipment,
40 which exceeds supply, leading to shortages and protocols for prioritized use. A disruptive event can
41 cause a mismatch between supply and demand in medical product supply chains in three ways:
42

- 43 1. Demand surge: An event drives demand for a medical product well above the normal
44 level for an extended period. For example, a major natural disaster, such as a tornado or
45 earthquake, can spike regional demand for certain medical products if these events result
46 in a significant number of casualties requiring medical care. As seen during COVID-19,
47 a pandemic can drive up global demand for many medical products.
- 48 2. Capacity reduction: One or more production or transport processes are impeded by lack
49 of assets, power, or people. For example, a natural disaster could cause a factory to lose
50 power and halt production, or regulatory barriers or manufacturing quality problems
51 could restrict the output of a supplier or producer and could even eliminate inventory

1 stock if a product is recalled. As seen during the COVID-19 pandemic, production of
2 some products decreased because of lockdown measures, as well as acute loss of
3 workers to quarantine and illness.

- 4 3. Coordination failure: Events that prevent coordination of supply to meet demand can
5 cause shortages of medical products even when total supply is sufficient to meet total
6 demand. For example, geopolitical issues or communication system failures during a
7 hurricane or other natural disaster can reduce or obstruct the delivery of emergency
8 supplies into a city or region.⁸

9
10 The COVID-19 pandemic led to such shortages in medical supplies as a combination of all three
11 ways, leading to gaps in medical supplies for routine health care (e.g., dialysis-related products)
12 and pandemic response (e.g., PPE, lab testing supplies and equipment, and ventilation-related
13 products) in most health care facilities around the world.

14
15 The medical supply chain may be influenced by U.S. insurance companies, hospitals, physicians,
16 employers, and regulatory agencies, with differing objectives among them. Demand for services is
17 determined by both available treatments and insurance coverage for those treatments. Decisions
18 made by one party often affect the options available to other parties, as well as the costs of these
19 options, in ways that are not well understood. Most of these complicated factors are also present, to
20 varying degrees, in industrial supply chains.

21
22 In 2021, virtually all U.S. hospitals and health care systems (99%) reported challenges in procuring
23 needed supplies, including shortages of key items and significant price increases. A Kaufman Hall
24 report noted that 80% of hospitals had significant supply shortages and had to seek new vendors for
25 supplies during the pandemic. Shortages in raw materials and components hampered the production
26 of both drugs and sophisticated medical devices. Manufacturing facilities struggled to keep up as
27 COVID-19 swept through the workplace. Labor shortages prevented medical products from being
28 transported to the places where they were needed most.⁹

29
30 Helium, a nonrenewable element found deep within the earth's crust, is essential for keeping
31 magnetic resonance imaging (MRI) machines cool enough to work. With a boiling point of minus
32 452 degrees Fahrenheit, liquid helium is the coldest element on Earth. Pumped inside an MRI
33 magnet, helium lets the current travel resistance-free. However, the supply of helium is running
34 low leaving hospitals wondering how to plan with a much scarcer supply. Currently, four of five
35 major U.S. helium suppliers are rationing the element.¹⁰ Shortages in aluminum, semiconductors,
36 wood and paper pulp, and resin are disrupting supplies of medical devices, with different business
37 sectors competing for the same raw materials. Those shortages have led to uneven supplies of
38 medical monitors, CT scan devices, packaging for medical supplies, and gloves. While only a
39 fraction of the world's semiconductors is in medical equipment compared with cars and consumer
40 electronics, the components are key to a range of medical devices such as MRI machines,
41 pacemakers, glucose monitors, CT scanners, defibrillators, multiparameter monitors, and
42 ultrasound machines. As a result, hospitals are experiencing long order delays for equipment
43 because of the semiconductor shortage.¹¹

44
45 Drugs used in the United States involve raw materials from all over the world. Many chemical
46 inputs are manufactured in India and China and then shipped to the United States. Regardless of the
47 root cause, drug shortages can lead to substitutions for available medications that are costlier and/or
48 less effective. In some instances, hospital pharmacies must compound and modify products, which
49 adds workload and potential error.¹² The AMA Council on Science and Public Health (CSAPH)
50 has issued eleven reports on drug shortages. AMA Policy H-100.956, "National Drug Shortages,"
51 directs the CSAPH to continue to evaluate the drug shortage issue and report back at least annually

1 to the House of Delegates on progress made in addressing drug shortages in the United States.
2 CSAPH Report 01-I-22 provides an update on continuing trends in national drug shortages and
3 ongoing efforts to further evaluate and address this critical public health issue.¹³
4

5 The United States recently experienced a surge in respiratory illnesses, a potential “triple-demic” of
6 three viruses: respiratory syncytial virus (RSV), the influenza virus, and the COVID-19
7 coronavirus. While antibiotics like amoxicillin typically are not effective against such respiratory
8 viruses, they can be important treatments for secondary bacterial infections that may occur when
9 respiratory tract defenses and the immune system in general are battling a viral infection. Despite
10 the best efforts to address root causes of drug shortages, the United States has a dysfunctional,
11 opaque medical supply chain. There is still no easy way to scale up production to meet excess
12 demand. Moreover, there remains a limited profit motive to do better, particularly for low-cost
13 medications such as amoxicillin.]

14 15 U.S. GOVERNMENT ACTIONS TO MITIGATE MEDICAL SUPPLY CHAIN ISSUES 16

17 During the COVID-19 public health emergency, the FDA took many actions to ensure that health
18 care professionals had timely and continued access to high-quality medical devices. These actions
19 included *Emergency Use Authorizations (EUAs)* and guidance permits to expand available
20 resources for diagnostic, therapeutic, and medical devices in high demand. Further, President
21 Trump invoked the *Defense Production Act* and released government funds to help American
22 companies build facilities and expand production capabilities for medical equipment.¹⁴
23

24 In October 2020, in response to Executive Order 1394410, the FDA published a *List of Essential*
25 *Medicines, Medical Countermeasures, and Critical Inputs* (described herein as EM). This
26 executive order sought to ensure sufficient, reliable, and long-term domestic production of these
27 products and minimize potential shortages. The published EM list contained 227 drug and
28 biological product essential medicines and countermeasures, including analgesics, antivirals,
29 anticoagulants, antihypertensives, and antimicrobials.¹⁵ The *Center for Drug Evaluation and*
30 *Research (CDER) Site Catalog* includes approximately 1,100 locations that manufacture at least
31 one product on the EM list. There are 1,686 sites that manufacture an active pharmaceutical
32 ingredient (API), of which 354 manufacture API for EM products. Currently, 23% of API
33 manufacturing sites are in the United States; for EM, this drops to 19%. These data illustrate that
34 only a minority of drug manufacturing sites are domestic. Overall, API and finish dose form
35 manufacturing are heavily dependent on foreign manufacturing sites.
36

37 Since early 2020, the United States has made progress in strengthening the health care supply chain
38 by addressing concerns regarding domestic manufacturing and supply chain surge capabilities. In
39 2021, President Biden issued Executive Order (EO) 14017, *On America’s Supply Chains*. The 100-
40 Day Review under this order directed the U.S. Department of Health and Human Services (HHS)
41 to identify products for which onshoring (bringing production back to the U.S.) may be advisable.
42 HHS subsequently issued a 2022 report that identifies successes and practical strategies to further
43 U.S. goals for America’s supply chain and industrial base. Particular efforts should be directed at
44 expanding the public health industrial base by working across government agencies, academia, and
45 the private sector, and strengthening capabilities to monitor and manage supply chain bottlenecks.¹⁶
46 Note that Section 510(j)(3) of the *Food, Drug and Cosmetic (FD&C) Act*, which was added by the
47 recent *CARES Act*, requires FDA registered sites to report annually the amounts of drugs
48 manufactured for U.S. commercial distribution. Combined with FDA information about the
49 location of manufacturing sites, these data should enable the FDA to perform better manufacturing
50 site surveillance.¹⁷

1 In 2020, the FDA reported 43 new drug shortages after a peak of 251 shortages in 2011.¹⁸ On the
2 surface, this looks like tremendous progress; however, this measurement does not consider the
3 scope, scale, or severity of the shortage. The FDA metric measures every shortage the same way,
4 whether a drug is dispensed 20 times or 20,000 times a month. Moreover, not every shortage is the
5 same. In response to the public health crisis, some U.S. hospital groups, startups, and nonprofits
6 began making their own sterile injectables and other medicines as a short-term workaround to
7 combat persistent drug shortages.¹⁹ Experts anticipate that efforts by hospitals to have more direct
8 control over their critical drug supply chains will continue to evolve as they work to find a
9 sustainable, cost-effective, and safe model. Joint public-private sector efforts, such as the creation
10 of a *Strategic Active Pharmaceutical Ingredient Reserve (SAPIR)*, will be instrumental in defining
11 how these products are supplied in the future.²⁰

12
13 The 2013 *Drug Supply Chain Security Act (DSCSA)* outlines steps to build an electronic,
14 interoperable system to track and trace prescription drugs.²¹ The original aim of the DSCSA was to
15 enhance the ability of the FDA to regulate drug safety and help protect patients. However, this
16 system could improve the management of drug product shortages as well.²² Serialization
17 (assignment of a unique serial number to each supplyable prescription product) in the drug supply
18 chain could vastly improve an organization’s ability to manage inventory. A pilot DSCSA program
19 with the FDA showed the potential for using IBM blockchain technology to connect disparate data
20 for tracking and tracing prescription medications and vaccines in the United States.²³

21
22 In 2022, the National Academies of Sciences, Engineering, and Medicine published the
23 congressionally mandated report, *Building Resilience into the Nation’s Medical Product Supply*
24 *Chains*. The report called for the FDA to track sourcing, quality, volume, and capacity information,
25 and to establish a public database for health systems, inclusive of failure-to-supply penalties in
26 contracts. In addition, the report recommended that the federal government optimize inventory
27 stockpiling to respond to medical product shortages.²⁴

28
29 While the federal government can generate greater economies of scale for the procurement of
30 health care supplies during a pandemic, local governments can identify lower socioeconomic
31 groups and minorities that are particularly vulnerable to both the health and economic aspects of a
32 pandemic. As a result, they can employ resources more efficiently for a rise or fall in cases and
33 hospitalizations.

34 35 ONSHORING AND NEARSHORING STRATEGIES

36
37 Concerns unleashed by the pandemic and dependence on foreign manufacturers combined to
38 increase risks and raise doubts regarding “just-in-time” practices.²⁵ The disruptions caused by this
39 approach have led to calls for greater domestic manufacturing capability through onshoring or
40 reshoring (bringing production back to the United States) or nearshoring (bringing production back
41 to friendly countries not far from the United States, such as Canada and Mexico). A European
42 Parliament report found modest benefits to reshoring in the United Kingdom, United States and
43 Japan and argued that reshoring should be primarily focused on specific critical sectors and
44 products with pronounced supply bottlenecks, rather than across-the-board. Targeted reshoring was
45 advised because host countries often do not have the production facilities and/or workforce
46 required for wholesale reshoring.²⁶ Both onshoring and nearshoring should consider the ownership
47 of the manufacturing: a foreign company can own domestic manufacturing facilities and still
48 monopolize production.

49
50 One of the key areas affected by the pandemic was the API market. Research by McKinsey shows
51 that supply chains in the pharmaceutical industry are more global than in other sectors, and there is

1 a tendency to source certain materials from a particular region. For instance, 86% of the
2 streptomycin in North America and 96% of the chloramphenicol in the European Union come from
3 China. Diversifying supply chain materials is an option that pharmaceutical companies could
4 pursue to reduce their exposure through onshoring. McKinsey estimates that 38% to 60% of the
5 international pharmaceutical trade, worth \$236 billion to \$377 billion in 2018, could be considered
6 for onshoring. Locally sourced API production will likely become an increasingly important part of
7 government policy and pharmaceutical company commercial strategy. However, diversifying
8 supply chains is expensive, and the cost of reconfiguring them will fall on consumers or
9 governments. Further, the risk from regional domestic disasters in the vicinity of manufacturing
10 and distribution facilities must be assessed.²⁷

11

12 The United States once led the world in semiconductor manufacturing yet has fallen behind. Other
13 countries, especially in Asia, made deliberate investments to build powerful chipmakers in their
14 own countries. Foreign state subsidies created a ~30% cost advantage for foreign chipmaking
15 plants, and the resulting advantage is startling: in 1990, the United States supplied 37% of the
16 world’s chips, but now only 11%. This outcome has undermined U.S. technology leadership with
17 significant economic and national security implications: a recent White House study concluded that
18 “our reliance on imported chips introduces new vulnerabilities into the critical semiconductor
19 supply chain.”²⁸

20

21 In 2019, the U.S. medical end-use market accounted for \$5.6 billion in total semiconductor sales—
22 roughly 11% of the global industrial semiconductor market and 1.3% of the total semiconductor
23 market. However, 47% of the chips sold worldwide are designed in the United States. Meanwhile,
24 the medical semiconductor segment is growing faster than the overall industrial semiconductor
25 market, which is driven by long-term trends of an aging population, the rise of telehealth, the move
26 to portable and wearable devices, and the applications of artificial intelligence.²⁹ Despite being a
27 small percentage of the overall semiconductor chip market, there is an urgent need for chips in
28 medical device manufacturing.³⁰

29

30 Recognition of chip vulnerabilities led Congress to pass and President Biden to sign the *CHIPS and*
31 *Science Act* in August 2022. This law provides \$52.7 billion in aid to the semiconductor industry
32 along with other incentives to build new semiconductor production facilities in the United States.³¹

33

34 OPPORTUNITIES TO IMPROVE MEDICAL SUPPLY CHAIN PERFORMANCE

35

36 Since disruptions in medical supply chains have the potential to seriously impact patient care and
37 safety, health care systems need the capacity to proactively foresee, absorb, and adapt to shocks
38 and structural changes in a way that allows them to sustain required operations, resume optimal
39 performance as quickly as possible, transform their structure and functions, and reduce their
40 vulnerability to similar shocks and structural changes in the future.³² Most experts agree that
41 stakeholders must come together to develop consistent, meaningful metrics that reflect a
42 sophisticated approach to managing and preventing shortages that pose risks to health care systems
43 and patients.

44

45 There are several automated technologies available that health care systems can use to quickly
46 access data and projections:

47

- 48 • Cloud-based, radio-frequency identification (RFID) technology allows for real-time
49 tracking that prevents shortages while enabling health care professionals to view their
50 inventory quickly and accurately.

- 1 • By tapping into the Internet of Things, internet-connected medical devices and equipment
2 enable different systems in health care organizations to speak to one another and ensure
3 information is updated across departments rather than being held up in siloes.
- 4 • A third option are analytics platforms, powered by artificial intelligence (AI), e.g., an
5 electronic health record (EHR) embedded in an AI platform. On these platforms,
6 cataloging allows users to distribute and curate all analytics in a single web-based action.
7 Users may also have access to benchmarking data so they can analyze their overall
8 performance.³³
9

10 In a recent McKinsey survey of U.S. health system and supply chain executives, nearly three-
11 quarters of survey respondents agreed that “the supply chain stands to assume an even more
12 strategic role.” Three themes emerged as critical to a high-performing supply chain function:
13

- 14 • *Engage front-line physicians in supply decisions.* In high-performing organizations,
15 physicians play an integral role in supply chain initiatives: they provide input on supplier
16 selection and contracting strategies, including their financial impact; they support
17 compliance with contract terms (for example, by committing to give a supplier a negotiated
18 share of business); they manage the use of supplies; and they contribute to achieving
19 financial, quality, or other goals.
- 20 • *Jointly set goals across facilities and functions.* Supply chain initiatives may require
21 meaningful changes in behavior by some clinicians, including shifting away from their
22 suppliers of choice to clinically similar suppliers used by their peers. To assist this change,
23 systems may consider providing incentives, which can be financial or nonfinancial and
24 may include a commitment to reinvest a percentage of savings in priorities of physicians.
- 25 • *Invest in accurate, actionable data and analytics.* Analytical tools are only useful if they
26 provide relevant insights to their users, which may require individual customization and,
27 for convenience, accessibility on multiple devices. For example, a supplies cost-per-case
28 tool, which shows the cost of all supplies for a given operating-room procedure, should
29 provide the relevant views for physicians so that they can see the supplies they use, cost
30 compared to supplies used by peers, alternative supply options, and quality outcomes.³⁴
31

32 At the 2019 Association for Health Care Resource & Materials Management (AHRMM)
33 conference of the American Hospital Association, speakers emphasized eight points to strengthen
34 relationships between physicians and PURE (Physicians Understanding, Respecting, and Engaging
35 Supply Chain) professionals:
36

- 37 • *Share meaningful data with physicians.* Physicians are empiricists, motivated by data. As a
38 result, health systems should provide meaningful data at a consistent cadence to
39 physicians, perhaps quarterly.
- 40 • *Welcome partnerships in achieving the strategic goals of the organization.* Hospital
41 systems that work with independent physicians should bring them into supply chain
42 decision-making to include clinical perspectives.
- 43 • *Use evidence-based principles to guide decision making.*
- 44 • *Place some restriction on the number of vendors used.* However, be mindful not to limit
45 physician preference items completely or force surgeons to use specific or substandard
46 products.
- 47 • *Provide context for supply chain decision making.* Organizations should be very
48 transparent regarding what relationships drive their supply chain decision-making, to
49 include the use of group purchasing organizations (GPOs). Physicians understand

- 1 economies of scale, price sensitivity and market trends, and want to play a role in finding
2 solutions.
- 3 • *Include practicing physicians as part of the decision-making team.* Many hospital
4 administrators do not have clinical backgrounds or currency, so it is important to have
5 physicians with clinical experience on supply chain leadership teams. Physicians can share
6 clinical insights to inform supply chain discussions, translate clinical and supply chain
7 languages, and provide credibility for communication with physicians.
 - 8 • *Update clinical pathways to include product categories that support evidence-based*
9 *medicine and minimize clinical variation.* Data should be used to create algorithms and
10 care pathways for high-volume procedures.
 - 11 • *Emphasize that supply chain sustainment needs logisticians and physicians.* Collaboration
12 is essential to anticipate and fulfill supply needs with timeliness and realism.³⁵

13
14 FUTURE OF THE MEDICAL SUPPLY CHAIN: IMPROVED TECHNOLOGY AND
15 PROCESSES, AND SITUATIONAL AWARENESS

16
17 While the pandemic caused major disruptions in health care with severe consequences, it also
18 spurred medical and technological innovations. Telemedicine has become common, medical
19 professionals have urged adoption of new models of care, shifting from cost-efficiency to long-
20 term planning, and public-private partnerships have been formed to deal with current and future
21 crises. One of the highest priorities for the medical supply chain is expansion, which includes more
22 than the expansion of infrastructure and transportation in areas that have less accessibility. Patient
23 care has historically been limited to a person's ability to arrive at a hospital or care facility and
24 restricted by the supply chain's capacity to provide swiftly the correct product for that patient's
25 individual need. Technology has recently enhanced treatment products to allow patients to receive
26 care outside of a traditional care facility. A patient's treatment can now follow them outside of a
27 hospital or medical practice with the use of telehealth communication, at-home testing kits, and at-
28 home treatment that can be sent right to the patient's door. This requires the medical supply chain
29 to extend past hospitals and include last-mile transportation to patients so that they do not have to
30 return to the hospital. At-home patient care also requires more treatments to become personalized.
31 The use of 3D printing and new forms of diagnostics allow for more personalized treatment to be
32 provided while saving manufacturing costs.

33
34 As physicians and health care organizations adapt to newer data processing capabilities, they can
35 more readily keep their information correct and consistent. Predictability is a must as we continue
36 to move towards standardizing patient experience and more at-home care. The medical supply
37 chain will need to implement strategies that help it become more predictable to physicians and
38 health care organizations who need high visibility on their needed products. Currently, medical
39 supply chain management lacks a unified, well-adopted data standard. The Global Trade Item
40 Number (GTIN) standard is available, but adoption rates remain low compared to the universal
41 product code (UPC) fully adopted in other industries. Clinical and regulatory requirements
42 necessitate tracking of device information through the supply chain and in clinical EHR systems.
43 Supply chain intermediaries bear responsibility for efficient supply chain integration.

44
45 Data will be utilized to anticipate product demand. Clean data will also help supply chains stay
46 agile and not allow disruptions to hold up the services they are working to provide. Discontinued or
47 back-ordered products can greatly disrupt a supply chain, though when such things can be more
48 easily resolved with data analysis, the supply chain can become much more predictable. Data usage
49 is one strategy that will help supply chain predictability, and several strategies can help a supply
50 chain stay consistent and save costs. Some strategies for resilience include expanding domestic
51 supply chain production, making product allocation needs-based, and increasing trust. The medical

1 supply chain will have data that, if it is fully captured and analyzed, will be essential for decision
2 making. Organized collection of data can greatly impact every stage of the supply chain, as each
3 segment can make predictions based on past data and optimize processes.

4
5 Data can greatly enhance a company’s capacity to be proactive, and predictive analytics can
6 amplify that capability. Predictive analytics will help the supply chain with decision-making and
7 offer a clear way to see the ebb and flow of supply and demand. Companies can use predictive
8 analytics in new ways that help bring visibility to inventory and ensure the right products are being
9 ordered and priced correctly and that there are enough items to meet demand. Predictive analytics
10 can also help companies be more proactive in situations that significantly impact the medical
11 supply chain. The COVID-19 pandemic created new aspects of health care to predict, like the
12 number of COVID-19 cases, and the number of patients needing treatment. Predictive analytics can
13 help companies prepare for these unforeseen circumstances and prepare the supply chain for future
14 unknowns.

15
16 The use of artificial and augmented intelligence (AI) is growing throughout the health care
17 industry: AI is being used to clean data and promote efficient human effort. There are even more
18 ways that AI can be used to enhance health care and save costs. AI and predictive analytics—while
19 being used nominally right now by physicians and health care organizations—can, should and will
20 be used to ensure the right items, from the right sources, at the right prices for the right outcomes
21 are ordered at the right times and in the right quantities to prevent shortages and price gouging.
22 This will help to ensure financial stability of medical practices and health care organizations, while
23 mitigating patient risk. AI can help supply chains keep up demand, by recommending stand-in
24 products if the preferred product is not available. AI algorithms can be used to fill the gap between
25 supply and demand while saving costs and eliminating human error.

26
27 Many health care organizations are addressing supply chain challenges with holistic solutions that
28 pair technology with other changes. For the supply chain to function efficiently, physicians need to
29 be involved in decision-making. Increasing supply chain resilience requires fostering an
30 organization-wide commitment from leaders to staff members and by investing time and resources
31 necessary to identify and address the root causes of supply chain challenges. Although technology
32 is a crucial enabler of resilience through supply chain digitalization, using it as the tip of the spear
33 to address weaknesses may only partially fix the issues. Comprehensive solutions that position
34 technology as a component alongside people and processes can help make the medical supply
35 chain more resilient. Several large health care organizations across the country have developed
36 partnerships with shared goals and vision between physicians and hospital administrations. What is
37 necessary to further these efforts is an investment in evidence tools and the creation of a physician
38 role in the supply chain, which is becoming more common.

39
40 Some disruptions in a patient’s care can be attributed to limited situational awareness between
41 physicians and the supply chain. When physicians do not have knowledge of the products in the
42 supply chain, they cannot provide the best treatment possible. When the supply chain lacks clear
43 communication with physicians, medical practices, and health care facilities, it is difficult to know
44 the demand for products and when they should arrive. The future of the medical supply chain
45 entails transparent communication of supply chain issues and patient needs between suppliers and
46 health care professionals. Supply chain professionals and physicians can work together to create
47 methods that enhance situational awareness. Physicians can articulate needs, and medical supply
48 chain professionals can provide information about the prices of products and transportation,
49 outcomes, and alternative options for their products. Addressing these issues can improve the
50 relationship between the supply chain and physicians and health care organizations. The medical

1 supply chain can gain physician trust by communicating regularly and providing insight into the
2 inner workings of logistics.

3
4 Adaptability and efficiency are crucial in today’s health care supply chain environment. If a
5 company’s methods are too rigid, it will not be able to adapt quickly to unexpected changes.
6 Furthering relationships between clinicians and suppliers will help a supply chain boost its
7 robustness. Having trusting relationships between distributors and manufacturers, as well as
8 effective contracting models, will create a strong network within the health care supply chain that
9 can adapt smoothly while providing the most efficient services possible. Effective supply chain
10 performance directly links to patient outcomes and clinical safety, influencing much more than
11 PPE. Prior to the COVID epidemic, many physician leaders recognized the value of supply chain
12 excellence; that value is now apparent to all physicians.

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